

Fact Sheet: Key Information on the Process for the First Round of Negotiations for the Medicare Drug Price Negotiation Program



In August 2022, President Biden signed the Inflation Reduction Act (IRA) of 2022 (P.L. 117-169) into law. 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 for 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 negotiated prices that will be effective beginning in 2026.

On August 29, 2023, CMS published the list of 10 drugs covered under Medicare Part D selected for the first cycle of negotiation.

Q: How were drugs selected for the first cycle of negotiation?

1. CMS identified potential qualifying single source drugs – that is, drugs for which at least seven years, or biologics for which at least 11 years, have elapsed between the FDA approval or licensure of the drug or biologic, and for which there is no generic or biosimilar competition.
2. CMS excluded certain orphan drugs, low-spend Medicare drugs, and plasma-derived products.
3. CMS determined which drugs are negotiation-eligible – that is, the 50 qualifying single source drugs with the highest gross Part D covered prescription drug costs, except for small biotech drugs.
4. The negotiation-eligible drugs were ranked according to highest total gross Part D covered prescription drug costs.

5. Finally, CMS selected from the ranked list of 50 negotiation-eligible drugs up to 10 drugs with the highest total gross Part D covered prescription drug costs, after excluding any biologics that qualified for delayed selection because CMS determined there is a high likelihood that a biosimilar will enter the market within a specified time.

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

CMS is approaching implementation of the new drug law, including the Medicare Drug Price Negotiation Program, with the goal of promoting transparency and engagement. 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. The process includes several steps, such as:

- Drug companies with a selected drug for the Negotiation Program 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 participating drug company with a selected drug to engage in a meeting on its data submission. CMS will also hold a public patient-focused listening session for each selected drug with patients and other interested parties. The patient-focused listening sessions will be held between October 30, 2023 and November 15, 2023. The listening sessions are subject to change, including postponement and/or cancellation.
- CMS will send an initial offer for each selected drug for which the drug company is participating in the Negotiation Program with CMS' proposal for the

maximum fair price and a concise justification 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 consider evidence related to therapeutic alternatives as well as other factors, such as costs of research and development and production and distribution of the selected drug.

- If agreement on a maximum fair price is not reached through the initial offer or counteroffer, CMS will invite each participating drug company for up to three negotiation meetings during Spring and Summer 2024 before the negotiation period ends on August 1, 2024.

Q: How will CMS develop the initial offer?

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. As required by the law, CMS must consider the following when determining the agency's initial offer:

- Manufacturer-submitted data related to the selected drug:
 - Research and development costs;
 - Unit costs of production and distribution;
 - Prior federal financial support;
 - Pending and approved patent applications, FDA exclusivities, and FDA applications and approvals; and
 - Market/revenue/sales data.
- Evidence about alternative treatments, as available:
 - The extent to which the selected drug represents a therapeutic advance compared to existing therapeutic alternatives, and the costs of such alternatives;
 - Prescribing information approved by the FDA for the selected drug and its therapeutic alternatives;
 - Comparative effectiveness of the selected drug, including impact for specific populations, such as individuals with disabilities, the elderly, the

terminally ill, children, and other populations; and

- The extent to which the drug and its therapeutic alternatives address an unmet medical need.

Q: What are the opportunities for public input in the negotiation process?

CMS is providing opportunities for engagement during the negotiation process. These include CMS-hosted patient-focused listening sessions for the selected drugs, which 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 this data on selected drugs can be found [here](#).

Q: Is it voluntary for drug companies to participate in the Negotiation Program?

Yes. The law connects a drug company's financial responsibilities under the voluntary Negotiation Program to that company's voluntary participation in the Medicaid and Medicare Part D programs. A drug company that manufactures a selected drug has several choices regarding participation in the Negotiation Program included but not limited to the following options:

1. the drug company with a selected drug may choose to participate in the Negotiation Program;
2. the drug company with a selected drug may opt out of the Negotiation Program and pay an excise tax on sales of the selected drug to Medicare during defined periods; or
3. the drug company with a selected drug may opt out of the Negotiation Program and avoid the excise tax on sales of the selected drug by withdrawing from

the Medicare and Medicaid programs. That is, a drug company of a selected drug that decides not to participate in the Medicare Drug Price Negotiation Program may voluntarily terminate the Medicare Drug Price Negotiation Program Agreement if it also ceases participation in the Medicaid Drug Rebate Program, the Medicare Coverage Gap Discount Program, and the Manufacturer Discount Program through the end of the price applicability period for the selected drug.

Q: What happens if a participating drug company and CMS do not agree on a maximum fair price?

CMS is committed to following the negotiation process specified by the law. All negotiations between CMS and the participating drug company of the selected drug must end at a certain date. For the first cycle of the Negotiation Program, the negotiation period ends August 1, 2024. Companies are expected to select one of the options outlined above by that date. For additional information about the excise tax, please consult materials provided by Department of the Treasury, which is the agency responsible for its implementation and enforcement.

Q: When will the negotiated maximum fair prices be available?

By September 1, 2024, CMS will publish any maximum fair prices agreed upon between CMS and participating drug companies for drugs selected for the first cycle of the Negotiation Program. Those maximum fair prices will be effective in 2026. CMS will make public an explanation of the agreed upon maximum fair prices by March 2025.

Q: How does the Negotiation Program affect people with Medicare?

