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December 22, 2025

VIA ELECTRONIC FILING – http://www.regulations.gov

Chris Klomp
CMS Deputy Administrator and Director of the Center for Medicare
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-10849
P.O. Box 8010
Baltimore, MD 21244-8010

Re: Drug Price Negotiation for Initial Price Applicability Year 2028 Under Sections 11001 and 11002 of the Inflation Reduction Act Information Collection Request (CMS-10849)

Dear Deputy Administrator Klomp:

The Pharmaceutical Research and Manufacturers of America (PhRMA) appreciates the opportunity to submit these comments in response to the Centers for Medicare and Medicaid Services' (CMS, the Agency) *Drug Price Negotiation for Initial Price Applicability Year 2028 Under Sections 11001 and 11002 of the Inflation Reduction Act Information Collection Request* (ICR or the ICR) *(CMS-10849)*. PhRMA represents the country's leading innovative biopharmaceutical research companies, which are laser-focused on developing innovative medicines that transform lives and create a healthier world. Together, we are fighting for solutions to ensure patients can access and afford medicines that prevent, treat, and cure disease. Over the last decade, PhRMA member companies have invested more than $850 billion in the search for new treatments and cures, and they support nearly five million jobs in the United States.[1]

PhRMA appreciates and supports this Administration's commitment to eliminating waste, fraud, and inefficiencies from the healthcare system. We would also like to emphasize that burdensome data collections and processes generate increased waste, which ultimately results in higher costs for American taxpayers. As such, while we acknowledge a small number of improvements in the revised ICR, PhRMA remains concerned with the lack of transparency, as well as inconsistent processes and methodology, within the Inflation Reduction Act (IRA) price setting program. This lack of consistency and transparency increases the burden on manufacturers and other data submitters, such as patient and provider advocates, and exacerbates the MFP program's harmful effects. Additionally, because of this wasteful process, CMS estimates the Agency will itself spend about 2.6 million dollars in one year receiving, reviewing, and processing "data elements" submitted in response to the Initial Price Applicability Year (IPAY) 2028

[1] PhRMA. (July 2025). 2025 PhRMA Annual Membership Survey. Available at: https://cdn.aglty.io/phrma/Report%20-%20PhRMA%202025%20Annual%20Membership%20Survey%20-%20July%202025.pdf

ICR,[2] which – like the burden estimate for manufacturers and other data submitters – is likely a significant underestimate.

Consistent with the President's goal to "improve the transparency of the Medicare Drug Price Negotiation Program,"[3] we also encourage the Administration to increase transparency into how CMS uses manufacturer and stakeholder-submitted data as part of the "clear and consistent" methodology required by statute. The current ICR's lack of transparency results in an opaque process with unclear decision-making standards and exceptionally comprehensive and burdensome data submission requirements that generate waste and violate the spirit and letter of the Paperwork Reduction Act (PRA).

Despite PhRMA's remaining concerns with the burdensome data collection process, as is consistent with prior comments, we commend CMS for its willingness to adopt some proposed changes contained in the revised ICR. PhRMA's response to the revised ICR, which we provide in more detail below, is summarized as follows:

- **Reporting of (e)(1) Factors by Indication.** PhRMA supports the Agency's decision to eliminate the requirement to report certain (e)(1) factors by indication.
- **Patents, Exclusivities, and Approvals.** PhRMA supports the Agency's removal of the previously proposed instruction for manufacturers to clearly identify patent(s) that are "composition of matter" patents.
- **Primary Manufacturer Identification of Proprietary Information.** PhRMA supports the revisions on identifying and justifying each item of proprietary information.
- **Patient Focused Experience Questions.** To support meaningful stakeholder engagement in the price setting process, CMS must allow patients and caregivers to comprehensively respond to patient experience questions without arbitrary character limitations.

The comments summarized in the four bullets above primarily address only revisions to the draft ICR. However, most of the ICR remains unchanged. Rather than reiterating all of PhRMA's previous recommendations on the mostly unchanged ICRs, we are attaching to this letter several Appendices previously submitted to the Agency. Specifically, we are attaching:

- Our August 29, 2025 comments on the draft ICR forms, which we hereby incorporate by reference and include as Appendix A;
- Our technical comments on data collection, included as an appendix to our IPAY 2028 comments as Appendix B; and
- A two-page document previously shared with the administration on ways to improve the burdensome and wasteful data collection process under the IRA as Appendix C.

* * *

I. Reporting of Manufacturer-Specific Data Elements [(e)(1) Factors] by Indication

PhRMA commends CMS' proposal to remove the requirement that manufacturers report certain Section 1194(e)(1) factors (hereinafter referred to as the "(e)(1) factors" or "manufacturer-specific factors") by indication. As our past comments on the IPAY 2026 and IPAY 2027 ICRs have described in

[2] CMS, IPAY 2028 Information Collection Request Draft Supporting Statement at 28-30.
[3] EO 14273, 90 Fed. Reg. 16441 (April 18, 2025).

detail, the previous Administration interpreted the statute in a manner that led them to require Manufacturer-Specific Data Elements that were flawed and incongruent with current biopharmaceutical manufacturer business practices. For example, CMS' reporting requirements for Research and Development (R&D) Costs is divided into several categories- an approach that is entirely misaligned with how manufacturers track, allocate, and publicly report these costs, creating significant compliance challenges under compressed timelines.

While this Administration's proposal to streamline R&D data for IPAY 2028 by collapsing R&D costs into two categories was a modest improvement, these changes are not sufficient to alleviate the unnecessary burden. Requiring manufacturers to separately report the costs of basic preclinical research for the selected drug and post-IND costs does not make the submitted data more relevant to determining MFP. What's more, the original requirement to additionally report multiple (e)(1) factors by indication, including some R&D Costs and Prior Federal Financial Support, was entirely infeasible as manufacturers cannot easily reconstruct highly detailed R&D costs or detailed accounts of federal financial support for drugs developed over a decade or more ago and across potentially multiple indications. These challenges have long been confounded by CMS' overly broad definition of QSSD to include products approved under different marketing authorization applications.

Despite these challenges, we applaud this Administration's decision to eliminate the requirement to report certain (e)(1) factors by indication and believe it represents an effort to address the burden and methodological inaccuracies that resulted from the past Administration's approach to implementation of the (e)(1) factors. Nevertheless, these changes do not sufficiently reduce the burden on manufacturers related to (e)(1) data submissions, nor does it ensure that the data submitted is more pertinent to determining MFP.

While we appreciate this Administration's willingness to consolidate some categories of R&D costs, as previously proposed, and remove the requirement that some of those factors be reported by indication, rather than continuing this highly flawed approach, PhRMA strongly recommends that CMS allow a single global response for all the manufacturer's R&D costs across all development programs, similar to a Form 10K for Securities and Exchange Commission (SEC) filing, and a single attestation (YES/NO) for recoupment with the option to provide a supporting narrative. Additionally, given the ICR requests a far broader and more detailed array of data than necessary or authorized, some of which appear grounded in erroneous assumptions about manufacturers' ability to gather such data, PhRMA recommends that CMS report how the data that is submitted is used to influence the determination of MFP. CMS has now had two cycles of data reporting and price-setting, and is positioned to evaluate whether the voluminous data submissions it mandates comply with the Paperwork Reduction Act. In the event that data collected is not found to be directly relevant to the MFP determination process, CMS should not burden manufacturers with collecting and reporting such factors.

II. Patents, Exclusivities, and Approvals

In the draft ICR forms proposed earlier this year (CMS-10849, OMB 0938-1452), CMS proposed to instruct manufacturers to clearly identify patent(s) that are "composition of matter" patents beginning in IPAY 2028. PhRMA strongly opposed this proposal. ***Therefore, we commend CMS for removing the instruction from the revised ICR.***

Patent law requires that all inventions be new, useful, and nonobvious to be patented, regardless of the innovation covered by the patent. Therefore, all patents covering a medicine should be considered equally and CMS should commit to refraining from putting greater emphasis on certain types of patents over others when setting prices. Additionally, given that there is no existing or proposed guidance establishing the utility of identifying specific types of patents, this requirement would not be relevant in determining the price of the selected product, and therefore, could violate the PRA as lacking utility vis a vis CMS' policy instructions.

III. Primary Manufacturer Identification of Information Submitted in Sections A through G that Should be Withheld as Proprietary Information

We appreciate revisions to the instructions for Q26 on how to identify the location of information that the Primary Manufacturer believes should be redacted and adding justifications specific to each piece of information. We believe this change will allow manufacturers to target justifications to each item of confidential commercial information. However, we reiterate that character limits on justifications may mean that a respondent is not able to fully articulate why information is proprietary. The 2,400-character limit (approximately 200 words) certainly should not constrain a manufacturer's ability to later claim that information is proprietary, or to avail themselves of protections included in FOIA regulations, including those at 45 CFR § 5.42. ***As PhRMA has previously advocated, CMS should create a process similar to that used under FOIA for notifying manufacturers and allowing for prospective adjudication, not only for public release, but also when the government plans to use data in a manner that may violate SSA § 1193(c).*** We refer readers to Part IV of the attached August 29, 2025 comment letter (Appendix A) for additional context on protecting confidential information.

IV. Patient Focused Experience Questions

As PhRMA has previously noted, CMS' arbitrary character and citation limits negatively impact the ability of all data submitters, including patients, caregivers, and manufacturers, to provide the narrative explanations CMS seeks to inform the price setting process. Instead of making strides to fix this oversight, CMS in the revised ICR has substantially restricted character limits on several patient-focused experience questions from 36,000 to 6,000 characters (or from 3,000 words to about 500 words), thereby limiting respondents' ability to answer questions comprehensively. Such restrictions, including on questions regarding patient information on the current and past medications used to treat their conditions (questions 30 and 31, respectively), materially discount the importance of meaningful engagement with patients and caregivers, who are often experts with lived experiences and opinions critical to CMS' decision making. ***To support meaningful stakeholder engagement in the price setting process, CMS must both seek robust patient experience information and allow for respondents to comprehensively respond to questions that they are uniquely poised to answer without arbitrary character limitations.***

* * *

PhRMA appreciates the opportunity to submit comments in response to the *Drug Price Negotiation for Initial Price Applicability Year 2028 Under Sections 11001 and 11002 of the Inflation Reduction Act Information Collection Request.* Please contact Elizabeth Carpenter (ecarpenter@phrma.org) and/or James Stansel (jstansel@phrma.org) if we can provide additional information or answer any questions related to our comments.

Sincerely,

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Elizabeth Carpenter	James C. Stansel
Executive Vice President	Executive Vice President and
Policy and Research	General Counsel
PhRMA	PhRMA

Appendix A

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August 29, 2025

VIA ELECTRONIC FILING – http://www.regulations.gov

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

Re: Drug Price Negotiation for Initial Price Applicability Year 2028 under Sections 11001 and 11002 of the Inflation Reduction Act (IRA) Information Collection Request (ICR) Forms (CMS-10849, OMB 0938-1452)

Dear Deputy Administrator Klomp,

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 2028 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 laser focused on developing innovative medicines that transform lives and create a healthier world. Together, we are fighting for solutions to ensure patients can access and afford medicines that prevent, treat and cure disease. Over the last decade, PhRMA member companies have invested more than $850 billion in the search for new treatments and cures, and they support nearly five million jobs in the United States.

We are heartened by this Administration's commitment to eliminating waste, fraud, and inefficiencies from the health care system. We support the goals expressed in the "Unleashing Prosperity Through Deregulation" executive order, to reduce the duplicative efforts and unnecessary administrative burdens that can cause inefficiencies and divert resources from patient care[2], as well as HHS' and CMS' efforts to reduce regulatory burdens.[3] Overly burdensome data collections and processes generate increased waste, which results in higher costs for American taxpayers.

Unfortunately, we were disappointed to see that the Administration's commitment to eliminating inefficiencies and burden on stakeholders did not carry through to this ICR. The lack of consistent processes and methodology throughout this document increases the burden on manufacturers and other data submitters, such as patient and provider advocates. This unpredictability and burden exacerbate the MFP program's harmful effects.

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[1] Available for viewing at: https://www.federalregister.gov/documents/2025/06/30/2025-11979/agency-information-collection-activities-proposed-collection-comment-request.
[2] EO 14192, 90 Fed. Reg. 9065 (Feb. 6, 2025).
[3] HHS, FDA Issue RFI on Deregulatory Plan to Lower Costs and Empower Providers, https://www.hhs.gov/press-room/fda-10-to-1-deregulatory-plan-to-lower-costs-empower-patients.html. *See also* Medicare Regulatory Relief, https://www.cms.gov/medicare-regulatory-relief-rfi.

We also encourage the Administration to increase transparency, consistent with the President's goal to "improve the transparency of the Medicare Drug Price Negotiation Program."[4] To date, CMS has declined to provide any meaningful insight into how it uses manufacturer- or stakeholder-submitted data as part of the "clear and consistent" methodology required by statute. This results in an opaque process with unclear decision-making standards and exceptionally comprehensive and burdensome data submission requirements that generate waste and violate the spirit and letter of the Paperwork Reduction Act (PRA).

As a result of this wasteful process, CMS estimates the Agency will itself spend about 2.6 million dollars in one year receiving, reviewing, and processing "data elements" submitted in response to the IPAY 2028 ICR,[5] which – like the burden estimate for manufacturers and other data submitters – is likely a significant underestimate.

Furthermore, the release timing raises questions over whether stakeholders will have a meaningful opportunity to comment on the forms. Although the IPAY 2028 draft guidance sought comment on many of the elements and definitions included in the ICRs, the ICRs were released the day after comments on the draft guidance were due. Thus, if CMS alters data elements or definitions, in response to comment, stakeholders may be denied an opportunity to comment on how a final ICR reflects those changes. CMS should ensure that any changes to the final ICRs that are adopted to reflect final guidance are also subject to a meaningful period of public comment and agency consideration.

Consistent with prior comments, PhRMA is concerned by the burdensome data collection process. We urge the Agency to establish a consistent process and methodology, encourage more meaningful stakeholder participation, improve predictability, and reduce unnecessary data submission burdens. Specifically, we recommend the following changes:

- **Reduce Unnecessary Bureaucracy in the Data Collection Process**
    - Align data submission requirements with current business practices;
    - Limit submission of R&D costs to a single amount related to a selected drug;
    - Count the cost of capital and acquisition costs when evaluating R&D costs;
    - Allow manufacturers the option to stipulate that they have recouped research and development (R&D) costs through a simple yes/no checkbox;
    - Do not require manufacturers to report on data possessed by a "Secondary Manufacturer"; and
    - Do not collect "forward-looking" forecasts during the data collection process as suggested in the draft guidance.
- **Improve Accountability and Efficiency**
    - Streamline and simplify data submission requirements to reduce unnecessary burden and improve CMS decision-making;
    - Address issues with the HPMS system, including removing unnecessary character limits; and
    - Clarify timing of the ICR data certification.

[4] EO 14273, 90 Fed. Reg. 16441 (April 18, 2025).
[5] CMS, IPAY 2028 Information Collection Request Draft Supporting Statement at 28-30.

- **Protect Patients and the Value of All Lives**
    - Place greater priority on the 1194(e)(2) factors vis a vis 1194(e)(1) factors. Within such (e)(2) factors, focus on those directly related to patient benefit and how the selected drug performs in the real world compared to clinically appropriate therapeutic alternatives;
    - Improve process and standards on selection of therapeutic alternatives; and
    - Do not rely on any cost-effectiveness measures – such as those including or based on the quality-adjusted life year or QALY – that can undervalue the lives of the elderly, the disabled, and persons with chronic diseases.
- **Protect Confidential Business Information**
    - Protect confidential commercial information, including by creating a data destruction schedule and notifying manufacturers when data is destroyed.

The recommendations listed above are only some of the key issues with the ICR and the IRA's data collection process and mostly relate to CMS' recent changes and other pressing concerns. Rather than reiterate all previous recommendations on the mostly unchanged ICRs, we are attaching to this letter several Appendices previously submitted to the Agency. Specifically, we are attaching:

- Our technical comments on data collection and renegotiation included as appendices to our IPAY 2028 comments as Appendices A and B, respectively; and
- A two-page document previously shared with the administration on ways to improve the burdensome and wasteful data collection process under the IRA as Appendix C.

* * *

I. Reduce Unnecessary Bureaucracy in the Data Collection Process

Manufacturer-Specific Data Elements [(e)(1) Factors]

Section 1194(e)(1) (hereinafter referred to as the "(e)(1) factors" or "manufacturer-specific factors") of the SSA describes the following manufacturer-specific data that CMS shall consider for purposes of negotiating the MFP of a selected drug: "(A) Research and development costs of the manufacturer for the drug and the extent to which the manufacturer has recouped research and development costs;" "(B) Current unit costs of production and distribution of the drug;" "(C) Prior Federal financial support for novel therapeutic discovery and development with respect to the drug;" "(D) Data on pending and approved patent applications, exclusivities recognized by the Food and Drug Administration, and applications and approvals under section 505(c) of the Federal Food, Drug, and Cosmetic Act or section 351(a) of the Public Health Service Act for the drug;" and "(E) Market data and revenue and sales volume data for the drug in the United States."

