August 21, 2023

William N. Parham, III, Director
Paperwork Reduction Staff
Office of Strategic Operations and Regulatory Affairs
Centers for Medicare & Medicaid Services
7500 Security Boulevard
Baltimore, Maryland 21244

Richard L. Revesz, Administrator
Office of Information and Regulatory Affairs
Office of Management and Budget
262 Old Executive Office Building
Washington, D.C. 20503

RE: Information Collection Request (ICR) for Drug Price Negotiation Process under Sections 11001 and 11002 of the Inflation Reduction Act (IRA) (CMS-10849, OMB 0938-NEW)

Dear Mr. Parham and Mr. Revesz:

AstraZeneca is a global, science-led biopharmaceutical company that focuses on the discovery, development and commercialization of prescription medicines, primarily for the treatment of diseases in three therapy areas – Oncology, Cardiovascular, Renal & Metabolism (CVRM) and Respiratory & Immunology. AstraZeneca operates in over 100 countries and its innovative medicines are used by millions of patients worldwide.

AstraZeneca appreciates this opportunity to submit comments in response to the Centers for Medicare & Medicaid Services (CMS) proposed information collection request (ICR) for the Drug Price Negotiation Process Under Sections 11001 and 11002 of the Inflation Reduction Act (IRA).[1] This document describes the information collection, via CMS's proposed "Counteroffer Form," that may occur during the negotiation process if the Primary Manufacturer chooses to develop and submit a written counteroffer to CMS's written initial offer during the drug price negotiation process for Initial Price Applicability Year 2026.

As a threshold matter, we note our appreciation that CMS revised the Counteroffer Form to permit the submission of up to 10 supporting charts, tables, or graphs. We also appreciate CMS's clarification regarding how manufacturers should request that certain information included in the Counteroffer Form be excluded from the public explanation of the MFP.[2] We are concerned, however, that CMS did not address many of our other comments submitted in

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[1] 88 Fed. Reg. 47,880 (July 25, 2023); https://www.cms.gov/regulations-and-guidance/legislation/paperworkreductionactof1995/pra-listing/cms-10849.

[2] We believe there may be a typo on the Counteroffer Form with respect to this policy, however. Specifically, "include" should be revised to "exclude" in the following language on page 3: "a request to *include* certain information from the counteroffer justification in CMS' public explanation of the MFP."

response to the 60-day notice in the updated Counteroffer Form. AstraZeneca thus continues to urge CMS to make revisions in response to our comments to improve data being collected as part of the negotiation process. In particular:

- CMS should expressly authorize participation in the counteroffer process by any Secondary Manufacturers;
- CMS's justification for its initial offer must be sufficient to enable manufacturers to adequately respond; and
- CMS should expand the data fields in the counteroffer form to permit the submission of additional information.

I. CMS Should Expressly Authorize Participation in the Counteroffer Process by any Secondary Manufacturers.

AstraZeneca remains concerned that the proposed Counteroffer Form is described as applicable only to the Primary Manufacturer (i.e., the manufacturer that holds the New Drug Application (NDA) or Biologics License Application (BLA) of a selected drug). This approach, together with CMS's limitations on the disclosure of information specific to the negotiation process, will impose an undue burden on a Primary Manufacturer and may interfere with the collection of useful information by CMS.

We recognize that CMS loosened some of the restrictions on Primary Manufacturers' disclosure of information regarding ongoing negotiations in the Revised Guidance. However, CMS notes in the Revised Guidance that "[i]f a Primary Manufacturer chooses to disclose proprietary information prior to the explanation of the MFP, then it will not be redacted in the explanation of the MFP." CMS also states that "[i]nformation exchanges concerning confidential and strategic business negotiations may violate the antitrust laws under certain circumstances and lead to other anticompetitive agreements." Nowhere in the guidance or the Counteroffer Form does CMS expressly permit the Primary Manufacturer to disclose confidential information regarding the negotiation process with Secondary Manufacturers.