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 participating 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: Who do the negotiated maximum fair prices apply to?

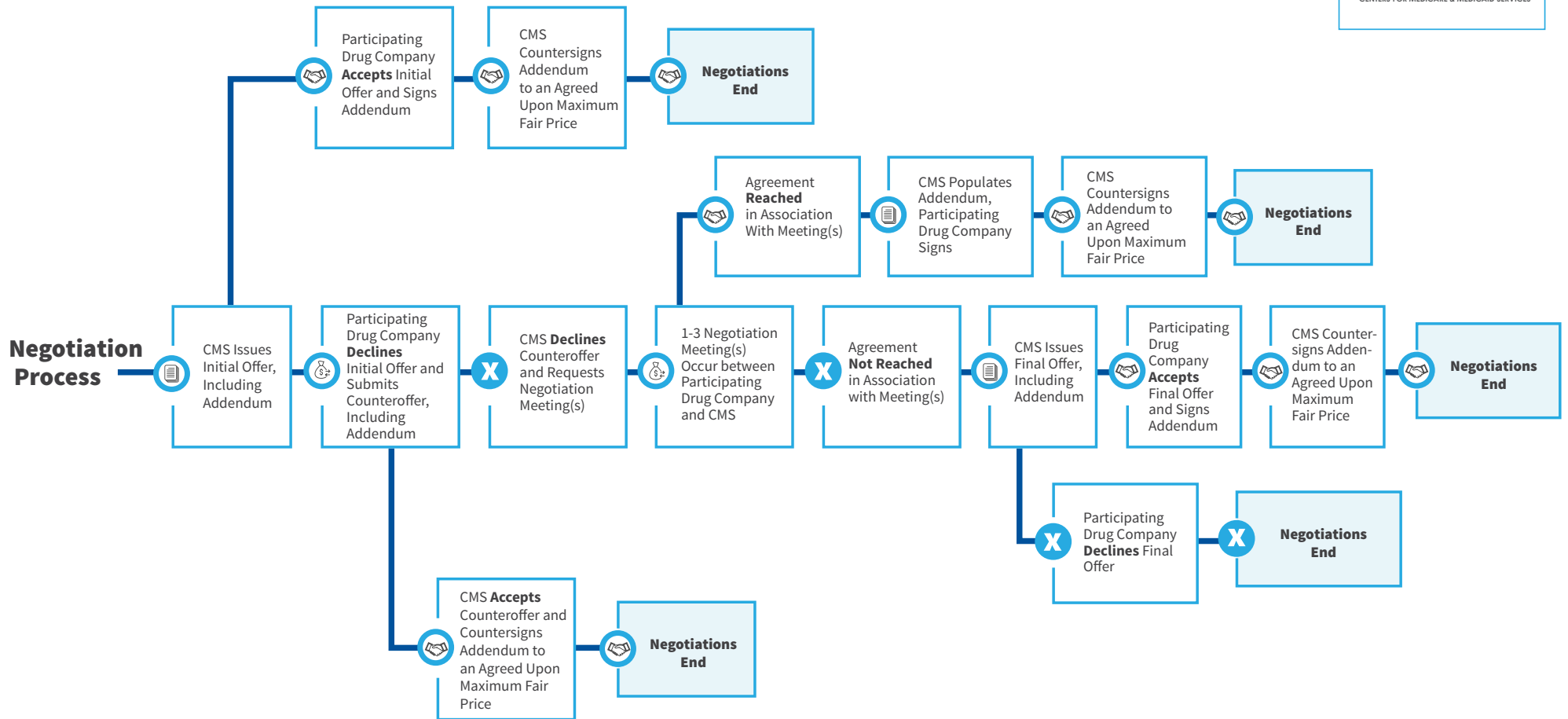
For the first cycle of the Negotiation Program, the negotiated maximum fair prices apply to an individual who is enrolled in a prescription drug plan under Medicare Part D or a Medicare Advantage-prescription drug plan under Medicare Part C (including an Employer Group Waiver Plan), if Part D coverage is provided under such plan for the selected drug. The maximum fair prices are not required to be made available to a person with Medicare who uses other sources of prescription drug coverage, such as a plan that receives the Retiree Drug Subsidy, prescription drug discount cards, or cash.

Q: Will CMS disclose information about the negotiation process?

CMS will make public an 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.

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. A participating drug company with a selected drug may choose to publicly discuss the negotiation process, and 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.

The below figure illustrates potential paths for negotiation between CMS and the drug company that manufactures a selected drug. Please see the **revised guidance** for more detail.



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

- **August 29, 2023** – CMS published the list of 10 drugs covered under Medicare Part D selected for negotiation for 2026.
- **October 1, 2023** – Deadline for drug companies that manufacture the drugs selected for the Negotiation Program for 2026 to decide whether they will 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 (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 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 forthcoming.

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 submissions.
- **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 participating drug company.
- **March 2, 2024** – Deadline for participating drug companies 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 negotiation meetings with participating drug companies, if a counteroffer is provided by the drug company and CMS does not accept the counteroffer.
- **August 1, 2024** – The negotiation period will end.
- **September 1, 2024** – CMS will publish the negotiated maximum fair prices for drugs selected for negotiation for 2026 for drug 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.
- **January 1, 2026** – Maximum fair prices negotiated for selected drugs become effective.