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August 29, 2025

VIA ELECTRONIC DELIVERY
http://www.regulations.gov

The Honorable Mehmet Oz, MD
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Hubert H. Humphrey Building
Room 445-G
200 Independence Avenue, SW
Washington, DC 20201

Re: Negotiation Data Elements and Drug Price Negotiation Process for Initial Price Applicability Year 2028 under Sections 11001 and 11002 (CMS-10849)

Dear Administrator Oz:

Amgen Inc. (Amgen) appreciates the opportunity to submit comments on the Information Collection Request (ICR) Form for 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) ("Data Elements and DPN Process ICR") posted in the Federal Register on June 30, 2025.[1]

Amgen is committed to using science and innovation to dramatically improve people's lives, improving access to drugs and biologics (collectively, "drugs," consistent with CMS's convention), and promoting high-quality care for patients. Amgen develops innovative medicines as well as biosimilar biological products. Thus, our interest is to ensure a robust market for, and improve patient access in the United States to, both innovative and biosimilar biological products.

Amgen remains deeply concerned that government price controls implemented under the guise of a fair "negotiation" under the Inflation Reduction Act of 2022 (IRA) are stymieing biopharmaceutical innovation at precisely the time when the world needs more new medicines to treat an aging population. Though we also continue to believe the IRA is unlawful, we submit

[1] 90 Fed. Reg. 27869 (June 30, 2025).

these comments on certain aspects of the Data Elements and DPN Process ICR for initial payment year (IPAY) 2028 as part of our ongoing commitment to patients and in an effort to bring to CMS's attention the myriad of problems the IRA contains and creates.

Biopharmaceutical innovation is key to improving public health and people's lives. We encourage CMS to consider the impact on innovation as well as the impact on biosimilars development and patient access as it develops guidance for this and other IRA-related programs.

Amgen strongly supports the comments of the Pharmaceutical Research and Manufacturers of America (PhRMA) on the Data Elements and DPN Process ICR.

I. CMS SHOULD LIMIT MANDATORY DISCLOSURES TO INFORMATION NECESSARY FOR PRICE SETTING AND REDUCE THE BURDEN ON MANUFACTURERS OF SELECTED DRUGS

We urge CMS to limit the burden of data production imposed on manufacturers of selected drugs. Under section 1193(a)(4) of the SSA, manufacturers must submit to CMS "information that the Secretary requires to carry out" price setting for a selected drug. Under section 1194(a)(2)(A) of the SSA, this information must be submitted less than 30 days after CMS identifies a product as a selected drug (that is, the period between February 1 and March 1).

Amgen and Amgen's subsidiary, Immunex Corporation ("Immunex"), have first-hand experience with this process in IPAY 2026 and IPAY 2027. For example, for IPAY 2026, anticipating that the Immunex product Enbrel® (etanercept) would be selected, Immunex began work on data production in Spring 2023, and it was still a challenge to submit all data by the October 2, 2023, submission deadline. In addition, it is not possible for manufacturers to accurately anticipate selection given year-to-year changes made by CMS on how products are selected for the DPNP. When this occurs without notice it increases the burden for manufacturers before the submission deadline. We estimate that at least 1,000-2,000 staff hours were required to assemble and submit the information for each data submission in IPAY 2026 and also in IPAY 2027. This burden is compounded when policy fluctuates from year-to-year allowing less time for preparation. Due to the burden to prepare submissions, Amgen recommends that CMS limit mandatory disclosures to that information that is necessary.

Furthermore, it is unclear to us how a significant portion of the information that was required to be submitted in both IPAY 2026 and IPAY 2027 was of use to CMS in its price setting exercise. For example, in both years CMS required manufacturers to report research and development (R&D) costs broken down into five categories. As we communicated to CMS in our comments on the IPAY 2026 and IPAY 2027 ICRs, our records did not break out costs in this way, so Amgen had to develop assumptions to satisfy the CMS reporting requirements. But for price setting purposes, CMS's final IPAY 2026 and IPAY 2027 guidance stated that it would consider adjusting the initial offer price upward or downward based on whether the manufacturer has recouped its <u>total</u> R&D costs, which suggests the five categories were irrelevant. Nor did the guidance provide any explanation of how the cost information, broken into the categories CMS demanded, was used. While the IPAY 2028 Data Elements and DPN Process ICR proposes to condense these five

categories into two categories, CMS could limit the burden on manufacturers by simply requiring them to attest whether R&D costs have been recouped for both the initial price selection process and if the product is subsequently selected for resetting of the Maximum Fair Price (MFP).

Another example is federal financial support. An objective indicator of federal financial support is a patent application containing a Government Interest Statement. Instead of simply relying on information that could be compiled based on a search of relevant patent applications (which is a significant burden in itself), CMS also required manufacturers to report tax credits or other types of funding that are insufficient to result in a Government Interest Statement. Amgen does not believe it is typical or ordinary to track this information in a way that would allow reasonably efficient collection and assessment, and CMS gave no guidance about what diligence it expected manufacturers to perform. Imposing this kind of burden on manufacturers seems arbitrary and unnecessary, especially when it is unclear to what degree CMS is using, or should use, such information to set prices of selected drugs.

In addition, the HPMS module CMS utilizes to collect data adds to the high level of burden. CMS requires manufacturers to submit what can be thousands of fields of data in the HPMS module. While we appreciate that for IPAY 2027, the HPMS module allowed for some data uploads, the HPMS system remains difficult to navigate. For example, the field names that CMS required to upload data did not always match the naming convention CMS used in the ICR. The uploads did not consistently work, resulting in additional staff hours to create tables for upload based on the ICR and HPMS user guide, troubleshoot whenever an upload failed, and manual data entry when upload failures could not be resolved.

We have provided only a few examples, but there are many more. We urge CMS to engage with manufacturers so there can be a better understanding of the types of information CMS "requires" for price setting and how manufacturers can provide this information as efficiently as possible and within a month after the selected drug publication date.

II. ADDITIONAL AREAS OF COMMENT ON DATA ELEMENTS AND DPN PROCESS ICR FOR INITIAL PAYMENT YEAR (IPAY) 2028

- **CMS should limit the required market data to existing pricing metrics with established methodologies. CMS should not require "forward-looking data."** Although CMS did not include a data element in the ICR for "forward-looking data," we remain concerned that CMS appears to be considering requiring such forecasts in the IPAY 2028 Draft Guidance.[2] We urge CMS not to move forward with its proposal to request "forward-looking data" as these are forecasts that may or may not be realized. In addition to the legal and policy reasons outlined in our comments on the IPAY 2028 Draft Guidance, such a policy would be burdensome on manufacturers as CMS requires primary manufacturers to certify that the data submission is "complete and accurate," and that notification will occur if information has

[2] IPAY 2028 Draft Guidance § 50.1.

changed.[3] Forecasts, by definition, constantly evolve based upon new information and changes to the business environment. Thus, it would be impossible for manufacturers to regularly notify CMS and it would be extremely burdensome as well for CMS to review every time this information has "changed." Required market data should be limited to existing pricing metrics with established methodologies. Such an approach will ensure consistency and comparability across submissions, while keeping the burden on submitting manufacturers commensurate with the value of submitted pricing information in CMS's development of MFP offers.

- **CMS should continue to include acquisition costs in the manufacturer's submission of information regarding R&D costs.** In IPAY 2026 and IPAY 2027, CMS included acquisition expenses in the R&D cost section and now proposes to exclude these costs for IPAY 2028. This new policy for 2026 treats products differently depending on whether they were developed in-house or acquired. If the policy goal is to adjust the initial offer based on whether the manufacturer has recouped its investment, CMS is making an arbitrary distinction.
- **CMS should specify how it will incorporate and quantify diverse inputs like specific populations, unmet need, etc.** Such an approach will allow manufacturers and other stakeholders to more efficiently provide meaningful input in the process.
- **CMS should clarify that "authoritative medical literature, and/or accepted standards of medical practice" should be relevant to the Medicare population when it considers off-label therapeutic alternatives.** Clinical guidelines outside the US would largely be irrelevant to the DPNP, as the practice of medicine may vary substantially compared to the US and this would exponentially increase the administrative burden on the agency to review unnecessary documents.
- **CMS should clarify how newer versus older data will be assessed, and how it plans to address gaps** if comparative evidence is lacking for newer therapeutic alternatives or if comparators in trials are now obsolete. The choice of new therapeutic alternatives outside of the drug class should be transparent and supportable.
- **CMS should clarify how input from various respondents will be prioritized and how it will arbitrate disagreements between respondent types on key inputs** like therapeutic alternatives, course of care, outcomes, and "meaningful" improvement.
- **CMS should avoid imposing arbitrary character limits on submissions.** CMS's 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.

The Data Elements and DPN Process ICR for IPAY 2028 makes few meaningful changes to the manufacturer required data elements from IPAY 2026 and IPAY 2027. Some of the changes would **increase** manufacturer burden and we urge CMS to avoid such policy changes like requesting "forward-looking" data that are contemplated in the IPAY 2028 Draft Guidance. Given the lack of meaningful changes, we are providing Amgen's comments on the IPAY 2026 ICR

[3] CMS, IPAY 2027 Negotiation Data Elements Form, CMS 10849 (Nov. 2024). *Available at:* https://www.reginfo.gov/public/do/PRAViewICR?ref_nbr=202411-0938-010.

dated May 22, 2023 in their entirety as Appendix A and Amgen's comments on the IPAY 2027 ICR dated September 3, 2024 in their entirety as Appendix B.

* * * * *

We appreciate CMS's consideration of these comments. Please do not hesitate to contact Yola Gawlik at (202) 320-1159 or ygawlik@amgen.com if you have any questions.

Sincerely,

Greg Portner
Senior Vice President
Global Government Affairs & Policy

Appendix A: Amgen's comments on the IPAY 2026 Information Collection Request (ICR) Form for Negotiation Data Elements under Sections 11001 and 11002 of the Inflation Reduction Act (IRA) (CMS-10847, OMB 0938-NEW) dated May 22, 2023

Appendix B: Amgen's comments on the IPAY 2027 Information Collection Request (ICR) Form for Negotiation Data Elements under Sections 11001 and 11002 of the Inflation Reduction Act (IRA) (CMS-10849, OMB 0938-1452) dated September 3, 2024.

Appendix A

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May 22, 2023

VIA ELECTRONIC DELIVERY

The Honorable Chiquita Brooks-LaSure
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Hubert H. Humphrey Building
Room 445-G
200 Independence Avenue, SW
Washington DC 20201

Re: Information Collection Request (ICR) Form for Negotiation Data Elements under Sections 11001 and 11002 of the Inflation Reduction Act (IRA) (CMS-10847, OMB 0938-NEW)

Dear Administrator Brooks-LaSure:

Amgen Inc. (Amgen) appreciates the opportunity to submit comments on the Information Collection Request (ICR) Form for Negotiation Data Elements under Sections 11001 and 11002 of the Inflation Reduction Act (IRA) ("Data Elements ICR") posted on the Centers for Medicare & Medicaid Services (CMS) website on March 21, 2023.

Amgen is committed to using science and innovation to dramatically enhance people's lives, improving access to drugs and biologics (collectively, "drugs," consistent with CMS's convention), and promoting high-quality care for patients. Amgen develops innovator medicines and biosimilar biological products. Thus, our interest is to ensure a robust market for, and improve patient access in the United States to, both innovator and biosimilar biological products.

Amgen also supports the comments of the Pharmaceutical Research and Manufacturers of America (PhRMA) and the Biotechnology Innovation Organization (BIO).

I. OVERARCHING CONCERNS

As an initial matter, Amgen remains extremely troubled that manufacturers will be compelled to participate in the Maximum Fair Price (MFP) program at all, including with respect to the Data Elements ICR that is the focus of this letter. The "negotiation" contemplated by the IRA is a negotiation in name only; it bears no resemblance to a traditional arms' length commercial

agreement. To the contrary, the IRA requires manufacturers to submit data in order to help CMS prepare for the "negotiation" and even dictates the format in which such data must be provided. This is all on pain of significant monetary penalties (CMPs) for failure to comply. Then, once CMS communicates an offer, manufacturers are restricted to making a counteroffer that is based only on certain factors listed in the statute. And all of this occurs against the threat of a crippling excise tax if the "negotiation" does not succeed. Any resulting "agreement" cannot be the result of a fair process and will in no way represent an agreed-upon mutual understanding between manufacturers and CMS.

Even assuming the IRA did not so coerce manufacturers, however, the data elements, including as addressed in the Data Elements ICR, present significant challenges and create inefficiencies. For instance, it will be impossible or infeasible for manufacturers to produce some of the information described the Data Elements ICR because manufactures would need to submit information that, though highly sensitive, is inappropriate and unnecessary for setting the MFP. Further, the data elements are requested in a manner that will generate unprecedented levels of burden for reporting to a government agency within an unrealistic timeline to appropriately address and verify in the format requested. This is particularly inappropriate given the excessive CMPs that can be imposed for failure to comply. [1] While we have tailored this letter to these and other concerns about the Data Elements ICR itself, in an attempt to engage in good faith with the opportunity to comment on the Data Elements ICR, we believe the entire process and law, of which the data elements are only a part, is fundamentally flawed.

CMS should publicly announce that the agency will take a flexible approach to data submission and enforcement, particularly in the early years of the program

In the Data Elements ICR, CMS has proposed incredibly detailed, burdensome, and, in many cases, confusing submission requirements for manufacturers. Furthermore, these requirements are supported by scant agency knowledge and experience, considering that this is the first year of the Maximum Fair Price (MFP) program and no comparable data collection has been carried out in the U.S. or, to our knowledge, anywhere in the world. Backing up these compelled disclosures are CMPs of $1 million per day.[2]

Moreover, many manufacturers may not be able to produce the information in the form and manner CMS has proposed. For example, in our comments below, Amgen has flagged several areas of concern, including research and development (R&D) costs specific to "[Food and Drug (FDA)]-approved indications" (Instructions to Section C), R&D costs for "failed or abandoned" products (Question 5), and product-specific federal financial support (Definitions for Section E).

In light of these issues, we recommend that CMS adopt a flexible approach to data collection, such as expressly allowing manufacturers to use reasonable assumptions and be open to communicating with manufacturers and working through submission challenges. We also urge the agency not to seek to impose CMPs where the manufacturer has submitted data to CMS in good faith. Publicly announcing these principles would help create a more cooperative environment.

[1] Social Security Act (SSA) §1197(b).
[2] *Id.*

The Data Elements ICR does not comply with the Paperwork Reduction Act (PRA)

Under regulations promulgated by the Office of Management and Budget (OMB), agency collection of information requests must demonstrate that the agency has taken:

> "every reasonable step to ensure that the proposed collection of information:
>
> > (i) Is the least burdensome necessary for the proper performance of the agency's functions to comply with legal requirements and achieve program objectives;
> >
> > (ii) Is not duplicative of information otherwise accessible to the agency; and
> >
> > (iii) Has practical utility. The agency shall also seek to minimize the cost to itself of collecting, processing, and using the information, but shall not do so by means of shifting disproportionate costs or burdens onto the public."[3]

The Data Elements ICR fails to satisfy each of these three requirements.

With respect to 5 C.F.R. § 1320.5(d)(1)(i) and (ii), we urge CMS to scale back the mandatory data submission requirements so that the agency: a) collects only information that the Department of Health and Human Services and other federal agencies do not already possess and b) permits manufacturers to submit information maintained in the usual course of business, rather than creating new data solely for the purpose of the MFP program, particularly in cases where it is not clear why data maintained in the usual course of business would not satisfy the needs of CMS.

In our comments that follow, we identify specific data elements that CMS should eliminate or modify to mitigate the burden on manufacturers without limiting CMS's ability to administer the MFP program.

In the "duplication of efforts" section of the Supporting Statement of the Data Elements ICR, CMS appears to try to sidestep the requirements of 5 C.F.R. § 1320.5(d)(1)(i) and (ii) regarding both burden and duplication by stating:

> "Some manufacturer-specific data described in sections 1193(a)(4) and 1194(e)(1) of the [Social Security Act (the Act)] may already be collected by CMS from manufacturers. However, the Act requires that manufacturer-submitted data must be obtained from the Primary Manufacturer."[4]

This is not actually the case. In no place does the IRA state that CMS cannot rely on data that it already possesses in lieu of obtaining it from manufacturers. Given the Paperwork Reduction Act and other initiatives by Congress and the federal government to reduce unnecessary regulatory burden, CMS should not read into the IRA a limitation that does not exist.

Moreover, the mandatory disclosure provisions of the IRA cited by CMS are best read as authorizing CMS to obtain information that it does not have. Under section 1194(e)(1),

[3] 5 C.F.R. § 1320.5(d)(1)(i)-(iii).
[4] Data Elements ICR, Supporting Statement at 4.

manufacturers that are compelled to participate in the MFP program must submit in the following general categories:

- Research and development costs of the manufacturer for the drug and the extent to which the manufacturer has recouped research and development costs.
- Current unit costs of production and distribution of the drug.
- Prior Federal financial support for novel therapeutic discovery and development with respect to the drug.
- Data on pending and approved patent applications, exclusivities recognized by the [FDA], 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.
- Market data and revenue and sales volume data for the drug in the United States.

Other than the fourth category, these are all categories of information that the government does not possess. For example, manufacturers historically have reported limited information on cost inputs to the government. In contrast, manufacturers already report detailed pricing information to the federal government, such as information related to average sales price, average manufacturer price, and best price, which is presumably why section 1194(e)(1) does not expressly reference pricing data. In the Data Elements ICR, CMS characterizes this pricing information as "market data and revenue and sales volume data." Setting aside whether it is reasonable to interpret the phrase "market data and revenue and sales volume data" to include pricing data, it is not reasonable for CMS to take the position that the IRA requires that this information must be obtained from manufacturers as a mandatory submission under the MFP program, as to do so would be "duplicative of information otherwise available to the agency" and unnecessarily burdensome.

Furthermore, section 1194(e)(1)(D) merely requires "[d]ata on" patents, exclusivities, and FDA approvals, suggesting that Congress felt that manufacturers were in the best position to catalogue the relevant information for CMS.[5] However, there is no reason to believe that Congress intended for manufacturers to produce actual patent applications, FDA submissions, and approval letters, all of which are readily accessible to the government.

With respect to 5 C.F.R. § 1320.5(d)(1)(iii), the Data Elements ICR is incredibly broad and burdensome, with no apparent "practical utility" as to how CMS would use most of the information for price setting. For example, in the Data Elements ICR, CMS proposes to require manufacturers to provide an extensive list of confidential commercial information characterized as "market data and revenue and sales volume data,"[6] yet, in its March 15, 2023 guidance document (MFP Guidance), CMS struggles to explain how it will use this data, other than indicating that "if the average commercial net price is lower than the preliminary price, CMS may consider adjusting the preliminary price downward."[7]

[5] *Id.*§ 1194(e)(1)(D).
[6] Data Elements ICR § G.
[7] Medicare Drug Price Negotiation Program: Initial Memorandum, Implementation of Sections 1191 – 1198 of the Social Security Act for Initial Price Applicability Year 2026, and Solicitation of Comments, § 60.3.4 (March 15, 2023).

Another example is that CMS is proposing to require disclosure of a poorly defined category of information labeled "U.S. commercial average net unit price– best."[8] Manufacturers already expend significant resources to report "best price" under the Medicaid Drug Rebate Program and CMS provides no rationale as to why it needs manufacturers to calculate and report this additional best price.

