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

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)

Dear Deputy Administrator Seshamani:

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. Since 2000, PhRMA member companies have invested more than $1.2 trillion in the search for new treatments and cures, including $100.8 billion in 2022 alone.[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, despite our concerns regarding government price setting of medicines, PhRMA articulated concrete, actionable recommendations 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. We strongly recommend the Agency revisit these decisions and pave an alternative path forward. Rather than reiterate our concerns on the mostly unchanged ICRs, we are attaching these recommendations as Appendices. PhRMA is attaching:

- Our comments on CMS' draft guidance for Initial Price Applicability Year (IPAY) 2027 as Appendix A;
- Our comments to CMS in response to the draft and revised IPAY 2026 "Negotiation Data Elements" ICR as Appendixes B and C, respectively; and

[1]Available for viewing at: https://www.cms.gov/regulations-and-guidance/legislation/paperworkreductionactof1995/pra-listing/cms-10849.
[2] PhRMA. (2023). 2023 PhRMA Annual Membership Survey. https://phrma.org/-/media/Project/PhRMA/PhRMA-Org/PhRMA-Refresh/Report-PDFs/A-C/PhRMA_membership-survey_single-page_70523_es_digital.pdf.

- Our comments to CMS in response to the draft and revised IPAY 2026 "Negotiation Data Exchange" ICR as Appendix D and E, respectively.

Unfortunately, CMS' changes to the ICR forms fail to address the vast majority of our prior comments, which focused on key considerations under the Paperwork Reduction Act (PRA). CMS now has a year of experience with this process and has still declined to make any significant changes to either the ICR form or the burden estimates. PhRMA members also have concrete experience with the process that validates the concerns we raised in our prior comments. A survey of members demonstrated that companies – operating under the assumption of selection – spent a minimum of six months of high-intensity effort to comply with CMS' data request. These efforts required complex coordination across many business functions, requiring new methods, and extensive sourcing, reviewing, fact-checking, and developing data – much of which is old and/or not readily available – under compliance pressure. Most importantly, the data elements required by CMS in the ICR reflect a fundamental misunderstanding and mischaracterization of how research and development (R&D) works. This fatally flawed approach, coupled with a very poor data collection system,[3] a poor user interface and lack of functionality necessitates a change in approach.

Despite stakeholders' experience with the process, the Agency continues to ask for an increasingly unreasonable amount of data from manufacturers, often requiring a lookback of one or more decades. This growing burden is compounded by the fact that the requested data is often inconsistent with business practices, operational definitions, and in many cases requires completely new processes to obtain. For example, the ICR requires collection of data that may be solely possessed by a "Secondary Manufacturer"[4] and thus particularly difficult for a Primary Manufacturer to obtain. On top of this already burdensome request, the ICR 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") within a one-month period. Perhaps most alarming is that the Agency has provided no transparency into how or if it even used the vast amounts of data collected during the IPAY 2026 price setting process, raising questions as to the goals behind the process. This underscores that not only are these ICRs fundamentally misaligned with the purposes and goals of the PRA, but that the Agency has made no effort to carefully consider the burden on stakeholders in alignment with its duties under the PRA.

Even despite feedback from the Office of Management and Budget (OMB),[5] CMS made only minimal changes to the ICR forms. Instead of refining the questions asked to be more relevant to the price setting process as PhRMA requested in previous comments, the IPAY 2027 ICR changes only increase the burden of data submissions and, in many cases, reduce the utility of the form. In fact, the data elements

[3] Specifically, CMS relied on the Health Plan Management System ("HPMS") for data entry, but HPMS is a form-based system that requires users to enter each text response in a separate field. The system does not include a functionality for users to automatically upload a spreadsheet into the form, requiring users to copy and paste or to manually enter each line item. If there are multiple NDCs listed, this entry can require cutting and pasting into hundreds or thousands of fields. In addition, HPMS did not provide a confirmation copy of submissions and significantly slowed in its processing when under the strain of multiple users.
[4] 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.
[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," "avoids unnecessary duplication," "reduces burden on small entities;" uses plain, coherent, and unambiguous language that is understandable to respondents;" is "consistent and compatible with current reporting and recordkeeping practices;" or informs respondents how the information was used previously so as to justify collection for another year of the IRA price-setting.

