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DATE: July 16, 2026

TO: Interested Parties

FROM: John Brooks, CMS Deputy Administrator and Director of the Center for Medicare

SUBJECT: Medicare Drug Price Negotiation Program: Draft Guidance, Manufacturer Effectuation of the Maximum Fair Price in 2028

Draft Guidance on Manufacturer Effectuation of the Maximum Fair Price in 2028 under the Medicare Drug Price Negotiation Program

10. Introduction

The purpose of this draft guidance is to provide interested parties with detailed processes and requirements related to manufacturer effectuation of the maximum fair price (MFP)[1] in 2028. Sections 11001 and 11002 of the Inflation Reduction Act of 2022 (IRA) (P.L. 117-169) establish the Medicare Drug Price Negotiation Program (hereinafter the "Negotiation Program") to negotiate MFPs 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 and subsequently amended.

This draft guidance sets forth policies regarding manufacturer effectuation of the MFP in 2028 with respect to selected drugs payable under Part B and/or covered under Part D. Additionally, this draft guidance describes procedures that may be applicable to drug manufacturers, Medicare Part D plan sponsors (both Prescription Drug Plans (PDPs) and Medicare Advantage Prescription Drug (MA-PD) Plans), Medicare Advantage organizations, pharmacies, mail order services, and other dispensing entities that dispense drugs covered under Medicare Part D (hereinafter "dispensing entities"), in addition to hospitals, physicians, and other providers of services and suppliers that furnish or administer drugs payable under Medicare Part B (hereinafter "Part B providers"). CMS will issue final guidance later this year setting forth CMS' final policies on the issues discussed in this draft guidance. In the final guidance, CMS may make changes to any policies discussed in this draft guidance in response to comments received or based on the agency's further consideration of the relevant issues.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 the final guidance, CMS may make changes to any policies if necessary to incorporate any enacted legislation impacting administration and operations of the Negotiation Program.

[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 manufacturer effectuation of the MFP in 2028 with respect to both selected drugs covered under Part D and selected drugs payable under Part B.[2] To facilitate program transparency, CMS is voluntarily soliciting comments on the topics in this draft guidance.

CMS published a proposed rule titled Medicare Drug Price Negotiation Program and Medicare Prescription Drug Benefit Program (CMS-4215-P),[3] which appeared in the Federal Register on June 16, 2026, that addresses policies related to the Negotiation Program for initial price applicability year 2029 and subsequent years. This proposed rule is open for public comment until August 17, 2026. The policies addressed in this draft guidance apply to manufacturer effectuation of the MFP in 2028 and are separate from provisions discussed in the proposed rule. CMS intends to address detailed MFP effectuation policies for 2029 and subsequent years in future rulemaking.

The Medicare Drug Price Negotiation Program: Final Guidance, Implementation of Sections 1191 – 1198 of the Social Security Act for Initial Price Applicability Year 2028 and Manufacturer Effectuation of the Maximum Fair Price in 2026, 2027, and 2028[4] (hereinafter referred to as "final guidance for initial price applicability year 2028") established the MFP effectuation policies for 2026, 2027, and 2028 for selected drugs covered under Part D and such policies currently remain in effect. As described in further detail below, this draft guidance restates such policies with respect to selected drugs covered under Part D for 2028. CMS has not substantively revised such policies in this draft guidance and currently does not anticipate making material changes for 2028 with respect to selected drugs covered under Part D, but reserves the right to make changes to any such policies in response to comments received or based on the agency's further consideration of the relevant issues, including experiences from monitoring ongoing manufacturer MFP effectuation for selected drugs covered under Part D in 2026. When issued later this year, the final guidance will supersede for 2028 only the sections of the final guidance for initial price applicability year 2028 with respect to MFP effectuation for selected drugs covered under Part D that are included and updated herein. In other words, the final guidance will be the applicable guidance for MFP effectuation for 2028 with respect to selected drugs covered under Part D and/or payable under Part B, as applicable.[5] The final guidance for initial price applicability year 2028 will continue to apply to Primary Manufacturer

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

[3] See: https://www.federalregister.gov/documents/2026/06/16/2026-12059/medicare-drug-price-negotiation-program-and-medicare-prescription-drug-benefit-program.

[4] See: https://www.cms.gov/files/document/ipay-2028-final-guidance.pdf.

[5] As explained in the final guidance for initial price applicability year 2028 and in this draft guidance, CMS does not expect Primary Manufacturers of drugs selected for initial price applicability year 2026 or initial price applicability year 2027 to provide access to the MFP of a selected drug to Part B providers in 2028. For drugs selected for initial price applicability year 2028 or with a renegotiated MFP for initial price applicability year 2028, Primary Manufacturers are required to provide access to the MFP of a selected drug to Part B providers in 2028, in addition to providing access to the MFP of a selected drug with respect to MFP-eligible Part D claims, as applicable.

effectuation of the MFP for selected drugs covered under Part D for 2026 and 2027, as set forth in the final guidance for initial price applicability year 2028. All sections of the final guidance for initial price applicability year 2028 that are not included and updated herein remain in effect for initial price applicability year 2028.

As discussed in sections 10 and 20 of this draft guidance, CMS has restated the MFP effectuation sections from final guidance for initial price applicability year 2028 with respect to MFP effectuation for selected drugs covered under Part D and does not intend to materially change such policies, which are currently in effect, for 2028. In this draft guidance, CMS expands upon these policies to incorporate processes for the flow of data and payment for selected drugs payable under Part B in 2028. Because the policies herein regarding MFP effectuation for selected drugs payable under Part B for 2028 are new, CMS welcomes, in particular, comments on topics related to MFP effectuation for selected drugs payable under Part B in this draft guidance.

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 September 18, 2026 will be considered. After considering the public comments received timely in response to this draft guidance, CMS will issue final guidance later this year for manufacturer effectuation of the MFP in 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.

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 MFP effectuation policies for the Negotiation Program for 2028, building on policies established in final guidance for initial price applicability year 2028 and applying CMS' experience during the first year of effectuating MFPs. In accordance with section 1193(a) of the Act, this draft guidance includes policies to describe how Primary Manufacturers of drugs selected for negotiation or renegotiation for initial price applicability year 2028 that reached an agreement on an MFP through negotiation or renegotiation, as applicable, must provide access to the agreed-upon MFP in 2028 to Part B providers with respect to MFP-eligible individuals[6] who are furnished or administered that selected drug during a price applicability period pursuant to the Medicare Drug Price Negotiation Program Agreement (hereinafter also referred to as an "Agreement"). This draft guidance also describes adjustments to Medicare Transaction Facilitator (MTF) operations to address structural differences (e.g., Medicare payment methodologies) between selected drugs covered under Part D and/or payable under Part B as well as to incorporate data sources for Part B Original Medicare (OM) and Medicare Advantage (MA). Furthermore, this draft guidance solicits comments on topics including, but not limited to, the approach for a standardized pricing metric to approximate acquisition cost for the purposes of calculating a standardized default refund amount (SDRA) to assist Primary Manufacturers in making the MFP available for Part B claims,[7] approaches to simplify the effectuation of the MFP operational process to reduce burden for Part B providers, Primary Manufacturers, and other interested parties, and enforcement considerations or approaches unique to Part B claims. Given the ongoing implementation of this program throughout 2026, CMS may make additional adjustments in the final guidance to reflect the agency's experience.

A Primary Manufacturer must effectuate any agreed-upon MFP for drugs selected for initial price applicability year 2028, including MFPs agreed upon following renegotiation, when dispensed, furnished, or administered to MFP-eligible individuals on or after January 1, 2028. To the extent appropriate and feasible, CMS has endeavored 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. The MTF will be expanded to support MFP effectuation for selected drugs payable under Part B beginning with initial price applicability year 2028.

CMS considered the comments and recommendations related to the MFP effectuation process for selected drugs payable under Part B that CMS received on the 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[8] (hereinafter referred to as "draft guidance for initial price applicability 2028"), including how any changes would correspond with MTF data and payment workflows, in the development of MFP effectuation policies for selected drugs payable under Part B.

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[6] MFP-eligible individual is defined in section 1191(c)(2)(B) of the Act and described in section 80 of this draft guidance.

[7] When referring to "Part B claim" or "Part B claims" this term collectively refers to OM claims data as well as MA encounter data for Part B items or services unless otherwise specified.

[8] See: https://www.cms.gov/files/document/ipay-2028-draft-guidance.pdf.

Topics that are not relevant to MFP effectuation in 2028 will not be addressed in this draft guidance. CMS refers readers to its website[9] for information on MFP effectuation policies in 2026 and 2027, Negotiation Program implementation for initial price applicability year 2028,[10] and the proposed rule[11] for Negotiation Program policies for initial price applicability year 2029 and subsequent years.

To help facilitate review for interested parties, CMS maintained the section numbering from prior guidance[12, 13] in this draft guidance specifically for sections that address MFP effectuation policies. CMS has also added new subsections in this draft guidance to address MFP effectuation policies for selected drugs payable under Part B. Because the scope of this draft guidance is limited to MFP effectuation policies and compliance and oversight of such policies in 2028, CMS did not include sections with unrelated policies as they are already addressed in final guidance for initial price applicability year 2028.

40.4 Providing Access to the MFP in 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 2028, provide access to the MFP to MFP-eligible individuals (as defined in section 1191(c)(2)(A) of the Act and described in section 80 of this draft guidance) and to 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, such Primary Manufacturers must also provide access to the MFP, or renegotiated MFP, as applicable, to Part B providers with respect to MFP-eligible individuals (as defined in section 1191(c)(2)(B) of the Act and described in 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 Health Plan Management System ("the CMS HPMS") and published in accordance with sections 30.4 and 60.6 of the final guidance for initial price applicability year 2028. 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.

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[9] See: https://www.cms.gov/priorities/medicare-prescription-drug-affordability/overview/medicare-drug-price-negotiation-program/guidance-policy-documents.

[10] See: https://www.cms.gov/files/document/ipay-2028-final-guidance.pdf.

[11] See: https://www.federalregister.gov/documents/2026/06/16/2026-12059/medicare-drug-price-negotiation-program-and-medicare-prescription-drug-benefit-program.

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

[13] See: https://www.cms.gov/files/document/ipay-2028-final-guidance.pdf.

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 final guidance for initial price applicability year 2028, the Primary Manufacturer has an ongoing obligation to timely report any changes to the 11-digit National Drug Codes (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 2028, CMS updates the MFP file as needed.[14] For initial price applicability year 2028, the MFP file will contain the single MFP for a 30-day equivalent supply of the selected drug and the NDC-9 per unit price and the Healthcare Common Procedure Coding System (HCPCS) code[15] dosage price and will be updated annually to show the inflation-adjusted MFP for the selected drug. Sections 60.5 and 60.6 of the final guidance for initial price applicability year 2028 contain more details related to the MFP file.

Under section 1860D-2(d)(1)(D) of the Act, as amended by section 11001(b) of the IRA, the negotiated prices used in payment by each Part D plan sponsor for each selected drug must not exceed the applicable MFP plus any dispensing fees for such drug.[16] 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[17] 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.

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

[15] For the purposes of this draft guidance, CMS refers to HCPCS Level II codes as "HCPCS codes" generally. HCPCS Level II codes were established for submitting claims for drugs and biological products, among other items, and are maintained by CMS. CMS, Healthcare Common Procedures Coding System (HCPCS) Level II Coding Procedures, https://www.cms.gov/medicare/coding/medhcpcsgeninfo/downloads/2018-11-30-hcpcs-level2-coding-procedure.pdf.

[16] 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 dispensing entities with respect to such MFP-eligible individuals who are dispensed that selected drug.

[17] For 2029 and subsequent years, CMS proposed to amend the regulatory definition of negotiated price at 42 CFR 423.100 to codify the requirement under section 1860D-2(d)(1)(D) of the Act that 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. See: Medicare Drug Price Negotiation Program and Medicare Prescription Drug Benefit Program (CMS-4215-P), https://www.federalregister.gov/documents/2026/06/16/2026-12059/medicare-drug-price-negotiation-program-and-medicare-prescription-drug-benefit-program.

Section 1193(a) of the Act also requires that the Primary Manufacturer provide access to the MFP for the selected drug to dispensing entities with respect to MFP-eligible individuals who are dispensed such drugs. Beginning in 2028, for drugs selected for initial price applicability year 2028 or with a renegotiated MFP for initial price applicability year 2028, Primary Manufacturers must also provide access to the MFP for the selected drug to 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/or 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 and/or Part B provider for the selected drug (as discussed in more detail in section 40.4.1 of this draft guidance) is no greater than the MFP.

A Primary Manufacturer must provide access to the MFP in one of two ways: (1) prospectively ensuring that the price paid by the dispensing entity and/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 and/or Part B provider's acquisition cost and the MFP. For selected drugs dispensed, furnished, or administered to MFP-eligible individuals, this means that, unless the dispensing entity's or Part B provider's acquisition cost for the selected drug is equal to or less than the MFP, or, as detailed in section 40.4.5 of this 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 either dispensed, furnished, or administered to an MFP-eligible individual (hereinafter the "14-day prompt MFP payment window").

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. This includes the obligation to make the MFP available for units of the selected drug that are manufactured, marketed, controlled, or sold by any Secondary Manufacturer(s) and dispensed, furnished, or administered to MFP-eligible individuals.[18] Commercial and other payers continue to have discretion to consider Medicare payment rates, including the MFP, in establishing their own payment policies.

[18] As described in section 40 of the final guidance for initial price applicability year 2028, for initial price applicability year 2028, CMS will refer to any entity other than the Primary Manufacturer 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 a New Drug Application (NDA) or Biologics License Application (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.

CMS has engaged an MTF Contractor[19] for the Negotiation Program to facilitate the exchange of data between Primary Manufacturers and dispensing entities. The Medicare Transaction Facilitator Data Module (MTF DM) supports the verification that the selected drug was dispensed to an MFP-eligible individual, as described in section 40.4.2 of the final guidance for initial price applicability year 2028 and this draft guidance. As discussed in section 40.4.2 of this draft guidance, CMS believes mandatory participation for Primary Manufacturers in the MTF's data exchange functionality is necessary to administer the Negotiation Program, as well as to promote compliance and oversight. In accordance with 42 CFR 423.505(q), Part D plan sponsors are required to include in their network pharmacy agreements a provision requiring dispensing entities to be enrolled in the MTF DM. Dispensing entity enrollment in the MTF DM is needed for necessary operations related to administration of the Negotiation Program and the Part D program, including creating and sending electronic remittance advices (ERAs) or remittances, facilitating continued access to selected drugs that are covered Part D drugs, and ensuring accurate Part D claims information and payment. The MTF DM would serve a similar purpose for selected drugs payable under Part B and CMS is considering policies related to Part B provider participation with the MTF DM, which are further described in section 40.4.2 of this draft guidance.

CMS has also engaged a separate MTF Contractor to support the Medicare Transaction Facilitator Payment Module (MTF PM). The MTF PM facilitates the pass through of payments from Primary Manufacturers that elect to use the MTF PM that complement the data-related activities of the MTF DM. The MTF PM is available to Primary Manufacturers for selected drugs covered under Part D and, starting in 2028, would also be available for selected drugs payable under Part B. Processes and requirements related to the MTF PM are further described in section 40.4.3 of this draft guidance.

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, which had applied to only selected drugs that are covered under Part D with respect to initial price applicability years 2026 and 2027. In anticipation of the effectuation of MFPs for selected drugs that are payable under Part B for initial price applicability year 2028, CMS anticipates conducting similar activities with respect to the MTF throughout late 2026 and 2027 that will include system testing and onboarding of Primary Manufacturers and Part B providers.

For policies related to MFP effectuation for selected drugs payable under Part B, CMS has, to the extent operationally feasible, aligned the policies to effectuate the MFP for Part B providers submitting claims to OM and Part B providers submitting claims to MA organizations. Under OM, Medicare pays Part B providers directly for items and services administered or furnished. In contrast, under MA, private health plans pay Part B providers either a contracted rate or a non-contracted rate in accordance with 42 CFR 422.214, as applicable. Because Part B providers

[19] 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.

may receive payment for furnishing or administering selected drugs payable under Part B under two distinct administrative and payment frameworks, there is added complexity for MFP effectuation for selected drugs payable under Part B compared to the uniform flow of claims data for selected drugs covered under Part D. Given differences between the administration of OM and MA and subsequent data availability to CMS, CMS is soliciting comments on alternative approaches to effectuating the MFP for selected drugs payable under Part B to acknowledge such differences. For example, CMS is evaluating a direct obligation for MA organizations to submit to the MTF DM Medicare Advantage claims data for selected drugs only to ensure Part B providers receive timely payment of MFP refunds. As discussed further in section 40.4.2.1.2 of this draft guidance, CMS intends to use MA encounter data as the source of information to provide claim-level data elements to Primary Manufacturers for selected drugs payable under Part B that are furnished or administered to an individual enrolled in Part C for 2028. CMS is soliciting input on other approaches to reduce operational complexity for MFP effectuation of selected drugs payable under Part B.

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

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 and/or Part B providers by retrospectively transmitting payment for the difference between the dispensing entity and/or Part B provider's acquisition cost and the MFP (i.e., the MFP refund amount) within the 14-day prompt MFP payment window. CMS recognizes that Primary Manufacturers, dispensing entities, and Part B providers may face significant challenges establishing a reliable actual acquisition cost for a selected drug that could be used to determine the MFP refund amount. Challenges to using each dispensing entity and/or Part B provider's actual acquisition cost for each particular dispensed, furnished, or administered unit of a selected drug may include differences in purchasing agreements with suppliers that contribute to variable drug costs among dispensing entities and/or Part B providers; the high number of dispensing entities and Part B providers which a Primary Manufacturer must account for when determining MFP refund payments; pricing variability among individual units of a selected drug within each dispensing entity's and/or Part B provider'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, furnished, or administered; pricing variation as a result of participation in large Group Purchasing Organizations (GPO); and restrictions and sensitivities around sharing proprietary pricing information with third-party vendors. However, nothing in this section precludes a Primary Manufacturer and dispensing entity and/or Part B provider from choosing to effectuate the MFP by calculating the MFP refund using a dispensing entity and/or Part B

provider's actual acquisition cost rather than a standardized pricing metric that serves as a reasonable proxy for the dispensing entity and/or Part B provider's acquisition cost.

CMS outlines in section 90.2.1 of this draft guidance the agency's process for determining when the MFP was made available and the specific information that may be considered when evaluating whether the MFP was made available in individual cases. Primary Manufacturers should consider CMS' MFP effectuation compliance monitoring and enforcement policies and procedures when determining whether an MFP refund is necessary to effectuate the MFP and when calculating the amount of such a refund; see section 90.2.1 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 reviews complaints regarding access to the MFP on a case-by-case basis and monitors overall trends and emerging compliance issues reported via the complaints and disputes system, including issues related to determining acquisition costs.

In light of the significant operational challenges associated with calculating real-time actual acquisition cost, Primary Manufacturers and dispensing entities and/or Part B providers may agree to use a standardized pricing metric to approximate acquisition cost for the purpose of calculating any MFP refund amount necessary to make the MFP available. Additionally, to address concerns raised by interested parties that the use of actual acquisition cost would create significant administrative burdens and potentially require dispensing entities to share proprietary or confidential pricing information with Primary Manufacturers, CMS uses a standardized pricing metric (Wholesale Acquisition Cost (WAC)) to calculate a "standard default refund amount" for Part D claims. Use of a standardized pricing metric to calculate an SDRA for Part B claims would provide similar benefits. CMS is soliciting comments on four options for the standardized pricing metric to approximate acquisition cost for the purpose of calculating an SDRA to assist Primary Manufacturers in making the MFP available for Part B claims, as described in section 40.4.1.2 of this draft guidance.

A Primary Manufacturer is obligated to calculate and pay an appropriate amount to ensure the dispensing entity and/or Part B provider has access to the MFP. 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 and/or Part B provider can work with a Primary Manufacturer to establish an agreed-upon MFP refund amount using the dispensing entity's and/or Part B provider's actual acquisition cost or an adjusted standardized pricing metric that ensures the MFP has been made available. The Primary Manufacturer would indicate such agreed-upon amount when reporting the claim-level payment elements, described in sections 40.4.3.1 and 40.4.4.2 of this draft guidance, to the MTF DM. As for cases where the MTF DM does not provide the Primary Manufacturer with a calculated SDRA, Primary Manufacturers are required to include information on their approach to calculating an MFP refund amount in the Primary Manufacturers' MFP Effectuation Plans as outlined in section 90.2.1 of this draft guidance.

As set forth in section 90.2.1 of this draft guidance, in its written plan for making the MFP available that is submitted to CMS, the Primary Manufacturer must include whether it will use

the dispensing entity's and/or Part B provider's actual acquisition cost or a reasonable proxy for such a cost, such as the standardized pricing metric used in the calculation of the SDRA, to provide retrospective refunds to a dispensing entity and/or Part B provider. If the Primary Manufacturer and a dispensing entity and/or Part B provider agree to make the MFP available via a retrospective refund calculated based on a reasonable proxy for the dispensing entity and/or the Part B provider's acquisition cost (e.g., the standardized pricing metric as used in the SDRA) as opposed to the dispensing entity's and/or Part B provider'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 and/or Part B provider. As discussed in section 90.2 of this draft guidance, when assessing whether a Primary Manufacturer provided access to the MFP to a dispensing entity and/or Part B provider with respect to a selected drug, absent information available to CMS indicating otherwise, CMS will consider provision of the SDRA to meet the Primary Manufacturer's obligation to make the MFP available. 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 and/or Part B provider believes that it has not received a retrospective refund that effectuates the MFP, CMS recommends the dispensing entity and/or Part B provider 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, to address issues regarding access to the MFP.

40.4.1.1 Retrospective Refund Amount to Effectuate the MFP and the Standardized Default Refund Amount for Drugs Covered Under Part D

For selected drugs covered under Part D, CMS believes that the WAC will generally best approximate the acquisition costs of Part D dispensing entities and offers a reliable method for calculating an SDRA for Primary 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.

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 for selected drugs covered under Part D. As described in section 40.4.2 of this draft guidance, the MTF DM will provide the Primary Manufacturer with the SDRA (i.e., for Part D claims, 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. For selected drugs covered under Part D, 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.[20]

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. In addition, as noted above, Primary Manufacturers are required to include information on their approach to calculating an MFP refund amount in their MFP Effectuation Plans, as outlined in section 90.2.1 of this draft guidance.

40.4.1.2 Retrospective Refund Amount to Effectuate the MFP and the Standardized Default Refund Amount for Drugs Payable Under Part B

In response to draft guidance for initial price applicability year 2028, CMS received feedback from a variety of interested parties regarding differences between Medicare coding and billing requirements for Part B claims and Part D claims, specifically the use of HCPCS codes on Part B claims to determine payment rather than the use of NDCs. This feedback identified two distinct operational challenges, each of which is addressed below.

