

ALERT

Initial Guidance Regarding the Inflation Reduction Act Medicare Drug Price Negotiation Program

March 20, 2023

The Inflation Reduction Act of 2022 (IRA) establishes the Medicare Drug Price Negotiation Program (Negotiation Program), which permits the government to negotiate drug prices for certain high expenditure, single source Medicare Part B and Part D drugs (for more information see Wiley's previous alert summarizing the IRA's Drug Price Negotiation Program). Under the Negotiation Program, the government will select 10 Part D drugs for negotiation for initial price applicability year 2026, and scale up to 20 Part B and Part D drugs by 2028. On March 15, 2023, the Centers for Medicare & Medicaid Services (CMS) released initial guidance for implementation of the Negotiation Program for 2026.

CMS's initial guidance provides detailed operational insight into key aspects of the Negotiation Program, including the following:

- CMS's process for identifying and selecting drugs for negotiation for 2026;
- Qualifications for manufacturers of selected drugs;
- The processes by which manufacturers will enter into contracts with CMS and submit data to inform CMS negotiations;
- Factors to be considered in manufacturer negotiations with CMS;
- Components of the negotiation process, including the provision of an initial offer and justification, required components of a counteroffer, and post-counteroffer processes and determinations;

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- Processes for how selected drugs may be removed from CMS’s selected drug list before, during, or after negotiations;
- Providing a definition for “maximum fair price [MFP] eligible individual”;
- Details for how CMS intends to monitor manufacturer compliance with the Negotiation Program, including through excise taxes and civil monetary penalties for those manufacturers who fail to comply with the Negotiation Program or their CMS agreement;
- Confirmation that Medicare Part D plans shall include each covered Part D drug that is a selected drug on Part D formularies during 2026 and all subsequent years for which the MFP of the selected drug is in effect; and
- Outlining how the Part B and Part D Prescription Drug Rebate Programs will apply to selected drugs.

The Negotiation Program guidance does not address topics that are unrelated to the Negotiation Program for initial price applicability year 2026 (such as the selection of Medicare Part B Drugs and renegotiation, which will take place in later years).

CMS is seeking comments on various aspects of its Negotiation Program guidance, set forth below. Comments are due to CMS by April 14, 2023. As noted in Wiley’s previous alert addressing best practices for submitting effective comments on IRA guidance, comments can be an important opportunity for stakeholders to shape policy and/or establish markers for reference in any administrative law proceedings that may arise in the future. CMS plans to release revised Negotiation Program guidance by Summer 2023 after considering the public comments received.

CMS is primarily seeking guidance on the following topics:

- Terms and conditions contained in the manufacturer agreement, including responsibilities for manufacturers and CMS;
- The approach for considering (1) the manufacturer-reported data elements and (2) evidence about alternative treatments;
- The process for the offer and counteroffer exchange between CMS and manufacturers;
- The content of an explanation for the maximum fair price (MFP) for a selected drug;
- The method for applying the MFP across different dosage forms and strengths of a selected drug;
- The dispute resolution process for specific issues that are not exempt from administrative and judicial review; and
- Processes for compliance monitoring and imposition of CMPs for violations.

Wiley’s multidisciplinary Medicare Drug Pricing team of experienced attorneys and advisors is well-equipped to assist entities with preparing comments on CMS guidance—including comments on the Medicare Drug Price Negotiation Program, due by April 14—or advise on any questions that may arise. For more information about the Medicare Drug Price Negotiation Program or the IRA generally, please contact one of the attorneys listed on this alert.