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December 26, 2024

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

Re: Negotiation Data Elements and Drug Price Negotiation Process for Initial Price Applicability Year 2027 under Sections 11001 and 11002 of the Inflation Reduction Act (IRA) Information Collection Request (ICR) (CMS-10849, OMB 0938-1452)

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) *Negotiation Data Elements and Drug Price Negotiation Process for Initial Price Applicability Year 2027 under Sections 11001 and 11002 of the Inflation Reduction Act (IRA) Information Collection Request* (ICR or the ICR), including the Federal Register Notice, Supporting Statement – Part A, ICR Form (CMS-10849, OMB, 0938-1452).[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. Over the last decade, PhRMA member companies have invested more than $800 billion in the search for new treatments and cures, and they support nearly five million jobs in the United States.[2] The biopharmaceutical industry is committed to working every day to discover and develop new treatments for patients with complex and debilitating diseases such as cancer, heart disease, rare genetic disorders, and many more.

In advance of Initial Price Applicability Year (IPAY) 2026, PhRMA articulated concrete, actionable recommendations focused on key considerations under the Paperwork Reduction Act (PRA) for CMS on implementation and application of both the negotiation data elements ICR (data elements ICR) and drug price negotiation process ICR (counteroffer ICR). Unfortunately, as it did with most comments, CMS disregarded these recommendations. For the draft IPAY 2027 ICR, released in July of this year, PhRMA again reiterated our concerns with how CMS' ICR forms have continued to fall far short of the regulatory requirements established by the Paperwork Reduction Act (PRA). Yet, the Agency, outside of increasing their estimate of burden from 500 hours to 1,000 hours – which is still likely an underestimate – made only small changes and again failed to address the ICR's deficiencies under the PRA.

The PRA was enacted in 1995 in response to the "enormous growth of our federal bureaucracy" and "its seemingly insatiable appetite for data."3 Regulations implementing the PRA establish that in order to receive OMB approval, agency information collection requests must demonstrate that the agency has taken "every reasonable step to ensure that the proposed collection of information:

[1]Available for viewing at: https://www.cms.gov/regulations-and-guidance/legislation/paperworkreductionactof1995/pra-listing/cms-10849.
[2] PhRMA. (2023). 2024 PhRMA Annual Membership Survey. https://phrma.org/-/media/Project/PhRMA/PhRMA-Org/PhRMA-Refresh/Report-PDFs/PhRMA_2024-Annual-Membership-Survey.pdf.
[3] *Dole v. United Steelworkers of Am*., 494 U.S. 26, 32 (1990)

(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

(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."[4]

As noted in previous comment letters, CMS continues to fail each element of this regulatory test. Our comments on these failings continue to be disregarded by the Agency. Despite feedback from the OMB,[5] CMS made only minimal changes to the ICR forms. Accordingly, rather than reiterate our concerns on the mostly unchanged ICRs, we are attaching these recommendations as Appendices:

- Our comments on CMS' draft guidance for IPAY 2027 as Appendix A;
- Our comments on CMS' draft IPAY 2027 ICR as Appendix B;
- Our comments to CMS in response to the draft and revised IPAY 2026 "Negotiation Data Elements" ICRs as Appendixes C and D, respectively; and
- Our comments to CMS in response to the draft and revised IPAY 2026 "Negotiation Data Exchange" ICRs as Appendixes E and F, respectively.

Because CMS' revised ICRs continue to fail OMB's regulatory test for the PRA, it is incumbent on OMB to work with CMS to further modify the form. OMB must intervene as it is clear that CMS itself does not truly view this process as "negotiation" and is unwilling to revise the form to comply with the PRA. Instead, CMS continues requesting inordinate amounts of data, without even reporting on whether or how it used such data throughout the IPAY 2026 process. These actions demonstrate that the Agency believes manufacturers have little recourse but to adhere to CMS' arbitrary demands. Moreover, the fact that CMS already has access to much of the requested manufacturer-reported data raises the question of why the Agency even needs to request this data from manufacturers in the first place and further shows how the Agency is ignoring its duties under the PRA.

