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Medicare's Initial Plans for the Medicare Drug Price Negotiation Program

by Matt Wetzel

On January 11, 2023, the Centers for Medicare & Medicaid Services ("CMS")—the federal agency tasked with putting into effect the Medicare provisions of the Inflation Reduction Act of 2022—issued a public memo offering further insight on next steps in implementing the Medicare Drug Price Negotiation Program for the initial year of price caps (i.e. 2026). Among the steps CMS outlines in the memo are how it plans to engage with the public on the negotiation program, how it intends to issue guidance, and a timeline for relevant dates.

Many have expressed concern (myself included) over the lack of mandatory notice-and-comment rulemaking contemplated by the Inflation Reduction Act. (As explained in my recent WLF *Legal Backgrounder*, the statute gives CMS authority to implement the program via "program instruction" instead of notice-and-comment public rulemaking for the program's first three years, 2026-2028.) In its January 11, 2023 memo, however, CMS clarifies that it will engage with the public on the program and will solicit some feedback via "voluntary" public comment periods.

In its January 11, 2023 memo, however, CMS clarifies that it will engage with the public on the program and will solicit some feedback via "voluntary" public comment periods, in addition to creating a new email address for regular public comments (IRARebateandNegotiation@cms.hhs.gov). CMS makes clear, however, that any such outreach is voluntary and any requests for public comment posted in the Federal Register will be voluntary. These requests will also be focused on narrow technical issues, with CMS noting that the timeline for these requests for public comment are subject to "non-statutory deadlines [that] may be adjusted by CMS at any time."

According to CMS's memo, there will be **four** opportunities for public comment on the Medicare Drug Price Negotiation Program. **The first opportunity relates to CMS's Initial Program Guidance**. With respect to the actual program guidance that will govern the Medicare Drug Price Negotiation Program for its first three years (2026-2028), CMS emphasizes that despite the IRA's instruction that the agency use program instructions, and not formal notice-and-comment rulemaking, to issue guidance, CMS will voluntarily solicit 30 days of public comment for its proposed program guidance for the initial 2026 year only. CMS expects to do so in "Spring 2023" (CMS's seasonal references are not defined in its memo), with the agency noting it plans to release its final program guidance for 2026 sometime in "Summer 2023." The proposed guidance will only address "key elements" like terms, conditions, and responsibilities in the manufacturer agreements; manufacturer-reported data elements and evidence about alternative treatments; the offer/counteroffer process; the explanation for the maximum fair price; and how the maximum fair price is applied across different dosage

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forms. The program guidance will address the imposition of penalties as well. CMS also seems to suggest that it will implement a dispute resolution process, but only for those issues that are subject to administrative and judicial review. (As highlighted in my Legal Backgrounder on the Inflation Reduction Act, much of the statute's provisions are exempt from administrative and judicial review.)

In addition, CMS will also issue three "information collection requests" or "ICRs" related to the Negotiation Program:*

- **Small Biotech Exception ICR**. CMS will seek public comment on an ICR related to the small biotech exception from the negotiation program for 2026-2028. To determine whether a manufacturer qualifies for the small biotech exception, CMS will look at the total Medicare expenditures for the specific drug at issue and total Medicare expenditures for all the manufacturer's qualifying single source drugs. Entities considered a "single employer" for Internal Revenue Code purposes are aggregated as one manufacturer for purposes of qualifying for small biotech exception eligibility. CMS's ICR on this topic will ONLY solicit information about a manufacturer's aggregation as a single employer to determine which covered drugs will qualify for the exception.
    - Initial Federal Register notice for 60-day public comment: "Winter 2023"
    - Federal Register notice to OMB with 30-day public comment: "Spring 2023"
- **Negotiation Data Elements ICR**. The IRA allows manufacturer-specific data to be considered during the price negotiations. The statute identifies R&D costs and the recoupment of those costs; unit costs of production and distribution; past federal funding for R&D; approved and pending patent applications; FDA-recognized exclusivities; and market data, revenue, and sales volume data. CMS's ICR on this topic will solicit information about a process for manufacturers and the public to voluntarily submit data about these factors and factors related to evidence about alternative treatments.
    - Initial Federal Register notice for 60-day public comment: "Spring 2023"
    - Federal Register notice to OMB with 30-day public comment: "Summer 2023"
- **Offer and Counteroffer Exchange ICR**. CMS states that this ICR will "outline the information that manufacturers must provide in any counteroffers."
    - Initial Federal Register notice for 60-day public comment: "Spring 2023"
    - Federal Register notice to OMB with 30-day public comment: "Summer 2023"

Later, on September 1, 2023, CMS will issue the first list of 10 Part D single-source drugs that will be subject to price negotiation and capped pricing effective January 1, 2026. Manufacturers

* This is a technical aspect of the federal regulatory process. The Paperwork Reduction Act requires that federal agencies estimate the cost burden to the public to fulfill certain requests for information required to implement a particular regulation. (Here, CMS is soliciting multiple data from manufacturers to implement the program, and CMS will issue three information collection requests to determine the cost burden on the public.) To do so, an agency will issue an Information Collection Request ("ICR") in the Federal Register, which is open for 60 days for the public to submit comments to the agency. The public is commenting on the information being collected, who the agency is collecting data from, why the agency is collecting the data, and the estimated cost burden to collect and submit the data. The agency will then take these comments into consideration, update its information request, and submit a final version to the Office of Management & Budget ("OMB") for review and approval. The agency does this in another Federal Register notice on which the public has 30 more days to comment.

then have until October 1, 2023 to sign the relevant agreement—and one more day to provide CMS with all of the required data elements.

While the January 11 memo and the launch of a new webpage demonstrate CMS's commitment to providing resources and awareness materials to stakeholders, we will continue to monitor CMS's public statements and information requests as the Medicare Drug Pricing Program unrolls, including whether the agency takes drug and biologics makers' comments into account in designing the program.