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ALERT

Part 2: Submitting Comments on the Inflation Reduction Act's Medicare Drug Rebate and Price Negotiation Program Guidance

March 1, 2023

The Inflation Reduction Act of 2022 (IRA), signed into law last August, seeks to overhaul the way Medicare buys and pays for prescription drugs. A regulatory undertaking of this scope is certain to generate a great deal of agency guidance and policies, many of which are open to industry comment, which can play an essential role in shaping the government's approach to implementation. On February 13, 2023, Wiley's multidisciplinary Medicare Drug Pricing team released an overview of the Centers for Medicare & Medicaid Services' (CMS) initial guidance related to the Medicare Prescription Drug Inflation Rebate Program under the IRA, which is now in its 30-day comment period, through March 11, 2023. The Wiley Medicare Drug Pricing team later released a February 22 summary of CMS's plan for implementing the Medicare Drug Price Negotiation Program (Negotiation Program), which will also be open for a 30-day comment period after its release this spring.

Kendra Norwood, a founding member of Wiley's Medicare Drug Pricing team, draws on her extensive experience drafting and reviewing industry comments on pending regulations and agency action, particularly those related to government procurements and purchasing programs, to offer some best practices for submitting effective comments.

Best Practices for Submitting Comments on CMS-Issued Guidance

As discussed above, both current and forthcoming CMS guidance will provide drug manufacturers, health plans, and other impacted stakeholders multiple opportunities to provide feedback on key

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aspects of the new Negotiation Program as well as the Inflation Rebate Program. Potentially impacted entities should begin preparing for the new Inflation Rebate and Drug Price Negotiation Programs by first reviewing the relevant portions of the IRA and current CMS guidance, and should then consider submitting comments whenever opportunities to do so are presented.

The comments CMS currently seeks on its initial guidance for the Inflation Rebate Program (due by March 11) should address the agency's plans for implementing the IRA's requirements for manufacturers to pay rebates to a Medicare trust fund for certain drugs and biological products with prices that increase faster than the rate of inflation.

This comment period, along with the anticipated comment period on the Negotiation Program, provides a valuable opportunity for drug manufacturers and other interested parties to potentially shape how CMS ultimately implements this new statutory requirement, which could have significant industry impacts and downstream effects. Additionally, given the possibility that certain proposed agency action can ultimately be found arbitrary or capricious through court challenges, any submissions made in response to CMS's requests for comments could potentially influence whether or how the Inflation Rebate and Negotiation Programs are implemented.

How Should Comments Be Structured?

Comments should start by identifying the Federal Register docket number or document identifier, as well as the Federal Register date, subject heading, and page number(s) of the content being commented upon. The comments should also include an introduction that explains why the submitting organization is interested in the subject matter and highlight any credentials or experience of the author that may make the comments especially noteworthy or distinguishable from other submissions.

Next, the comments should include a background section that clearly identifies the issues being commented upon and states all recommendations upfront. The background section should be followed by an analysis that details each argument presented and provides any evidence to support the positions asserted. A conclusion should follow that summarizes the main points and reiterates the recommendations. Comments should also include citations for all information and research relied on.

What Makes Comments Effective?

The most effective comments will be those considered persuasive by the agency, or a court of law should the agency action be challenged as arbitrary, capricious, an abuse of discretion, or otherwise unlawful. In general, persuasive comments explain in detail why the submitting entity has decided to make the suggestions provided, including the specific impacts the agency's proposal will have on the submitting organization. The most helpful comments also provide rigorous information about whether the proposed agency action is necessary, the industry and market costs and benefits of the proposed program or action, as well as any other policy alternatives that should be considered. Well-drafted comments can sometimes persuade the agency that it has failed to follow the law or best practices, or that a better alternative exists.

These kinds of comments are more likely to make a difference. Should the agency fail to adopt the recommendations made or provide reasonable responses to the issues raised in a set of well-drafted comments, this failure can possibly provide a basis for the courts to set aside the challenged agency action.

What Is the Process for Preparing Comments?

Before preparing comments, it is often useful to ask, "Why is this new program or agency action required?" or "What problem is the agency trying to address through this new program or proposed action?" The answers to these questions can usually help inform the content and guide preparation of comments.

Other important considerations to keep in mind when preparing comments include:

- Whether the proposed program or agency action is based on the best available scientific, technical, economic, or other information;
- Whether the costs (or cost savings) of the intended program or action are justified by its benefits;
- Whether the agency's proposed program or action has been designed in a cost-effective manner;
- Whether the proposed program or action will cause disproportionate effects on certain groups or individuals;
- Whether existing agency rules or regulations have created or contributed to the problem the new program or proposed agency action seeks to address;
- Whether the new program or proposed action is based on a coherent theory, and whether there are any flaws in that theory;
- Whether there is a legal mandate or other need for the program or proposed action; and
- Whether the new program or proposed action is consistent and compatible with existing rules.

In sum, written responses to an agency's requests for comments should be well-organized, persuasive, properly cited, adequately supported, and thoughtfully considered.

Other Opportunities for Stakeholder Feedback

In addition to submitting comments, stakeholders have other ways to provide feedback on implementing the Inflation Rebate and Drug Price Negotiation Programs. Drug manufacturers may participate in monthly one-hour calls with CMS, during which manufacturers are encouraged to ask questions and provide feedback on implementing Negotiation Program provisions. Stakeholders also are invited to share feedback to CMS by email at IRARebateandNegotiation@cms.hhs.gov.

Wiley's multidisciplinary Medicare Drug Pricing team is closely monitoring IRA developments and is available to help develop comments on CMS guidance—including comments on the Inflation Rebate Program, due by March 11—or advise on any questions that may arise. For more information about the Inflation Rebate Program, the Medicare Drug Price Negotiation Program, or the IRA generally, please contact one of the attorneys listed on this alert.