Fact Sheet: Medicare Drug Price Negotiation Program Final Guidance for 2027 and Manufacturer Effectuation of the MFP in 2026 and 2027

MEDICARE DRUG PRICE NEGOTIATION PROGRAM
CENTERS FOR MEDICARE & MEDICAID SERVICES

In August 2022, President Biden signed 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 covered under Part D were selected for the first cycle of negotiations and now have negotiated prices,[1,2] which the statute refers to as maximum fair prices (MFPs), that will go into effect beginning January 1, 2026, based on negotiations and agreements reached between CMS and participating drug companies.

On October 2, 2024, CMS issued final 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 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 final guidance also includes additional policies regarding how participating drug companies will make any agreed-upon 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 drug companies 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 who need them.

With the negotiated prices, which are set to go into effect in 2026 for the first 10 selected drugs, people enrolled in Medicare prescription drug coverage would save, under the projected defined standard benefit design, an estimated $1.5 billion. These savings from the Negotiation Program are in addition to savings from other provisions in the IRA, such as the first ever cap on annual out-of-pocket drug costs for people with Medicare prescription drug coverage.

Q: What changed between the draft guidance and the final guidance for the second cycle of negotiations and MFP availability in 2026 and 2027?

The **draft guidance** published on May 3, 2024, sought public comments on nearly all aspects of the requirements and procedures for implementing the Negotiation Program for the second cycle of negotiations, which begins in 2025. Any MFPs that are agreed upon during this second cycle of negotiations will be effective in 2027. The draft guidance also sought public comment on additional policies regarding how participating drug companies will make any agreed-upon negotiated prices available in 2026 and 2027. This final guidance, published on October 2, 2024, builds on the draft guidance and responds to public comments submitted during the 60-day comment period. Changes reflected in the final guidance include, but are not limited to:

- Announced CMS will host up to 15 patient-focused roundtable events and a town hall meeting to receive patient-focused and clinically-oriented information on selected drugs for consideration in its initial offer development.

[1] https://www.cms.gov/files/document/fact-sheet-negotiated-prices-initial-price-applicability-year-2026.pdf
[2] https://www.cms.gov/files/zip/file-negotiated-prices-also-known-maximum-fair-prices-statute.zip

- Revised the timing of negotiation meetings between CMS and participating drug companies, so that the first optional negotiation meeting will occur after the initial offer is issued and before the statutory due date for participating drug companies that elect to submit statutory written counteroffers. If CMS rejects a participating drug company's statutory written counteroffer, CMS will offer up to two more optional negotiation meetings.
- Announced additional price exchange opportunities between CMS and participating drug companies that can occur during the period between CMS' rejection of the Primary Manufacturer's statutory written counteroffer, if applicable, and one week before final offers are due to be sent by CMS.
- Provided requirements and parameters for exchange of data among dispensing entities (e.g., pharmacies), participating drug companies, and CMS via the Medicare Transaction Facilitator Data Module (MTF DM), to provide data needed to facilitate access to MFPs of selected drugs for dispensing entities, to provide claim-level data elements to participating drug companies where a selected drug was dispensed to a person who was verified to be MFP-eligible, and to generate an Electronic Remittance Advice that uses the X12 835 standard adopted under HIPAA (ERA) or a remittance for paper checks, as applicable, for MFP refund payments passed through the MTF Payment Module (PM) by drug companies that participate in the MTF PM.
- Established a voluntary payment facilitation functionality through the MTF PM for participating drug companies to help support access to the MFP by passing payment from the Primary Manufacturer through the MTF PM to the dispensing entity, and by establishing a credit/debit ledger system to track changes in MFP refund payment for adjustment claims and other claim revisions for MFP refund payments passed through the MTF PM.
- Clarified requirements and parameters for drug companies based on when they elect to pass payment through the MTF PM and when they do not.
- Outlined requirements and parameters for payments passed to the dispensing entity outside of the MTF PM by drug companies, including details on reporting requirements that drug companies must provide when reporting on payments made outside of the MTF PM and requirements for MFP effectuation plans that drug companies must provide to CMS outlining how they will make the MFP available to dispensing entities, such as pharmacies, outside of the MTF PM.
- Established that in its MFP effectuation plan, a Primary Manufacturer must include a process for mitigating material cashflow concerns for dispensing entities as a result of potential delays created by reliance on retrospective MFP refunds within the 14-day prompt MFP payment window.
- Established a process for pharmacies, such as sole proprietor rural or urban pharmacies with high volume of Medicare Part D prescriptions dispensed, pharmacies that predominantly rely on prescription revenue to maintain business operations, long term care pharmacies, 340B entities with in-house pharmacies, or I/T/U pharmacies, to self-identify if they anticipate material cashflow concerns at the start of the initial price applicability year due to reliance on the retrospective MFP refunds within the 14-day prompt MFP payment window. CMS would then provide this information to participating drug companies to inform development of their MFP effectuation plans.
- Revised aspects of the complaint and dispute processes related to MFP effectuation.