Issue 1: *Identifying Whether a Claim Billed with a HCPCS Code is MFP-Eligible*
Unlike Part D claims, which use the NDC for a specific drug for billing and payment, Part B claims use HCPCS codes. A single HCPCS code could include or correspond with multiple NDCs, including NDCs for both selected and non-selected drugs. Therefore, it is not always possible to determine from the HCPCS code alone whether the specific drug furnished or administered to a beneficiary is a selected drug with an applicable MFP (hereinafter "MFP-eligible NDC"). This challenge could arise when a generic drug relies on a selected drug, that is approved under an NDA, as its listed drug in the Orange Book. In such circumstances where the generic drug is approved after the selected drug is selected (and before such selected drug is deselected from the Negotiation Program), CMS may assign both the generic drug and the selected drug to the same HCPCS code.

This challenge is illustrated by the following scenario: drug X is a selected drug for initial price applicability year 2028, has one NDC-11 assigned to HCPCS code J1234, and is marketed under one approved NDA. Drug Y, a generic drug that has drug X as its listed drug, is determined to be

[20] 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, that overwhelmingly supported 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.

approved and marketed on a date between November 2, 2026, and March 31, 2028. In this scenario, selected drug X would remain a selected drug for calendar year 2028, the MFP would apply for 2028, and drug X would not cease to be a selected drug until January 1, 2029, as described in section 70 of the final guidance for initial price applicability year 2028. If drug X and drug Y share the same HCPCS code, for the period of time for which drug X and drug Y are both approved and marketed and before drug X is deselected from the Negotiation Program, the Primary Manufacturer of drug X cannot readily determine based on the HCPCS code alone whether a given claim for J1234 represents the furnishing or administration of drug X's NDC-11, and therefore whether the MFP for drug X should apply. Table 1 illustrates this scenario.

Table 1: Illustrative Example of a Scenario that Describes MFP-Eligible and Non-MFP Eligible NDCs Assigned to a Shared HCPCS Code

Product	**HCPCS Code**	**NDC**	**Selected Drug Status**	**Relevant Timing Considerations for Deselection and MFP of Drug X**	**Result with Respect to Selected Drug Status for the Negotiation Program and Use of HCPCS Codes**
Drug X	J1234	NDC-11#1	Selected drug for initial price applicability year 2028	MFP applies beginning January 1, 2028	Drug X remains a selected drug for 2028 and ceases to be a selected drug on January 1, 2029. MFP ceases to apply on January 1, 2029.
Drug Y (generic of drug X)	J1234	NDC-11#2	Not a selected drug	MFP never applies. Date on which CMS determines that Drug Y is approved and marketed is between November 2, 2026, and March 31, 2028	Drug X and drug Y share the same HCPCS code. During 2028 it is unclear to Primary Manufacturer of drug X whether shared HCPCS code included furnishing or administration of drug X's NDC-11 and therefore whether MFP for drug X must apply.

To address this issue and for the purpose of facilitating the effectuation of MFP in such cases, CMS is considering different approaches, described in the options below, to identify MFP-eligible claims where an MFP-eligible NDC-11 for a selected drug has been administered or furnished to an MFP-eligible individual.

Options to Address Issue 1: Identifying MFP-Eligible Claims Billed with a HCPCS Code

CMS is considering three options to address the challenge of identifying whether a claim billed with a HCPCS code represents the furnishing or administration of an MFP-eligible NDC-11 for a selected drug.

Option 1: *Require Reporting of Selected Drug and Non-Selected Drug Modifiers*
CMS is considering requiring the use of a claims modifier to indicate whether an MFP-eligible NDC for a selected drug was administered or furnished. Specifically, CMS could establish two modifiers that would be reported on OM claims submitted for a HCPCS code that includes a selected drug: one modifier to indicate an MFP-eligible NDC for a selected drug was administered or furnished and a second modifier to indicate an NDC for a non-selected drug was administered or furnished. For example, when a HCPCS code that includes a selected drug is used, the illustrative "JM" modifier would be used to report that an MFP-eligible NDC for a selected drug was administered or furnished and the illustrative "JN" modifier would be used to report that an NDC for a non-selected drug was administered or furnished. MFP-eligible NDCs and HCPCS codes for selected drugs would be listed on the Selected Drug List and MFP file published on the CMS website.[21] See Table 2 below for an illustrative description of this method. CMS would use the illustrative "JM" modifier to identify the number of billing units of a HCPCS code associated with the NDC(s) for the selected drug and facilitate effectuation of the MFP by the Primary Manufacturer. CMS would use the illustrative "JN" modifier to identify the number of billing units of a HCPCS code associated with the NDC(s) that are not MFP-eligible but assigned to the same HCPCS code as the selected drug. In addition to considering a regulatory billing requirement for Part B providers with respect to OM, CMS is considering establishing a requirement, which would be proposed in the appropriate rulemakings, to require the collection of selected drug and non-selected drug modifiers by MA organizations on all encounters for drugs payable under Part B submitted for a HCPCS code that includes a selected drug and the submission of such data to CMS. CMS is also considering creating edits in the OM claims processing systems to ensure that relevant HCPCS codes are reported with the correct modifier.

Table 2: Illustrative Example: Separate Modifiers to Report MFP-Eligible and Non-MFP-Eligible NDCs within a HCPCS Code

HCPCS Code	Drug Name	Selected Drug	Illustrative Modifier	Illustrative Short Descriptor
J1234	Drug X	Yes	JM	Use for NDCs for selected drug
J1234	Drug Y	No	JN	Use for NDCs for non-selected drug

Option 2: *Require Reporting of NDC-11s on All Part B Claims*
A second option that CMS is considering to address Issue 1 described above and in Table 1 is to require reporting of the NDC-11 in addition to the HCPCS code for each Part B claim. If NDC-11s were reported on Part B claims in addition to the HCPCS code, then the MTF DM would be able to identify when, as described in Table 1, drug X was administered or furnished on a claim and transmit the claim-level data elements associated with drug X to the Primary

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

Manufacturer. Likewise, when an NDC associated with drug Y was administered or furnished, the MTF DM would not transmit the associated claim-level data elements for the administration of drug Y, given that drug Y is not a selected drug. In addition to considering a requirement for Part B providers with respect to OM, CMS is considering establishing a requirement, which would be proposed in the appropriate rulemakings, to require MA organizations to collect NDC-11s on claims for HCPCS codes that include a selected drug from providers furnishing or administering selected drugs payable under Part B and submit such data for encounters for selected drugs payable under Part B to CMS. CMS is also considering establishing edits in the OM claims processing systems to ensure that relevant NDC-11s are reported. Under Option 2, CMS would not need to require a selected drug or non-selected drug modifier to be submitted on Part B claims (Option 1).

Option 3: *Establish Separate HCPCS Codes for Selected Drugs and Non-Selected Drugs that Would Otherwise Share a HCPCS Code*

A third approach that CMS is considering to address Issue 1 described above and in Table 1 is premised on the current HCPCS code assignment structure applicable to selected drugs for initial price applicability year 2028 that are payable under Part B. Under current HCPCS code assignment practice, biological products approved under a BLA, including the reference biological product and any biosimilar biological products, are each assigned unique HCPCS codes. Accordingly, for initial price applicability year 2028, the selected drugs that are payable under Part B, which are all biological products approved under a BLA, are each assigned a unique HCPCS code that includes only NDC-11(s) for the selected drug; if a biosimilar product were approved it would also be assigned a unique HCPCS code. Under Option 3, CMS would adopt an approach for HCPCS code assignment for selected drugs for initial price applicability year 2028 approved under an NDA analogous to HCPCS code assignment practices for biological products approved under a BLA. That is, for a generic drug that identifies a selected drug as its listed drug in the Orange Book and that is approved during the period in which the selected drug remains in the Negotiation Program, then that generic drug product would receive its own unique HCPCS code distinct from the HCPCS code assigned to the selected drug. For example, if in a future year, a generic drug to a selected drug for initial price applicability year 2028 that is approved under an NDA, is approved after the selected drug is selected and before such selected drug is deselected from the Negotiation Program (e.g., the scenario described in Table 1), CMS would establish a HCPCS code for the generic drug that is unique and separate from the HCPCS code that includes a selected drug. In addition, CMS is considering a variation on this Option 3, in which separate HCPCS codes would be assigned to each selected drug for initial price applicability year 2028 and for each therapeutic equivalent product of that selected drug.

Under this approach, CMS would not require Part B providers to submit and/or MA organizations to collect and submit additional claims modifiers (as described in Option 1) or NDC-11s on Part B claims (as described in Option 2) for purposes of identifying MFP-eligible claims for initial price applicability year 2028 selected drugs. Instead, CMS would rely on the unique HCPCS code assigned to the selected drug as sufficient to identify whether a claim represents the furnishing or administration of an MFP-eligible NDC-11 for a selected drug.

Solicitation of comments on how to address Issue 1: CMS is soliciting comments on the three options described above for identifying MFP-eligible claims for selected drugs payable under Part B that are billed using a HCPCS code. CMS invites comments on the operational feasibility and administrative burden of Option 1 including the likelihood of modifier misreporting and burden required to affix modifiers in the way described; the operational feasibility and administrative burden of Option 2 including the extent to which Part B providers currently capture NDC-11 information on claims for other payers, the systems changes required, the timeline needed for implementation, and whether NDC-11 reporting would provide sufficient accuracy to support MFP eligibility determinations; and feedback on Option 3 including any comments on the implications of establishing separate HCPCS codes for selected and non-selected drugs that would otherwise be assigned to the same HCPCS code and the feasibility of relying solely on HCPCS code assignment for MFP eligibility identification. Finally, CMS is soliciting comments on the impact and/or burden of the options described on interested parties, including, but not limited to, Part B providers and MA organizations. CMS also welcomes general comments on the relative merits, limitations, and implementation challenges of each option.

Issue 2: *Calculating the SDRA for Selected Drugs Payable Under Part B When Billed with a HCPCS Code*

A separate but related challenge arises in calculating the SDRA for selected drugs payable under Part B. In response to draft guidance for initial price applicability year 2028, interested parties noted that differences in acquisition costs and billing methodologies between drugs payable under Part B and drugs covered under Part D make it difficult to apply the same SDRA calculation process used for drugs covered under Part D, as outlined in section 40.4.1 of the final guidance for initial price applicability year 2028, to drugs payable under Part B.

Because drugs payable under Part B are generally paid at the HCPCS code level, and because a single HCPCS code can include multiple NDCs each with a potentially different WAC, the acquisition cost for a drug billed under a given HCPCS code may vary across NDCs assigned to that HCPCS code. Furthermore, as discussed in connection with Issue 1, for most Part B claims, the specific NDC furnished or administered is not currently required to be reported on OM claims and, therefore, may not be known to CMS.[22] These factors necessitate development of alternative methodologies for calculating the SDRA for selected drugs payable under Part B. Described below are the options CMS is considering to address this issue.

Options to Address Issue 2: Calculating the SDRA for Selected Drugs Payable Under Part B When Billed with a HCPCS Code

As described above, the use of HCPCS codes rather than NDCs on Part B claims necessitates a different approach to calculating the SDRA compared to selected drugs covered under Part D. To address this, CMS is considering four options, described below, and summarized in Table 3.

[22] Exceptions include crossover claims from Medicaid for dual eligible beneficiaries and for the End-Stage Renal Disease (ESRD) transitional drug add-on payment adjustment.

Table 3: Options to Calculate the SDRA for Selected Drugs Payable Under Part B

Option	Pricing Metric	NDC-11 Required on the Claim	Key Dependency
Option 1a	Average WAC across NDC-11s of selected drug, weighted by ASP sales volume	No	Relies on ASP sales volume data reported to CMS for weighting
Option 1b	Published WAC for each NDC-11	Yes	Requires NDC-11 collection on Part B claims
Option 2a	Average ASP across NDC-11s of selected drug, weighted by ASP sales volume	No	Relies on ASP information reported to CMS, including ASP sales volume data for weighting
Option 2b	Average ASP across NDC-11s of selected drug, weighted by Part B claims volume	Yes	Relies on ASP information reported to CMS and requires NDC-11 reporting on Part B claims

CMS is soliciting comments on options for calculating the SDRA on claims for selected drugs payable under Part B (i.e., the standardized pricing metric per unit minus the MFP per unit, then multiplied by the billing units on the claim). Under Option 1a, CMS would calculate a weighted average of the WACs of NDC-11s of a selected drug assigned to the HCPCS code that includes the NDCs of the selected drug. CMS would weight the WAC for each NDC-11 of the selected drug by the Average Sales Price (ASP) sales volume as reported in the ASP Data Collection System. CMS would use the WAC price as published in pharmaceutical pricing database compendia at the time the calculation is being determined (e.g., quarterly) for periodic publication of updates to the SDRA. Under Option 1b, CMS would collect the NDC-11 on claims for selected drugs payable under Part B, as outlined in Option 2 to address Issue 1 above, and use the WAC price for the applicable NDC-11 as published in pharmaceutical pricing database compendia as of the "Claim From Date" of the Part B claim. Under Option 2a and Option 2b, CMS would use a volume-weighted average ASP-based approach, volume-weighted based on either the ASP sales volume or submitted Part B claims respectively, to calculate the SDRA for Part B claims for selected drugs payable under Part B. Table 4 provides an illustration of how the volume data (ASP sales volume data for Options 1a and 2a, and claims volume data for Option 2b) would be used to inform the volume-weighted average calculation per NDC-11 unit described in Options 1a, 2a, and 2b.

To operationalize Options 1a, 2a, and 2b, CMS would use NDC-level data from the ASP Data Collection System (i.e., the ASP Portal). ASP data is required to be submitted to the ASP Portal within 30 days after the close of each calendar quarter, and CMS uses that data to calculate payment amounts under section 1847A of the Act for the quarter that is two quarters after the quarter for which data was submitted. Likewise, to calculate the SDRA as described in Options 1a, 2a, and 2b, for a selected drug furnished or administered during a particular quarter, CMS would use the ASP data reported by the manufacturer for the quarter two quarters prior to the quarter during which the selected drug was administered or furnished. Due to the ASP reporting timeline described above, this is the most recent ASP data available to the agency. For example,

sales data from January 1, 2028, to March 31, 2028 is submitted to CMS by April 30, 2028, and would be applied to SDRA calculations for the furnishing or administration of a selected drug with a "Claim From Date" during the quarter that begins July 2028. We acknowledge this would result in a two-quarter lag between the quarter of ASP sales occurrence and when the sales data would be used to calculate the SDRA. However, CMS believes that relying on ASP data reported for the quarter two quarters prior to the quarter during which the selected drug was administered or furnished to calculate the SDRA under Options 1a, 2a, and 2b would best balance using the most recently reported ASP data to approximate acquisition cost for the quarter in which the selected drug was administered or furnished with operational feasibility. We considered but do not currently believe that it is operationally practicable to require manufacturers to report ASP data to CMS for selected drugs payable under Part B on an accelerated timeline.

Table 4: Example Calculation of the Weighted Average Per-Unit Standardized Pricing Metric for a Selected Drug

NDC-11 Values	Cost[23] per NDC-11 Unit	Sales Volume Data- Units	Ratio of Total Sales Volume	Weighted Average Cost per HCPCS Unit[24]
NDC-11#1	$1.00	10,000 units	66.7%	$1.33
NDC-11#2	$2.00	5,000 units	33.3%	$1.33

Option 1a: *SDRA is calculated using the average of the WACs for all NDC-11s of a selected drug assigned to a HCPCS code that includes a selected drug, weighted by ASP sales volume*
Under the first option for calculating the SDRA for selected drugs payable under Part B, referred to throughout this draft guidance as Option 1a, CMS would calculate the standardized pricing metric used in the calculation of the SDRA using a volume-weighted average of the per-unit WAC(s) for each selected drug's NDC-11(s) assigned to a HCPCS code that includes a selected drug. As discussed later in this section, when calculating the standardized pricing metric included in the SDRA file, which will be used to calculate the SDRA at the claim level, CMS would obtain the per-unit WAC from published pharmaceutical pricing database compendia for each NDC-11(s) of a selected drug and the billing units per package from the NDC-HCPCS Crosswalk[25] for each NDC-11 assigned to the HCPCS code that includes a selected drug. CMS would use the following weighting methodology to determine the SDRA:

- Step 1: Standardize WAC to per HCPCS billing unit amount
    - CMS would standardize the per-unit WAC(s) to the corresponding HCPCS code billing unit level using the same HCPCS billing unit as listed in the NDC-HCPCS Crosswalk for that quarter.
- Step 2: Convert ASP sales volume to HCPCS billing unit equivalent
    - CMS would then determine the total HCPCS billing units for each NDC-11 of the selected drug in a quarter by multiplying the volume of ASP units sold of each

[23] Cost is represented by the standardized pricing metric, ASP or WAC, described in Options 1a, 2a, or 2b.
[24] "Weighted Average Cost per HCPCS Units" is calculated by multiplying the "Cost per NDC-11 Unit" and the "Ratio of Total Sales Volume" and then summing the total for each NDC-11. For example (($1.00 x 66.7% =$.667) + ($2.00 x 33.3% = $0.667) = $1.33.
[25] See: https://www.cms.gov/medicare/payment/part-b-drugs/asp-pricing-files.

NDC-11 as reported to the ASP portal for a quarter by the number of billable units per NDC-11 reporting unit as listed in the NDC-HCPCS Crosswalk for that quarter (i.e., convert from ASP units sold to the HCPCS billable units).

- Step 3: Calculate weighted WACs based on HCPCS billing units
    - CMS would then weight the per-unit WACs using ASP sales volume data based on the proportion of the volume of total HCPCS billing units for each NDC-11 of the selected drug assigned to the selected drug HCPCS code (Example: See "Ratio of Total Sales Volume" in Table 4).
- Step 4: Sum average weight per unit WAC
    - CMS would then sum the average weighted per-unit WAC(s) across NDC-11(s) assigned to a HCPCS code (Example: See "Weighted Average Cost per HCPCS Unit" in Table 4).

In a scenario where there is only one NDC-11 assigned to the HCPCS code that includes a selected drug, CMS would obtain the per-unit WAC for the single NDC-11 and standardize to the HCPCS billing units, if necessary.

The SDRA would be calculated using the per-unit volume-weighted average of the WACs for the selected drug NDC-11(s) assigned to each HCPCS code that includes a selected drug, as described above, minus the per-unit MFP as of the "Claim From Date" indicated on the Part B claim, multiplied by the billing units administered or furnished for the HCPCS code that includes a selected drug. The SDRA would be transmitted by the MTF DM to the Primary Manufacturer as part of the transmitted claim-level data elements.

Should CMS establish the approach to collect NDC-11s on Part B claims of selected drugs as discussed in Option 2 to address Issue 1 above, there would not be a need to calculate volume-weighted average WACs under the HCPCS code because the NDC-11 used on the claim would be known and could be used to calculate the SDRA, and the approach described under Option 1a would be unnecessary. Option 1b describes an approach to calculating the SDRA in such a scenario in which the NDC-11 is provided on the Part B claim.

Option 1b: *SDRA is calculated using the WAC as published in the pharmaceutical pricing database compendia; CMS collects NDC-11 data on Part B claims*
Under Option 1b, CMS would use the WAC, as published in pharmaceutical pricing database compendia, as of the "Claim From Date" of the Part B claim, as the standardized pricing metric to calculate the SDRA. This option would require that CMS collect the NDC-11 on Part B claims of selected drugs and standardize the per-unit level of each NDC-11's WAC to the billing units for the billed HCPCS code, if necessary. This approach to reporting and collection of NDC-11s on Part B claims of selected drugs is described earlier in Option 2 to address Issue 1 of this draft guidance. The MTF DM would provide the Primary Manufacturer with the SDRA as part of the transmitted claim-level data elements.

Option 2a: *SDRA is calculated using the average of the reported ASPs for all NDC-11s of a selected drug assigned to a HCPCS code that includes a selected drug, weighted by ASP sales volume*

In this option, referred to throughout this draft guidance as Option 2a, CMS would use a volume-weighted average of the reported ASPs for each NDC-11(s) for a selected drug assigned to the HCPCS code(s) that include a selected drug, as the standardized pricing metric to calculate the SDRA for each HCPCS code that includes a selected drug. CMS would use the following weighting methodology to determine the SDRA:

- Step 1: Standardize ASP to per HCPCS billing unit amount
    - CMS would standardize the ASP(s) for each NDC-11 to the corresponding HCPCS code billing unit level using the same billing units per NDC-11 reporting unit as listed in the NDC-HCPCS Crosswalk for that quarter.
- Step 2: Convert ASP sales volume to HCPCS billing unit equivalent
    - CMS would then determine the total HCPCS billing units for each NDC-11 of the selected drug in a quarter by multiplying the volume of ASP units sold of each NDC-11 as reported to the ASP portal for a quarter by the number of billable units per NDC-11 reporting unit as listed in the NDC-HCPCS Crosswalk for that quarter (i.e., convert from ASP units sold to the HCPCS billable units).
- Step 3: Calculate weighted ASPs based on HCPCS billing units
    - CMS would then weight the per-unit ASPs using ASP sales volume data based on the proportion of the volume of total HCPCS billing units for each NDC-11 of the selected drug assigned to the selected drug HCPCS code (Example: See "Ratio of Total Sales Volume" in Table 4).
- Step 4: Sum average weight per unit ASP
    - CMS would then sum the average weighted per-unit ASP(s) across NDC-11(s) assigned to a HCPCS code (Example: See "Weighted Average Cost per HCPCS Unit" in Table 4).

In a scenario where there is only one NDC-11 assigned to the HCPCS code that includes a selected drug, CMS would obtain the per-unit ASP for the single NDC-11 and standardize to the HCPCS billing units, if necessary.

The SDRA would be calculated using the per-unit volume-weighted average of the ASPs for the selected drug NDC-11(s) assigned to each HCPCS code that includes a selected drug, as described above, minus the per-unit MFP as of the "Claim From Date" indicated on the Part B claim, multiplied by the billing units administered or furnished for the HCPCS code that includes a selected drug. The SDRA would be transmitted by the MTF DM to the Primary Manufacturer as part of the transmitted claim-level data elements.

Option 2b: *SDRA is calculated using the average of the reported ASPs for all NDC-11s of a selected drug assigned to a HCPCS code that includes a selected drug, volume-weighted by NDCs from Part B claims*

Under Option 2b, CMS would use a claims-based, volume-weighted average of the Primary Manufacturer's reported ASPs for each selected drug's NDC-11(s) assigned to the HCPCS code(s) that include a selected drug, as the standardized pricing metric to calculate the SDRA. This would require the collection of the NDC-11(s) on Part B claims for selected drugs as described in Option 2 to address Issue 1 of this section. Unlike Option 2a, which uses ASP units reported to volume-weight the selected drug NDC-11(s), for Option 2b, CMS would use the

billing units reported on submitted Part B claims for selected drug NDC-11(s) to volume-weight the NDC-11-level ASPs under each HCPCS code that includes a selected drug. In contrast to Option 2a, CMS would weight the selected drug NDC-11(s) based on Part B claims data. This could be beneficial for two reasons: (1) Part B claims data is limited to Medicare reimbursement only rather than ASP sales data, which reflects units sold to all purchasers in the United States, and (2) using Part B claims data avoids reliance on ASP Portal data, which may not be complete due to reporting exceptions for certain drugs. CMS would use the following weighting methodology to determine the SDRA:

- Step 1: Standardize ASP to per unit amount
    - CMS would standardize the per-unit ASP(s) for each NDC-11 to the corresponding HCPCS code billing unit level using the HCPCS billing units per NDC-11 reporting unit as listed in the NDC-HCPCS Crosswalk for that quarter.
- Step 2: Calculate weighted ASPs based on HCPCS billing units on Part B claims
    - CMS would weight the per-unit ASPs using the submitted billing units reported on Part B claims for selected drugs payable under Part B[26] of each NDC-11 of the selected drug assigned to the selected drug HCPCS code (Example: See "Ratio of Total Sales Volume" in Table 4).
- Step 3: Sum average weight per unit ASP
    - CMS would then sum the average weighted per-unit ASP(s) across NDC-11(s) assigned to a HCPCS code (Example: See "Weighted Average Cost per HCPCS Unit" in Table 4).