However, as in prior years, the ICR requests a far broader and more detailed array of data than necessary or authorized, some of which appear grounded in erroneous assumptions about manufacturers' ability to gather such data, significantly increasing the difficulty and burden of complying with the collection. For example, CMS continues to divide R&D costs into several categories—an approach that goes far beyond how manufacturers typically track or report this data and may conflict with standard document retention practices.[6]

[6] Draft IPAY 2028 Guidance at p. 206 (Appendix A).

While CMS' effort under the current Administration to streamline R&D data is a small step in the right direction, CMS still maintains artificial categories of R&D that do not reflect how R&D costs are tracked and reported in the ordinary course of business, and thus does not adequately alleviate manufacturer burden associated with data submissions or make submitted data more relevant to determining MFP. By aligning data submission requirements with the PRA and current business practices, CMS could improve the utility and accuracy of submitted data and reduce manufacturer burden.

In addition, the ICR questions continue to 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. The ICR offers no way for manufacturers to fully explain the complex and non-linear path of pharmaceutical innovation, which often involves costly setbacks, restarts, and dead ends.[7]

This section of our comments delineates examples of PhRMA's areas of concern based on the scope of information requested. These comments endeavor to ensure that the data required are essential to the operation of the Program and support an efficient process for both manufacturers and CMS staff.

R&D Costs and Recoupment

PhRMA reiterates our appreciation for CMS' attempt to streamline the definitions of research and development costs and hopes this signals some recognition that current data requirements are unworkable for manufacturers. However, we remain concerned about the subdivision of R&D reporting requirements into multiple categories and believe that condensing multiple subdivisions of R&D costs into two categories maintains artificial distinctions and does not go far enough to reduce burden. ***As detailed in PhRMA's past comments, PhRMA believes the current approach to assessing R&D costs and recoupment is flawed for the following reasons:***

- The quantity and type of data manufacturers are required to submit are not consistent with current business practices and standard data retention policies;
- CMS' assessment of "failed and abandoned" products is inaccurate and entirely disconnected from how R&D is conducted and documented in practice;
- Removal of product acquisition costs from the IPAY 2028 ICR further restricts the scope of reportable R&D costs and disregards the fact that an acquiring company pays for the value of the R&D that was carried out to develop the selected drug; and
- Requiring a Primary Manufacturer to submit R&D cost data on behalf of a Secondary Manufacturer is inappropriate and overly burdensome, particularly when the requested data includes proprietary information such as sensitive pricing metrics.

In its 2026 and 2027 IPAY Guidance, CMS' reporting requirements for R&D costs were misaligned with how manufacturers actually track, allocate, and publicly report costs, creating significant compliance challenges under compressed timelines. While CMS' proposed streamlining of R&D reporting requirements for IPAY 2028 is a modest improvement, it does not go far enough to reduce the overall burden of data collection. CMS' reporting methodology remains inconsistent with how manufacturers track cost information, thus raising concerns for companies seeking to comply under a very tight deadline. Manufacturers also may not have documentation and retention policies that would allow them to reconstruct all the R&D costs of products that have been on the market for seven or eleven years (or

[7] Sertkaya A., Beleche T., Jessup A. (June 2024). Costs of Drug Development and Research and Development Intensity in the US, 2000-2018. *JAMA Netw Open.* Available at: https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2820562

more), and which were under development for many years before approval, at the level of specificity that CMS is requesting. Manufacturers cannot easily reconstruct highly detailed R&D costs for drugs developed over a decade or more ago, especially given CMS' overly broad definition of QSSD to include products approved under different applications.

Beyond being impractical to collect due to misalignment with current business practices, many of the factors CMS considers are insufficient for accurately determining R&D costs and recoupment. For example, costs for "abandoned and failed" products with the same "mechanism of action" may be difficult if not impossible for companies to attribute to a drug development program in the ways CMS has specified. In addition, limiting the costs for abandoned and failed products to solely those with the same mechanism of action is short-sighted and ignores the reality of drug development investment decisions, which could include products that have different mechanisms of action but are in the same therapeutic area. This is because investment decisions in biopharmaceutical R&D include factors that extend well beyond the mechanism of action of the drug candidate. These difficulties are compounded when drug products are developed through the efforts of multiple companies, through early-stage R&D licensing arrangements, or other partnerships. Preclinical investments in platform technologies or tools like artificial intelligence (AI) are shared across programs, making product-level cost allocation, especially for pre-clinical development activities, nearly impossible. CMS' approach demands a level of precision that is impractical, burdensome, and disconnected from how R&D is conducted and documented in practice.

Additionally, as we discussed in our comments in response to the IPAY 2028 draft guidance, ***PhRMA strongly opposes CMS' removal of acquisition costs from the calculation of R&D costs for a particular drug.*** An acquiring company pays for the value of the R&D already carried out by the selling company. The acquiring company also must weigh whether its money is better spent on the acquisition or investing internally in R&D. Furthermore, if a manufacturer has acquired a selected drug, CMS' position appears to be that the manufacturer may have *no* R&D costs to report. Yet, reporting an R&D cost of zero or minimal amounts would not be representative of the actual costs that went into developing and bringing the product to market.

PhRMA urges this Administration to address both the burdens and methodological flaws stemming from the previous Administration's implementation of the (e)(1) factors, and to consider PhRMA's longstanding concerns regarding the overall validity of CMS' approach to assessing "R&D recoupment," including the need to revise the ICR to reflect the inherent limitations of the current data collection process and the challenges of quantifying such information with any degree of certainty.

Additionally, PhRMA strongly recommends that CMS allow a single global response for all the manufacturer's R&D costs across all development programs, similar to a Form 10K for Securities and Exchange Commission (SEC) filing, and a single attestation (YES/NO) for recoupment with the option to provide a supporting narrative. CMS should place minimal weight on recoupment and specify that it will not be used to reduce an MFP.

Cost of Capital

PhRMA recommends that CMS count the cost of capital when evaluating R&D costs.

The IPAY 2028 draft ICR proposes to eliminate cost of capital adjustments. PhRMA opposes this proposal because it improperly undervalues R&D costs. The Congressional Budget Office (CBO) has acknowledged that "R&D spending is...influenced by the expected costs of developing a new drug, including those incurred in the preclinical research phase and in clinical trials. In addition to those out-of-pocket expenses, drug companies incur capital costs that result from tying up funds in the drug-

development process for years before they generate earnings from those investments. *Those capital costs reflect the returns that the funds could have earned if they had been invested in other ways.*"[8]

CMS already misconceives R&D costs, including by focusing narrowly on the selected drug rather than the enterprise-wide investment made by manufacturers and investors. Eliminating cost of capital adjustments makes this misconception worse. Academic studies of the cost of drug development employ a cost of capital adjustment, with estimated adjustments of 11 percent, noting that: "the real cost of capital represents the rate of inflation-adjusted return that the sponsor would otherwise be able to earn at the same risk level as the investment in the drug candidate that has been selected .... The estimated value for the biopharmaceutical sector ranges from 8.1% to as high as 14.5%."[9] A report by ASPE used an 11 percent cost of capital.[10] CMS cites to accounting rules for its proposed omission of capital costs;[11] however, these accounting rules are designed to standardize financial reporting, not to arrive at drug-specific costs of R&D at an individual selected drug level as the ICR requires. In any case, CMS does not explain why such accounting rules should supersede the consistent governmental and economic literature on R&D costs, all of which demonstrate that omitting cost of capital significantly understates the true cost of R&D investments given the protracted timelines and high risks inherent to drug development. CMS should continue to allow for cost of capital adjustments.

Patents and Exclusivities

PhRMA is concerned that for IPAY 2028, CMS will instruct manufacturers to clearly identify patent(s) that are "composition of matter" patents. Patent law requires that all inventions be new, useful, and non-obvious to be patented, regardless of the innovation covered by the patent. Therefore, all patents covering a medicine should be considered equally and CMS should refrain from putting greater emphasis on certain types of patents over others when setting prices. Additionally, given that there is no existing or proposed guidance establishing the utility of identifying specific types of patents, it is unclear how this new requirement would be relevant in determining the price of the selected product, and therefore, may violate the PRA as lacking utility vis a vis CMS' policy instructions.

Collection of Net Part D Price

CMS notes that it will collect net Medicare Part D average unit price as part of market data and revenue and sales data, requiring that all manufacturer or coverage gap discounts be eliminated from such net pricing. PhRMA has previously noted that factoring these discounts into the net Part D price conflicts with Congress' directive to exempt selected drugs from the manufacturer discount program. If CMS bases MFPs on a metric that subtracts out the manufacturer discounts, then CMS is setting the MFP, in part, based on such discounts, even though Congress specifically required that the drugs *not* be subject to such discounts.

It is particularly inappropriate to use the metric of "net Part D prices" (which also reflect statutory manufacturer discounts in Part D) to set MFPs *in Part B* when drugs have both Part B and Part D utilization. Incorporating Part D manufacturer discounts into Part B MFPs would improperly incorporate

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[8] CBO, Research and Development in the Pharmaceutical Industry. (April 2021). Available at https://www.cbo.gov/publication/57126 (emphasis added). Summarizing academic studies that estimate R&D cost, CBO also noted "the studies also all apply a cost-of-capital adjustment to each company's R&D spending to reflect the lag between investment and return on investment."

[9] Sertkaya A., et al. (June 2024). Costs of Drug Development and Research and Development Intensity in the US, 2000-2018. *JAMA Network Open*. Available at https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2820562. The article cites to DiMasi J., et al. (May 2016). Innovation in the pharmaceutical industry: new estimates of R&D costs, *J Health Econ.* (2016). Available at: https://www.sciencedirect.com/science/article/abs/pii/S0167629616000291?via%3Dihub

[10] ASPE Office of Science and Data Policy, New Estimates of the Cost of Preventive Vaccine Development. (December 2024). Available at: https://aspe.hhs.gov/sites/default/files/documents/dddeb3748f486324a493a8a6d27f4338/aspe-vaccine-costs-brief.pdf

[11] IPAY 2028 Draft Guidance at footnote 128.

statutory, Part D program-specific discounts created by Congress specifically for the Part D program into the Part B program.

Forward-Looking Market Data

PhRMA applauds CMS for not including "forward-looking market data" as a data requirement for selected drugs and strongly encourages the Agency to refrain from requiring "forward-looking" forecasts in future rulemaking and ICRs. As explained in PhRMA's comments in response to the IPAY 2028 draft guidance, forward-looking market data is inappropriate for collection as both a policy and legal matter, as the statute does not authorize predictive collections. Furthermore, CMS requires primary manufacturers to certify that data submissions are "complete and accurate," and to notify CMS of any changes. However, forecasts inherently evolve with new information and shifting business conditions, making ongoing notification impractical. Requiring a delegated official to certify the "completeness" and "accuracy" of a forecast imposes undue responsibility, as forecasts are speculative by nature. Moreover, forecasts are not "data" in the ordinary sense—defined as factual information like measurements or statistics. Predictions lack the empirical basis necessary to meet this definition.

II. Improve Accountability and Efficiency

Data Submission Requirements

The 28-day timeline to submit information to the Agency after drug selection is unreasonable, and in many cases, infeasible absent significant preparation in advance of selection. A survey of PhRMA members demonstrated that companies – operating under the assumption of selection – spent a minimum of six months of high-intensity effort averaging over 7,700 hours of staff labor across 21 business functions to comply with CMS' IPAY 2026 data request. These efforts required complex coordination across many business functions, requiring new methods, and extensive sourcing, reviewing, fact-checking, legal analysis, 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 R&D is collected and reported, as discussed earlier in this letter.

Beyond the burden of answering all the questions and sub-questions within the lengthy ICR forms, 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 by a "Secondary Manufacturer"[12]) all within a 28-day period.

Furthermore, adhering to an arbitrary 28-day deadline for the (e)(2) factors places significant pressure on third parties interested in data submission, particularly doctors with a full-time job treating patients or those who may have access to fewer resources. This could deter those stakeholders from responding to CMS' burdensome requests although their feedback and input should be critical to the Agency's decision-making process.

Compounding this issue, there still 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 or 2027 price setting processes. While the ICR submission is burdensome and wasteful for manufacturers, the lack of transparency into how submitted data is used may also further deter participation from the public as they may decide that CMS may not consider their responses and thus not spend the time needed to complete the ICR. As such, as part of the Administration's efforts to reduce waste and regulatory burdens, ***CMS should consider extending the***

[12] 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.

deadline for (e)(2) data submission and only collect information through the ICR process that is directly relevant to the Agency's MFP setting process.

HPMS Data Submission

Unfortunately, the Health Plan Management System ("HPMS") relied on for data entry adds burden to the ICR process given it was not created for this purpose and as such relies on a poor user interface and lacks needed functionality. HPMS is a form-based system that requires users to enter each text response in a separate field, and the experience is made worse by arbitrary character limits imposed by the Agency. Not only are the character limits unnecessarily restrictive and limiting (even including spaces in the final count), but they are also short-sighted, especially when considering the often long and complicated names for compounds, medical conditions, and other information relevant to drug development and treatment effects. Furthermore, to date, the system has not included functionality for users to automatically upload a spreadsheet into the form, requiring users to copy and paste or to manually enter each line item.[13] If there are multiple NDCs for a selected drug, this entry can require cutting and pasting into hundreds or thousands of fields. In addition, in the IPAY 2026 and 2027 cycles, HPMS did not provide a confirmation copy of submissions, and its processing slowed significantly when under the strain of multiple users. Only one person can enter data at a time which then further restricts companies trying to gather and enter the required data within the 28-day timeframe. ***CMS should update the HPMS data collection system and address the poor user interface and lack of functionality.***

Data Certification

The previous Administration included an overly broad "certification" in Sections H and J, despite not being required by statute. The language requires all respondents to certify that the information submitted is "complete and accurate."[14] Respondents must also agree to notify CMS in a timely manner upon becoming aware "that any of the information submitted in this form has changed or is otherwise inaccurate."[15] According to the terms of this certification, any misrepresentations by manufacturers may give rise to liability, including under the False Claims Act.

Nothing in the statute requires such a certification. This contrasts with other provisions in the Social Security Act (SSA), which specifically require such certifications. For example, section 1124(c)(3)(A) requires the Secretary to promulgate regulations for disclosure of ownership and other information that ensure that "the facility certifies, as a condition of participation and payment under [Medicare and Medicaid], that the information reported by the facility…is, to the best of the facility's knowledge, accurate and current."