CMS also provides no explanation as to why it would mandate disclosure of "quarterly total U.S. unit volume."[9] As the IRA is a Medicare-only price setting program, it is not obvious why CMS needs manufacturers to report non-Medicare unit volume. Even if one could guess at potential uses for such information, this is sensitive, potentially market-moving information that manufacturers should not be disclosing to CMS, or any third-party, without good reason.

Under 5 C.F.R. § 1320.5(d)(1)(iii), information collections must be limited to information that has "practical utility." CMS has not met this requirement with respect to the Data Elements ICR.

Finally, Congress did not give CMS carte blanche in the IRA. Under section 1193(a)(4)(B) of the SSA, CMS may require manufacturers to submit "information that the Secretary requires to carry out" the agency's price setting activities. In order for CMS to be authorized to mandate disclosure of information, CMS must articulate why the agency "requires" such information for the MFP program—or, in other words, why it has "practical utility." It has failed to do so in both the MFP Guidance and the Data Elements ICR, and thus, mandating the submission of this information is not only contrary to OMB regulations but also inconsistent with the IRA.

Other principles for all data elements

Data elements required to be submitted by manufacturers should reflect the following principles, in order to streamline and reduce the administrative burden placed on Primary Manufacturers:

- *Consistency with other agency reporting requirements*. Data elements such as non-federal average manufacturer price (non-FAMP) should be reported in a manner identical to how manufacturers are required to report to other government agencies in order to save time and labor costs on re-formatting for selected drug submissions given the short turnaround time requested.
- *Flexibility to supplement timely submissions*. CMS should provide manufacturers the option to supplement their submissions after the October 2, 2023 deadline if new data, documentation, or other substantive developments arise. Given the 30-day deadline established by the IRA and the massive amounts of data involved, manufacturers, as a practical matter, likely will be unable to provide all of the requested data. It would benefit both CMS and manufacturers for CMS to allow manufacturers to supplement their submissions, although we recognize that the IRA requires that manufacturers submit by October 2 some minimum amount of information in the five categories under section 1194(e)(1) of the SSA.
- *No word limits*. Throughout the ICR, CMS provides extremely limited space in the data fields via word and citation limits. Given the scope of these requests, and the lack of clarity in many of the terms applicable to the information to be collected, manufacturers may require additional space to adequately address these requests.

[8] Data Elements ICR § G.
[9] *Id.*

II. COMMENTS ON SPECIFIC DATA ELEMENTS

Section B. Non-FAMP Data Collection

Amgen recommends that CMS use the annual non-FAMP already reported by manufacturers to the U.S. Department of Veterans Affairs (VA) as defined in 38 U.S.C. § 8126(h)(5).[10] The annual non-FAMP is calculated using data from the 12-month period that aligns with the federal fiscal year (October 1-September 30). For 2021, this would be the annual non-FAMP value reported to the VA by November 15, 2021, calculated using transactions from October 1, 2020 through September 20, 2021. As discussed above, this would be consistent with 5 C.F.R. § 1320.5(d)(1)(i) and(ii), which requires CMS to make every reasonable effort to ensure that information collected is "the least burdensome necessary for the performance of the agency's functions" and "[i]s not duplicative of information otherwise accessible to the agency."[11] We also ask that manufacturers have the ability to make timely restatements.

Amgen further requests that CMS clarify that the units for non-FAMP may be different from the units on the Part D Prescription Drug Event record, which uses National Council for Prescription Drug Program defined values. CMS should recommend that manufacturers report the unit measure for non-FAMP in the explanatory field for Section B. More specifically, for all pricing metrics, the unit the manufacturer reports should match the unit used in the original metric. Due to the burden on respondents, as well as the CMP implications and related exposure, CMS must perform any cross-walking necessary.

Section C. Research & Development Costs and Recoupment

General Comments

CMS should provide manufacturers the option to attest that R&D costs have been recouped

Providing data in response to CMS's proposed detailed definition of R&D costs, broken into six specific categories, would impose an immense burden on manufacturers. We are concerned that CMS is under the impression that manufacturers track and maintain R&D cost information at a level of detail that does not correspond with the ordinary course of business of manufacturers. An attempt at compliance would require Amgen to review prior expense records and retrospectively flag them by product and CMS R&D cost category. It may prove to be an impossible task to assemble and submit accurate information, but, even if did not, it would be immensely time consuming, expensive, and burdensome. It would be even more challenging for older products, such as those subject to the MFP program, and products acquired through merger or acquisition. That the challenges of assembling this data will vary according to products—not to mention across manufacturers—makes it extremely unlikely that CMS will ever receive data homogenous enough to allow for meaningful analysis (assuming that is what CMS intends to do).

Such burdensome requirements are not necessary for CMS to carry out the MFP program. In the MFP Guidance, CMS appears to be proposing to consider only the binary question of whether the manufacturer has recouped total R&D costs related to the product, stating that it will

[10] 38 U.S.C. §8126(h)(5).
[11] 5 C.F.R. §1320.5(d)(1)(i), (ii).

consider adjusting the initial offer price upward or downward based on whether the manufacturer has recouped its costs.[12]

To accomplish the same policy purpose while mitigating burden on manufacturers, CMS should give manufacturers the option to attest that they have recouped R&D costs.

CMS should not finalize its proposal to require reporting of R&D costs in six categories

If manufacturers are to report drug-specific costs, we ask that CMS permit total R&D costs, not broken down by category. Again, there is apparently no policy purpose behind the six categories, it would be burdensome to divide costs in this artificial way, and we believe that overall, it will result in confusion and less accurate reporting.[13]

For products acquired by a manufacturer, CMS should permit manufacturers to report as R&D costs acquisition costs attributable to R&D

In the Data Elements ICR, CMS instructs manufacturers to exclude acquisition costs.[14] This is an ill-conceived policy that CMS should reverse when it issues its final guidance document. Given that, in the MFP Guidance, CMS proposes to adjust the initial offer price upward or downward based on whether the manufacturer has recouped R&D costs, it appears that CMS believes that molecules developed in-house should be assigned greater value than products that have been acquired. This distinction makes no business sense. Manufacturers such as Amgen are constantly investing in their internal R&D as well as evaluating opportunities to "buy R&D" through external acquisitions. In either case, the value of the therapy is the same to patients, health care providers, and payers. The product may also be of greater benefit to patients in the hands of an acquiring company if the company has better capability to market and manufacture a reliable supply of the product. Furthermore, when developing reasonable allocation methodologies related to R&D costs, a manufacturer would never exclude acquisition costs because such an approach would understate, in some cases drastically, the manufacturer's investment.

Instructions for Section C

Manufacturers should be permitted to include costs for label-enabling research

If CMS moves forward with mandating disclosure of product-specific information and with requiring detailed categorization of R&D costs, we ask that CMS explicitly broaden the definition of R&D costs to include costs incurred for label-enabling research and for ongoing research.

The Data Elements ICR proposes that R&D costs include only costs "incurred by the Primary Manufacturer for all FDA-approved indications of a drug...."[15] Read narrowly, limiting R&D costs to those incurred for "FDA-approved indications" would fail to reflect the breadth of significant R&D investment that many manufacturers make in approved drug products. Manufacturers may

[12] MFP Guidance § 60.3.4.

[13] Amgen also would support the two alternative options proposed by PhRMA: 1) allowing manufacturers to allocate a percentage of total R&D to the selected drug based on a generally accepted standard and 2) allowing manufacturers to provide data in two broader categories: a) costs of R&D *before* initial FDA approval and b) costs of R&D *after* FDA approval, which would include Phase IV costs, allowing for reasonable assumptions and allocations of spending for the selected drug.

[14] Data Elements ICR §C.

[15] *Id.*

routinely incur R&D costs concerning new routes of administration, dosing regimens, delivery devices, or other uses that improve patient experience or convenience. While this research may not result in a new FDA-approved indication, such new conditions of use are reflected in the drug labeling. We therefore urge CMS to explicitly permit manufacturers to submit R&D costs associated with all label-enabling New Drug Application (NDA) or Biologics License Application (BLA) supplements. We recommend that CMS permit manufacturers to submit such cost information in response to Question 6 ("All Other R&D Costs").

Perhaps more importantly given the CMPs associated with manufacturer-reported data elements, Amgen does not track R&D costs based on whether it specifically resulted in an "FDA-approved indication," and it would be infeasible or impossible to reconstruct this information, so we would likely be unable to provide the information in the form requested.

CMS should permit manufacturers to include costs for ongoing research

The Data Elements ICR also states that CMS intends to exclude from R&D costs the "costs associated with ongoing basic pre-clinical research, clinical trials, and pending approvals."[16] Ongoing research and clinical trials frequently result in new uses that meaningfully contribute to the value offered by a drug. Such research may later result in an approval—a category of cost included in the proposed R&D cost definition—yet CMS proposes to preclude a manufacturer from including ongoing costs simply if a drug happens to be selected for negotiation before completion of the research. We request that CMS permit manufacturers to include ongoing research when reporting R&D costs.

Question 5

CMS should not differentiate between successful and "failed or abandoned" products

As Amgen currently tracks R&D costs, all discovery and preclinical developmental costs are categorized the same (and, under framework of the Data Elements ICR, would be reported under Question1) and we do not differentiate between molecules that were later studied in clinical trials and "products with the same active moiety / active ingredient or mechanism of action as the selected drug that did not make it to clinical trials."[17] In fact, it is inappropriate at the pre-clinical stage to make distinctions between "products" because the end-result "product" may not be clear at this early stage because critical details including routes of administration and dosing regimens may be determined through clinical trials.

Question 6

CMS should clarify that it is appropriate for manufacturers to include royalty payments attributable to R&D costs in this category

In cases where rights to a product are split between multiple manufacturers, agreements between manufacturers may require royalty payments attributable to R&D costs. We believe such costs should be reported in response to Question 6, and we ask that CMS expressly clarify this.

[16] *Id.* § C, Instructions.
[17] *Id.* § C, Question 5.

Question 7

CMS should choose whether to consider R&D costs and revenue on a global or U.S. basis and be consistent

CMS has proposed to *include* in the total lifetime net revenue calculation the "global, total lifetime net revenue"[18] yet *exclude* from R&D costs any "costs associated with receiving foreign approvals."[19] This lack of symmetry in the assessment of revenues versus expenses inappropriately disadvantages manufacturers. It essentially penalizes manufacturers for international sales while failing to recognize a manufacturer's investment in research that supported the approvals that enabled such marketing. As a matter of consistency and as but one step toward fairness, CMS should adopt a uniform approach to inclusion (or exclusion) of international revenues and expenses.

Section D: Current Unit Costs of Production and Distribution

Instructions for Section D

Sales and marketing costs should be included as costs of distribution

Under the Data Elements ICR, CMS proposes to exclude "marketing costs" from the definition of "current unit costs of production and distribution of the selected drug."[20] We believe this apparent bias against sales and marketing is misplaced. After FDA approves a product, patients may not see the benefit of it unless manufacturers expend resources to educate health care providers (through disease state education, and information regarding the safety and efficacy of the product itself, and patient support services) and to negotiate with payers for access to the product. These functions are critical to create awareness of the disease and the product's efficacy so that the product reaches appropriate patients. Excluding marketing costs creates an inaccurate picture of the full costs of production and distribution related to a product.

Manufacturers should report liquid injectable units based on weight rather than volume

Amgen assesses production costs per unit for liquid injectable drugs using micrograms or milligrams, which reflects the ingredient weight. We believe this is also the industry standard.

In the Data Elements ICR, CMS is proposing that manufacturers report costs using liquid volume, referencing the National Council for Prescription Drug Programs (NCPDP) Billing Unit Standards.[21] As suggested by the title, the NCPCP standards were developed for billing purposes and, in fact, providers typically bill payers for injectables using milliliter-based units. But they do not reflect current industry practices for tracking costs per unit. Accordingly, CMS should switch to weight-based reporting when it finalizes its reporting guidance.

[18] *Id.* § C, Question 7.
[19] *Id.* § C, Instructions.
[20] *Id.* § D, Instructions,
[21] *Id.*

CMS should permit manufacturers to determine the most appropriate 12-month period for reporting costs

CMS proposes that manufacturers report average unit costs during the 12-month period ending May 31, 2023.[22] Manufacturers are unlikely to track information in this way, instead typically using a calendar or fiscal year approach. There seems to be little or no benefit to CMS prescribing such an unusual reporting period, given the burden it would impose on manufacturers. Therefore, CMS should allow manufacturers to determine their own period based on current business practices.

Manufacturers should have flexibility to align allocation between production and distribution with existing business practices

Certain aspects of CMS's definitions of "costs of production" and "costs of distribution" are inconsistent with Amgen's existing business practices. For example, Amgen treats packaging, packaging materials and labeling as costs of production, but these costs are defined as costs of distribution under the Data Elements ICR.[23] Given that whether a cost is categorized as a production or distribution cost has no bearing on CMS's price setting activities, and to mitigate unnecessary burden, CMS should permit manufacturers to characterize production and distribution costs consistent with usual business practices.

Section E: Prior Federal Financial Support

General Comments

Disclosure should be limited to Government Interest Statements

We encourage CMS to limit the data disclosure requirements for prior federal financial support to funding that resulted in a patent application containing a Government Interest Statement and/or research where a patent assignee was a U.S. government agency.

CMS should establish a defined look back period

We encourage CMS to narrow the relevant time period for this request to federal financial support received within the last 10 years of the BLA/NDA approval. As currently written, the time period starts at the beginning of the research and development program,[24] which for some drugs, will have occurred more than 30 years ago, and in some instances by a predecessor company that no longer exists. This would seemingly require companies to try to track down financial and tax records for several decades and perhaps well before this type of data was routinely kept in electronic form. It is unclear whether companies could meet this request without limiting the time frame.

[22] *Id.*
[23] *Id.*
[24] *Id.* § E, Definitions.

Definitions for Section E

CMS should not require manufacturers to provide the "federal financial support" data on a product-specific basis

Under the Data Elements ICR, CMS proposes to define "federal financial support for novel therapeutic discovery and development" to include tax credits, direct financial support, grants or contracts, and any other funds provided by the federal government that support discovery, research, and development "related to the selected drug."[25] We urge CMS to reconsider this request, and instead require disclosure only of Government Interest Statements, because companies do not typically track financial or tax credits on a product-by-product basis. In fact, there is not any meaningful way to calculate such product-specific taxes or credits given that the amount of taxes or credits potentially associated with one product is highly interdependent on what happens with other products and aspects of the business.

Section F: Patents, Exclusivities, and Approvals

Definitions for Section F

CMS should limit disclosure to patents directed to the active ingredient

We encourage CMS to limit the data disclosure requirements to only those patents and patent applications with a specific claim directed to the active ingredient of the selected drug, rather than more generic patents that, for example, cover a specific manufacturing process, a process for purifying a drug substance, or a process of formulating a drug substance that could be used to manufacture a number of different pharmaceutical products.

CMS should clarify the definitions and instructions for Section F to promote clarity and accuracy

We have the following recommendations for the definitions under Section F:

- The definitions section states that exclusivity refers to certain delays and prohibitions on the approval of competitor drugs "that attach upon approval of a drug."[26] CMS instead should refer to exclusivity attaching upon "approval of an NDA/BLA or approval or submission of a supplement to such application." Some types of regulatory exclusivity, including orphan exclusivity and new clinical investigation exclusivity, may attach upon FDA approval of a supplement after initial approval of a drug. In addition, pediatric exclusivity may attach after submission of a supplement reporting results of pediatric testing.
- According to the definitions section, the phrase "active and pending FDA applications and approvals"[27] would include "all applications for approval" under specified federal statutes. We recommend that CMS clarify that the phrase "applications and approvals" includes "all applications or supplements." Inclusion of supplements is appropriate and appears to be consistent CMS's intention. Omission of the word "supplements" may cause unnecessary confusion.

[25] *Id.* § E, Definitions, Question 10.
[26] *Id.* § E, Definitions.
[27] *Id.*

- With respect to the definition of applications and approvals, we also suggest that CMS state that manufacturers need only list potential label-enabling supplements and approvals. We request that CMS explicitly exclude manufacturing or other chemistry, manufacturing, and controls supplements. A manufacturer may submit numerous manufacturing-related supplements over the life of a drug. Providing a detailed listing would be burdensome to manufacturers while offering little-to-no value to CMS during the price negotiation process.

Instructions for Section F

The period for reporting FDA exclusivities and approvals should explicitly include dates of supplements

The instructions provide that for Questions 13 through 16, the time period for reporting "ends on the date the most recent NDA/BLA was approved for the selected drug."[28] We recommend amending the instruction so that the reporting period ends on the date that "the most recent NDA/BLA *or supplement* was approved for the selected drug." Adding the reference to a "supplement" would more clearly capture situations where orphan exclusivity, pediatric exclusivity, and new clinical investigation exclusivity are earned based on submission of a post-marketing supplement.

Question 13

Manufacturers should not be required to upload patent applications

In the table under Question 13, CMS appears to be proposing to require that manufacturers upload patent applications. We question what purpose a patent application might serve in CMS's price setting process. That said, to the extent there is relevant information contained in a patent application, CMS should obtain it directly from the Patent and Trademark Office (PTO). Requiring manufacturers to upload patent applications would be unnecessarily burdensome for manufacturers because older applications may not be available in electronic format, especially considering the 30-day turnaround time to submit data. The government already has access to patent applications through the PTO. CMS therefore should obtain patent applications from PTO to the extent they are necessary to the MFP program.

Question 15

CMS should acknowledge uncertainties regarding expiration of regulatory exclusivity

Question 15 asks that manufacturers list each type of applicable regulatory exclusivity and the corresponding "Exclusivity Expiration Date."[29] Not every licensure of a biological product is considered a "first licensure" that qualifies for its own 12-year exclusivity period. Whereas FDA's Orange Book and Purple Book provide authoritative information on the date of expiration of many types of regulatory exclusivity, FDA does not routinely proactively publish in the Purple Book (or otherwise) determinations about Reference Product Exclusivity for Biological Products or the date of expiration. We recommend that CMS acknowledge that in some cases there may be some

[28] *Id.* § E, Instructions.
[29] *Id.* § E, Question 15.

uncertainty as to whether a particular product has received 12-year Reference Product Exclusivity and ask manufacturers to provide their best judgment as to the expiration date of such exclusivity.

Question 16

The "submission number" column should be deleted

Question 16 prompts manufacturers to include a "submission number"—in addition to an "application number"—for all active and pending applications and approvals.[30] It appears that "submission number" intends to refer to the numbers used internally by manufacturers to track their submissions in serial order. We believe that this number would have no meaning to CMS. We ask that CMS remove this field from Question 16.

Section G: Market Data, Revenue, and Sales Volume Data

Questions 21 (340B Ceiling Price), 27 (Federal Supply Schedule), and 29 (Big Four)

We ask CMS to clarify which units should be included

For each of these three questions, it is not clear whether manufacturers should report: 1) all units subject to the ceiling price under the program, whether they are sold for the ceiling price or a lower, sub-ceiling price or 2) only units actually sold at the ceiling price. CMS should clarify the information it is seeking so that all manufacturers will provide consistent information.

Question 33

CMS should strike the column "Manufacturer Average Net Unit Price to Part D Plan Sponsors-Without Patient Assistance Programs"

The HHS Office of the Inspector General (OIG) has made clear that manufacturers may not offer copay assistance to Part D enrollees,[31] and manufacturers do not currently provide such assistance to Medicare beneficiaries. Accordingly, there is no need for this column under Question 33.