In a scenario where there is only one NDC-11 assigned to the HCPCS code that includes a selected drug, CMS would obtain the per-unit ASP for the single NDC-11 of the selected drug and standardize to the HCPCS billing units, if necessary.

The SDRA would be calculated using the per-unit volume-weighted average of the ASPs for the selected drug NDC-11(s) assigned to each HCPCS code that includes a selected drug minus the MFP as of the "Claim From Date" of the Part B claim, multiplied by the billing units administered or furnished of the HCPCS code that includes a selected drug. The SDRA would be transmitted by the MTF DM to the Primary Manufacturer as part of the transmitted claim-level data elements.

Solicitation of comments on how to address Issue 2: CMS is soliciting comments on both the WAC-based approaches (Options 1a and 1b) and the ASP-based approaches (Options 2a and 2b) for calculating the SDRA for selected drugs payable under Part B. With respect to the WAC-based options, interested parties have noted that WAC may not accurately reflect acquisition costs for selected drugs payable under Part B as it does not account for discounts and rebates offered to some Part B providers or price concessions negotiated with GPOs. CMS invites comments on the appropriateness and adequacy of WAC as a proxy for acquisition cost for

[26] If CMS were to establish this approach in final guidance, to allow for claim run-out or claims lag between when a service occurs and when the claim is available from the database, CMS would use claims data from the first available quarter, after accounting for claim run-out to occur to weight the NDC-11(s). For example, data from claims for dates covering January 1, 2028, to March 31, 2028, would be applied to SDRA calculations in the quarter that begins in July 2028.

selected drugs payable under Part B, the general limitations of WAC as a standardized pricing metric for selected drugs payable under Part B, and, specific to Options 1b and 2b, the incremental burden and operational complexity of requiring NDC-11 reporting on Part B claims as a prerequisite to this approach. With respect to the ASP-based options, ASP is an established pricing metric for drugs payable under Part B, reflecting a drug's net sales price inclusive of rebates and discounts offered to all U.S. purchasers, subject to certain statutory exceptions. CMS invites comments on the appropriateness and adequacy of ASP as a proxy for acquisition cost for selected drugs payable under Part B, the accuracy and timeliness of manufacturer-reported ASP data for SDRA calculation purposes, and the relative merits and limitations of Options 2a and 2b. CMS also welcomes comments on the comparative merits and limitations of the WAC-based and ASP-based approaches across all four options.

If CMS elects to establish Option 1a, Option 2a, or Option 2b, CMS would revise the Manufacturer Submission of Average Sales Price (ASP) Data for Medicare Part B Drugs and Biological and Supporting Regulations Information Collection Request (ICR) (OMB Control Number 0938-0921)[27] to reflect that ASP reporting for a selected drug is part of CMS' Negotiation Program administration and oversight of manufacturer compliance under sections 1193(a)(5), 1196(a)(1) through (3), and 1196(b) of the Act.

CMS is also considering creating and maintaining a public SDRA file for selected drugs payable under Part B that includes their HCPCS code and the calculated SDRA (depending on which standardized pricing metric calculation methodology may be adopted in final guidance based on further consideration and responses to comment solicitations). CMS would publish this SDRA file to provide transparency to interested parties on the standardized pricing metric used in the SDRA calculation for selected drugs payable under Part B, including Part B providers seeking to estimate an MFP refund payment for purposes of reconciliation and expected cash flow where applicable and where the Primary Manufacturer determines that using the SDRA is appropriate to make the MFP available. Consistent with the frequency in which CMS publishes quarterly Medicare Part B payment limit files, CMS intends to update the SDRA file quarterly for January, April, June, and October and would make the files available on the CMS website to download. CMS is considering updating the calculation for the standardized pricing metric no more frequently than quarterly, consistent with the frequency of ASP reporting CMS is also considering which column headers to include in the SDRA file. Example headers include "HCPCS code," "Calculated Standardized Pricing Metric," "NDC-11," "Selected Drug Name," "Pricing Metric Type," "Effective Date," and "HCPCS Code Billing Unit." CMS is soliciting comments on the described SDRA file layout including, but not limited to, how interested parties might use such a file, the appropriateness of the example column-level data elements to include in the file, how issuance of the file could support transparency and operational use by interested parties, and the appropriate frequency of file updates.

If CMS elects to establish a requirement for the collection of NDC-11s on Part B claims and pursues the approach described in Option 1b, CMS may reconsider the need to publish a SDRA file. In that case, CMS would instead use the published WAC from pharmaceutical compendia at the NDC-11 level on the "Claim From Date" of the Part B claim to calculate the SDRA included in the claim-level data elements, thereby eliminating the need for the publication of such a file.

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[27] See: https://www.reginfo.gov/public/do/PRAViewICR?ref_nbr=202508-0938-003.

Similar to the approach for selected drugs covered under Part D, if the MTF DM is not able to calculate the SDRA for a Part B claim due to the standardized pricing metric not being available as of the "Claim From Date" of the Part B 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. 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 Part B provider has access to the MFP and is responsible for calculating that refund amount. Primary Manufacturers are required to include information on their approach to providing access to the MFP, including in such a scenario as described, in its MFP effectuation plan, as outlined in section 90.2.1 of this draft guidance. In addition, CMS is soliciting comment on whether there are certain types of Part B providers (e.g., critical access hospitals, rural sole community hospitals, children's hospitals, Prospective Payment System (PPS)-exempt hospitals) where there are unique considerations for the applicability of an SDRA due to differences in billing practices and methodologies.

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 exchanging key data files necessary for MFP effectuation.

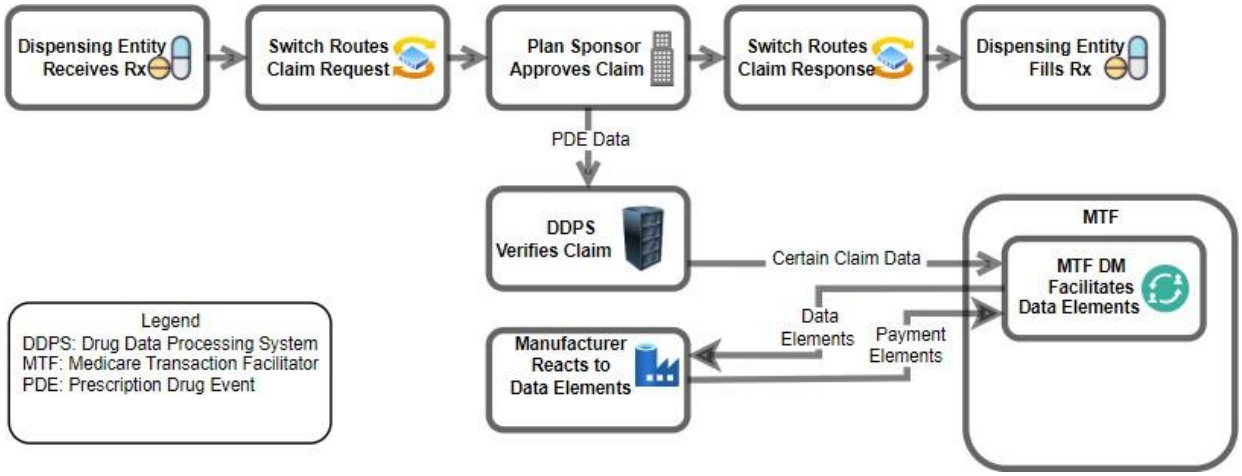
Under 42 CFR 423.505(q), Part D plan sponsors are required to include in their pharmacy agreements provisions requiring dispensing entities to be enrolled in the MTF DM (or any successor to the MTF DM). CMS strongly encourages Part B provider participation with the MTF DM and is considering a process to provide seamless enrollment between the Medicare Provider Enrollment, Chain, and Ownership System (PECOS) and the MTF DM, as discussed further in section 40.4.3.4 of this draft guidance. Dispensing entity and/or Part B provider participation in the MTF DM is necessary for operations related to administration of the Negotiation Program and the Part D, Part B, and MA programs, including creating and making available remittances to accompany paper checks or an ERA that uses the X12 835 standard adopted under the Health Insurance Portability and Accountability Act of 1996 (HIPAA), providing access to the complaints and disputes submission portal, facilitating continued access to selected drugs that are covered under Part D and/or payable under Part B, and ensuring accurate Part D and Part B claims processing and payment. 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 and/or Part B providers any transaction or other fees for the pass through of the MFP refund to the dispensing entity and/or Part B provider.

For 2028, Primary Manufacturers, dispensing entities, and/or Part B providers shall not be required to pay any fees to participate in the MTF DM, including but not limited to user fees or transaction fees, as CMS will bear the cost of operationalizing the MTF DM.

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, administered, or furnished to an MFP-eligible individual and furnish the manufacturer with certain claim-level data elements confirming that a selected drug was dispensed, administered, or furnished to an MFP-eligible individual and identifying the dispensing entity or Part B provider that dispensed, administered, or furnished 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 via paper check, as applicable, for payments the Primary Manufacturer passes through the MTF PM.

For illustrative purposes, Figure 1 depicts a basic conceptual overview of the mandatory MTF DM data flow for selected drugs covered under Part D. CMS leverages Part D claims data (Prescription Drug Event (PDE) data) in this data exchange.

Figure 1: Diagram of MTF Data Flow for Selected Drugs Covered Under Part D



For illustrative purposes, Figures 2 and 3 depict a basic conceptual overview of the mandatory MTF DM data flow for selected drugs payable under Part B for both the OM and MA programs, respectively. CMS would leverage Part B claims data for Part B items and services 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. CMS is 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.

Figure 2: Diagram of MTF Data Flow for Selected Drugs Payable Under Part B in Original Medicare

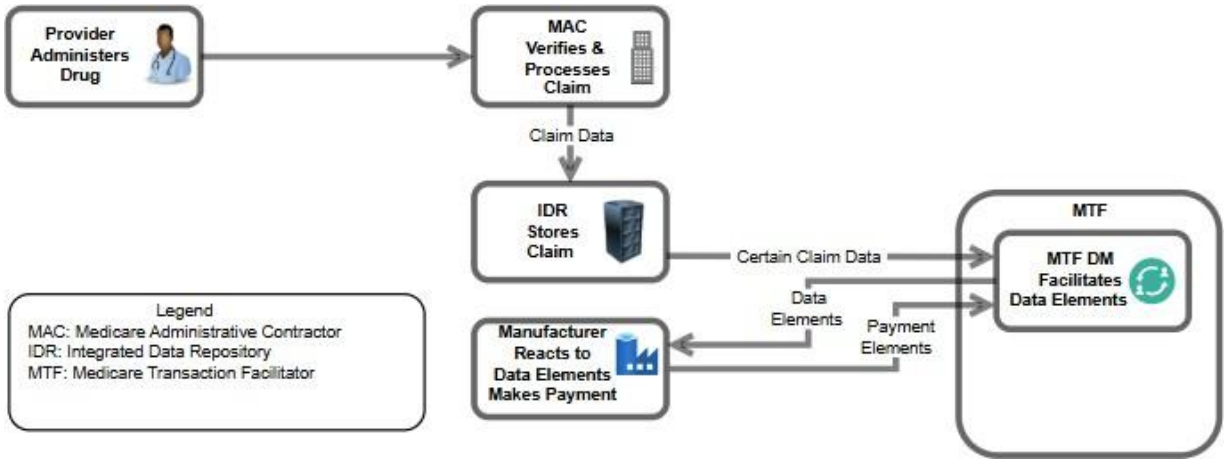
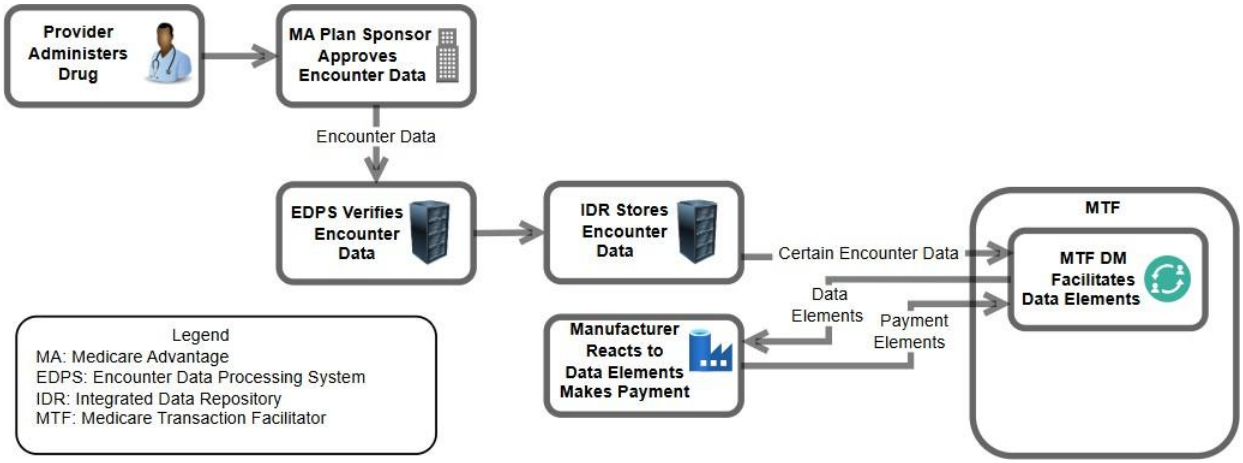


Figure 3. Diagram of MTF Data Flow for Selected Drugs Payable Under Part B in Medicare Advantage



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 year 2028 to register with the MTF DM by May 1 of the calendar year before the MFP would go into effect; in other words, Primary Manufacturers with MFPs that will take effect on January 1, 2028 will need to enroll by May 1, 2027. CMS would also 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 DM; all Primary Manufacturers will be required to sign an MTF DM User Agreement[28] with CMS during the MTF DM enrollment process. Primary Manufacturers who elect to participate in the MTF PM will also be required to sign the Medicare Transaction Facilitator Payment Module Contractor Agreement (hereinafter the "MTF PM User Agreement") with the MTF PM Contractor. These MTF agreements establish the rights and responsibilities of all parties involved in the MTF. The MTF agreements contain data use, privacy, and security requirements to protect the data elements received from and transmitted to the MTF. The Primary Manufacturer will have one MTF DM User Agreement; if the Primary Manufacturer is the Primary Manufacturer of multiple selected drugs for which it agrees to MFPs, including, for example, selected drugs with MFPs in effect for different years, the Primary Manufacturer will add all such selected drugs to the same signed MTF DM User Agreement. CMS intends to establish an addendum to the MTF agreements for Primary Manufacturers of selected drugs payable under Part B. Further details on the addendum will be provided in future guidance or technical instructions.

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 Medicare Drug Price Negotiation Program: Revised Guidance, Implementation of Sections 1191 – 1198 of the Social Security Act for Initial Price Applicability Year 2026[29] (hereinafter referred to as "revised guidance for initial price applicability year 2026"), Medicare Drug Price Negotiation Program: Final Guidance, Implementation of Sections 1191 – 1198 of the Social Security Act for Initial Price Applicability Year 2027 and Manufacturer Effectuation of the Maximum Fair Price in 2026 and 2027[30] (hereinafter referred to as "final guidance for initial price applicability year 2027"), or final guidance for initial price applicability year 2028, 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 Primary 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.

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[28] See: https://www.cms.gov/priorities/medicare-prescription-drug-affordability/overview/medicare-drug-price-negotiation-program/medicare-transaction-facilitator-general-resources.
[29] See: https://www.cms.gov/files/document/revised-medicare-drug-price-negotiation-program-guidance-june-2023.pdf.
[30] See: https://www.cms.gov/files/document/medicare-drug-price-negotiation-final-guidance-ipay-2027-and-manufacturer-effectuation-mfp-2026-2027.pdf.

If the Medicare Drug Price Negotiation Program Agreement with respect to a selected drug is terminated in accordance with section 40.6 of the final guidance for initial price applicability year 2028, 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 the 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, or furnishings or administrations, as applicable, 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, or furnishings or administrations, as applicable).

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. Namely, because there is a runout period for claims for selected drugs dispensed, furnished, or administered, as applicable, 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 the 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 and/or Part B provider, either directly or through the supply chain, or through a retrospective refund to a dispensing entity and/or Part B provider, 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, including in instances in which the Primary Manufacturer determines no MFP refund payment is due on a claim because the selected drug was prospectively purchased at MFP or the exception at section 1193(d)(1) of the Act (related to 340B discounts) applies, to communicate to dispensing entities and Part B providers the MFP refund amount the Primary Manufacturer determined to be necessary on the claim and the Primary Manufacturer's reported method for determining such refund amount. 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 a civil monetary penalty (CMP) 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, or the final guidance for initial price applicability year 2028, as applicable).

40.4.2.1.1 Claim-level Data Elements for Part D Claims

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 5. 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 5: MTF DM Part D 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

MTF DM Data Elements List	Purpose	Data Source
Process Date	Identifies MTF processed date	MTF
Transaction Code	Indicates original claim, adjustment, reversal, MTF DM enrollment status of dispensing entity, etc.	MTF
Medicare Source of Coverage	Identifies coverage under Medicare Part D	MTF
Date of Service	Verifies MFP eligibility	PDE Record
Service Provider Identifier Qualifier	Verifies MFP eligibility	PDE Record
Service Provider Identifier	Verifies MFP eligibility	PDE Record
Prescription/Service Reference Number	Verifies MFP eligibility	PDE Record
Prescriber ID	Identifies prescriber	PDE Record
Prescriber ID Qualifier	Identifies prescriber	PDE Record
Fill Number	Verifies MFP eligibility	PDE Record
Product/Service Identifier	Verifies MFP eligibility	PDE Record
Quantity Dispensed	Assists the manufacturer in calculating a refund	PDE Record
Days' Supply	Assists the manufacturer in calculating a refund	PDE Record
340B Claim Indicator (as voluntarily reported by dispensing entity)	Assists the manufacturer in assessing applicability of section 1193(d)(1) of the Act	PDE Record
Contract Number	Verifies MFP eligibility	PDE Record
Wholesale Acquisition Cost (WAC) Per Unit on Date of Service of 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	MTF

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

The combination of "Date of Service," "Service Provider Identifier Qualifier," "Service Provider Identifier," "Prescription/Service Reference Number," and "Fill Number" identify unique Part D claims. Other data elements listed in Table 5 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.[31] A dispensing entity may voluntarily apply these indicators to a Part D claim to indicate the claim is being billed for a 340B drug.[32] 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). To improve efficiency, in future rulemaking related to MFP effectuation policies for 2029 and subsequent years, CMS is considering aligning enrollment and payment methods for dispensing entities and Part B providers by removing the dispensing entity payment preference selection from the enrollment process and removing the "Service Provider Payment Method Preference" field from the claim-level data elements. If proposed, such changes would take effect no earlier than 2029. If adopted, the payment method for MFP refunds passed through the MTF PM to dispensing entities would default to electronic payment unless an extenuating circumstance exists as discussed with respect to Part B providers in section 40.4.3.4 of this draft guidance. CMS is soliciting comments on removing the dispensing entity payment preference selection in the future, particularly regarding

[31] See: https://www.cms.gov/files/document/2025-pde-file-layouts.pdf.
[32] 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.

concerns with this change for dispensing entities that currently prefer receiving MFP refunds through the MTF PM via paper check.

"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 for Part D claims, then multiplied by the quantity dispensed, as 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 CMS gains experience from monitoring ongoing manufacturer effectuation of retrospective MFP refunds, 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 the Drug Data Processing System (DDPS), a CMS system used to process all Medicare PDE records and related data, resulting in dual verification of both an individual's eligibility for Part D and Part D coverage of the selected drug for each claim being transmitted. When a Part D plan sponsor receives a claim for a selected drug from a dispensing entity, 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.[33]

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 5 for MFP-eligible claims for transmittal to the applicable Primary Manufacturer.[34] The MTF DM also will confirm that NDCs on PDE records received from DDPS appear on the list of NDCs for the selected drug maintained in the CMS HPMS prior to sending to the Primary Manufacturer. Therefore, because MFP eligibility status of the individual has been twice verified, by the plan sponsor and DDPS, and the selected drug NDC has been verified 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.[35]

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[33] 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.

[34] At this time for 2026, 2027, and 2028, 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.

[35] In accordance with 42 CFR 423.325(a)(3), a PDE record for a paid claim transaction associated with a PDE record that was previously rejected by CMS must be submitted by a Part D sponsor at least once every 90 calendar days

Therefore, CMS intends to continue 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. DDPS edits are identified as related to the determination and verification of MFP eligibility if they directly relate to the data elements listed in Table 5 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 is posted on the CMS website for 2026 and 2027. If necessary, CMS will update this list and post the updated list for 2028 in the future.

CMS intends to process claims in the following manner:

1. If a claim does not have any DDPS edits, the MTF DM will transmit the claim-level data elements to the Primary Manufacturer to initiate the 14-day prompt MFP payment window.
2. If a claim, through DDPS processing, cleared all of the DDPS edits that are on CMS' list of edits directly related to MFP eligibility and only has DDPS edits that are not on such CMS list, the MTF DM will transmit the claim-level data elements to the Primary Manufacturer to initiate the 14-day prompt MFP payment window because it has been verified that the selected drug of the Primary Manufacturer was dispensed to an MFP-eligible individual.
3. If a claim has DDPS edits that are on CMS' list of edits directly related to MFP-eligibility or has not yet cleared all of the DDPS edits that are on such CMS list of edits, the MTF DM will not transmit the claim-level data elements to the Primary Manufacturer because it has not been verified that the selected drug of the Primary Manufacturer was dispensed to an MFP-eligible individual. The MTF DM will monitor for resolution of these edits. If all such edits directly related to MFP-eligibility are resolved within 90 days of the rejection, then the MTF DM will transmit the claim-level data elements to the Primary Manufacturer to initiate the 14-day prompt MFP payment window. If the edits are not resolved within this timeframe and the Primary Manufacturer participates in the MTF PM, the MTF DM will notify the dispensing entity that no refund payment has been paid for the claim through a remittance. If the edits are not resolved within this timeframe and the Primary Manufacturer does not participate in the MTF PM, the MTF DM will transmit claim-level data elements from the PDE record to the Primary Manufacturer and indicate it has unresolved DDPS edits directly related to MFP-eligibility. In this case, the claim-level data elements are transmitted for informational purposes only and therefore do not initiate the 14-day prompt MFP payment window and do not require the Primary Manufacturer to respond with claim-level payment elements. However, the Primary Manufacturer may notify the dispensing entity that no refund payment has been paid for the claim. If a subsequent PDE record for the claim indicates these edits are resolved, the MTF DM will transmit the claim's data elements to the Primary Manufacturer and initiate the 14-day prompt MFP payment window.