Next, ***CMS should remove the requirement of timely notification of changed or "otherwise inaccurate" information to avoid unintended noncompliance with the certification and unnecessary burden***. The scientific field continues to evolve with new publications and disclosures. As a result, this term of the certification, with no specification of the applicability of a time limit, adds an ongoing burden and uncertainty for all submitters that CMS suggests could lead to legal liabilities and consequences. It is unclear why CMS requires continued data submission or how the Agency will spend resources reevaluating the new data. The renegotiation process makes this even more opaque as in the draft Guidance CMS states that while manufacturers may voluntarily submit data to be considered for renegotiation, this submission is separate from the "ongoing obligation to update…original data

[13] CMS notes on page 5 of the draft ICR that additional instructions on submitting data for applicable sections via "a template upload" will be available in a form user guide. It is not clear what is meant by this language. We urge CMS to provide clarity and develop a functionality that will allow uploads of the most commonly used methods for gathering data, including excel spreadsheets.
[14] CMS, ICR Form at 44-45.
[15] *Ibid.*

submissions."[16] While PhRMA recommends a less onerous and threatening certification (for example, that data submitted is based on the respondent's best understanding of the data available at the time of submission), at the very least, ***CMS should clarify the certification requirements so that manufacturers must only update submissions if the submitter becomes aware that information was incorrect as of the time of submission.***

Conflicts of Interest

PhRMA continues to urge the Agency to consider all potential conflicts of interest for data submitters completing Section I of the ICR form. This includes payers and pharmacy benefit managers (PBMs). As such, people who either work for or receive funding from these entities should also be required to disclose these affiliations. Furthermore, footnote 38 includes language identifying "affiliated with the manufacturer" as a person who "…has been asked by the manufacturer to respond to this ICR or to advise the manufacturer on the Negotiation program, regardless of compensation."[17] Simply being "asked" to respond to an ICR, or advising a manufacturer about a patient or caregiver's needs or experiences with a drug, particularly when no compensation is involved, is not an "affiliation." Manufacturers have relationships and communications with patients, caregivers, and advocates to ensure their products are meeting individuals' needs and to understand individual experiences with a certain drug product. Simply asking a person to respond or advising when the ICR is open for submissions does not create a conflict of interest – especially when the ICR is only open for a short period of time and can be difficult to find on CMS' website. ***The Agency should identify potential conflicts of interest only when compensation is involved and expand the potential conflicts of interest identified to include persons who received remuneration from other entities in the health care system such as, but not limited to, payers and PBMs.***

III. Protect Patients and Value of all Lives

Prioritize 1194(e)(2) factors

CMS and the previous Administration have continually declined to provide any insight into how the collected 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 prioritized (i.e., if – as suggested by PhRMA and other key stakeholders[18] – CMS will assign priority to the Section I factors that reflect the benefit the selected drug brings to patients, caregivers, and society). Over-indexing to the (e)(1) factors could stall innovation, as basing prices on manufacturer costs, instead of the value and benefits conferred by the innovation, sends perverse, unintended signals to manufacturers, devalues and disincentivizes R&D, and jeopardizes innovation and progress for future medicines. As such, ***the Agency should clarify its methodology and assign a higher weight to (e)(2) factors as compared to the (e)(1) factors with an emphasis on those that actually reflect the benefit the selected drug brings to patients, caregivers, and society.***

Within the prioritized (e)(2) factors, CMS should consider all improvements a selected drug provides compared to its therapeutic alternatives – including advances important to patients and caregivers. Given the significant concerns that cost-effectiveness methodologies, including the quality-adjusted life year (QALY) and measures based on the QALY – including but not limited to measures like the equal life years gained (evLYG) or generalized risk-adjusted cost-effectiveness (GRACE) – undervalue the lives of the elderly, the disabled, and persons with chronic diseases, ***the Agency should avoid all cost-effectiveness methodologies to instead focus on comparative clinical-effectiveness research***. In

[16] IPAY 2028 Guidance at § 50.1.
[17] CMS, ICR form at 47.
[18] McElwee F., Cole A., Garrison L.P., Towse A. (June 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

addition, ***CMS should ensure that cost is never considered as part of the therapeutic advance definition. To increase accountability and transparency in the price setting process, CMS should also provide greater transparency on the types of evidence it will rely on when evaluating data, such as the extent to which a selected drug represents a therapeutic advance or addresses an unmet medical need, and the effects of the selected drug on specific populations.***

Therapeutic Alternative Selection

As stated in our previous comments, CMS should not consider non-drug therapeutic alternatives. Identification of therapeutic alternatives represents a critical element of the MFP process, yet it is also a notoriously difficult element[19,20] of any process for evaluating comparative costs and benefits of different medicines or other health care interventions. CMS' MFP explanations for the IPAY 2026 drugs illustrate this complexity: the agency appears to have considered an average of 6.5 therapeutic alternatives across each of the ten selected drugs (ranging from one to ten therapeutic alternatives per selected drug) but provided few specifics as to how the agency ultimately selected specific therapeutic alternatives, beyond vague statements on a "holistic" approach.[21]

As PhRMA has stated previously, therapeutic alternative selection should be based on the most clinically appropriate alternative informed by product labels, clinical guidelines, and input from experts with real-world experience, including patients, practicing physicians, and pharmaceutical manufacturer(s). However, the agency's compressed timetable for input, combined with vague, poorly defined standards for therapeutic alternative selection, makes it exceptionally difficult for manufacturers and other stakeholders to efficiently provide meaningful input on a selected drug relative to its therapeutic alternatives, and raises the risk that CMS will not identify the most clinically appropriate options. Especially as Part B medicines become eligible for price setting in IPAY 2028, introducing further complexity, the potential scenarios that must be considered by data submitters grows increasingly burdensome and also increases the likelihood that a data submitter will submit irrelevant data that involves a product not under consideration as a therapeutic alternative. As such, ***CMS should publish the potential therapeutic alternative(s) under consideration for each selected drug when selected drugs are announced and allow data submitters to comment on CMS' proposal as part of their data submission package***.

Unmet Medical Need

The ability of a medicine to address an "unmet need" is of great significance to patients, caregivers, and clinicians and demonstrates a product's unique value as compared to its therapeutic alternatives. Patients present with unique needs. Such clinical nuance requires that patients work with their providers to decide the best course of treatment. However, CMS continues to use an overly narrow definition of "unmet medical need," which could dissuade manufacturers from pursuing advances that may be important to patients or can improve patient lives due to the risk that price setting will undervalue this innovation.

First, the Agency continues to rely on questions like 42b, which asks respondents to "…describe the extent to which [the selected drug] currently addresses (or does not address) an unmet medical need."[22] However, products may be selected years after they were approved to address a specific need or gap.

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[19] Ciarametaro M., Frohberg E., Moselle S., Banks J., Sullivan M., Thornton M., Patel D. (June 2025). Variability of Comparator Drugs in Ex-US HTAs Offers Lessons for the IRA. Avalere Health. Available at: https://advisory.avalerehealth.com/insights/variability-of-comparator-drugs-in-ex-us-htas-offers-lessons-for-the-ira

[20] Hernandez I., et al. (December 2023). Medicare drug price negotiation: The complexities of selecting therapeutic alternatives for estimating comparative effectiveness. *J Manag Care Spec Pharm*. Available at: https://pmc.ncbi.nlm.nih.gov/articles/PMC10909583/

[21] National Pharmaceutical Council. (January 2025). "Maximum Fair Price" Explanations for IPAY 2026 Drugs. Available at: https://www.npcnow.org/sites/default/files/2025-01/MFP%20Explanation%20Files%20IPAY%202026%20NPC%20Policy%20Evidence%20Brief%202025_01.pdf

[22] CMS, ICR form at 65.

Thus, this question and similar questions ignore the value a selected drug offers across its lifecycle. ***CMS should reframe its questions and definitions to capture unmet need from launch.***

Second, the narrow definition ignores other types of unmet need, which could contribute to why a doctor prescribes a particular treatment to one patient versus another. Unfortunately, many needs important to patients, doctors, caregivers, and society are not captured in the health technology assessment methodologies developed by economists and are not included by CMS in its data collection efforts. These other factors (i.e., patient satisfaction, adherence, mode of administration) represent important elements of value to patients and caregivers,[23] and ***CMS should revise its definition of "unmet medical need" and related questions to better capture and include these factors.***

Finally, CMS should ensure that respondents have appropriate space to discuss how a product has addressed patient unmet needs since product launch. In spite of the already restrictive character limits, the Agency further limited the ability for respondents to comment on the value of selected drugs by combining the previously separate questions on the extent to which a selected drug represents a therapeutic advance and/or an unmet need into one single question (e.g., Question 35). This is concerning as it could undervalue the distinct benefits a selected drug brings compared to its therapeutic alternative(s). ***The Agency should rectify this by either increasing the arbitrary character limit or keeping questions on therapeutic advance and unmet medical need separate and allowing respondents to answer each distinct question.***

Quality-Adjusted Life Years

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 rooted in the QALY or another similar metric, as the basis for policy decisions risks further undervaluing the lives of the elderly, the disabled, and underserved and underrepresented people of color who are already at higher risk of not receiving the care they need. PhRMA continues to be concerned that the Agency will rely on cost-effectiveness metrics and disagrees with CMS' decision to remove the checkbox attesting that the QALY was not used as part of the data submission package.

While we understand that not all stakeholders will understand cost-effectiveness measures, given the breadth of data CMS considers (some of the MFP explanations included almost 300 sources), it is unlikely the Agency will be able to confirm that the studies do not use cost-effectiveness measures in a way that does not discriminate against certain populations. The previous Administration already found ways to utilize the QALY despite language in statute[24] prohibiting government use of the QALY in Medicare and concerns from academics, patients and disability groups.[25] The public MFP explanations for one drug selected in IPAY 2026 cited almost 50 studies[26] that relied on the QALY while two explanations[27,28] cited QALY-based cost-effectiveness decisions made by the United Kingdom's National

[23] Alliance for Patient Access. (August 2023). At What Price? Available at: https://allianceforpatientaccess.org/wp-content/uploads/2023/08/AfPA_At-What-Price_Policy-Paper_August-2023.pdf
[24] SSA § 1182(e).
[25] Sawhney T. G., Dobes A., O'Charoen S. (July 2023). QALYs: The Math Doesn't Work. *JHEOR*. Available at: https://jheor.org/article/83387-qalys-the-math-doesn-t-work
[26] Gratie D., et al. (May 2025). Is the IRA Drug Price Negotiation an Evidence-Based Practice? A Critical Analysis of the Evidence Reviewed by CMS for IRA Drug Price Negotiations and Implications for Future Submissions. Value in Health 28(S1). Available at: https://www.ispor.org/heor-resources/presentations-database/presentation-cti/ispor-2025/poster-session-3/is-the-ira-drug-price-negotiation-an-evidence-based-practice-a-critical-analysis-of-the-evidence-reviewed-by-cms-for-ira-drug-price-negotiations-and-implications-for-future-submissions
[27] CMS. (December 2024) File for the MFP Explanation for Eliquis. Available at: https://www.cms.gov/priorities/medicare-prescription-drug-affordability/overview/medicare-drug-price-negotiation-program/selected-drugs-and-negotiated-prices
[28] CMS. (December 2024) File for the MFP Explanation for Xarelto. Available at: https://www.cms.gov/priorities/medicare-prescription-drug-affordability/overview/medicare-drug-price-negotiation-program/selected-drugs-and-negotiated-prices

Institute for Health and Care Excellence (NICE).[29] CMS should not be relying on these studies and should not consider cost-effectiveness metrics, even if the data submitter claims they do not believe their submission undervalues the lives of the elderly, the disabled, or the terminally ill. As stated by Congressman Hern when introducing legislation to more fully protect patients against use of the QALY: "QALY measurements strip humanity away from a patient, leaving only dollar signs and data points. That has no place in our healthcare system. Every person deserves to be treated with dignity and respect and given the best care available."[30] CMS should reconsider its decision to remove the attestation that prevents academics and other third parties from submitting data relying on these fatally flawed metrics. ***Instead, CMS should not only add the attestation back into the ICR, but the Agency itself should also attest that it is not using QALYs or other cost-effectiveness metrics in the evidence used to set MFP – including if the Agency reviews reports from foreign health technology assessment bodies or treatment guidelines that cite health technology assessment reviews as the basis for their recommendations. To help build public trust in the MFP process, CMS should increase transparency into the type of evidence used to not only inform future data submissions but also ensure the Agency is prioritizing data from patients and doctors with prescribing experience, along with comparative clinical-effectiveness research that provides insight into a medicine's real-world performance, without undervaluing the lives of the elderly, the disabled, or the terminally ill.***

IV. Protect Confidential Business Information

Data Confidentiality

Despite handling confidential and highly sensitive business data, CMS has failed to articulate a reasonable data retention policy or data destruction schedule. Furthermore, despite recommendations, CMS has not developed or published a specific security protocol to ensure the cybersecurity of systems holding manufacturer-specific data. Nor has CMS articulated a process for notifying manufacturers and allowing for prospective adjudication when the government plans to use data in a manner that may violate the IRA. The IRA places narrow restrictions on the Secretary's use of proprietary information submitted by a manufacturer. Generally stated (and with a limited exception for disclosure to the Comptroller General), proprietary information may be used by the Secretary *only* for purposes of carrying out the price setting provisions of the IRA.[31] This language restricts CMS not just from disclosing or publicly releasing proprietary information, but also from internally using it for unauthorized purposes. CMS should create a process under which manufacturers are alerted and may object to any potential unauthorized internal use. ***PhRMA recommends that under this Administration, CMS improve its oversight practices by developing and soliciting comments on a robust confidentiality and data security protocol for protecting manufacturer proprietary information.***

* * *

PhRMA appreciates the opportunity to submit comments in response to the Drug Price Negotiation for Initial Price Applicability Year 2028 under Sections 11001 and 11002 of the Inflation Reduction Act Information Collection Request. We continue to urge CMS to reduce burden on data submitters and the Agency by limiting the data that must be provided to elements essential to operation of the Program; leveraging data already available to CMS as much as possible; avoiding outdated metrics that devalue

[29] NICE. (July 2025). NICE health technology evaluations: the manual. Available at: https://www.nice.org.uk/process/pmg36/chapter/economic-evaluation-2

[30] Cammack K. (June 2025). Reps. Cammack and Hern Introduce Legislation to Protect Patients in Federal Health Programs. Available at: https://cammack.house.gov/media/press-releases/reps-cammack-and-hern-introduce-legislation-protect-patients-federal-health

[31] Specifically, section 1193(c) of the Social Security Act states: " (c) Confidentiality of Information.—Information submitted to the Secretary under this part by a manufacturer of a selected drug that is proprietary information of such manufacturer (as determined by the Secretary) 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."

certain lives, protecting confidential commercial information as required by law; and providing 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.

Sincerely,

-----s-------	-----s-------
Elizabeth Carpenter	James C. Stansel
Executive Vice President	Executive Vice President and
Policy & Research	General Counsel
PhRMA	PhRMA

Appendix A: Information Collection and Negotiation Process

As in prior years, the Centers for Medicare & Medicaid Services' (CMS, the Agency) draft Initial Price Applicability Year (IPAY) 2028 Guidance fails to establish a clear, consistent methodology for arriving at maximum fair prices (MFPs). Meeting this basic standard is not only required by the statute[32] but is also essential for ensuring accountability of government decision-making. The lack of consistent methodology – reflected in the Guidance and Appendix A of the Draft Guidance (relating to definitions for purposes of collecting data) – creates unpredictability and adds unnecessary burden, exacerbating the MFP program's harmful effects.

To date, CMS has declined to provide any meaningful insight into how it uses manufacturer- or stakeholder-submitted data as part of the "clear and consistent" methodology required by statute. The draft 2028 Guidance unfortunately continues to leave this problem unaddressed. This results in manufacturers facing an opaque process with unclear decision-making standards, exceptionally burdensome data submission requirements, and little recourse but to adhere to the agency's arbitrary demands, even when these demands violate the spirit and letter of the Paperwork Reduction Act (PRA). The lack of transparency throughout the entirety of the price setting process underscores this approach as it remains uncertain whether the Agency even knows what information it needs, which could be a contributing factor for why the Agency continues requesting lengthy and at times irrelevant data from key stakeholders.

Further, some of the potential changes for which CMS seeks input would worsen, rather than mitigating, the harmful effects of the Inflation Reduction Act's (IRA) drug price controls. We are particularly concerned about the Agency soliciting comments on potential new starting points for the initial offer in the IPAY 2028 draft guidance, including "the unit cost of production and distribution of the selected drug" and "other domestic reference prices." These factors – which would further devalue and discourage research and development of new medicines and risk introducing further uncertainty into a process that is already unpredictable – should be rejected by CMS. Additionally, as discussed in detail later in the appendix, PhRMA continues to advocate that CMS should place greater emphasis on the 1194(e)(2) factors relative to 1194(e)(1) factors as manufacturer-specific factors are less relevant for determining MFPs.

CMS' lack of transparency may also discourage participation from patients, caregivers, clinicians, and other key stakeholders. With no transparency into how – or if – CMS is using data or the stories from these stakeholders, there is a risk that key stakeholders will stop replying to the Agency, as they may not feel that the significant investment required to submit data 28 days post selection or forfeit an afternoon for a roundtable or town hall is worth the time or effort. To address this, CMS should clarify how it uses submitted data in the MFP explanations, enabling stakeholders to tailor future submissions to what matters most in the Agency's decision-making.

Consistent with prior comments, PhRMA urges CMS to make basic improvements in the Guidance document's provisions on methodology and process and streamline and modify the upcoming Information Collection Request (ICR) in order to establish a consistent process and methodology,

[32] SSA § 1194(b)(1) ("The Secretary shall develop and use a consistent methodology and process.")

encourage more meaningful stakeholder participation, improve predictability, and reduce unnecessary data submission burdens. Specifically, we recommend the following changes:

- **Information Collection Request / Appendix A of the Draft Guidance:**
  - Streamline and simplify data submission requirements to reduce unnecessary burden and improve CMS decision-making; and
  - Clarify timing of ICR data certification.

- **Manufacturer-Specific Data Elements [1194(e)(1)]:**
  - Eliminate unnecessary regulatory burden and correct methodological inaccuracies;
  - Align data submission requirements with current business practices;
  - Limit submission of R&D costs to a single amount related to a selected drug;
  - Allow manufacturers the option to stipulate that they have recouped research and development (R&D) costs through a simple yes/no checkbox;
  - Do not place greater emphasis on the 1194(e)(1) factors when adjusting the preliminary price;
  - Clarify how data on pending and approved patents will be used to adjust MFP; and
  - Do not collect "forward-looking" forecasts during the data collection process.

