# Medicare Drug Price Negotiation Program: Draft Guidance for Manufacturer Effectuation of the Maximum Fair Price in 2028

MEDICARE DRUG PRICE NEGOTIATION PROGRAM
CENTERS FOR MEDICARE & MEDICAID SERVICES

On July 16, 2026, the Centers for Medicare & Medicaid Services (CMS) issued **program guidance** that provides interested parties with detailed processes and requirements for manufacturer effectuation of the maximum fair price (MFP) 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 program's requirements 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This draft guidance sets forth policies regarding manufacturer effectuation of the MFP in 2028 for selected drugs payable under Part B and/or covered under Part D. The **Medicare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** ("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. 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.

Additionally, this draft guidance describes procedures that may apply to drug manufacturers, Medicare Part D plan sponsors (both Prescription Drug Plans [PDPs] and Medicare Advantage Prescription Drug [MA-PD] Plans), Medicare Advantage (MA) organizations, pharmacies, mail order services, and other 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").

There will be a 60-day public comment period on the draft guidance. CMS encourages all interested parties to submit comments so that CMS can consider them as we develop the final guidance for release this fall. Comments can be submitted via email 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.

Topics that are not relevant to MFP effectuation in 2028 are not addressed in this draft guidance.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

## Overview of MFP Effectuation for Selected Drugs Payable under Part B

Consistent with section 1193(a) of the Act, this draft guidance describes for the first time 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 for MFP-eligible individuals who are administered or furnished that selected drug during a price applicability period pursuant to the Medicare Drug Price Negotiation Program Agreement (hereinafter also referred to as an "Agreement"). 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.

CMS has engaged a Medicare Transaction Facilitator (MTF) contractor for the Negotiation Program to facilitate the exchange of information between Primary Manufacturers and dispensing entities and/or Part B providers (as applicable). The MTF Data Module (MTF DM) supports the verification that the selected drug was dispensed, administered, or furnished to an MFP-eligible individual. CMS has also engaged a separate MTF contractor to support the MTF Payment Module (MTF PM). The MTF PM facilitates payments from Primary Manufacturers and complements MTF DM data-related activities. This draft guidance describes adjustments to MTF operations to address structural differences (e.g., Medicare billing 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 MA.

**MTF DM: Overview of Data Facilitation 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 with the policies for effectuation of the MFP for dispensing entities.

Key MTF DM policies for Part B claims include, but are not limited to:

**Data Sources for Part B Claims.** Medicare Administrative Contractors (MACs) adjudicate OM claims for selected drugs payable under Part B and submit the claims to CMS' Integrated Data Repository (IDR). CMS intends to obtain data on OM claims for selected drugs payable under Part B from the IDR. 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.

Medicare Advantage organizations adjudicate MA claims for selected drugs payable under Part B and submit MA encounter data from the claims to the Encounter Data System (EDS). CMS intends to leverage MA encounter data submitted by MA organizations from MA claims for selected drugs payable under Part B and transmit such data to the MTF DM. In the draft guidance, CMS is soliciting comments on how to use MA encounter data more efficiently for MFP effectuation, such as considerations for a new requirement for MA organizations to submit MA 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 and requirements to include 11-digit National Drug Codes (NDC-11) and 340B modifiers on MA encounter data.

**Prompt 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 time frame 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 would start the 14-day prompt MFP payment window, within which the Primary Manufacturer must transmit the claim-level payment elements for each claim or encounter, as applicable, identified in the MTF DM claim-level data elements transmitted to the Primary Manufacturer. Also, if applicable, the Primary Manufacturer must transmit payment of an amount that provides access to the MFP when an MFP refund is appropriate.

**MTF DM Enrollment.** Consistent with requirements for Primary Manufacturers of selected drugs covered under Part D, CMS intends to require all Primary Manufacturers of selected drugs payable under Part B that reach an agreed-upon MFP for initial price applicability year 2028 to register with the MTF DM. CMS strongly encourages Part B provider participation with the MTF DM and is considering a process to use data from the Medicare Provider Enrollment, Chain, and Ownership System (PECOS) to facilitate the enrollment process. In addition, CMS is considering potential regulatory options to require any contract between the MA organization and a provider for participation in one or more of the MA organization's networks 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 a MFP, the provider must be enrolled in the MTF DM.