Primary Manufacturers may not impose additional reporting requirements on dispensing entities to support MFP eligibility verification, regardless of whether the Primary Manufacturer utilizes

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from receipt of a rejection until the PDE record is accepted unless the claim associated with the rejected PDE record is reversed or deleted, or the PDE record that was rejected is otherwise found to have been submitted in error.

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 Personally Identifiable Information (PII) or Protected Health Information (PHI) could increase privacy and security risks, even with the use of an encrypted identifier. Furthermore, in accordance with X12 835 standards (ASC X12N Technical Report Type 3 Version 005010), patient names are not required for ERAs associated with retail pharmacy claims. Therefore, additional patient information is also unnecessary for the Primary Manufacturer to comply with the requirement to create and transmit ERAs for MFP refunds for Part D claims using the X12 835 standard adopted under HIPAA for electronic funds transfers not facilitated by the MTF PM, as discussed in section 40.4.4.1 of this draft guidance. 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 5 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.

40.4.2.1.2 Claim-level Data Elements for Part B Claims

In accordance with section 1193(a) of the Act, Primary Manufacturers must provide access to the MFP to Part B providers with respect to MFP-eligible individuals to whom selected drugs are administered or furnished. As defined in section 1191(c)(2)(B) of the Act and set forth in section 80 of this draft guidance, MFP-eligible individuals include individuals enrolled in an MA plan under Part C. Claim-level data elements for Part B claims are obtained from OM claims and MA encounter data. The differences in the MTF utilization of OM claims and MA encounter data are described within this section of draft guidance.

This section of the draft guidance establishes a requirement for CMS to disclose to Primary Manufacturers via the MTF DM the claim-level data elements for Part B claims for HCPCS code(s) that include a selected drug that are listed in Table 6 below. 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 would be sent to the Primary Manufacturers, CMS believes that the selected data elements provide the minimum necessary information to verify the selected drug was furnished or administered to an MFP-eligible individual.

Table 6: MTF DM Part B Claim-Level Data Elements[36]

MTF DM Data Elements List	Purpose	Data Source
Record ID	Identifies the type of record, such as claim detail, file header, and file trailer	MTF
MTF Internal Claim Number (ICN)	Identifies the internal unique identifier assigned by the MTF to support claim adjustments	MTF
MTF XRef ICN	Links an adjustment to previous MTF ICN	MTF
Process Date	Identifies MTF processed date	MTF
Transaction Code	Indicates original claim, adjustment, reversal, MTF DM enrollment status of Part B provider, etc.	MTF
Medicare Source of Coverage	Identifies coverage under Medicare Part B or Part C	MTF
Claim From Date	Verifies MFP eligibility	IDR Record
Billing Provider NPI	Verifies MFP eligibility	IDR Record
Claim Control Number	Verifies MFP eligibility	IDR Record
Medicare Beneficiary Identifier	Verifies MFP eligibility	IDR Record
Beneficiary Last Name	Verifies MFP eligibility	IDR Record
HCPCS Code	Verifies MFP eligibility	IDR Record
Claim Line NDC Code (if reported by Part B provider)	Verifies MFP eligibility	IDR Record
Claim Line Service Unit Quantity	Assists the manufacturer in calculating a refund	IDR Record
HCPCS Modifier Code "TB" (or successor modifier) (if reported by Part B provider)	Assists the manufacturer in assessing applicability of section 1193(d)(1) of the Act	IDR Record
HCPCS Modifier Code "JW" (or successor modifier) (if reported by Part B provider)	Identifies claim lines identified as discarded units	IDR Record
Wholesale Acquisition Cost (WAC) Per HCPCS code (weighted) or ASP	Provides list price on claim from date	MTF

[36] These elements are representative examples only. CMS may update the exact claim-level data elements depending on, among other considerations, the policies adopted for identification of Part B claims and SDRA formula and will provide such notice in guidance or technical instructions as operations develop.

MTF DM Data Elements List	Purpose	Data Source
Per HCPCS code on Claim From Date (TBD)		
Maximum Fair Price (MFP) Per Unit or HCPCS code on Claim From Date	Assists the manufacturer in calculating a refund	MTF
Standard Default Refund Amount (SDRA) (SDRA formula to be established in final guidance)	Assists the manufacturer in calculating a refund	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
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

CMS intends that the combination of "Claim From Date," "Billing Provider NPI," and "Claim Control Number" would be used to identify unique Part B claims. Other data elements listed in Table 6 would provide additional information about each claim to the Primary Manufacturer that may be necessary in calculating the retrospective refund, if applicable, including "HCPCS Code," "Claim Line NDC Code," "Claim Line Service Unit Quantity," "WAC Per HCPCS code (weighted) or ASP Per HCPCS code on Claim From Date," and "MFP per unit or HCPCS code on Claim From Date." The "Medicare Beneficiary Identifier" and "Beneficiary Last Name" claim-level data elements would be necessary to create ERAs using the X12 835 standard adopted under HIPAA for payments not passed through the MTF PM as discussed in section 40.4.4.1 of this draft guidance. In accordance with X12 835 standards, patient information is required for ERAs associated with all claims that are not retail pharmacy claims. Therefore, these data elements are necessary for the Primary Manufacturer to comply with the requirement to create and transmit ERAs for MFP refunds for Part B claims using the X12 835 standard adopted under HIPAA for electronic funds transfers not facilitated by the MTF PM. Although providing specific information on individual beneficiaries that constitutes PII or PHI could increase privacy and security risks if not properly protected by the Primary Manufacturer consistent with the terms of the MTF DM User Agreement, CMS has determined that the benefits of consistency

and standardization—achieved by requiring ERAs to comply with the X12 835 standard—for Primary Manufacturers and Part B providers outweigh those risks. CMS is soliciting feedback to confirm this determination or suggestions for alternative approaches. CMS is also soliciting feedback on the combination of claim-level data elements necessary to identify unique Part B claims and the minimum necessary claim-level data elements for Part B claims for HCPCS code(s) of a selected drug listed in Table 6 that are provided to Primary Manufacturers to calculate the retrospective refund.

Beginning January 1, 2025, CMS requires all 340B covered entities, including hospital-based and non-hospital-based entities, that submit claims for separately payable Part B drugs and biologicals to report the "TB" modifier (or successor modifier) on claim lines for drugs acquired through the 340B Program on OM claims. The MTF's provision of the "HCPCS Modifier Code 'TB'" data element does not represent or imply that CMS verified the 340B status of the claim nor that Part B providers are required to include this code on claim submissions. "Transaction Code" would 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, including a list of the Transaction Codes, is located on the Medicare Transaction Facilitator website.[37] 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 would 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 would be provided in future technical instructions.

The claim-level data elements that the Primary Manufacturer would receive from the MTF DM will include the SDRA determined by either Option 1 or Option 2, as discussed in section 40.4.1.2 of this draft guidance, then multiplied by the billing units administered or furnished, as described in section 40.4.1 of this draft guidance. As described in section 40.4.2.1.1 of this draft guidance, regardless of whether the Primary Manufacturer chooses to pass payment through the MTF PM, the Primary Manufacturer would be responsible for calculating and paying an appropriate amount to the Part B provider to effectuate the MFP, as 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. 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.

Unlike for multiple dose containers or packages, when a separately payable drug from a single-dose container or single-use package is furnished or administered to an individual enrolled in Medicare Part B, Medicare pays the provider or facility for the furnished or administered amount and for any discarded amount identified by the JW modifier, up to the labeled amount of the product. When Part B providers purchase such drugs, their purchase price is inclusive of discarded amounts. Therefore, Primary Manufacturers would be responsible for providing access to the MFP for both furnished or administered and discarded amounts of selected drugs that are

[37] See: https://www.cms.gov/priorities/medicare-prescription-drug-affordability/overview/medicare-drug-price-negotiation-program/medicare-transaction-facilitator-general-resources.

available from single-dose containers or single-use packages for Part B claims. Claim lines for furnished or administered units and claim lines for discarded units belonging to the same claim would appear as separate entries in the claim-level data elements file. The "Claim Line Service Unit Quantity" field transmitted with the claim-level data elements would reflect the units for each category independently. Therefore, units for furnished or administered drug and units for discarded drug would be reported with their respective claim-level data elements. The MTF would include the field "HCPCS Modifier Code "JW"" with claim-level data elements for discarded units when present on OM claims and MA encounters. Likewise, the "JW" modifier would not be included with claim-level data elements for furnished or administered units of claims with discarded units. The MTF's provision of the "HCPCS Modifier Code "JW"" data element does not represent or imply that CMS verified the accuracy of the discarded units. The "Claim Line Service Unit Quantity" field will reflect only the quantity reported on the claim line that includes the JW HCPCS modifier code on Part B claims. The quantity of drug administered or furnished during the same service will be reported on a separate record within the claim-level data elements. This separate record will not include the "HCPCS Modifier Code "JW"" field populated and will only contain the quantity of drug administered or furnished.

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.

Claim-level Data Elements for OM Claims

For OM claims, the MTF DM would provide Primary Manufacturers with data that has been verified through the OM Claims Adjudication Process, a CMS system used to validate OM claims, resulting in verification of an individual's eligibility for Part B and whether the selected drug is payable under Part B for each claim being transmitted. Unlike Part D, which requires reconciliation across both plan sponsor submissions and DDPS, OM claims are adjudicated directly through CMS and rely on a single CMS-based validation process.

After CMS verifies MFP eligibility through the OM Claims Adjudication Process for the individual related to the claim, CMS, via the Integrated Data Repository (IDR), would transmit the claims data for the OM claim for the selected drug to the MTF DM, which would prepare the file of claim-level data elements listed in Table 6 for MFP-eligible claims for required transmittal to the applicable Primary Manufacturer.[38] The MTF DM would confirm that the HCPCS code(s), as well as the appropriate modifier or NDC-11 as discussed in section 40.4.1.2 of this draft guidance, if applicable, on OM claims received from the IDR appear on the list of HCPCS codes that include a selected drug maintained in the selected drug list and MFP file prior to sending to the Primary Manufacturer. Therefore, because MFP eligibility status of the individual would have been verified by the OM Claims Adjudication Process, and the HCPCS code, as well as the appropriate modifier or NDC-11 as discussed in section 40.4.1.2 of this draft guidance, if applicable, that includes a selected drug would have been verified by the MTF DM before the

[38] At this time for 2028, this file transmittal will exclude claim-level data elements from any OM claims for a compounded drug. Compounded drugs payable under Part B are typically reported with HCPCS code J7999 or other Not Otherwise Classified HCPCS codes.

data elements are sent from the MTF DM to the Primary Manufacturer, the data elements would have been verified as involving a selected drug payable under Part B that was furnished or administered to an individual who is MFP-eligible.

While OM claims include a wide range of data that is necessary for payment, only a subset is directly relevant to and necessary for verifying that a selected drug of the Primary Manufacturer was furnished or administered to an MFP-eligible individual. When an OM claim completes the adjudication process and is sent to the Healthcare Integrated General Ledger Accounting System (HIGLAS) for payment processing,[39] the claim would also be sent to the MTF DM. OM claims that are approved to pay have cleared edits that verify the individual to whom the selected drug was administered or furnished is MFP-eligible and the drug is payable under Part B prior to claim processing for final action. Based on our analysis, changes to the claim after the completion of the adjudication process and transmission to HIGLAS for payment processing and final action claim status designation are typically related to financial reconciliation, such as payment cycle processing or offset adjustments, and do not affect the MFP eligibility of a claim. Requiring an OM claim to complete payment and reach final action before the MTF DM transmits claim-level data elements to the Primary Manufacturer would delay transmission to the Primary Manufacturer of claims that have been verified as an administration or furnishing of the selected drug to an MFP-eligible individual by a week or more, which in turn could potentially cause financial strain for Part B providers by delaying payment of an MFP refund on such claim. Therefore, CMS would use OM claims that have completed the adjudication process and are approved to pay to generate and transmit the claim-level data elements to the Primary Manufacturer to initiate the 14-day prompt MFP payment window. OM claims that are re-adjudicated after the MTF DM receives the claim would be addressed through the MTF credit/debit ledger system, as described in section 40.4.3 of this draft guidance for a Primary Manufacturer that participates in the MTF PM. OM claims that are re-adjudicated after the MTF DM receives the claim for a selected drug for a Primary Manufacturer that makes payment outside of the MTF PM is described in section 40.4.4.4 of this draft guidance.

Primary Manufacturers may not impose additional reporting requirements on Part B providers to support MFP eligibility verification, regardless of whether the Primary Manufacturer utilizes the MTF PM, since claim-level data elements will be derived from claims that have been verified for Medicare eligibility by CMS.

Once the data has been verified by the OM Claims Adjudication Process, the MTF DM would make the claim-level data elements listed in Table 6 available to the Primary Manufacturer to notify them that the selected drug was furnished or administered to an MFP-eligible individual. Claim-level data would be batched across all claims available to the MTF DM as received for all HCPCS codes that include a selected drug.

Claim-level Data Elements for Medicare Advantage Records

CMS does not receive claims from MA organizations; it receives MA encounter data that MA organizations submit for the purpose of risk adjustment. This data contains claims information for items and services provided to individuals enrolled in an MA plan. While CMS uses MA

[39] See: https://www.cms.gov/files/document/r13569otn.pdf.

encounter data primarily in the development and application of a risk adjustment payment model, it may also use and release these data for other purposes not inconsistent with 42 CFR 422.310(f). CMS intends to use MA encounter data to facilitate manufacturer effectuation of the MFP for selected drugs payable under Part B and furnished or administered to individuals enrolled in Part C as the data includes many fields from the underlying claim that are necessary to facilitate the Primary Manufacturer's obligation to make the MFP available. Therefore, CMS believes that use of certain data elements from MA encounter data in lieu of the actual claim provides the minimum necessary information needed to facilitate manufacturer effectuation of the MFP for selected drugs payable under Part B administered or furnished to individuals enrolled in Part C. Additionally, since CMS receives MA encounter data directly from MA organizations, CMS intends to leverage the existing MTF DM data exchange to facilitate transmission of MA data elements from MA encounters to the Primary Manufacturers, which would minimize additional reporting burden on MA organizations (see Figure 1).

For MA encounter data for Part B items and services, the MTF DM would provide Primary Manufacturers with data that was submitted by the MA organization to the Medicare Advantage Encounter Data System (EDS).[40] CMS, using EDS, would also perform verification steps to validate that the individual was enrolled in an MA plan under Part C on the date of service reported on the encounter data record, which is then transmitted to the IDR. That is, under this approach, once an MA organization submits an encounter record to the EDS, no further action is required by the MA organization to review or verify the claim-level data elements extracted from the encounter record before the data elements are transmitted from the MTF DM to the Primary Manufacturer.

Currently, when an MA organization receives a claim for a selected drug from a Part B provider, inclusive of contract and non-contract Part B providers, before making payment, the MA organization verifies that the beneficiary listed on the claim is enrolled in Medicare Part C and the furnished or administered drug is payable under Part B. After the MA organization verifies that the beneficiary listed on the claim is enrolled in Medicare Part C and whether the selected drug is payable, subject to any applicable utilization management policies or procedures, it approves payment to the Part B provider. Then, as part of the existing MA encounter data submission requirements, the MA organization sends the data on the claim as an MA encounter record to EDS. Per 42 CFR 422.310(g)(2)(ii), the final risk adjustment data submission deadline is no earlier than January 31 of the year following the payment year. In recent internal analysis, CMS observed that 85 percent of MA encounter data are submitted by MA organizations within 60 days of the claim from date. Separate from this draft guidance, CMS is evaluating whether to propose a new regulatory requirement for 2028 that MA organizations submit encounter data for encounters for selected drugs payable under Part B on a timeline that is shorter than the MA encounter data submission timeline under 42 CFR 422.310 to ensure Part B providers receive timely payment of MFP refunds by Primary Manufacturers who elect a retrospective reimbursement model. CMS is considering allowing MA encounter data for selected drugs payable under Part B and submitted to CMS to be used for risk adjustment unless the MA organization submits a corrected MA encounter record in accordance with deadlines codified in 42 CFR 422.310(g). CMS does not intend for this requirement to apply to encounters for drugs not selected for the Negotiation Program. An amendment to regulations would require notice and

[40] See: https://security.cms.gov/pia/encounter-data-processing-system.

comment rulemaking. Any potential new requirement for MA organizations to report encounter data for selected drugs payable under Part B to support the effectuation of the MFP for selected drugs payable under Part B would not alter an MA organization's obligations related to the submission of risk adjustment data, including an obligation to submit data to correct overpayments, in accordance with 42 CFR 422.310.

CMS, using EDS, also performs verification steps to validate that the individual was enrolled in an MA plan under Part C on the date of service reported on the encounter data record, which is then transmitted to the IDR. Data in the IDR would then be transmitted to the MTF DM, which would prepare the file of claim-level data elements listed in Table 6 for MFP-eligible claims for transmittal to the applicable Primary Manufacturer.[41] Prior to transmission to the Primary Manufacturer, the MTF DM would also confirm that the HCPCS code on the MA encounter record received from the IDR appears on the list of HCPCS codes that include a selected drug maintained on the Selected Drug List and MFP File and that a modifier signifying a selected drug or NDC-11 for a selected drug, as applicable, in accordance with the discussion in section 40.4.1.2 of this draft guidance, appears on such record. Therefore, considering that Part C enrollment status of the individual has been twice verified, by the MA organization and EDS, and that furnishing or administration of the selected drug has been verified by the MTF DM before the data elements are sent from the MTF DM to the Primary Manufacturer, the data elements would have been verified as involving a selected drug payable under Part B that was furnished or administered to an MFP-eligible individual.

Data validation edits are applied against MA encounter data submitted to EDS to ensure the information accepted by the system is in accordance with risk adjustment data submission and processing instructions. MA encounter records are deemed final action once all EDS edits are resolved. CMS recognizes that encounter data is collected for risk adjustment purposes and EDS edits are designed to ensure accuracy and completeness of risk adjustment data. As such, certain EDS edits do not directly relate to verification of the MFP eligibility of a claim for the purposes of the Negotiation Program. For administrative efficiency and to minimize new reporting obligations on manufacturers and Part B providers, CMS would leverage the existing MA encounter data flow to support verification of MFP eligibility through the MTF DM data exchange.

While MA encounter data for Part B items and services include a wide range of data that is necessary for MA risk adjustment purposes, only a subset of the MA encounter data elements is directly relevant to and necessary for verifying that a selected drug of the Primary Manufacturer was furnished or administered to an MFP-eligible individual. Requiring all EDS edits to be resolved before the MA encounter 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 an administration or furnishing of the selected drug to an MFP-eligible individual, which in turn could cause financial hardship for Part B providers by delaying payment of an MFP refund on such claims.

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[41] At this time for 2028, this file transmittal will exclude claim-level data elements from any MA encounters for a compounded drug. Compounded drugs payable under Part B are typically reported with HCPCS code J7999 or other Not Otherwise Classified HCPCS codes.

Therefore, CMS intends to maintain a separate list of EDS edits, which would be posted on the CMS website, 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. EDS edits would be identified as related to the determination and verification of MFP eligibility if they directly relate to the data elements listed in Table 6 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 MA encounter data. CMS is in the process of identifying EDS edits that are related to the determination and verification of MFP eligibility. CMS is soliciting comments on this compilation of EDS edits for its stated purpose and suggestions for EDS edits to include or exclude.

CMS intends to identify MA encounter data for transmission to Primary Manufacturers by the MTF DM in the following manner:

1. If MA encounter data does not have any EDS edits, the MTF DM would transmit the claim-level data elements to the Primary Manufacturer to initiate the 14-day prompt MFP payment window.
2. If MA encounter data, through EDS processing, cleared all of the EDS edits that are on CMS' list of edits directly related to MFP eligibility and only have EDS edits that are not on such CMS list,[42] the MTF DM would 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 administered or furnished to an MFP-eligible individual.
3. If MA encounter data have EDS edits that are on CMS' list of edits directly related to MFP-eligibility or have not yet cleared all of the EDS edits that are on such CMS list of edits, the MTF DM would 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 administered or furnished to an MFP-eligible individual. The MTF DM would 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 would transmit the claim-level data elements to the Primary Manufacturer to initiate the 14-day prompt MFP payment window. If the edits are not resolved within this timeframe and the Primary Manufacturer participates in the MTF PM, the MTF DM would notify the Part B provider that no refund payment has been paid for the MA encounter through a remittance. CMS is evaluating options for handling claims where the edits are not resolved within this timeframe and the Primary Manufacturer does not participate in the MTF PM. If subsequent MA encounter data indicates these edits are resolved, the MTF DM would transmit the MA encounter's data elements to the Primary Manufacturer and initiate the 14-day prompt MFP payment window.

Primary Manufacturers may not impose additional reporting requirements on Part B providers to support MFP eligibility verification, regardless of whether the Primary Manufacturer utilizes the

[42] The policies herein regarding the MTF DM's use of MA encounter data with EDS edits for purposes of facilitating manufacturer effectuation of the MFP for selected drugs do not affect MA organizations' obligations to address the edits for the encounters to be considered for the purposes of risk adjustment.

MTF PM since claim-level data elements would be derived from encounters that have been verified for Medicare eligibility by both the MA organization and EDS.

Once the data has been verified by the MA organization and EDS, and the MTF DM has verified that a claim has no EDS edits directly related to MFP-eligibility, the MTF DM would make the claim-level data elements listed in Table 6 available to the Primary Manufacturer to notify them that the selected drug was administered or furnished to an MFP-eligible individual. Claim-level data would be batched across all encounters available to the MTF DM as received for all HCPCS code(s) that include a selected drug.

CMS also considered an alternative process that would require MA organizations to provide data directly to Primary Manufacturers, but CMS believes such a process would be more burdensome on manufacturers and MA organizations and add unnecessary complexity to the overall data exchange process for OM claims and MA encounters.

CMS is also evaluating proposing through rulemaking another approach that would establish an obligation for MA organizations to submit directly to the MTF DM claims data for selected drugs payable under Part B only to ensure Part B providers receive timely payment of MFP refunds. Like the proposal above, this approach would also ensure timely payment of retrospective MFP refunds without impacting existing MA encounter data reporting timelines. This approach further would ensure CMS has access to data elements reported on claims for transmission to Primary Manufacturers. If CMS moves forward with proposing through rulemaking an obligation for MA organizations to submit data directly to the MTF DM or directly to Primary Manufacturers, such a requirement would not take effect before 2029.