- **Evidence About Alternative Treatments [1194(e)(2)]:**
  - Place greater emphasis on the 1194(e)(2) factors vis a vis 1194(e)(1) factors. Within such (e)(2) factors, focus on those directly related to patient benefit and how the selected drug performs in the real world compared to clinically appropriate therapeutic alternatives;
  - Clarify how CMS will weigh different data elements in MFP price-setting;
  - Improve process and standards on selection of therapeutic alternatives;
  - Reject alternative starting points such as the unit cost of production and distribution or domestic reference pricing as a starting point for the initial offer;
  - Support meaningful stakeholder engagement; and
  - Strengthen safeguards against use of quality-adjusted life years (QALYs) and related metrics.

I. Information Collection Request Data Burden and Noncompliance with Paperwork Reduction Act

In advance of IPAY 2026, PhRMA articulated concrete and actionable recommendations focused on key considerations under the Paperwork Reduction Act (PRA) for the implementation and application of the price setting process. Unfortunately, as it did with most comments, the Agency disregarded our recommendations and continued with its burdensome and inefficient process. For IPAY 2027, PhRMA again reiterated our concerns with how CMS' ICR forms are overly burdensome and, as a result, continue to fall far short of the three-prong regulatory test established by the PRA.[33] Yet, the previous administration made only minor changes – along with a modest and underestimated increase in burden estimates - while failing to address the ICR's inefficiencies and PRA noncompliance.

[33] 5 C.F.R. § 1320.5(d)(1)(i)-(iii)

The PRA was enacted in 1995 due to the "enormous growth of our federal bureaucracy" and "its seemingly insatiable appetite for data."[34] However, the previous administration ignored PRA requirements to "minimize and control burdens and maximize the practical utility"[35] of information collections and instead imposed an overly burdensome and complicated process to collect data. This is not only a waste of pharmaceutical manufacturer resources but also is an inefficient use of CMS staff time. There is no evidence[36] that CMS even considered the majority of information provided to the agency to determine the MFPs for IPAY 2026, yet – instead of complying with the PRA and reducing the burden on all data submitters – the previous administration allowed the ICR to balloon from a 47-page form in IPAY 2026 to 73 pages in IPAY 2027.

Further, the 28-day timeline to submit information to the Agency after drug selection is unreasonable and, in many cases, infeasible absent significant preparation in advance of selection. The information requested by CMS is not only vast and far-reaching, but it often requires a lookback of one or more decades along with complex coordination across many business functions under compliance pressure. The intensive process of then quality- and fact-checking the compiled data in order to certify this submission (which can be nearly impossible if possessed solely by a "Secondary Manufacturer") is extremely burdensome and can require substantial time compiling and analyzing data in advance of this compressed 28-day period. The Agency adds to this burden as it is unclear if respondents must continually update their ICR submissions or if they must only modify their submission(s) if it later becomes clear that the information submitted was incorrect based on the information available at the time of submission or if the data changes (e.g., due Medicaid Best Price restatement window). This resubmission process is burdensome and, given the lack of transparency into the MFP setting-process, it remains unclear why CMS requires continued data submission or how the Agency evaluates this data. The renegotiation process makes this even more opaque as CMS states that while manufacturers may voluntarily submit data to be considered for renegotiation, this submission is separate from the "ongoing obligation to update . . . original data submissions."[37] ***PhRMA recommends CMS clarify the certification requirements so that manufacturers must only update submissions if the submitter becomes aware that information was incorrect as of the time of submission.***

Furthermore, there is little evidence to validate why CMS needs the requested information as the Agency has provided no transparency into how, or even if, it used the vast amounts of data collected during the IPAY 2026 and IPAY 2027 price setting process. The IPAY 2026 "explanations" mostly repeated information available in Guidance instead of providing any assurance that CMS truly needed all the information collected. Nor has CMS articulated a data destruction schedule for the vast amounts of proprietary information it has collected or will collect. Not only do these flaws raise questions as to the goals behind the process, but it underscores a lack of consideration for the burden the request imposes or CMS' duties under the PRA.

PhRMA appreciates that CMS is soliciting feedback on the forthcoming ICR for IPAY 2028, and that the Administration is considering streamlining the MFP price-setting factors to reduce burden and improve efficiency. To this end, ***we again urge CMS to consider the requirements and intent of the PRA and,***

[34] *Dole v. United Steelworkers of Am.*, 494 U.S. 26, 32 (1990)
[35] 5 C.F.R. § 1320.1
[36] CMS. (December 2024). MFP Explanations. Available at: https://www.cms.gov/priorities/medicare-prescription-drug-affordability/overview/medicare-drug-price-negotiation-program/selected-drugs-and-negotiated-prices
[37] IPAY 2028 Guidance at § 50.1.

consistent with our prior comments to the Agency[38] along with the comments included in this Appendix, streamline and simplify the data submission requirements of the ICR – particularly but not limited to the manufacturer-specific data elements.

II. Manufacturer-Specific Data Elements [(e)(1) Factors]

Section 1194(e)(1) (hereinafter referred to as the (e)(1) or manufacturer-specific factors) of the IRA describes the following manufacturer-specific data that CMS shall consider for purposes of negotiating the MFP of a selected drug: "(A) Research and development costs of the manufacturer for the drug and the extent to which the manufacturer has recouped research and development costs;" "(B) Current unit costs of production and distribution of the drug;" "(C) Prior Federal financial support for novel therapeutic discovery and development with respect to the drug;" "(D) Data on pending and approved patent applications, exclusivities recognized by the Food and Drug Administration, and applications and approvals under section 505(c) of the Federal Food, Drug, and Cosmetic Act or section 351(a) of the Public Health Service Act for the drug;" and "(E) Market data and revenue and sales volume data for the drug in the United States."

For IPAY 2026 and IPAY 2027, the previous Administration interpreted the statute in a manner that led them to require Manufacturer-Specific Data Elements that were flawed and incongruent with current business practices. As stated above, many of the elements requested for collection violated the PRA in terms of both utility and necessity. For example, CMS continues to divide R&D costs into several categories—an approach that goes far beyond how manufacturers typically track or report this data and may conflict with standard document retention practices.[39]

While CMS' effort to streamline R&D data is a small step in the right direction, collapsing multiple subdivisions of R&D costs into two categories while still requiring manufacturers to include basic pre-clinical research for indications of the selected drug and post-IND costs among other costs does not adequately alleviate manufacturer burden associated with data submissions or make submitted data more relevant to determining MFP. CMS has significant opportunities to align data submission requirements with the PRA and current business practices to improve the utility and accuracy of submitted data and reduce the burden that manufacturers face in adhering to the current requirements.

In addition, 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. The ICR offers no way for manufacturers to fully explain the complex and non-linear path of pharmaceutical innovation, which often involves costly setbacks, restarts, and dead ends.

Research and Development Costs

PhRMA appreciates that CMS is soliciting comments on opportunities to streamline the definitions research and development costs and hopes this signals some recognition that the current data requirements

[38] PhRMA. (September 2024). PhRMA Comments on IPAY 2027 Negotiation Data Elements and Negotiation Process ICRs. Available at: https://www.regulations.gov/comment/CMS-2024-0198-0018
[39] Draft IPAY 2028 Guidance at p. 206 (Appendix A)

are unworkable for manufacturers. However, we remain concerned about the subdivision of R&D reporting requirements into more than one category and believe the changes do not go far enough to reduce the burden on manufacturers. Additionally, PhRMA opposes CMS removal of acquisition costs as part of the overall calculation of R&D costs for a particular drug. An acquiring company pays for the value of the R&D already carried out by the selling company. The acquiring company also must weigh whether its money is better spent on the acquisition or investing internally in R&D. Furthermore, if a manufacturer has acquired the selected drug, CMS' position appears to be that the manufacturer may have *no* R&D costs to report. Yet, reporting an R&D cost of zero or minimal amounts would not be representative of the actual costs that went into developing and bringing the product to market. While PhRMA supports consolidating reporting and greater transparency, ***we strongly urge the new Administration to address the burden and methodological inaccuracies that resulted from the past Administration's approach to implementation of the (e)(1) factors.***

In its 2026 and 2027 IPAY Guidance, CMS' reporting requirements for R&D costs have been misaligned with how manufacturers actually track, allocate, and publicly report costs, creating significant compliance challenges under compressed timelines. While CMS' proposed streamlining of reporting requirements for IPAY 2028 is a modest improvement, it does not go far enough to reduce the overall burden of data collection. Manufacturers cannot easily reconstruct highly detailed R&D costs for drugs developed over a decade or more ago, especially given CMS' overly broad definition of QSSD to include products approved under different applications.

Additionally, costs for "abandoned and failed" products with the same "mechanism of action" may be difficult if not impossible for companies to attribute to a drug development program in the ways CMS has specified. This is because of the nature of investment decisions in biopharmaceutical R&D, which include factors that extend well beyond the mechanism of action of the drug candidate. These difficulties are compounded when drug products are developed through the efforts of multiple companies, through early-stage R&D licensing arrangements, or other partnerships. Preclinical investments in platform technologies or tools like artificial intelligence (AI) are shared across programs, making product-level cost allocation, especially for pre-clinical development activities, nearly impossible. CMS' approach demands a level of precision that is impractical, burdensome, and disconnected from how R&D is conducted and documented in practice.

As noted below, CMS should amend the Guidance to allow manufacturers to stipulate, without more, that they have recouped R&D costs through a simple yes/no checkbox. In the alternative, CMS should limit required submission of R&D costs to a single, total amount related to the selected drug, while allowing companies to voluntarily provide supplemental data. In addition, manufacturers should be given the opportunity to provide a supporting narrative.

Research and Development Cost Recoupment

PhRMA continues to be concerned about the validity of CMS' approach to capturing "R&D recoupment" - which does not account for all distribution and supply chain costs required to get products to market, among other concerns - and urges the Agency to acknowledge the concept's flaws and the difficulty of accurately quantifying and complying with it. As PhRMA and others have continually noted, very few

drug candidates that enter clinical trials are ultimately FDA-approved – in fact, just 12 percent.[40] Companies plan R&D across entire portfolios, expecting that only a few successful drugs will generate enough revenue to offset the many costly failures.[41] As a result, CMS' interpretation of the IRA requirement to consider R&D costs at the product level and the extent to which they have been recouped is not only impractical—given how investments are tracked—but also unnecessary under the statutory language. CMS' fundamental misunderstanding of the economics of the biopharmaceutical marketplace exacerbates this flawed provision by continuing to require companies to report in a manner not required by the IRA, such as providing detailed R&D costs and the extent to which they have been recouped, as well as by subdividing such costs into more than one subcategory.

While we appreciate CMS' willingness to consolidate some categories of R&D costs, rather than continuing this highly flawed approach, PhRMA strongly recommends that CMS allow a single global response for all the manufacturer's R&D costs across all development programs, similar to a Form 10K for Securities and Exchange Commission (SEC) filing, and a single attestation (YES/NO) for recoupment with the option to provide a supporting narrative. In addition, CMS should place minimal weight on recoupment and specify that it will not be used to reduce an MFP determined on the basis of a drug's therapeutic and clinical attributes. If a respondent stipulates "YES" that they have recouped research costs, then CMS need not gather any additional information. If a manufacturer checks "NO," then the manufacturer should be allowed the flexibility to provide an explanation, free of word limits, as to how the costs weren't recouped . This approach would also accord with section 1194(e)(1)(A), which merely requires that CMS consider R&D costs and the extent to which they have been recouped. CMS could reason that in cases where a manufacturer stipulates it has recouped R&D costs, the agency would have no need to further include R&D costs in the price-setting analysis (as the costs have been recouped); whereas, in cases where the data show a manufacturer has not recouped R&D costs, such information may inform an upward adjustment to MFP.

Patents and Exclusivities

For IPAY 2028, CMS seeks "comment on…whether CMS should put greater emphasis on certain section 1194(e)(1) factors when adjusting the preliminary price," or "whether CMS should consider and potentially adjust the preliminary price based on" the data described in item D above (data on pending and approved patent applications and exclusivities) "independent of considering other section 1194(e)(1) factors in totality."[42]

First, it is not clear what CMS means by "consider[ing] and potentially adjust[ing] the preliminary price based on" on pending and approved patent applications, exclusivities recognized by the Food and Drug Administration, and applications and approvals under section 505(c) of the Federal Food, Drug, and Cosmetic Act or section 351(a) of the Public Health Service Act for the drug "independent of considering other section 1194(e)(1) factors in totality." For example, it is not clear whether this statement means that CMS is considering giving this factor more weight than all other factors, and if so, how much weight. Nor is it clear whether CMS would increase or reduce the preliminary price based on the described

[40] DiMasi J.A., Grabowski H.G., Hansen R.W. (February 2016). Innovation in the pharmaceutical industry: New estimates of R&D costs. *J Health Econ.* Available at: https://pubmed.ncbi.nlm.nih.gov/26928437/
[41] Parry B., Moss R. (July 2024). Making more medicines that matter. McKinsey and Company. Available at: https://www.mckinsey.com/industries/life-sciences/our-insights/making-more-medicines-that-matter
[42] IPAY 2028 Draft Guidance, at 137

patents, exclusivities, and marketing applications. ***PhRMA requests that CMS clarify how it intends to consider and weigh the 1194(e)(1) factors and confirm that it will not use these factors to reduce prices.*** Moreover, in describing patents, exclusivities, and approvals that fall under item D above, CMS appears to have changed the term "related" (used to describe patents in the IPAY 2027 Guidance)[43] to "relevant,"[44] and it is not clear whether this change is substantive. CMS should clarify the significance of this change (if any) in the final Guidance.

Second, ***PhRMA urges CMS to consider the data described in item D—i.e., pending and approved patent applications, exclusivities, and pending or approved marketing applications—as markers of a product's innovative nature, the investment that the manufacturer made in developing the product, and the lack of therapeutic alternatives, all of which are factors that weigh in favor of increasing the preliminary price.***

Request for Comment on "Forward-Looking" Market Data

In section 50.1 of the draft Guidance, CMS solicits comment on the collection of additional, forward-looking "market data" for the selected drug. CMS suggests this data could include forecasted net revenue and volume data for the selected drug for future periods and provides examples of a manufacturer's annual forecast of U.S. net revenue, volume by indication, and net pricing for the selected drug itemized by the relevant market channel (e.g., Medicare, Medicaid, commercial or other); and annual gross-to-net ratio trend for the selected drug across all market channels and market share percentages and volume, by indication. CMS states that "these types of data are consistent with the section 1194(e)(1)(E) factor of 'market data and revenue and sales volume data for the drug in the United States.'" "Forward-looking" market data is inappropriate for collection as both a policy and legal matter. As a policy matter, forward-looking data is a forecast that may or may not be realized. Moreover, CMS requires primary manufacturers to certify that the data submission is "complete and accurate," and that notification will occur if information has changed.[45] Forecasts, by definition, constantly evolve based upon new information and changes to the business environment. Thus, it would be impossible to regularly notify CMS when information has "changed." In addition, requiring a delegated official to certify to the "completeness" and "accuracy" of what is merely a forecast places undue, unfair responsibility on such certifiers, who cannot reasonably opine as to whether the predictions will occur. Finally, a forecast does not constitute "data." In interpreting statutes, agencies must use the "ordinary meaning of terms unless context requires a different result."[46] The ordinary meaning of "data" is "factual information (such as measurements or statistics) used as a basis for reasoning, discussion, or calculation."[47] A prediction is not empirical, factual information akin to a "measurement" or a "statistic." In the case of MFPs, CMS' example of the gross-to-net ratio trend is particularly inapt, given that MFP will have a direct impact on net sales. Indeed, CMS may understand that it is stretching the meaning of the statute, as the agency states that its request for forecasted data is merely "consistent" with section 1194(e)(1)(E). This may

[43] IPAY 2027 Final Guidance, at 309
[44] IPAY 2028 Draft Guidance, at 210
[45] Centers for Medicare and Medicaid Services. (November 2024). IPAY 2027 Negotiation Data Elements Form, CMS 10849. Available at: https://www.reginfo.gov/public/do/PRAViewICR?ref_nbr=202411-0938-010. (Note: PhRMA continues to recommend that CMS revise the certification so that it applies *only* to the information available to the individual at the time of the certification)
[46] *Gonzales v. Carhart*, 550 U.S. 124, 152 (2007)
[47] Merriam-Webster. (n.d.) data. Merriam-Webster.com. Available at: https://www.merriam-webster.com/dictionary/data

indicate that the agency understands the statute does not clearly permit collection of predictions. ***For the above reasons, CMS should not collect "forward-looking" forecasts in its ICR.***

