

Fact Sheet: Medicare Drug Price Negotiation Program Draft Guidance for Initial Price Applicability Year 2028 and Manufacturer Effectuation of the Maximum Fair Price in 2026, 2027, and 2028



The Centers for Medicare & Medicaid Services (CMS) issued **draft guidance** that details requirements and parameters for the third cycle of negotiations and the first cycle of renegotiations for the Medicare Drug Price Negotiation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, which will occur during 2026 and may result in negotiated maximum fair prices (MFPs) that would become effective in 2028. In accordance with the Inflation Reduction Act (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 drugs meet certain renegotiation eligibility and selection criteria. This draft guidance also includes additional clarifications and policies regarding how participating manufacturers will make any agreed upon negotiated MFPs available in 2026, 2027, and 2028 for drugs covered under Part D.

Overview of Policies for the Third Cycle of Negotiations

CMS continues to build on 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 New for initial price applicability year 2028, this draft guidance addresses the selection and negotiation of drugs payable under Part B as well as the potential requirements and process for renegotiation for drugs previously negotiated for initial price applicability years 2026 and 2027.

Introduction of Part B Drugs

Starting with the initial price applicability year 2028, the IRA adds to the Negotiation Program drugs that are payable under Part B. In this draft guidance, CMS is incorporating a potential process to identify eligible drugs and a potential process for ceiling calculations and applying the MFP for such drugs. Consistent with the IRA, CMS is expanding the small biotech exception policy to address drugs payable under Part B. CMS will address manufacturer effectuation of the MFP for selected drugs payable under Part B in the future and is soliciting comments on specific topics for consideration.

Renegotiation

For initial price applicability year 2028, the IRA directs CMS to choose for renegotiation certain drugs that were negotiated for initial price applicability years 2026 or 2027. This draft guidance establishes the potential requirements to identify renegotiation-eligible drugs in accordance with statutory requirements. CMS will apply the statutory criteria¹ to identify renegotiation eligible drugs, including those with new indications, material changes to negotiation factors, and changes in monopoly status. In conjunction with releasing this draft guidance, CMS is proposing a new, voluntary data collection for some drug manufacturers that were chosen for initial price applicability years 2026 and 2027. This will inform renegotiation eligibility and selection.

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 conduct a holistic inquiry of available information and circumstances of the renegotiation-eligible drug to consider the likelihood that, upon renegotiating with participating manufacturers, the renegotiated MFP would represent a 15 percent or greater change relative to the current MFP and whether the change in MFP is likely to have a significant impact on the Medicare program.

Finally, this draft guidance establishes the potential process that CMS will follow to renegotiate selected drugs.

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

Other topics in the draft guidance include, but are not limited to:

- **Statutory Exclusions from Drug Selection:** Various draft requirements related to the Biosimilar Delay and Small Biotech Exception (SBE), including requests for a second year of Biosimilar Delay, rebates owed when a biosimilar does not enter the market as expected, and SBE requests for drugs payable under Part B.
- **MFP Effectuation for Drugs Covered Under Part D:** Draft requirements that participating manufacturers must meet in making the MFP available to dispensing entities, including updating factors that CMS will consider in assessing MFP availability.
- **Medicare Transaction Facilitator Data Module (MTF DM):** Draft 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 covered under Part D was dispensed to a verified MFP-eligible individual to facilitate access to MFPs of selected drugs for dispensing entities.
- **Initial Offer Development:** Draft approach for considering the manufacturer-reported data elements and evidence about alternative treatments when developing an initial offer to participating manufacturers.
- **Part D Formulary Inclusion of Selected Drugs:** Draft policies related to statutory requirements regarding the Part D formulary inclusion of selected drugs, including the 2027 and 2028 implementation of the statutory successor regulation providing an exception to this requirement.

Opportunities for Stakeholders to Provide Specific Ideas to Improve the Negotiation Program:

CMS is implementing the Medicare Drug Price Negotiation Program consistent with the goals of achieving greater value to beneficiaries and taxpayers while continuing to foster innovation.

This draft guidance is open for a 45-day public comment period that closes on June 26, 2025 at 11:59 PM PT. CMS is requesting comments on the draft guidance, specifically seeking feedback on topics such as:

Increased Transparency in the Negotiation Process:

- Data sources used to make determinations on bona fide marketing.
- Potential approaches to calculate the MFP for selected drugs that are not paid based on average sales price (ASP) or wholesale acquisition cost (WAC).
- Alternative approaches to determine the starting point for initial offer development.
- Whether CMS should put greater emphasis on certain clinical evidentiary factors when adjusting the starting point to determine the preliminary price or on certain manufacturer-submitted data when adjusting the preliminary price.

Considerations for Burden Reduction:

- Whether applying the negotiation process to renegotiation is practicable and whether there are specific changes that should be made.
- Potential revisions to definitions that would further streamline the submitted information required by Primary Manufacturers across the selected drugs.

Considerations for MFP Effectuation and the MTF:

- Consideration for future modifications to manufacturer effectuation of MFP refund payments and the framework of the MTF flow of data (MTF DM) and payment (MTF PM) to incorporate selected drugs payable under Part B.
- Considerations for data or policy clarifications to facilitate access to the MFP for individuals enrolled in Medicare Advantage plans.