ICR now extends for 69 pages, with the majority of questions included in Sections A – I comprising of multiple subparts. Additionally, the form continues to require respondents to submit vast amounts of data with unreasonable speed -- in just 28 days post-selection -- despite the difficulty, such as the form's inconsistency with ordinary business record-keeping and the difficulty faced by Primary Manufacturers in obtaining this data from "Secondary Manufacturers". To compile, review, and certify the requested data in the given timeframe, Primary Manufacturers must either risk waiting for the selection announcement and then certify a submission it could not have compiled and fact checked in 28days or are forced to assume they will be selected and spend countless hours and extraordinary expense compiling this information – a process, which, in part it will have to repeat if it is ***not*** selected during that year's IPAY. Even operating under the assumption that it will be selected, manufacturers will still struggle to certify the accuracy of their submissions as in a number of cases, CMS asks for this data to cover the preceding three years including the "calendar year ending December 31, 2024"[6] – even though that data may not be complete and ready for submission within the two months required to meet the March 1, 2025 deadline.

It is clear that CMS itself does not truly view this process as "negotiation". Instead, CMS' proposal to continue requesting inordinate amounts of data – without even reporting on whether or how it used such data throughout the IPAY 2026 process – shows that the Agency believes manufacturers have little recourse but to adhere to the Agency's arbitrary demands. The data collection process is not only flawed but it requires a significant amount of time and financial investment, well beyond the Agency's unchanged estimate of 704.25 hours at a total cost of $85,184.13 across a biopharmaceutical manufacturer. In fact, PhRMA members reported estimates averaging over 7,700 hours of staff labor to comply, with approximately 21 business functions involved in responding, and a significant need to employ external consultants, such as outside counsel.[7] These excessive and unworkable demands for manufacturer-specific data place an undue burden on manufacturers of selected drugs, while ultimately appearing irrelevant to the Agency's determined price. 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.

Unfortunately, patients and caregivers will ultimately bear the brunt of CMS' unworkable demands. CMS' approach to determining the Maximum Fair Price (MFP) for selected drugs has significant implications for patient access[8] and biopharmaceutical innovation.[9] Yet, instead of working with manufacturers and key stakeholders – like patients, clinicians, and caregivers – to mitigate these potential unintended consequences by considering the critical data on the clinical benefit that selected drugs can offer to patients, caregivers, and society, CMS instead focuses on collecting unnecessary and irrelevant data. Moreover, they do this while refusing to give any insight into how *and if* any of the data provided – including data submitted by these key stakeholders – was used in setting MFPs.

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[6] Draft Questions 16, 20, 22.
[7] 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.
[8] Hayden Consulting Group. (Sep 2023). IRA: Patient Access to Therapeutic Options. Available at: https://haydencg.com/ira-patient-access-to-therapeutic-options/.
[9] Philipson TJ, Ling Y, Chang R. (Oct 2023). The Impact of Price Setting at 9 Years on Small Molecule Innovation Under the Inflation Reduction Act.* The University of Chicago. Available at: https://bpb-us-w2.wpmucdn.com/voices.uchicago.edu/dist/d/3128/files/2023/10/Small-Molecule-Paper-Final-Oct-5-2023.pdf.

I. Requirements of the PRA and CMS' Noncompliance with these Requirements

The PRA was enacted in 1995 in response to the "enormous growth of our federal bureaucracy" and "its seemingly insatiable appetite for data". Regulations implementing the PRA establish that in order to receive Office of Management and Budget (OMB) approval, agency information collection requests must demonstrate that the agency 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
>
> (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."[10]

As noted previously, CMS continues to fail each element of this regulatory test.

First, CMS' proposed requirements for data submission – particularly related to manufacturer-specific data – are well in excess of what the Agency needs to implement the IRA's MFP provisions and fall well short of PRA compliance. The data requested is not the "least burdensome necessary" and CMS has not shown it is even considering the burden on respondents. The Agency has not fixed basic issues that increase burden, including in cases where the data elements will be impossible for the manufacturers to collect (e.g., cases where the original developer of a product no longer exists, or data cannot be reported at the level of precision requested by CMS given the incongruence with business practices for recording and accessing information) or fundamental issues with the Health Plan Management System (HPMS) portal that both PhRMA and its member companies raised in previous comments. In fact, the Agency has actually increased the length and the burden placed on the public through these forms and has not demonstrated that it is attempting to reduce the burden or seeking a way to be the "least burdensome necessary".