By including dire warnings regarding information sharing in the Revised Guidance, while failing to expressly permit the sharing of confidential information with Secondary Manufacturers, CMS is limiting its own ability to collect useful information via the Counteroffer Form by discouraging collaboration with Secondary Manufacturers. Specifically, where multiple manufacturers are involved with a given drug, each of the manufacturers may have unique information and perspectives regarding the drug and its value, all of which should be considered for purposes of the Negotiation Program regardless of which manufacturer owns the NDA/BLA. As previously commented, it would be burdensome, and in some cases impossible, for the Primary Manufacturer to complete the Counteroffer Form without being able to share information regarding the negotiation process with Secondary Manufacturers. AstraZeneca therefore continues to recommend that CMS clarify that its data sharing restrictions in no way restrict a Primary Manufacturer from coordinating with any Secondary Manufacturer(s) to complete the Counteroffer Form.

II. CMS's Justification for its Initial Offer Must be Sufficient to Enable Manufacturers to Respond.

As outlined in the proposed Counteroffer Form, CMS would require a Primary Manufacturer to provide: (1) a written counteroffer for the MFP per 30-day equivalent supply of the selected drug; (2) a justification of the counteroffer based on the section 1194(e) factors: and (3) a response to the justification provided in CMS's initial offer including why the information submitted by the manufacturer on the section 1194(e) factors does not support the written initial offer made by CMS and better supports the manufacturer's counteroffer.

We remain unable to provide informed comments on the burden of completing the Counteroffer Form because we have yet to see the level of detail that CMS intends to provide in its justification for the initial MFP offer. On the one hand, we appreciate CMS's statements in the Revised Guidance that "CMS will include information that helps the Primary Manufacturer understand the range of evidence and other information submitted pursuant to section 1194(e) that CMS found compelling in developing its initial offer. Because this information will be shared with the Primary Manufacturer, CMS believes the concise justification will be meaningful and provide information that will enable the manufacturer to develop its counteroffer."

However, CMS goes on to state that the Agency "does not plan on issuing a template for the initial offer or the concise justification" and instead "will release redacted information regarding the initial offer with the MFP explanation no later than March 1, 2025." It remains unclear to AstraZeneca how this policy will enable manufacturers to adequately respond to CMS's initial offer, which will be due 30 days after receipt of the initial offer (i.e., on or around March 1, 2024—a full year prior to the release of the template). We therefore reiterate our prior comments that CMS ensure the initial offer include at least the following information to ensure that information collected via the Counteroffer Form is clear and useful for purposes of the negotiation process:

- How CMS weighed each of the factors in section 1194(e) of the Act, as applicable to the drug, and the adjustments made by CMS to the starting point using each such factor.
- Specific data sources consulted and relied upon by CMS in weighing each of the section 1194(e) factors and why.
- The therapeutic alternatives identified by CMS for purposes of applying the section 1194(e)(2) factors, including the evidence the Agency relied upon to select those therapeutic alternatives, the potential therapeutic alternatives the Agency considered and did not select, and the evidence the Agency considered in rejecting such therapeutic alternatives.
- Any section 1194(e) factors CMS found inapplicable to the drug and why.

III. CMS Should Expand the Data Fields in the Counteroffer Form to Permit the Submission of Additional Information.

AstraZeneca remains concerned that the proposed Counteroffer Form would not permit a manufacturer to provide a sufficient rationale or adequate documentation for its counteroffer.

There are also certain aspects of how CMS describes use of the Counteroffer Form that do not align with the current version of that form. To improve the quality, utility, and consistency of the information collected, and to ensure the Counteroffer Form can achieve its intended purpose, AstraZeneca therefore continues to recommend that CMS amend the Counteroffer Form to include each of the following:

- Fields to submit the manufacturer's methodology for calculating the equivalent 30-day supply, as well as how the manufacturer's MFP counteroffer is weighted across dosage forms and strengths, if different from the methodologies used by CMS.
- A field for signature by the authorized representative of the Primary Manufacturer

IV. Conclusion

AstraZeneca thanks you for the opportunity to submit comments regarding the ICR and look forward to continuing to engage with CMS as it implements the Negotiation Program for IPAY2026 and beyond. I can be reached at sarah.arbes@astrazeneca.com with any questions.

Sincerely,

Sarah Arbes
Head, U.S. Federal Government Affairs & Policy

Cc: Lara Strawbridge, Deputy Director for Policy, Medicare Drug Rebate and Negotiations Group at the Center for Medicare