

Fact Sheet: Medicare Drug Price Negotiation Program Revised Guidance



CENTERS FOR MEDICARE & MEDICAID SERVICES

In August 2022, President Biden signed the Inflation Reduction Act (IRA) of 2022 (P.L. 117-169) into law. The new law makes improvements to Medicare that will expand benefits, lower drug costs, and improve the sustainability of the Medicare program for generations to come. The law provides meaningful financial relief for millions of people with Medicare by improving access to affordable treatments and strengthening Medicare, both now and in the long run.

For the first time, the law provides Medicare with the ability to directly negotiate the prices of certain high expenditure, single source drugs without generic or biosimilar competition. On March 15, 2023, the Centers for Medicare & Medicaid Services (CMS) issued initial guidance detailing the requirements and parameters of the Medicare Drug Price Negotiation Program, including requests for public comment on key elements. On June 30, 2023, CMS issued revised guidance detailing the requirements and parameters of the Medicare Drug Price Negotiation Program for the first round of negotiations, which will occur during 2023 and 2024 and result in prices that will be effective beginning in 2026.

Q: What is the Medicare Drug Price Negotiation Program?

The new drug law permits Medicare to negotiate the price of covered prescription drugs for the first time through the Medicare Drug Price Negotiation Program (or “Negotiation Program”). The law authorizes Medicare to directly negotiate drug 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. For the first year of the Negotiation Program, CMS will select up to 10 high expenditure, single source drugs for negotiation. For the drug companies of selected drugs that elect to participate in the Negotiation Program, the maximum fair prices that are negotiated will apply beginning in 2026. CMS will select up to an additional 15 drugs for negotiation for 2027, up to an additional 15 drugs (including drugs covered under Part B) for 2028, and up to an additional 20 drugs for 2029 and subsequent years.

Q: How will this new program improve Medicare?

Medicare will be able to negotiate directly with drug companies for the price of certain high expenditure drugs covered under Medicare Part D and eventually, Part B, that do not have generic or biosimilar competition. 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.

Q: How will people with Medicare benefit under the Negotiation Program?

Under the new law, Medicare will be able to negotiate directly with drug companies to lower the price of some of the costliest brand-name drugs covered under Medicare Part D and eventually Part B. CMS is committed to ensuring meaningful access to the selected drugs. As required by law, Medicare prescription drug plans, including standalone Part D plans and Medicare Advantage-prescription drug plans, must include on their formularies the selected drugs for which CMS and the drug company have agreed to a maximum fair price. CMS will use its comprehensive formulary review process for Medicare prescription drug plans to assess any practices that may undermine access to selected drugs for people with Medicare.

Q: What changed between the initial guidance and revised guidance for the Negotiation Program?

The initial program guidance published on March 15, 2023 sought public comment on aspects of the requirements and procedures for implementing the Negotiation Program for the first round of negotiations. On June 30, 2023, CMS published revised guidance with changes from the initial guidance to improve transparency and foster an effective negotiation process, such as:

- Clarifications of how CMS will identify selected drugs (e.g., CMS will only consider active designations and

approvals when evaluating a drug for the orphan drug exclusion);

- Revisions for and clarifications of the process applicable for participating drug companies of selected drugs (e.g., confidentiality policy revised to state that CMS will release information about the negotiation when the explanation of the maximum fair price is published and that drug companies may choose to publicly discuss the negotiation at their discretion);
- Clarifications of how CMS will consider the negotiation factors (e.g., clarified that CMS will review and consider certain cost-effectiveness measures to the extent permitted by statute for the first round of negotiation);
- Clarifications of how CMS will engage in compliance and oversight activities (e.g., CMS clarified that the agency intends to engage a Medicare Transaction Facilitator to facilitate the exchange of data between supply chain entities to verify eligibility of maximum fair price-eligible individuals);
- Clarifications regarding Part D formulary inclusion for selected drugs (e.g., clarified CMS will expect Medicare prescription drug plans to provide CMS with a reasonable justification to support the submitted plan design for non-preferred tier placement of a selected drug with a maximum fair price and will use its existing formulary review process to assess any instances where Part D plans place selected drugs on non-preferred tiers or apply utilization management); and
- Inclusion of additional opportunities for drug companies and members of the public to engage with CMS during the negotiation process on the selected drugs (e.g., through patient-focused listening sessions).