III. Evidence About Alternative Treatments [1194(e)(2)]

Emphasizing 1194(e)(2) Factors Related to Patient Benefit

Section 1194(e)(2) (hereinafter referred to as the (e)(2) factors) of the IRA allows for all stakeholders to submit evidence on the selected drug's performance in the real world. The previous Administration declined to provide any insight or clarity into CMS' methodology including, but not limited to, any information or structure around how the different sections will be weighted. ***As PhRMA and other key stakeholders[48] have previously recommended, CMS should (a) assign a greater weight to (e)(2) factors as compared to the (e)(1) factors; and (b) within such (e)(2) factors, assign greater weight to those that actually reflect the benefit the selected drug brings to patients, caregivers, and society and will help encourage the generation of additional evidence on the comparative health benefits of different treatments. As a corollary, to the extent (e)(1) factors are considered, CMS should place less weight on the (e)(1) factors that would diminish medicines' benefits and could stagnate innovation if overweighted***. Basing prices for medicines on costs incurred by the manufacturer, instead of the value and benefits conferred by the innovation, sends perverse, unintended signals to manufacturers that devalue and disincentivize R&D and pose a significant threat to innovation and progress for future medicines. Manufacturers require a clear understanding as to whether innovation and progress will be valued under CMS' price setting framework. As such, ***CMS should provide greater transparency on the types of evidence it will rely on when evaluating data, such as the extent to which a selected drug represents a therapeutic advance or addresses an unmet medical need, and the effects of the selected drug on specific populations.***

Therapeutic Alternative Selection

Identification of therapeutic alternatives represents a critical element of the MFP process, yet it is also a notoriously difficult element of any process for evaluation of the comparative costs and benefits of different medicines or other health care interventions. To date, CMS Guidance has not provided meaningful clarity on the evidence or process the agency uses to select therapeutic alternatives, a shortcoming that is retained in the IPAY 2028 draft Guidance. This is illustrated by CMS' release of MFP explanations for the IPAY 2026 drugs, which indicate that the agency considered an average of 6.5 therapeutic alternatives across each of the ten selected drugs (ranging from one to ten therapeutics alternatives per selected drug) but provided little specific information about how the agency ultimately selected specific therapeutic alternatives beyond vague statements on use of a "holistic" approach.[49] Selection of clinical comparators can be highly variable, raising questions about whether the decision was

[48] McElwee F., Cole A., Garrison L.P., Towse A. (June 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

[49] National Pharmaceutical Council. (January 2025). "Maximum Fair Price" Explanations for IPAY 2026 Drugs. Available at: https://www.npcnow.org/sites/default/files/2025-01/MFP%20Explanation%20Files%20IPAY%202026%20NPC%20Policy%20Evidence%20Brief%202025_01.pdf

informed by other factors or objectives of the government's decision-making, rather than clinical appropriateness.[50]

As PhRMA has stated previously, therapeutic alternative selection should be based on the most clinically appropriate alternative informed by conversations with and data submissions from experts with real-world experience, including patients, practicing physicians, and pharmaceutical manufacturer(s). However, the agency's extremely compressed timetable for input, combined with vague, poorly defined standards for therapeutic alternative selection, makes it exceptionally difficult for manufacturers and other stakeholders to efficiently provide meaningful input on a selected drug relative to its therapeutic alternatives, and raises the risk that CMS will not identify the most clinically appropriate options. Especially as Part B medicines become eligible for price setting in IPAY 2028, introducing further complexities, CMS must also ensure maximum transparency on the process and mechanics of how they are utilizing therapeutic alternatives to calculate a product's MFP. Without these necessary insights, manufacturers will have no visibility into whether there are gaps or issues in the process, which could ultimately impact pricing. As such, ***CMS should publish the potential therapeutic alternative(s) under consideration for each selected drug when selected drugs are announced and allow data submitters to comment on CMS' proposal as part of their data submission package***. This would significantly reduce stakeholder burden by allowing data submitters to tailor their submissions to CMS and limit the potential scenarios stakeholders currently need to consider when preparing ICR responses.

Consideration of Non-Drug Therapeutic Alternatives

PhRMA appreciates the Agency seeking feedback on whether health care services payable under Part A or B could be considered as therapeutic alternative(s), but we do not believe that would be an appropriate step at this time. CMS has not yet provided clear enough standards or an open enough process to provide assurance that the agency will consistently select appropriate therapeutic alternative even among competing medicines. Expanding therapeutic alternatives to include health care services would increase the risk of CMS selecting clinically inappropriate comparators, while at the same time creating increased burden on data submitters to submit even more information and analysis. There is also a lack of visibility into the Agency's selection of therapeutic alternatives which creates no pathways for stakeholders to provide input on CMS' selection even when they believe CMS' selection may be incorrect. Because of these unaddressed issues, ***it would be premature for the Agency to broaden the consideration of potential therapeutic alternatives to non-drug alternatives.***

Starting Point for Initial Offer

PhRMA is opposed to the use of alternative starting points for initial offers such as those for which CMS solicits comments in the draft guidance. In particular, we are concerned by consideration of a starting point between the price of the therapeutic alternative(s) and the "unit cost of production and distribution," or potential use of "domestic reference prices."[51] As noted above, this approach fails to consider the important clinical and quality of life benefits provided by MFP-selected medicines. As a result, it would devalue treatment advances and discourage continue progress against unmet medical needs, significantly

[50] Hernandez I., et al. (December 2023). Medicare drug price negotiation: The complexities of selecting therapeutic alternatives for estimating comparative effectiveness. *J Manag Care Spec Pharm*. Available at: https://pmc.ncbi.nlm.nih.gov/articles/PMC10909583/

[51] IPAY 2028 Draft Guidance at p. 131, § 60.3.2

exacerbating the damaging effects of the Program. **PhRMA strongly encourages CMS to reject consideration of alternative methodologies for establishing a starting point for negotiation such as domestic reference pricing or unit cost of production and distribution.**

Stakeholder Engagement

While PhRMA appreciates CMS' attempts to improve stakeholder engagement with patients, caregivers, patient advocates, and practicing physicians, the MFP process still falls well short of supporting meaningful patient engagement. For example, CMS frequently releases important information too late in its process, which prevents engagement. In the case of the stakeholder events, CMS failed to release the redacted transcripts from April 2025's events until over a month later in June – after CMS sent impacted manufacturers the Agency's initial offer for IPAY 2027. CMS also held its stakeholder events in the middle of a weekday, on short notice, placing a barrier on patients, caregivers, or practicing clinicians who needed to work or faced another type of conflict. By doing so, CMS severely limited who could participate and as a result, reduced the valuable insight that could impact CMS' evaluation of evidence and its MFP determination. Similarly, allowing these stakeholders only one month to complete the 1194(e)(2) section of the ICR –an interpretation the Agency did not have to adopt under the statute[52] – creates additional barriers for many stakeholders including those who are disabled or underfunded, or otherwise come from a disadvantaged background. CMS also continues to rely on a black box process that may discourage stakeholders from spending their time providing input that they fear the Agency will not take into consideration. For example, the IPAY 2026 MFP explanations primarily repeated existing Guidance instead of providing stakeholders with any insight into CMS' process or if CMS incorporated patient-centered data. ***As PhRMA has previously recommended, we urge CMS to make improvements in the process of soliciting stakeholder input and improve transparency into how this input influences the agency's decision-making. Without fundamental improvements, CMS risks creating the impression of tokenism in which patient and clinician input is sought but not actually considered.***

Quality-Adjusted Life Years

As PhRMA has repeatedly stressed in previous comments, cost-effectiveness metrics such as the Quality-Adjusted Life Year (QALY) should not be used by CMS in setting MFPs in accordance with section 1557 of the Affordable Care Act, section 504 of the Rehabilitation Act, as well as sections 1182(e) and 1194(e) of the Social Security Act. CMS' decision to continue considering analyses that include cost-effectiveness measures, including QALY-alternatives that use the same underlying and discriminatory math,[53] is both misguided and unnecessary. Using cost-effectiveness metrics as the basis for policy decisions risks undervaluing the lives of the elderly, the disabled, and other groups considered to have less than "perfect" health. While we understand that not all stakeholders will understand cost-effectiveness measures, given the breadth of data CMS considers (some of the MFP explanations included almost 300 sources), it is unlikely the Agency will be able to confirm that the studies do not use cost-effectiveness

[52] As PhRMA has previously noted, the statute does not specifically require that manufacturers and other stakeholders submit the information described in section 1194(e) by March 1. Instead, the March 1 deadline applies to non-FAMP data as well as certain other information, but does not cross-reference section 1194(e). SSA § 1194(b)(2)(A) cites to information described in § 1193(a)(4), which includes non-FAMP data as well as certain other information the Secretary absolutely "requires" to carry out price setting, but does not contain a reference to § 1194(e)

[53] National Council on Disability. (November 2022). Alternatives to QALY-Based Cost-Effectiveness Analysis for Determining the Value of Prescription Drugs and Other Health Interventions. Available at: https://www.ncd.gov/report/alternatives-to-qaly-based-cost-effectiveness-analysis-for-determining-the-value-of-prescription-drugs-and-other-health-interventions/

measures in a way that does not discriminate against certain populations. CMS should reconsider its decision to remove the attestation that prevents academics and other third parties from submitting data relying on these fatally flawed metrics. ***Instead, CMS should prioritize data from patients and doctors with prescribing experience, along with clinical effectiveness research that provides insight into a medicine's real-world performance, without undervaluing or discriminating against the lives of the elderly, the disabled, or the terminally ill.***

Appendix B: Renegotiation

I. CMS Cannot Rely Solely on the Existence of Part B Utilization to Justify Renegotiation

The Inflation Reduction Act (IRA) outlines clear requirements governing the identification of renegotiation-eligible drugs and the selection of drugs for renegotiation for years beginning with initial price applicability year (IPAY) 2028. Section 1194(f)(2) of the Social Security Act (SSA) limits "renegotiation-eligible" drugs to drugs that meet strict criteria:

> (1) A change in monopoly status occurs (for IPAY 2028 this is limited from a short-monopoly drug to a long-monopoly drug);
>
> (2) A new indication is added to the drug; or
>
> (3) The Secretary determines there has been a "material change" in any of the factors enumerated in SSA § 1194(e).

In addition, under SSA § 1194(f)(3), for criteria (2) and (3) the Secretary may select only those drugs for which the Secretary "expects renegotiation is likely to result in a significant change" in the maximum fair price (MFP).

The Centers for Medicare and Medicaid Services (CMS) states that it "anticipate[s] that selected drugs from [IPAYs] 2026 and 2027 with Part B utilization are likely to be determined to be "renegotiation-eligible drugs" and "selected for renegotiation" for IPAY 2028.[54] Yet, CMS does not explain: (1) why these drugs would qualify as "renegotiation-eligible drugs" under the statutory criteria; or (2) why they would meet the statutory requirements to be selected for renegotiation even assuming they fell within a category of "renegotiation-eligible drugs." Nor is the relationship between these statutory requirements and the existence of Part B utilization self-evident. ***Accordingly, there is no reason to conclude that a "Part D" selected drug with some Part B utilization necessarily or even probably meets the IRA's renegotiation criteria.***

The only possible basis for a selected drug to qualify as a renegotiation-eligible drug absent a change in monopoly drug status or a new indication is if the Secretary determines there has been a "material change" in any of the factors enumerated in paragraph (1) or (2) of SSA § 1194(e). The mere existence of Part B utilization is not listed in either the manufacturer-specific data elements in section 1194(e)(1) or the factors relating to therapeutic alternatives in section 1194(e)(2). Moreover, there is no reason why the existence of Part B utilization in a drug selected as a "Part D" drug would represent a *material change* in any of these factors. Importantly, we have heard nothing about selected drugs from IPAY 2026 or 2027 that acquired new Part B indications after their selection – and the continued existence of preexisting Part B utilization would not be any kind of change at all, let alone a "material change" in any of the section 1194(e) factors. The only "change" that has occurred is that, starting with IPAY 2028, the IRA's drug selection criteria takes into account Part B spending;[55] but this does not amount to a "material change" in the factors enumerated in section 1194(e) with respect to a selected drug.

[54] IPAY 2028 Draft Guidance § 130.1 at 190.
[55] SSA § 1192(d).

CMS similarly has failed to explain its conclusion that selected drugs from IPAYs 2026 or 2027 with Part B utilization would "likely" be selected for renegotiation. Absent a change in monopoly drug status, CMS may only select renegotiation-eligible drugs for which it "expects renegotiation is likely to result in a significant change" in the MFP.[56] But there is no basis for expecting a significant change in the MFP with respect to a previously selected drug with Part B utilization, as the continued existence of Part B utilization does not alter the factors outlined in section 1194(e), let alone "materially" change any of those factors in a way that would be expected to result in a significant change in MFP. These factors provide "the basis" for CMS to determine the "offers" and "counteroffers" during the renegotiation process, and therefore CMS cannot consider other data or information.[57]

Finally, the possibility of a "significant change" in MFPs from including selected drugs from IPAYs 2026/2027 with Part B utilization in the first renegotiation cycle conflicts with CMS' own statements. CMS recognizes that renegotiation eligibility and selection will begin approximately 15 months after the end of the price setting period for IPAY 2026 selected drugs and immediately after the end of the price setting period for IPAY 2027 selected drugs. Given this short timeframe, CMS states that it "does not expect" that it would be likely that renegotiation would result in a "significant change" to the MFPs for drugs selected for IPAYs 2026 and 2027, "except in unanticipated or unusual circumstances."[58] CMS states that such unusual circumstances could include a new indication being added to the drug shortly after the end of the price setting period, or unit costs increasing significantly due to a shortage of a key ingredient shortly after the end of the price setting period. CMS does not provide any reasoning as to why Part B utilization alone would constitute a "significant change" in the MFP.

CMS' statement that it "anticipate[s]" that IPAY 2026/2027 selected drugs with Part B utilization likely will be selected for renegotiation[59] conflicts with CMS' stated expectation that renegotiation of IPAY 2026/2027 selected drugs will not result in a "significant change" to MFPs absent "unanticipated or unusual circumstances."[60] The continued existence of Part B utilization is not an "unanticipated or unusual circumstance[]." The draft guidance does not attempt to reconcile its contrasting statements about renegotiation of IPAY 2026/2027 selected drugs, nor does it identify any connection between the existence of Part B utilization for a selected drug from IPAY 2026 or 2027 and the statutory requirements for renegotiation eligibility and selection.[61] If Congress meant for Part B utilization alone to be a categorical trigger for renegotiation selection, it could have expressly stated as such when it enumerated the statutory requirements for selection.

II. Outside of Monopoly Status Changes, No IPAY 2026 or IPAY 2027 Selected Drugs Should Be Selected for Renegotiation in IPAY 2028 (Unless Requested by the Selected Drug Manufacturer)

As described above, CMS itself recognizes in the draft program guidance that it is unlikely drugs selected for IPAYs 2026 or 2027 would experience a "significant change" to the product's MFP, given the short

[56] SSA § 1194(f)(3)(C).
[57] SSA § 1194(f)(4)(B) (requiring the renegotiation process to be consistent to the extent practicable with the statutory methodology and process for negotiation, including reliance on the factors enumerated in section 1194(e)).
[58] Draft Guidance § 130.2.1 at 197.
[59] Draft Guidance § 130.1 at 190.
[60] Draft Guidance § 130.2.1 at 197.
[61] See *Encino Motorcars, LLC v. Navarro*, 579 U.S. 211 (2016) (explaining that where an agency has failed to "give adequate reasons for its decisions," "its action is arbitrary and capricious and so cannot carry the force of law").

time between the end of negotiation for these IPAYs and the start of process for IPAY 2028. CMS should thus affirmatively commit to not selecting for renegotiation any IPAY 2026 or 2027 drugs (outside of the statutorily-required change in monopoly status or in the absence of the manufacturer requesting renegotiation). An affirmative commitment would avoid CMS and manufacturers engaging in the resource-intensive, but unnecessary and duplicative, price setting process so close in time to the original negotiation.

III. CMS Should Raise the Threshold of a "Significant Change" in the MFP for Renegotiation Selection

CMS proposes a two-pronged, "holistic inquiry" approach for determining if renegotiation would lead to a "significant change" in the MFP for the purpose of determining renegotiation eligibility for drugs that have a new indication and/or a "material change" in any of the Section 1194(e)(1) or (e)(2) factors. Under the proposed approach, CMS would require that the selected drug meet both of the following two criteria: (1) that renegotiation is likely to result in a 15 percent or greater change in the MFP; and (2) that the expected change in the MFP would have a significant impact on the Medicare program (e.g., program spending, beneficiary cost-sharing).