Questions 37 and 38

CMS should delete these questions because they are redundant to Question 19

In Question 37, CMS requests data on unit type and volume by quarter for five years by National Drug Code. In Question 19, CMS asks for the same information, plus Wholesale Acquisition Cost. CMS should delete Questions 37 and 38, so manufacturers are not required to provide the same information twice.

[30] *Id.* § E, Question 16.

[31] See, e.g., OIG Special Advisory Bulletin: Pharmaceutical Manufacturer Copayment Coupons (September 2014).

Section H: Evidence About Alternative Treatments

Instructions for Questions 40 through 43

CMS should clarify that it will consider quality of life data

Consistent with the prohibition against certain uses of Quality of Life Years (QALYs) under section 1194(e)(2) of the Act, CMS instructs submitters not to "include as evidence comparative clinical effectiveness research that treats extending the life of an elderly, disabled, or terminally ill individual as of lower value than extending the life of an individual who is younger, nondisabled, or not terminally ill."[32] However, it is important that CMS clarify that submitters may submit, and CMS will consider, evidence regarding the impact of a therapy on quality of life, provided that it does not treat extending the life of an elderly, disabled, or terminally ill individual as of lower value than extending the life of an individual who is younger, nondisabled, or not terminally ill.

Question 40

CMS should seek input on the selection of therapeutic alternatives

In this question, CMS requests information regarding prescribing information with respect to therapeutic alternatives of a selected drug,[33] but it is unclear how CMS will identify therapeutic alternatives and to what extent manufacturers and other stakeholders will be permitted to comment on them. To minimize burden of submission and increase likelihood that the information submitted to CMS is relevant and useful, CMS should publicly identify the therapeutic alternative, as well as any resources (e.g., clinical guidelines) it relied upon to identify the therapeutic alternative, on which it seeks information in response to Question 40 and communicate this information at the same time it announces the products selected for the MFP program. We also request that CMS seek input with respect to whether it has selected the appropriate therapeutic alternatives, either through Question 40 or otherwise.

The word limit is insufficient

As discussed above, there should be no word or character limits for any of the explanatory fields in this information collection, particularly in early years of the MFP program as CMS learns the types and quantity of information that is helpful to administration of the program. If CMS decides to finalize a word limit, we request that CMS increase the 1,000 word limit to 5,000 for Question 40 given the breadth of information available for selected drugs that have been studied for several years and have several indications.

Question 41

CMS should clarify that submitters are not required to submit information regarding all indications

As currently proposed, respondents are asked to submit all information on all potential comparators across all indications within the 30-day deadline, with no bounds on the potential universe of products.[34] We request that instructions be updated to confirm that data for every

[32] Data Elements ICR § H, Instructions.
[33] *Id.* § H, Question 40.
[34] *Id.* § H, Question 41.

indication for the selected drug is not required. This will allow manufacturers to focus the available word count on the priority indications where the selected drug is most commonly used.

The word and citation limits are insufficient

If CMS decides to finalize a word limit, we request that CMS increase the 3,000 word limit to 10,000 for Question 41 given the breadth of information available for selected drugs that have been studied for several years and have several indications. Likewise, CMS should increase the citation limit from 50 to 200.

Question 42

The word and citation limits are insufficient

If CMS decides to finalize a word limit, we request that CMS increase the 3,000 word limit to 10,000 and increase the citation limit from 50 to 200.

Question 43

The word and citation limits are insufficient

If CMS decides to finalize a word limit, we request that CMS increase the 1,000 word limit to 5,000 and increase the citation limit from 50 to 200.

* * * * *

We appreciate your consideration of our comments on the Information Collection Request (ICR) Form for Negotiation Data Elements under Sections 11001 and 11002 of the Inflation Reduction Act (IRA) ("Data Elements ICR"). Please contact Giana Mandel by telephone at (571)-228-6637 or by e-mail at gmandel@amgen.com if you have any questions about our comments.

Regards,

Greg Portner

Senior Vice President

Global Government Affairs and Policy

Appendix B

Greg Portner
Senior Vice President

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September 3, 2024

VIA ELECTRONIC DELIVERY
http://www.regulations.gov

The Honorable Chiquita Brooks-LaSure
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Hubert H. Humphrey Building
Room 445-G
200 Independence Avenue, SW
Washington, DC 20201

Re: Negotiation Data Elements and Drug Price Negotiation Process for Initial Price Applicability Year 2027 under Sections 11001 and 11002 (CMS-10849)

Dear Administrator Brooks-LaSure:

Amgen Inc. (Amgen) appreciates the opportunity to submit comments on the Information Collection Request (ICR) Form for 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) ("Data Elements and DPN Process ICR") posted in the Federal Register on July 2, 2024.

Amgen is committed to using science and innovation to dramatically improve people's lives, improving access to drugs and biologics (collectively, "drugs," consistent with CMS's convention), and promoting high-quality care for patients. Amgen develops innovative medicines as well as biosimilar biological products. Thus, our interest is to ensure a robust market for, and improve patient access in the United States to, both innovative and biosimilar biological products.

Amgen remains deeply concerned that government price controls implemented under the guise of a fair "negotiation" under the Inflation Reduction Act of 2022 (IRA) are stymieing biopharmaceutical innovation at precisely the time when the world needs more new medicines to treat an aging population. Though we also continue to believe the IRA is unlawful, we submit these comments on certain aspects of the Data Elements and DPN Process ICR for initial

payment year (IPAY) 2027 as part of our ongoing commitment to patients and in an effort to bring to CMS's attention the myriad problems the IRA contains and creates.

Biopharmaceutical innovation is key to improving public health and people's lives. We encourage CMS to consider the impact on innovation as well as the impact on biosimilars development and patient access as it develops guidance for this and other IRA-related programs.

Amgen strongly supports the comments of the Pharmaceutical Research and Manufacturers of America (PhRMA) and the Biotechnology Innovation Organization (BIO) on the Data Elements and DPN Process ICR.

I. CMS SHOULD LIMIT MANDATORY DISCLOSURES TO INFORMATION NECESSARY FOR PRICE SETTING AND REDUCE THE BURDEN ON MANUFACTURERS OF SELECTED DRUGS

We urge CMS to limit the burden of data production imposed on manufacturers of selected drugs. Under section 1193(a)(4) of the SSA, manufacturers must submit to CMS "information that the Secretary requires to carry out" price setting for a selected drug. Under section 1194(a)(2)(A) of the SSA, this information must be submitted less than 30 days after CMS identifies a product as a selected drug (that is, the period between February 1 and March 1).

Amgen's subsidiary Immunex Corporation ("Immunex") has first-hand experience with this process. Anticipating that the Immunex product Enbrel® (etanercept) would be selected for IPAY 2026, Immunex began work on data production in Spring 2023, and it was still a challenge to submit all data by the October 2, 2023, submission deadline. We estimate that at least 1,000-2,000 staff hours were required to assemble and submit the information. It would have been impossible to assemble these data within 30 days.

Furthermore, it is unclear to us how a significant portion of the information that was required to be submitted was of use to CMS in its price setting exercise. For example, CMS required manufacturers to report research and development (R&D) costs broken down into five categories. As we communicated to CMS in our comments on the IPAY 2026 ICR, our records did not break out costs in this way, so Immunex had to develop assumptions to satisfy the CMS reporting requirements. But for price setting purposes, CMS's final IPAY 2026 guidance stated that it would consider adjusting the initial offer price upward or downward based on whether the manufacturer has recouped its <u>total</u> R&D costs, which suggests the five categories were irrelevant. Nor did the guidance provide any explanation of how the cost information, broken into the categories CMS demanded, was used. CMS could limit the burden on manufacturers by simply requiring them to attest whether R&D costs had been recouped.

Another example is federal financial support. An objective indicator of federal financial support is a patent application containing a Government Interest Statement. Instead of simply relying on information that could be compiled based on a search of relevant patent applications (which is a significant burden in itself), CMS also required manufacturers to report tax credits or other types of funding that are insufficient to result in a Government Interest Statement. Amgen does not

believe it is typical or ordinary to track this information in in a way that would allow reasonably efficient collection and assessment and CMS gave no guidance about what diligence it expected manufacturers to perform. Imposing this kind of burden on manufacturers seems arbitrary and unnecessary, especially when it is unclear to what degree CMS is using, or should use, such information to set prices of selected drugs.

In addition, the HPMS module CMS utilizes to collect data adds to the high level of burden. CMS requires manufacturers to submit what can be thousands of fields of data and the HPMS module requires manufacturers to manually enter each data point. For example, the system does not allow for the upload of an Excel file that contain these data—which would largely streamline the submission.

We have provided only a few examples, but there are many more. We urge CMS to engage with manufacturers so there can be a better understanding of the types of information CMS "requires" for price setting and how manufacturers can provide this information as efficiently as possible and within a month after the selected drug publication date.

The Data Elements and DPN Process ICR for IPAY 2027 makes few meaningful changes to the manufacturer required data elements from IPAY 2026 and some of the changes would **increase** manufacturer burden, such as newly needing to provide net Medicare Part D data. Given the lack of meaningful changes, we are providing Amgen's comments on the IPAY 2026 ICR dated May 22, 2023 in their entirety as Appendix A.

II. ADDITIONAL AREAS OF COMMENT ON DATA ELEMENTS AND DPN PROCESS ICR FOR INITIAL PAYMENT YEAR (IPAY) 2027

- **CMS should not add a data submission requirement for Part D net price**. CMS was able to calculate a Part D net price for drugs selected for IPAY 2026 and should not increase manufacturer burden by requiring this new data element, which would impose new tracking and data aggregation requirements on manufacturers.
- **CMS should finalize the option for manufacturers to submit a dossier.** This option offers manufacturers more flexibility to submit information demonstrating the value of a selected drug to patients.
- **CMS should avoid imposing arbitrary character limits on submissions.** CMS's 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.
- **CMS should clarify how input from various respondents will be prioritized and how it will arbitrate disagreements between respondent types on key inputs** like therapeutic alternatives, course of care, outcomes, and "meaningful" improvement.
- **Manufacturers have extensive experience across multiple study designs, and input in this regard should not be limited to researchers.** In fact, different indications may require different study types and comparative effectiveness approaches, and manufacturers are uniquely qualified to provide guidance in this regard. CMS should specify how it will incorporate and quantify diverse inputs like specific populations, unmet need, etc.

- **CMS should clarify how newer vs older data will be assessed, and how it plans to address gaps** if comparative evidence is lacking for newer therapeutic alternatives or if comparators in trials are now obsolete. The choice of new therapeutic alternatives outside of the drug class should be transparent and supportable.

* * * * *

We appreciate CMS's consideration of these comments. Please do not hesitate to contact Yola Gawlik at (202) 320-1159 or ygawlik@amgen.com if you have any questions.

Sincerely,

Greg Portner
Senior Vice President
Global Government Affairs & Policy

Appendix A: Amgen's comments on the IPAY 2026 Information Collection Request (ICR) Form for Negotiation Data Elements under Sections 11001 and 11002 of the Inflation Reduction Act (IRA) (CMS-10847, OMB 0938-NEW) dated May 22, 2023

Bristol Myers Squibb™

VIA ELECTRONIC DELIVERY

August 29, 2025

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

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

Dear Deputy Administrator Klomp:

Bristol Myers Squibb (BMS) appreciates the opportunity to comment on the Centers for Medicare & Medicaid Services (CMS) *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.*[1]

At BMS, we are inspired by a single vision—transforming patients' lives through science. Our talented employees come to work every day dedicated to the mission of discovering, developing, and delivering innovative medicines that help patients prevail over serious diseases. We combine the agility of a biotech with the reach and resources of an established pharmaceutical company to create a global leading biopharma company. In oncology, hematology, immunology, cardiovascular disease, and neuroscience—with one of the most diverse and promising pipelines in the industry—we focus on innovations that drive meaningful change.

BMS supports Medicare policies that promote beneficiary access to new and effective medical treatments and help ensure Medicare patients benefit from the innovation that defines the U.S. health care system. We do not support the so-called Medicare "negotiation" policies contained in the *Inflation Reduction Act (IRA)*. We are extremely concerned by the impact that these policies will have on clinical research in addition to current and future innovation for patients.[2]

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[1] CMS, "Drug Price Negotiation for Initial Price Applicability Year 2028 under Sections 11001 and 11002 of the Inflation Reduction Act Information Collection Request Forms" (June 30, 2025), *available at* https://www.cms.gov/regulations-and-guidance/legislation/paperworkreductionactof1995/pra-listing/cms-10849.

[2] For these reasons, BMS has filed a federal lawsuit asking a court to declare the IRA unconstitutional. BMS believes that, in the absence of full repeal of the IRA's drug pricing provisions, significant clarity and reforms are necessary in several critical areas. Although our comments are designed to help CMS in these areas as it implements the process that Congress established in the IRA, nothing we say in this comment letter should be construed as suggesting that CMS can cure the constitutional flaws in the statute that Congress wrote. The IRA takes BMS' property without just compensation and compels manufacturers to express "agreement" that there is a "negotiation," and that the resulting government-mandated price is the "maximum fair price" (MFP). But as we have noted in our litigation, there are no true negotiations or agreements involved, and the price is not fair.

The IRA will have vast ramifications for patients, providers, manufacturers, and other stakeholders across the country. BMS is concerned that CMS' implementation of the IRA could have sweeping negative repercussions with respect to Medicare beneficiary access to needed medicines, and, indeed, for all patients. It is vital for CMS to give meaningful consideration of and response to stakeholder feedback on its proposals, particularly as the Agency updates its approach for Initial Price Applicability Year (IPAY) 2028.

BMS appreciates the opportunity to provide the following comments on the Drug Negotiation ICR. We intend our input to help CMS improve transparency and clarity of IRA implementation. Our recommendations reflect and are driven by our deep expertise in pharmaceutical innovation, delivery and supply chain, and access, as well as our experience with the IRA to date,[3] and we offer them to help mitigate against the negative consequences the ICR would have on innovation and, most importantly, patients.

Key comments include:

- Scope and Burden of Information: BMS continues to be concerned with the scope and burden of information CMS requires with the ICR submission. The burden associated with the process of completing and submitting the required data is significantly higher than what CMS has estimated. Even for the appropriate data elements that manufacturers can provide, the breadth of information coupled with the strict timelines makes the submission far more burdensome than it needs to be. For example, much of the requested data, such as government price reporting information, is already available to CMS, while others are publicly available, creating additional and unnecessary burden. Moreover, there may be information to which manufacturers do not reasonably have access or cannot provide with reasonable efforts. We urge CMS to work and engage with manufacturers to seek learnings that can inform how the Agency can reduce burden in the future.
- Inappropriateness of Methodology: The data requested by CMS does not accurately reflect the true cost of innovation or getting a selected drug to patients—and often, costs associated with drug development and delivery are significantly higher that what the Agency's requested costs portray. BMS strongly urges CMS to place less emphasis on factors such as research and development (R&D) recoupment and more emphasis on the selected drug's therapeutic and clinical attributes, which are the true measure of innovation. The manufacturer-specific data elements also do not reflect the realities of supplying product to the market, as channel complexities, access, and additional costs are not accounted for in the submission. We urge CMS to account for these measures to the extent possible by providing an opportunity for manufacturers to submit a more complete view of the drug development and delivery process; and if CMS cannot commit to these updates, then BMS urges CMS to considerably de-emphasize the magnitude of adjustment based on manufacturer-specific data. BMS asserts that only information germane to establishing an MFP for the Medicare market should be included in a manufacturer's submission. Therefore, we ask that CMS only finalize submission requirements

[3] In general, we refer CMS to BMS' comments in response to: the "Medicare Drug Price Negotiation Program: Draft Guidance, Implementation of Sections 1191 – 1198 of the Social Security Act for Initial Price Applicability Year (IPAY) 2028 and Manufacturer Effectuation of the "Maximum Fair Price" (MFP) in 2026, 2027, and 2028", released on May 13, 2025 (hereinafter referred to as the "IPAY 2028 comments"); and the "Negotiation Data Elements and Drug Price Negotiation Process for Initial Price Applicability Year 2027 under Sections 11001 and 11002 of the Inflation Reduction Act Information Collection Request", released on July 2, 2024 (hereinafter referred to as the "IPAY 2027 Negotiation Data Elements ICR comments").

that are essential for operationalizing the MFP process and to do in the least burdensome manner possible.

- Evidence About Alternative Treatments: BMS continues to highlight the significantly limited opportunity manufacturers have to share evidence about alternative treatments. It is extremely difficult for manufacturers to respond with constrained limits and provide comprehensive evidence on un-specified therapeutic alternatives across multiple indications. This is further exacerbated by CMS' proposal to combine the questions on therapeutic advance and unmet need (Question 35). The burden associated with this is tremendous, and the Agency could alleviate some of this by creating scoping discussions to improve efficiency for both manufacturers and CMS. CMS should also consider an appropriate forum and method for different stakeholders to provide input, and we urge the Agency to provide transparency and explicit rationale for decision making. Moreover, BMS recommends the Agency adopt a structured, transparent consultation process where relevant stakeholders are permitted to provide input in a format most suited to their expertise; and appropriately considers stakeholder feedback in selecting the appropriate therapeutic alternatives.

General Instructions:

- Transparency, Clarity, and Burden: BMS remains concerned with the lack of methodology and transparency in how CMS will weigh the data elements submitted and be used in the establishment of the initial offer. This opacity severely limits a manufacturer from being able to appropriately prepare for the MFP process and puts manufacturers—as well as other stakeholders—at an extreme disadvantage to provide a meaningful submission. Therefore, we urge CMS to provide a more complete and transparent methodology to improve the data elements process. This should include a more clear, formulaic approach to how CMS weighed each factor in the establishment of the initial offer to provide manufacturers with more predictability and a better understand of how the Agency adjusts the MFP based on the data submitted. Additionally, there continues to be a lack of clarity and guidance in how the manufacturers are to respond to intricate questions resulting in manufacturers making reasonable assumptions with their submissions, creating inconsistencies and inequity in how CMS views the information to establish an MFP across selected products. There may also be information requested to which manufacturers do not reasonably have access to or cannot provide with reasonable efforts, further driving inequities across data submissions and subsequent evaluations. The ICR represents an increasingly significant financial and operational burden for manufacturers, especially as Part B drugs are becoming eligible for price setting, yet CMS' burden estimate is not on the correct order of magnitude for manufacturers to complete the submission. We recommend CMS engage with manufacturers who have gone through this process to confidentially discuss their experiences preparing for and submitting the ICR to leverage lessons learned in an effort to reduce burden in the future.
- Confidentiality of Submitted Information: Although BMS appreciates CMS for providing manufacturers the opportunity to designate which data submitted in the ICR is confidential and proprietary, and therefore not subject to public disclosure, we continue to emphasize the importance of the Agency ensuring adequate safeguards are in place to protect confidential information. It is imperative that CMS takes the necessary steps that would guarantee manufacturers' trade secret, proprietary, and other confidential commercial information is protected from disclosure, including the opportunity for manufacturers to receive notice of potential disclosure and the opportunity to object to such disclosure.

Section B: Non-FAMP Data Collection

BMS appreciates CMS' effort to provide clarity in the instructions for how manufacturers should input data when a non-FAMP. CMS provides a new example in the definition of a non-FAMP package where the Agency states "*for an NDC-11 that represents a carton containing 25mg/mL in a single dose vial, the non-FAMP package would be the vial*".[4] We request clarification on this definition as we believe the non-FAMP package would be one carton.

