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August 24, 2023

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Office of Management and Budget (OMB)
725 17th St NW
Washington, DC 20503
Attn: OMB Desk Officer

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

To The OMB Desk Officer:

The Pharmaceutical Research and Manufacturers of America (PhRMA) is pleased to submit these comments in response to the Centers for Medicare & Medicaid Services' (CMS, the Agency) Information Collection Request for Drug Price 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), and the Comment Summary Responses submitted to the Office of Management and Budget.[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.

PhRMA submitted comments on CMS' original ICR, noticed in the Federal Register on April 18th, 2023 for a 60-day comment period.[2] Unfortunately, CMS fails to address significant aspects of these comments, including: eliminating the primary/secondary manufacturer construct proposed by CMS; 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; fully eliminating the word limit on the manufacturer counteroffer justification, particularly in the first year; and modifying the certification requirement so it is not unduly burdensome. While CMS has increased the burden estimate (from 79 to 204 hours per selected drug), PhRMA continues to believe that the Agency has significantly underestimated the burden of its demands.

Rather than reiterate prior comments, PhRMA is attaching our comments on CMS' initial Guidance (Appendix A), our comments to CMS and OMB in response to the initial and revised Negotiation Data

[1] See 88 Fed. Reg. 47880 (Jul. 25, 2023); https://www.cms.gov/regulations-and-guidance/legislation/paperworkreductionactof1995/pra-listing/cms-10849; https://www.reginfo.gov/public/do/DownloadDocument?objectID=133856200.
[2] 88 Fed. Reg. 23680 (Apr. 18, 2023).

Elements ICRs (Appendix B and C), and our comments to CMS on the initial Negotiation Process ICR (Appendix D) as well as outlining in this letter the main reasons CMS' ICR continues in its failure to comply with the letter and spirit of the PRA.

Unnecessary Word and Other Limits

While PhRMA recognizes CMS increased the word limit on a manufacturer's justification of its counteroffer in the "Free Response" portion of the Counteroffer Form from 1,500 words to 2,500 words, PhRMA still urges the Agency to eliminate all word limits across the data submission process, particularly in the first year. A word count of 2,500 words equals slightly more than half a page for each of the nine factors CMS must consider in price-setting.[3] This is insufficient for manufacturers to provide a meaningful and substantive justification. Moreover, CMS has subdivided these nine factors into multiple subparts, resulting in a 47-page information collection for the negotiation data elements.[4] Limiting manufacturers to five pages for the counter-offer justification, when CMS found it necessary to issue 47 pages for the initial negotiation data elements information collection, demonstrates how grossly disproportionate and unfounded CMS' word limits are and how limiting responses may affect the utility of the responses provided.

Further, while CMS will allow an option to upload tables, charts, and/or graphs alongside the counteroffer justification, it limits the submission to ten visual representations, and states that any tables or charts consisting of text only will not be considered. CMS does not explain or justify why a limit of ten is reasonable, nor why text-based charts or tables will not be considered. Charts or graphs may more clearly represent complicated data than text-based explanations; thus, it is particularly puzzling that CMS would place a limit on these visual attachments or refuse to consider text-based tables or charts. Likewise, CMS fails to offer any justification for a limit of fifty citations. Again, such limitations affect the utility of the information provided.

Access to Secondary Manufacturer Information

Primary Manufacturers may not necessarily have access to Secondary Manufacturers' information, particularly within the deadlines required under the MFP program. While CMS notes that Primary Manufacturers may have "agreements" with Secondary Manufacturers, it fails to address or even acknowledge the narrow window (revised guidance and template Final Agreement not issued by CMS until late June/early July, just three months before data submission will be due to CMS; only 30 days between drug selection and data submission) for revising such agreements. OMB should prevail on CMS to further explain its reasoning on this issue and create exceptions for Primary Manufacturers unable to revise their agreements with Secondary Manufacturers or unable to provide data from such Secondary Manufacturers.

Written Communication to Facilitate Manufacturer Input

While we appreciate that the revised Guidance allows for one additional meeting between selected drug manufacturers and CMS (which would occur before CMS makes its initial offer), we still are concerned

[3] SSA § 1194(e).
[4] https://www.cms.gov/regulations-and-guidance/legislation/paperworkreductionactof1995/pra-listing/cms-10847.

by the lack of clarity regarding what information CMS will evaluate and how CMS will evaluate this information. CMS notes in the 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. Although this justification could play an important role in a manufacturers' consideration and development of a counteroffer, the Agency provides no detail or template on what it will or will not include in its concise justification.