Second, the PRA requires agencies to ensure they do not demand already available data to avoid duplication. Yet, CMS has yet to offer a reasonable explanation for why it requires "publicly available" data, including fields like the "Federal Supply Schedule" and "Big Four Prices". CMS' explanation that a manufacturer could potentially have marginally more up-to-date data on such fields does not explain why the PRA would permit an agency to impose such a heavy burden on respondents in return for a hypothetical minimal benefit.

Finally, the Agency has not shown the data collected has any practical utility as there is no transparency in whether the submitted data is being used. There is no evidence that the vast amount of data sought by CMS actually informs the Agency's MFP decision-making. Indeed, in its draft guidance for IPAY 2027, CMS proposes exceedingly vague standards for how it will evaluate manufacturer-submitted data. CMS states that it will consider these data in "totality," and will use them to apply "upward," "downward" or "no" adjustments to the preliminary price. CMS states it will "consider each factor in isolation or in combination with other factors." In discussing each factor, CMS states that it "may" consider adjusting the preliminary price based on the data submitted, but then also states that its overall adjustment to price based on such data may "differ" from the examples it provides.[11] The collection process shifts

[10] 5 C.F.R. § 1320.5(d)(1)(i)-(iii).

[11] IPAY 2027 Draft Guidance at § 60.3.4. Note, PhRMA provided concrete recommendations on information collection in our comments to CMS in response to the draft and revised IPAY 2026 "Negotiation Data Elements" ICR. Please see Appendices B and C to this letter.

disproportionate costs and burden onto the public as the ICR seeks duplicative information and information that may not even be relevant to price setting.

To correct these shortcomings and comply with the PRA, PhRMA strongly suggests CMS review the suggestions in PhRMA's previous comments on reducing the burden posed by both ICR forms as well as the comments below.

II. General Comments and Recommendations

We continue to urge CMS to provide a format for data collection that facilitates flexibility, consistency, and compliance rather than unjustifiably increasing burdens on respondents and exposing them to potential liability. The below comments summarize some, but not all, of PhRMA's general concerns and recommendations to improve the ICR, to be considered in concert with our recommendations in our prior comments.

Burden Estimate:

Despite the increasing reporting burden relative to last year's ICR and numerous comments underscoring how CMS has underestimated this burden, the agency continues to report the same reporting burden estimate. Although the Agency states in the Supporting Statement that it is "considering design alternatives for Sections A, B, D, and G of the [data elements ICR] Form to reduce Primary Manufacturer data submission burden," these changes have not been implemented. In fact, CMS has only increased this burden with a drastic increase in the number of questions and length of the data elements ICR form. Yet, the Agency continues to unreasonably insist that manufacturers (across all team members working on a submission) will spend only 500 hours each (unchanged from IPAY 2026) to gather and submit the information CMS requires for the data elements ICR at a cost of about $52,720 per respondent (only slightly increased from IPAY 2026's estimate of about $51,600 per respondent). CMS also estimates that it will only take respondents 204.25 hours (unchanged from IPAY 2026) at a cost of approximately $32,460 per respondent (slightly *decreased* from IPAY 2026's estimate of approximately $32,730 per respondent) to develop and submit the information required by the counteroffer ICR. Such estimates are unreasonable on their face, but especially given CMS' estimate that the Agency will spend more than this amount for its own work (e.g., the Agency estimates it will cost approximately $1,118,600 to review the Section 1194(e) data submissions from Primary Manufacturers and the public and modify the HPMS system across the 15 selected drugs (approximately $74,570 per product)).

Timeline Considerations:

CMS' approach to the data elements ICR is fundamentally flawed. CMS' process requires submitters to consider every possible scenario with no bounds on the potential universe of products in just 28 days. As noted in previous comments, PhRMA believes that CMS must publicly identify the therapeutic alternative(s) or the therapeutic alternative(s) under consideration, along with any resources (e.g., manufacturer feedback, clinical guidelines, advisory panels, etc.) prior to the data submission. CMS could accomplish this and alleviate some of these issues by creating a scoping process in advance of the drug selection announcement to help determine potential therapeutic alternative(s) under consideration. Otherwise, not only will manufacturers of *potential* therapeutic alternatives feel compelled to submit potentially irrelevant data, but the data CMS receives from the public through Section I will be more likely to contain irrelevant and unnecessary data. While we appreciate CMS including the option to submit a dossier in Question 36 to support more narrative answers to Questions 30 through 35 and Question 37, it does not significantly reduce the burden on manufacturer data submitters given the universe of potential scenarios.