In particular, we ask OMB to work with CMS to revise its ICR form to minimize the reporting requirements and burden while still allowing manufacturers the ability to submit relevant supporting information on the selected product(s). To comply with the PRA, the requested information must not be unduly burdensome and must have utility by being directly relevant to the Agency's price setting process. CMS must demonstrate it truly needs and uses the information requested. If the information requested is not relevant or duplicates information the Agency already possesses, the Agency is required by the PRA to reduce and/or eliminate these reporting requirements and allow manufacturers to direct resources towards researching new treatments and cures for patients battling diseases, instead of seeking irrelevant,

[4] 5 C.F.R. § 1320.5(d)(1)(i)-(iii).

[5] Please see: https://www.reginfo.gov/public/do/PRAViewICR?ref_nbr=202306-0938-013 (requiring CMS to "provide an analysis of the 2026 negotiation data submissions from manufactures [sic] including, but not limited to, a meta-analysis of data from sections C: Research and Development Costs and Recoupment and D: Current Unit Costs of Production and Distribution. Also, in its 2027 ICR submission, CMS will address how it made improvements to the agency's ability to audit the manufacturers' data and improvements to the data collection more broadly from its analysis of the 2026 negotiation data."). CMS has not explained how it complies with this OMB request. CMS also appears to view the requirements of the PRA as perfunctory—ready to make the requisite certifications under the PRA without seriously evaluating whether the 2027 collection could reasonably be viewed as meeting such certifications. These include: certifying that each question in the collection is "necessary," "is not unnecessarily duplicative," "reduces ...burden on ...small entities;" uses "plain, coherent, and unambiguous terminology and is understandable to those who respond," is "consistent and compatible, to the maximum extent practicable, with the existing reporting and recordkeeping practices," and informs respondents how the information was used previously so as to justify collection for another year of the IRA price-setting. 5 C.F.R. § 1320.9

duplicative, and burdensome information that may not even be owned by so the so-called "Primary Manufacturer." Finally, it is incumbent on OMB and CMS to evaluate whether CMS used the volumes of information it required in the information requests for IPAY 2026. If CMS did not use such information, or only tangentially evaluated such information, CMS must revise its information collection requests accordingly.

I. CMS Noncompliance with PRA Requirements

In our previous comments, we have gone into great detail on how CMS is noncompliant with PRA requirements. Rather than restate the breadth of those comments here, please refer to our previous comments attached as Appendices to this letter. A brief summary of our key concerns with CMS' ICR follows below.

CMS previously acknowledged receipt of comments on the IPAY 2026 data elements ICR that noted the proposed submission requirements (i) are burdensome; (ii) request a large volume of data and/or level of detail Primary Manufacturers may not have access to; (iii) are unreasonable in light of the narrow, 30-day time frame manufacturers have to respond to the ICR; and (iv) would be better effectuated if respondents could employ reasonable assumptions regarding data submission.[6] Many of these comments were repeated in submissions received by the Agency during the 60-day comment period on the draft IPAY 2027 ICR. Yet, CMS has done little to reduce the burden on respondents and, in some cases, has even increased the burden of submission. For example, the length of the data elements ICR form increased from 47 pages to 73 pages between the IPAY 2026 ICR and IPAY 2027 ICR. Yet, the burden estimate, which was already significantly underestimated, has remained inordinately low.

Beyond the burden of answering all the questions and sub-questions within the lengthy 73-page data elements ICR form, the timeline by which the Agency requests this vast and far-reaching data submission is unreasonable and, in many cases, infeasible. The information requested by CMS often requires a lookback of one or more decades and also requires the intensive process of quality- and fact-checking the compiled data (which can be nearly impossible if possessed solely by a "Secondary Manufacturer"[7]) all within a 28-day period. On top of this, there is little evidence to validate why CMS needs the information requested as the Agency has provided no transparency into how or even if it used the vast amounts of data collected during the IPAY 2026 price setting process. Not only does this raise questions as to the goals behind the process, but it underscores a lack of consideration for the burden the request imposes on stakeholders or its duties under the PRA. At the end of the day, it is clear CMS' requests are fundamentally misaligned with the purposes and goals of the PRA.

As another example, CMS is often unclear in the ICR, which creates additional burden on data submitters and conflicts with PRA requirements to simplify and clarify reporting requirements.[8] While flexibility is important, CMS has not given clear instructions to manufacturers on how to report data (particularly financial data), potentially resulting inconsistencies across submissions. Such inconsistency can create an inequity in how CMS views submitted information to establish an MFP.