**Part B Claim-Level Data Elements.** CMS intends to provide certain claim-level data elements for Part B claims via the MTF DM to Primary Manufacturers. These include data elements used in Part B claims but not in Part D claims, such as Healthcare Common Procedure Coding System (HCPCS) codes. CMS believes that these data elements provide the minimum necessary information to verify the selected drug was furnished or administered to an MFP-eligible individual.

**Retrospective Refund Amount to Effectuate the MFP and the Standardized Default Refund Amount (SDRA) for Selected Drugs Payable Under Part B**

A Primary Manufacturer may meet its statutory obligation under section 1193(a)(3) of the Act to make the MFP available to Part B providers by retrospectively transmitting payment for the difference between the 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 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. Given the significant operational challenges associated with calculating real-time actual acquisition cost, Primary Manufacturers and Part B providers may agree to use a standardized pricing metric to approximate acquisition cost for calculating any MFP refund amount necessary to make the MFP available. CMS uses a standardized pricing metric (Wholesale Acquisition Cost [WAC]) to calculate a "standard default refund amount" for Part D claims. In this draft guidance, CMS is soliciting comments on four options for the standardized pricing metric to approximate acquisition cost for calculating an SDRA to assist Primary Manufacturers in making the MFP available for Part B claims. These options are:

1a. SDRA is calculated at the HCPCS code level 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 Average Sales Price (ASP) reported volume.

1b. SDRA is calculated at the NDC-11 level using the WAC as published in the pharmaceutical pricing database compendia. This option would require CMS to collect the NDC-11 data on Part B claims.

2a. SDRA is calculated at the HCPCS code level 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-reported sales volume.

2b. SDRA is calculated at the HCPCS code level 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 on Part B claims. This option would require CMS to collect the NDC-11 data on Part B claims.

**Nonduplication with 340B Ceiling Price**

Under section 1193(d)(1) of the Act, the Primary Manufacturer of a selected drug is not required to provide MFP access if the selected drug is subject to an agreement described in section 340B(a)(1) of the Public Health Service (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. Under section 1193(d)(2) of the Act, the Primary Manufacturer is required to provide MFP access to Part B providers in a nonduplicated amount to the 340B ceiling price if the MFP for the selected drug is lower than the 340B ceiling price for it. CMS is not, currently, assuming responsibility for nonduplication of discounts between the 340B ceiling price and MFP.

**MFP-Eligible Individuals in 2028**

Under section 1191(c)(2)(B) of the Act, a "maximum fair price eligible individual" or "MFP-eligible individual" with respect to selected drugs payable under Part B means an individual enrolled under Medicare Part B or in an MA plan under Part C to whom a selected drug is furnished or administered by a Part B provider, and for which payment may be made under Part B for such selected drug. CMS is establishing for 2028 that when an MA plan uses coinsurance, the dollar amount of in-network coinsurance for selected drugs payable under Part B for MFP-eligible individuals enrolled in an MA plan must be calculated based on a price that is no more than the MFP. This policy's objective 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, just as it would have been if the individual had been enrolled under OM.

**MTF Onboarding in 2028**

CMS intends to issue an updated MTF Information Collection Request (ICR) package for a 60-day public comment period in the summer of 2026. The revised ICR will include updates to integrate Part B providers into MFP effectuation operations (e.g., a new Part B provider MTF Enrollment form segment) and provide general enhancements and revisions to collected information based on lessons learned during 2026 program operations, including updates to the MFP Effectuation Plan and Complaints & Disputes Submission forms. CMS intends to begin onboarding Primary Manufacturers with selected drugs for initial price applicability year 2028 by May 1, 2027.

## Additional Resources

- Regulations, Guidance, and Policy Documents for the Medicare Drug Price Negotiation Program – **https://www.cms.gov/initiatives/medicare-prescription-drug-affordability/overview/medicare-drug-price-negotiation-program/guidance-policy-documents**
- Medicare Transaction Facilitator General Resources – **https://www.cms.gov/priorities/medicare-prescription-drug-affordability/overview/medicare-drug-price-negotiation-program/medicare-transaction-facilitator-general-resources**