Topics that are not relevant to the Negotiation Program for 2026, such as renegotiation, are not addressed in the revised guidance issued for 2026, the first year that negotiated prices will apply. CMS will provide additional information in the future related to program guidance for 2027 and 2028.

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

Public feedback will contribute to the success of the Negotiation Program. CMS is using many tools to ensure interested parties' voices are heard on implementation of the new drug law.

One tool was the 30-day comment period for the initial guidance, which concluded April 14, 2023. CMS received more than 7,500 comment letters in response to the initial 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, labor unions, pharmaceutical and biotechnology manufacturers, pharmacies, pharmacy benefit managers (PBMs), providers, state governments, trade associations, venture capital firms, and wholesalers. CMS will make public copies of the timely comment letters that CMS received on the Inflation Reduction Act website at <https://www.cms.gov/inflation-reduction-act-and-medicare> in July 2023.

In the revised guidance, CMS outlined additional opportunities for engagement during the negotiation process. These include meetings with manufacturers of selected drugs in Fall 2023 as well as CMS-hosted patient-focused listening sessions for the selected drugs. The listening sessions will be open to the public, including patients, beneficiaries, caregivers, consumer and patient organizations, and other interested parties, to share patient-focused input on therapeutic alternative(s) to the selected drugs, how the selected drugs address unmet medical need, and the impact of selected drugs on specific populations. Separately, the public is also invited to submit data on therapeutic alternatives to the selected drugs, data related to unmet medical need, and data on impacts on specific populations by October 2, 2023.

Additional information about the listening sessions and how to submit data on selected drugs will be shared in the future.

Q: How is CMS structuring the negotiation process with the drug companies of selected drugs?

As discussed in detail in the revised guidance, CMS set out a process for the first round of negotiations that engages drug companies and the public throughout. CMS is approaching implementation of the new drug law with the goal of promoting transparency and engagement. The process includes several steps, such as:

- CMS will announce the list of selected drugs no later than September 1, 2023.
- Drug companies and the public will have an opportunity to submit data and information on the selected drugs to CMS no later than October 2, 2023.

- During the Fall 2023, CMS will invite each drug company with a selected drug to engage in a meeting on its data submission. CMS will also hold patient-focused listening sessions for the selected drugs.
- CMS will send an initial offer of a maximum fair price for each selected drug with a concise justification to participating drug company no later than February 1, 2024, and companies will have 30 days to respond to the initial offer by accepting the offer or providing a counteroffer, if desired. In developing an initial offer, CMS will start with evidence related to therapeutic alternatives and, then consider other factors, such as costs of research and development and production and distribution of the selected drug.
- During the Spring and Summer 2024, CMS will invite each participating drug company for up to 3 negotiation meetings during the negotiation period, which ends August 1, 2024.

Q: What is the confidentiality policy for the negotiation process

CMS revised the confidentiality policy for the negotiation process based on comments and further considerations. After consideration of the comments received, CMS has sought to appropriately balance transparency and confidentiality. As described in the revised guidance, CMS, as part of the public explanation of the maximum fair prices published in March 2025, will make public a narrative explanation of the negotiation process and the agreed-upon maximum fair price of a selected drug, as well as share additional non-proprietary information that was part of the negotiation process, including information submitted by other interested parties related to the selected drug and its therapeutic alternatives. A drug company with a selected drug may choose to publicly discuss the negotiation process. Generally, CMS plans to wait to release information about the negotiation process until CMS publishes the explanation of the maximum fair price of the selected drug. However, if a drug company chooses to disclose information prior to the publication of the explanation of the maximum fair price, then CMS may decide to make early disclosures about the negotiation process as well.

Q: What are the key dates for implementation of this new program for the first year of negotiation?

