

The IRA's Negotiation Process ICR and Revised Negotiation Program Guidance

July 27, 2023

On July 25, 2023, the Centers for Medicare & Medicaid Services (CMS) republished its Drug Price Negotiation Process Information Collection Request (Negotiation Process ICR). The Negotiation Process ICR, which was originally published on April 18, 2023, requests public comment on the counteroffer that drug manufacturers whose drugs are selected for negotiation with CMS under the Inflation Reduction Act of 2022 (IRA)'s Medicare Drug Price Negotiation Program (Price Negotiation Program) may submit after receiving CMS's initial offer of a "maximum fair price" for the drug (for more information see Wiley's alert summarizing the Price Negotiation Program; the Price Negotiation Program allows CMS to negotiate drug prices for certain high expenditure, single source Medicare Part B and Part D drugs). Negotiated prices for the drugs selected by CMS for the Price Negotiation Program will go into effect beginning in 2026.

The current negotiation process described in the April 18 Negotiation Process ICR is set to proceed as follows:

- By February 1, 2024, CMS will make a written initial offer to each manufacturer of a drug selected for the Price Negotiation Program with the proposed maximum fair price for that drug.
- Manufacturers who choose not to accept CMS's initial offer may choose to submit a written counteroffer.
- After receiving a manufacturer's counteroffer, CMS has thirty (30) days to provide a written response. If CMS does not accept the counteroffer, CMS and the manufacturer may participate in up to three (3) in-person, virtual, or hybrid negotiation meetings.

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- If CMS and the manufacturer do not agree on a maximum fair price during negotiations, CMS will provide a final written offer of a maximum fair price for the manufacturer's drug.
- Each offer and counteroffer made throughout the negotiation process must be accompanied by the Counteroffer Form contained in the April 18 Negotiation Process ICR.

Public comments on the Negotiation Process ICR are due to the Office of Management and Budget by August 24, 2023.

The Negotiation Process ICR follows CMS's June 30, 2023 publication of revised guidance (Revised Guidance) regarding implementation of the Price Negotiation Program. The 92-page Revised Guidance summarizes key changes to the initial Price Negotiation Program Guidance (Initial Guidance), published on March 15, 2023, based on CMS's review of more than 7,500 public comments (see Wiley's prior alert summarizing the Initial Guidance), and sets forth the revised policies relating to negotiations for drugs whose negotiated prices will go into effect in 2026.

CMS has noted that the Revised Guidance clarifies key aspects of the Initial Guidance, including regarding:

- How CMS will identify drugs selected for negotiation;
- The negotiation process applicable to participating manufacturers of selected drugs;
- How CMS will consider the various information that manufacturers must submit in advance of negotiations;
- How CMS will engage in compliance and oversight activities throughout negotiations; and
- The Part D formulary inclusion for selected drugs.

CMS's Revised Guidance also identifies opportunities for engagement with stakeholders in Fall 2023, when CMS will offer public "patient-focused" listening sessions and hold meetings with manufacturers of drugs selected for negotiation. CMS will provide additional information about the public listening sessions later this summer.

Other key upcoming dates for the Price Negotiation Program include the following:

- During Summer 2023, CMS will publish a template Price Negotiation Program Agreement, to be used between CMS and the selected drug manufacturers.
- By September 1, 2023, CMS will publish the list of up to 10 Medicare Part D drugs selected for negotiation for 2026.
- By October 1, 2023, selected manufacturers will sign agreements to participate in the Price Negotiation Program.
- By October 2, 2023, selected manufacturers will submit information to CMS for consideration in the negotiation of a maximum fair price.

Wiley's multidisciplinary Medicare Drug Pricing team of experienced attorneys and advisors is well-equipped to assist with preparing comments on CMS guidance—including comments on the Negotiation Process ICR, due by August 24—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.