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. OMB should ensure that CMS creates and utilizes a template or some other form to ensure the justification provides adequate information to manufacturers that allows manufacturers to understand how various factors influenced the initial offer. This information will help reduce the burden on respondents by enabling 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 as needed.

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. As such, OMB should work with CMS to make sure that a comprehensive form is created and used to make sure all selected drug manufacturers have sufficient information as outlined in our previous comments to CMS.

Certification Requirements

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.

CMS responded to comments asking that it remove the reference to "completeness," or at least define what constitutes a "complete submission," by stating: "a complete submission is a full submission that reflects the standards described in this ICR and the revised guidance and is within the respondent's information, knowledge, and/or experience."[5] This explanation sheds no further light on how CMS will evaluate completeness. The explanation incorporates unspecified, open-ended standards of the entire ICR, as well as CMS' revised guidance. CMS' explanation in response to comments uses the word, "full," without defining what a "full" submission means.

Consistent with our comments on the Negotiation Data Elements ICR, OMB should prevail upon CMS to modify the terms of the certification so that it requires submitters to agree that information is accurate and prepared in good faith and after reasonable efforts, without an ill-defined requirement for "completeness." If CMS retains the requirement for completeness, at a minimum, the Agency should define "complete" only to mean that all sections of the form have been filled out. It simply is not rational to require a

[5] https://www.reginfo.gov/public/do/DownloadDocument?objectID=133856200

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 would make it impossible for "Primary Manufacturers" to certify the accuracy and completeness of these data if such data are included in a justification.

CMS also should remove the requirement of timely notification of changed information to avoid unintended noncompliance of the certification and unnecessary burden. CMS failed to respond to comments that this term of the certification is particularly burdensome and lacking in utility, because it has no time limit, fails to recognize the ongoing nature of scientific discovery and clinical research, and fails to recognize that data and information evolve over time.

In response to the initial round of comments on the counter-offer information collection, CMS could have clarified that information should be corrected if it becomes clear that, at the time of submission, the information was in error. Instead, CMS notes it "believes" that the "timely notification of changed information requirement in the certification is necessary for the Medicare Drug Price Negotiation Program as it ensures the MFP is negotiated based on the most current data." This statement fails to respond to the comments noted above. We urge OMB to work with CMS to update this certification and remove the problematic statement about changed information.

Finally, OMB should require CMS to eliminate its vague statement of liability that misrepresentations "may" give rise to an unspecified "liability," "including" liability under the False Claims Act. CMS responds to comments by noting that the certification language aligns with "other information collection requests related to the Negotiation Program."[6] But CMS' only point of comparison is the newly created "Negotiation Program" (that is, price-setting) under the IRA, not more established information collections. It is hardly compelling to justify the certification's liability statement by citing to other, newly created collections under price-setting, and not long-standing or even more recent agency information collections. OMB should work with CMS to ensure that its liability statement accords with more typical information collections, and prohibit CMS from creating its new, unspecified liability certification.

Burden Estimate

As stated in our previous comments to CMS, the burden estimate is likely a significant underestimate. We recognize CMS modified its estimate and now states that it expects each manufacturer respondent will have a burden of 204.25 hours and a total cost of $32,731.39 per respondent.[7] However, given (a) the novelty of the program, (b) the scope of information being requested, (c) the need to evaluate the section 1194(e)(2) data submitted by other respondents, and (d) the number and potential variety of national drug codes CMS includes as one "qualifying single source drug," PhRMA anticipates that time

[6] Id. at 9.
[7] Supporting statement at 8-9

spent preparing, evaluating, and submitting the counter-offer form will be several multiples of CMS' estimate. OMB should carefully evaluate CMS' burden estimate to ensure accuracy.

Conclusion

PhRMA appreciates the opportunity to submit comments on the revised ICR. This letter includes our key priorities but does not represent the totality of our concerns with CMS' ICR or the ICR process. We urge OMB to review PhRMA's prior comments, and ensure CMS complies with the PRA in implementing the price-setting provisions of the IRA.

Please contact Judith Haron at jharon@phrma.org and/or Randy Burkholder at rburkholder@phrma.org if there is additional information we can provide or if you have any questions about our comments.

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