Additionally, as stated in prior comments, requiring all data to be collected, certified, and submitted, without an opportunity to supplement, in less than one month is unreasonable given the substantial amount of information requested. Furthermore, it disadvantages patients, caregivers, and other key

respondents from traditionally underrepresented or underserved communities who may not be as well-funded or able to pull together this data on such short notice. To mitigate these issues CMS should consider: (a) reducing the burden of the data collected; (b) allowing all respondents to supplement data submissions; and (c) extending data collection deadlines wherever possible. CMS should seek the most accurate and complete picture possible when setting prices that can have serious implications and consequences for America's seniors and disabled individuals enrolled in Medicare. In addition, a supplemental response may not always be necessary, and manufacturers should not be penalized should they choose not to submit a dossier if the answers are otherwise sufficient.

Lack of Substantial Changes to the Manufacturer Data Elements:

The Manufacturer Data Elements continue to be flawed and incongruent with current business practices. As stated above, many of the questions in this section also violate the PRA in terms of both utility and necessity. For example, CMS continues to break R&D costs into five categories. As we have previously explained, this subdivision is well beyond how manufacturers report such data in other contexts, how they organize data, and potentially contravenes manufacturers' document retention policies.[12] Furthermore, the breadth of R&D cost data required to be submitted in order for CMS to determine if these costs have been "recouped" is unnecessary and based on a fundamentally flawed concept of "recoupment". As PhRMA and others have continually noted, very few drug candidates among those entering clinical trials are ultimately successful in reaching approval by the FDA—in fact, just 12 percent.[13] Companies account for these odds when they plan their R&D programs across portfolios and ultimately rely on the revenues from a few successful medicines to discover new medicines and to help recoup costs of the many failures across their entire portfolio of medicines. Therefore, not only is this information nearly impossible to collect in the manner in which CMS requests it, given the nature by which R&D investment occurs, but it serves no practical utility as the question of recoupment could be simply answered via a checkbox (e.g., if the product has "recouped" its investment or not). Moreover, CMS relies on flawed logic for the purposes of assessing recoupment by comparing some of the costs associated with selected medicines to global, total lifetime manufacturer revenue figures, clearly violating accounting matching principles. For these reasons, we continue to reiterate prior comments recommending CMS amend the ICR to allow a single global response for all manufacturer's R&D costs across all development programs, similar to a Form 10k for Securities and Exchange Commission filing, and a single attestation (YES/NO) for recoupment.

Furthermore, much of the data CMS requests is duplicative of data CMS already has access to and which is already publicly available. For example, CMS continues to demand expansive and burdensome data – such as "any patents that are, have been, or may be listed for the selected drug in the FDA Orange Book or Purple Book; utility patents that claim the drug product (formulation or composition), drug substance (active ingredient), metabolites or intermediaries of a selected drug, method(s) of using the drug, or method(s) of manufacturing the drug; and design patents that, for example, claim a design on the packaging of the selected drug". We continue to urge CMS to procure information on approved patent applications from the FDA's Orange Book and Purple Book listing and relevant drug information regarding approved drug applications under the FDCA and PHSA from Drugs@FDA as these are publicly available data sources. Likewise, the expanded patent information requested this year is also available from the USPTO using the patent public search tool. Similar to prior comments, we continue to recommend that manufacturers should be permitted to check a box stating that CMS may use these publicly available resources in lieu of manufacturer submission of duplicative data.

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[12] Note: On p. 11 of the supporting statement, CMS says: "There are no special circumstances that would require information collection for the [data elements and counter-offer] forms . . . to be conducted in a manner that requires respondents to [among other things] … Retain records, other than health, medical, government contract, grant-in-aid, or tax records for more than three years." CMS should confirm this certification.

