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CMS Deputy Administrator and Director of the Center for Medicare
Centers for Medicare & Medicaid Services
Department of Health and Human Services
7500 Security Boulevard
Baltimore, MD 21244-8016
Attention: PO Box 8016

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

Dear Deputy Administrator Seshamani:

The Pharmaceutical Research and Manufacturers of America (PhRMA) is pleased to submit comments in response to the Centers for Medicare & Medicaid Services' (CMS, the Agency) *Information Collection Request for Drug Negotiation Process under Sections 11001 and 11002 of the Inflation Reduction Act* (ICR or the ICR), including the Federal Register Notice, Supporting Statement – Part A, and the ICR Form (Counteroffer Form) (CMS-10849, OMB, 0938-NEW).[1] PhRMA represents the country's leading innovative biopharmaceutical research companies, which are devoted to discovering and developing medicines that enable patients to live longer, healthier, and more productive lives. Since 2000, PhRMA member companies have invested more than $1.1 trillion in the search for new treatments and cures, including $102.3 billion in 2021 alone.

Under the "Medicare Drug Price Negotiation Program" (the Program) established in Sections 11001 and 11002 of the Inflation Reduction Act of 2022 (P.L. 117-169), codified in Sections 1191 through 1198 of the Social Security Act (SSA or the Act), a manufacturer of a selected drug may opt to submit a written counteroffer within 30 days of receipt of a written initial offer from CMS as part of the process the agency employs to set a "lowest maximum fair price" as required under the Act. The ICR and Counteroffer Form set forth the process and format CMS intends to follow for operationalizing the counteroffer process. Below we discuss several substantive and procedural concerns with the ICR and Counteroffer Form and recommend revisions to address them, including:

(1) Eliminating the primary/secondary manufacturer construct proposed by CMS;

(2) Developing a process for earlier, more effective communication between the manufacturer and CMS by providing for meetings earlier in the process;

[1] 88 Fed. Reg. 23,680 (Apr. 18, 2023); Centers for Medicare and Medicaid Services (CMS), Information Collection Request for Drug Negotiation Process under Sections 11001 and 11002 of the Inflation Reduction Act (CMS-10849, OMB, 0938-NEW), Supporting Statement – Part A (Apr. 18, 2023), https://www.cms.gov/regulations-and-guidance/legislation/paperworkreductionactof1995/pra-listing/cms-10849; CMS, Information Collection Request for Drug Negotiation Process under Sections 11001 and 11002 of the Inflation Reduction Act, ICR Form (Apr. 18, 2023), https://www.cms.gov/regulations-and-guidance/legislation/paperworkreductionactof1995/pra-listing/cms-10849.

(3) Creating a tool to provide information on the "30-day equivalent supply" so manufacturers can assess potential maximum fair prices (MFPs) at the level of specific National Drug Codes (NDC);

(4) Developing a template for the "concise justification" CMS will provide as part of its initial offer, so the manufacturer can understand how evidence and factors informed the offer;

(5) Eliminating the word limit on the manufacturer counteroffer justification;

(6) Modifying the certification requirement so it is not unduly burdensome;

(7) Recalculating the reporting burden estimate; and

(8) Ensuring that any proprietary information is protected in accordance with statutory requirements.

Eliminate the Primary/Secondary Manufacturer Construct

Consistent with our April 14th comments (attached with this submission as Appendix A) on CMS' initial Guidance[2] (Guidance, or the Guidance) on the Medicare Drug Price Negotiation Program and May 22nd comments (attached with this submission as Appendix B) on CMS' draft Information Collection Request for Negotiation Data Elements[3] (Negotiation Data Elements ICR), PhRMA strongly recommends that CMS eliminate the "Primary/Secondary" manufacturer construct in its entirety from the Program, including in the counteroffer process. The ICR Form indicates that a counteroffer must be submitted by a "Primary Manufacturer" of a selected drug. To the extent that more than one entity satisfies the IRA's definition of "manufacturer" for a selected drug, CMS plans to designate the entity that holds the New Drug Application(s) (NDA(s))/Biologics License Application(s) (BLA(s)) for the drug to be the "Primary Manufacturer."