- **January 11, 2023** – CMS released a memo and timeline on how it will engage members of the public (including people with Medicare, consumer advocates, prescription drug companies, Medicare Advantage and Part D plans, health care providers and pharmacies, and other interested parties) on key policies, make requests for information, and inform the public on other implementation timelines and milestones.
- **January 24, 2023** – CMS issued its first data collection process essential to carrying out the first year of the Negotiation Program. The first information collection request included a data collection process to gather information necessary to identify which small biotech drugs qualify for the exception in the first year of the Negotiation Program. This information collection request was open for public input for 60 days.
- **March 15, 2023** – CMS issued initial guidance to implement the Medicare Drug Price Negotiation Program with a 30-day comment period on key elements.
- **March 21, 2023** – CMS issued its second data collection process, which asked for input on data and information the federal government will collect for consideration when negotiating the maximum fair prices, and invited public comments. This information collection request was open for public input for 60 days.
- **April 14, 2023** – The 30-day comment period on the initial guidance to implement the Medicare Drug Price Negotiation Program closed.
- **April 18, 2023** – CMS issued its third data collection process, which asked for input on data and information to be submitted in the offer and counteroffer process, and invited public comments. This information collection request was open for public input for 60 days.
- **April 24, 2023** – CMS issued its revised data collection process to gather information necessary to identify which small biotech drugs qualify for the exception in the first year of the Negotiation Program. This information collection request was open for public input for 30 days.

- **May 22, 2023** – Deadline for drug companies that manufacture certain biosimilars to submit an initial delay request under the Special Rule to delay the selection and negotiation of biologics for biosimilar market entry.
- **June 1, 2022 - May 31, 2023** – The time period for the data on total expenditures under Medicare Part D that will be used to determine negotiation-eligible drugs for initial price applicability year 2026 (the first year of negotiation).
- **June 30, 2023** – CMS issued its revised guidance for the Negotiation Program for initial price applicability year 2026 and issued the revised data collection process and invited public comments on the data and information the federal government will collect for consideration when negotiating the maximum fair prices. This information collection request is open for public input for 30 days.
- **July 3, 2023** – The deadline for drug companies to submit a request for a drug to qualify for the small biotech drug exception.
- **Summer 2023** – CMS will issue the revised data collection process and invite public comments on data and information to be submitted in the offer and counteroffer process. This information collection request will be open for public input for 30 days. In addition, CMS will publish the Manufacturer Agreement template.
- **September 1, 2023** – Deadline for CMS to publish the list of up to 10 drugs selected for negotiation for 2026.
- **October 1, 2023** – Deadline for participating drug companies that manufacture the drugs selected for the Negotiation Program for 2026 to sign agreements to participate in the Negotiation Program.
- **October 2, 2023** – Deadline for drug companies that manufacture the drugs selected for the Negotiation Program for 2026 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.
- **Fall 2023** – CMS will provide additional engagement opportunities through patient-focused listening sessions. These listening 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 listening sessions will be shared in the late summer.
- **Fall 2023** – CMS will provide an additional engagement opportunity for participating drug companies that manufacture selected drugs to meet with CMS to discuss their October 2 data submission.
- **February 1, 2024** – Deadline for CMS to send an initial offer of a maximum fair price for a selected drug with a concise justification to each company participating in the Negotiation Program.
- **March 2, 2024** – Deadline for participating companies that manufacture selected drugs to accept the initial offer of a maximum fair price or propose a counteroffer, if desired. Companies have 30 days from receiving CMS' initial offer to respond.
- **Spring/Summer 2024** – CMS will provide up to three meetings during the negotiation period with companies that manufacture selected drugs.
- **August 1, 2024** – The negotiation period will end.
- **September 1, 2024** – CMS will publish the negotiated maximum fair prices for those drugs selected for negotiation for 2026 for companies participating in the Negotiation Program.
- **March 1, 2025** – Deadline for CMS to publish the explanation of the maximum fair prices that have been negotiated for drugs selected for negotiation for 2026. In the interest of balancing transparency and confidentiality, as part of the public explanation of the agreed-upon maximum fair price, CMS will publish a narrative explanation of the negotiation process and certain additional information. Any information submitted by drug companies during the negotiation process that constitutes confidential commercial or financial information will be considered proprietary and will be redacted.
- **January 1, 2026** – Maximum fair prices negotiated for selected drugs become effective.

