

Fact Sheet: Medicare Drug Price Negotiation Program Draft Guidance for 2027 and Manufacturer Effectuation of the Maximum Fair Price in 2026 and 2027



In August 2022, President Biden enacted the prescription drug law called the Inflation Reduction Act of 2022 (IRA) (P.L. 117-169). The law makes improvements to Medicare that expand benefits, lower drug costs, and improve the sustainability of the Medicare program both now and in the long term. The law provides Medicare with the ability to directly negotiate the prices of certain high expenditure, single source drugs that do not have generic or biosimilar competition.

In June 2023, the Centers for Medicare & Medicaid Services (CMS) issued [revised guidance](#) detailing the requirements and parameters of the [Medicare Drug Price Negotiation Program](#) (Negotiation Program) for the first cycle of negotiations. Ten drugs were selected for the first cycle of negotiations, and the outcome of these negotiations may result in lower prices for Medicare that would be effective beginning in 2026. On May 3, 2024, CMS issued [draft guidance](#) that details requirements and parameters for the second cycle of negotiations for the Negotiation Program, which will occur during 2025 and may result in negotiated Maximum Fair Prices (MFPs) that would be effective beginning in 2027. In accordance with the law, CMS will select up to 15 additional drugs covered under Part D for this second cycle of negotiations. This draft guidance also includes additional policies regarding how participating drug companies will make any agreed upon negotiated MFPs available in 2026 and 2027.

Q: What is the Medicare Drug Price Negotiation Program?

The prescription drug law allows Medicare to directly negotiate with participating manufacturers the prices for certain high expenditure, single source Medicare drugs covered under Part B or Part D, meaning only those drugs for which there is no generic or biosimilar competition. These drugs are some of the costliest for Medicare and for patients. Medicare's new ability to negotiate prices for covered drugs will improve drug affordability for people with Medicare and lower costs for the Medicare program, improving access to innovative, life-saving treatments for people that need them.

Last year, CMS selected for negotiation 10 drugs covered under Medicare Part D and is currently in negotiations with the drug companies that make those drugs. Any negotiated prices, called MFPs, will be announced later this year and take effect beginning in 2026. In 2025, CMS will select for negotiation up to an additional 15 drugs covered under Part D with any negotiated prices effective in 2027. In the third cycle, CMS will select up to an additional 15 drugs (including drugs covered under Part B) with any negotiated prices effective in 2028, and then up to an additional 20 drugs for 2029 and subsequent years.

Q: What's new in this draft guidance for the Negotiation Program?

This new [draft guidance](#) builds on the [previous revised guidance](#) published last year, which implemented policies for the first cycle of negotiations. This draft guidance outlines new requirements for the second cycle of negotiations, which begins in 2025 and will result in MFPs effective for 2027. This draft guidance also includes additional policies regarding how participating drug companies will make any agreed upon negotiated prices available in 2026 and 2027. Topics covered in the draft guidance include, but are not limited to:

- Approach for considering (1) the manufacturer-reported data elements and (2) evidence about alternative treatments in developing an initial offer to participating drug companies.
- Plans for CMS to receive patient-focused information on selected drugs for consideration in its initial offer development.
- Process and format for the offer and counteroffer exchange between CMS and drug companies.
- Requirements and parameters for exchange of data among dispensing entities (e.g., pharmacies) and participating drug companies, via a Medicare Transaction Facilitator (MTF), to provide data needed to facilitate access to MFPs of selected drugs for dispensing entities and to provide claim-level data elements to Primary Manufacturers

where a selected drug was dispensed to a person who was verified to be MFP-eligible.

- Solicitation of comment on options for the Medicare Transaction Facilitator (MTF) to provide a voluntary payment facilitation functionality for participating drug companies and dispensing entities to help support access to the MFP.
- Requirements participating drug companies must meet in making the MFP available to MFP-eligible individuals and dispensing entities.

Revisions in the draft guidance build on lessons learned from implementing the Negotiation Program to date, and CMS welcomes comments on these policies.

Q: How can the public provide input on the Medicare Drug Price Negotiation Program and the drugs selected for negotiation?

CMS is approaching implementation of the prescription drug law with the goal of promoting transparency and engagement. CMS is using many tools to ensure interested parties' voices are heard on implementation of the prescription drug law. Public feedback will contribute to the success of the Negotiation Program.

This draft guidance is open for a 60-day public comment period, which has been extended based on feedback CMS received from interested parties in response to the 30-day comment period provided for the revised guidance for initial price applicability year 2026. CMS is requesting comment on all elements of the draft guidance (except for the section pertaining to the administration of the excise tax) and is specifically seeking feedback on topics such as:

- The date by which CMS will inform a Biosimilar Manufacturer if the biosimilar named in a successful Initial Delay Request is licensed and marketed during the initial delay period, as well as the types of documentation and information that may constitute "clear and convincing evidence, the manufacturer of [a] biosimilar biological product has made a significant amount of progress" towards both licensure and marketing of such biosimilar to inform CMS' future policy development regarding Additional Delay Requests.
- The format, scope, and logistics of patient-focused events to improve upon the design of the patient-focused listening sessions from initial price applicability year 2026.