"Primary Manufacturers" legally do not have access to "Secondary Manufacturer" information and, thus, the proposed Primary/Secondary Manufacturer policy contemplated in the Guidance should be eliminated. As Primary Manufacturers will not be able to procure and certify to information from Secondary Manufacturers, CMS is proposing an unrealistic standard that will often be impossible for manufacturers to meet. CMS should instead enter into separate agreements with each entity that satisfies the definition of manufacturer to obtain any essential information throughout the MFP setting process, including as it pertains to the counteroffer process.

Develop Process for Earlier, More Meaningful Manufacturer Engagement, Including Meetings Prior to the Counteroffer

In the Guidance and ICR, CMS proposes to allow up to three potential in-person or virtual meetings between a manufacturer and CMS as part of the MFP decision-making process, but only at the end of the process in instances where a manufacturer's written counteroffer is not accepted by CMS. Meetings at this stage, while useful, come far too late in the process to enable communication between the manufacturer and CMS that will be essential at earlier stages of the process. As recommended in prior comments, PhRMA urges CMS to revise its process to allow earlier, more meaningful manufacturer engagement to include meetings *before* the counteroffer stage of the process. Earlier meetings will be particularly important given the broad range and disparate types of data from manufacturers and public stakeholders that will factor into MFP decision-making, as well as the difficulty CMS will face in

[2] *Medicare Drug Price Negotiation Program: Initial Memorandum, Implementation of Sections 1191 – 1198 of the Social Security Act for the Initial Price Applicability Year 2026, and Solicitation of Comments*

[3] 88 Fed. Reg. 16,983 (Mar. 21, 2023); Centers for Medicare and Medicaid Services (CMS), Information Collection Request for Negotiation Data Elements under Section 11001 and 11002 of the Inflation Reduction Act, Supporting Statement – Part A (Mar. 21, 2023), https://www.cms.gov/regulations-and-guidance/legislation/paperworkreductionactof1995/pra-listing/cms-10847; CMS, Information Collection Request for Negotiation Data Elements under Section 11001 and 11002 of the Inflation Reduction Act, ICR Form (Mar. 21, 2023), https://www.cms.gov/regulations-and-guidance/legislation/paperworkreductionactof1995/pra-listing/cms-10847..

evaluating submitted data and conveying it to the manufacturer in a timely way. Given the broad range of data required throughout this price setting process, we also would encourage CMS to consider notifying manufacturers that their drugs are being considered for selection prior to the formal public announcement and initiation of the information collection request. As discussed in Section III.h. of our Guidance comments, PhRMA recommends that CMS offer manufacturers the opportunity to meet a minimum of three times *prior to* a counteroffer, including after drug selection but prior to initiation of the price setting process; prior to presentation of an initial offer; and, after presentation of the initial offer. PhRMA requests that CMS consider the concerns we raised in our comments on the Guidance, including, but not limited to, the insufficient number of meetings in the price setting process.

Create a Tool or Spreadsheet for Manufacturers to Evaluate How a Proposed MFP for a Selected Drug's "30-Day Equivalent Supply" Breaks Down by National Drug Code (NDC)

The Counteroffer Form requires manufacturers to submit a price for a selected drug in the form of a "single price per 30-day equivalent supply." The Form indicates that this format should be used "rather than unit – such as tablet, capsule, injection – or per volume or weight metric" and should be weighted across dosage forms and strength, as applicable. PhRMA reiterates the request from Section III.m. of our comments on the Guidance for CMS to provide better clarity as to how CMS plans to compute 30-day equivalent supplies to aid manufacturers in understanding the Agency's application of a single Maximum Fair Price (MFP) across dosage forms and strengths. We urge CMS to provide manufacturers with CMS' calculated 30-day equivalent supply for each NDC-9; the total number of units dispensed for each NDC-9 in the 2022 Part D Prescription Drug Event (PDE) data; and an electronic tool or Excel spreadsheet with CMS' 10-step calculation approach for applying the MFP across different dosage forms and strengths. Given the novelty of the program, the complexity of CMS' calculation, and the need to verify data inputs, it is imperative that manufacturers be able to review both the data and calculation methodology used by CMS.