[13] DiMasi JA, Grabowski HG, Hansen RW. (Feb 2016). Innovation in the pharmaceutical industry: New estimates of R&D costs. J Health Econ. 47:20-33. DOI: 10.1016/j.jhealeco.2016.01.012. Available at: https://pubmed.ncbi.nlm.nih.gov/26928437/

It is CMS' responsibility under the PRA to not only be committed to reducing burden whenever possible but also provide justification for each element of data. If these elements cannot be justified as they do not directly influence CMS' MFP decision-making, CMS must reformulate its request to reduce the associated burden.

Lack of Clarity:

CMS has not provided any insight or clarity into how the data will be used or even if the data will be used in the Agency's decision-making. This includes, but is not limited to, any information or structure around how the different sections will be weighted (i.e., if -- as suggested by PhRMA and other key stakeholders[14] -- CMS will assign a greater weight to the Section I factors that actually reflect the benefit the selected drug brings to patients, caregivers, and society), and Section G asking for the "Manufacturer Net Medicare Part D price," inclusive of coverage gap discounts "and other supply chain concessions (e.g., wholesale discounts) not reflected in the sum of the plan-specific enrollment weighted amounts calculation," reported at the NDC-11 level.[15] As noted by PhRMA in our comments on the IPAY 2027 initial guidance, the terms "other supply chain concessions" and "wholesale discounts" are poorly defined and overly broad. Furthermore, CMS is suggesting that manufacturers report aggregate price concessions for supply chain entities across the pharmaceutical supply chain, but this calculation would not accurately reflect the net price to Medicare Part D plans at the NDC-11 level as price concessions for supply chain entities are not net prices available to Part D plans. As such, this calculation is not only an inaccurate accumulation of discounts for CMS to require but represents significant burden upon Primary Manufacturers that would be required to track and aggregate these price concessions at the NDC-11 level, which would go well beyond the burden permitted under the PRA.

Furthermore, PhRMA commented in response to CMS' IPAY 2027 Draft Guidance that the proposal to net out coverage gap discounts (or manufacturer discounts) as part of establishing the starting point for developing an initial offer for a selected drug circumvents Congress' directive to exempt selected drugs from being subject to such discounts.[16]

CMS has also not provided any clarity or articulated a process for arriving at one MFP across multiple indications or multiple products containing the same active ingredient or moiety. This is particularly concerning given CMS' overbroad interpretation of qualifying single source drug, which improperly treats new dosage forms and formulations containing the same active ingredient or moiety as the same drug, even if the drug was approved under a different marketing application. As a result, biopharmaceutical companies are already reconsidering the economic feasibility of investing in post-approval R&D, including whether to bring new drug or biological products to market that could provide valuable new treatment options for different diseases or patient populations, or provide a new method of administration. We are concerned that the granularity of the data and the questions included in the ICR suggest CMS may be exploring a prevalence or volume weighted approach to setting the price, without any explanation in guidance or this ICR of how these data will be used. This will devalue drugs with multiple indications in the price setting process and thereby further discourage post-approval R&D. We urge CMS to consider the compounded effect this approach may have on R&D investments to bring forward these critical treatment advances to meet unmet patient need.

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[14] McElwee F., Cole A., Garrison L.P., Towse A. (Jun 2024). Federal Support Should Not Be A Factor In Determining Pharmaceutical Prices Under The IRA. Health Affairs Forefront. DOI: 10.1377/forefront.20240613.956455 Available at: https://www.healthaffairs.org/content/forefront/federal-support-should-not-factor-determining-pharmaceutical-prices-under-ira.

[15] Although PhRMA disagrees that the Agency should use coverage gap discounts at all in the price-setting, we note that the Agency already has access to these data.

[16] PhRMA comments IPAY 2027 draft guidance, note 18. Specifically, 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.

Lack of Transparency:

As stated above, it is clear from CMS' approach to the ICR that CMS believes manufacturers have little recourse but to adhere to the agency's arbitrary demands – even when they violate the spirit and standards of the PRA. CMS has not made adequate attempts to reduce the burden placed on manufacturers and it is not clear if CMS is even utilizing the massive amounts of data requested from manufacturers. It is not apparent if CMS even knows what information it needs, as the Agency to date has not explained precisely how it uses manufacturer- and stakeholder-submitted information to develop a replicable MFP or the "clear and consistent" methodology required by statute.

