August 24, 2023

Via Electronic Filing - RegInfo.gov

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

Re: ICR Reference Number: 202307-0938-009. Information Collection Request for Drug Price Negotiation Process under Sections 11001 and 11002 of the Inflation Reduction Act (CMS-10849).

To The OMB Desk Officer:

Boehringer Ingelheim Pharmaceuticals, Inc. (BI) welcomes the opportunity to submit comments in response to the Centers for Medicare & Medicaid Services' (CMS or 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, ICR Form (CMS-10849, OMB, 0938-NEW), and the Comment Summary Responses submitted to the Office of Management and Budget.[1] BI adopts and incorporates by reference the comments submitted on these documents by the Pharmaceutical Research and Manufacturers of America (PhRMA). We offer the following comments to elaborate and expand on certain issues raised.

BI is a leading research-driven biopharmaceutical company committed to innovation in areas of high unmet medical need. Accordingly, BI has a significant interest in CMS's implementation of the Inflation Reduction Act (IRA). While BI supports the goal of ensuring patient access to affordable, life-enhancing medicines, it has significant concerns relating to aspects of the ICR, including concerns that it includes unlawful and impracticable—even impossible—data reporting limitations and processes.

Under federal regulations, "an agency shall demonstrate that it has taken every reasonable step to ensure that the proposed collection of information:

(i) Is the least burdensome necessary for the proper performance of the agency's functions to comply with legal requirements and achieve program objectives;

(ii) Is not duplicative of information otherwise accessible to the agency; and

[1] 88 Fed. Reg. 47,880 (July 25, 2023); CMS, Information Collection Request for Drug Price Negotiation Process under Sections 11001 and 11002 of the Inflation Reduction Act (July 25, 2023), https://www.cms.gov/regulations-and-guidance/legislation/paperworkreductionactof1995/pra-listing/cms-10849 (includes Supporting Statement, ICR Form, and Crosswalk of Changes Between 60-Day Notice and 30-Day Notice); CMS, Response to Public Comments Received for CMS-10849, OMB 0938-NEW (Uploaded July 25, 2023), https://www.reginfo.gov/public/do/PRAViewDocument?ref_nbr=202307-0938-009.

(iii) Has practical utility. The agency shall also seek to minimize the cost to itself of collecting, processing, and using the information, but shall not do so by means of shifting disproportionate costs or burdens onto the public."[2]

In multiple instances, CMS's ICR fails to meet this standard. The following sections detail the extraordinary burdens BI will face in converting the mandated 30-day equivalent supply to a price per dosage form and strength of the selected drug and in meeting arbitrary word limits that curtail the "completeness" of a counteroffer justification.

I. By Failing to Provide a Clear Method for Manufacturers to Convert the "30-Day Equivalent Supply" for Each Dosage Form and Strength of the Selected Drug, CMS Imposes an Unreasonable Burden on Manufacturers

In its comments to the initial ICR, PhRMA asked CMS to provide "an electronic tool or Excel spreadsheet with CMS'[s] 10-step calculation approach for applying the MFP across different dosage forms and strengths."[3] In response to this comment, CMS noted that it "will share inputs on the 30-day equivalent supply methodology so that the Primary Manufacturer will have visibility into the implied unit prices based on the MFP for each dosage form and strength throughout the negotiation process."[4] While CMS's response is a step in the right direction, it stops short of providing a tool or spreadsheet to validate the calculation—relying instead on manufacturers to reverse engineer the calculation based on the "inputs" and the methodology CMS provides.[5] BI is concerned that, without clear instructions from CMS, the novelty of calculating a 30-day equivalent supply will add to a manufacturer's considerable burden of drafting a counteroffer within the short 30 day timeframe.[6]

As the ICR notes, the manufacturer may "reference information provided by CMS during the negotiation process . . . to understand how the 30-day equivalent supply counteroffer price will convert into prices for each dosage form and strength of the selected drug."[7] Since pharmaceutical pricing is not typically calculated by 30-day equivalent supply, understanding the actual price of each dosage form and strength of the selected drug will be critical to develop a counteroffer that fairly values the product. In recognition of the importance of this conversion, and the complexity of producing such novel calculations under short statutory deadlines, OMB should require that CMS commit to providing assistance or clear guidance to manufacturers to ensure that conversions from 30-day equivalent supply to a selected drug's list price are correct.

