Medicare Drug Price Negotiation Program Final Guidance for Initial Price Applicability Year 2028 and Manufacturer Effectuation of the Maximum Fair Price in 2026, 2027, and 2028

MEDICARE DRUG PRICE NEGOTIATION PROGRAM
CENTERS FOR MEDICARE & MEDICAID SERVICES

Today, the Centers for Medicare & Medicaid Services (CMS) issued **final guidance** that details requirements and parameters for the third cycle of negotiations and the first cycle of renegotiations for the Medicare Drug Price Negotiation Program ("Negotiation Program"), which will occur during 2026 and may result in negotiated Maximum Fair Prices (MFPs) that would be effective beginning in 2028. In accordance with the Inflation Reduction Act of 2022 (IRA), CMS will select up to 15 additional negotiation-eligible drugs covered under Part D and/or payable under Part B for this third cycle of negotiations. CMS may also select drugs negotiated in the first or second cycles of negotiation to be renegotiated, if those selected drugs meet certain eligibility and selection criteria. This final guidance also includes additional clarifications and policies regarding how participating manufacturers will make any agreed upon negotiated MFPs available in 2026, 2027, and 2028.

This fact sheet outlines key policies in the final guidance, including key changes from **draft guidance**, which was released on May 12 and was open for a 45-day public comment period that closed on June 26, 2025.

Overview of Policies for the Third Cycle of Negotiations:

CMS has built upon policies established for the first two cycles of negotiations and outlines new requirements for the third cycle of negotiations with a particular focus on increasing transparency in the Negotiation Program. New for initial price applicability year 2028, in accordance with the law, this final guidance addresses how drugs or biological products payable under Part B will be eligible for negotiation as well as the requirements and process for renegotiation.

Introduction of Part B Drugs:

Starting for initial price applicability year 2028, the IRA adds drugs or biological products payable under Part B to the Negotiation Program. Consistent with the IRA, CMS incorporates a process of identifying and selecting negotiation-eligible drugs or biological products that are payable under Part B, as well as the process steps for ceiling calculations and application of the MFP for such products. Additionally, CMS expands the Small Biotech Exception ("SBE") policy to address drugs or biological products payable under Part B. CMS will address manufacturer effectuation of the MFP for selected drugs or biological products payable under Part B in future policymaking.

Renegotiation:

Beginning with initial price applicability year 2028, the IRA directs CMS to choose certain drugs for renegotiation from among selected drugs that were negotiated for initial price applicability years 2026 or 2027. This final guidance establishes the requirements to identify renegotiation-eligible drugs and to select drugs for renegotiation in accordance with statutory requirements. CMS will apply the statutory criteria[1] to identify renegotiation eligible drugs to include drugs with a new indication, drugs with a material change to a negotiation factor, and drugs that change monopoly status. In conjunction with release of this final guidance, CMS issued a streamlined, voluntary data collection from Primary Manufacturers of initial price applicability years 2026 and 2027 selected drugs to inform renegotiation eligibility and selection for a 30-day comment period.

[1] See section 1194(f)(2) of the Social Security Act.

All drugs that are eligible for renegotiation due to a change in monopoly status will be selected for renegotiation. Among the remaining renegotiation-eligible drugs, CMS will select those with a new indication or material change that is likely to result in a significant change to the MFP. CMS will determine whether renegotiation is likely to result in a significant change to the MFP if the renegotiated MFP is likely to represent at least a 15 percent change to the current MFP and that the renegotiated MFP is likely to impact the Medicare program. CMS' review of these two criteria will be a holistic inquiry based on the totality of the information available and the circumstances of the renegotiation-eligible drug.

Finally, this final guidance establishes the process steps that CMS will follow to conduct a renegotiation for drugs that are selected.

