

ALERT

Submitting Comments on the Inflation Reduction Act's Medicare Drug Price Negotiation Program Guidance

February 22, 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. The government will begin by negotiating the prices of (i) 10 Part D drugs in 2026, after which it will negotiate the prices for (ii) 15 Part D drugs in 2027; (iii) 15 Part B and Part D drugs in 2028; and (iv) 20 Part B and Part D drugs in 2029.

The IRA excludes certain drugs from the negotiation process, including:

- Drugs with an available generic or biosimilar;
- Drugs that are less than 7 years (for small molecule drugs) or 11 years (for biological products) from their FDA-approval dates;
- Until 2029, “small biotech drugs” (defined as those that account for less than 1% of Part D or Part B spending and at least 80% of a manufacturer’s total spending under each Part);
- Low spend Medicare drugs (defined as those with spending of less than \$200 million between June 1, 2022 and May 31, 2023);
- Orphan drugs; and
- Plasma-derived products.

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Drug manufacturers that do not comply with the Negotiation Program may be subject to excise taxes and civil monetary penalties.

The Centers for Medicare & Medicaid Services (CMS) recently published a timeline setting forth initial actions for the Negotiation Program. Per its timeline, CMS will release guidance on the Negotiation Program for public comment throughout winter and spring 2023. Following the comment periods discussed below, CMS will publish the 10 Part D drugs selected for negotiation for 2026 on September 1, 2023. CMS's negotiations with manufacturers of drugs selected for negotiation will take place from October 1, 2023 until August 1, 2024, after which CMS will publish the maximum fair prices for the negotiated drugs on September 1, 2024.

Industry Comments Invited for Negotiation Program Guidance

The IRA instructs CMS to implement the Negotiation Program "by program instruction or other forms of program guidance" rather than by standard notice and public comment rulemaking.¹ Nonetheless, in its January 11, 2023 public memo, CMS expressed its commitment to "collaborating with and engaging the public in the policy-making process," including by "engag[ing] with interested parties through national stakeholder calls, quarterly strategic meetings, and monthly technical calls with CMS staff."²

CMS's memo includes a timeline setting forth when CMS will release initial guidance and information collection requests (ICRs) relating to the Negotiation Program, as well as opportunities for public input. Key dates are as follows:

- On January 24, 2023, CMS published its first ICR with a 60-day notice and public comment period. The ICR invites comments on the burden to complete the application for excepting small biotech drugs from the IRA's definition of "negotiation-eligible drug" (the "Small Biotech Exception"). Comments are due to CMS on March 27, 2023.
- In Spring 2023, CMS will issue initial guidance on the Negotiation Program's negotiation process for 2026. As with its previously issued initial guidance on the IRA's Medicare Prescription Drug Inflation Rebate Program, CMS's initial guidance on the negotiation process will provide for a 30-day comment period.
- In Spring 2023, CMS also will publish ICRs regarding the (i) data and information the federal government must collect for consideration when negotiating maximum fair prices, and (ii) information to be included in the Negotiation Program's offer and counteroffer process. These ICRs will provide for 60-day notice and comment periods.
- CMS's January 11 memo provides that CMS will request comment on the following elements of the Negotiation Program:
 - Terms and conditions contained in the manufacturer agreement, including the manufacturer's and Secretary of Health and Human Services' responsibilities;
 - Approach for considering (1) the manufacturer-reported data elements, and (2) evidence about alternative treatments;

- Process for the offer and counteroffer exchange between the Secretary 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; and
 - Processes for compliance monitoring and imposition of civil monetary penalties for violations.
- In Summer 2023, CMS will:
 - Issue revised guidance for the Negotiation Program for 2026; and
 - Submit its ICRs on the negotiation data elements and offer and counteroffer process to the Office of Management and Budget (OMB); the ICRs will be published with a 30-day notice and comment period.

CMS seems committed to hearing, and presumably learning, from industry about its foray into direct drug purchasing – affording interested parties, particularly drug manufacturers, a golden opportunity to shape this new and emerging policy. Wiley’s multidisciplinary Medicare Drug Pricing team has deep experience in drug pricing, government contracting, and aiding clients in their drafting and submission of comments. In Part 2 of this Alert, Kendra Norwood, a partner in Wiley’s Government Contracts Practice, will provide tips for submitting comments that could help move the needle as CMS grapples with the complex and intricate world of drug pricing and negotiations.

1 <https://www.congress.gov/bill/117th-congress/house-bill/5376/text>.

2 <https://www.cms.gov/files/document/medicare-drug-price-negotiation-program-next-steps-implementation-2026.pdf>.