Section C: Research and Development (R&D) Costs and Recoupment

BMS remains concerned that the data elements CMS will use to establish the MFP do not adequately capture the value and benefit of a drug to patients and the broader health system. CMS should balance these factors such that the Agency prioritizes rewarding innovation and preserving advancements in patient care. In contrast, placing a greater emphasis on R&D recoupment, as the Agency seeks to do, is a flawed approach that ignores certain biopharmaceutical realities – such as high risk-reward of pharmaceutical innovation and the wide range of costs incurred beyond R&D. It's imperative that CMS consider metrics that provide a more complete picture of the drug development and commercialization process to contextualize this broader investment. BMS strongly urges CMS to place a lesser emphasis on R&D recoupment, and more emphasis on the selected drug's therapeutic and clinical attributes which is the true measure of innovation.

Our specific comments on the Research and Development Costs and Recoupment elements follow.

- Acquisition Costs: BMS appreciates CMS' proposal to streamline the question in Section C in an effort to ease reporting burden on manufacturers. However, BMS opposes the removal of the question related to reporting acquisition costs of the selected drug. Costs associated with a manufacturer acquiring another is a common practice of unlocking innovation and should be viewed as an essential component to providing a comprehensive, accurate assessment of total R&D costs. Moreover, the cost of acquisition is a significant investment; and by not accounting for these costs, CMS may inadvertently undervalue the selected drug as the reported R&D costs would not truly reflect the innovation it took to bring medicines to the patients who need them most. Therefore, *all* costs incurred by the manufacturer to develop the selected drug should be considered, especially when assessing the total lifetime revenue.
- Global and U.S. Total Lifetime Net Revenue for the Selected Drug: BMS strongly opposes CMS' intent to use global, total lifetime manufacturer net revenue for the selected drug. This requirement would include net sales information from countries outside of the U.S. and has no place in establishing an MFP that is specifically based on a U.S. policy change intended for the U.S. market. While CMS notes it only intends to include R&D costs for FDA-approved indications, which is a U.S. cost and regulatory metric, the Agency seems to be calculating the "recoupment" of these U.S. costs by comparing them to global total lifetime net revenues, thereby violating a matching principle of expenses incurred and revenues earned, which will likely unfairly disadvantage manufacturers. In addition, total net revenues earned in countries outside of the U.S. are already subject to manufacturer-payer agreements. Inclusion of those agreements (by virtue of capturing global net sales) in the development of the initial offer is a double dip that further penalizes manufacturers. If CMS is set on its approach and intends to utilize global, total lifetime manufacturer net revenue then, at a minimum, the Agency should recognize the costs

[4] CMS, Drug Negotiation ICR, p. 11

of ongoing research and significant, necessary expenditure incurred for international product launches and line extensions.

Section D: Current Unit Costs of Production and Distribution

BMS notes that there are several challenges with obtaining the information CMS requests about current unit costs of production and distribution at the drug-specific level. Manufacturers will be responsible for submitting data that will serve as the basis for "offers" and "counteroffers", and the associated costs and data inputs should be determined and reported in accordance with generally accepted accounting principles. The current scope of the information is too narrow and does not reflect the realities of bringing a selected drug to market. CMS should broaden the definition to consider expenses associated with non-manufacturing facilities that contribute to the cost of developing and marketing a selected drug, such as freight, global quality, and the supply chain organization. Additionally, there could be legitimate business transactions necessitated by patient access concerns that result in manufacturers incurring transfer prices. We ask CMS to be flexible with its approach and consider a broad view of costs of production and distribution.

Section E: Prior Federal Financial Support

BMS maintains the only prior federal financial support that should be reported is funding that directly resulted in a patent application containing a Government Interest Statement and/or research where a patent assignee was a U.S. government agency. Therefore, we request CMS broaden this definition.

Section F: Patents, Exclusivities, and Approvals

BMS supports protection of intellectual property (IP) rights and believes that an effect IP framework is essential for the viability of the biopharmaceutical industry and efforts to deliver innovation that addresses unmet patient needs. The discovery and development of new medicines is a long, complex, and rigorous process. BMS is concerned that the data elements CMS is requesting contradict the framework that was intended to protect and encourage innovation. CMS' requests for patent information related to the selected to the drug is broad and ambiguous, making the submission process unnecessarily burdensome for manufacturers. This is further complicated by the 300-word limit on the Explanation of Patents (Expired and Non-Expired) and Patent Applications (Question 9).

Section G: Market Data and Revenue and Sales Volume Data

BMS strongly opposes CMS' requests for the submission of data on pricing metrics that do not reflect an actual Medicare price and thereby should have no bearing on a Medicare-negotiated price. The IRA statute only refers to the submission of a manufacturer's non-FAMP, and not any of the other pricing metrics the Agency is requesting in the ICR. Therefore, CMS should adhere to the clear statutory requirements and should only seek to obtain the information that is required to establish the MFP. By creating a Medicare negotiation scheme, Congress directed CMS to use market data, revenue, and sales volume data to come up with a new pricing metric reflective of the Medicare market. By referring to final Federal Supply Schedule (FSS) and Big Four prices, CMS would be capturing complexities of those calculations that should not apply to IRA price setting. Reference to FSS and Big Four prices could result in unintended consequences, for example, reducing or eliminating manufacturers' voluntary discounts that lead to lower prices for those government channels. Such pricing may be inherently short-term and would serve as an inappropriate benchmark for setting a longer-term price. CMS also seeks to create

new methodologies, such as multiple variations of U.S. commercial unit prices. Practically, only information that is currently available via standard price reporting conventions should be included in the manufacturer's submission. Furthermore, not only are these methodologies not relevant in establishing a Medicare-based price, but they would be near impossible for manufacturers to develop and validate within a 30-day timeframe. BMS asserts the only information germane to establishing an MFP for the Medicare market should be included in the manufacturer's submission (i.e., commercial and/or non-Medicare government pricing information should not form the basis of a Medicare price). Therefore, BMS urges CMS to remove these extraneous reporting requirements. The Agency cannot, and should not, impose an obligation to divulge virtually all pricing information for the drug, including proprietary, otherwise reported, and irrelevant information. BMS objects to CMS' proposed ICR in this section based on appropriateness, relevance, duplication, excessive scope, and undue burden.

Section I: Evidence About Alternative Treatments

BMS urges CMS to consider a robust body of information when assessing a selected drug's impact on unmet need and therapeutic advance. This holistic consideration should extend beyond rigid health care costs and health outcomes to consider the impact of medicines on society – such as improvements to patients' and caregivers' lives, and efficiency and quality in the health care system. To aid in this effort, BMS encourages CMS to consider critical elements to capture the full- and long-term value of a treatment, including health outcomes, both from clinical trials and real-world evidence, medical association guidelines, and Medicare-recognized compendia. It is also important to consider situations in which medicines treat conditions with a limited number of treatment alternatives, as well as innovation and societal progress that is achieved in treating serious medical conditions, including incremental success achieved to address unmet needs and provide hope to patients.

Additionally, we strongly oppose CMS' follow-up question in Question 25 asking respondents to state whether they or their organization "is affiliated with a manufacturer of the selected drug or its therapeutic alternative(s)"[5]. This characterization fails to acknowledge that there are other conflicts of interest that exist in the process beyond affiliation with the manufacturer. We urge CMS to remove, or at a minimum, revise the question to not dissuade respondents from completing the submission.

Our thematic comments on the Evidence About Alternative Treatments elements follow.

Manufacturer-Focused Questions

- Off-Label Use: BMS cautions CMS on the consideration of off-label therapeutic alternatives, as well as those in difference pharmacologic classes, unless supported in either one or more of the compendia or in peer-reviewed medical literature. CMS must prioritize the most appropriate therapeutic alternatives and seek input from manufacturers and other stakeholders on these alternatives through a separate scoping process before comparative effectiveness evidence is submitted to focus those submissions only on prioritized alternatives, reducing burden to both manufacturers and CMS.
- Potential Therapeutic Alternatives: As CMS will examine a large volume of evidence across multiple indications and multiple therapeutic alternatives within each indication and conduct several simultaneous assessments, BMS urges the Agency to plan for an incorporate additional, early dialogue with manufacturers, or at a minimum, issue advance notice about the therapeutic

[5] CMS, Negotiation ICR, p. 47

alternatives that are likely to be considered. It places undue burden on manufacturers to complete the ICR submissions without the knowledge of which therapeutic alternatives CMS intends to compare the selected drug to. It is extremely difficult for manufacturers to respond with constrained limits and provide comprehensive evidence on un-specified therapeutic alternatives across multiple indications. The establishment of scoping discussions or the provision of advance notice of the therapeutic alternatives considered by the Agency would alleviate burden and improve efficiency for both manufacturers and CMS. Manufacturers should also have insight into CMS' literature review and the opportunity to provide input on the accuracy of the proposed value capture to ensure the proper consideration of information between a selected drug and alternatives. Therapeutic alternatives should be selected based on clinical appropriateness and not narrowed based on least costly alternatives. Therefore, BMS requests the opportunity to submit comparative effectiveness evidence data after CMS has identified indications and therapeutic alternatives. For example, oncology therapies can have dozens of indications, and the value proposition across these indications is unique given a patient's specific needs; and for fixed-dose combinations, as well as single agents used in combination, value assessments have additional complexity. The consequences of inaccurate value determination can lead to restricted patient access.

- Clinical Comparative Effectiveness: BMS appreciates CMS' commitment to avoiding the use of comparative clinical effectiveness research in a manner that devalues extending the lives of elderly, disabled, or terminally ill individuals, including the exclusion of Quality Adjusted Life Years (QALYs) from such assessments. We also recognize that the Agency has removed the question that required respondents to indicate whether their submission includes any cost-effectiveness measures or methods. BMS strongly emphasizes that CMS should not anchor value assessments for selected drugs in cost-effectiveness analyses (CEA). While it is being explored to account for differential value of health improvement in different contexts, there is no consensus on the ability of these methods to adequately address considerations across populations. For example, while Equal Value of Life Years Gained (evLYG) has gained traction in limited academic settings, most methodological and ethical limitations of the QALY still apply to the evLYG and could be used to limit patient access by utilizing value for money comparisons to arbitrary thresholds. Additionally, BMS strongly recommends that CMS perform its own checks and due diligence to ensure that any analyses based on QALY or other cost effectiveness measures are excluded from review, and allow manufacturers to validate CMS' evidence evaluations, which would provide further safeguards against discriminatory metrics being used to assess value of important medicines.
- Therapeutic Advance and Unmet Medical Need: CMS proposes to combine the previously separate questions on therapeutic advance and unmet need (Question 35), BMS is opposed to this new structure as these should remain distinct questions. It is important that CMS does not conflate these two defined characteristics of a selected drug as they represent different aspects of the innovative process to develop and bring a medicine to patients. This act of combining the questions would also significantly hinder manufacturers' ability to provide detailed, comprehensive evidence on the extent to which the selected drug represents a therapeutic advance and/or addresses an unmet medical need given the significant decrease in the word and citation limits. Furthermore, we continue to encourage CMS to take a broad, holistic view of unmet medical need. As the Agency will be assessing medicines in the middle of their life cycles, BMS recommends that unmet need be considered from initial approval from the time of assessment. Additional value should be particularly considered for those medications that treat serious medical conditions, including those that make incremental steps toward curative goals or significantly reduce the risk of adverse events compared to their alternatives. Unmet need

should encompass a spectrum of characteristics, such as: alternative dosing regimens; route of administration; reduction of side effects; and shorter treatment periods. While we support driving toward patient centered outcomes, CMS should provide more transparency into how qualitative considerations translate into an adjustment to the starting point. Therefore, BMS urges CMS to clearly state how the Agency came to a determination that a selected drug did or did not represent a therapeutic advance or an unmet need, as well as provide examples of what evidence it would consider as sufficiently supporting therapeutic advance and/or addressing an unmet need.

- Specific Populations and Patient Experience: We encourage CMS to consider subgroup/population analysis as a core assessment with safety and efficacy and that evidence from these studies be considered of equal priority to evidence from larger studies that are better powered to draw comparative effectiveness conclusions. We also recommend CMS consider evidence in other subpopulations, including patients with comorbidities, when data is available, and ask that CMS request respondents to speak to the quality of evidence and/or be prepared to assess that quality during the Agency's internal review process.
- Dossier Submission: We appreciate the ability for manufacturers to submit a comprehensive evidence package in the Academy of Managed Care Pharmacy (AMCP) dossier format. However, we are concerned that CMS' request for a manufacturer to submit an outline of the location of information addressing manufacturer-focused questions along with providing word-constrained responses to the questions further increasing burden and duplication.

Patient- or Caregiver-Focused Input, Clinical-Focused Input, Health Research-Focused Input, Other Public Input

BMS supports efforts by CMS to directly and actively solicit input from patients, beneficiaries, caregivers, and consumer and patient organizations as it is critical for the Agency to consider a variety of perspectives throughout the data submission and review process. Although CMS has taken positive steps in the right direction to engage various stakeholders, there are additional actions the Agency can take to make this input process as user-friendly as possible. We provide non-exhaustive suggestions below:

- Improved Input: BMS urges CMS, to the extent feasible, to move beyond the HPMS system for non-manufacturer respondents and use a more user-friendly system for feedback. We also encourage CMS to remove arbitrary word limits to allow stakeholders to fully capture their experience using, prescribing, and/or researching the selected drug. Additionally, while CMS includes definitions for terms in the instructions of this section, we recommend the Agency create a user-friendly glossary or a feature that would allow stakeholders to hover their computer mouse over the terms defined in the instructions and have the definition pop up embedded within the question itself. Accordingly, we encourage CMS to weigh responses, particularly clinical responses, based on the appropriateness and expertise of the respondent.
- Targeted Beneficiary Outreach: BMS encourages CMS to conduct targeted proactive beneficiary outreach to increase participation and create user-friendly materials and resources to aid in the completion of the submission. For example, the creation of a step-by-step "how to" guide or video to share with patients, patient advocacy organizations, and medical societies interested in submitting the ICR.

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BMS appreciates the opportunity to comment on the Negotiation Data Elements ICR. We would be pleased to discuss these comments in further detail. Should you have any questions or concerns, please contact Katie Verb, Executive Director, Policy & Reimbursement and Strategic Alliances, U.S. Policy & Government Affairs, at katie.verb@bms.com

Sincerely,

/s/

Katie Verb
Executive Director, Policy & Reimbursement and Strategic Alliances
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August 29, 2025

VIA ELECTRONIC SUBMISSION

William N. Parham, III
Director
Office of Strategic Operations and Regulatory Affairs
Centers for Medicare & Medicaid Services (CMS)
7500 Security Boulevard
Baltimore, Maryland 21244

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)

Director Parham,

Eli Lilly and Company (Lilly) appreciates the opportunity to provide comments on the Initial Price Applicability Year 2028 (IPAY28) Information Collection Request (ICR). Lilly is one of the country's leading innovation-driven, research-based pharmaceutical and biotechnology corporations. Our company is devoted to seeking answers for some of the world's most urgent medical needs through discovery and development of breakthrough medicines and technologies and through the health information we offer. Ultimately, our goal is to develop products that save and improve patients' lives.

As a member of the Pharmaceutical Researchers and Manufacturers Association of America (PhRMA), Lilly largely joins in their comments on this ICR and encourages CMS to carefully consider the input of this organization. That said, Lilly would like to offer the following comments to highlight certain topics and Lilly-specific positions.

Lilly has made several suggestions in advance of the initial price applicability years to lower the burden of data collection and reporting while maintaining or improving the consistency and reliability of the data reported to CMS. While some of these suggestions have been incorporated into the ICR, we remain concerned that CMS has underestimated the time, effort, and seniority level required to develop and implement the components necessary to stand up the "Medicare Drug Price Negotiation Program" (Program). Given the complexity and importance of this process, we also remain concerned with CMS's arbitrary limits on the number of characters that can be used to explain the documentation in this submission. CMS's proposed revision to this year's instructions that the character limits include spaces between words is particularly troubling.

CMS proposes requiring manufacturers to submit detailed data beyond what the authorizing statute, U.S. GAAP, and U.S. Securities and Exchange Commission (SEC) standards mandate.[1] This adds an unnecessary compliance burden for the Program, one that is not alleviated by the changes made to Section C in the current draft ICR. The necessity of such data collection is questionable given the lack of clarity to the extent CMS uses the vast amounts of data collected from manufacturers in the Program. We urge CMS to limit data requests to only what is statutorily specified and essential for the Program's function.

The proposed ICR remains inconsistent with the Paperwork Reduction Act (PRA)[2] which requires that agencies collect data in the least burdensome way necessary – i.e., in a manner that enables the agency's function, complies with the authorizing statute, achieves the applicable agency objectives, and ensures practical utility.[3] The ICR sets up an excessively burdensome reporting regime that exceeds the agency's needs and offers limited utility to the Program.

In addition, as CMS evolves its approach for evidence assessment, further perspective should be considered regarding the appropriate scope of therapeutic alternatives, the integration of international clinical guidelines, and the critical need to ensure that only high-quality studies inform price-setting decisions. We urge CMS to define the therapeutic alternative scope in a manner that is clinically meaningful and aligned with current treatment paradigms, thereby avoiding overly broad or inappropriate comparators that could distort value assessments. CMS should prioritize peer-reviewed studies, and limit comparisons to drugs within the same class and mechanism of action to avoid justifying inappropriate off-label options or basing price decisions on comparators that could substantially undervalue the clinical/societal benefits of selected drugs and discourage ongoing investment in related areas. Comparisons beyond a similar mechanism of action or drug class create price signals that will undermine the investment model that has made the U.S. the global leader in scientific discovery and undermine efforts to defeat serious chronic diseases. Furthermore, we recommend that international guidelines be used as a complementary resource rather than a primary determinant given important differences in patient populations, health systems, and standards of care.

Section C: Research and Development (R&D) Costs and Recoupment

1. CMS Should Allow Manufacturers to Stipulate R&D Recoupment Ensuring the Least Burden Necessary to Achieve Statutory and Program Objectives Without Underreporting or Inaccurate Reporting of Key Information

[1] The U.S. SEC and other governmental bodies do not require external reporting of costs (including research and development costs) or profits at a product-specific level, and manufacturers may not prepare standard financial statements with this data at a product-specific level.
[2] *See United States v. Ionia Mgmt. S.A.*, 498 F. Supp. 2d 477, 487 (D. Conn. 2007), *citing Dole v. United Steelworkers of America,* 494 U.S. 26, 32 (1990) (explaining that the PRA was enacted in response to the "enormous growth of our federal bureaucracy" and "its seemingly insatiable appetite for data").
[3] 5 C.F.R. § 1320.5(d)(1)(i)-(iii).

While CMS has made efforts to streamline certain reporting metrics, this simplification creates an imbalance that risks underreporting critical information necessary to understand the full value of a selected medicine. For example, overly simplified treatment of acquisition cost, collapsed allowable costs, removal of cost of capital, and per-unit cost changes may inappropriately exclude relevant expenditures. Conversely, the inclusion of forward-looking market data could lead to overreporting by capturing speculative or non-recouped funds. This imbalance is particularly evident in CMS's approach to R&D cost reporting.

CMS proposes to continue to require that manufacturers identify R&D expenses for a selected drug, determine categorization of said expenses, and perform various ad hoc calculations to include, exclude, or allocate such expenses pursuant to CMS's specific and novel instructions. This collection goes well beyond the statutory requirement to submit information on "research and development costs of the manufacturer for the drug," which does not require manufacturers to subdivide and categorize this information as proposed in the ICR.[4] The statute merely requires manufacturers to report on "the extent to which the manufacturer has recouped research and development costs," which requires neither the proposed categorization of R&D data nor the reporting of global or U.S. lifetime net revenue.[5] And, as we have described previously, neither U.S. GAAP nor SEC require external reporting of R&D costs at a product-specific level, nor are manufacturers otherwise required to categorize and calculate R&D data in this way. Manufacturers will incur meaningful data collection burden to generate the data in the manner that CMS proposes.