CMS' lack of transparency may also have the unintended consequence of "chilling" participation from patients, caregivers, clinicians, and other key stakeholders. Unless CMS provides some form of insight into how it is using the data these stakeholders take the time to provide, potential data submitters may not feel that their investment is worth the time or the effort. To avoid this, CMS must transparently demonstrate that it is carefully considering the data provided both through the ICR process and the stakeholder listening sessions by releasing information on what information the Agency considered and what types of stakeholders (e.g., patient, academic researcher, biopharmaceutical manufacturer) the data originated from.

Lack of Context:

CMS continues to ask questions that fall far short of capturing the full context surrounding the requested data. We support CMS' goal of prioritizing patient perspectives in its decision-making, and as such, continue to ask CMS to ensure that its data collection seeks to fully understand the market and any unintended consequences from price setting. For example, Section C splits R&D costs in artificial ways which provides no vehicle to adequately describe the full innovation story of a selected drug and the non-linear process pharmaceutical innovation usually takes, with many starts, stops, and dead ends, all of which entail significant costs. Additionally, the value of a drug must be considered across the product's lifecycle, not just at the time of selection which may be years after a drug was approved to address a specific need or gap. Thus, some of the language used by CMS in Section I, such as that the Agency will consider whether a selected drug is "currently meeting an unmet need" [emphasis added], misses much of this context and should be reframed to capture whether patients, clinicians, and other key stakeholders believe the selected drug has met an unmet need *from launch*. Finally, Section D also does not explicitly consider certain supply chain costs (e.g., wholesaler fees, other distribution costs) that are critical to CMS understanding the true "current unit costs of production and distribution" that a manufacturer incurs for the drug. MFPs rooted in data that lack context, such as the examples described above, fail to appreciate the full value of selected drugs which could have real consequences for patients including, but not limited to, potential access barriers.

Unnecessary Character and Citation Limits:

As PhRMA has previously noted, CMS' arbitrary word and citation limits negatively impact the ability of all data submitters, including patients, caregivers, and manufacturers, to provide the narrative explanations CMS seeks. Especially given the various scenarios that must be accounted for – as CMS does not announce or supply the therapeutic alternative(s) under consideration prior to the data submission deadline – CMS is depriving respondents of the ability to provide important contextual and narrative information on the selected drug and its therapeutic alternative(s). Instead of making strides to fix this oversight, CMS doubled down on limiting respondents' freedom to answer questions comprehensively by replacing word limits with character limits. Considering that many of the questions ask for scientific or technical answers – both of which require long and technical terminology – CMS' change may actually shorten the answers data submitters are allowed to provide.

Protection of Proprietary Information:

While we appreciate CMS adding questions 28 and 64 to allow respondents to identify information that should be withheld by CMS under FOIA Exemption 3 and/or 4,[17] this is only a first step as there are other proprietary/confidential commercial information concerns that go beyond FOIA.

First, Congress drafted the IRA to impose on CMS an obligation to vigorously protect manufacturer-submitted proprietary data – a protection that extends beyond simply withholding it from FOIA releases. Such information shall be "used only by the Secretary or disclosed to and used by the Comptroller General of the United States for purposes of carrying out this part [Part E of Title XI of the Social Security Act]".[18] CMS should recognize this limitation in its form(s) and explain how it will ensure information is used only to carry out the price-setting provisions of the IRA (as well as whether the agency will establish a process similar to the "reverse FOIA" process to allow submitters to be notified of and possibly contest any "use" of submitted data for purposes other than carrying out the IRA price-setting provisions).

In addition, CMS should amend the ICR to be clear that the agency continues to be bound by regulations at 45 CFR Part 5, including (1) the requirement that CMS allow submitters to designate information as confidential commercial information *after* submitting it; and (2) requiring CMS to engage in a pre-disclosure notification process, including in cases where a submitter did not designate information as confidential-commercial and the government has "substantial reason to believe that information . . . could reasonably be considered exempt . . . as [confidential commercial information]". [19]

CMS also should remove all character/word limits for explanations, so entities are not limited in describing the confidential commercial or proprietary nature of the submission.

Finally, as stated in previous comments, CMS needs a robust security protocol for protecting manufacturer proprietary information. In IPAY 2026 draft guidance comments, PhRMA already provided comments and recommendations on how CMS could create a robust confidentiality and data security protocol.