To inform CMS' assessment of the topics discussed in this section, CMS is soliciting comments on operational and timing considerations for reporting MA encounter data for selected drugs payable under Part B only, which CMS is considering proposing to take effect as early as 2028, or requiring MA organizations to submit Part C claims data for selected drugs payable under Part B only directly to Primary Manufacturers or directly to the MTF DM, which, as noted above, would not take effect before 2029. CMS anticipates implementing these changes through future rulemaking if CMS were to move forward with such changes.

40.4.2.1.3 MFP Payment Window

For operational consistency with manufacturer prompt payment requirements for selected drugs covered under Part D and to ensure Part B providers receive MFP refunds promptly, CMS intends to require the same 14-day timeframe for selected drugs payable under Part B as for selected drugs covered under Part D. For Part D claims and Part B claims, 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 or encounter, as applicable, 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 11:59 PM PT on day 14 authorizing payment to the dispensing entity and/or Part B provider; 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 and/or Part B provider on or before 11:59 PM PT on 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 the MFP refund payment is considered to have occurred when the Primary Manufacturer takes the last step on its part to make the payment to the dispensing entity and/or Part B provider. In cases where the MTF PM is used, this final step for the MFP refund payment is the authorization via the payment elements for the MTF PM to send the payment to the dispensing entity and/or Part B provider in the amount directed by the Primary Manufacturer. In cases where the payment is made outside of the MTF PM, the final step is the Primary Manufacturer sending the MFP refund amount to the dispensing entity and/or Part B provider (e.g., electronically or by mailing a paper check, if applicable) because the submission of payment elements alone will not result in the dispensing entity and/or Part B provider 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, or the final guidance for initial price applicability year 2028, 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 or HCPCS codes that include a selected drug subject to an MFP, including those manufactured, marketed, controlled, or 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 and/or Part B provider 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 7 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 7: 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 and/or Part B provider	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 funds transfer to and transmission of MFP refund payment by the MTF PM.	Transmit the MFP refund payment to the dispensing entity and/or Part B provider, and transmit payment elements to the MTF DM once payment has been transmitted.	
Deadline For Action	No later than 11:59 PM PT on Day 14 after the MTF DM transmits the claim-level data elements to the Primary Manufacturer, with the clock beginning (Day 0) on the day the MTF DM transmits the claim-level data to the Primary Manufacturer.		
Payment Transmission Date Recorded as:	The system-generated date and time the payment elements sent by the Primary Manufacturer are received by the MTF DM, authorizing electronic funds transfer to and transmission of MFP refund payment by the MTF PM.	The date and time the MFP refund payment is transmitted from the Primary Manufacturer to the dispensing entity and/or Part B provider, 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 and/or Part B provider (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 and/or Part B Provider Enrollment in the MTF DM

In accordance with 42 CFR 423.505(q), Part D plan sponsors, starting in contract year 2026, are required to include in their pharmacy agreements provisions requiring the pharmacy to be enrolled in the MTF DM. CMS strongly encourages Part B provider enrollment in the MTF DM and is considering potential regulatory options to require Part B provider enrollment. CMS is evaluating a potential regulatory requirement that, consistent with 42 CFR 423.505(q) with respect to Part D plans and network pharmacies, would require any contract between the MA organization and a provider, or between a first tier, downstream, or related entity and a provider on the MA organization's behalf for participation in one or more of the MA organization's networks to include a provision requiring that if the provider furnishes or administers selected drugs payable under Part B, during the period when such drugs are subject to an MFP, the provider must be enrolled in the MTF DM. Dispensing entity and/or Part B provider enrollment in the MTF DM is needed for necessary operations related to administration of the Negotiation Program and the Part D, OM, and MA programs, including creating and making available remittances or ERAs (except when MFP refund payments are made outside of the MTF PM), maintaining access to the complaints and disputes submission portal, facilitating continued access to selected drugs that are covered under Part D or payable under Part B, and ensuring accurate Part D claims and Part B claims and payment. The MTF DM will provide dispensing entities and/or Part B providers 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 and/or Part B provider's banking information, in order to support the Primary Manufacturer in making available to the dispensing entity and/or Part B provider 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 the claims payment determination and amount with how the payment was made, including the electronic funds transfer information, if applicable. Dispensing entities and/or Part B providers need an ERA or remittance to close out open accounts receivable for each claim for which a Primary Manufacturer owes an MFP refund.

CMS has developed a flexible, efficient enrollment process that accommodates various structures to: (1) provide the MTF DM with bank account information and a secure location for creating and making available the ERA or remittance, as applicable; (2) maintain the accuracy of that information over time; and, (3) maintain the functionality necessary to receive ERAs or remittances, as applicable. Information collected from dispensing entities and/or Part B providers will support payment pass through both for the MTF PM and Primary Manufacturers choosing to operate their own payment arrangements. Information that dispensing entities and/or Part B providers will provide will include but is not 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.[43] Dispensing entities that enroll in the

[43] CMS intends to issue a revision of the currently approved Medicare Transaction Facilitator for 2026 and 2027 under Sections 11001 and 11002 of the Inflation Reduction Act (IRA) Information Collection Request (ICR) (OMB 0938-1483), with a revised title of, Medicare Transaction Facilitator for 2028 under Sections 11001 and 11002 of the Inflation Reduction Act (IRA) ICR this summer for a 60-day comment period. See: https://www.reginfo.gov/public/do/PRAViewICR?ref_nbr=202503-0938-001.

MTF DM will also indicate their election of whether they prefer receiving payments through electronic funds transfers, which will be the default election 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 their indicated preference, or to the Part B provider through electronic funds transfer, unless an extenuating circumstance exists as discussed in section 40.4.3.4 of this draft guidance. 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 method of payment for dispensing entities that have indicated their preference to receive electronic transfer of funds and for Part B providers. 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 method of payment. For Part B providers that have indicated that there is an extenuating circumstance preventing them from receiving payment electronically, the Primary Manufacturer would need to ensure access to the MFP through a mutually agreed-upon process outside of the MTF PM. CMS intends to issue a revision of the approved Medicare Transaction Facilitator for 2026 and 2027 under Sections 11001 and 11002 of the Inflation Reduction Act (IRA) Information Collection Request (ICR) (OMB 0938-1483) with a revised title of Medicare Transaction Facilitator for 2028 under Sections 11001 and 11002 of the Inflation Reduction Act (IRA). CMS intends to publish this revised ICR for 60-day public comment period this summer.[44]

CMS recognizes that the success of the Negotiation Program is, in part, dependent on Medicare beneficiaries' access to selected drugs through dispensing entities and/or Part B providers, which in turn necessitates that dispensing entities and/or Part B providers—particularly those that rely primarily on prescription or drug administration revenue to maintain business operations—are able to timely access the MFP. Therefore, during the MTF DM enrollment, CMS will ask dispensing entities and/or Part B providers to self-identify whether they are a dispensing entity and/or Part B provider 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.

In the MTF DM user interface, CMS will provide Primary Manufacturers with an up-to-date list of dispensing entities that have self-identified as anticipating material cashflow challenges. Similarly, CMS would maintain a list of Part B providers that have self-identified as anticipating material cashflow challenges and make the list available to Primary Manufacturers in the MTF DM user interface. Because both of these lists are generated from dispensing entity- and/or Part B provider-submitted information, the lists in the MTF DM will reflect the current information available and will be subject to change based on the latest information dispensing entities and/or Part B providers submit. Primary Manufacturers may use this list to inform development and

[44] See: https://www.reginfo.gov/public/do/PRAViewICR?ref_nbr=202503-0938-001.

implementation of their mitigation processes for addressing material cashflow concerns. For example, CMS expects dispensing entities and/or Part B providers 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, long-term care pharmacies, 340B covered entities with in-house pharmacies, Indian Health Service, Tribal, and Urban Indian (I/T/U) pharmacies, rural hospitals, and independent physician clinics —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 and/or Part B providers to ensure continued beneficiary access to their selected drugs. CMS will evaluate the degree to which this dispensing entity and/or Part B provider self-identification process provides useful data for Primary Manufacturers in developing MFP Effectuation Plans and may reconsider this approach in the future.

Dispensing entities and/or Part B providers that enroll in the MTF DM must certify that information provided to the MTF DM is accurate and up to date. CMS will require each dispensing entity and/or Part B provider 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. CMS is considering making updates to the MTF DM User Agreement as necessary to account for Part B providers and intends to provide stakeholders with more information prior to beginning MTF DM Part B provider enrollment. During enrollment, dispensing entities and/or Part B providers 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 and/or Part B providers 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 and/or Part B providers is further developed, additional requirements for dispensing entities and/or Part B providers may be necessary to support making this information available.

For Part D claims, to assist dispensing entities in reconciling MFP refund payments, regardless of a Primary Manufacturer's election to use the MTF PM to pass through payment, CMS expects Part D plan sponsors to include SDRAs on all Part D claims for selected drugs with a negotiated MFP in effect. The National Council for Prescription Drug Programs (NCPDP) provides instruction to Part D plan sponsors regarding this new message, which will furnish dispensing entities with an estimate of the manufacturer MFP refund amount equal to the SDRA as calculated by the plan sponsor. If the SDRA accurately reflects the dispensing entity's acquisition costs, a dispensing entity may use this estimated amount to create an accounts receivable. NCPDP furnishes additional direction to plan sponsors on implementing the SDRA on the claim response. The SDRA is an estimate and is not a guarantee of payment of an MFP

refund by a Primary Manufacturer or an indication that payment of a refund amount equal to the SDRA will be sufficient to provide access to the MFP. The Primary Manufacturer is responsible for calculating and paying an appropriate amount to the dispensing entity to effectuate the MFP, and there are situations where an MFP refund may not be applicable (e.g., the selected drug was purchased prospectively at or below the MFP) or the SDRA may be insufficient to provide access to the MFP.

Dispensing entities and/or Part B providers 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, dispensing entities, and Part B providers 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 the MFP may not have been made available.

40.4.3 MTF Payment Facilitation

CMS has established a payment facilitation functionality using the MTF PM to support the facilitation of MFP refund payments between Primary Manufacturers, dispensing entities, and Part B providers in a reliable, predictable, and consistent manner while reducing significant burden or cost.

In response to the draft guidance for initial price applicability year 2028, CMS received feedback from interested parties that CMS should consider building upon the established MTF DM and MTF PM framework outlined for the effectuation of the MFP for MFP-eligible Part D claims to support the effectuation of MFP refund payments from Primary Manufacturers to Part B providers for selected drugs payable under Part B. Interested parties noted in their comments that there does not exist a system currently available for Primary Manufacturers to issue MFP refund payments directly to Part B providers for MFP-eligible claims in which it is determined that an MFP refund payment is owed in order to effectuate the MFP. Based on the feedback provided by interested parties and to support Primary Manufacturers in the transmission of MFP refund payments to Part B providers, CMS intends to leverage the MTF PM framework described herein with respect to selected drugs payable under Part B. In section 40.4.3.3 of this draft guidance, CMS describes the policies that are specific and applicable to the transmission of MFP refund payments to Part D dispensing entities and, in section 40.4.3.4 of this draft guidance, CMS describes the policies that are specific and applicable to the transmission of MFP refund payments to Part B providers.

Additionally, some interested parties commented to CMS that the agency should consider leveraging the Medicare Administrative Contractors (MACs) to support the effectuation of MFP refund payments from Primary Manufacturers to Part B providers for selected drugs payable under Part B. While CMS acknowledges the arguments in favor of building upon the existing framework for Part B provider payment for OM claims, at this time, CMS declines to move forward with this approach given the operational complexity and the necessary expansion of services and functions required of the MACs to fulfill the necessary functions to transmit MFP refund payments and the associated remittances for Part B providers submitting claims to OM and MA organizations. Additionally, CMS believes that Part B providers would likely still need to interact with the MTF DM to investigate the status of claims for selected drugs, initiate

disputes and complaints, interact with the MTF Help Desk and other related services that are exclusively available through the MTF DM, meaning that Part B providers will still likely need to enroll and interact with the MTF DM to be able to access those listed services. For these reasons, CMS believes the best course of action is to build upon the MTF, which can handle both OM and MA data (i.e., MA encounter records).

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 and/or Part B providers. Participation in the MTF PM is voluntary for Primary Manufacturers, which have the option of passing MFP refund payments to dispensing entities and/or Part B providers 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 and/or Part B provider 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 sections 40.4.3.3 and 40.4.3.4 of this draft guidance, the MTF PM will not require an affirmative election of participation by dispensing entities and/or Part B providers for the MTF PM to pass along MFP refund payments submitted by the Primary Manufacturer.

For 2028, Primary Manufacturers, dispensing entities, and/or Part B providers shall not be required to pay any fees to participate in the MTF PM, including but not limited to user fees or transaction fees, as CMS will bear the cost of operationalizing the MTF PM. However, as the Negotiation Program evolves and the number of selected drugs increases, CMS is considering whether, in future rulemaking, it will be necessary to establish user fees or transaction fees paid by Primary Manufacturers to sustain MTF PM operations. CMS is not establishing a definition for the terms "user fees" or "transaction fees" in this draft guidance but considers user fees to be representative of a regularly occurring fee for accessing the MTF PM (e.g., an annual fee) and considers transaction fees to be representative of costs paid by the Primary Manufacturer for each authorization of payment through the MTF PM. To inform CMS' assessment of the topic, CMS is soliciting comments on the scope and structure of potential user fees or transaction fees for the MTF PM in future years.

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) of the Act to provide access to the MFP to dispensing entities and/or Part B providers for MFP-eligible individuals who are dispensed, furnished, or administered selected drugs. While the statute does not provide CMS with an express role in effectuating the MFP, the MTF PM serves in a ministerial, facilitating role that assists Primary Manufacturers in meeting their statutory obligations by passing through refund payments paid by participating Primary Manufacturers to dispensing entities and/or Part B providers.

The purpose of the voluntary MTF PM is to connect the Primary Manufacturer to the dispensing entity and/or Part B provider and to facilitate transmission of an MFP retrospective refund on MFP-eligible claims of selected drugs from the Primary Manufacturer to the dispensing entity and/or Part B provider in accordance with section 1193(a)(3) of the Act. The MTF PM: (1) provides Primary Manufacturers with a mechanism for electronic transfer of funds or payment by paper check to facilitate MFP refund payments to dispensing entities and/or Part B providers;

and, (2) provides 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.

The combined data and payment facilitation functionality present in the MTF DM and the MTF PM discussed here, and depicted in Figures 4, 5, and 6 below, attempts to address the interests expressed by dispensing entities, Part B providers, 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. Figures 4, 5, and 6 represent 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 and/or Part B provider through the MTF PM. Even if the Primary Manufacturer elects to participate in the MTF PM, the Primary Manufacturer and dispensing entity and/or Part B provider 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 Figures 4, 5, and 6 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.

Figure 4: Diagram of MTF Payment Flow for Primary Manufacturers that Participate in the MTF PM for Selected Drugs Covered under Part D

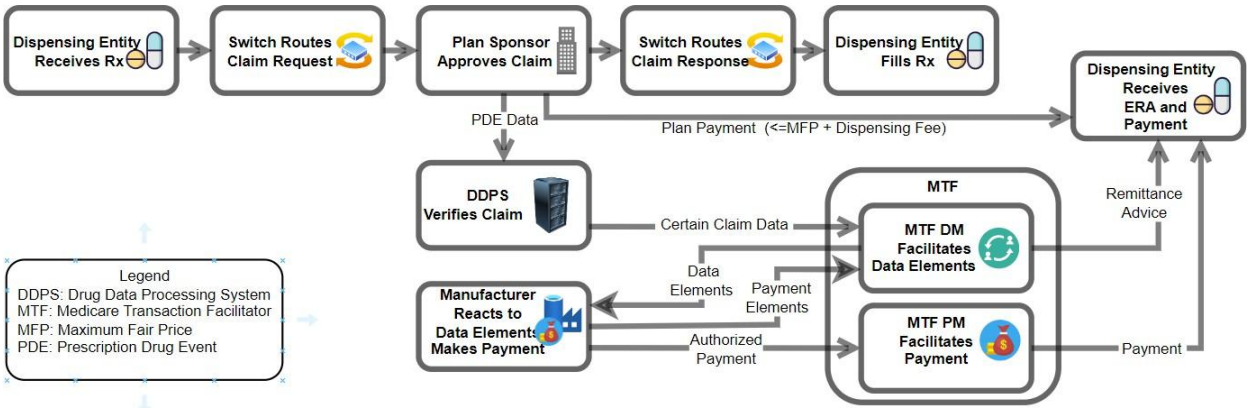


Figure 5: Diagram of MTF Payment Flow for Primary Manufacturers that Participate in the MTF PM for Selected Drugs Payable under Part B in Original Medicare

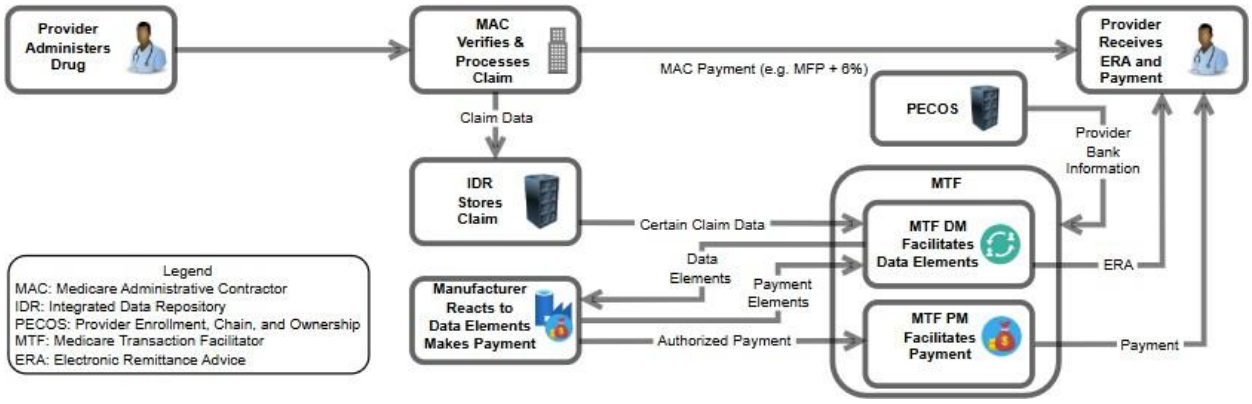
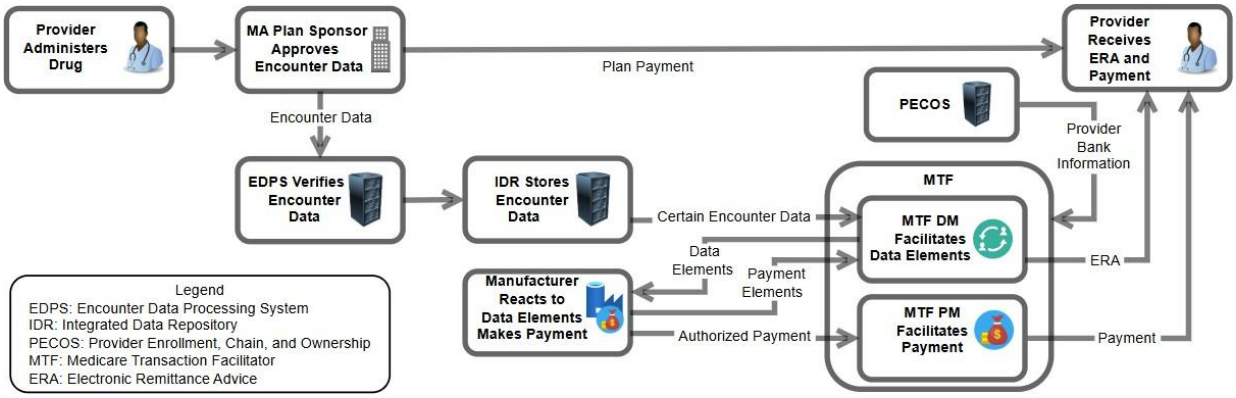


Figure 6: Diagram of MTF Payment Flow for Primary Manufacturers that Participate in the MTF PM for Selected Drugs Payable under Part B in Medicare Advantage



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 and/or Part B providers does 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/or Part B providers, 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 and/or Part B provider 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/or Part B provider and shall not otherwise discharge the Primary Manufacturer's statutory obligation to make the MFP available. Neither CMS nor its MTF Contractors assert independent control over the disposition of deposited payment amounts or direct payment transfers; instead, the MTF Contractors 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 and/or Part B providers identified by the Primary Manufacturer in its claim-level payment elements.

Because the MTF PM only passes payments between Primary Manufacturers and dispensing entities and/or Part B providers (as applicable), 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 and/or Part B provider on the Primary Manufacturer's behalf in anticipation of a future MFP refund payment from the Primary Manufacturer to the dispensing entity and/or Part B provider. CMS expects and encourages interested parties to work together as necessary to develop mechanisms to ensure timely effectuation of MFP refund payments consistent with statute, CMS' guidance, and all other applicable laws, regulations, and guidance, including without limitation the Anti-Kickback Statute. For example, the following approaches might be pursued by interested parties to provide timely payment, potentially focused on dispensing entities and/or Part B providers 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 and/or Part B providers 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 Part B providers; and/or, (3) Primary Manufacturers could leverage established relationships between dispensing entities, Part B providers, and claim reconciliation vendors (e.g., PSAOs in Part D and/or claim clearinghouses in Part B) to establish accounts that are pre-funded by the Primary Manufacturer for the claim reconciliation vendor to use to disburse MFP refund payments to dispensing entities and/or Part B providers, with the claim reconciliation vendors facilitating any necessary financial, reconciliation, and administrative services for the dispensing entity and/or Part B provider, 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 and/or Part B provider, 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 and/or Part B provider (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 and/or Part B providers 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 nor Part B providers 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 at this time.

Scenarios may arise where the MTF PM is responsible for temporarily holding unclaimed funds, for example, a dispensing entity and/or Part B provider ceases operations, yet the MTF PM still receives MFP refund payments designated for that dispensing entity and/or Part B provider from the Primary Manufacturer. 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 and/or Part B provider, but the dispensing entity and/or Part B provider 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 and/or Part B provider.

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.[45] Issues arising from the operational work of facilitating MFP refund payments via the MTF will be resolved in accordance with MTF technical instructions and user guides, and aligned with the applicable MTF agreements. CMS does not assume responsibility for any liability arising from the performance of MTF PM activities.

To participate in the MTF PM, a Primary Manufacturer will indicate to CMS its intention to use the MTF PM as part of the Primary Manufacturer's written plan for effectuating the MFP, described in section 90.2.2 of this draft guidance. At the time of enrollment in the MTF DM,[46] 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 and/or Part B providers. 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 and/or Part B providers. 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 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 and/or Part B providers.

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[45] See: https://www.cms.gov/files/document/manufacturer-mtf-pm-user-agreement.

[46] 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.

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 and/or Part B provider to make payments outside the MTF PM with respect to that dispensing entity and/or Part B provider. Section 40.4.3 of this draft guidance discusses the Primary Manufacturer's reporting requirements under each scenario, respectively.