While we appreciate that CMS finally increased the burden estimate from just 500 hours to 1,000 hours, asking for respondents to undertake 1,000 hours of data collection within a 28-day time period nonetheless represents a violation of CMS' duties under the PRA. Moreover, the 1,000-hour burden estimate still significantly underappreciates the obligations placed on manufacturers. As discussed in our previous comments, a survey of PhRMA members reported estimates averaging over 7,700 hours of staff labor to comply, with approximately 21 business functions involved in responding. Members also

[6] CMS, Response to Public Comments Received for CMS-10847 at 1-2.
[7] While PhRMA is not reiterating our comments on the "Primary" and "Secondary" manufacturer construct in this letter, we refer readers to PhRMA's comments on the IPAY 2026 and 2027 guidance and the IPAY 2026 negotiation data elements ICR.
[8] 5 C.F.R. § 1320.9(c)

reported a significant need to employ external consultants, such as outside counsel, to complete the IPAY 2026 ICR. These obligations will have only increased in response to the IPAY 2027 ICR given it is substantially longer.[9]

The burden placed on manufacturers and other respondents is clearly unreasonable, especially when considering CMS already has access to much of the requested manufacturer-reported data and refuses to provide evidence that the requested data is truly relevant to the price setting process. The "manufacturer-specific" data elements remain largely irrelevant[10] to the price setting process and the time spent collecting or analyzing those submissions appears largely wasted.

In addition to not complying with the PRA's requirements to minimize burden, CMS has also failed to demonstrate that its information collection will maximize practical utility.[11] As one example, as mentioned above, there are continued inconsistencies between CMS' IRA guidance and the ICRs which may lead to different interpretations, assumptions, and data submissions which will ultimately lead to inconsistencies in the way CMS evaluates the data underscoring the lack of practical utility. Furthermore, PhRMA continues to object to CMS' proposal in Section G of the ICR to include coverage gap discounts and other "supply chain concessions" in the definition of "Manufacturer net Medicare Part D price" (with the revised ICR now requiring *both* (i) an average net Part D unit price and (ii) an average unit price – "best"). As PhRMA has now twice explained, if CMS intends to include these discounts to determine the prices of selected drugs, it is effectively circumventing the intent of Congress that selected drugs should not be subject to manufacturer discounts,[12] the successor discount program to the coverage gap discount program. In other words, Congress intended to separate MFP from the Part D discount programs, yet CMS ignores this by considering such discounts in setting the MFP.

Rather than forcing expenditure of time and resources on data collection that seems to serve no purpose, CMS could focus on working with manufacturers and key stakeholders – like patients, clinicians, and caregivers – to mitigate any potential unintended consequences from price setting by considering and prioritizing the critical data on the clinical benefit that selected drugs can offer to patients, caregivers, and society. Unfortunately, CMS continues to use these ICRs as a way to force manufacturers to comply with the Agency's arbitrary demands by placing an inordinate amount of burden on data submitters that, ultimately, has little to do with "negotiation."

II. Conclusion

PhRMA appreciates the opportunity to submit comments on the revised ICR. This letter outlines our key concerns regarding CMS' current and continuing noncompliance with the PRA but does not detail the totality of our concerns with CMS' voluminous ICR. 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.

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[9] A company survey of experience indicates that the information collection process was extraordinarily more burdensome than CMS estimated despite the extensive recommendations PhRMA provided to CMS on how to more productively facilitate collection. CMS not only requested information that was almost impossible to collect but also in a manner that significantly differed from corporate record-keeping.

[10] See, e.g., McElwee F, Cole A, Garrison LP, Towse A. June 14, 2024. Federal Support Should Not Be A Factor In Determining Pharmaceutical Prices Under The IRA. Health Affairs Forefront. Available at: https://www.healthaffairs.org/content/forefront/federal-support-should-not-factor-determining-pharmaceutical-prices-under-ira

[11] 5 C.F.R. §§ 1320.1; 1320.9(a).

[12] *See* PhRMA comments IPAY 2027 draft guidance, note 18. The IRA exempts selected drugs from the Manufacturer Part D discount program that begins in 2025, and which is the successor to the Coverage Gap Discount Program. SSA § 1860D-14C(g)(2)(B).

Please contact James Stansel (jstansel@phrma.org) and/or Elizabeth Carpenter (ecarpenter@phrma.org) if there is additional information we can provide or if you have any questions about our comments.

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