PhRMA is generally supportive of CMS utilizing specific criteria in its "holistic inquiry" approach for determining renegotiation eligibility. However, we urge the Agency to consider not just whether a "significant change" in the MFP would have financial impacts on the Medicare program and beneficiaries, but also whether that change would lead to greater value to patients. CMS should also work to ensure that there is as much transparency as possible in its determination of renegotiation eligibility—especially for drugs that meet eligibility criteria through a "material change" in the negotiation factors that CMS determines would cause a "significant change" in the MFP. However, most notably, PhRMA believes that CMS should raise the threshold for determining whether an expected change in a drug's MFP would be "significant."

Using CMS' own reasoning it should raise the expected percent change in the MFP threshold from 15 percent to at least 35 percent. CMS notes in the draft program guidance that a 15 percent or greater expected change in the MFP "is consistent with the range of percent reductions in the ceiling price that is statutorily defined for drugs selected for renegotiation due to monopoly status changes." However, it remains unclear how CMS reached 15 percent as a consistent comparator based upon statutorily defined non-federal average manufacturer price (non-FAMP) ceiling changes when a selected drug switches monopoly status.

For drugs selected for initial price applicability years prior to IPAY 2030, the change in non-FAMP ceiling when a selected drug changes monopoly status equals 35 percent, not 15 percent. Section 1194(c)(4)(B)(ii) of the Act explicitly excludes drugs selected for IPAYs 2026 – 2029 from the definition of an "extended-monopoly drug" where the manufacturer has entered into an agreement. CMS acknowledged this, stating: "no selected drug will have a monopoly status change to extended-monopoly for purposes of renegotiation-eligibility" in 2028. Accordingly, the only drugs eligible for renegotiation selection for IPAY 2028 based upon a change in monopoly status will be those that change from short-monopoly to long-monopoly status. Using CMS' own reasoning that a "significant change" in the MFP should be consistent with percent reductions in the statutory non-FAMP ceiling price for different monopoly lengths, CMS should re-define the threshold to equal at least 35 percent. Setting the threshold to at least 35 percent for expected change in the MFP if a drug were to undergo renegotiation due to either

a new indication or material change in the section 1194(e) factors would align with the percentage change in the non-FAMP applicable percentage between short-monopoly (75 percent) and long-monopoly (40 percent) drugs, which would achieve the very consistency CMS cites as its goal in defining a "significant change" in the MFP.

In addition, even if CMS were to include in its analysis the non-FAMP ceiling applicable to extended-monopoly drugs, its proposal for a 15 percent change is arbitrary and does not follow the statute. The applicable percentages included in statute range from 75 percent of non-FAMP for short-monopoly drugs, to 65 percent of non-FAMP for extended-monopoly drugs (10 percentage point, or 13 percent change from short-monopoly), to 40 percent of non-FAMP for long-monopoly drugs (25 percentage point, or 38 percent change from extended monopoly). Put another way, none of the changes in monopoly status are associated with either a 15 percent or 15 percentage point reduction in the applicable percentage of the non-FAMP for determining the statutory ceiling price. As noted above, agencies are required to provide "adequate reasons" for their decisions.[62] CMS has failed to explain how its proposed 15 percent threshold accords with the statutory provisions on the various non-FAMP ceilings of 75, 65 and 40 percent. CMS should adopt the threshold of at least 35 percent starting in 2028, and extend it through 2030, during which the only changes in monopoly status for selected drugs will be from short-monopoly to long-monopoly.

Finally, raising the threshold to at least 35 percent will reduce the time and resource burden for both the Agency and manufacturers of selected drugs, especially if the price setting program continues to grow by CMS newly selecting and/or renegotiating already selected drugs. CMS is required to ensure that its renegotiation process is, "to the extent practicable … consistent with the methodology and process established" for annual price setting under section 1194(b) of the Act.[63] To ensure both manufacturers and CMS can adequately and thoughtfully engage in the offer and counter-offer process, and that the renegotiation process includes the patient and clinical voices essential to understanding each treatment's clinical value, CMS should choose a threshold that does not result in an inordinate number of medicines being chosen for renegotiation. Doing so could also reduce market volatility that may occur if a drug is selected for renegotiation each time a new indication or material change in the 1194(e) factors leads to an expected 15 percent or greater change in the drug's MFP.

IV. CMS Should Reduce Mandatory Data Submission Burden on Manufacturers of Drugs Selected for Renegotiation

CMS details in the IPAY 2028 draft program guidance that it will utilize both voluntary and mandatory data submissions to inform the renegotiation process. CMS notes that while the statute does not require the Agency to collect data from primary manufacturers to determine if there is a new indication or material change in the section 1194(e) factors, it will collect a subset of new (e)(1) data as a voluntary submission from the primary manufacturers whose product does not have a change to monopoly status for the purposes of renegotiation eligibility. Once a drug is selected for renegotiation, CMS will collect new information for all section 1194 (e)(1) data elements. This data submission will be *mandatory* for primary manufacturers to submit via the negotiation data elements ICR (data elements ICR) and will share the same submission deadline as the ICR for the annual price setting process.

[62] *Encino Motorcars, LLC v. Navarro*, 579 U.S. 211 (2016).
[63] SSA § 1194(f)(4)(B).

PhRMA appreciates the voluntary nature of the data submission to support the determination of eligibility for renegotiation. However, as PhRMA has previously stated[64] and further articulates in Appendix D of our IPAY 2028 draft program guidance comments, CMS' information collection request (ICR) forms are currently egregiously burdensome to stakeholders and continue to fall short of the three-prong regulatory test established by the Paperwork Reduction Act (PRA).[65] Yet, meaningful changes to rectify those concerns and comply with the PRA have not materialized, leaving data submitters spending countless staff hours compiling arbitrary data under intense compliance pressure. To date, it remains unclear how CMS uses the data elements required for ICR responses in the price setting process, or how it intends to use the information during the renegotiation process.

In order to address concerns regarding the overly burdensome data submission required for renegotiation, ***CMS should allow primary manufacturers to submit updates to the original data elements ICR, rather than requiring them to submit an entirely new ICR. To support this process, CMS should allow primary manufacturers to attest to ICR responses that have not significantly changed since the submission of the original data elements ICR. CMS should also be as transparent as possible with manufacturers on how they are using newly submitted information and recalculating the MFP for drugs selected for renegotiation.***

Subjecting manufacturers of selected drugs to repeated negotiation and renegotiation processes is burdensome, inefficient, and out of line with the Administration's focus on reducing needless regulation that hinders innovation and economic growth. A survey of PhRMA members reports that staff labor to populate the data elements ICR exceeds 7,700 hours on average across various business functions, consultants, and outside counsel. These demands will only be amplified if manufacturers are forced to resubmit the entire 73-page ICR for drugs selected for renegotiation. Allowing manufacturers to attest that information has not significantly changed will reduce the overall resource burden on stakeholders and introduce greater efficiency into the renegotiation process.

[64] See PhRMA comments on 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).

[65] 5 C.F.R. § 1320.5(d)(1)(i)-(iii).

Appendix C: Data Collection under the IRA Is Wasteful and Unnecessarily Burdensome

The IRA requires the Secretary to consider specific factors in setting Maximum Fair Prices, which include both manufacturer specific factors as well as evidence about the selected drug and treatment alternatives. The Biden Administration's decisions about how to define the factors, as well as the process for collecting the resulting data is unnecessarily burdensome and has led to significant waste. As a result, several PhRMA members reported **averaging over 7,700 hours of staff labor across 21 business functions to comply** in IPAY 2026. Further, in IPAY 2027, manufacturers have approximately 40 days from the announcement of the selected drug list to submit an inordinate amount of data.

Key Issues with Specific Data Elements

Primary and Secondary Manufacturer Construct: CMS has created a definition of "Primary" and Secondary" Manufacturer, a construct which does not exist in the statute. Generally, the "Primary Manufacturer" is defined by CMS as the company that "holds" the NDA/BLA and the "Secondary Manufacturer" is another manufacturer on the NDA/BLA or a company that markets the drug under an agreement with the Primary. Under this CMS created construct, the Primary is responsible for the Secondary, including submitting information.

Key Issues:

- Creates unneeded complexity and undue burden by requiring one corporate entity to submit information on behalf of another (under threat of civil penalties).
- "Primary Manufacturers" may not have the time to quality- and fact-check the data possessed solely by a "Secondary Manufacturer."
- Much of the data CMS requests is proprietary, such as sensitive pricing metrics. Yet, CMS requires one corporate entity to obtain and report such proprietary data on behalf of another.

R&D Costs: Though the IRA directs CMS to consider R&D costs, CMS has chosen in guidance to subdivide R&D costs into seven distinct categories, including "Acquisition Costs," "Basic Pre-Clinical Research Costs" and "Abandoned and Failed Drug Costs," among others.

Key Issues:

- Division of R&D costs into different categories is misaligned with the reality of how biopharmaceutical R&D is conducted and tracked by manufacturers; this results in manufacturers having to re-analyze decades-old data to adhere to CMS' arbitrary asks.
- Overlooks that manufacturers may not have the ability to reconstruct all the R&D costs of selected products, and those which were under development for many years before approval, at the level of specificity that CMS is requesting.

R&D Recoupment: The IRA directs CMS to consider the extent to which R&D costs for a selected drug have been "recouped." CMS guidance directs manufacturers to submit global and U.S. total lifetime net revenue for the selected drug to determine the extent to which the manufacturer has recouped R&D costs.

Key Issues:

- Takes an approach that reflects a fundamental misunderstanding of the economics of the global biopharmaceutical marketplace and the highly risky nature of drug development CMS's approach fails to recognize that revenues from the small proportion of highly successful medicines are relied on to not only recoup their own costs but fund investment in high-risk areas.

Federal Financial Support: While the IRA dictates that CMS should consider prior federal financial support for R&D related to the selected drug, CMS broadly defines this factor to seek detailed and often

decades-old information from when research began, even if it was prior to when the "Primary Manufacturer" acquired the drug.

Key Issues:

- Requires data that has never been "assigned" or "allocated" to a specific FDA-approved indication, meaning many manufacturers will not be able to comply with CMS' collection, particularly for decades-old historical costs.
- Interprets the statute to include information not commonly thought of as financial support for research. For example, orphan drug tax credits are critical to incentivize innovation and are not akin to the government providing direct support to a company's research efforts.

Production and Distribution Costs: While the IRA directs CMS to consider the costs of production and distribution of a selected drug, CMS has expanded this definition to include data such as purchase of raw ingredients, quality control, operating costs for personnel, etc. (production costs) and packaging, labeling, shipping, and operating costs (distribution costs).

Key Issue: Requires a level of additional detail and specificity that goes against standard practice and may not be accessible (for example, requiring the production and distribution unit costs to be reported separately for each NDC-11 of the selected drug, including any NDC-11 marketed by a "Secondary Manufacturer," an issue because such data is not typically recorded at this level).

Pricing Data: While the IRA directs CMS to consider U.S. market data, revenue, and sales volume for the selected drug, CMS expands this in guidance to cover a broad range of pricing data such as Average Manufacturer Price, Medicaid Best Price, FFS, and Big 4 pricing, which are unique to their specific programs.

Key Issue: Requires reporting of numerous pricing metrics under "Market Data and Revenue and Sales Volume Data," all of which are sensitive in nature, outside the scope of the statute, and are inappropriate reference points for Medicare as they represent the structure and population of entirely different markets.

Therapeutic Alternatives: The IRA directs CMS to consider evidence about alternative treatments with respect to the selected drug. However, information on "therapeutic alternative(s)" for the selected drugs are not disclosed to the manufacturer prior to data submission.

Key Issue: Fails to provide transparency into how therapeutic alternatives are selected, increasing the burden on manufacturers and other respondents who must submit all information on all potential comparators.

Recommendations

Overall Process

- Provide additional time for manufacturers to submit data and research to support MFP determinations.
- Provide insight into how data will be used in the Agency's decision-making process, including but not limited to any information or structure around how the different data elements will be weighted.
- Allow manufacturers to check a box stating that CMS may use publicly available resources in lieu of manufacturer submission of duplicative data wherever possible (e.g., Orange Book, Purple Book)

Primary and Secondary Manufacturer Construct

- Remove the "Primary" and "Secondary" manufacturer construct (or in the alternative, respondents need not report on data from secondary manufacturers).

R&D Costs & Recoupment

- Amend the ICR to allow a single global response for R&D costs (instead of capturing at a granular level), like a Form 10-K for Securities and Exchange Commission (SEC) filing, and a single attestation (YES/NO) regarding the extent to which these costs have been "recouped."

Federal Financial Support

- Require reporting of only one total figure, which includes all relevant financial support, directly related to the selected drug.

Production and Distribution Costs

- Allow discretion for manufacturers to describe production and distribution costs which they can report and to provide a narrative explanation describing how these costs were calculated.

Pricing Data

- Withdraw the pricing metrics that exist nowhere but in this program (i.e., all variations of "U.S. commercial average net unit price" and "manufacturer average net unit price to Part D plan sponsors, respectively. CMS also already maintains Part D pricing data).
- Do not collect metrics, such as best price, FSS, and Big 4 pricing.
- Collect only one year of data for some financial data elements such as various market data, revenue, and sales volume data.

Therapeutic Alternatives

- Publish therapeutic alternatives that will be used to evaluate selected drugs– when the selected products are announced.

Protection of Proprietary Information/Certification

In addition, we are happy to discuss protecting proprietary data in a manner that is more in line with the statute and typical security protocols, as well as the over-broad "certification" statement Biden's CMS included at the end of the form as nothing in the statute requires it.

Appendix B

Re: Medicare Drug Price Negotiation Program: Draft Guidance, Implementation of Sections 1191 – 1198 of the Social Security Act for Initial Price Applicability Year 2028 and Manufacturer Effectuation of the Maximum Fair Price in 2026, 2027, and 2028

Appendix D: Information Collection and Negotiation Process

As in prior years, the Centers for Medicare & Medicaid Services' (CMS, the Agency) draft Initial Price Applicability Year (IPAY) 2028 Guidance fails to establish a clear, consistent methodology for arriving at maximum fair prices (MFPs). Meeting this basic standard is not only required by the statute[1] but is also essential for ensuring accountability of government decision-making. The lack of consistent methodology – reflected in the Guidance and Appendix A of the Draft Guidance (relating to definitions for purposes of collecting data) – creates unpredictability and adds unnecessary burden, exacerbating the MFP program's harmful effects.

To date, CMS has declined to provide any meaningful insight into how it uses manufacturer- or stakeholder-submitted data as part of the "clear and consistent" methodology required by statute. The draft 2028 Guidance unfortunately continues to leave this problem unaddressed. This results in manufacturers facing an opaque process with unclear decision-making standards, exceptionally burdensome data submission requirements, and little recourse but to adhere to the agency's arbitrary demands, even when these demands violate the spirit and letter of the Paperwork Reduction Act (PRA). The lack of transparency throughout the entirety of the price setting process underscores this approach as it remains uncertain whether the Agency even knows what information it needs, which could be a contributing factor for why the Agency continues requesting lengthy and at times irrelevant data from key stakeholders.

Further, some of the potential changes for which CMS seeks input would worsen, rather than mitigating, the harmful effects of the Inflation Reduction Act's (IRA) drug price controls. We are particularly concerned about the Agency soliciting comments on potential new starting points for the initial offer in the IPAY 2028 draft guidance, including "the unit cost of production and distribution of the selected drug" and "other domestic reference prices." These factors – which would further devalue and discourage research and development of new medicines and risk introducing further uncertainty into a process that is already unpredictable – should be rejected by CMS. Additionally, as discussed in detail later in the appendix, PhRMA continues to advocate that CMS should place greater emphasis on the 1194(e)(2) factors relative to 1194(e)(1) factors as manufacturer-specific factors are less relevant for determining MFPs.

CMS' lack of transparency may also discourage participation from patients, caregivers, clinicians, and other key stakeholders. With no transparency into how – or if – CMS is using data or the stories from these stakeholders, there is a risk that key stakeholders will stop replying to the Agency, as they may not feel that the significant investment required to submit data 28 days post selection or forfeit an afternoon for a roundtable or town hall is worth the time or effort. To address this, CMS should clarify how it uses

[1] SSA § 1194(b)(1) ("The Secretary shall develop and use a consistent methodology and process.")

submitted data in the MFP explanations, enabling stakeholders to tailor future submissions to what matters most in the Agency's decision-making.