---

[2] 5 C.F.R. § 1320.5(d)(1)(i)-(iii).
[3] PhRMA, Comments on CMS Negotiation Offer Exchange ICR Form at 3, https://www.regulations.gov/comment/CMS-2023-0064-0011.
[4] Response to Public Comments at 7.
[5] *Id.*; *See* CMS, Medicare Drug Price Negotiation Program: Revised Guidance, Implementation of Sections 1191-1198 of the Social Security Act for Initial Price Applicability Year 2026 at 137-140, https://www.cms.gov/files/document/revised-medicare-drug-price-negotiation-program-guidance-june-2023.pdf.
[6] *See* SSA § 1194(b)(2)(C).
[7] ICR at 3.

II. CMS's Reasoning for Imposing an Arbitrary Word Limit on a Manufacturer's Counteroffer Justification Unreasonably Shifts the Costs of Collecting the Counteroffer Information to Manufacturers

CMS's revised 2,500 word limit for question 3 (the "justification of the counteroffer") is inadequate and imposes undue burdens on manufacturers because (1) it prevents manufacturers from providing a complete justification in accordance with the certification statement, (2) it provides insufficient space to address all the listed elements in question 3, and (3) contrary to CMS's assertion, longer submissions would not prevent the Agency from adhering to statutory time periods for setting the MFP.

By limiting the words available to provide a justification for a counteroffer, CMS undercuts its own requirement for manufacturers to certify that a submission is "complete and accurate."[8] CMS has stated that "[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."[9] As discussed below, the "standards described in this ICR" include different categories of information, all of which must fit within the 2,500 word limit. By imposing this strict word limit, CMS has created an artificial and unnecessary tension between its requirements of a "complete" submission and one limited to 2,500 words.

The 2,500 word limit is particularly inappropriate given the scope of information CMS requires in a counteroffer justification. According to the directions for question 3, a manufacturer must justify the proposed counteroffer by (1) providing information on the **nine** factors listed in section 1194(e) of the Social Security Act, (2) responding to CMS's justification for the initial offer, and (3) explaining why the original data submitted by the manufacturer does not support CMS's initial offer. Alone, any one of these categories would be appropriately addressed with more than 2,500 words. Together, the word limit is insufficient to touch on all the categories required by CMS with the proper level of detail.

Finally, CMS's purported justification for the word limit is unconvincing. In response to comments urging CMS to remove the word limit entirely, the Agency noted that "a word limit is needed due to statutory time constraints in the negotiation process."[10] CMS further explained that it needed to "allow sufficient time" for the negotiation process including "up to three post-counteroffer negotiation meetings and a final offer, as applicable."[11] CMS concluded that the 2,500 word limit provides "an appropriate balance between affording Primary Manufacturers the opportunity to share relevant information and ensuring that the negotiation process can be completed within the statutory time limits."[12] BI disagrees with this reasoning.

The current word limit accounts for roughly five single-spaced pages. Adding the 10 visual representations and 50 citations permitted by the ICR may bring the total submission package to 20 pages. It stretches credulity for CMS to suggest that any increase in the word limit would prevent the Agency from meeting statutory deadlines. Rather, by adopting an arbitrary and insufficient word limit, CMS has shifted the burden of collecting and processing the information to manufacturers in clear violation of federal regulations. We therefore urge

[8] ICR at 7.
[9] Response to Public Comments at 8.
[10] *Id* at 5.
[11] *Id*.
[12] *Id*.

OMB to remove any word limit and give manufacturers the discretion and space necessary to present a complete case for the MFP counteroffer.

* * *

Conclusion

Boehringer Ingelheim appreciates the opportunity to provide feedback on these proposals and looks forward to working with CMS and OMB to inform the development of meaningful policy solutions.

Thank you for considering these comments and those submitted by PhRMA. If you require any additional information or have questions, please contact Michael Penn, Head of Public Policy at (203) 791-6680 or michael.penn@boehringer-ingelheim.com.

Sincerely,

Bridget Walsh
Vice President
Government Affairs & Public Policy
Boehringer Ingelheim Pharmaceuticals, Inc.

Christine Marsh
Senior Vice President
Value and Access
Boehringer Ingelheim Pharmaceuticals, Inc.