The final guidance builds on applied experience and lessons learned from implementing the Negotiation Program to date.

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.

One such tool was the 60-day comment period for the draft guidance, which concluded July 2, 2024. CMS received 145 timely comment letters in response to the draft guidance, representing a wide range of views from academic experts and thought leaders, consumer and patient organizations, data vendors/software technology entities, health plans, health care providers, health systems, individuals, pharmaceutical and biotechnology manufacturers, pharmacies, pharmacy benefit managers (PBMs), trade associations, and wholesalers. CMS is making public copies of the timely comment letters that CMS received on the IRA website at **https://www.cms.gov/inflation-reduction-act-and-medicare/medicare-drug-price-negotiation** at the same time CMS publishes this final guidance.

In the final guidance, CMS outlined additional opportunities for engagement during the negotiation process. These include meetings with participating drug companies of selected drugs in Spring 2025 as well as patient-focused and clinical-focused public engagement events for the selected drugs. CMS will host up to 15 patient-focused roundtable events that will aggregate selected drugs by condition when appropriate and will be open to patients, patient advocacy organizations, and caregivers. These events are intended to share patient-focused input on topics such as patient experience, therapeutic alternative(s) to the selected drugs, the extent to which the selected drugs address unmet medical need, and the impact of selected drugs on specific populations. CMS will also host one town hall meeting focused on clinical considerations related to the selected drugs. CMS encourages practicing clinicians, researchers, and other interested parties to register to participate in the town hall meeting.

Separately, the public is also invited to submit data by March 1, 2025, on topics such as patient experiences with the conditions or diseases treated by the selected drugs, as well as experiences taking the selected drugs and therapeutic alternatives to the selected drugs, prescribing information for the selected drugs and therapeutic alternatives, comparative effectiveness data for the selected drugs and therapeutic alternatives, and/or information on the extent to which the selected drugs address unmet medical need. Additional information about these patient-focused and clinical-focused public engagement events and how to submit data on selected drugs will be shared in the future.

Q: Will CMS change the negotiation process with participating drug companies for the second year of negotiations?

The negotiation process will adhere to statutory requirements set forth by the IRA and remain similar to the process used in the first cycle of negotiations, with a few changes made based on CMS' experience and learnings, including those from public feedback. For the second cycle of negotiations, the first optional negotiation meeting between CMS and a participating drug company will occur after the initial offer is issued and before the statutory due date for participating drug companies that elect to submit statutory written counteroffers. If CMS rejects the participating drug company's statutory written counteroffer, CMS will offer up to two more optional negotiation meetings. Additionally, CMS is offering additional price exchange opportunities in which CMS and participating drug companies can initiate additional written offers and counteroffers via the additional price exchange functionality in CMS Health Plan Management System (HPMS), if applicable, during the period between CMS' rejection of the participating drug company's statutory written counteroffer, if applicable, and one week before final offers are due. CMS believes these revisions to the negotiation process provide further opportunities for productive exchanges between CMS and participating drug companies throughout the negotiation period.