Section H. Certification:

PhRMA reiterates comments on the significant issues associated with the required certification included in this Section. Please refer to our 2026 comments.

Section I Data Submission Affiliations:

PhRMA continues to have serious concerns over the definition of "affiliated with the manufacturer of the selected drug" as used in Question 29. This shortsighted definition goes beyond other definitions of affiliations to include non-financial relationships. Additionally, although unclear on this point, the draft ICR could be read to request a response not just from researchers (as was the case for IPAY 2026) but from all respondents, including patients and caregivers. This could chill participation as some stakeholders may engage with manufacturers but do not have a conflict of interest as that term is commonly understood. Indeed, labeling such relationships as "conflicts" does a disservice to the patients and caregivers who may seek out relationships with manufacturers precisely because these manufacturers' products provide important therapeutic benefits for their or a loved one's condition. Finally, CMS ignores all other conflicts of interest, including from payers or pharmacy benefit managers that have a vested interest in profiting off drug prices with no countervailing interest in ensuring continued development of new medicines for patients.

[17] 5 U.S.C. § 552(b)(3), (4)
[18] Social Security Act § 1193(c)
[19] 45 C.F.R. §§ 5.41-5.42

Changes to Section I

While PhRMA appreciates many of the changes made to Section I, including splitting the questions into relevant sections and writing the "Patient- or Caregiver-Focused Input" section in a more lay-friendly way, we continue to have concerns with the information sought by the Agency. Some of the questions (e.g., Questions 33A, 33B, 56A, 56B) seek information that CMS should already be able to access. Furthermore, these new questions seem to discount the importance of meaningful engagement with patients and caregivers, who are often experts with lived experiences and opinions critical to CMS' decision-making.[20] For example, the patient and caregiver section (Questions 38 – 44) does not include a question asking respondents for their thoughts on potential therapeutic alternatives despite directly asking researchers (Question 53) and clinicians (Question 47c) for their thoughts. Furthermore, CMS fails to ask patients and caregivers for what they consider to be patient-important or centered outcomes the Agency should consider, although it asks academics for clinical outcomes (Question 54b) and clinicians for outcomes they use to "assess improvement or treatment response (Question 46b).

Equity Considerations:

To fully include and incorporate voices from diverse and potentially medically underserved populations in its analyses, CMS should actively seek out the viewpoints and lived experiences of communities most impacted by the therapeutic areas treated by the selected drugs. While we cannot comment on the stakeholders who submitted and had data considered by CMS, as the Agency has provided no transparency into that process, observers have noted that speakers at listening sessions were primarily white and under the age of 65.[21] This is not necessarily reflective of the populations that will be most impacted by CMS' price-setting. As stated earlier in this letter, the ICR process and timeline inherently disadvantages those from under-resourced communities. Furthermore, the manner in which the Agency is seeking input on research metrics (e.g., only asking researchers questions on methodologies via Question 54A) raises questions on how CMS is considering metrics related to equity. In fact, the Agency's willingness to potentially consider cost-effectiveness measures so long as they do not discriminate against someone "who is elderly, disabled, or terminally ill" raises concern that CMS may rely on metrics known to undervalue communities of color.[22,23]

Separately, PhRMA appreciates the step forward the Agency took to attempt to collect demographic information from patient and caregiver respondents. This information can help CMS ensure that it is considering data and information that reflects the populations treated by a selected drug. To this end, PhRMA suggests the Agency collect this information from all non-manufacturer respondents. This includes collecting information from clinician respondents on approximately how many days per month a clinician sees patients and basic information on the population treated (e.g., percent of patients treated taking the selected drug, practice zip code) to make sure the Agency prioritizes data from providers working with and reflecting the views of the populations most likely to be impacted by CMS' price setting decisions. To hold itself responsible for meeting these goals and creating a more patient-centric process, CMS also must commit itself to transparency. This includes releasing summarized information

[20] Oehrlein E.M., Edwards H.A., Howarth T.J., Vandigo J. (Nov 2023). Listening Sessions Can Help CMS Become More Patient-Centered. Here's How The Sessions Could Be More Effective. Health Affairs Forefront. DOI: 10.1377/forefront.20231031.623114. Available at: https://www.healthaffairs.org/content/forefront/listening-sessions-can-help-cms-become-more-patient-centered-here-s-sessions-could-more.