Consistent with prior comments, PhRMA urges CMS to make basic improvements in the Guidance document's provisions on methodology and process and streamline and modify the upcoming Information Collection Request (ICR) in order to establish a consistent process and methodology, encourage more meaningful stakeholder participation, improve predictability, and reduce unnecessary data submission burdens. Specifically, we recommend the following changes:

- **Information Collection Request / Appendix A of the Draft Guidance:**
  - Streamline and simplify data submission requirements to reduce unnecessary burden and improve CMS decision-making; and
  - Clarify timing of ICR data certification.
- **Manufacturer-Specific Data Elements [1194(e)(1)]:**
  - Eliminate unnecessary regulatory burden and correct methodological inaccuracies;
  - Align data submission requirements with current business practices;
  - Limit submission of R&D costs to a single amount related to a selected drug;
  - Allow manufacturers the option to stipulate that they have recouped research and development (R&D) costs through a simple yes/no checkbox;
  - Do not place greater emphasis on the 1194(e)(1) factors when adjusting the preliminary price;
  - Clarify how data on pending and approved patents will be used to adjust MFP; and
  - Do not collect "forward-looking" forecasts during the data collection process.
- **Evidence About Alternative Treatments [1194(e)(2)]:**
  - Place greater emphasis on the 1194(e)(2) factors vis a vis 1194(e)(1) factors. Within such (e)(2) factors, focus on those directly related to patient benefit and how the selected drug performs in the real world compared to clinically appropriate therapeutic alternatives;
  - Clarify how CMS will weigh different data elements in MFP price-setting;
  - Improve process and standards on selection of therapeutic alternatives;
  - Reject alternative starting points such as the unit cost of production and distribution or domestic reference pricing as a starting point for the initial offer;
  - Support meaningful stakeholder engagement; and
  - Strengthen safeguards against use of quality-adjusted life years (QALYs) and related metrics.

I. Information Collection Request Data Burden and Noncompliance with Paperwork Reduction Act

In advance of IPAY 2026, PhRMA articulated concrete and actionable recommendations focused on key considerations under the Paperwork Reduction Act (PRA) for the implementation and application of the price setting process. Unfortunately, as it did with most comments, the Agency disregarded our recommendations and continued with its burdensome and inefficient process. For IPAY 2027, PhRMA again reiterated our concerns with how CMS' ICR forms are overly burdensome and, as a result, continue

to fall far short of the three-prong regulatory test established by the PRA.[2] Yet, the previous administration made only minor changes – along with a modest and underestimated increase in burden estimates - while failing to address the ICR's inefficiencies and PRA noncompliance.

The PRA was enacted in 1995 due to the "enormous growth of our federal bureaucracy" and "its seemingly insatiable appetite for data."[3] However, the previous administration ignored PRA requirements to "minimize and control burdens and maximize the practical utility"[4] of information collections and instead imposed an overly burdensome and complicated process to collect data. This is not only a waste of pharmaceutical manufacturer resources but also is an inefficient use of CMS staff time. There is no evidence[5] that CMS even considered the majority of information provided to the agency to determine the MFPs for IPAY 2026, yet – instead of complying with the PRA and reducing the burden on all data submitters – the previous administration allowed the ICR to balloon from a 47-page form in IPAY 2026 to 73 pages in IPAY 2027.

Further, the 28-day timeline to submit information to the Agency after drug selection is unreasonable and, in many cases, infeasible absent significant preparation in advance of selection. The information requested by CMS is not only vast and far-reaching, but it often requires a lookback of one or more decades along with complex coordination across many business functions under compliance pressure. The intensive process of then quality- and fact-checking the compiled data in order to certify this submission (which can be nearly impossible if possessed solely by a "Secondary Manufacturer") is extremely burdensome and can require substantial time compiling and analyzing data in advance of this compressed 28-day period. The Agency adds to this burden as it is unclear if respondents must continually update their ICR submissions or if they must only modify their submission(s) if it later becomes clear that the information submitted was incorrect based on the information available <u>at the time of submission</u> or if the data changes (e.g., due Medicaid Best Price restatement window). This resubmission process is burdensome and, given the lack of transparency into the MFP setting-process, it remains unclear why CMS requires continued data submission or how the Agency evaluates this data. The renegotiation process makes this even more opaque as CMS states that while manufacturers may voluntarily submit data to be considered for renegotiation, this submission is separate from the "ongoing obligation to update . . . original data submissions."[6] ***PhRMA recommends CMS clarify the certification requirements so that manufacturers must only update submissions if the submitter becomes aware that information was incorrect as of the <u>time of submission</u>.***

Furthermore, there is little evidence to validate why CMS needs the requested information as the Agency has provided no transparency into how, or even if, it used the vast amounts of data collected during the IPAY 2026 and IPAY 2027 price setting process. The IPAY 2026 "explanations" mostly repeated information available in Guidance instead of providing any assurance that CMS truly needed all the information collected. Nor has CMS articulated a data destruction schedule for the vast amounts of proprietary information it has collected or will collect. Not only do these flaws raise questions as to the

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[2] 5 C.F.R. § 1320.5(d)(1)(i)-(iii)
[3] *Dole v. United Steelworkers of Am.*, 494 U.S. 26, 32 (1990)
[4] 5 C.F.R. § 1320.1
[5] CMS. (December 2024). MFP Explanations. Available at: https://www.cms.gov/priorities/medicare-prescription-drug-affordability/overview/medicare-drug-price-negotiation-program/selected-drugs-and-negotiated-prices
[6] IPAY 2028 Guidance at § 50.1.

goals behind the process, but it underscores a lack of consideration for the burden the request imposes or CMS' duties under the PRA.

PhRMA appreciates that CMS is soliciting feedback on the forthcoming ICR for IPAY 2028, and that the Administration is considering streamlining the MFP price-setting factors to reduce burden and improve efficiency. To this end, ***we again urge CMS to consider the requirements and intent of the PRA and, consistent with our prior comments to the Agency[7] along with the comments included in this Appendix, streamline and simplify the data submission requirements of the ICR – particularly but not limited to the manufacturer-specific data elements.***

II. Manufacturer-Specific Data Elements [(e)(1) Factors]

Section 1194(e)(1) (hereinafter referred to as the (e)(1) or manufacturer-specific factors) of the IRA describes the following manufacturer-specific data that CMS shall consider for purposes of negotiating the MFP of a selected drug: "(A) Research and development costs of the manufacturer for the drug and the extent to which the manufacturer has recouped research and development costs;" "(B) Current unit costs of production and distribution of the drug;" "(C) Prior Federal financial support for novel therapeutic discovery and development with respect to the drug;" "(D) Data on pending and approved patent applications, exclusivities recognized by the Food and Drug Administration, and applications and approvals under section 505(c) of the Federal Food, Drug, and Cosmetic Act or section 351(a) of the Public Health Service Act for the drug;" and "(E) Market data and revenue and sales volume data for the drug in the United States."

For IPAY 2026 and IPAY 2027, the previous Administration interpreted the statute in a manner that led them to require Manufacturer-Specific Data Elements that were flawed and incongruent with current business practices. As stated above, many of the elements requested for collection violated the PRA in terms of both utility and necessity. For example, CMS continues to divide R&D costs into several categories—an approach that goes far beyond how manufacturers typically track or report this data and may conflict with standard document retention practices.[8]

While CMS' effort to streamline R&D data is a small step in the right direction, collapsing multiple subdivisions of R&D costs into two categories while still requiring manufacturers to include basic pre-clinical research for indications of the selected drug and post-IND costs among other costs does not adequately alleviate manufacturer burden associated with data submissions or make submitted data more relevant to determining MFP. CMS has significant opportunities to align data submission requirements with the PRA and current business practices to improve the utility and accuracy of submitted data and reduce the burden that manufacturers face in adhering to the current requirements.

In addition, 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. The ICR offers no way for manufacturers to fully

[7] PhRMA. (September 2024). PhRMA Comments on IPAY 2027 Negotiation Data Elements and Negotiation Process ICRs. Available at: https://www.regulations.gov/comment/CMS-2024-0198-0018

[8] Draft IPAY 2028 Guidance at p. 206 (Appendix A)

explain the complex and non-linear path of pharmaceutical innovation, which often involves costly setbacks, restarts, and dead ends.

Research and Development Costs

PhRMA appreciates that CMS is soliciting comments on opportunities to streamline the definitions research and development costs and hopes this signals some recognition that the current data requirements are unworkable for manufacturers. However, we remain concerned about the subdivision of R&D reporting requirements into more than one category and believe the changes do not go far enough to reduce the burden on manufacturers. Additionally, PhRMA opposes CMS removal of acquisition costs as part of the overall calculation of R&D costs for a particular drug. An acquiring company pays for the value of the R&D already carried out by the selling company. The acquiring company also must weigh whether its money is better spent on the acquisition or investing internally in R&D. Furthermore, if a manufacturer has acquired the selected drug, CMS' position appears to be that the manufacturer may have *no* R&D costs to report. Yet, reporting an R&D cost of zero or minimal amounts would not be representative of the actual costs that went into developing and bringing the product to market. While PhRMA supports consolidating reporting and greater transparency, ***we strongly urge the new Administration to address the burden and methodological inaccuracies that resulted from the past Administration's approach to implementation of the (e)(1) factors.***

In its 2026 and 2027 IPAY Guidance, CMS' reporting requirements for R&D costs have been misaligned with how manufacturers actually track, allocate, and publicly report costs, creating significant compliance challenges under compressed timelines. While CMS' proposed streamlining of reporting requirements for IPAY 2028 is a modest improvement, it does not go far enough to reduce the overall burden of data collection. Manufacturers cannot easily reconstruct highly detailed R&D costs for drugs developed over a decade or more ago, especially given CMS' overly broad definition of QSSD to include products approved under different applications.

Additionally, costs for "abandoned and failed" products with the same "mechanism of action" may be difficult if not impossible for companies to attribute to a drug development program in the ways CMS has specified. This is because of the nature of investment decisions in biopharmaceutical R&D, which include factors that extend well beyond the mechanism of action of the drug candidate. These difficulties are compounded when drug products are developed through the efforts of multiple companies, through early-stage R&D licensing arrangements, or other partnerships. Preclinical investments in platform technologies or tools like artificial intelligence (AI) are shared across programs, making product-level cost allocation, especially for pre-clinical development activities, nearly impossible. CMS' approach demands a level of precision that is impractical, burdensome, and disconnected from how R&D is conducted and documented in practice.

As noted below, CMS should amend the Guidance to allow manufacturers to stipulate, without more, that they have recouped R&D costs through a simple yes/no checkbox. In the alternative, CMS should limit required submission of R&D costs to a single, total amount related to the selected drug, while allowing companies to voluntarily provide supplemental data. In addition, manufacturers should be given the opportunity to provide a supporting narrative.

Research and Development Cost Recoupment

PhRMA continues to be concerned about the validity of CMS' approach to capturing "R&D recoupment" - which does not account for all distribution and supply chain costs required to get products to market, among other concerns - and urges the Agency to acknowledge the concept's flaws and the difficulty of accurately quantifying and complying with it. As PhRMA and others have continually noted, very few drug candidates that enter clinical trials are ultimately FDA-approved – in fact, just 12 percent.[9] Companies plan R&D across entire portfolios, expecting that only a few successful drugs will generate enough revenue to offset the many costly failures.[10] As a result, CMS' interpretation of the IRA requirement to consider R&D costs at the product level and the extent to which they have been recouped is not only impractical—given how investments are tracked—but also unnecessary under the statutory language. CMS' fundamental misunderstanding of the economics of the biopharmaceutical marketplace exacerbates this flawed provision by continuing to require companies to report in a manner not required by the IRA, such as providing detailed R&D costs and the extent to which they have been recouped, as well as by subdividing such costs into more than one subcategory.

While we appreciate CMS' willingness to consolidate some categories of R&D costs, rather than continuing this highly flawed approach, PhRMA strongly recommends that CMS allow a single global response for all the manufacturer's R&D costs across all development programs, similar to a Form 10K for Securities and Exchange Commission (SEC) filing, and a single attestation (YES/NO) for recoupment with the option to provide a supporting narrative. In addition, CMS should place minimal weight on recoupment and specify that it will not be used to reduce an MFP determined on the basis of a drug's therapeutic and clinical attributes. If a respondent stipulates "YES" that they have recouped research costs, then CMS need not gather any additional information. If a manufacturer checks "NO," then the manufacturer should be allowed the flexibility to provide an explanation, free of word limits, as to how the costs weren't recouped . This approach would also accord with section 1194(e)(1)(A), which merely requires that CMS consider R&D costs and the extent to which they have been recouped. CMS could reason that in cases where a manufacturer stipulates it has recouped R&D costs, the agency would have no need to further include R&D costs in the price-setting analysis (as the costs have been recouped); whereas, in cases where the data show a manufacturer has not recouped R&D costs, such information may inform an upward adjustment to MFP.

Patents and Exclusivities

For IPAY 2028, CMS seeks "comment on…whether CMS should put greater emphasis on certain section 1194(e)(1) factors when adjusting the preliminary price," or "whether CMS should consider and potentially adjust the preliminary price based on" the data described in item D above (data on pending and approved patent applications and exclusivities) "independent of considering other section 1194(e)(1) factors in totality."[11]

First, it is not clear what CMS means by "consider[ing] and potentially adjust[ing] the preliminary price based on" on pending and approved patent applications, exclusivities recognized by the Food and Drug Administration, and applications and approvals under section 505(c) of the Federal Food, Drug, and

[9] DiMasi J.A., Grabowski H.G., Hansen R.W. (February 2016). Innovation in the pharmaceutical industry: New estimates of R&D costs. *J Health Econ.* Available at: https://pubmed.ncbi.nlm.nih.gov/26928437/
[10] Parry B., Moss R. (July 2024). Making more medicines that matter. McKinsey and Company. Available at: https://www.mckinsey.com/industries/life-sciences/our-insights/making-more-medicines-that-matter
[11] IPAY 2028 Draft Guidance, at 137

Cosmetic Act or section 351(a) of the Public Health Service Act for the drug "independent of considering other section 1194(e)(1) factors in totality." For example, it is not clear whether this statement means that CMS is considering giving this factor more weight than all other factors, and if so, how much weight. Nor is it clear whether CMS would increase or reduce the preliminary price based on the described patents, exclusivities, and marketing applications. ***PhRMA requests that CMS clarify how it intends to consider and weigh the 1194(e)(1) factors and confirm that it will not use these factors to reduce prices.*** Moreover, in describing patents, exclusivities, and approvals that fall under item D above, CMS appears to have changed the term "related" (used to describe patents in the IPAY 2027 Guidance)[12] to "relevant,"[13] and it is not clear whether this change is substantive. CMS should clarify the significance of this change (if any) in the final Guidance.