CMS indicates that it will use R&D costs to determine whether to adjust the preliminary price upward or downward; it does not specify whether or how it will use this information required as distinct from total R&D costs. CMS can achieve its goals without requiring manufacturers to mine old financial records or develop new manual methods to organize historical data into CMS's required categories just for the Program. Simply, CMS does not need all the information it is requesting, and it is requesting an unprecedented amount of information.

To drastically reduce the reporting burden on manufacturers and improve consistency of manufacturer data submissions, we recommend that CMS amend its reporting requirement to allow a single global response in which a manufacturer can attest whether it has recouped its R&D costs. If a manufacturer certifies that it has recouped its R&D costs, then CMS need not gather any additional information, either as to R&D costs or global and U.S. lifetime net revenue. If a manufacturer does not or cannot certify that it has recovered its R&D costs, then the manufacturer can provide additional information.

Section H: Certification of Submission of Sections A through G for Primary Manufacturers

[4] Social Security Act (SSA) §§ 1193(a)(4), 1194(e)(1)(A).
[5] *Id.*

CMS proposes revising this certification to require Primary Manufacturers to acknowledge increased liability for misrepresentations. CMS cites Section 1197(c)(7) of the Social Security Act for this authority, but that section does not exist, and CMS has not otherwise identified under what authority it purports to impose these penalties. We encourage CMS to abandon its proposed changes given this uncertainty.

Section I: Evidence on Alternative Treatments

1. The Therapeutic Alternative Scope Should be Limited to Medicines with the Same Mechanism of Action or Drug Class

CMS intends to identify therapeutic alternatives based on a broad set of properties, including chemical class, therapeutic class, and mechanism of action, and to consider alternatives across different pharmacologic classes introduces significant variability that risks undermining the scientific integrity of the evaluation. Drugs within the same mechanism of action or class are designed to interact with biological systems in similar ways, enabling more valid and clinically meaningful comparisons. This approach aligns with established pricing practices, such as those used in commercial market baskets, which traditionally focus on drugs within the same class to ensure fairness and consistency. Moreover, narrowing the scope improves the relevance of submitted clinical evidence, as studies and real-world data are more likely to be applicable when comparing therapies with similar treatment goals and patient populations. A focused evaluation also supports transparency and predictability for manufacturers and stakeholders, helping them anticipate which drugs may be considered alternatives and reducing ambiguity in CMS's selection process.

Importantly, this scientifically appropriate scope aligns with CMS's stated goal of minimizing administrative burden, as broader scopes require extensive justification and documentation that may not be readily available or clinically relevant. Given the recent reduction in the number of allowable citations, it is both practical and prudent to limit the scope of therapeutic alternatives to those within the same drug class or mechanism of action.

2. The Use of International Guidelines Should be Restricted to Prevent the Inclusion of Off-Label Alternatives

CMS's expanded definition of off-label uses to include "authoritative medical literature" and "accepted standards of medical practice" raises significant concerns. International guidelines may reflect different regulatory standards, clinical practices, and approval pathways. Relying on them risks introducing therapies that have not been vetted or approved by the FDA, undermining the integrity of U.S.-based evaluations. Such off-label alternatives based on international standards may not be clinically appropriate or comparable to the selected drug in the U.S. context, distorting the value assessment of a selected medicine and unfairly positioning therapies that serve unique roles in the U.S. Restricting the use of international guidelines ensures that all therapeutic comparisons are grounded in U.S. standards, ensuring fair and clinically relevant evaluations.

3. **To Ensure the Inclusion of High-Quality Studies from Non-Academic Sources, CMS Should Replace the Term "Academic" with "Peer-Reviewed"**

The draft guidance instructs manufacturers to submit information from various sources, including academic studies and papers, systematic reviews, government reports, and clinical guidelines. However, the use of the term "academic" is unnecessarily restrictive and may exclude high-quality, peer-reviewed studies authored by practicing physicians and other experts outside of academia. These non-academic sources often provide real-world insights that are more applicable to CMS's goals of evaluating therapeutic value and proven benefits. Academic studies, while valuable, may be limited in scope or relevance to diverse care settings. Replacing "academic" with "peer-reviewed" ensures that all scientifically validated research, regardless of institutional affiliation, is eligible for consideration, thereby expanding the evidence base, promoting equity in data contribution, and improving the relevance and applicability of submitted materials.

4. **There Should Not Be Quantity Limitations When Providing Citations on the Therapeutic Value of a Selected Medicine**

Imposing a citation limit risks undermining the integrity and completeness of the evidence base that manufacturers and stakeholders can present. High-quality, peer-reviewed studies, whether from academic institutions or practicing clinicians in community setting. offer diverse and complementary insights into therapeutic value, clinical outcomes, and real-world effectiveness. Limiting the number of citations arbitrarily will exclude critical data needed to support nuanced arguments, particularly when evaluating complex therapies or conditions with varied treatment pathways.

Moreover, CMS's stated goal of promoting transparency and informed decision-making is best served by allowing comprehensive documentation of proven benefits, not by restricting the volume of supporting evidence. A flexible, quality-driven approach to citations—rather than a numeric cap—ensures that CMS receives the most relevant and scientifically sound information to guide fair and accurate price negotiations.

Finally, imposing a citation limit is incompatible with CMS's mandate that manufacturers provide all relevant information or face significant penalties. There is no assurance that the CMS might come back later and fault a manufacturer for not citing a particular study. What, whether, or how CMS uses citations is its business, but it should not muzzle manufacturers that endeavor to provide a complete record of evidence on alternative treatments.

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Lilly is appreciative for the opportunity to respond to the ICR. We sincerely appreciate your thoughtful consideration of the issues discussed in this letter and look forward to working with you in the future on these topics. Please do not hesitate to contact Derek Asay at Asay_Derek_L@Lilly.com with any questions.

Sincerely,

Derek L. Asay
Senior Vice President,
Government Strategy and Federal Accounts

Shawn O'Neail
Senior Vice President,
Global Government Affairs

August 25, 2025

VIA ELECTRONIC SUBMISSION —

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Centers for Medicare and Medicaid Services
Office of Strategic Operations and Regulatory Affairs
Division of Regulations Development
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RE: Drug Price Negotiation for Initial Price Applicability Year (IPAY) 2028 under Sections 11001 and 11002 of the Inflation Reduction Act Information Collection Request (ICR) (CMS-10849, OMB 0938-1452)

Dear Director Parham,

GSK is writing in response to the Centers for Medicare & Medicaid Services' (CMS's or the Agency's) proposed IPAY 2028 Information Collection Request (ICR), as GSK reasonably believes that one or more GSK product(s) may be directly impacted and subject to price setting under the Inflation Reduction Act (IRA). Given those potential implications, GSK has a vested interest in the development, interpretation, and application of the final IPAY 2028 policies that will be issued by CMS. As CMS finalizes this ICR, GSK appreciates the Agency's willingness to solicit comments to understand stakeholder impacts and concerns related to implementation. While GSK is a member of PhRMA and supports its comments on this issue, we respectfully submit these more targeted comments in response to CMS's Proposed ICR Forms.[1]

GSK is a global biopharma leader with the ambition and purpose to unite science, technology, and talent to get ahead of disease together. With a clear and defined focus on leading the way in disease prevention, GSK's aim is to positively impact the health of more than 2.5 billion people over the next ten years. GSK supports policy solutions that transform our healthcare system to one that rewards innovation, prevents the onset and progression of disease, improves patient outcomes, and achieves higher-value care.

GSK appreciates CMS's proposed changes to the ICR data elements that will help facilitate manufacturers' timely and efficient completion. For example, GSK is supportive of CMS reducing the number of questions in Section I. This will help facilitate manufacturers' ability to comply and provide all required elements of the ICR form.

However, GSK is concerned with several elements of the proposed ICR data elements and has some technical recommendations for the ICR that will further help manufacturers comply with the information request and allow the Agency to implement IPAY 2028 policies in a way that is consistent with the underlying statute and policy goals of the IRA:

[1] GSK recognizes that CMS will receive many comments on this ICR. GSK lays out the letter in this framework in order to ensure that CMS knows where to consider our recommendations within the larger ICR.

Recommendation: GSK strongly recommends that CMS continue to consider acquisition costs in Section C (Research and Development (R&D) Costs and Recoupment).

GSK strongly opposes CMS's proposal to remove acquisition costs from the scope of reportable R&D costs under Section C. When a manufacturer purchases a company, or an asset already in development, the costs and value of the R&D that has already been completed is included in the acquisition price. In this sense, the acquisition price is a cost that is reflective of research, clinical progress, and novel drug and biologic development that have been completed and achieved up to that point.

If CMS were to finalize this proposal, there may be situations in which a manufacturer who acquired a selected drug will be required to report *little to no R&D costs*. This would unfairly penalize certain manufacturers and lead to an absurd result that completely fails to capture the steep investment and related manufacturer costs associated with developing medicines and bringing a product to market. More broadly, this approach could potentially hinder innovation by making acquisitions and similar transactions less viable for manufacturers. Most problematically, it could result in some promising therapies never being brought to market.

Moreover, the underlying statute's reference to R&D costs does not make any distinction between internally incurred R&D costs and acquisition costs, which reflect the market's valuation of the acquired company's or asset's R&D costs up to that point. The IRA directs the Secretary to collect and consider "[r]esearch and development costs" and Section C is intended to capture costs associated with R&D. Because acquisition costs are a tangible and accurate measure of R&D costs, they should be included as reportable R&D costs under Section C. For these reasons, GSK strongly urges CMS to continue to include acquisition costs when considering R&D costs and recoupment.

If CMS chooses to finalize the exclusion of acquisition costs from R&D costs under Section C, then manufacturers of selected drugs that were acquired should not be required to complete Section C. Excluding acquisition costs would lead to an inaccurate and incomplete evaluation of R&D costs, and basing an initial price offer on this section would be arbitrary and unjustified.

Recommendation: CMS should reconsider its proposed approach for defining "failed or abandoned product costs."

CMS proposes to limit reporting for "failed or abandoned product costs" to those products with the same mechanism of action as the selected drug that either did not make it to clinical trials or did not receive FDA approval. GSK is concerned that this proposal does not consider the realities of modern biopharmaceutical R&D and fails to account for the significant burden for manufacturers to allocate costs under this approach. Investment decisions for drug candidates are not necessarily limited to a single mechanism of action, and scientific knowledge and infrastructure developed for multiple drug candidates can be leveraged to accelerate development and commercialization for one drug candidate with a particular mechanism of action that differs from other candidates included in the same program. Moreover, investments in platform technologies and tools, such as artificial intelligence, support multiple programs simultaneously, making it virtually impossible to accurately allocate costs for individual products, particularly for preclinical development activities. We are concerned that CMS's approach would require a level of granularity that is highly difficult to implement accurately, that would not appropriately and fully measure the costs of development, and that is misaligned with how R&D activities are actually carried out and recorded in practice.

Recommendation: GSK thanks CMS for the flexibility provided in Section E (Prior Federal Financial Support) regarding reporting timelines and acquired products, but would appreciate some additional clarity on this requirement.

GSK appreciates CMS providing for some flexibility when federal funding information is not available for all quarters in the applicable time period, and, for acquired products, having the applicable time period begin when a selected drug was acquired by the Primary Manufacturer.

Regarding the latter, GSK would appreciate if the Agency could further clarify that, for acquired products, manufacturers are only required to provide information on federal support that took place after the product was acquired; and for all products, that the reporting requirements end at the most recent NDA/BLA approval. This confirmation would enable

manufacturers to ensure that they are adequately able to comply with the information request. For example, given that manufacturers of acquired products have no way of deducing federal financial support prior to the acquisition, it would be helpful to have CMS more explicitly affirm that this is not necessary.

Recommendation: GSK recommends more effective and accurate ways for CMS to determine information regarding patents, exclusivities, and approvals than manufacturer reporting in Section F.

GSK believes that manufacturers should not be required to provide information regarding patents, exclusivities, and approvals, as this is a duplicative and inefficient way for the Agency to procure this data. The federal government already has this information within its various agencies--more specifically, these pieces of information are already known by the Food and Drug Administration and United States Patent and Trademark Office and, as such, do not need to be dually provided by another entity. Given that CMS has existing avenues to obtain this information in more comprehensive and formalized ways than manufacturer reporting through the ICR, the Agency should leverage those sources. This way, the Agency can obtain this information in a streamlined manner, and manufacturers can devote more time to reporting detailed information on other types of data that the Agency can only collect from manufacturers. Asking manufacturers for information CMS can obtain elsewhere adds undue burden to manufacturers as they would need to work across functions to compile and verify the requested information amidst the already significant and underestimated level of burden manufacturers face to complete the ICR. Requiring this action of manufacturers takes away time manufacturers could devote to other aspects of the ICR that are more relevant for them to report on.

We also note our concern with respect to CMS's instruction for manufacturers to identify "which patent or patents is the composition of matter patent(s)," which suggests the Agency may place greater weight on certain types of patents over others. We ask that CMS clarify that it will not place greater weight on certain types of patents when setting prices. We also ask that the Agency explain why this new requirement is relevant in the context of determining the price of a selected product.

Recommendation: GSK appreciates CMS streamlining Section I (Evidence on Alternative Treatments). GSK also thanks CMS for explicitly stating it will not consider quality-adjusted life years (QALYs) and urges the Agency to comprehensively assess all provided evidence to ensure this is the case.

GSK thanks CMS for its efforts to simplify Section I, such as by combining questions on therapeutic advance and unmet need, to reduce respondent burden and duplication across questions.

GSK also thanks CMS for affirming that it will not consider QALYs or any evidence from comparative effectiveness research in a manner that treats extending the life of an individual who is elderly, disabled, or terminally ill as of lower value than extending the life of an individual who is younger, non-disabled, or not terminally ill. GSK reminds the agency that QALYs are explicitly excluded from the negotiation program in statute[2] and must be wholly removed from any considerations that go into an initial price offer, including through the way the Agency collects information in the ICR form and/or through a robust internal evaluation process. GSK would support efforts from the Agency to strengthen ICR requirements around data submission to ensure compliance with statute.

Given the harm associated with QALYs and related methodologies, we also urge CMS to consider avoiding all methodologies that treat some lives as being of lesser value than others and to focus on and prioritize data from patients and doctors with prescribing experience as well as clinical-effectiveness research.

Recommendation: GSK recommends that CMS strongly consider public submissions, including those submitted outside the comment period, when determining therapeutic alternatives and comparative value.

GSK appreciates CMS's efforts to enable members of the public to optionally submit evidence about alternative treatments and reinforces the value of public input when determining alternative treatments and comparative value. GSK asks, however, that the Agency consider extending the timeline for stakeholders to submit information after drug selection.

[2] Section 1194(e)(2) of the Social Security Act (SSA).

The existing 28-day deadline can be onerous and unrealistic for many stakeholders whose perspectives are invaluable but who, due to professional and personal responsibilities, may be unable to meet this arbitrary timeline.

Recommendation: GSK recommends that CMS treat National Drug Codes (NDCs) that are discontinued or correspond to sample packages, inner packages, or private labels similarly to how it plans to treat NDCs that are not marketed nor controlled by the submitting manufacturer or any secondary manufacturer.

To reduce administrative burden, GSK recommends CMS treat categories of NDCs consistently to simplify the reporting process for manufacturers and avoid potential confusion/misrepresentation. Specifically, under Sections A and G reporting, GSK recommends CMS treat NDCs that are discontinued or correspond to sample packages, inner packages, or private labels in the same way as those flagged as not marketed or controlled by the Primary Manufacturer and/or the Secondary Manufacturer. Should CMS implement this approach, it will avoid the need for complex tracking and reporting of data that may be of limited relevance for IPAY calculations, thereby freeing up CMS resources. Treating NDCs differently results in unnecessary burden, which is already at concerning levels.

Recommendation: GSK recommends CMS reassess the burden on Primary Manufacturers associated with collecting data on behalf of Secondary Manufacturers and recommends CMS clarify and resolve Primary Manufacturer burdens related to Authorized Generics.

Reduce Primary Manufacturers' Collection Requirements on Behalf of Secondary Manufacturers

As stated in GSK's IPAY 2027 ICR comments previously submitted to CMS, GSK remains concerned regarding CMS's expectations for Primary Manufacturers to collect, report, and certify data on behalf of Secondary Manufacturers. Primary Manufacturers do not have access to the Secondary Manufacturer's proprietary information, such as Non-FAMP and Best Price data or their supporting reasonable assumptions. Indeed, requiring Primary Manufacturers to submit such data from Secondary Manufacturers places Primary Manufacturers in jeopardy of not just violating the terms of their contractual agreements with Secondary Manufacturers but also of running afoul of competition law tenets.

Furthermore, a Primary Manufacturer cannot obligate (i.e., legally compel) the Secondary Manufacturer to provide the data and is limited in its ability to ensure the accuracy of any data submitted by the Secondary Manufacturer. Simply put, a Primary Manufacturer has no means to enforce compliance by a Secondary Manufacturer. Given these complexities, CMS should require the Primary and the Secondary Manufacturer to independently submit and to certify their respective data, particularly for data that is possessed solely by the Secondary Manufacturer and to which the Primary Manufacturer does not have access. Alternatively, CMS should engage and request responses and/or data directly from the Secondary Manufacturer(s).

If the Agency chooses not to do either, we urge CMS to exercise caution related to the required timeline for data submission and/or the issuance of civil monetary penalties (CMPs) associated with noncompliance, given the untenable and burdensome position on Primary Manufacturers.

Clarify and Resolve Primary Manufacturer Burden Related to Authorized Generics

Under CMS's proposed ICR for IPAY 2028, there is an additional nuance of manufacturer burden as it relates to Primary and Secondary Manufacturer obligations. While such nuance is more focused on MFP effectuation, we note that the ICR process shapes CMS's implementation of the program – as the government ICR process takes into consideration "undue burden" across an array of stakeholders. With that in mind, we note that from a Primary Manufacturer perspective, we are concerned that CMS is significantly underestimating the burden and at times infeasibility of complying with information submission and effectuation plan requirements, particularly when an authorized generic (AG) exists.

For example, AG Secondary Manufacturers are independent companies, and the Primary Manufacturer does not have access to or input on a Secondary Manufacturer's product pricing strategies to retail pharmacies. The AG's pricing strategies are confidential and can make the standard default refund amount (SDRA) not a viable option for rebate adjudications. These complexities may result in varied pricing bases, and MFP rebate amounts, by pharmacy. In some instances, the only way a Primary/Secondary Manufacturer is able to meet the MFP requirements (based on CMS's proposed ICR) is for manufacturers to overpay in the context of MFP effectuation.

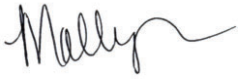
Further, Primary Manufacturers would have to obtain all information from the Secondary Manufacturer, which adds to the already burdensome process. Moreover, as GSK has stated in previous comments, not only is the process burdensome to Primary Manufacturers, but the timeline CMS set forth to achieve this proposed requirement obligates Primary Manufacturers to ensure that information is collected by the Secondary Manufacturer and accurately submitted - all within the 14-day timeframe. The CMS 14-day timeline is simply too short of a window to ensure that Primary Manufacturer can monitor compliance with the statute's requirements, especially in cases where an AG exists.