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

MFP-eligible individuals will not pay more than the MFP for the selected drug at the pharmacy counter or when purchasing from another dispensing entity. The participating Primary 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 final guidance, CMS will engage a Medicare Transaction Facilitator (MTF) contractor 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. Participation in the MTF DM will be mandatory for Primary Manufacturers. As part of future rulemaking, CMS intends to require plan sponsors to include in their pharmacy agreements provisions requiring dispensing entities to enroll in the MTF DM for purposes of data

exchange, which will include (1) providing bank account information and a secure location for making available the ERA or remittance; (2) maintaining the accuracy of that information over time; (3) maintaining the functionality necessary to receive ERAs or remittances, as applicable; and (4) self-identifying whether they are a dispensing entity that anticipates having material cashflow concerns due to reliance on the retrospective MFP refunds within the 14-day prompt MFP payment window. CMS intends to make this banking information available to Primary Manufacturers of selected drugs to support Primary Manufacturers when they transmit MFP refund payments to dispensing entities directly, including the dispensing entities' preference for receiving electronic transfer of funds or payment via paper check and delivery of ERAs or remittances (for paper checks) to dispensing entities for claim reconciliation purposes. In the final guidance, CMS also established that the MTF PM will be available to Primary Manufacturers to pass MFP refund payments through to dispensing entities to help effectuate access to the MFP. In response to concerns expressed by manufacturers related to the handling of claim adjustments or reversals, in the final guidance, CMS outlined the MTF's role in tracking Part D claims for selected drugs that are reversed or adjusted when the Primary Manufacturer participating in the MTF PM has transmitted MFP refund payment through the MTF PM, including instruction for how the Primary Manufacturer may use the credit/debit ledger system to identify and reconcile claims paid through the MTF PM and subsequently identified as a 340B claim. CMS intends that dispensing entities 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, however further technical specifications will be outlined in technical guidance. CMS will provide the list of dispensing entities self-identified as having material cashflow concerns to Primary Manufacturers to assist in the development of their MFP effectuation plans and require Primary Manufacturers to include their approach to mitigating material cashflow concerns in their MFP effectuation plans.

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

- **May 3, 2024** — CMS issued draft guidance for the Negotiation Program for initial price applicability year 2027, and manufacturer effectuation of the maximum fair price 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 was open for public input for 60 days.
- **July 2, 2024** — CMS issued a revised information collection request 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 was open for public input for 60 days.
- **October 2, 2024** — CMS issued final guidance to implement the Negotiation Program for initial price applicability year 2027 and for manufacturer effectuation of the MFP in 2026 and 2027. CMS also issued the Small Biotech Exception and Biosimilar Delay Information Collection Request for Initial Price Applicability Year 2027 for a 30-day comment period.
- **Late 2024** — CMS will issue a revised information collection request 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 statutory written counteroffer process. This information collection request will be open for public input for a 30-day comment period.
- **December 2024** — Anticipated 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 under 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 participating drug companies 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 selected drugs and their therapeutic alternatives, if any, data related to unmet medical need, and data on impacts to specific populations, among other considerations.
- **Spring 2025** — CMS will host additional patient-focused and clinical-focused public engagement sessions. CMS will host up to 15 patient-focused roundtable events that will aggregate selected drugs by condition when appropriate and will be open to patients, patient advocacy organizations, and caregivers, to share patient-focused input. CMS will also host one town hall meeting focused on clinical considerations related to the selected drugs. Additional information about these public engagement sessions will be shared in the future. CMS also will provide an optional opportunity for participating drug companies 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.
- **June 2025** — CMS will host up to one optional negotiation meeting with each participating drug company, which will occur after the initial offer is issued and before the response to the initial offer and the statutory written counteroffer, if applicable, is due.
- **July 1, 2025** — Deadline for participating drug companies to accept CMS' initial offer of a maximum fair price or propose a statutory written counteroffer, if desired. Drug companies have 30 days from receiving CMS' initial offer to respond.
- **Summer 2025** — CMS will respond to statutory written counteroffers from participating drug companies within 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 up to two optional negotiation meetings during the negotiation period as well as additional written price exchanges.
- **September 30, 2025** — Last day for negotiation meetings to take place.
- **October 8, 2025** — Last date by which CMS and participating drug company might exchange an additional written offer or counteroffer.
- **October 15, 2025** — Deadline for CMS to send final maximum fair price offer to participating drug companies, if agreement was not reached during the negotiation meetings or the additional price exchange process.
- **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 ends.
- **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** — Any agreed-upon maximum fair prices negotiated for selected drugs from the second cycle of negotiations become effective.