Considerations for Manufacturer Oversight and Compliance:

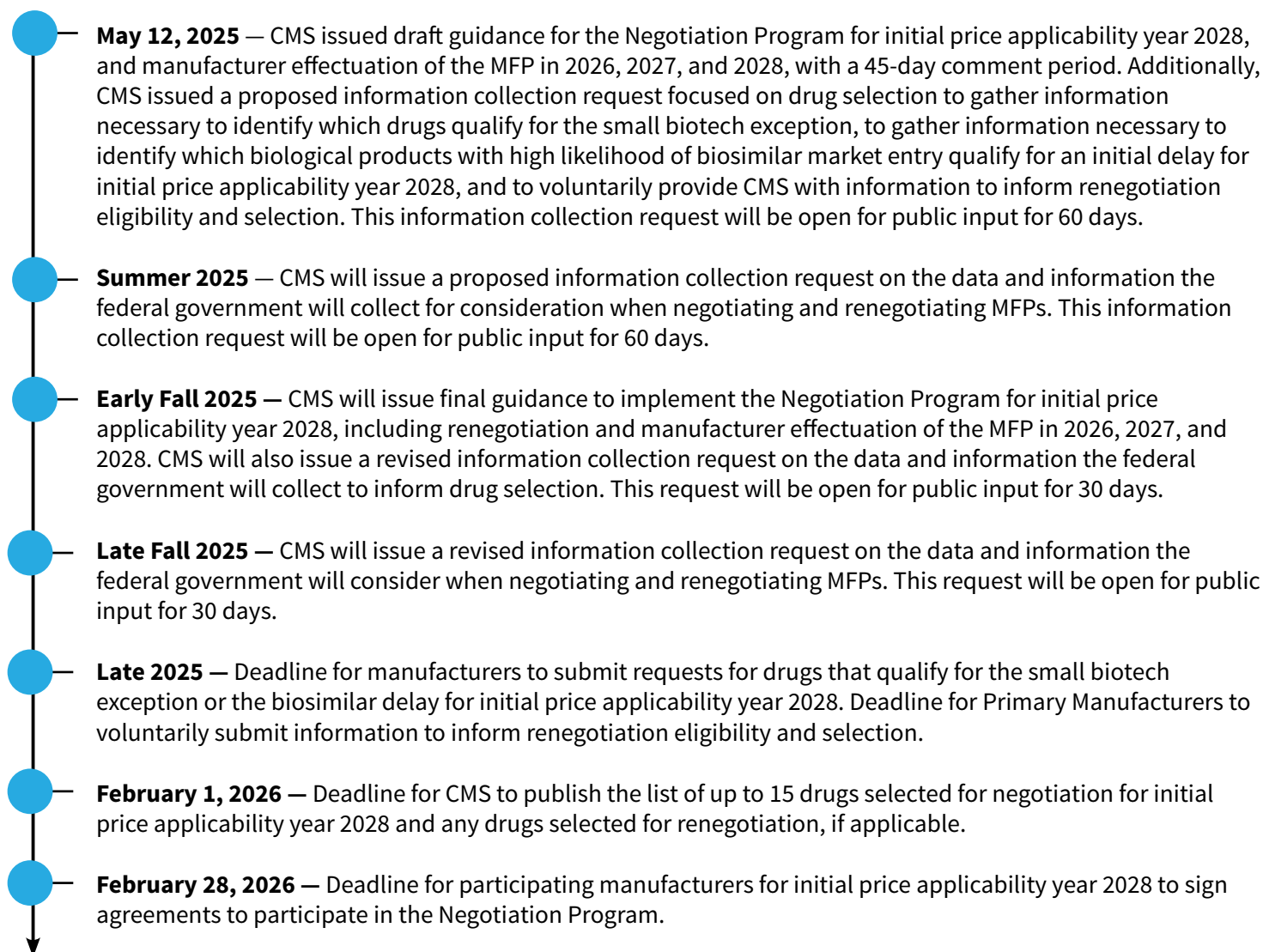
- Considerations and modifications to the described framework for manufacturer oversight and compliance, such as considerations for selected drugs payable under Part B, including changes to the MFP effectuation plans, disputes and complaint process, and required documentation when complaints are filed.

More information on how to submit comments can be found in the draft guidance. Comments received by Thursday, June 26 at 11:59 PM PT, will be considered for final guidance. CMS anticipates issuing final guidance for initial price applicability year 2028 and manufacturer effectuation of the MFP in 2026, 2027, and 2028 in Fall 2025.

Additional Resources

- Negotiation Program Drug Selection Information Collection Request for Initial Price Applicability Year 2028 (CMS-10844, OMB 0938-1443) — <https://public-inspection.federalregister.gov/2025-08423.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?



- March 1, 2026** — Deadline for manufacturers of the drugs selected participating in the Negotiation Program for initial price applicability year 2028 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. Specifically, CMS intends to host up to 15 patient-focused roundtable events and one town hall meeting for all selected drugs, focused on the clinical considerations related to the selected drugs. 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 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. 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 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.
- 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 process.
- January 1, 2027** — Any agreed-upon maximum fair prices negotiated for selected drugs from the second cycle of negotiations become effective.
- March 1, 2027** — Deadline for CMS to publish an explanation of any maximum fair prices resulting from the initial price applicability year 2028 negotiation 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 will be considered proprietary and will be redacted.
- January 1, 2028** — Any agreed-upon maximum fair prices negotiated or renegotiated for selected drugs from the third cycle of negotiations become effective.