GSK recommends that CMS separate the IPAY data MFP effectuation requirements between the Primary Manufacturer and AG Secondary Manufacturer. If pharmacy contract price is utilized for MFP effectuation, GSK recommends CMS clarify that the Primary/Secondary Manufacturers are not required to have agreements with every pharmacy to use a contract price basis. GSK also recommends that CMS clarify the agency will not impose Primary Manufacturer liability (e.g., CMPs) where effectuation is dependent on a Secondary Manufacturer's information submissions. Overall, these technical adjustments would help manufacturers report accurately and make the entire submission process more efficient and user-friendly.

****

GSK appreciates the opportunity to comment on the IPAY 2028 ICR. Please contact me at molly.m.burich@gsk.com if you have any questions about the topics discussed in our comments or if GSK can provide any further information.

Sincerely,



Molly Burich

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August 28, 2025

VIA Electronic Filing at regulations.gov

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

Re: Negotiation Data Elements and Drug Price Negotiation Process for Initial Price Applicability Year 2028 under Sections 11001 and 11002 (CMS-10849, OMB 0938-1452)

Dear Director Klomp:

On behalf of Johnson & Johnson (J&J), we submit the following comments in response to the Centers for Medicare & Medicaid Services' (CMS, the Agency) Information Collection Request (ICR) on Negotiation Data Elements and Drug Price Negotiation Process for Initial Price Applicability Year 2028 under Sections 11001 and 11002 (CMS-10849, OMB 0938-1452).

At J&J, we are driven by a passion to achieve the best version of health for everyone, everywhere, for as long as possible. In the next decade, we will see more transformation in health than in the past century – and we are ready to lead the way. Focusing exclusively on transformational healthcare innovation allows us to move with purpose and speed to tackle the world's toughest health challenges. Innovating across the full spectrum of healthcare solutions puts us in a unique position today to deliver tomorrow's breakthroughs to our current and future patients, including Medicare, Medicaid, and Marketplace beneficiaries.

Reduce Unnecessary Regulatory Burden and Revise the ICR to Align with Statute, Reduce Operational Burden, and Prioritize Factors that Emphasize Value to Medicare Beneficiary

We have significant concerns with this ICR, as it continues to require a significant volume of information that is in excess of the statutory requirements needed for the factor analysis, is overly focused on cost factors instead of the data requirements for the evidence required to assess a drug's value over time for the Medicare population, and imposes substantial requirements conflicting with current best business, financial and operational practices, and systems. There have been limited changes since the IPAY 2026 Negotiation Data Elements ICR.

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In line with recent Executive Orders focused on reducing regulatory burden and unlawful regulations, we strongly urge CMS to revise this ICR to reduce unnecessary reporting burden.[1] We are concerned that the burden estimates contained within the ICR are underestimates and do not reflect the actual burden associated with this ICR for negotiations or renegotiations, despite showing up to 2,000 hours and over $3,000,000 per manufacturer response. J&J responded to the Requests for Information on deregulation from the Office of Management and Budget (OMB) and CMS with suggestions on how the negotiation program can be run more efficiently and be more aligned to the Administration's goals to reduce regulatory burden. Consistent with the Administration's stated goals to reduce regulatory burden that stifles American businesses and ingenuity, we recommend CMS remove reporting requirements that exceed statutory requirements or duplicate submission of data already available to the Agency, provide flexibility in the form and format of data reported, including removal of word limitations, and prioritize value to beneficiaries. We further ask CMS to provide transparency into how the submitted elements are weighted and used to inform CMS' initial offer.

We urge CMS to align the ICR with requirements under the Paperwork Reduction Act (PRA), which require that information collection:

> "(i) Is the least burdensome necessary for the proper performance of the agency's functions to comply with legal requirements and achieve program objectives;
>
> (ii) Is not duplicative of information otherwise accessible to the agency; and
>
> (iii) Has practical utility. The agency shall also seek to minimize the cost to itself of collecting, processing, and using the information, but shall not do so by means of shifting disproportionate costs or burdens onto the public."[2]

Please see Appendix A below for J&J's detailed comments and recommendations submitted in September and December 2024, as well as Appendix B for our comments on the negotiation factors included in the Draft IPAY 2028 Draft Guidance Comments. We urge CMS to adopt these recommendations, which are summarized at a high level below:

- *Improve HPMS and Remove Unnecessary Character Limitations in the ICR*
- *Limit Timely Notification Requirements for Standard Refiles*
- *Allow for Flexibility in Format for Reporting Monetary Amounts*
- *Rescind Policies that Hold Primary Manufacturers Responsible for Secondary Manufacturers*
- *Simplify Research & Development (R&D) Reporting*
- *Remove Overly Prescriptive Methodology for Determining Production and Distribution Costs*

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[1] E.O. 14192, *Unleashing Prosperity through Deregulation*, and E.O.14219, *Ensuring Lawful Governance and Implementing the President's "Department of Government Efficiency" Deregulatory Initiative*
[2] 5 C.F.R. § 1320.5(d)(1)(i)-(iii)

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- *Streamline Prior Federal Financing Support Reporting*
- *Remove R&D Tax Credit Reporting Requirements*
- *Remove Questions on Expired Patients and Regulatory Exclusivities*
- *Remove Questions that Require Submission of Pricing Data Beyond Non-FAMP*
- *Update the Certification of Submission to Recognize the Need for Reasonable Assumptions and to Account for Character Limitations*
- *Clarify the Approach for Comparative Value Assessment*
- *Provide Timely Public Access to Medicare Data*
- *Provide Greater Flexibility for Manufacturer-Focused Questions*
- *Clarify Patient and Caregiver Focused Input Questions*

J&J Recommendations for New Changes to ICR

In addition to our comments detailed in Appendix A, J&J recommends CMS adopt the following changes to new changes in the ICR.

Research & Development Cost and Recoupment

J&J appreciates that CMS has reduced the number of questions required in reporting R&D costs but continues to feel that the revisions do not extend far enough, nor do they address the fundamental flaws in the Agency's approach. We strongly recommend that CMS simplify the process in reporting R&D costs and a manufacturer's recoupment via a simple attestation which is outline in greater detail in the attached appendices. Further, the ICR advances flawed changes, which are fundamentally misaligned with normal business practices and the ways in which R&D costs are actually calculated or captured. We strongly urge CMS to:

- *Maintain that the calculation of the "costs for failed and abandoned" drugs not be limited by mechanism of action.* In the ICR, CMS erroneously narrows the definition of the "cost for failed and abandoned" drugs to be limited to those with the same mechanism of action. In doing so, CMS neglects to recognize that the development of new drugs are advanced in many ways and are not exclusive to a mechanism of action. Beyond the misalignment with the approach to the development of new drugs, this narrowed definition does not adequately address the challenges associated with calculating R&D costs in acquired therapies.
- *Include acquisition costs in the calculation of drug development costs and recoupment.* J&J strongly opposes the removal of acquisition costs in the reporting of R&D costs. While additional R&D may take place, the initial R&D already completed is captured in the cost of acquisition and must therefore be included in the calculation of R&D costs for the selected drug. Failing to do so would result in a deeply inaccurate representation of the true costs of R&D and should therefore be included in primary manufacturers' submission.

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- *Allow for cost of capital and inflation adjustments in calculation of manufacturer's recoupment.* CMS also removes the cost of capital and inflation adjustments in the ICR which is highly problematic as it further demonstrates ways in which the accurate capturing of R&D costs is undermined and misaligned with normal business practices. We strongly encourage CMS to adjust its approach to allow for the cost of capital and inflation to align with normal business practices as well as the true costs of R&D.

Patent and Exclusivities

In addition to our concerns with the restrictive character limitations for Questions 9 – 11, J&J opposes the new requirement for IPAY 2028 for manufacturers to clearly identify patents that are "composition of matter" patents. We ask CMS to remove this requirement and equally consider all patents covering a medicine. We are concerned that this requirement conflicts with the PRA mandate for information collections to have practical utility. Given that there is no existing or proposed guidance establishing the utility of identifying specific types of patents, the utility or relevance of this information in determining the price of the selected product is unclear, and we ask CMS to remove this requirement.

Evidence on Alternative Treatments

In this IPAY 2028 ICR, CMS rearranged the ordering of the questions within Section I to begin with those focused on patient experience. While we appreciate the refinements made to the questions within this Section, they do not go far enough in addressing the concerns we have advanced in previous years. J&J is deeply concerned by the approach CMS has chosen to adopt in implementing this program for the many reasons outlined here and in the attached appendices. Chief among them is the magnitude by which the Agency has considered the 1194(e)(1) or cost-related data factors as opposed to the 1194(e)(2) or the factors related to the clinical profile of the selected drug which are discussed in Section I.

While the cost-related factors are required, CMS should use its discretion to more adequately consider the clinical profile of the drug and ensure a transparent process in doing so. We urge CMS:

- Ensure that evidence collected on a selected drug most appropriately captures the clinical benefit it delivers to patients,
- Include an executive summary in submissions as a critical means of presenting a significant amount of information succinctly. Doing so would also assist the Agency in reviewing and processing this information.
- Clarify and remove limitations on the number of graphs and figures that supplement submissions as this aligns with the typical presentation of scientific and clinical information of a drug. Limitations on the number of figures is arbitrary and hinders the quality of information available to the Agency.

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Please see Appendix A below for J&J's comments in response to the CMS IPAY 2027 ICRs submitted in December and September 2024, and Appendix B for our comments submitted in June 2025 on the Negotiation Factors outlined in the IPAY 2028 Draft Guidance. We refer CMS to these comments and strongly urge CMS to reduce unnecessary reporting burden by removing reporting requirements that exceed statutory requirements or duplicate submission of data already available to the Agency, provide flexibility in the form and format of data reported, including removal of word limitations, and prioritize value to beneficiaries.

Sincerely,

Jacqueline Roche

Jacqueline Roche
Head, Payment and Delivery Policy
Johnson & Johnson

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Appendix A:Johnson & Johnson Response to Revised IPAY 2028 ICR

December 23, 2024

Via Electronic Filing - RegInfo.gov

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

Re: Negotiation Data Elements and Drug Price Negotiation Process for Initial Price Applicability Year 2027 under Sections 11001 and 11002 of the Inflation Reduction Act (IRA) Information Collection Request

To OMB Desk Officer,

On behalf of Johnson & Johnson (J&J), we submit the following comments in response to the Centers for Medicare & Medicaid Services' (CMS, the Agency) **Negotiation Data Elements and Drug Price Negotiation Process for Initial Price Applicability Year 2027 under Sections 11001 and 11002 of the Inflation Reduction Act (IRA) Information Collection Request.**

At Johnson & Johnson (J&J), we are driven by a passion to achieve the best version of health for everyone, everywhere, for as long as possible. In the next decade, we will see more transformation in health than in the past century – and we are ready to lead the way. Focusing exclusively on transformational healthcare innovation allows us to move with purpose and speed to tackle the world's toughest health challenges. Innovating across the full spectrum of healthcare solutions puts us in a unique position today to deliver tomorrow's breakthroughs to our current and future patients, including Medicare, Medicaid, and Marketplace beneficiaries. Our strength in both biology and medical technology means we are accelerating advances in care – from cell therapy to AI-assisted robotic surgery. We are using our wide range of expertise to address healthcare challenges that can be tackled by medical technology and innovative medicine, such as cancer, cardiovascular disease, and eye health. Our reach and depth across a continuum of

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healthcare and technology solutions give J&J the ability to impact health for humanity profoundly.

J&J recognizes that CMS made small revisions from the previous ICR published in July, 2024 that are aligned to some of J&J's recommendations, including to put forward a definition for "discontinued date", align to a three-year reporting period for Section G (market data and revenue and sales volume), and remove of the question related to off label uses. However, we continue to have significant concern with this ICR, as it continues to require a significant volume of information that is in excess of the statutory requirements needed for the factor analysis, is overly focused on cost factors instead of the data requirements for the evidence required to assess a drug's value over time for the Medicare population, and imposes substantial requirements conflicting with current best business, financial and operational practices, and systems. In fact, CMS has made minimal changes since the IPAY 2026 Negotiation Data Elements ICR.

We continue to urge CMS to align the ICR with the three principles advanced in our previous ICR comments:

1. Align reporting requirements directly with, and not exceeding, the statute;
2. Prioritize operational feasibility and simplicity, including leveraging data already required for federal reporting programs, utilizing information and resources otherwise available within the Government; and
3. Commit to prioritizing those factors that emphasize value to the Medicare beneficiary. This flexibility is offered in the statute.

Please see Appendix below for the comments submitted in September. We refer CMS to these comments and continue to strongly urge CMS to reduce unnecessary reporting burden by removing reporting requirements that exceed statutory requirements or duplicate submission of data already available to the Agency, provide flexibility in the form and format of data reported, including removal of word limitations, and prioritize value to beneficiaries.

Sincerely,

Jacqueline Roche

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Appendix:

September 3, 2024

VIA Electronic Filing at regulations.gov

Meena Seshamani, M.D., Ph.D.
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

Re: Negotiation Data Elements and Drug Price Negotiation Process for Initial Price Applicability Year 2027 under Sections 11001 and 11002 (CMS-10849)

Dear Administrator Seshamani:

On behalf of Johnson & Johnson (J&J), we submit the following comments in response to the Centers for Medicare & Medicaid Services' (CMS, the Agency) **Information Collection Request (ICR): Negotiation Data Elements and Drug Price Negotiation Process for Initial Price Applicability Year (IPAY) 2027 under Sections 11001 and 11002 (ICR)**.

At Johnson & Johnson (J&J), we are driven by a passion to achieve the best version of health for everyone, everywhere, for as long as possible. In the next decade, we will see more transformation in health than in the past century – and we are ready to lead the way. Focusing exclusively on transformational healthcare innovation allows us to move with purpose and speed to tackle the world's toughest health challenges. Innovating across the full spectrum of healthcare solutions puts us in a unique position today to deliver the breakthroughs of tomorrow. Our strength in both biology and medical technology means we're accelerating advances in care – from cell therapy to AI-assisted robotic surgery. We are using our wide range of expertise to address healthcare challenges that can be tackled by both medical technology and innovative medicine such as cancer, cardiovascular disease, and eye health. Our reach and depth across a continuum of healthcare and technology solutions give J&J the ability to profoundly impact health for humanity.

J&J urges CMS to revise and align the ICR with the three principles advanced in our previous ICR comments.

1. Align reporting requirements directly with, and not exceeding, the statute;

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2. Prioritize operational feasibility and simplicity, including leveraging data already required for federal reporting programs, utilizing information and resources otherwise available within the Government; and
3. Commit to prioritizing those factors that emphasize value to the Medicare beneficiary. This flexibility is offered in the statute.

We are concerned that CMS has not aligned the ICR with these principles and has made minimal changes to the ICR since IPAY 2026. As with the ICR for IPAY 2026, this ICR requires a significant volume of information that is in excess of the statutory requirements needed for the factor analysis, is overly focused on cost factors instead of the data requirements for the evidence required to assess a drug's value over time for the Medicare population, and imposes substantial requirements conflicting with current best business, financial and operational practices, and systems.

We remain concerned that the ICR fails to comply with the criteria outlined within the Paperwork Reduction Act (PRA). These criteria require that information collection:

> *"(i) Is the least burdensome necessary for the proper performance of the agency's functions to comply with legal requirements and achieve program objectives;*
>
> *(ii) Is not duplicative of information otherwise accessible to the agency; and*
>
> *(iii) Has practical utility. The agency shall also seek to minimize the cost to itself of collecting, processing, and using the information, but shall not do so by means of shifting disproportionate costs or burdens onto the public."*[3]

We continue to strongly urge CMS to reduce unnecessary reporting burden by removing reporting requirements that exceed statutory requirements or duplicate submission of data already available to the Agency, provide flexibility in the form and format of data reported, including removal of word limitations, and prioritize value to beneficiaries.

Negotiation Data Elements ICR Form

General Instructions

Remove Restrictive Word Limitations

CMS is updating the ICR form to remove character limitations imposed for IPAY 2026 and replace those with word limitations for IPAY 2027. J&J is concerned with any limits imposed on manufacturers' ability to provide complete information. Word or character limits impose an undue burden on manufacturers by requiring them to truncate complete responses, restricting the ability of manufacturers to provide complete information. Considering the significant ramifications of providing incomplete or inaccurate information, including the risk of civil

[3] 5 C.F.R. § 1320.5(d)(1)(i)-(iii)

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monetary penalties, manufacturers should have the ability to provide as much detail as needed in the ICR form in order to provide complete and accurate information. Therefore, we urge CMS to remove word limitations throughout the ICR form.

Recommended Improvements to the HPMS System

J&J recommends CMS make improvements to the HPMS system to reduce data entry challenges experienced in IPAY 2026 and improve the user experience. Considering the significant volume of information required for submission, the HPMS system was cumbersome to use, particularly for uploading information and reviewing and verifying information submitted. We recommend CMS ensure the HPMS System is better equipped to support the submission of large amounts of data. An updated system should enable rapid data entry without freezing during data input and submission, provide simple cut and paste capabilities, enable attachments including charts and tables to be part of the record, allow manufacturers to access and review submitted data and information prior to certification, and provide report downloading capabilities to facilitate systematic manufacturer review and verification. We recommend CMS allow manufacturers to submit the required data using an upload template instead of requiring manual entry through the system.

CMS Should Limit Timely Notification Requirements for Standard Refiles

In the instructions, CMS states that manufacturers must "timely notify" CMS of any changes to the submitted information. J&J notes that the Medicaid Drug Rebate Program requires a standard refile. Medicaid Best Price refiles can occur quarterly and often reflect a nominal change in the Best Price. Therefore, to reduce the burden on manufacturers for insignificant changes resulting from standard refiles, we recommend CMS implement a minimum threshold to define the minimum change from Best Price refiles for which timely notification would be required.

We further recommend that CMS set a date after the conclusion of the "negotiation" period and establishment of the "maximum fair price" (MFP) on which manufacturers would stop reporting changes to submitted information. For example, for IPAY 2026, we recommend that CMS clarify that manufacturers would no longer be required to notify CMS of changes to submitted information after September 1, 2024.

Allow Flexibility in Format for Reporting Monetary Amounts

J&J is concerned with the rigid format and detail required for reporting monetary amounts. We continue to urge CMS to limit the data required for submission to that data outlined in the statute and to provide flexibility in reporting detail and format with the opportunity for manufacturers to explain values reported. Specifically for monetary amounts, we urge CMS to provide manufacturers with the ability to report a range of estimates with the ability to explain rather than an exact figure. This format would better align with the PRA requirement to ensure the collection of information "is the least burdensome for the proper performance of the agency's functions to comply with legal requirements and achieve program objectives".

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Selected Drug Information (Section A)

Primary Manufacturers Cannot Be Held Responsible for Secondary Manufacturers or Third Party Manufacturers with Whom They Have No Contracts

Under Section A, CMS outlines the requirement for Primary Manufacturers to review the list of NDC-11s prepopulated by CMS for a selected drug, correct the list, and provide required information outlined in Section A for those NDC-11s. We are concerned with this requirement given CMS' use of the Primary/Secondary Manufacturer construct. CMS's Primary/Secondary Manufacturer construct is inoperable and disregards the reality that different participants in the pharmaceutical supply chain are free to create new NDCs without express consent or authorization from or knowledge of the NDA/BLA holder. Primary Manufacturers have no control over or timely visibility into their NDC updates. The Secondary Manufacturer definition overreaches to encompass repackers for which Primary Manufacturers neither have a contract with nor have authorized the provision of repacking services or creation of NDCs. Actions to update NDCs may be taken by third parties with which manufacturers may have no relationship and no visibility into independent arrangements where they create new NDCs for repacking purposes. Therefore, CMS should remove any requirement for Primary Manufacturers to report Selected Drug Information for NDC-11s not created or expressly authorized by the Primary Manufacturer.

