

**NewsBREAK | March 16****CMS Releases Initial Guidance for Medicare Drug Price Negotiation Program**

- On March 15, the Centers for Medicare & Medicaid Services (CMS) released initial guidance for key elements of the new Medicare Drug Price Negotiation Program. This guidance describes how CMS intends to implement the Negotiation Program for initial price applicability year 2026 (Jan. 1, 2026 to Dec. 31, 2026), the first year the negotiated prices will apply.
- The guidance specifies the requirements that will be applicable to manufacturers of Medicare Part D drugs that are selected for negotiation and the procedures that may be applicable to manufacturers of Medicare Part D drugs, Medicare Part D plans (both Prescription Drug Plans (PDPs) and Medicare Advantage Prescription Drug Plans (MA-PDs)), and providers and suppliers that furnish Medicare Part D drugs.
- In developing the initial offer, CMS will focus on the clinical benefit that the drug provides to people with Medicare, including whether the drug addresses an unmet medical need and its impact on specific populations compared to its therapeutic alternatives. For its initial offer, CMS intends to:
  - Identify any therapeutic alternatives for the selected drug.
  - Use the Part D net price for the therapeutic alternatives 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.
  - Evaluate the clinical benefit of the selected drug (as compared to any therapeutic alternatives), including whether the selected drug meets an unmet medical need and the selected drug's impact on specific populations.
  - Apply further adjustments by the manufacturer-specific factors outlined in the law to determine the initial offer price.
- Although some of the guidance is being issued as final without awaiting public comments, CMS is seeking comment on several key elements, as specified in the guidance. Comments are due by April 14, 2023. AMCP will be drafting and submitting comments where appropriate.
- CMS anticipates issuing revised guidance in summer 2023.

See the guidance for additional information.

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### More on This Topic

- [Medicare Drug Price Negotiation Program Initial Guidance](#)
- [Fact sheet](#)
- [Drug Price Negotiation Program timeline](#)

For questions, please reach out to [Tyler Thorne](#).

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