- The approach to facilitating negotiation within the statutory deadlines, including whether three negotiation meetings are necessary and whether it would be preferable to contemplate an additional written offer to be made in lieu of one or more meetings.
- The claims-level data elements to be transmitted by the Medicare Transaction Facilitator (MTF) to help manufacturers and dispensing entities effectuate the MFP.
- Options for structuring Medicare Transaction Facilitator payment facilitation functionality to support voluntary payment facilitation from participating manufacturers to participating dispensing entities to help effectuate access to the MFP for MFP-eligible individuals.
- Potential revisions to definitions that would further standardize and improve the consistency of submitted information across the selected drugs, facilitate CMS' interpretation of the submitted information, and reduce the reporting burden on Primary Manufacturers.

More information on how to submit comments can be found in the draft guidance. Comments received by 11:59 PT on July 2, 2024, will be considered for final guidance. CMS anticipates issuing final guidance for initial price applicability year 2027 and for manufacturer effectuation of the MFP in 2026 and 2027 in fall 2024.

Q: How will CMS support drug companies in making the MFP available to dispensing entities?

Any MFP-eligible individual will not pay more than the MFP for the selected drug at the pharmacy counter or when purchasing from another dispensing entity. The participating manufacturer of a selected drug is required to ensure the MFP is made available to those eligible individuals and to the pharmacies, mail order services, and other entities that dispense the selected drugs to such individuals. As described in the draft guidance, CMS will engage a Medicare Transaction Facilitator (MTF) to facilitate the exchange of data between dispensing entities, and drug companies regarding claims information for selected drugs dispensed to individuals verified to be MFP-eligible. In the draft guidance, CMS is soliciting comments on options that would support interested parties through a voluntary payment functionality to help facilitate retrospective MFP refund payments, from a participating manufacturer to

a participating pharmacy, mail order service, or other dispensing entity, to help effectuate access to the MFP for MFP-eligible individuals.

Q: What are the key dates for the Negotiation Program for initial price applicability year 2027?

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- May 3, 2024** — CMS issued draft guidance for the Negotiation Program for initial price applicability year 2027, and manufacturer effectuation of the MFP in 2026 and 2027, with a 60-day comment period. Additionally, CMS issued a revised information collection request to gather information necessary to identify which drugs qualify for the small biotech exception and which biologics with high likelihood of biosimilar market entry qualify for an initial delay for 2027. This information collection request will be open for public input for 60 days.
 - Summer 2024** — CMS will issue a revised information collection on the data and information the federal government will collect for consideration when negotiating MFPs, as well as the data and information to be submitted in the offer and counteroffer process. This information collection request will be open for public input for 60 days.
 - Fall 2024** — CMS will issue final guidance to implement the Negotiation Program for initial price applicability year 2027 as well as on manufacturer effectuation of the MFP in 2026 and 2027. Additionally, CMS will issue the two revised information collections on (1) information necessary to identify which drugs qualify for the small biotech exception and which biologics with high likelihood of biosimilar market entry qualify for an initial delay for 2027 and (2) data and information to be submitted in the negotiation process. These information requests will be open for public input for 30 days.
 - Mid-December 2024** — Deadline for drug companies to submit a request for a drug to qualify for the small biotech exception and biosimilar delay.
 - February 1, 2025** — Deadline for CMS to publish the list of up to 15 drugs covered by Part D selected for negotiation for initial price applicability year 2027.
 - February 28, 2025** — Deadline for participating drug companies for initial price applicability year 2027 to sign agreements to participate in the Negotiation Program.
 - March 1, 2025** — Deadline for drug companies that manufacture the drugs selected for the Negotiation Program for 2027 and that have signed an agreement to participate in the Negotiation Program to submit manufacturer-specific data to CMS for consideration in the negotiation 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 2025** — 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 2025** — CMS intends to provide an additional engagement opportunity for participating drug companies that manufacture selected drugs to meet with CMS to discuss their data submission.
 - June 1, 2025** — Deadline for CMS to send an initial offer of a maximum fair price for a selected drug with a concise justification to each drug company participating in the Negotiation Program.
 - July 1, 2025** — Deadline for participating drug companies that manufacture selected drugs to accept the initial offer of a maximum fair price or propose a counteroffer, if desired. Drug companies have 30 days from receiving CMS' initial offer to respond.

-  **Summer 2025** — CMS will respond to counteroffers from participating drug companies 30 days after receipt of a counteroffer or within 60 days of sharing the initial offer, whichever is later. CMS and participating drug companies may engage in negotiation meetings during the negotiation period.
-  **October 31, 2025** — Deadline for participating drug companies to accept or reject final maximum fair price offer from CMS.
-  **November 1, 2025** — The negotiation period will end.
-  **November 30, 2025** — Deadline for CMS to publish any negotiated maximum fair prices resulting from the initial price applicability year 2027 negotiation process.
-  **March 1, 2026** — Deadline for CMS to publish an explanation of any maximum fair prices resulting from the initial price applicability year 2027 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 drug companies during the negotiation process that constitutes confidential commercial or financial information will be considered proprietary and will be redacted.
-  **January 1, 2027** — Maximum fair prices negotiated for selected drugs become effective.