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 and/or Part B provider 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/or Part B provider. Additionally, the receipt of the MFP refund payment by the dispensing entity and/or Part B provider (either electronically or via paper check) does not constitute the dispensing entity and/or Part B provider's agreement that access to the MFP has been provided by the Primary Manufacturer.

40.4.3.1 Required Primary Manufacturer Reporting of Claim-Level Payment Elements for MFP Refund Payments When a 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 and/or Part B provider 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 complete and accurate claim-level payment elements to the MTF DM within 14-days after the MTF DM sends the claims-level data elements in Table 5 or Table 6 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, or the Primary Manufacturer asserts that the claim is subject to the exception under section 1193(d)(1) of the Act in accordance with section 40.4.5 of this draft guidance. 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 and/or Part B provider 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 5 or Table 6 in sections 40.4.2.1 and 40.4.2.2 of this draft guidance, respectively; and, (2) the claim-level payment elements listed in Table 8 below associated with each claim within 14 days of receipt of the claim-level data elements in Table 5 or Table 6. 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 and/or Part B providers when Primary Manufacturers choose to pass payment through the MTF PM. As CMS further develops operational and 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 and/or Part B provider 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. MFP refund payments for MFP-eligible claims paid through the MTF PM occur following the Primary Manufacturer's authorization of such payment by transmitting the claim-level payment elements. CMS intends to continue to prioritize expeditious pass through of payment to the dispensing entity and/or Part B provider as it continues to develop the MTF PM functionalities along with 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 and in accordance with section 40.4 of this draft guidance 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, or the final guidance for initial price applicability year 2028, as applicable).

Table 8: Example Manufacturer Claim-Level Payment Elements List for Primary Manufacturers Passing Payment through the MTF PM[47]

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 9)
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 and/or Part B provider, prior to the application of any credits
Transaction Code[48]	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 and/or Part B provider may have an arrangement in place where the selected drug is prospectively purchased by the dispensing entity and/or Part B provider 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.[49] Examples of these justification codes, listed in Table 9, include codes indicating the selected drug was prospectively purchased at or below the MFP; the Primary Manufacturer and dispensing entity and/or Part B provider have a separately negotiated refund amount distinct from the SDRA; or the Primary Manufacturer claims an exception under section 1193(d)(1) of the Act (related to 340B discounts). CMS believes that identifying standardized justifications for the claim-level payment elements will allow Primary Manufacturers to establish efficient

[47] These elements are representative examples only. CMS may update the exact claim-level payment elements and will provide such notice in guidance or technical instructions as operations develop.

[48] 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.

[49] Nothing in this section precludes a Primary Manufacturer and a dispensing entity and/or Part B provider from reaching agreements outside of the MTF to establish an adjusted refund amount based on the dispensing entity's and/or Part B provider'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.

processes to provide such information to the MTF. CMS intends to work with interested parties to add justification codes, if necessary, to meet reporting needs.

When a Primary Manufacturer reports a code other than "1" for the "Method for Determining MFP Refund Amount" claim-level payment element, it will be required to maintain supporting documentation as outlined in section 90.2.1 of this 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 9: Examples of Justification Codes and Values for the "Method for Determining MFP Refund Amount" Claim-Level Payment Element for Primary Manufacturers[50]

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 and/or Part B provider, a contractual outside agreement with the dispensing entity and/or Part B provider establishing an acquisition cost agreed to between the Primary Manufacturer and the dispensing entity and/or Part B provider, or other evidence of the dispensing entity's or Part B provider'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 selected drug sold at or below MFP, or an outside agreement between the Primary Manufacturer and dispensing entity and/or Part B provider establishing prospective purchasing of the selected drug at or below MFP

[50] These codes are representative examples only. CMS may update the exact Justification Codes and will provide such notice in guidance or technical instructions as operations develop. 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)
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 or Billing Provider NPI" matching the claim-level data elements the MTF DM transmitted to the Primary Manufacturer is for the covered entity or its contract pharmacy
5	No Refund Transmitted – Payment Transmission Attempted but Unsuccessful	This code would be available in the event a Primary Manufacturer attempts to transmit an MFP refund to a dispensing entity and/or Part B provider 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 generally accepted accounting principles (GAAP)-compliant method of accounting for claims reconciliation, and how that was used to calculate any transmitted refund
8	Amount Other than Standard Default Refund Amount Transmitted – Section 1193(d)(2) Scenario	• At a minimum, either records from the Primary Manufacturer's process for ensuring 340B nonduplication of claims and the conclusion reached for the claim, where the process has demonstrated a valid and reliable method to accurately identify 340B eligibility, or demonstrated confirmation from a 340B covered entity or

Code	Value	Examples of Documentation to Maintain (see section 90.2 of this draft guidance)
		from any vendor/third-party administrator that the 340B covered entity employs to determine 340B eligibility status • Documentation that the 340B ceiling price is greater than MFP and the "Service Provider Identifier or Billing Provider NPI" matching the claim-level data elements the MTF DM transmitted to the Primary Manufacturer is for the covered entity or its contract pharmacy

By transmitting the claim-level payment elements to the MTF DM including the "MTF PM Facilitation Indicator" indicating that payment should be made through the MTF PM, the Primary Manufacturer will authorize the electronic funds transfer of payment equal to the total refunds to be paid through the MTF PM and the transmission of such MFP refund payments by the MTF PM to the dispensing entities and/or Part B providers 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 or Billing Provider 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 and/or Part B providers included in the claim-level payment elements using the dispensing entities' or Part B providers' documented banking information and 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 and/or Part B provider. 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 and/or Part B providers. 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.

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 and/or Part B provider. When a mutually agreed-upon process is implemented, the Primary Manufacturer must 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 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 and/or Part B providers electronically or through paper check, the MTF will maintain a credit/debit ledger system that tracks credits and debits related to MFP refunds. For dispensing entities, the system will track at the dispensing entity NPI-level (that is, the Service Provider Identifier transmitted with the claim-level data elements), for each selected drug based on information reported by the Primary Manufacturer in the claim-level payment elements. For Part B providers, the system will track at the Billing Provider NPI level for each HCPCS code that includes a selected drug based on information reported by the Primary Manufacturer in the claim-level payment elements.

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 and/or Part B provider 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 details.

If a Primary Manufacturer terminates participation in the MTF PM, CMS or its MTF Contractors 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 MTF Contractors 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. It is the responsibility of the Primary Manufacturer to work with dispensing entities and/or Part B providers if a Primary Manufacturer believes funds are owed for the outstanding credits and to continue to make payments to dispensing entities and/or Part B providers 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 and/or Part B providers.

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, the final guidance for initial price applicability year 2027, or the final guidance for initial price applicability year 2028, as applicable, and the Agreement, credits and debits will remain in the credit/debit ledger system and will be transferred to the new Primary Manufacturer.

40.4.3.2.1 Primary Manufacturer and MFP Refund Payment Adjustments due to Part D Claim Amendments Through the MTF PM

To address changes in MFP refund payments due to claim reversals, adjustments, or determinations that a claim for a selected drug covered under Part D is not MFP-eligible after the Primary Manufacturer has transmitted claim-level payment elements, the MTF will maintain a credit/debit ledger system that tracks credits and debits related to MFP refunds at the dispensing entity NPI-level for each selected drug for Primary Manufacturers that participate in the MTF PM and where payment is facilitated through the MTF PM. The credit/debit ledger system will accommodate a variety of revisions to incoming PDE information, including reversals or adjustments originating from updated PDE information received from DDPS. The Primary Manufacturer is responsible for reviewing all such credit and debit amounts to confirm their accuracy.

- To address adjustments and reversals, whether these occur before the 14-day prompt MFP payment window has elapsed or after the Primary Manufacturer has transmitted the claim-level payment elements to the MTF DM, the MTF DM will transmit updated claim-level data elements to the Primary Manufacturer, including the "MTF XRef ICN" (see Table 5) that links an adjustment to the previous MTF ICN.
- Each set of claim-level data elements, including claim-level data elements associated with an adjusted claim, has a distinct 14-day prompt MFP payment window.
- For adjustments, when a Primary Manufacturer participating in the MTF PM has already transmitted the claim-level payment elements to the MTF DM in response to the original claim, the Primary Manufacturer will identify and authorize the correct payment amount based on the reported claim adjustment in its claim-level payment elements submitted in response to the adjusted claim.
- For adjustments, when a Primary Manufacturer participating in the MTF PM has not transmitted the claim-level payment elements to the MTF DM in response to the original claim, the Primary Manufacturer must respond to the original set of claim-level data

elements within the 14-day prompt MFP payment window of the original claim. In such instances, the Primary Manufacturer may transmit the claim-level payment elements based on the adjusted claim-level data elements.

- When a Primary Manufacturer initiates a reversal or adjustment to claim-level payment elements, the Primary Manufacturer would update the "Transaction Code" from the claim-level data elements (see Table 8) 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 5 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 any adjusted MFP refund payment made by the Primary Manufacturer. The MTF DM will subsequently instruct the MTF PM to apply the specified credit or debit. The MTF PM will apply credits or debits at the dispensing entity NPI-level for each selected drug. The MTF PM may require additional authorization for fund transfer of the MFP refund, if applicable, from the Primary Manufacturer as technical and operational details develop.

For claims designated as full reversals from DDPS before the Primary Manufacturer has transmitted the claim-level payment elements, the Primary Manufacturer will see the claim removed in its feed of claim-level data elements. For claims designated as full reversals after the Primary Manufacturer has transmitted the claim-level payment elements, for a Primary Manufacturer participating in the MTF PM, the MTF DM will instruct the MTF PM to issue a credit equal to the previously paid MFP refund payment, unless no MFP refund payment was authorized in which case the credit amount would be equal to zero. Primary Manufacturers will not need to submit claim-level payment elements back to the MTF DM for full reversals. Neither CMS nor its MTF Contractors will independently determine, control, or verify the amount of the credit resulting from any claim reversal from DDPS. The Primary Manufacturer is responsible for reviewing all such credit amounts to confirm their accuracy. The MTF DM will issue a record to the Primary Manufacturer to document the occurrence of a full reversal and, in the case of a credit accrual in the MTF PM as a result of the issuance of a full reversal after the claim-level payment elements have been transmitted, a receipt file will be issued to the Primary Manufacturer to provide notice of the accrued credit.

As part of MFP effectuation, the Primary Manufacturer participating in the MTF PM will authorize the MTF PM, through transmission of the claim-level payment elements, to send to a dispensing entity a lump sum payment equal to the total refunds to be paid as indicated when reporting the claim-level payment elements. If the Primary Manufacturer has credits accrued with respect to a selected drug for the dispensing entity NPI for which it has authorized an MFP refund payment, the MTF PM will automatically credit the Primary Manufacturer and the MTF PM will indicate to the MTF DM that, for impacted claims, an accrued credit was applied. Primary Manufacturers will not need to provide authorization for the application of credits. The MTF DM will use this information to inform the ERA or remittance, as applicable, that is made

available to the dispensing entity. The MTF DM also will update its 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. Dispensing entities and participating Primary Manufacturers are able to view the status of available credits and MFP refunds through the MTF.

40.4.3.2.2 Primary Manufacturer and MFP Refund Payment Adjustments due to Part B Claim Amendments Through the MTF PM

To address changes in MFP refund payments due to claim reversals, adjustments, or determinations that a claim is not MFP-eligible after the Primary Manufacturer has transmitted claim-level payment elements, the MTF will maintain a credit/debit ledger system that tracks credits and debits related to MFP refunds at the Part B Billing Provider NPI level for the HCPCS code(s) that includes a 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 claim information, including reversals or adjustments originating from updated claim information received from the IDR or from EDS. The Primary Manufacturer is responsible for reviewing all such credit and debit amounts to confirm their accuracy.

- To address adjustments and reversals, whether these occur before the 14-day prompt MFP payment window has elapsed or after the Primary Manufacturer has transmitted the claim-level payment elements to the MTF DM, the MTF DM will transmit updated claim-level data elements to the Primary Manufacturer, including the "MTF XRef ICN" (see Table 6) that links an adjustment to the previous MTF ICN.
- Each set of claim-level data elements, including claim-level data elements associated with an adjusted claim, has a distinct 14-day prompt MFP payment window.
- For adjustments, when a Primary Manufacturer participating in the MTF PM has already transmitted the claim-level payment elements to the MTF DM in response to the original claim, the Primary Manufacturer will identify and authorize the correct payment amount based on the reported claim adjustment in its claim-level payment elements submitted in response to the adjusted claim.
- For adjustments, when a Primary Manufacturer participating in the MTF PM has not transmitted the claim-level payment elements to the MTF DM in response to the original claim, the Primary Manufacturer must respond to the original set of claim-level data elements within the 14-day prompt MFP payment window of the original claim. In such instances, the Primary Manufacturer may transmit the claim-level payment elements based on the adjusted claim-level data elements.
- When a Primary Manufacturer initiates a reversal or adjustment to claim-level payment elements, the Primary Manufacturer would update the "Transaction Code" from the claim-level data elements (see Table 8) 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 6 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 Billing Provider NPI of the Part B provider. The MTF DM's assessment will in no way constitute an endorsement or determination of the appropriateness of any adjusted MFP refund payment made by the Primary Manufacturer. The MTF DM will subsequently instruct the MTF PM to apply the specified credit or debit. The MTF PM will apply credits or debits at the Part B provider Billing Provider NPI level for each selected drug. The MTF PM may require additional authorization for fund transfer of the MFP refund, if applicable, from the Primary Manufacturer as technical and operational details develop.

For claims designated as full reversals before the Primary Manufacturer has transmitted the claim-level payment elements, the Primary Manufacturer will see the claim removed in its feed of claim-level data elements. For claims designated as full reversals after the Primary Manufacturer has transmitted the claim-level payment elements, for a Primary Manufacturer participating in the MTF PM, the MTF DM will instruct the MTF PM to issue a credit equal to the previously paid MFP refund payment, unless no MFP refund payment was authorized, in which case the credit amount would be equal to zero. Primary Manufacturers will not need to submit claim-level payment elements back to the MTF DM for full reversals. Neither CMS nor its MTF Contractors will independently determine, control, or verify the amount of the credit resulting from any claim reversal. The Primary Manufacturer is responsible for reviewing all such credit amounts to confirm their accuracy. The MTF DM will issue a record to the Primary Manufacturer to document the occurrence of a full reversal and, in the case of a credit accrual in the MTF PM as a result of the issuance of a full reversal after the claim-level payment elements have been transmitted, a receipt file will be issued to the Primary Manufacturer to provide notice of the accrued credit.

As part of MFP effectuation, the Primary Manufacturer participating in the MTF PM will authorize the MTF PM, through transmission of the claim-level payment elements, to send to a Part B provider a lump sum payment equal to the total refunds to be paid as indicated when reporting the claim-level payment elements. If the Primary Manufacturer has credits accrued with respect to a selected drug for the Part B Billing Provider NPI for which it has authorized an MFP refund payment, the MTF PM will automatically credit the Primary Manufacturer and the MTF PM will indicate to the MTF DM that, for impacted claims, an accrued credit was applied. Primary Manufacturers will not need to provide authorization for the application of credits. The MTF DM will use this information to inform the ERA or remittance, as applicable, that is made available to the Part B provider. The MTF DM also will update its 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 Part B providers and participating Primary Manufacturers will be able to view the status of available credits and MFP refunds through the MTF.

40.4.3.3 Pass Through Payment to a Dispensing Entity When a Primary Manufacturer Participates in the MTF PM for Drugs Covered Under Part D

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. 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.

CMS received feedback from dispensing entities that they prefer having the option to identify a reconciliation vendor to access an ERA, or a remittance if payment is issued by paper check, on their behalf. Additionally, dispensing entities under the same parent organization requested the ability to receive payment through a single entity and to allow for groups of pharmacies to enroll together instead of each pharmacy being required to enroll individually, to streamline both the disbursement of funds and the enrollment process. In response to this feedback, enrollment in the MTF DM will provide the dispensing entity with the option to have a PSAO, reconciliation contractor, or other vendor as indicated during the enrollment process, access the ERA or remittance, as applicable, and receive MFP refund payments on behalf of the dispensing entity, as well as the option for chains to designate a single or central pay option for dispensing entities under common ownership. CMS has issued instructions on enrollment procedures, with considerations for the ability for chains to enroll groups of dispensing entities and functionality

for integrating PSAOs, reconciliation vendors, and other third-party vendors in the enrollment process.[51] 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. Dispensing entities may prevent unnecessary delays in receipt of MFP refund payments by ensuring third-party vendors, if applicable, are enrolled 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. When a Primary Manufacturer elects to pass payment through the MTF PM and a dispensing entity has indicated a preference to receive payment in the form of a paper check, the MTF PM will issue a paper check using the Primary Manufacturer's funds and on behalf of the Primary Manufacturer. 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.

As described above in section 40.4.3 of this draft guidance, CMS established the MTF PM to assist Primary Manufacturers and dispensing entities in effectuating MFP refund payment between parties in a reliable, predictable, and consistent manner without incurring significant burden or cost. Despite the respective enrollment obligations of Primary Manufacturers and dispensing entities in the MTF DM as articulated in sections 40.4.2.1 and 40.4.2.2 of this draft guidance, based on CMS' review of comments and other feedback from interested parties, CMS has extended the availability of the MTF PM to Primary Manufacturers for use in instances in which a dispensing entity has not enrolled in the MTF DM. Specifically, a Primary Manufacturer that participates in the MTF PM may elect to utilize the MTF PM to pass through MFP refund payments to dispensing entities that have not enrolled in the MTF DM. In such cases, as described further below, the MTF PM will send a paper check for the MFP refund amount, in the amount authorized by the Primary Manufacturer's claim-level payment elements, to the registered mailing address that is listed in the NCPDP database for the dispensing entity.

If the MTF DM receives a PDE record for a dispensing entity that has not enrolled in the MTF DM, the MTF DM will indicate through inclusion of a transaction code on the claim-level data elements transmitted to the Primary Manufacturer that the dispensing entity is not enrolled in the MTF DM. For Primary Manufacturers that participate in the MTF PM, if the Primary Manufacturer elects to utilize the MTF PM to make any MFP refund payment necessary to effectuate the MFP with respect to a claim from a dispensing entity that is not enrolled in the MTF DM, the Primary Manufacturer can, in accordance with the requirements of section 40.4.3 of this draft guidance, transmit the claim-level payment elements within the 14-day prompt MFP payment window, indicating, if applicable, the MFP refund payment amount and authorizing an MFP refund payment amount to be transmitted through the MTF PM to the dispensing entity. In

[51] See: https://www.cms.gov/files/document/dispensing-entity-mtf-agreement-final.pdf.

this scenario, after receipt of the claim-level payment elements from the Primary Manufacturer, the MTF PM will issue a paper check to the registered mailing address that is listed in the NCPDP database for the dispensing entity not enrolled in the MTF DM. If the dispensing entity that is not enrolled in the MTF DM wishes to obtain the associated remittance advice that corresponds to the paper check issued to the dispensing entity's registered address in the NCPDP database, the dispensing entity has the option to do the following: (1) enroll with the MTF DM to receive access to the remittance(s) for the issued paper check(s) and establish a secure delivery location for remittances associated with future MFP refund payments; or, (2) contact the MTF Helpdesk[52] and provide the necessary information to facilitate the issuance of a remittance via a secure delivery method for the issued paper check.

If a Primary Manufacturer that is enrolled in the MTF PM elects not to utilize the MTF PM to make an MFP refund payment necessary to effectuate the MFP with respect to a claim from a dispensing entity that is not enrolled in the MTF DM, the Primary Manufacturer must transmit payment to the dispensing entity outside of the MTF PM when provided with notice from the MTF DM that a dispensing entity is not enrolled in the MTF DM. If payment is transmitted outside of the MTF PM, Primary Manufacturers must transmit claim-level payment elements to the MTF PM in accordance with section 40.4.4 of this draft guidance.

40.4.3.4 Pass Through Payment to Part B Providers When a Primary Manufacturer Participates in the MTF PM for Drugs Payable Under Part B

CMS acknowledges a significant number of Part B providers will likely enroll in the MTF DM to receive timely and efficient MFP refund payments and the associated remittances or ERAs, as applicable, from Primary Manufacturers that elect to pass MFP refund payments through the MTF PM. Thus, the MTF DM will need to obtain the necessary enrollment and payment details from different types of Part B providers to support the transmission of MFP refund payments from Primary Manufacturers to Part B providers for MFP-eligible claims. Additionally, in comments provided on draft guidance for initial price applicability year 2028, interested parties expressed concern to CMS that enrollment in an additional payment system to facilitate the receipt of MFP refund payments from Primary Manufacturers that elect to transmit payments through the MTF PM may be burdensome to Part B providers and could involve the provision of duplicative enrollment and payment details that Part B providers already provide to established Medicare provider payment systems. To address this concern, CMS intends to simplify the enrollment of Part B providers in the MTF DM by leveraging Part B providers' provision of enrollment and payment information to PECOS in order to establish enrollment profiles in the MTF DM for Part B providers that are prepopulated with Part B provider demographic and payment details. As outlined in section 40.4.2.2 of this draft guidance, Part B providers will affirm the payment account information as part of the Part B provider's enrollment in the MTF DM. Once the Part B provider affirms the payment account details, for Primary Manufacturers that elect to transmit MFP refund payments through the MTF PM on a claim for a selected drug payable under Part B, the corresponding payment information will be used to deposit the MFP refund payment issued by the Primary Manufacturer for MFP-eligible claims in the form of an electronic funds transfer deposit. CMS is soliciting feedback on this approach and if there are

[52] See: https://mtf.helpdesk.cms.gov/home.

other ways in which CMS might simplify the effectuation of the MFP operational process to reduce burden for Part B providers.

Upon enrollment in the MTF DM, Part B providers will provide or affirm the information outlined in section 40.4.2.2 of this draft guidance, including establishing access to the ERA or remittance that the MTF DM makes available for corresponding MFP refund payments made through the MTF PM by participating Primary Manufacturers. 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 DM and, if applicable, pays the MFP refund amount to the Part B provider through the MTF PM, then the MTF DM will generate an ERA or remittance for the Part B provider for purposes of reconciling the Primary Manufacturer's retrospective MFP refunds with previously created accounts receivable. The MTF DM will produce ERAs that use the X12 835 standard adopted under HIPAA. As outlined in section 40.4.2.2 of this draft guidance, MFP refund payments to Part B providers for claims of selected drugs that are payable under Part B that are transmitted through the MTF PM will be associated with a corresponding ERA or remittance advice that will be made available for the Part B provider to reconcile MFP refund payments associated with MFP-eligible claims as determined by the Primary Manufacturer.