Summary of other topics in the final guidance include, but are not limited to:

- **Statutory Exclusions from Drug Selection:** Various requirements related to the SBE and Biosimilar Delay, including SBE requests for drugs or biological products payable under Part B, requests for a second year of Biosimilar Delay, and rebates owed when a biosimilar biological product (a "Biosimilar") does not enter the market as expected. In conjunction with release of this final guidance, CMS issued a data collection for a 30-day comment period for the SBE and Biosimilar Delay.
- **MFP Effectuation:** CMS provided further detail on the information CMS will use when determining whether the MFP was made available by Primary Manufacturers to specific dispensing entities.
- **Medicare Transaction Facilitator Data Module (MTF DM):** Requirements and parameters for exchange of data among dispensing entities and participating manufacturers, via a Medicare Transaction Facilitator, to provide claim-level data elements to Primary Manufacturers where a selected drug was dispensed to a verified MFP-eligible individual to facilitate access to MFPs of selected drugs for dispensing entities.
- **Initial Offer Development:** Approach for considering (1) the manufacturer-reported data elements and (2) evidence about alternative treatments in developing an initial offer to participating manufacturers.
- **Part D Formulary Inclusion of Selected Drugs:** Policies related to the 2027 and 2028 implementation of the successor regulation providing an exception to the Part D formulary inclusion of selected drugs requirement.

Summary of Key Changes in the Final Guidance:

CMS is approaching implementation of the Negotiation Program consistent with the goals of achieving greater value for beneficiaries and taxpayers and continuing to foster innovation.

CMS requested comments on all elements of the draft guidance (except for the section pertaining to the administration of the excise tax). CMS revised policies in the draft guidance that are reflected in the final guidance, including, but not limited to:

- **Fixed Combination Drugs:** CMS is not making a change to the fixed combination drug policy in this final guidance. However, CMS describes its intent to address this program's integrity risk and that it is continuing to consider the appropriate policy to implement in rulemaking beginning initial price applicability year 2029.
- **Treatment of Vaccines for Infectious Diseases:** CMS clarified that, for vaccines for infectious diseases, it will identify a potential qualifying single source drug as all dosage forms and strengths of the vaccine with the same antigen component(s) and the same holder of the BLA, inclusive of products that are marketed pursuant to different BLAs. CMS specified that for each unique potential qualifying single source drug that CMS identifies based on its antigen component(s), CMS will use the earliest date of approval for any BLA or supplemental BLA associated with the potential qualifying single source drug for purposes of determining the time eligibility.
- **Orphan Drug Exclusion:** CMS expanded the Orphan Drug Exclusion in accordance with amendments to the Orphan Drug Exclusion enacted in the "Working Families Tax Cuts Act" (P.L. 119-21).

- **Identification of Negotiation-Eligible Drugs:** CMS described how Medicare Advantage (MA) expenditures will be used to calculate Total Expenditures for drugs and biological products payable under Part B.
- **Negotiation Meetings:** CMS revised the timing for negotiation meetings and the procedures for the meetings, including the meeting materials and agenda.
- **Issuance of the Final Offer:** CMS revised the deadline by which it will provide the final offer to Primary Manufacturers for initial price applicability year 2028.
- **Monitoring of Access to the MFP in 2026, 2027, and 2028:** CMS further clarified that when assessing whether a Primary Manufacturer provided access to the MFP to a dispensing entity with respect to a selected drug, absent information available to CMS indicating otherwise, CMS will consider wholesale acquisition cost (WAC) to be an appropriate proxy for a dispensing entity's acquisition cost. CMS also provided additional detail on the information CMS will consider when engaged in case-specific determinations as to whether a Primary Manufacturer met its statutory obligation to make the MFP available to a specific dispensing entity.
- **Centralized Intake System for Complaints and Disputes:** CMS provided additional information on the initial threshold review, triage, and outreach that it will complete when an issue is received via the centralized intake system for complaints and disputes.

Additional Resources

- **Revised Drug Selection Information Collection Request – https://www.federalregister.gov/public-inspection/2025-18979/agency-information-collection-activities-proposals-submissions-and-approvals**
- **Public Comments: Medicare Drug Price Negotiation Program Draft Guidance – https://www.cms.gov/files/document/public-comments-ipay-2028-draft-guidance.pdf**
- **Medicare Drug Price Negotiation Program – https://www.cms.gov/priorities/medicare-prescription-drug-affordability/overview/medicare-drug-price-negotiation-program**

Q: What are the key dates for the Negotiation Program for initial price applicability year 2028?