[21] Patterson J. (May 2024). Breadth of Patient and Stakeholder Input in CMS's Drug Price Negotiation Program: A Content Analysis of the 2023 Patient-Focused Listening Sessions. National Pharmaceutical Council. Available at: https://www.npcnow.org/resources/breadth-patient-and-stakeholder-input-cmss-drug-price-negotiation-program-content.

[22] Stetler P. (Mar 2023). The Eugenic Roots of 'Quality Adjusted Life Years,' and Why They Matter. Washington Post. Available at: https://www.washingtonpost.com/made-by-history/2023/03/08/qlay-disabilities/.

[23] Andrade G. (Jan 2024). Ethical Shortcomings of QALY: Discrimination Against Minorities in Public Health. Cambridge Quarterly of Healthcare Ethics. 1-8. doi:10.1017/S0963180123000580. Available at: https://www.cambridge.org/core/journals/cambridge-quarterly-of-healthcare-ethics/article/abs/ethical-shortcomings-of-qaly-discrimination-against-minorities-in-public-health/04012151EAB7F9629D55D672EEA4CB22.

on the demographic information of respondents participating in the data collection process, the number and types (e.g., patient, clinician, academic) of respondents that submitted data, participated in listening sessions, and had data used by CMS in its MFP calculation to ensure the Agency considers information from a wide range of diverse stakeholders.

Quality-Adjusted Life Years and Similar Cost-Effectiveness Metrics:

As stated in PhRMA's prior comments, CMS' decision to rely on flawed cost-effectiveness standards in MFP decision-making is both misguided and unnecessary. Reliance on cost-effectiveness measures, whether it is rooted in the quality-adjusted life year (QALY) or another similar metric, as the basis for policy decisions risks further discriminating against the elderly, the disabled, and underserved and underrepresented people of color who are already at higher risk of not receiving the care they need.

CMS should not consider cost-effectiveness metrics, even if the data submitter claims they do not believe their submission discriminates against the elderly, the disabled, or the terminally ill. The Agency has a duty to make sure it relies on the best data possible to make sure its MFP decision-making does not exacerbate any existing health disparities and considers (to the degree feasible in CMS policy decision-making) the differing needs of individual patients and sub-populations. As such, to ensure CMS does not use any cost-effectiveness measures in its decision-making – in accordance with Section 1557 of the Affordable Care Act and Section 504 of the Rehabilitation Act – the Agency must, at the very minimum, make clear that Question 63 is mandatory for all respondents and that CMS will not consider cost-effectiveness measures in its decision-making. Furthermore, Question 56c is the only question that contains a reminder that CMS will not use the QALY or evidence that potentially discriminates against the selected (elderly, disabled, or terminally ill) populations despite asking for methodologies. Yet in the same section, CMS asks for potential frameworks to consider in Questions 54a, and questions on evidence in Questions 54c and 57. Any time that CMS asks a question in which the respondent could respond with evidence generated via a QALY or other similar cost-effectiveness measures, it must contain a reminder that respondents should not submit this evidence as CMS will not consider it or use it in its decision-making.

Technical Improvements

In addition to the comments above, PhRMA noted a few technical discrepancies the Agency should consider for improving the functionality of the ICR forms. This includes renaming the "Patient-Focused Experience" header to be more inclusive of respondent types and to match the description in the instructions that calls the section "Patient- or Caregiver-Focused Input". Furthermore, there are small typographical errors the Agency should fix including in Question 39A where it asks "How do the condition(s) you listed in Question 39 impact your daily life and well-being or the daily life and well-being of someone you provide care for?" This question should refer back to Question 38 instead of 39. Additionally, despite asking for different information, Questions 46 and 47 are both confusingly titled "Treatment-related Questions". Finally, CMS should consider the readability and navigation of Section I for public respondents, especially if seeking information from those actually enrolled in Medicare. This includes ensuring the form is both easily accessible, without a large number of "clicks" to navigate to the form from CMS' homepage, and easily navigable, so respondents can readily find required questions and navigate to the desired section(s).

III. Conclusion

PhRMA appreciates the opportunity to submit comments in response to the *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.* We continue to urge CMS to limit the data that must be provided to elements essential to operation of the Program; leverage data already available to CMS as much as possible; and provide additional time for supplemental data

submission to the greatest extent possible. 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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