Include in the ICR a Template that Describes How Submitted Data and MFP Factors Influenced CMS' Initial Offer

CMS notes in the proposed Counteroffer Form that it will provide a manufacturer with a "concise justification" for its initial offer based on factors described in Section 1194(e), as required by the SSA. This justification will play an important role in a manufacturers' consideration and development of a counteroffer, but the agency provides no detail on what it will or will not include in its concise justification. CMS should revise the ICR to include a template that will be used by the agency to provide the "concise justification" for its initial offer at a level that enables manufacturers to understand how data and MFP factors influenced the agency offer. Because these evaluations will need to occur on an indication-specific level (as reflected in CMS' Guidance), the template should convey summary information on data and factors on an indication-by-indication basis. As discussed in Section III.j. of our comments on the Guidance, PhRMA recommends that the template include information similar to the final published explanation, and that such justifications identify key pieces of information, including:

- Therapeutic alternative(s) for a selected drug (for each indication) and the rationale for selecting each therapeutic alternative;
- How CMS calculated the ceiling price;
- CMS's starting point and how it established this starting point;
- How each of the factors listed in section 1194(e) were weighed relative to one another in CMS' decision-making and details on how the starting point was adjusted upwards or downwards based on these factors;

- Data and analysis CMS developed and considered supporting each factor, including evidence provided by third parties CMS engaged formally or informally;
- If any data or evidence considered by CMS was generated from a study that referenced or relied on the Quality-Adjusted Life-Year (QALY) or other potentially discriminatory metrics;
- Benefits and impacts of a selected drug CMS considered; and
- Stakeholders (e.g., patients, caregivers, clinicians, and manufacturers), and other government agencies and organizations CMS engaged, formally or informally, including how stakeholder input explicitly informed CMS' determination of the MFP and selection of each therapeutic alternative.

We also believe that CMS should release information on the data and analysis that CMS received formally and informally (e.g., non-proprietary information on comparative effectiveness of treatments received through the Data Elements ICR process) but chose to not include in its determination of MFP as part of the initial justification. CMS should also outline any remaining questions or uncertainties that arose while formulating the initial offer. This information will allow manufacturers to be more responsive to CMS and tailor their counteroffer response to the information CMS deems most relevant and/or make the case for why CMS should reconsider information that may be particularly important to key stakeholders including patients and caregivers.

This detail and template are essential since the manufacturer must provide a justification in its counteroffer through a "Free Response" box that comprehensively responds to CMS' reasoning in the Agency's initial offer. As with the manufacturer justification of its counteroffer (addressed below), it is important for CMS to provide adequate detail in its concise justification of the initial offer. The statutory requirement to provide a "concise" justification simply means that the Agency should not include extraneous, unnecessary detail, but it does not permit an incomplete justification, and it does not relieve the Agency of the responsibility to explain how it considered, evaluated, and weighted each factor in deciding on an initial offer. CMS should provide more information on the substance of the template it will use for providing the initial justification and ensure it allows manufacturers to understand how various factors influenced the initial offer for different indications. CMS should also allow manufacturers the ability and sufficient time to review and refute the contents of CMS' justification before it is made public.

Eliminate Word Limit on Manufacturer Counteroffer Response

PhRMA urges CMS to eliminate all word limits across the data submission process including the 1,500-word limit on a manufacturer's justification of its counteroffer in the "Free Response" portion of the Counteroffer Form. A 1,500-word limit equals only about 2.5 pages. Based on the breadth of data CMS seeks for manufacturers to submit and the requirement for manufacturers to provide a justification for a counteroffer based on these factors, a response limited to 1,500 words will not allow for a meaningful response that covers the essential elements that are to be considered in the process. Manufacturers will inevitably be required to eliminate key details to meet the word limit requirement. Given the potential widespread impacts on patients and innovation from the MFP process, CMS would benefit from being able to evaluate the full scope of data on each selected product and therapeutic alternatives. Thus, CMS should remove any limitations on the breadth and type of data submitted by manufacturers when data is both initially shared with CMS and as part of this counteroffer process. Additionally, similarly to Negotiation Data Elements ICR, CMS should provide space for manufacturers to attach studies or other key pieces of information that support the manufacturer's counteroffer response.