September 30, 2025 — CMS issued final guidance to implement the Negotiation Program for initial price applicability year 2028, including renegotiation and manufacturer effectuation of the MFP in 2026, 2027, and 2028. CMS also issued a revised information collection request on the data and information the federal government will collect to inform drug selection that will be open for public input for 30 days.

Late Fall 2025 — CMS will issue a revised information collection request on the data and information the federal government will consider when negotiating and renegotiating MFPs that will be open for public input for 30 days.

Mid-December 2025 — Deadline for manufacturers to submit a request for a drug to qualify for the SBE or the Biosimilar Delay. Deadline for manufacturers to voluntarily submit information to inform renegotiation eligibility and selection.

February 1, 2026 — Deadline for CMS to publish the list of up to 15 drugs selected for negotiation for initial price applicability year 2028 and any additional drugs selected for renegotiation, if applicable. CMS will also release the list of the up to 50 top negotiation-eligible drugs based on combined Total Expenditures under Part B and Part D from which the drugs selected for negotiation in initial price applicability year 2028 were chosen.

February 28, 2026 — Deadline for participating Primary Manufacturers for initial price applicability year 2028 to sign agreements to participate in the Negotiation Program, whether for negotiation or renegotiation, as applicable.

March 1, 2026 — Deadline for manufacturers of the drugs selected for the Negotiation Program for initial price applicability year 2028 that have signed an agreement to participate in the Negotiation Program to submit manufacturer-specific data to CMS for consideration in the negotiation or renegotiation of a maximum fair price. In addition, this is the deadline for the public to submit data on therapeutic alternatives to the selected drugs, data related to unmet medical need, and data on impacts to specific populations, among other considerations.

Spring 2026 — CMS intends to provide additional public engagement opportunities. These engagement sessions will be open to the public, including patients, beneficiaries, caregivers, patient/consumer advocacy organizations, and other interested parties to participate. Additional information about these public engagement sessions will be shared in the future.

Spring 2026 — CMS intends to provide an additional engagement opportunity for participating Primary Manufacturers of selected drugs to meet with CMS to discuss their data submission.

June 1, 2026 — Deadline for CMS to send an initial offer of a maximum fair price for a selected drug with a concise justification to each manufacturer participating in the Negotiation Program.

July 1, 2026 — Deadline for participating manufacturers of selected drugs to accept the initial offer of a maximum fair price or propose a counteroffer, if desired (if the initial offer is sent on June 1, 2026). Manufacturers have 30 days from receiving CMS' initial offer to respond.

Summer 2026 — CMS will respond to counteroffers from participating manufacturers 30 days after receipt of a counteroffer or within 60 days of sharing the initial offer, whichever is later. CMS and participating manufacturers may engage in negotiation meetings during the negotiation period. CMS and participating manufacturers may reach an agreement during the negotiation meeting process or may exchange additional written offers or counteroffers, as described in the final guidance, during the negotiation period.

September 30, 2026 — Deadline by which CMS will issue its final offer.

October 31, 2026 — Deadline for participating manufacturers to accept or reject final maximum fair price offer from CMS.

November 1, 2026 — The negotiation period ends.

November 30, 2026 — Deadline for CMS to publish any negotiated or renegotiated maximum fair prices resulting from the initial price applicability year 2028 negotiation or renegotiation process.

March 1, 2027 — Deadline for CMS to publish an explanation of any maximum fair prices resulting from the initial price applicability year 2028 negotiation or renegotiation process. In the interest of balancing transparency and confidentiality, as part of the public explanation of an agreed-upon maximum fair price, CMS will publish a narrative explanation of the negotiation process and certain additional information. Any information submitted by participating manufacturers during the negotiation process that constitutes confidential commercial or financial information of the Primary Manufacturer or a Secondary Manufacturer (as defined in CMS guidance) will be considered proprietary and will be redacted.

January 1, 2028 — Maximum fair prices negotiated or renegotiated for selected drugs become effective.