Second, ***PhRMA urges CMS to consider the data described in item D—i.e., pending and approved patent applications, exclusivities, and pending or approved marketing applications—as markers of a product's innovative nature, the investment that the manufacturer made in developing the product, and the lack of therapeutic alternatives, all of which are factors that weigh in favor of increasing the preliminary price.***

Request for Comment on "Forward-Looking" Market Data

In section 50.1 of the draft Guidance, CMS solicits comment on the collection of additional, forward-looking "market data" for the selected drug. CMS suggests this data could include forecasted net revenue and volume data for the selected drug for future periods and provides examples of a manufacturer's annual forecast of U.S. net revenue, volume by indication, and net pricing for the selected drug itemized by the relevant market channel (e.g., Medicare, Medicaid, commercial or other); and annual gross-to-net ratio trend for the selected drug across all market channels and market share percentages and volume, by indication. CMS states that "these types of data are consistent with the section 1194(e)(1)(E) factor of 'market data and revenue and sales volume data for the drug in the United States.'" "Forward-looking" market data is inappropriate for collection as both a policy and legal matter. As a policy matter, forward-looking data is a forecast that may or may not be realized. Moreover, CMS requires primary manufacturers to certify that the data submission is "complete and accurate," and that notification will occur if information has changed.[14] Forecasts, by definition, constantly evolve based upon new information and changes to the business environment. Thus, it would be impossible to regularly notify CMS when information has "changed." In addition, requiring a delegated official to certify to the "completeness" and "accuracy" of what is merely a forecast places undue, unfair responsibility on such certifiers, who cannot reasonably opine as to whether the predictions will occur. Finally, a forecast does not constitute "data." In interpreting statutes, agencies must use the "ordinary meaning of terms unless context requires a different result."[15] The ordinary meaning of "data" is "factual information (such as measurements or statistics) used as a basis for reasoning, discussion, or calculation."[16] A prediction is not

[12] IPAY 2027 Final Guidance, at 309
[13] IPAY 2028 Draft Guidance, at 210
[14] Centers for Medicare and Medicaid Services. (November 2024). IPAY 2027 Negotiation Data Elements Form, CMS 10849. Available at: https://www.reginfo.gov/public/do/PRAViewICR?ref_nbr=202411-0938-010. (Note: PhRMA continues to recommend that CMS revise the certification so that it applies *only* to the information available to the individual at the time of the certification)
[15] *Gonzales v. Carhart*, 550 U.S. 124, 152 (2007)
[16] Merriam-Webster. (n.d.) data. Merriam-Webster.com. Available at: https://www.merriam-webster.com/dictionary/data

empirical, factual information akin to a "measurement" or a "statistic." In the case of MFPs, CMS' example of the gross-to-net ratio trend is particularly inapt, given that MFP will have a direct impact on net sales. Indeed, CMS may understand that it is stretching the meaning of the statute, as the agency states that its request for forecasted data is merely "consistent" with section 1194(e)(1)(E). This may indicate that the agency understands the statute does not clearly permit collection of predictions. ***For the above reasons, CMS should not collect "forward-looking" forecasts in its ICR.***

III. Evidence About Alternative Treatments [1194(e)(2)]

Emphasizing 1194(e)(2) Factors Related to Patient Benefit

Section 1194(e)(2) (hereinafter referred to as the (e)(2) factors) of the IRA allows for all stakeholders to submit evidence on the selected drug's performance in the real world. The previous Administration declined to provide any insight or clarity into CMS' methodology including, but not limited to, any information or structure around how the different sections will be weighted. ***As PhRMA and other key stakeholders[17] have previously recommended, CMS should (a) assign a greater weight to (e)(2) factors as compared to the (e)(1) factors; and (b) within such (e)(2) factors, assign greater weight to those that actually reflect the benefit the selected drug brings to patients, caregivers, and society and will help encourage the generation of additional evidence on the comparative health benefits of different treatments. As a corollary, to the extent (e)(1) factors are considered, CMS should place less weight on the (e)(1) factors that would diminish medicines' benefits and could stagnate innovation if overweighted***. Basing prices for medicines on costs incurred by the manufacturer, instead of the value and benefits conferred by the innovation, sends perverse, unintended signals to manufacturers that devalue and disincentivize R&D and pose a significant threat to innovation and progress for future medicines. Manufacturers require a clear understanding as to whether innovation and progress will be valued under CMS' price setting framework. As such, ***CMS should provide greater transparency on the types of evidence it will rely on when evaluating data, such as the extent to which a selected drug represents a therapeutic advance or addresses an unmet medical need, and the effects of the selected drug on specific populations.***

Therapeutic Alternative Selection

Identification of therapeutic alternatives represents a critical element of the MFP process, yet it is also a notoriously difficult element of any process for evaluation of the comparative costs and benefits of different medicines or other health care interventions. To date, CMS Guidance has not provided meaningful clarity on the evidence or process the agency uses to select therapeutic alternatives, a short-coming that is retained in the IPAY 2028 draft Guidance. This is illustrated by CMS' release of MFP explanations for the IPAY 2026 drugs, which indicate that the agency considered an average of 6.5 therapeutic alternatives across each of the ten selected drugs (ranging from one to ten therapeutics alternatives per selected drug) but provided little specific information about how the agency ultimately selected specific therapeutic alternatives beyond vague statements on use of a "holistic" approach.[18]

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[17] McElwee F., Cole A., Garrison L.P., Towse A. (June 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

[18] National Pharmaceutical Council. (January 2025). "Maximum Fair Price" Explanations for IPAY 2026 Drugs. Available at: https://www.npcnow.org/sites/default/files/2025-01/MFP%20Explanation%20Files%20IPAY%202026%20NPC%20Policy%20Evidence%20Brief%202025_01.pdf

Selection of clinical comparators can be highly variable, raising questions about whether the decision was informed by other factors or objectives of the government's decision-making, rather than clinical appropriateness.[19]

As PhRMA has stated previously, therapeutic alternative selection should be based on the most clinically appropriate alternative informed by conversations with and data submissions from experts with real-world experience, including patients, practicing physicians, and pharmaceutical manufacturer(s). However, the agency's extremely compressed timetable for input, combined with vague, poorly defined standards for therapeutic alternative selection, makes it exceptionally difficult for manufacturers and other stakeholders to efficiently provide meaningful input on a selected drug relative to its therapeutic alternatives, and raises the risk that CMS will not identify the most clinically appropriate options. Especially as Part B medicines become eligible for price setting in IPAY 2028, introducing further complexities, CMS must also ensure maximum transparency on the process and mechanics of how they are utilizing therapeutic alternatives to calculate a product's MFP. Without these necessary insights, manufacturers will have no visibility into whether there are gaps or issues in the process, which could ultimately impact pricing. As such, ***CMS should publish the potential therapeutic alternative(s) under consideration for each selected drug when selected drugs are announced and allow data submitters to comment on CMS' proposal as part of their data submission package***. This would significantly reduce stakeholder burden by allowing data submitters to tailor their submissions to CMS and limit the potential scenarios stakeholders currently need to consider when preparing ICR responses.

Consideration of Non-Drug Therapeutic Alternatives

PhRMA appreciates the Agency seeking feedback on whether health care services payable under Part A or B could be considered as therapeutic alternative(s), but we do not believe that would be an appropriate step at this time. CMS has not yet provided clear enough standards or an open enough process to provide assurance that the agency will consistently select appropriate therapeutic alternative even among competing medicines. Expanding therapeutic alternatives to include health care services would increase the risk of CMS selecting clinically inappropriate comparators, while at the same time creating increased burden on data submitters to submit even more information and analysis. There is also a lack of visibility into the Agency's selection of therapeutic alternatives which creates no pathways for stakeholders to provide input on CMS' selection even when they believe CMS' selection may be incorrect. Because of these unaddressed issues, ***it would be premature for the Agency to broaden the consideration of potential therapeutic alternatives to non-drug alternatives.***

Starting Point for Initial Offer

PhRMA is opposed to the use of alternative starting points for initial offers such as those for which CMS solicits comments in the draft guidance. In particular, we are concerned by consideration of a starting point between the price of the therapeutic alternative(s) and the "unit cost of production and distribution," or potential use of "domestic reference prices."[20] As noted above, this approach fails to consider the important clinical and quality of life benefits provided by MFP-selected medicines. As a result, it would

[19] Hernandez I., et al. (December 2023). Medicare drug price negotiation: The complexities of selecting therapeutic alternatives for estimating comparative effectiveness. *J Manag Care Spec Pharm*. Available at: https://pmc.ncbi.nlm.nih.gov/articles/PMC10909583/

[20] IPAY 2028 Draft Guidance at p. 131, § 60.3.2

devalue treatment advances and discourage continue progress against unmet medical needs, significantly exacerbating the damaging effects of the Program. **PhRMA strongly encourages CMS to reject consideration of alternative methodologies for establishing a starting point for negotiation such as domestic reference pricing or unit cost of production and distribution.**

Stakeholder Engagement

While PhRMA appreciates CMS' attempts to improve stakeholder engagement with patients, caregivers, patient advocates, and practicing physicians, the MFP process still falls well short of supporting meaningful patient engagement. For example, CMS frequently releases important information too late in its process, which prevents engagement. In the case of the stakeholder events, CMS failed to release the redacted transcripts from April 2025's events until over a month later in June – after CMS sent impacted manufacturers the Agency's initial offer for IPAY 2027. CMS also held its stakeholder events in the middle of a weekday, on short notice, placing a barrier on patients, caregivers, or practicing clinicians who needed to work or faced another type of conflict. By doing so, CMS severely limited who could participate and as a result, reduced the valuable insight that could impact CMS' evaluation of evidence and its MFP determination. Similarly, allowing these stakeholders only one month to complete the 1194(e)(2) section of the ICR –an interpretation the Agency did not have to adopt under the statute[21] – creates additional barriers for many stakeholders including those who are disabled or underfunded, or otherwise come from a disadvantaged background. CMS also continues to rely on a black box process that may discourage stakeholders from spending their time providing input that they fear the Agency will not take into consideration. For example, the IPAY 2026 MFP explanations primarily repeated existing Guidance instead of providing stakeholders with any insight into CMS' process or if CMS incorporated patient-centered data. ***As PhRMA has previously recommended, we urge CMS to make improvements in the process of soliciting stakeholder input and improve transparency into how this input influences the agency's decision-making. Without fundamental improvements, CMS risks creating the impression of tokenism in which patient and clinician input is sought but not actually considered.***

Quality-Adjusted Life Years

As PhRMA has repeatedly stressed in previous comments, cost-effectiveness metrics such as the Quality-Adjusted Life Year (QALY) should not be used by CMS in setting MFPs in accordance with section 1557 of the Affordable Care Act, section 504 of the Rehabilitation Act, as well as sections 1182(e) and 1194(e) of the Social Security Act. CMS' decision to continue considering analyses that include cost-effectiveness measures, including QALY-alternatives that use the same underlying and discriminatory math,[22] is both misguided and unnecessary. Using cost-effectiveness metrics as the basis for policy decisions risks undervaluing the lives of the elderly, the disabled, and other groups considered to have less than "perfect" health. While we understand that not all stakeholders will understand cost-effectiveness measures, given the breadth of data CMS considers (some of the MFP explanations included almost 300

[21] As PhRMA has previously noted, the statute does not specifically require that manufacturers and other stakeholders submit the information described in section 1194(e) by March 1. Instead, the March 1 deadline applies to non-FAMP data as well as certain other information, but does not cross-reference section 1194(e). SSA § 1194(b)(2)(A) cites to information described in § 1193(a)(4), which includes non-FAMP data as well as certain other information the Secretary absolutely "requires" to carry out price setting, but does not contain a reference to § 1194(e)

[22] National Council on Disability. (November 2022). Alternatives to QALY-Based Cost-Effectiveness Analysis for Determining the Value of Prescription Drugs and Other Health Interventions. Available at: https://www.ncd.gov/report/alternatives-to-qaly-based-cost-effectiveness-analysis-for-determining-the-value-of-prescription-drugs-and-other-health-interventions/

sources), it is unlikely the Agency will be able to confirm that the studies do not use cost-effectiveness measures in a way that does not discriminate against certain populations. CMS should reconsider its decision to remove the attestation that prevents academics and other third parties from submitting data relying on these fatally flawed metrics. ***Instead, CMS should prioritize data from patients and doctors with prescribing experience, along with clinical effectiveness research that provides insight into a medicine's real-world performance, without undervaluing or discriminating against the lives of the elderly, the disabled, or the terminally ill.***

Appendix C

Data Collection under the IRA Is Wasteful and Unnecessarily Burdensome

The IRA requires the Secretary to consider specific factors in setting Maximum Fair Prices, which include both manufacturer specific factors as well as evidence about the selected drug and treatment alternatives. The Biden Administration's decisions about how to define the factors, as well as the process for collecting the resulting data is unnecessarily burdensome and has led to significant waste. As a result, several PhRMA members reported **averaging over 7,700 hours of staff labor across 21 business functions to comply** in IPAY 2026. Further, in IPAY 2027, manufacturers have approximately 40 days from the announcement of the selected drug list to submit an inordinate amount of data.

Key Issues with Specific Data Elements

Primary and Secondary Manufacturer Construct: CMS has created a definition of "Primary" and Secondary" Manufacturer, a construct which does not exist in the statute. Generally, the "Primary Manufacturer" is defined by CMS as the company that "holds" the NDA/BLA and the "Secondary Manufacturer" is another manufacturer on the NDA/BLA or a company that markets the drug under an agreement with the Primary. Under this CMS created construct, the Primary is responsible for the Secondary, including submitting information.

Key Issues:

- Creates unneeded complexity and undue burden by requiring one corporate entity to submit information on behalf of another (under threat of civil penalties).
- "Primary Manufacturers" may not have the time to quality- and fact-check the data possessed solely by a "Secondary Manufacturer."
- Much of the data CMS requests is proprietary, such as sensitive pricing metrics. Yet, CMS requires one corporate entity to obtain and report such proprietary data on behalf of another.

R&D Costs: Though the IRA directs CMS to consider R&D costs, CMS has chosen in guidance to subdivide R&D costs into seven distinct categories, including "Acquisition Costs," "Basic Pre-Clinical Research Costs" and "Abandoned and Failed Drug Costs," among others.

Key Issues:

- Division of R&D costs into different categories is misaligned with the reality of how biopharmaceutical R&D is conducted and tracked by manufacturers; this results in manufacturers having to re-analyze decades-old data to adhere to CMS' arbitrary asks.
- Overlooks that manufacturers may not have the ability to reconstruct all the R&D costs of selected products, and those which were under development for many years before approval, at the level of specificity that CMS is requesting.

R&D Recoupment: The IRA directs CMS to consider the extent to which R&D costs for a selected drug have been "recouped." CMS guidance directs manufacturers to submit global and U.S. total lifetime net revenue for the selected drug to determine the extent to which the manufacturer has recouped R&D costs.

Key Issues:

- Takes an approach that reflects a fundamental misunderstanding of the economics of the global biopharmaceutical marketplace and the highly risky nature of drug development CMS's approach fails to recognize that revenues from the small proportion of highly successful medicines are relied on to not only recoup their own costs but fund investment in high-risk areas.

Federal Financial Support: While the IRA dictates that CMS should consider prior federal financial support for R&D related to the selected drug, CMS broadly defines this factor to seek detailed and often decades-old information from when research began, even if it was prior to when the "Primary Manufacturer" acquired the drug.

Key Issues:

- Requires data that has never been "assigned" or "allocated" to a specific FDA-approved indication, meaning many manufacturers will not be able to comply with CMS' collection, particularly for decades-old historical costs.
- Interprets the statute to include information not commonly thought of as financial support for research. For example, orphan drug tax credits are critical to incentivize innovation and are not akin to the government providing direct support to a company's research efforts.

Production and Distribution Costs: While the IRA directs CMS to consider the costs of production and distribution of a selected drug, CMS has expanded this definition to include data such as purchase of raw ingredients, quality control, operating costs for personnel, etc. (production costs) and packaging, labeling, shipping, and operating costs (distribution costs).

Key Issue: Requires a level of additional detail and specificity that goes against standard practice and may not be accessible (for example, requiring the production and distribution unit costs to be reported separately for each NDC-11 of the selected drug, including any NDC-11 marketed by a "Secondary Manufacturer," an issue because such data is not typically recorded at this level).

Pricing Data: While the IRA directs CMS to consider U.S. market data, revenue, and sales volume for the selected drug, CMS expands this in guidance to cover a broad range of pricing data such as Average Manufacturer Price, Medicaid Best Price, FFS, and Big 4 pricing, which are unique to their specific programs.

Key Issue: Requires reporting of numerous pricing metrics under "Market Data and Revenue and Sales Volume Data," all of which are sensitive in nature, outside the scope of the statute, and are inappropriate reference points for Medicare as they represent the structure and population of entirely different markets.

Therapeutic Alternatives: The IRA directs CMS to consider evidence about alternative treatments with respect to the selected drug. However, information on "therapeutic alternative(s)" for the selected drugs are not disclosed to the manufacturer prior to data submission.

Key Issue: Fails to provide transparency into how therapeutic alternatives are selected, increasing the burden on manufacturers and other respondents who must submit all information on all potential comparators.

Recommendations

Overall Process

- Provide additional time for manufacturers to submit data and research to support MFP determinations.
- Provide insight into how data will be used in the Agency's decision-making process, including but not limited to any information or structure around how the different data elements will be weighted.
- Allow manufacturers to check a box stating that CMS may use publicly available resources in lieu of manufacturer submission of duplicative data wherever possible (e.g., Orange Book, Purple Book)

Primary and Secondary Manufacturer Construct

- Remove the "Primary" and "Secondary" manufacturer construct (or in the alternative, respondents need not report on data from secondary manufacturers).

R&D Costs & Recoupment

- Amend the ICR to allow a single global response for R&D costs (instead of capturing at a granular level), like a Form 10-K for Securities and Exchange Commission (SEC) filing, and a single attestation (YES/NO) regarding the extent to which these costs have been "recouped."

Federal Financial Support

- Require reporting of only one total figure, which includes all relevant financial support, directly related to the selected drug.

Production and Distribution Costs

- Allow discretion for manufacturers to describe production and distribution costs which they can report and to provide a narrative explanation describing how these costs were calculated.

Pricing Data

- Withdraw the pricing metrics that exist nowhere but in this program (i.e., all variations of "U.S. commercial average net unit price" and "manufacturer average net unit price to Part D plan sponsors, respectively. CMS also already maintains Part D pricing data).
- Do not collect metrics, such as best price, FSS, and Big 4 pricing.
- Collect only one year of data for some financial data elements such as various market data, revenue, and sales volume data.

Therapeutic Alternatives

- Publish therapeutic alternatives that will be used to evaluate selected drugs– when the selected products are announced.

Protection of Proprietary Information/Certification

In addition, we are happy to discuss protecting proprietary data in a manner that is more in line with the statute and typical security protocols, as well as the over-broad "certification" statement Biden's CMS included at the end of the form as nothing in the statute requires it.