Moreover, to collect and report information not maintained and often unknown by Primary Manufacturers would require significant time beyond what is already required in the "negotiation" process. CMS indicates its intent to publish the NDC-11 listing on February 1 and require Primary Manufacturers to collect, submit and certify all selected drug information by March 1. Especially for NDCs that are unknown to Primary Manufacturers, compliance with CMS's reporting requirement will require substantial investigative work that cannot be completed in 29 days. Therefore, at a minimum, we urge CMS to provide Primary Manufacturers with additional time to report selected drug information for the selected NDCs by providing Primary Manufacturers with a preliminary listing of the NDCs in advance of the February 1 publication. Providing Primary Manufacturers with a preliminary listing of NDCs prior to publication on February 1 will provide Primary Manufacturers with additional time to start the review and investigative process for "unknown" NDC-11s.

CMS Should Clarify Definitions for Private Label Distributor and Discontinued Date

In addition, CMS outlines definitions for Section A in the ICR, including for "Private label distributor." J&J recommends CMS revise the definition for "Private label distributor" to clarify that the definition applies only when drugs are commercially distributed. The revised definition should read: "With respect to a particular drug, a person who did not manufacture, repack, relabel, or salvage the drug but under whose label or trade name the drug is commercially distributed (21 C.F.R. § 207.1)."

In section A, CMS outlines the requirement for manufacturers to indicate if the NDC-11 has been discontinued and to provide the date of discontinuation if so. In order to improve clarity,

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J&J recommends CMS provide a definition to represent the last lot expiration date of the drug or, if applicable, the date on which the drug was withdrawn. "Withdrawn" here references when the product is pulled from the shelf by the manufacturer for health or safety reasons.

Research and Development Costs (Section C)

Urge CMS to Simplify R&D Reporting

We continue to be concerned that CMS is requesting collection of information exceeding what is necessary for CMS to perform its function to assess research and development (R&D) costs and the extent drug developers have recouped these costs. Further, CMS does not provide an explanation regarding the utility of this data in this manner and why it is essential to implementing the Program.

In this ICR, CMS is revising the format of questions for Section C to break the questions down individually rather than listing them in one table, as was the format in IPAY 2026. This revised format increases reporting burden beyond the IPAY 2026 ICR, which was already overly burdensome on Primary Manufacturers, and is contrary to the tenets of the PRA. In addition, we are concerned that this revised format further restricts the word limits. Therefore, we ask CMS not to finalize this revised format.

As we previously stated in our past comments, we encourage CMS to simplify the R&D reporting requirements outlined in the ICR to allow the Primary Manufacturer to offer an attestation in instances where the manufacturer believes it has fully recouped R&D costs for the selected drug. In instances where the manufacturer indicates that R&D costs have been recouped, then CMS does not need additional information. The burden associated with the historical data gathering that will be required to satisfy the reporting requirements under this section is significant, and CMS should not impose such significant burden in instances where manufacturers indicate they have recouped R&D costs.

However, in instances where the manufacturer has not recouped costs, manufacturers should provide relevant information to the Agency. In those cases, CMS should allow increased flexibility in manufacturers' responses to this question to allow for the appropriate cost determination that aligns with internal and/or industry financial practices. Additionally, in these instances, CMS should allow manufacturers to include indirect R&D costs after pre-clinical development. These are actual costs to the manufacturer and are currently not accounted for under the details that CMS provided for R&D.

J&J remains concerned with the flawed definition of R&D costs that does not reflect actual costs or align with statute. For example, under Question 6, Global and U.S. Total Lifetime Net Revenue for the Selected Drug, CMS describes that it will "use both the Primary Manufacturer's global and U.S. total lifetime net revenue for the selected drug to determine the extent to which the Primary Manufacturer has recouped R&D costs for the selected drug." We continue to encourage the Agency to employ great caution in avoiding discrepancies in their calculation for R&D costs and recoupment by seeking to understand "global lifetime revenue" but only considering R&D costs associated with "FDA-approved indications." Limiting R&D investments

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to those that have only been approved in a US setting while seeking global revenue represents a significant flaw in the Agency's approach.

Current Unit Costs of Production and Distribution (Section D)

CMS Should Remove Its Overly Prescriptive Methodology for Determining Production and Distribution Costs

Aligned to our previous comments, J&J continues to be concerned with the burden on manufacturers stemming from CMS' prescriptive methodology for determining production and distribution costs. This methodology is not outlined in statute and relies on data that may not be available to manufacturers. For example, certain costs may not be available at the product level, such as various overhead functions. While CMS does allow manufacturers to explain methodology, it will require substantial time and resources to perform the needed calculations and allocations that are not typical in our current operations. Therefore, we urge CMS to remove this overly prescriptive methodology for determining production and distribution costs.

Prior Federal Financial Support (Section E)

Streamline Prior Federal Financing Support Reporting and Remove R&D Tax Credit Reporting Requirement

J&J urges CMS to leverage data available from other sources, such as data directly available through government grant programs that provide financial support to manufacturers. To reduce the reporting burden, we ask CMS to permit manufacturers to submit a single federal financial support number along with an explanation detailing the support included.

Further, we continue to be concerned that the requirement for manufacturers to submit information on R&D tax credits exceeds the statutory requirements. The US tax credit for R&D is a credit for increasing R&D activity, requiring entities to surpass a baseline level of R&D spend. It is aggregated and cannot be directly correlated between dollars spent and credit received for any single product. For example, for J&J, the R&D credit is based on the consolidated filing of all J&J legal entities included in the filings, which spans beyond pharmaceuticals and includes consumer goods, medical technology, etc. Therefore, these tax credits which are not product-specific and not required by the IRA should not be considered for this section as it is impossible to allocate the credit at a product-specific, or even sector-specific, level.

Patents, Exclusivities, and Approvals (Section F)

CMS Should Remove Word Restrictions that Hinder Ability to Answer Questions 13 – 15

As stated above, we are opposed to the restrictive word limits throughout this ICR, including for Questions 13 - 15. We are particularly concerned that for Question 13, the word limit has

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decreased significantly from 2026. This decrease is problematic because this question requires reporting of explanations of active, expired and pending patents, which may be a lengthy submission. In view of the significant fines for providing information that is perceived as inaccurate or misleading, CMS should remove these word limits which hinder the ability of Primary Manufactures to comply with the ICR, and the onerous reporting for Questions 13-15.

CMS Should Remove Question 12 and 14 on Expired Patents and Regulatory Exclusivities

Given that under CMS' definition for qualifying single source drug, a product is aggregated based upon active moiety (e.g., across dosage forms and strengths), the required reporting of *expired* patent information and exclusivities is overly burdensome. The utility of such information to the negotiation is questionable. The PRA requires a straightforward utility for collected data, and therefore, we urge CMS to remove these questions.

Market Data and Revenue and Sales Volume (Section G)

CMS Does Not Have Authority to Require Submission of Pricing Data Aside from Non-FAMP

CMS does not have the authority to require submission of pricing data aside from Non-FAMP, as Non-FAMP is the only pricing metric specified in the IRA. J&J does not support mandatory reporting of additional pricing data points from other federal and commercial programs that are proprietary and unnecessary for program implementation. This pricing data is not required for the Program, as they are reflected in prices from separate and distinct programs, which should have no bearing on the determination of the MFP. The statute does not require the submission of this data, and therefore, J&J urges CMS to remove questions in this section that require the submission of pricing data beyond Non-FAMP.

We are also concerned with the significant and unnecessary burden imposed on manufacturers by the required reporting of data points included under this section that are already reported to federal agencies (including Best Price, Federal Supply Schedule (FSS) price, Big Four price). Because these data are already available to CMS from within the Government, under the PRA, it is inappropriate to impose reporting burden when the 2024 data is already available to the Agency. We are concerned that CMS is requiring manufacturers to submit information that is duplicative with other programs including some price points for Q4 2024 that manufacturers will still be calculating at the time of submission for IPAY 2027 in March 2025 (e.g. validation of unit rebate amount (URA), 340B calculations; etc).

Moreover, several of the data points outlined under Section G represent new and significant reporting requirements not already calculated or reported by manufacturers for any other programs. For example, J&J does not calculate or disclose many of the data elements outlined under these questions including Commercial and Medicare Part D average unit net price, average net unit price without patient assistance programs, and best average net unit price; and we also

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do not calculate gross to net revenue deductions at the NDC level, as these calculations are performed across an entire brand.

Lastly, as stated above, we urge CMS to improve the HPMS system to allow for an upload template instead of the cumbersome manual key in approach from IPAY 2026, with the ability to download submissions for validation prior to certification.

Ensure Consistency in Three Year Reporting Under Section G

Under Section G, CMS is revising the submission timeframe from five years to three years. While we appreciate this update, we note that question 18 asks "Was a Medicaid best price determination ever made for a calendar quarter for the selected drug during the most recent five years?". Therefore, we ask CMS to revise this question to align to three years.

Strongly Oppose Addition of the Medicare Part D Price Points

J&J urges CMS to remove Questions 26 and 27 on Manufacturer Net Medicare Part D Price from the required manufacturer data. We note that CMS removed Net Medicare Part D Price from the required data for IPAY 2026 in its previous Revised ICR, and we are opposed to CMS' re-introduction of it for 2027. J&J underscores these data points are not contemplated as information for submission in the statute and would impose a significant organizational burden on manufacturers, as they do not align with existing reporting requirements or accounting procedures.

Certification of Submission of Sections A through G for Primary Manufacturers (Section H)

CMS Should Update the Certification to Recognize the Need for Reasonable Assumptions and Account for the Restrictive Word Limitations

J&J continues to have concerns with the certification statement. As we have previously commented, given the word limitations, which we oppose, it is not reasonable to require certification that information is "complete" when the ability to provide information is restricted, and therefore, we ask CMS to remove this from the certification statement. Furthermore, while we agree that the information submitted should be accurate, we reemphasize our ask for CMS to explicitly acknowledge that manufacturers will have made reasonable assumptions given CMS' vague requirements and the significant challenges stemming from conflicts between the requirements outlined in ICR and manufacturer and industry accounting practices.

Evidence on Alternative Treatments (Section I)

Urge CMS to Clarify Its Approach for Comparative Value Assessment

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J&J remains concerned and opposes CMS' emphasis on manufacturer-specific and cost-related data, which undervalues and discredits the importance of a drug's clinical benefit as compared to its therapeutic alternative. As currently proposed, the approach is at odds with determining a drug's unique value based on its impact on beneficiaries' health and lives. This is evidenced by the overemphasis on what the Agency considers the mandatory submission of manufacturer-specific data, which is approximately 90 percent of the entire set of questions, compared to what the Agency set as optional submission to questions on the evidence focused on therapeutic impact and comparative effectiveness, unmet need and prescribing. Additionally, we are concerned that the counter-offer meetings for selected drugs do not provide for sufficient opportunity for meaningful engagement and discussion of these critical value factors prior to CMS offering its determination of the "MFP".

CMS should also outline its approach for an exchange that defines the parameters of its comparative value assessment. Instituting a more inclusive and transparent process would help CMS to fully understand the evidence landscape and receive feedback on the necessary steps of the selection of therapeutic alternatives. The Agency should rely on meaningful disease-specific and patient-centric instruments that more accurately capture the impact of treatments on patients and their caregivers to aid in understanding the total value of selected therapies for each population.

CMS Should Provide Timely Public Access to Medicare Data

We are concerned with the lack of transparency and timely availability of data that may be required for the ICR, including reporting prevalence and utilization estimates. For example, Medicare spend data has a 2-year lag, and Medicare patient claims data is not publicly available. Therefore, we ask CMS to make public, in a timely manner, Medicare spending and claims data to allow manufacturers to prepare for drug selection.

CMS Should Allow for Submission of an Executive Summary that Highlights Manufacturer Priority Information

J&J urges CMS to allow the submission of an executive summary. The executive summary is a clear succinct summation of the factors outlined in section 1194(e)(1) of the Act enabling CMS reviewers to comprehend and utilize the information as the basis for the initial assessment and offer. The executive summary is the only place where the manufacturer can tell the full value story for the selected product across the responses to the multiple questions in the ICR. The executive summary should be reviewed to ensure consistency of interpretation of evidence across reviewers and to highlight the manufacturer prioritized comments.

We also ask CMS to p*rovide greater flexibility for manufacturer-focused questions (Questions 30 – 37)*

- *Question 30*: Off-label Use

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J&J notes that manufacturers may have limited evidence of off-label use due to guardrails around manufacturers on studying off-label use of a product, and restrictions on promoting off-label uses. To be consistent with FDA compliance standards, CMS should consider if off-label use is appropriate to ask manufactures to submit.

While CMS is allowing manufacturers to submit optional information on off-label use for selected drugs, we note that therapeutic alternatives must have the same FDA indications and should not be identified through off-label use. When it is not possible to find therapeutic alternatives with the same indication, therapeutic alternatives without the same indications should be assessed differently than products that have the indication.

- *Question 31:* Potential Therapeutic Alternatives
  This question requests a list of therapeutic alternatives. J&J urges CMS to increase word count and allow for manufacturers to submit a rationale for therapeutic alternatives listed. We also ask CMS to provide manufacturers with the opportunity to provide input on drugs that are not appropriate to consider as a therapeutic alternative and why.

- *Question 34*: Therapeutic Advance and Unmet Medical Need
  J&J urges CMS to consider improvements in patient and provider experience as part of therapeutic advance. For example, this could include new routes of administration which improve patient experience.

- *Question 37*: Visual Representations to Support Responses to Questions 30 Through 35
  While CMS states that up to 10 PDF files may be submitted, we ask that CMS clarify that each PDF may have multiple figures.

Patient and Caregiver Focused Input Questions Must Be Clear (Questions 38-44)

The process for patients and caregivers to provide focused input for IPAY 2026 was not readily known and was not user friendly, which resulted in a missed opportunity for individuals and organizations to provide accurate and authentic feedback to CMS. It is critical that CMS make the process of providing patient and caregiver feedback simple, and we recommend that CMS minimize any questions requesting personal health information (PHI), which could deter patients and caregivers from engaging in the process. Additionally, we recommend that CMS provide greater transparency to manufacturers regarding how the patient/caregiver input is used, including a summary of findings and explanation of how the information impacted the Agency's assessment of the selected drug before the initial offer.

While we appreciate that CMS has made some improvements to the wording for the patient / caregiver focused input questions, we continue to encourage the Agency to clarify these questions further. For example, CMS should clarify further the information Question 38a2 is

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seeking, including whether this question is looking to establish the time of diagnosis from the patient's perspective. For Question 40a2, CMS provides as an example a list of factors that may have affected the choice of medication. We recommend that CMS provide a more comprehensive list and include insurance coverage, physician recommendations based on clinical guidelines, and physician recommendations based on clinical experience. For Question 43, we request CMS allow patients/caregivers to provide citations to support their decision-making and responses.

For the Clinical-Focused Experience Questions, CMS Should Include Additional Questions to Better Understand the Responding Physician's Level of Experience with the Selected Drug or Therapeutic Alternatives (Questions 45-51)

J&J strongly advises CMS to consider input primarily from clinicians with documented experience prescribing and managing patients with the selected drug or therapeutic alternatives. J&J recommends CMS add additional questions to fully understand the respondent's clinical experience in order to determine if it is appropriate to include responses in the selected drug's evaluation. For example, we recommend CMS add questions to understand a clinician's years of experience, number of patients treated, and specialized training in the disease area where the selected drug is indicated must be assessed for level of experience and expertise to enable CMS to determine if the Agency should include a responder's input in its evaluation of the selected drug. Moreover, we recommend that CMS ask respondents to provide citations to support subjective claims in Question 46b, and recommend CMS ask respondents how much significance/weight they give guidelines in treatment decisions and which specific guidelines they used.

*****

J&J appreciates the opportunity to submit comments in response to the *Negotiation Data Elements and Drug Price Negotiation Process for Initial Price Applicability Year 2027 under Sections 11001 and 11002 of the Inflation Reduction Act (IRA) Information Collection Request.* We urge CMS to revise the ICR to align reporting requirements directly with the statute, prioritize operational feasibility and simplicity, and prioritize those factors that emphasize value to the Medicare beneficiary. For questions, please contact jroche8@its.jnj.com.

Sincerely,

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Appendix B: Johnson & Johnson Response to CMS IPAY 2028 Draft Guidance

June 26, 2026

Chris Klomp
Deputy Administrator and Director of the Center for Medicare
Centers for Medicare & Medicaid Services
7500 Security Boulevard
Baltimore, MD 21244-1859

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

Dear Deputy Administrator Klomp:

On behalf of Johnson & Johnson (J&J), we submit the following comments in response to the Centers for Medicare & Medicaid Services' (CMS, the Agency) *Draft Guidance, Implementation of Sections 1191 – 1198 of the Social Security Act for Initial Price Applicability Year (IPAY) 2028 and Manufacturer Effectuation of the "Maximum Fair Price" in 2026, 2027, and 2028* (Draft Guidance).

At J&J, we are driven by a passion to achieve the best version of health for everyone, everywhere, for as long as possible. In the next decade, we will see more transformation in health than in the past century – and we are ready to lead the way. Focusing exclusively on transformational healthcare innovation allows us to move with purpose and speed to tackle the world's toughest health challenges. Innovating across the full spectrum of healthcare solutions puts us in a unique position today to deliver tomorrow's breakthroughs to our current and future patients, including Medicare, Medicaid, and Marketplace beneficiaries.

Despite our serious concern with the Inflation Reduction Act (IRA) and the Medicare Drug Price Negotiation program (the Program), J&J seeks to continue our engagements with CMS to address our concern about the implementation of this program and the far-reaching impacts of the IRA on biopharmaceutical innovation and access to life-saving treatment. We respectfully offer the following comments and strongly encourage their implementation as CMS finalizes IPAY 2028 Guidance. We look forward to continuing our active partnership with CMS to achieve our mutual goals of improving quality and outcomes for the patients we serve.

