National Pharmaceutical Council

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Ms. Lara Strawbridge
Deputy Director for Policy, Medicare Drug Rebate and Negotiations
Centers for Medicare & Medicaid Services
U.S. Department of Health and Human Services
7500 Security Boulevard
Baltimore, MD 21244-8016

Submitted Electronically via: http://www.regulations.gov

RE: CMS–10849 Information Collection Request for Drug Price Negotiation Process under Sections 11001 and 11002 of the Inflation Reduction Act (IRA)

Dear Deputy Director Strawbridge:

The National Pharmaceutical Council (NPC) appreciates the opportunity to submit comments regarding the Centers for Medicare & Medicaid Services (CMS) Notice, *CMS–10849 Information Collection Request for Drug Price Negotiation Process under Sections 11001 and 11002 of the Inflation Reduction Act* (ICR or the ICR).

NPC is a health policy research organization dedicated to the advancement of good evidence and science and to fostering an environment in the United States that supports medical innovation. We have rich experience conducting research and disseminating information about the critical issues of evidence, innovation and the value of medicines for patients. Our research helps inform important healthcare policy debates and supports the achievement of the best patient outcomes.

The Inflation Reduction Act (IRA or the Act) creates a new price-setting mechanism that will change the economic incentives for bringing new medicines to market and investing in ongoing post-approval research and development. NPC's research and that of others have found that public policies that reduce the incentives to invest in research and development result in less innovation, fewer treatment options, and lower life expectancy.[1] We understand that CMS has a statutory requirement to implement the IRA, incorrectly portrayed as "negotiation," as it forces manufacturers to accept CMS's final price, face an unreasonable excise tax, or exit the market. In implementing the Act, CMS should seek to establish a process that accurately values

[1] Ciarametaro M and Buelt L. Assessing the effects of biopharmaceutical price regulation on innovation. 2022. https://www.npcnow.org/resources/assessing-effects-biopharmaceutical-price-regulation-innovation; Thomas A. Abbott & John A. Vernon, 2007. "The cost of US pharmaceutical price regulation: a financial simulation model of R&D decisions," Managerial and Decision Economics, John Wiley & Sons, Ltd., vol. 28(4-5), pages 293-306; Leonard D. Schaeffer Center for Health Policy & Economics. Annual Report 2020. https://healthpolicy.usc.edu/wp-content/uploads/2021/03/Schaeffer-Center-2020-Annual-Report.pdf

medicines and maintains patient access, two goals that necessitate robust and iterative stakeholder engagement.

NPC appreciated the opportunities to provide input on the *Medicare Drug Price Negotiation Program: Initial Memorandum, Implementation of Sections 1191 – 1198 of the Social Security Act for Initial Price Applicability Year 2026, and Solicitation of Comments* (Guidance or the Guidance) as well as the Data Negotiation Element ICR for CMS's Drug Price Negotiation Program. We further appreciate the opportunity to comment on this Drug Price Negotiation Process ICR. NPC encourages CMS to structure its initial written offer and the counteroffer form in ways that promote transparent exchange and evaluation of evidence on the value and clinical benefit of selected drugs. Specifically, we recommend that CMS:

1. Establish a transparent, replicable structure for CMS's initial written offer.
2. Provide opportunities for in-person CMS-manufacturer engagement before manufacturers' submission of their written counteroffers.
3. Remove inappropriate constraints while acknowledging response burden.

Establish a transparent, replicable structure for CMS's initial written offer.

This counteroffer form, even in combination with the Guidance, provides no meaningful insight into how CMS will evaluate drugs or the factors considered during the price-setting process. The instructions for the counteroffer form state that manufacturers should provide a justification of the counteroffer, based on the factors in section 1194(e) of the Act, that responds to the justification provided in CMS's written initial offer. However, no details on the structure or content of CMS's offer have been communicated. More robust transparency surrounding CMS's drug evaluation process, evidentiary standards, and the format of the initial offer would not only align with fundamental government transparency and best practices for comparative effectiveness research but would also facilitate more efficient and productive communication between manufacturers and the Agency. The need for transparency is further underscored by the statutory requirement that the written counteroffer be submitted within 30 days of receiving the written initial offer from CMS, which constrains flexibility and CMS-manufacturer discussions following the initial offer.

We encourage CMS to promote transparency by publishing its evaluation framework and the structure of the initial offer before beginning the evaluation process. The Instructions for Completing the Counteroffer Form indicate that manufacturers should respond to the justification provided in CMS's initial offer and provide the reasons the manufacturer believes information related to the selected drug and its therapeutic alternatives do not support the written offer. In order to do so, manufacturers must be given a clear and comprehensive rationale for the initial offer price, including the Agency's evaluation of evidence submitted by diverse stakeholders. Specifically, we recommend that CMS include a number of data elements in the initial evaluation framework with specific details in its initial offer:

1) the therapeutic alternative(s) considered for each indication for selected drugs and the rationale for selection;

2) the application of the definition of unmet need to each indication of selected drugs;
3) the full range of benefits and impacts considered for each indication;
4) the internal process and rationale for determining which benefits and impacts were considered;
5) a list of each stakeholder consulted;
6) the source(s) of evidence considered, particularly of patient, clinicians and any de novo analyses conducted by CMS;
7) how each benefit and impact considered influenced the final MFP, to include any algorithms, calculations, or modeling that related to MFP determination, as well as rationale for evidence that was not considered; and
8) the Agency's evaluation of the quality of submitted evidence based on accepted rubrics for evaluating study quality;
9) the limitations of the data collected and uncertainties in CMS's decision-making.