In alignment with the policy outlined in section 40.4.3.3 of this draft guidance for dispensing entities, the MTF PM will not require an affirmative election of participation by Part B providers for the MTF PM to pass along MFP refund payments submitted by the Primary Manufacturer. CMS is considering an approach where Part B providers that enroll in the MTF DM will be issued MFP refund payments from the MTF PM in the form of an electronic funds transfer (EFT), which aligns with the established payment practices and with Medicare payment standards for Part B providers, to reduce operational complexity and administrative burden on the MTF and enrolled Part B providers, unless there is an extenuating circumstance that requires the Part B provider to receive payment in the form of a paper check. PECOS does not include functionality for a Part B provider to select or designate a preference to receive Medicare payments via paper check. CMS will provide future technical instruction on the process and allowable types of extenuating circumstances for which issuance of a paper check would be permitted. CMS is soliciting comments on example scenarios that may constitute an extenuating circumstance in which a Part B provider would require issuance of payment from the Primary Manufacturer in the form of a paper check.

CMS would leverage enrollment and payment details from PECOS, as outlined in section 40.4.2.2 of this draft guidance to develop Part B provider enrollment profiles in the MTF DM. The MTF DM will use the registered bank account details in PECOS to deliver MFP refund payments in the form of an electronic funds transfer by the Primary Manufacturer and through the MTF PM for participating Primary Manufacturers that authorize the transmission of such a payment. Although the payment and enrollment information reported to PECOS is designed to serve a different purpose than transmitting MFP refund payments from the MTF PM, aligning these reporting processes across systems provides meaningful operational benefits for both Part B providers and CMS. For Part B providers, this alignment eliminates the need to maintain and update payment information across multiple systems whenever changes are required, thereby reducing administrative burden and minimizing the risk of data inconsistencies. For CMS, this

alignment maintains consistency and congruence of information across enrollment and payment systems and simplifies the management of updates and modifications to Part B provider payment details that are imported from PECOS into the MTF DM. This alignment enhances compatibility between enrollment and payment platforms, reduces operational complexity, minimizes redundant data entry, and streamlines updates to ensure that changes are accurately reflected across workflows. Accordingly, while PECOS and the MTF PM serve distinct functions, harmonizing their processes and reporting requirements creates a more efficient, accurate, and Part B provider-friendly administrative environment that benefits all interested parties.

A Primary Manufacturer that participates in the MTF PM may elect to use the MTF PM to pass through MFP refund payments to Part B providers that have not enrolled in the MTF DM. As described above in this section, the MTF DM will establish enrollment and payment profiles in the MTF DM for Part B providers using PECOS to establish the requisite information for the MTF PM to transmit MFP refund payments to Part B providers from participating Primary Manufacturers. If a Part B provider does not affirm the established enrollment and payment details in the MTF DM, nor provide the requisite user information for the MTF DM, the MTF PM will send a paper check for the MFP refund amount authorized by the Primary Manufacturer's claim-level payment elements to the registered mailing address that is listed in PECOS for the Part B provider. If the Primary Manufacturer elects to utilize the MTF PM to make any MFP refund payment necessary to effectuate the MFP with respect to a claim from a Part B provider that is not enrolled in the MTF DM, the Primary Manufacturer can, in accordance with the requirements of section 40.4.3 of this draft guidance, transmit the claim-level payment elements within the 14-day prompt MFP payment window, indicating, if applicable, the MFP refund payment amount and authorizing an MFP refund payment amount to be transmitted through the MTF PM to the Part B provider. If the Part B provider that is not enrolled in the MTF DM wishes to obtain the associated remittance advice that corresponds to the paper check issued to the Part B provider's registered mailing address in PECOS, the Part B provider has the option to do the following: (1) enroll with the MTF DM to receive access to the remittance(s) for the issued paper check(s) and establish a secure delivery location for remittances associated with future MFP refund payments; or, (2) contact the MTF Helpdesk[53] and provide the necessary information to facilitate the issuance of a remittance via a secure delivery method for the issued paper check.

If a Primary Manufacturer that is enrolled in the MTF PM elects not to utilize the MTF PM to make an MFP refund payment necessary to effectuate the MFP with respect to a claim from a Part B provider that is not enrolled in the MTF DM, the Primary Manufacturer must transmit payment to the Part B provider outside of the MTF PM when provided with notice from the MTF DM that a Part B provider is not enrolled in the MTF DM. If payment is transmitted outside of the MTF PM, Primary Manufacturers must transmit claim-level payment elements to the MTF PM in accordance with section 40.4.4 of this draft guidance.

CMS understands that some Part B providers may prefer to receive MFP refund payments transmitted through the MTF PM and the associated ERA or remittance issued by the MTF DM through a claim reconciliation vendor for purposes of payment and claims reconciliation. CMS is soliciting comments on whether the MTF DM and MTF PM should account for such preferences

[53] See: https://mtf.helpdesk.cms.gov/home.

and how Part B providers intend to leverage claim reconciliation vendors for purposes of receiving MFP refund payment and the associated claims reconciliation for MFP refund payments transmitted through the MTF PM.

40.4.4 MFP Refund Payments When a Primary Manufacturer Makes a 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 and/or Part B provider 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 and/or Part B providers 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 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 and/or Part B provider on a payment arrangement outside of the MTF.

40.4.4.1 Primary Manufacturer Payment Outside of the MTF PM

Table 5 and Table 6 in section 40.4.2 of this draft guidance list 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 intends to make information available through the MTF DM, such as the bank account information and designated destination for ERAs or remittances for dispensing entities and Part B providers enrolled in the MTF DM, to support the Primary Manufacturer's creation and transmission of an ERA or remittance to the dispensing entity and Part B provider. For dispensing entities, the MTF DM also will provide the Primary Manufacturer with 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 and/or Part B provider 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 and/or Part B provider. Figure 7 represents the flow of data and payment if the Primary Manufacturer makes payment outside of the MTF PM for dispensing entities. Figure 8 and Figure 9 represent the flow of data and payment if the Primary Manufacturer makes payment outside of the MTF PM for Part B providers for both the OM and MA programs, respectively.

Figure 7: Diagram of MTF Data Flow when Primary Manufacturers Make Payment Outside of the MTF PM for Selected Drugs Covered under Part D

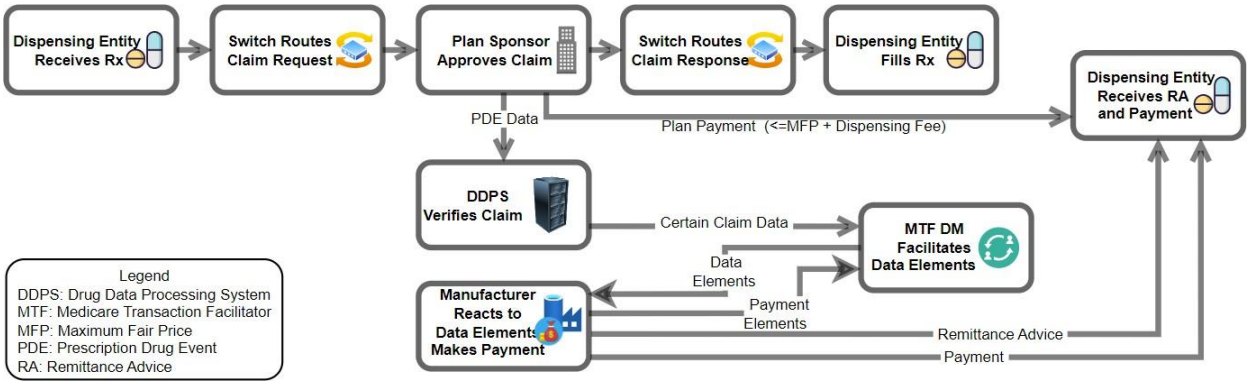


Figure 8: Diagram of MTF Payment Flow when Primary Manufacturers Make Payment Outside of the MTF PM for Selected Drugs Payable under Part B in Original Medicare

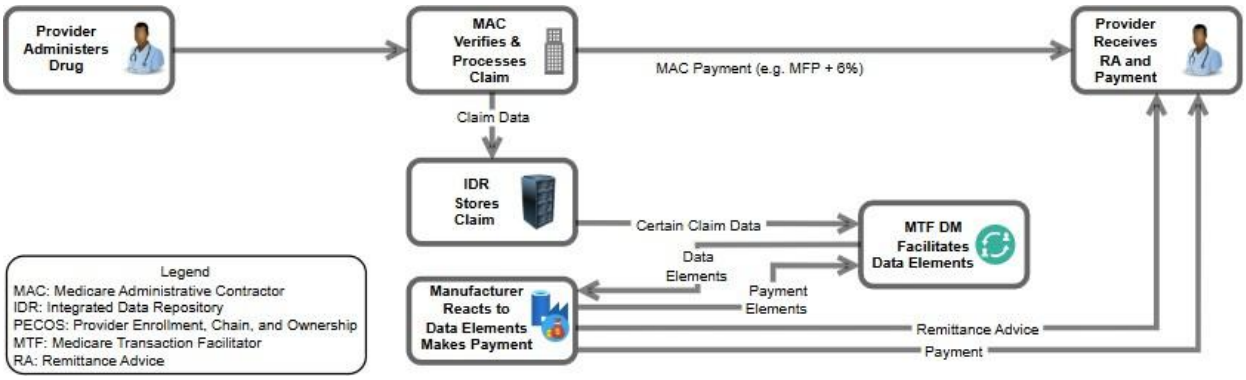
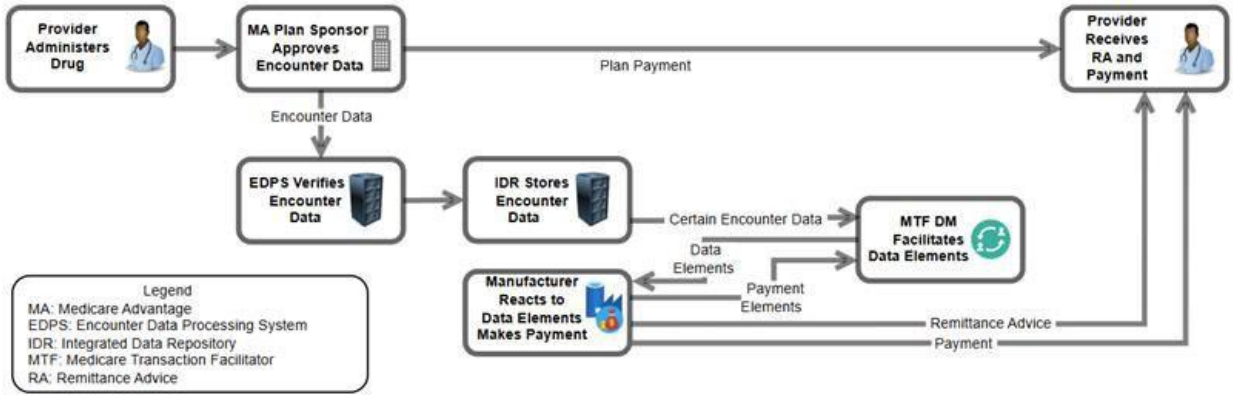


Figure 9: Diagram of MTF Payment Flow when Primary Manufacturers Make Payment Outside of the MTF PM for Selected Drugs Payable under Part B in Medicare Advantage



In instances in which the Primary Manufacturer does not use the MTF PM to facilitate payments to a dispensing entity and/or Part B provider, 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 and/or Part B providers outside of the MTF PM, Primary Manufacturers will be required to submit claim-level payment elements to the MTF DM that detail MFP refund payments made directly to dispensing entities and/or Part B providers, 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 and in Table 7 of this draft guidance, these retrospective refund payments by the Primary Manufacturer to the dispensing entity and/or Part B provider would be provided through a process that is mutually agreed to by the Primary Manufacturer and the dispensing entity and/or Part B provider 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 and/or Part B providers any transaction or other fees for the pass through of the MFP refund to the dispensing entity and/or Part B provider.

40.4.4.2 Required Primary Manufacturer Reporting of Claim-Level Payment Elements for MFP Refund Payments When a 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 and/or Part B provider 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 complete and accurate 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, or the Primary Manufacturer asserts that the claim is subject to the exception under section 1193(d)(1) of the Act in accordance with section 40.4.5 of this draft guidance. 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 5 or Table 6 in section 40.4.2 of this draft guidance; and, (2) the claim-level payment elements listed in Table 10 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 10: Example Manufacturer Claim-Level Payment Elements List when Primary Manufacturers Make Payment Outside of the MTF PM[54]

Payment Elements	Purpose
MTF PM Facilitation Indicator	Indicates whether transmission of the MFP refund should be facilitated through the MTF PM.
MFP Refund Transmission Date	Indicates when the MFP refund was transmitted by the Primary Manufacturer.[55]
MFP Refund Transmission Time	Indicates when the MFP refund was transmitted by the Primary Manufacturer.
Method for Determining MFP Refund Amount	Indicates the basis on which the MFP refund amount was determined (refer to Table 7 in section 40.4.3.1 of this draft guidance).
Amount Calculated as the MFP Refund	Documents the amount determined as the MFP refund prior to the application of any credits. Payment element should be populated with the final calculated MFP

[54] The elements with their definitions and values for MFP effectuation related to Part D claims are listed in the MTF Manufacturer Refund Notice (MRN), Manufacturer Refund Advice (MRA), and Manufacturer Refund Receipt (MRR) Interface Control Document (ICD) in the MTF General Resources website: https://www.cms.gov/priorities/medicare-prescription-drug-affordability/overview/medicare-drug-price-negotiation-program/medicare-transaction-facilitator-general-resources. The ICD will be updated in the future to reflect MFP effectuation for Part B claims.

[55] The recipient is the dispensing entity and/or Part B provider 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 and/or Part B provider. For MFP refunds paid via paper check, the Primary Manufacturer reports the date on which the paper check was mailed to the dispensing entity and/or Part B provider.

Payment Elements	Purpose
	refund amount if payment was an adjustment to a previous claim or encounter.
Amount of Payment Transmitted as the MFP Refund	Documents the amount transmitted to the dispensing entity and/or Part B provider as the MFP refund.
Transaction Code[56]	Indicates if the MFP refund payment is in response to an original claim or encounter, 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 10) prior to sending claim-level payment elements to the MTF. "Amount Calculated as the MFP Refund" is a claim-level payment element in which the Primary Manufacturer documents the amount determined as the MFP refund for the claim or encounter prior to the application of any credits. "MFP Refund Transmission Date" and "MFP Refund Transmission Time" are claim-level payment elements that are required for MFP refund payments made outside of the MTF PM. As discussed in section 40.4.3.1 of this 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 must report the date and time that electronic payment was transmitted or the date that a paper check was mailed to a dispensing entity and/or Part B provider.

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 upon between the Primary Manufacturer and dispensing entities and/or Part B providers. Additional details on specific claim-level payment elements that may be reported to the MTF DM when the Primary Manufacturer does not use the MTF PM will be provided in future technical instructions.

The claim-level payment elements must be submitted to the MTF DM within the 14-day prompt MFP payment window, including when the claim-level payment elements indicate that no MFP refund payment is made in response to the claim-level data elements received. If an MFP refund payment is transmitted in response to the claim-level data elements received, the Primary Manufacturer should submit claim-level payment elements after sending the paper check or electronic payment of the MFP refund to the dispensing entity and/or Part B provider 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 and in accordance with section

[56] 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.

40.4 of this draft guidance 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, or the final guidance for initial price applicability year 2028, 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 or encounter 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.[57] Examples of these justification codes, listed in Table 9 in section 40.4.3.1 of this draft guidance, include codes indicating the selected drug was prospectively purchased at or below the MFP, the Primary Manufacturer and dispensing entity and/or Part B provider 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 claim-level payment elements will allow Primary Manufacturers to establish efficient processes to provide such information to the MTF DM. 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 and/or Part B provider 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 and/or Part B provider; in this case, it is the responsibility of the Primary Manufacturer to ensure that an ERA is created and transmitted to the dispensing entity and/or Part B provider for electronic transfer of funds. In instances where a Primary Manufacturer makes non-electronic payments outside of

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

the MTF PM, the Primary Manufacturer must make available a remittance to the dispensing entity and/or Part B provider.

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 and/or Part B providers outside of the MTF PM, this date and time must reflect the date and time that the Primary Manufacturer sent the payment to the dispensing entity and/or Part B provider. 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 and/or Part B provider 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.

40.4.4.3 Dispensing Entity and/or Part B Provider 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 and/or Part B provider 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 and/or Part B providers 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 and/or Part B providers 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 and/or Part B provider uses the X12 835 standard adopted under HIPAA and can be utilized by dispensing entities and/or Part B providers to close accounts receivable. Primary Manufacturers should have access to bank account information and a designated destination for ERA transmissions for dispensing entities and/or Part B providers through the MTF DM. The MTF DM will collect this information when dispensing entities and Part B providers enroll, and CMS intends 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. Regardless of a Primary Manufacturer's participation in the MTF PM, or a dispensing entity's or Part B provider's enrollment in the MTF DM, the Primary Manufacturer remains obligated to provide access to the MFP.

CMS encourages the dispensing entity and/or Part B provider 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 and/or Part B provider or the Primary Manufacturer can use the complaint process outlined in section 90.2.2 of this draft guidance. Dispensing entities and/or Part B providers 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 of this draft guidance and may issue a decision regarding whether the MFP was made available to the dispensing entity and/or Part B provider.

40.4.4.4 Primary Manufacturer and MTF PM MFP Refund Payment Adjustments Due to Claim Amendments When a Primary Manufacturer Makes a 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 and/or Part B providers 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 dispensed, administered, or

furnished 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 Public Health Service (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.[58] Under section 1193(d)(2) of the Act, the Primary Manufacturer is required to provide access to the MFP to 340B covered entities in a nonduplicated amount to the 340B ceiling price if the MFP for the selected drug is lower than the 340B ceiling price for the selected drug.

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

To illustrate how the 340B nonduplication provision would apply in cases where the dispensing entity and/or Part B provider'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 provides access to the MFP of a selected drug to the dispensing entity and/or Part B provider 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 and/or Part B providers, 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

[58] Hereinafter, and solely for the purpose of this draft guidance, a claim for a selected drug that is dispensed, furnished, or administered to an MFP-eligible individual who is eligible to be dispensed, furnished or administered such selected drug at a covered entity described in section 340B(a)(4) of the PHS Act, and for which the selected drug is subject to an agreement described in section 340B(a)(1) of the PHS Act, is referred to as a "340B-eligible claim." CMS does not determine nor verify 340B eligibility and expects manufacturers and covered entities to continue to be responsible for statutory obligations pursuant to section 340B of the PHS Act regarding proper identification of 340B-eligible patients and covered outpatient drugs dispensed to such patients.

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 for Part D claims, a provider or prescriber ID alone (whether the "Service Provider ID" or the "Prescriber ID," as included in Table 5 in section 40.4.2.1 of this draft guidance) 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 ceiling price.

CMS continues to receive 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 and Part B claims transmitted to the MTF to remove claims for which the Primary Manufacturer is not required to provide access to the MFP under the nonduplication provision at section 1193(d)(1) of the Act.[59]

Considering numerous factors such as those outlined below, CMS is not, at this time, assuming 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 Primary Manufacturer has discharged its obligation to provide access to the MFP. CMS is continuing to explore the feasibility of incorporating 340B-related transactional data from 340B covered entities or their TPAs identifying claims eligible under section 1193(d)(1) of the Act into MTF processes in the future. For example, CMS continues to consider ways to incorporate asynchronous 340B data into MTF processes in the future.

If it is subsequently determined that a claim for a selected drug was a 340B-eligible claim but an MFP refund was provided for that claim, and the 340B ceiling price for the selected drug is determined to be lower than the MFP, then the Primary Manufacturer may use the credit/debit ledger system described in section 40.4.3.2 of this 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, Part B providers, 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

[59] 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.

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,[60] the MTF would pass along the 340B indication data as applicable to the Primary Manufacturer when the MTF shares the claim-level data elements with each Primary Manufacturer. Part B providers that are covered entities are required to report a 340B modifier on OM claim lines for separately payable Part B drugs and biologicals acquired through the 340B Program[61] and for such claims, the MTF would pass along the 340B modifier data as applicable to the Primary Manufacturer when the MTF shares the claim-level data elements with each Primary Manufacturer. In addition, CMS is considering a regulatory requirement for MA organizations to submit 340B modifiers in encounter data to identify drugs purchased under the 340B Program. 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 CFR 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. 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 interested parties (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 interested parties to ensure the process is not unduly burdensome for dispensing entities, 340B covered entities, and patients.

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[60] 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.

[61] See: https://www.cms.gov/files/document/revised-part-b-inflation-rebate-340b-modifier-guidance.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 (HRSA) 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.

80. MFP-Eligible Individuals in 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 dispensing entity, an individual who is enrolled in a prescription drug plan under Medicare Part D or an MA–PD plan under 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,[62] and for whom no PDE record is produced for the claim.

In addition to providing access to the MFP of a selected drug with respect to MFP-eligible Part D claims, for drugs selected for initial price applicability year 2028 or with a renegotiated MFP for initial price applicability year 2028, Primary Manufacturers must provide access to the MFP of a selected drug to Part B providers with respect to a drug furnished or administered to MFP-eligible individuals enrolled under Part B, including an individual who is enrolled in a MA plan under Part C, in accordance with section 1193(a)(3)(B) of the Act.

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 Part B provider, an individual who is enrolled under Medicare Part B or in an MA plan under Part C (including an Employer Group Waiver Plan), if payment may be made under Part B for such selected drug. The MFP is not required to be made available to a Medicare beneficiary who only uses other sources of coverage or cash and for whom no Part B claim is produced for the claim.

MA plan requirements under 42 CFR Part 422 will apply to selected drugs which are payable under Part B. Therefore, in accordance with section 1852(a)(1)(B)(iv)(VII) of the Act, as amended by section 11001(b)(1)(B) of the IRA ("Application under MA of cost-sharing for Part B drugs based off of negotiated price"), and as currently required under 42 CFR 422.100(j)(1)(i)(F) for all drugs payable under Part B, in-network cost sharing established by an MA plan for selected drugs payable under Part B may not exceed the cost sharing required under OM. In addition, pursuant to the requirement in section 11001(c) of the IRA that CMS use program instruction or other forms of program guidance to implement section 11001 of the IRA, including amendments made by such section, CMS is establishing for 2028 that when an MA plan uses coinsurance, the dollar amount of in-network coinsurance for selected drugs payable

[62] 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.

under Part B for individuals enrolled in MA plans must be calculated based on a price that is no more than the MFP. This policy is to help ensure that the maximum coinsurance amount an MFP-eligible individual enrolled in an MA plan pays for a selected drug payable under Part B is based on the MFP of such selected drug in the same manner as it would have been if the individual had been enrolled under OM. CMS is soliciting comments on this policy, which is a new requirement to ensure that MA cost-sharing for selected drugs payable under Part B is based on the MFP as provided for by section 11001(b)(1)(B) of the IRA. Finally, CMS notes that in accordance with 42 CFR 422.100(f)(6)(i), MA plans are not permitted to establish out-of-network cost sharing for selected drugs payable under Part B that is greater than 50 percent coinsurance or an actuarially equivalent copayment value. To ensure that out-of-network cost sharing for selected drugs payable under Part B is calculated based on a price that does not exceed the MFP, CMS is considering future rulemaking to establish that for selected drugs payable under Part B, 50 percent coinsurance or an actuarially equivalent copayment value under 42 CFR 422.100(f)(6)(i) must be calculated based on a price that is equal to or less than the MFP. CMS is soliciting comments on whether a potential requirement to establish that MA plans must calculate the 50 percent out-of-network coinsurance cap for selected drugs payable under Part B based on the MFP would implement necessary and sufficient safeguards to ensure MA enrollees are not subject to benefit design that discriminates on the basis of health status-related factors or is likely to substantially discourage enrollment by certain MA-eligible individuals, as prohibited by section 1852(b)(1) of the Act.