Modify the Certification Requirement

The Certification statement of the Counteroffer Form requires manufacturers to certify that the submission is "complete and accurate" and requires manufacturers to "timely notify CMS" if information submitted has changed. In addition, it requires signing a statement regarding liability under the False Claims Act. In alignment with our comments on the Negotiation Data Elements ICR, CMS should modify the terms of the certification to require all submitters to agree that information is accurate and prepared *in good faith and after reasonable efforts*, with no requirement for completeness. If CMS retains the requirement for completeness, at a minimum "complete" should be defined to mean all sections of the form have been filled out. It is simply not rational to require a certification to completeness and accuracy when CMS bases the counteroffer process on negotiation factors for which the Agency seeks an extensive set of data while simultaneously limiting the number of words in the "Free Response." Furthermore, as noted above and in previous comments to CMS, in some cases "Primary Manufacturers" legally do not have access to "Secondary Manufacturer" information which makes it impossible for "Primary Manufacturers" to certify the accuracy and completeness of this data.

CMS also should remove the requirement of timely notification of changed information to avoid unintended noncompliance of the certification and unnecessary burden. This term of the certification, with no specification of the applicability of a time limit, adds an ongoing burden for submitters. Given the ongoing nature of scientific discovery and clinical research, data on cost and evidence on the uses of medicines (both for a selected drug and treatment alternatives) will continue to evolve over time and that new data will continually become available. Taken literally, CMS' requirement would mean that respondents would have an ongoing obligation to regularly update the counter-offer explanation to represent the most current scientific discoveries and evidence. We do not believe CMS intends such a burdensome obligation; nor that CMS is authorized to threaten penalties for failure to engage in these ongoing updates. We urge CMS to excise the "changed information" requirement from its collection.

Recalculate Reporting Burden Estimate, Which Likely is a Significant Underestimate

CMS estimates a total burden of 792.5 hours (79.25 hours * 10 respondents) and a total cost of $99,870.10 ($9,987.01 per respondent * 10 respondents) for manufacturer completion and submission of information in the Counteroffer Form. CMS explains it expects each manufacturer respondent will use a team of lawyers, health care professionals, economists, and business operation specialists to complete the form. PhRMA requests that CMS recalculate this reporting burden estimate, which we view as significantly underestimating the total actual burden and cost of responding based on the breadth of data to be considered as a result of this ICR and business operations required to evaluate counteroffer options. The estimated burden and cost also raise questions about the substantive nature of the "concise justification" CMS intends to provide to manufacturers as part of the price setting process, as well as concerns about the comprehensiveness of such justification, if each manufacturer respondent's response is anticipated to require only 79.25 hours to complete. Notably, CMS' estimate of its own costs and hours (in Table 2 of the Supporting Statement) appears to assign significantly more time to the Agency than to the manufacturers who will be gathering, presenting, and distilling counter-offer information.

Ensuring That Any Proprietary Information is Protected in Accordance with Statutory Requirements

As discussed in our previous comments on the Guidance and the Negotiation Data Elements ICR, protection of manufacturer confidential data is critically important. We note that it is likely that manufacturers may submit proprietary data to CMS to help justify the submitted counteroffer. As such, PhRMA recommends that CMS protect confidential information beyond the protections of FOIA Exemption 4, share its confidentiality policy for comment, and ensure contractors and others with access to manufacturer data have agreements with CMS that adequately protect the high volumes of proprietary information CMS will collect. Please see Section I.d. of our Guidance comments for additional recommendations and feedback on the need for CMS to protect proprietary information.

Conclusion

PhRMA appreciates the opportunity to submit comments in response to the *Information Collection Request for Drug Negotiation Process under Sections 11001 and 11002 of the Inflation Reduction Act*, including the Federal Register Notice, Supporting Statement – Part A, and the ICR Form. PhRMA urges CMS to carefully consider our recommendations for revising the Counteroffer Form and related process.

Please feel free to contact James Stansel at jstansel@phrma.org and/or Jennifer Bryant at jbryant@phrma.org if there is additional information we can provide or if you have any questions about our comments.

Sincerely,

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