In addition, CMS outlined in its Guidance an initial process for setting a single price across all dosage forms and strengths using an average price per 30-day equivalent supply for the selected drug. The use of loading doses, weight-based dosing, and severity-based dosing are common clinical practices that result in the amount of medicine being used by one patient being different than that used by others. These complexities of calculating a 30-day equivalent supply emphasize the need for further clarity on CMS's process as well as ongoing and open communication with manufacturers. We further recommend that CMS provide in its initial offer detailed explanations of its calculation of 30-day equivalent supplies, including how its weighting and assumptions compare with actual use across the Medicare population. This information will be vital for manufacturers of selected drugs with variable dosing to formulate a responsive counteroffer.

Provide opportunities for in-person CMS-manufacturer engagement before manufacturers' submission of their written counteroffers.

NPC encourages CMS to implement a transparent and inclusive evaluation process to improve credibility and support for their price-setting and counteroffer process. Robust engagement with manufacturers is critical to establishing credibility and is consistent with the practices and policies of other payers and regulators. The ICR Form, along with CMS's initial Guidance, states that up to three in-person or virtual negotiation meetings will be possible "if the written counteroffer is not accepted by CMS." This approach limits the opportunity for manufacturers to meaningfully inform and participate in the "negotiation" process, which is complicated by an inflexible negotiation data elements form with arbitrary word counts and as discussed below, an unjustifiably constrained counteroffer form. These restrictions run counter to established

principles for drug evaluation, which encourage active engagement of all key stakeholders in all stages of an evaluation process.[2]

We urge CMS to engage manufacturers at additional points during the MFP process beyond those specified in the initial Guidance and counteroffer ICR, including *at a minimum,* in-person meetings: (1) after drug selection, and (2) prior to CMS presenting the initial offer. The latter of these meetings would provide opportunities for CMS to discuss the initial offer and its rationale with manufacturers before the start of the 30-day submission deadline for a counteroffer. In-person meetings to discuss CMS's rationale for their initial offer will improve transparency and reduce manufacturers' burden of responding to the initial offer within the short time frame established by the statute.

Remove inappropriate constraints while acknowledging response burden.

In its implementation of the IRA, NPC urges CMS to promote a collaborative approach to information exchange that allows stakeholders, including manufacturers, opportunities to provide comprehensive evidence on drug value. The ability of stakeholders to communicate relevant information should not be constrained by arbitrary and limited word counts. Answers to Question 3 on the initial counteroffer form are limited to 1500 words. In those 1500 words, manufacturers are expected to: respond to the justification provided in CMS's initial offer; provide the reasons the manufacturer believes information submitted by the primary manufacturer and other available data related to the selected drug and its therapeutic alternatives do not support the written offer; and provide justification of their counteroffer based on the factors in section 1194(e) of the Act. The arbitrary word limit imposed on the manufacturer's counteroffer unjustifiably constrains their ability to meaningfully engage with CMS in scientific dialogue on the evidence evaluation and inform CMS's decision-making surrounding their counteroffer. We urge CMS to eliminate restrictive word counts for information collection responses.

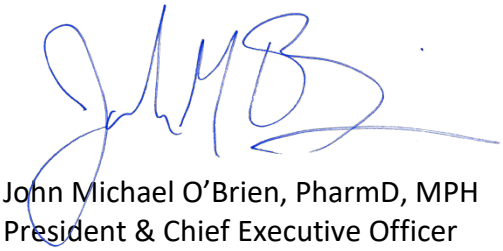
The counteroffer form states that the time required to complete this ICR is estimated to average 79 hours per response, including the time to review instructions, search existing data resources, gather the data needed, and complete and review the information collection. An informed response to an initial offer that both responds to the initial offer and provides robust justification for a counteroffer necessitates far more than 79 hours. We encourage CMS to reduce the burden associated with the counteroffer by establishing a robust, replicable evaluation framework and transparently communicating – through 2 pre-offer meetings, the initial offer letter, and any additional in-person meetings – its application of the framework to a price determination. Doing so would improve transparency and reduce manufacturers' burden of writing counteroffer responses to include relevant information for CMS's evaluation.

[2] Drummond M, Schwartz JS, Jansson B, Luce BR, Neumann BR, Seibert U, Sullivan SD. Principle 10. Key Principles for the Improved Conduct of Health Technology Assessments for Resource Allocation Decisions. International Journal of Technology Assessment in Health Care. 2008. 24:3:250.

Conclusion

The National Pharmaceutical Council appreciates the opportunity to submit comments in response to this ICR and looks forward to ongoing opportunities to engage with CMS as it implements the Medicare Drug Price Negotiation Program. Please contact me at john.obrien@npcnow.org or (202) 827-2080 if we may provide any additional information.

Sincerely,



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