Fact Sheet: Medicare Drug Price Negotiation Program Initial Guidance

MEDICARE DRUG PRICE NEGOTIATION PROGRAM
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 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, and announced the next steps for how the agency will implement the new program for 2026, which is the first year in which negotiated prices will apply.

Q: What is the Medicare Drug Price Negotiation Program?

The new drug law permits Medicare to negotiate the price of 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 Part B or Part D drugs, 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 Part D high expenditure, single source drugs for negotiation, meaning only those drugs for which there is no generic or biosimilar competition. The maximum fair prices that are negotiated for these drugs will apply beginning in 2026. CMS will select up to an additional 15 Part D drugs for negotiation for 2027, up to an additional 15 Part B or Part D drugs for 2028, and up to an additional 20 Part B or Part D 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 Medicare Part D and eventually, Part B drugs that do not have generic drugs or biosimilar competition. Medicare's new ability to negotiate drug prices will mean lower drug costs for people with Medicare and 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 Medicare Part D drugs and, eventually Part B drugs. This means people with Medicare will pay lower costs for these drugs because their cost-sharing will be based on the price established in the Negotiation Program.

Q: What's included in the initial program guidance for the Negotiation Program?

The initial program guidance published on March 15, 2023 specifies the requirements and procedures for implementing the Negotiation Program for the first round of negotiations, which will occur during 2023 and 2024 and result in prices effective in 2026. Among other things, the initial guidance details how CMS intends to identify selected drugs, consider factors in negotiation, conduct the negotiation process, and establish the requirements for manufacturers of selected drugs.

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

Q: Can the public provide input on this new program?

Public feedback will contribute to the success of the Negotiation Program, and this initial guidance is one tool, among many, CMS will use to ensure interested parties' voices are heard on implementation of the new drug law.

CMS is seeking public comment on key elements in the initial guidance, including:

- Terms and conditions contained in the manufacturer agreement (i.e., once a drug is selected, this is the document that manufacturers will sign to start the negotiation), including the manufacturer's and CMS' responsibilities.
- Approach for considering (1) the manufacturer-reported data elements and (2) evidence about alternative treatments.
- Process for the offer and counteroffer exchange between CMS and manufacturers.
- Content of an explanation for the maximum fair price.
- Method for applying the maximum fair price across different dosage forms and strengths of a selected drug.
- Dispute resolution process for specific issues that are not exempt from administrative and judicial review under section 1198.
- Processes for compliance monitoring and imposition of civil monetary penalties for violations.

More information on how to submit comments can be found in the initial guidance. Comments received by April 14, 2023, will be considered for revised guidance. Due to timing considerations, CMS is not soliciting comments on certain aspects of the guidance. CMS anticipates issuing revised guidance for the first year of negotiation in Summer 2023.

Q: How will CMS define qualifying single source drugs for the purposes of the Negotiation Program?

Consistent with the law, CMS will define a "qualifying single source drug" as a covered part D drug that meets the following criteria:

1. For drug products, the drug is approved by the Food and Drug Administration (FDA) and, as of September 1, 2023, at least seven years have elapsed since the date of approval.
2. For biological products, the biological is licensed by the FDA and, as of September 1, 2023, at least 11 years have elapsed since the date of such licensure.
3. The drug or biological is not listed as a reference drug for a generic or biosimilar product.

In accordance with the law, this definition of qualifying single source drugs excludes certain orphan drugs, certain low-spending Medicare drugs, and plasma-derived biological products. CMS will aggregate across all dosage forms and strengths of a drug or biological product, including new formulations of the drug, with the same active moiety and same manufacturer for drug products and same active ingredient and same manufacturer for biological products.

Q: How will CMS develop its initial offer to drug manufacturers?

CMS will consider factors outlined in the law related to manufacturer-specific data and available evidence about alternative treatments for negotiation. In developing the initial offer, CMS intends to focus on the clinical benefit that the drug provides to people with Medicare as well as whether the drug addresses an unmet medical need and its impact on specific populations compared to its therapeutic alternatives. To formulate an initial offer, CMS intends to:

1. Identify therapeutic alternative(s), if any, for the selected drug;
2. Use the Part D net price for the therapeutic alternative(s) that are Part D drugs and/or Part B average sales price (ASP) for the therapeutic alternatives that are Part B drugs to determine a starting point in developing an initial offer; and
3. Evaluate the clinical benefit of the selected drug (including compared to its therapeutic alternative(s)), including whether the selected drug meets an unmet medical need and the selected drug's impact on specific populations; and
4. Apply further adjustments by the manufacturer-specific factors outlined in the law to determine the initial offer price.
5. CMS will not make or accept any offers for the maximum fair price that is above the statutorily defined ceiling price in the law.

CMS intends to determine a single price for a 30-day equivalent supply of the selected drug (rather than per unit—tablet, capsule, injection—or per volume or weight

metric), and to establish procedures to compute and apply it across dosage forms and strengths, as applicable. CMS is soliciting comment on its intended approach to developing a starting price for the initial offer.

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 is **open for public input** until March 27, 2023.

March 15, 2023 – CMS issues initial guidance with a 30-day comment period on key elements to implement the Medicare Drug Price Negotiation Program.

April 14, 2023 – The 30-day comment period on key elements of the initial guidance to implement the Medicare Drug Price Negotiation Program closes.

Spring 2023 – CMS will issue its second data collection process and invite public comments, which will ask for input on data and information the federal government will collect for consideration when negotiating the maximum fair prices. This information collection request will be open for public input for 60 days.

Spring 2023 – CMS will issue its third data collection process and invite public comments, which will ask for input on 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.

May 22, 2023 - Deadline for companies of 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 Medicare Part D negotiation-eligible drugs for initial price applicability year 2026 (the first year of negotiation).

Summer 2023 – CMS will revise its guidance as needed for the negotiation process for initial price applicability year 2026 and publish updated information collection requests. CMS will seek additional comment on the information collection requests. In addition, CMS will also publish the Manufacturer Negotiation Agreement template. The deadline for drug companies to submit a request for a drug to qualify for the small biotech drug exception will occur in June 2023.

September 1, 2023 – CMS will publish the list of up to 10 Medicare Part D drugs selected for negotiation for 2026.

October 1, 2023 – Deadline for companies of drugs selected for the Negotiation Program for 2026 to sign agreements to participate in the negotiation process.

October 2, 2023 – Deadline for companies of drugs selected for the Negotiation Program for 2026 to submit manufacturer-specific data to CMS to consider in the negotiation of a maximum fair price.

February 1, 2024 – CMS sends 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 – Companies of selected drugs have 30 days from receiving CMS' initial offer of a maximum fair price for a selected drug to accept the offer or propose a counteroffer, if desired.

August 1, 2024 – The negotiation period ends.

September 1, 2024 – CMS will publish the negotiated maximum fair prices for drugs selected for negotiation for 2026.

January 1, 2026 – Maximum fair prices are effective for selected drugs.