80.1 Direct Member Reimbursement and Access to the MFP for Selected Drugs in 2028

Direct member reimbursement (DMR) requests are requests for reimbursement submitted by Part D enrollees 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 Part D enrollee for the difference between the cash price paid to the dispensing entity and the plan allowance (if out-of-network) or negotiated price (if in-network) for drugs covered under Part D accessed from both out-of-network and in-network dispensing entities, neither 42 CFR 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.[63]

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

[63] 42 CFR 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 CFR 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.

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 an internal analysis, less than one-hundredth of a percent of final action claims submitted in 2024 for the 10 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 CFR 423.124(a) and (c)) or at an in-network dispensing entity, when the selected drug is covered under the Part D benefit (for example, 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, respectively, 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 individual's Part D benefit is not used at the point of sale, and the dispensing entity does not bill the individual's Part D plan. Rather, the dispensing entity charges the individual the cash price established by itself, and the individual's status as an MFP-eligible individual is determined 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 the 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.

Consistent with section 80.1 of final guidance for initial price applicability year 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. If the MFP-eligible individual owes

coinsurance rather than a copayment, the payment would be calculated by multiplying the plan coinsurance by the MFP plus the dispensing fee rather than multiplying the plan coinsurance by the cash price paid by the enrollee at the point-of-sale. 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. On January 9, 2026, CMS issued a memo through the CMS HPMS with examples related to reporting PDEs for selected drugs for DMR requests involving in-network and out-of-network claims.[64]

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 into the MFP eligibility of the individual at the point of sale and therefore requires an alternate procedure to effectuate the MFP for the MFP-eligible individual. In DMR situations, the dispensing entity has already received the cash payment from the individual at the point of sale, at the cash price established by the dispensing entity, and is not involved in the submission of the claim to the Part D plan sponsor 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.

CMS is soliciting comments on DMR or other unique scenarios for selected drugs payable under Part B in which alternate procedures may be necessary to effectuate the MFP for MFP-eligible individuals. CMS is specifically interested in unique scenarios for selected drugs payable under Part B in which alternate procedures may be necessary to effectuate the MFP for MFP-eligible individuals who are enrolled in MA plans under Part C.

90.2 Monitoring of Access to the MFP in 2028

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

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 dispensing entity at the point-of-sale, to dispensing entities with respect to such MFP-eligible individuals who are dispensed the selected drug, and to Part B providers with respect to such MFP-eligible individuals who are furnished or administered the selected drug, as applicable. 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

[64] See: https://www.cms.gov/files/document/additional-prescription-drug-event-record-reporting-examples-implementation-inflation-reduction-act.pdf.

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 sections 40.4 of this draft guidance, including with respect to units of the selected drug manufactured, marketed, controlled, or sold by any Secondary Manufacturer(s). 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/or Part B providers, as applicable, that dispense, administer, or furnish the selected drug to an MFP-eligible individual, as discussed in section 80 of this draft guidance.

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 and/or Part B providers to support the verification that the selected drug was dispensed, administered, or furnished 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 and/or Part B providers 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, NDC-11s, or HCPCS codes that include a selected drug are added or removed for the selected drug and annually to show the inflation-adjusted MFP for the selected drug. 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. 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, Part B providers, and MFP-eligible individuals to know the MFP for a selected drug and determine whether they were provided access to the MFP.

As related to the exclusion of a claim from MFP refunds under section 1193(d)(1) of the Act, Primary Manufacturers are 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.

Specifically for claims subject to the exception under section 1193(d)(1) of the Act, to avoid duplication of discounts between MFP and the 340B ceiling price, Primary Manufacturers may identify claims from the data elements transmitted by the MTF that are 340B-eligible and for which the 340B ceiling price is lower than the MFP. If a Primary Manufacturer determines that it

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

If CMS determines through audits, investigations, or complaints from dispensing entities, Part B providers, 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 selected drugs covered under Part D and/or payable under Part B, CMS will notify the Primary Manufacturer of its noncompliance and, as applicable and at the agency's discretion, offer an opportunity to mitigate the noncompliance and request the Primary Manufacturer take other corrective actions such as adopting process improvements to prevent future lapses in MFP effectuation. Failure to make the MFP available in accordance with section 40.4 of this draft guidance may result in CMS imposing the appropriate CMPs as set forth in section 100.1 of this draft guidance. A Primary Manufacturer's mitigation of noncompliance and/or compliance with a corrective action request does not preclude CMS from issuing a CMP for the underlying violation.

Dispensing entities and/or Part B providers are encouraged to review their accounts receivable to determine whether a Primary Manufacturer has accurately paid all the claims the dispensing entity and/or Part B provider believes are MFP-eligible claims and to work with the Primary Manufacturer to resolve discrepancies. The dispensing entity and/or Part B provider 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, 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 used to determine that refund amount for Part D claims and Part B claims. This includes the reasons considered in

sections 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 entity and/or Part B provider at or below MFP, or the claim being excluded from the Primary Manufacturer's obligation to provide access to the MFP under section 1193(d)(1) of the Act.

CMS recognizes that the data elements from PDE records and Part B claims data transmitted by the MTF to Primary Manufacturers may include those from claims that should be subject to a different refund amount than the SDRA, if any, including claims described under section 1193(d)(2) of the Act, claims for selected drugs prospectively purchased at or below MFP, or claims for which the Primary Manufacturer may claim an exception under section 1193(d)(1) of the Act. As noted in sections 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 covered under Part D in the course of the agency's general oversight activities, and when making case-specific determinations as to whether MFP was made available in specific circumstances, absent information available to CMS indicating otherwise, CMS will consider WAC to be an appropriate proxy for a dispensing entity's acquisition cost. Therefore, CMS will consider provision of the SDRA (which is equal to WAC minus the MFP) to meet the Primary Manufacturer's obligation to make MFP available, absent information available to CMS indicating otherwise.

In section 40.4.1.2 of this draft guidance, CMS discusses multiple options for determining the SDRA for Part B claims. CMS intends to establish an approach to monitoring and oversight that aligns with the final Part B SDRA policy to consistently assess whether a Primary Manufacturer is providing access to the MFP to Part B providers with respect to MFP-eligible individuals who are furnished or administered the selected drug. As discussed in section 40.4 of this draft guidance, the 14-day prompt MFP payment window would apply to selected drugs covered under Part D and selected drugs payable under Part B. CMS intends to align the policies for selected drugs payable under Part B with the policies for selected drugs covered under Part D discussed in this section of this draft guidance to the extent appropriate and feasible but is soliciting comments on any compliance and oversight considerations or approaches unique to MFP effectuation with respect to selected drugs payable under Part B.

When engaged in case-specific determinations as to whether a Primary Manufacturer provided access to the MFP to a dispensing entity and/or Part B provider with respect to a selected drug, CMS will consider contextual information available to the agency, including as applicable: the invoice amount from the dispensing entity and/or Part B provider (if available); documentation maintained by the Primary Manufacturer supporting its MFP refund amount (as described in section 40.4.3.1 of this draft guidance); the MFP refund amount provided by the Primary Manufacturer, as indicated in the "Total MFP Refund Amount" field on the Primary Manufacturer's claim-level payment elements, where available, or as determined based on other supporting documentation in the event the claim-level payment elements are deemed to be inaccurate; other documentation regarding the dispensing entity's and/or Part B provider's actual

acquisition costs such as documentation of an arrangement for prospective purchase at the MFP or other alternative arrangement evidencing acquisition cost (e.g., establishment of an agreed-upon proxy for MFP refund calculation as described in section 40.4.1 of this draft guidance); and the commercial reasonableness of costs incurred by the dispensing entity and/or Part B provider related to the procurement of the selected drug (if available). CMS will make a determination based on this assessment as to whether the Primary Manufacturer made the MFP available. If CMS makes a determination that the Primary Manufacturer failed to make the MFP available, CMS will follow the process outlined in section 100.1 of this draft guidance.

Consistent with section 1193(a)(5) of the Act, in the course of this assessment, to further its inquiry into whether MFP was made available, CMS may request information from relevant parties such as Primary Manufacturers, dispensing entities, Part B providers, or other entities involved in the supply chain. For example, documentation or data related to the Primary Manufacturer's MFP refund calculation may inform CMS' assessment of whether the MFP refund provided by the Primary Manufacturer was sufficient to make the MFP available to the dispensing entity and/or Part B provider. 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, Part B providers, wholesalers, or other supply chain entities to better evaluate whether MFP was made available. Submitted documentation will be considered as part of CMS' fact-specific assessment of whether MFP was made available in the course of the agency's investigation, audit, and/or enforcement actions.

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

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 both Part D claims and Part B 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 and Part B 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 and/or Part B provider's acquisition cost was greater than WAC or ASP (as considered under Option 2 if such option is adopted in the final guidance), and therefore, the MFP was not made available to that dispensing entity and/or Part B provider). If CMS determines upon further investigation—whether through audits of this documentation, voluntary outreach from covered entities or their TPAs, complaints from dispensing entities and/or Part B providers, 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, 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 the MFP

Consistent with section 40.4 of this draft guidance, the Primary Manufacturer may make the 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 and/or Part B providers as required to ensure the MFP is made available to dispensing entities and/or Part B providers; (2) prospectively ensuring that the price paid by the dispensing entity and/or Part B provider when acquiring the drug is no greater than the MFP; or, (3) using some combination of these two approaches.

CMS divides the MFP Effectuation Plan into two sections. The first section, due from Primary Manufacturers by June 1 of the calendar year before the beginning of the selected drug's price applicability period, includes information that most directly impacts dispensing entities and/or Part B providers (for example, the Primary Manufacturer's indication of whether they intend to use the MTF PM to process MFP refund payments). The remainder of the required information for the MFP Effectuation Plan is due September 1 of the calendar year before the beginning of the selected drug's price applicability period. This approach is intended to allow CMS time to evaluate information on the MFP Effectuation Plan that will most directly impact dispensing entities and/or Part B providers 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. The specific contents, requirements, and instructions for the

information in each of the two sections will be detailed in the related Information Collection Request form.

To provide a clear, concise method of collecting the requested information, CMS included an MFP Effectuation Plan form in the Medicare Transaction Facilitator for Initial Price Applicability Year 2026 and 2027 ICR, published for a 60-day public comment in Fall 2024, and for a 30-day public comment period in Spring 2025; CMS published the final ICR in the Federal Register on May 9, 2025. CMS intends to publish a revised version of this ICR to address 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 that can be populated by a Primary Manufacturer within the MTF DM during its enrollment and subsequently updated as needed.

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 from initial price applicability years 2026 or 2027 is also the Primary Manufacturer of a selected drug for initial price applicability year 2028, then the Primary Manufacturer may amend its previously submitted plan to include the selected drug for initial price applicability year 2028, 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 and/or Part B providers 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, 2027, with any amendments to the remainder of the plan 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 and/or Part B providers 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 interested parties (e.g., supply chain entities) upon request.

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 Manufacturer's 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 must also indicate its general plan and procedures for contacting and receiving communications from dispensing entities and/or Part B providers. CMS understands that the Primary Manufacturer and dispensing entities and/or Part B providers 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 and/or Part B providers 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, 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.

As discussed in section 40.4.2.2 of this draft guidance, CMS will allow dispensing entities and/or Part B providers 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. In its MFP Effectuation Plan, a Primary Manufacturer must include a process for mitigating material cashflow concerns for such dispensing entities and/or Part B providers, as applicable. Thus, a Primary Manufacturer must include in its MFP Effectuation Plan a process for either dispensing entities and/or Part B providers, as applicable, if its selected drug is only covered under Part D or payable under Part B. In the event a Primary Manufacturer has a selected drug that is covered under Part D and is payable under Part B, or has multiple selected drugs that are covered under Part D and are payable under Part B, its MFP Effectuation Plan must include a process or processes for mitigating cashflow concerns that address both dispensing entities and Part B providers. For Primary Manufacturers' consideration in developing their mitigation processes, CMS will make a list of the self-identified dispensing entities and/or Part B providers, as applicable, available to Primary Manufacturers in the MTF DM as that information is available (i.e., as these dispensing entities and Part B providers complete their MTF DM enrollment and submit the self-identifications); this list will be available to manufacturers on-demand in the MTF DM user interface and will be refreshed regularly to reflect up-to-date information available from dispensing entities and Part B providers. This list is provided as informational only and Primary Manufacturers will not need to update their MFP Effectuation Plans in response to updates to the list of dispensing entities and/or Part B providers who have self-identified as anticipating having material cashflow concerns. CMS recognizes a Primary Manufacturer may establish its own eligibility criteria for determining which dispensing entities and/or Part B providers 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 may include, but are not limited to, prospective purchasing agreements or accelerated MFP refund timelines. CMS will consider the information provided by a Primary Manufacturer in its mitigation process when conducting a risk assessment of the Primary Manufacturer's MFP Effectuation Plan. As stated earlier in this section, 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 40.4.3.1 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 and/or Part B providers that receive electronic transfer of funds through the

MTF PM, and provide the remittance and paper checks to dispensing entities, and Part B providers when applicable, 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 and/or Part B providers 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 and/or Part B provider 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 access to the MFP for dispensing entities and Part B providers that are not receiving reimbursements electronically (e.g., paper checks, prospective discounts, etc.). In its MFP Effectuation Plan, a Primary Manufacturer should document its mutually agreed upon separate payment arrangement with a dispensing entity and/or Part B provider consistent with section 40.4.4.1 of this draft guidance with respect to payments made outside of the MTF PM. As discussed in section 40.4.2.2 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. With respect to Part B providers, CMS is currently evaluating methods of providing necessary electronic payment information to Primary Manufacturers that choose to establish their own electronic payment methods to reimburse Part B providers. All of the Primary Manufacturer's payment facilitation methods will be assessed for their consistency with the requirements set forth in sections 40.4.3 through 40.4.4 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 and/or Part B provider (e.g., when the Primary Manufacturer will use the applicable actual acquisition cost or a standardized pricing metric, such as WAC or ASP, 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 40.4.3.1 and 40.4.4.2 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 and/or Part B providers (remittances for electronic payments must use the X12 835 standard adopted under HIPAA). If a Primary Manufacturer elects to operate its own system to account for this

information, it must provide information regarding its method of maintaining a comprehensive, GAAP-compliant system.

There are other specific examples of criteria CMS has identified as important to make MFP available and that a Primary Manufacturer should consider including in its electronic and paper check payment facilitation methods if it: (1) chooses not to participate in the MTF PM; or, (2) has, or plans to have, alternative arrangements with certain dispensing entities and/or Part B providers even if the Primary Manufacturer will ordinarily use the MTF PM to pass through MFP refund payments. These examples include, but are not limited to, a Primary Manufacturer's data transmission method to return the data elements listed in Table 8 to the MTF DM, frequency of returning the data elements listed in Table 8 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 is made available with respect to units of the selected drug manufactured, marketed, controlled or sold by a Secondary Manufacturer and dispensed, furnished, or administered to MFP-eligible individuals.

If a Primary Manufacturer and Part B provider and/or 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 and therefore may be subject to a CMP for such violation.

Consistent with their standard business practices, dispensing entities and/or Part B providers should review their accounts receivable and determine whether a Primary Manufacturer has made MFP refund payments on all the claims the dispensing entity and/or Part B provider believes are MFP-eligible claims, in the amounts the dispensing entity and/or Part B provider believes are sufficient to effectuate the MFP. Dispensing entities and Part B providers should understand that alternative arrangements made with a Primary Manufacturer outside of the MTF PM are private contracts between the parties; 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 and/or Part B providers 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. Primary Manufacturers, Part B providers, 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 it is providing access to the MFP 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 distribute, dispense, furnish, or administer the selected drug to MFP-eligible individuals, including dispensing entities and Part B providers. 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 and applicable sections of the final guidance for initial price applicability year 2028. 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 has established a centralized intake system for receiving reports related to access to the MFP with respect to MFP-eligible individuals and dispensing entities and Part B providers that dispense, furnish, or administer 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 includes 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. The complaint and dispute submission form is available to complete and submit on a web-based portal for Primary Manufacturers, dispensing entities, Part B providers, and other relevant interested parties (e.g., beneficiaries); these interested parties will also be able to submit a complaint via a toll-free telephone number.

Complaints and disputes must be submitted to CMS no later than 120 calendar days from the date of the subject of the complaint or dispute. Upon receipt of a reported issue, a threshold review will be completed, including a review to ensure, among other factors, that the issue is timely, contains supporting documentation or an explanation as to why supporting documentation is not available, and contains enough information on the face of the submission for CMS to move forward with the triage process, and to identify the appropriate track, either as a complaint or dispute, as described below. Once the issue has been identified as either a complaint or dispute, it will be triaged and prioritized, taking into account market factors, including but not limited to the monetary value and/or the number of claims at issue; and the extent to which the price made available to the dispensing entity and/or the Part B provider appears to differ from the MFP, among other factors. This prioritization is to ensure CMS is reviewing all submissions systematically and in appropriate order considering the potential impact on the dispensing entity and/or Part B provider, Primary Manufacturer or other

stakeholder submitting the issue. For example, a complaint that includes substantial financial ramifications to either the dispensing entity or Part B provider, or the Primary Manufacturer, will be prioritized for review, investigation, and resolution compared to complaints with lesser financial impact. CMS is committed to reviewing all submitted issues in a timely and efficient manner; prioritization will allow CMS to identify and address the most urgent concerns. After a complaint or dispute is triaged, as part of the investigation, CMS may reach out to impacted parties, as appropriate, to request additional information or documentation as needed. CMS intends to include more information about the operationalization of the complaint and dispute processes in future technical instruction.

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

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

The initiation of a dispute on a claim does not negate the Primary Manufacturer's statutory responsibility to make the MFP available to the dispensing entity and/or Part B provider for an MFP-eligible claim subject to a dispute. Nor does initiating a dispute affect the Primary Manufacturer's obligation to transmit the claim-level payment elements for such claim within the 14-day prompt MFP payment window, including the manufacturer-determined MFP refund amount (if any) and the appropriate transaction code. As is the case for any claim, whether it is under dispute or not, the Primary Manufacturer may make individual determinations about whether an MFP refund is appropriate, and, if so, the amount of the MFP refund, to effectuate the MFP. If the Primary Manufacturer provides an MFP refund on a claim for which there is a dispute, and the dispute results in an updated amount required to make the MFP available, the Primary Manufacturer can use the manufacturer-initiated adjustment processes described in section 40.4.3.2 of this draft guidance, for Primary Manufacturers utilizing the MTF PM, and resubmit a previously processed claim based on new information (i.e., the outcome of a dispute in this circumstance); a manufacturer-initiated adjustment should include the Transaction Code indicating that the claim-level payment elements are being sent independent of claim-level data elements received by the MTF DM to adjust claim-level payment elements previously sent by the Primary Manufacturer. Primary Manufacturers who elect not to use the MTF PM can utilize

the method they have established for handling changes to payment amounts, as discussed in section 40.4.4.4 of this draft guidance; and then complete the manufacturer-initiated adjustment in the MTF DM, utilizing the Transaction Code described in section 40.4.2.1 of this draft guidance, as this Transaction Code is available to all Primary Manufacturers, regardless of whether they utilize the MTF PM or not.

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

One type of complaint may include operational issues with the MTF originating from MTF users participating in the MTF DM or the MTF PM. For this type of complaint, CMS provides (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 is accessible to quickly provide answers to Primary Manufacturers, dispensing entities and Part B providers regarding daily operations of the MTF.

A second type of complaint may be related to reports that the MFP was not made available, including instances where a dispensing entity and/or Part B provider 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 MFP 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/or Part B providers, 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/or Part B providers and Primary Manufacturers to work together in good faith to resolve any issues regarding MFP availability. Contact information for dispensing entities and/or Part B Providers, and Primary Manufacturers, will be made available in the MTF DM user interface to facilitate these efforts. Proof of any efforts to resolve the issue should be submitted once the complaint is filed. If, as a result of these efforts, the Primary Manufacturer determines that an additional MFP refund amount is needed to make the MFP available to the dispensing entity and/or Part B provider, the Primary Manufacturer can follow the process for submitting revised claim-level payment elements in section 40.4.3.2 of this draft guidance, or a method for handling changes to payment amounts outside of the MTF PM, depending on whether or not the initial payment was made through the MTF PM. All complaints submitted will receive a response from CMS explaining the next steps that CMS may take.

Complaints related to a lack of MFP availability may not always require a specific resolution but will be reviewed by CMS and may trigger an investigation under CMS' obligation to administer the Negotiation Program and to provide monitoring and oversight of MFP availability.

Investigations may lead to enforcement action, as described in section 100 of the revised guidance for initial price applicability year 2026, the final guidance for initial price applicability year 2027, or the final guidance for initial price applicability year 2028, as applicable. 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/or Part B providers and emerging compliance issues, and to make process improvements in the implementation of the complaint and dispute process as applicable.

CMS' approach to complaints and disputes is the same for both selected drugs payable under Part B and selected drugs covered under Part D. However, CMS is soliciting comments on differences in approach that may be necessary for effective complaint and dispute resolution with respect to Part B claims. For example, interested parties are encouraged to comment on whether the 120-calendar day deadline for submission of complaints and disputes provides adequate time for interested parties to utilize the complaint and dispute process for Part B claims.

100.1 Failure of a Primary Manufacturer to Ensure Access to a Price Less Than or Equal to the MFP in 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 and/or Part B providers with respect to MFP-eligible individuals who are dispensed, 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/or 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/or 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/or Part B providers that dispense, furnish, or administer the selected drug with respect to MFP-eligible individuals, and the MFP for such drug for such year. For the purposes of calculating this CMP in instances where CMS has determined that a Primary Manufacturer failed to make MFP available to a dispensing entity and/or Part B provider, CMS will engage in the assessment described above in sections 90.2, 90.2.1, and 90.2.2 of this draft guidance to determine the price made available to the dispensing entity and/or the Part B provider and the difference between such price and the MFP.

CMS intends to align the policies for selected drugs payable under Part B with the policies for selected drugs covered under Part D discussed in section 100.1 of this draft guidance to the extent appropriate and feasible but is soliciting comments on any enforcement considerations or approaches unique to Part B claims. As described in sections 40.4. and 90.2 of this draft guidance, CMS will monitor for compliance and audit, as needed, to ensure that the MFP or a price lower than the MFP is being made available for the selected drug.

In an instance where an updated MFP is reached through renegotiation as described in section 130 of final guidance for initial price applicability 2028, CMS may impose a CMP if the Primary Manufacturer fails to make the renegotiated MFP available in accordance with section 40.4 of this draft guidance and section 130 of final guidance for initial price applicability 2028. 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 and/or Part B provider and the renegotiated MFP for such drug for such year.