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J&J is a member of Pharmaceutical Researchers and Manufacturers of America (PhRMA) and Biotechnology Innovation Organization (BIO) and echoes their comments in response to this Draft Guidance. Our recommendations are as follows:

Recommendations on CMS Drug Selection Policies

I. Recognize Clinical Value of Fixed Combo Drugs and Urge CMS not to Finalize any Changes to the Definition of a Fixed Combination Drug
II. Conform the Qualified Single Source Drug (QSSD) Definition to Well-Established Statutory Definitions
III. Remove the Extra-Statutory "Bona Fide" Marketing Standard
IV. Strictly Adopt the Statutory Language Related to the Plasma-Derived Product Exclusion from QSSD
V. Rescind CMS Successor Regulation on Interchangeable Biologic Products
VI. Promote Predictability and More Fully Assess the Likelihood of a Biosimilar's Licensing and Marketing in Implementation of "Biosimilar Pause"
VII. Revise Orphan Drug Exclusion (ODE) Policies to Protect Pharmaceutical Innovation for Rare Diseases
VIII. Rescind Policies that Hold Primary Manufacturers Accountable for Secondary Manufacturers

Recommendations on Drug "Negotiation" Process

I. Remove Proposal to Collect Forward Looking "Market Data"
II. Adopt Recommended Changes to Factors and Appendix A
III. Improve the Timeline Required of Manufacturers to Submit Manufacturer Data
IV. Improve the Registration Process for Patient Listening Sessions and Provide Greater Transparency on How the Agency Uses Stakeholder Input to Inform the "Negotiation" Process and Determination of "MFP"
V. Enhance Transparency for "MFP" Ceiling Price Calculations, and Calculate "MFP" Ceiling Price at the Lowest Unit of Measure (LUM)
VI. Further Clarify the Information and Process Needed on Renegotiation Criteria and Timelines

Requirements to Operationalize "MFP" Effectuation in IPAY 2026 and 2027

I. Ensure Long Term MTF Support for Operational Feasibility, as No Private Solution Exists
II. Provide Manufacturers with Immediate Clarification on MTF Technical Requirements and Functionality, and a Clear and Accelerated Testing Schedule

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III. Provide Clarity on Credit / Debit Ledger and Dispute Process, and Ensure Claims Data Transparency for Reversals
IV. Implement Solutions to Provide Accessibility and Usability of 340B Claims Data to Manufacturers Seeking to Comply with Statutory Obligations to Effectuate the "MFP"
V. Establish a CMS Pre-funded "MFP" Discount Pool to Address Pharmacy Cashflow Concerns
VI. Ensure Manufacturers Acting in Good Faith Receive Protection from Civil Monetary Penalties for Circumstances Outside of their Control, Including Delayed Release of Technical Requirements or MTF Operational Failures
VII. Finalize Proposal Related to Claims with Drug Data Processing System (DDPS) Edits
VIII. Continue Formulary Inclusion Exceptions for All Future IPAY Periods

J&J Recommendations for "MFP" Effectuation under Part B

I. Consider Key Differences for "MFP" Effectuation for Part B from the Process Established for Part D
II. Provide Visibility to Manufacturer Required Claims Data for Part B "MFP" Effectuation
III. Adopt a Standard Default Refund Amount (SDRA) Under Part B Based on Average Sales Price
IV. Exclude "MFP" from the Calculation of ASP to Minimize Access Risks for Patients under "MFP" Effectuation and for Accurate Calculation on Inflation Rebates

Recommendations on CMS Drug Selection Policies

Recognize Clinical Value of Fixed Combo Drugs and Urge CMS not to Finalize any Changes to the Definition of a Fixed Combination Drug

CMS should reject any deviation from the existing approach to fixed combination drugs due to the evident absence of legal authority and the lack of scientific expertise noted above. CMS does not have the legal authority under the IRA to treat "fixed combination drugs" with multiple, distinct, active ingredients as the same QSSD as single active ingredient products. There is no statutory basis for this approach that impermissibly expands the QSSD definition beyond the clear statutory language of the IRA and Congressional intent. The IRA does not impose or permit the addition of a requirement that all active ingredients or moieties of a fixed combination drugs be "biologically active" against the treated disease or make a "clinically meaningful difference." In fact, these terms are not referenced at all in the IRA.

Further, the Agency does not possess the requisite scientific expertise to make subjective determinations as to whether any active ingredient is "biologically active" against the

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disease states the drug is indicated for and whether it results in a "clinically meaningful difference." CMS' guidance is also inconsistent with the Food and Drug Administration's (FDA) definition of a fixed combination drug, and CMS has provided no legal or scientific basis for treating certain fixed combination drugs differently from others particularly when CMS does not have the requisite scientific expertise. FDA has affirmatively determined fixed combination products to be a separate drug from any single active included in the fixed combination based on the different molecular structural features of the fixed combination. Active ingredients, whether biologically active against the disease state or not, serve clinical purposes and provide benefits that have been acknowledged by the FDA.

CMS' request for input on a new approach to fixed combination drugs reflects a fundamental misunderstanding of the value of fixed combination medications. The example that CMS uses—addition of a second active ingredient that "affects the bioavailability" of the first active ingredient—assumes that such a combination would not result in a "clinically meaningful difference." This assumption is wrong. Fixed combination drugs, in which one active ingredient improves the bioavailability of the second active ingredient, are created by drug developers and approved by the FDA specifically because they provide clinically meaningful improvements for patients. Active ingredients that affect bioavailability can determine whether the product works at all or whether it works considerably better. These new products generate specific benefits, which include improving patient outcomes, reducing adverse events, increasing the tolerability of the drug, improving patient adherence, reducing dose administration time by hours for each administration, and by providing an alternative route of administration for patients with poor venous access. These advances, which would only be possible via such fixed combination drugs, generate an improved patient experience, which is evident in the overwhelming patient preference for fixed combination drugs. In addition, these products produce significant economic benefits due to reduced administration costs, fewer hospital visits, and enhanced overall efficiency within healthcare settings.

Such a policy change would directly disincentivize development of these important products that deliver clear benefits for patients and reduce healthcare costs by creating undue uncertainty. CMS' potential new approach would make it economically infeasible to develop these important therapies, which require costly research and clinical trials. We urge CMS not to finalize any changes to the definition of a fixed combination drug.

Conform the Qualified Single Source Drug (QSSD) Definition to Well-Established Statutory Definitions

CMS' QSSD definition is inconsistent with the plain language of the IRA, and CMS erroneously relies on language that applies only to the determination of eligibility for the small biotech exemption to aggregate products approved under separate New Drug Applications (NDAs) or Biologics License Applications (BLAs) into a single QSSD. In addition, CMS' decision to aggregate products in this way creates a significant disincentive

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to continued product development, which will have a negative impact on important innovation for patients. CMS should conform the QSSD definition to the statutory requirements such that to be included in a QSSD, each individual drug product or biological product must be approved or licensed under the same NDA or BLA, either as part of the original application or under a supplement to such application, and at least seven years or 11 years after the date of FDA approval or licensure (as applicable) before the selected drug publication date.

Remove the Extra-Statutory "Bona Fide" Marketing Standard

We object to CMS' "bona fide" marketing standard. § 1192(e) states that the presence of an "approved and marketed" generic drug under Federal Food, Drug and Cosmetic Act § 505(j) or biosimilar under PHS § 351(k) results in the exclusion of the reference product from the definition of a QSSD. This is a critically important protection provided to manufacturers that face generic competition and, therefore, already are subject to substantial pricing pressure. In articulating this protection, the plain language of the statute refers to a generic drug or biosimilar that is "marketed."

However, CMS creates a new standard to determine whether a reference drug or biological is excluded from the definition of a QSSD and, therefore, protected from price setting. That new standard – not found in the statute – requires "bona fide marketing" of the generic drug or biosimilar.

This change in substantive legal standard is troubling for several reasons. First CMS has effectively added the phrase "bona fide" to the statute. Second, the standard is undefined and based on the Agency's subjective determination of this standard. Regulated parties are provided no notice as to what CMS believes is "bona fide" marketing and what is not. The criteria to be applied are not disclosed, creating substantial uncertainty for manufacturers and others seeking to understand which products are eligible for selection. Further, this approach deviates significantly from CMS' established and objective approach in determining if a product has been marketed under the Part D Program or the Medicaid Drug Rebate Program (MDRP).

An extra-statutory "bona fide" marketing standard, applied to generic drugs and biosimilars, undermines the statutory purpose as clearly articulated by Congress in the text to protect otherwise qualifying single source drugs from the compulsory discounting mechanism. There is significant risk that the protection intended by Congress will be rendered null if CMS applies this subjective and unauthorized standard. We therefore urge CMS to remove the "bona fide" marketing requirement and apply the statute as written.

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Strictly Adopt the Statutory Language Related to the Plasma-Derived Product Exclusion from QSSD

We strongly recommend CMS adhere to the statutory language describing the plasma-derived product exclusion outlined in section 1192(e)(3)(C) of the Act and ensure that CMS references multiple sources to make this determination. In section 30.1.3, CMS notes that the Agency considers "plasma-derived product is a licensed biological product that is derived from human whole blood or plasma, as indicated on the approved product labeling."[4] Aligned with the Agency's current and prior guidance, CMS should continue to reference multiple sources, such as the drug's approved label and other FDA resources like the Approved Blood Products List. We also encourage CMS to reference the totality of relevant therapies and refer to the FDA's Cellular and Gene Therapy Products website to clarify that other plasma-derived products are appropriately captured in this exclusion.

Rescind CMS Successor Regulation on Interchangeable Biologic Products

In section 110.1 of the Draft Guidance, CMS discusses the successor regulation provision related to the immediate substitution of new interchangeable biologic products for selected drugs as finalized in the Final CY 2026 Part D Redesign Program Instructions. J&J continues to oppose CMS' decision on the successor regulation issue and to allow such substitution. We believe that allowing immediate or maintenance substitution of biosimilars undercuts the IRA's explicit requirement that Part D sponsors include the *selected drugs* on their formularies. Furthermore, we believe that allowing biosimilar substitution exceeds CMS' authority because the plain language of the statute applies only to generic drugs.

Promote Predictability and More Fully Assess the Likelihood of a Biosimilar's Licensing and Marketing in Implementation of "Biosimilar Pause"

The statute allows specific biosimilar manufacturers to request a "pause" before selecting the reference product for "Maximum Fair Price" ("MFP") price-setting. This pause is intended to give time for the biosimilar product to obtain approval and commence marketing, provided CMS determines there is a "high likelihood" that the biosimilar will be "licensed and marketed." However, we are concerned that CMS' interpretation of the "high likelihood" standard unnecessarily restricts access to this pause. J&J specifically encourages CMS to consider additional evidence, including related to patent disputes, and forward-looking statements on operational readiness investments, when assessing the "high likelihood" of a biosimilar's licensing and marketing. Lastly, we continue to have

[4] Section 30.1.3 of the Draft Guidance, Page 18

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concerns with the bona fide marketing standard's applicability here as was articulated above.

Revise Orphan Drug Exclusion (ODE) Policies to Protect Pharmaceutical Innovation for Rare Diseases

Current guidelines disqualify a drug from the ODE immediately upon receiving a second orphan designation or a new indication outside of its initial designation, regardless of whether it involves a different rare disease or another type of disease. In the Draft Guidance, CMS outlines that it will apply the seven or 11 year selection eligibility timeline retroactively from the date of initial approval or licensure. J&J disagrees with this approach, and we urge CMS to instead use the date a drug's ODE status ceases as the basis for determining the seven or 11 years of drug selection eligibility.

CMS should start the eligibility clock from the point of ODE status loss, rather than reverting to the original approval date. This approach will create a more consistent framework for determining eligibility for price setting and support continued innovation for these rare diseases under the program, ensuring fair access to treatments for patients.

Rescind Policies that Hold Primary Manufacturers Accountable for Secondary Manufacturers

The IRA provides a statutory definition for "manufacturer" which states "… any entity which is engaged in production…OR the packaging, repackaging, labeling, relabeling, or distribution of prescription drug products." Despite this clear statutory definition, CMS has used guidance to establish a conflicting interpretation of what entities qualify as a "manufacturer," and define new terminology for "Primary Manufacturer" and "Secondary Manufacturer." CMS has assigned responsibility and liability to Primary Manufacturers for the information and actions of corporate entities that the Agency deems "Secondary Manufacturers." The concept and terms "Primary Manufacturer" and "Secondary manufacturer" are not referenced in the IRA, and CMS' use of these terms improperly ignores and overrides the statutorily adopted manufacturer definition in a manner that exceeds CMS authority.

Primary Manufacturers do not have the legal or operational authority to compel a Secondary manufacturer's compliance with required information sharing or pricing actions. Primary Manufacturers do not have access to the required data elements for Secondary manufacturers required for submission to CMS, and do not have the authority needed to ensure their compliance with providing access to the "MFP". Organizations deemed by CMS as Primary Manufacturers and Secondary manufacturers are in many instances distinct and unaffiliated entities. Primary and Secondary manufacturers can be

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direct competitors in a market and have no incentive to exchange or provide commercial practices. There is nothing in the guidance that obligates Secondary manufacturers to cooperate or comply with Primary Manufacturers. In fact, use of the Primary / Secondary manufacturer construct heightens exposure to federal and state antitrust laws due to the required sharing of proprietary information. This concern was noted by CMS in its February 2016 Medicaid Program Final Rule in which the Agency agreed not to finalize its proposal on sharing of pricing data between competing manufacturers and recognized the challenges of obtaining pricing information from non- related manufacturers.

Further, even if a Primary Manufacturer were willing to try to compel a Secondary Manufacturer to share required information for submission to CMS or providing access to the "MFP" on eligible claims, it would be overly burdensome, as it would require restructuring of contracts and business terms, as well as the establishment of a process to obtain the information. We strongly oppose any policy that would apply Civil Monetary Penalties (CMPs) to Primary Manufacturers for the actions or inactions of Secondary manufacturers in making the "MFP" available.

CMS should rescind policies that hold Primary Manufacturers accountable for Secondary Manufacturers. We recommend that CMS use the unique product labeler ID assigned to each entity by the FDA to better identify Primary Manufacturer instead of reviewing only the holder of an NDA or BLA. To ensure compliance with the IRA's statutory requirements to provide access to the "MFP" on eligible claims, CMS should establish a process in which each manufacturer is responsible for effectuating the "MFP" on their own National Drug Code (NDC). CMS can enable this by requiring Secondary manufacturers to enter into separate agreements with CMS and the MTF for "MFP" effectuation.

Recommendations on Drug "Negotiation" Process

Remove Proposal to Collect Forward Looking "Market Data"

In Section 50.1 of the Draft Guidance, CMS outlines its approach to manufacturer-specific data and solicits comment on the inclusion of "forward-looking" market data, which could include, but not be limited to, a range of information from forecasted net revenue and volume by indication, net pricing, and annual gross-to-net ratio trends across market channels. J&J opposes the collection of this information and requests CMS to remove this data element from the final guidance and future ICR.

This type of information is not fact, inconsistent, and beyond the scope of the definition of data. The use of projections is highly problematic as they are, at best, estimates, based on assumptions and external factors that are subject to change and should not be used as the

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basis for CMS decision-making. We further oppose inclusion of "forward-looking" market data as we believe this request is beyond what is required by section 1194(e)(1)(E) and is inconsistent with the definition of data as forecast information is an estimation, not objective, empirical fact. The submission of these projections would challenge a manufacturer's ability to certify that the data submitted to CMS is complete and accurate. Lastly, we remain highly concerned that the potential utilization of this type of information and the potential for such information to become available would jeopardize manufacturers' ability to comply with regulations in place by the Securities and Exchange Commission. Projections and analyses of how a drug may perform in the market and different channels are kept strictly confidential to ensure that this type of data does not inappropriately influence investors or external entities, ensuring consistency with manufacturer's obligations under Securities and Exchange Commission requirements.

We again strongly encourage CMS to remove the inclusion of "forward-looking" market data from its final guidance and ICR as collection of this information is inconsistent and highly dynamic, reaches beyond what is required in statute, and defies the definition of data.

Adopt Recommended Changes to Factors and Appendix A

As discussed in the Sections 50.1, 50.2, and 60.3.1 of the Draft Guidance and within Appendix A of the Draft Guidance, CMS outlines definitions that will be used in collected data for the "negotiation" program. In this Draft Guidance, CMS seeks comments from the public about the inclusion of considering healthcare services as potential therapeutic alternatives, ways to streamline definitions of the factors considered during "negotiation" and seeks input regarding the Primary Manufacturer's research and development (R&D) costs. Aligned to comments J&J has submitted in the past, we continue to recommend a number of changes to the following definitions outlined in Appendix A:

- *Research and Development (R&D) Costs*
  J&J continues to recommend that CMS simplify the process for reporting R&D costs. In the Draft Guidance, CMS reduces the amount of information manufacturers are required to submit to simplify the reporting of R&D costs. While we appreciate this change and support its inclusion in the final guidance, we continue to believe that the cost reporting structure can be significantly further simplified. As noted in our previous comments, J&J recommends that CMS simplify the R&D reporting requirements to allow the Primary Manufacturer to offer an attestation in instances where the manufacturer believes to have fully recouped the R&D costs. While collection of R&D data for the purposes of determining Primary Manufacturer cost recoupment is required by statute, we continue to have concern that the approach currently outlined by CMS is

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unnecessarily burdensome. The calculation of R&D spending may not be compatible with existing financial accounting practices and neglects the multi-faceted and interlinked elements that comprise the research ecosystem, which may result in an incomplete and inaccurate calculation of R&D investment and ignore indirect costs. CMS' approach on R&D costs does not accurately reflect the true costs of innovation or the associated risk. We urge CMS to simplify R&D cost reporting as one reported number that meets the requirements of the statute.

- *Consideration of Health Care Services as Therapeutic Alternatives*
  In Section 60.3.1, CMS solicits comments on the potential to consider health care services as potential therapeutic alternatives to the selected drug. J&J is concerned by this proposal as it lacks detail and does not provide a consistent measure by which to consider therapeutical alternatives to the selected drug and therefore does not support this proposal. Fundamentally, the comparison of costs of a drug to health care services is challenging as they are priced and reimbursed using very different methodologies. For instance, CMS' own approach in calculating reimbursement for healthcare services administered in the inpatient setting relies on the Medicare Severity Diagnosis Related Groups (MS-DRGs) reimbursement methodology. The calculation of this reimbursement depends on a number of inputs and is the average of costs submitted by a hospital for several procedures and services assigned to the MS-DRG. Clearly, this methodology differs substantially from the pricing and reimbursement methodology used for drugs. As currently proposed, CMS has provided very little detail on how a health care service would be selected or identified, how the comparison of costs would be calculated, and the way in which this information would inform the "MFP". For the reasons outlined above, we do not support CMS' proposal to consider healthcare services as a potential therapeutic alternative to the selected drug.

- *Prior Federal Financial Support*
  J&J recommends CMS remove data related to prior federal financial support from manufacturer submission requirements. We continue to have concerns, as described in our comments from previous years, that CMS uses an overly broad definition for novel therapeutic discovery and development of a selected drug to set the "MFP" and the potential unintended consequence that it will be a factor to reduce the "MFP". Further we oppose CMS' inclusion of tax credits for orphan disease drugs as a form of Federal financial support. These tax credits were established as an incentive for drug development for the treatment of individuals, and Medicare beneficiaries, with rare diseases. The inclusion of these tax credits as a form of prior Federal financial support

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to adjust, or reduce, the "MFP", would be entirely antithetical and works against the necessary supports to the development of orphan disease drugs.

Operationally, the reporting of this data is challenging as many of these data elements are not known to manufacturers, or the level of granularity requested is not captured. Therefore, we recommend CMS remove these data from manufacturer submission requirements or limit this information solely to funding that resulted in a patent application containing a Government Interest Statement and/or research where a patent assignee was a US government agency.

- *Patents, Exclusivities, and Approvals*
  As part of the "negotiation" process, CMS requires the Primary and/or Secondary Manufacturer to submit data on patents and regulatory exclusivities. J&J has submitted extensive comments in previous years on the importance of patents and exclusivities in the incentive to develop novel and innovative therapies and the need for CMS to revise its guidance on the way in which it collects this information. As noted previously, a patent is a constitutionally protected property right granted by the US Patent and Trademark Office that protects new and innovative invention and are an essential incentive that allow innovative pharmaceutical companies to take on the considerable risk, and make the substantial investments, required to develop new medicines that benefit patients. Upon expiration of this exclusivity period, generic companies are permitted to reference innovator clinical data which facilitates generic entry. Together, patent and regulatory exclusivities provide the predictable incentive framework necessary for the development of innovative medicines, which in turn yield significant benefits for patients.

  We again encourage the Agency to revise its guidance so that: (A) expired and non-public patents and (B) expired regulatory exclusivities are not required for submission. Instead, this information should be disclosed at the discretion of the Primary and/or Secondary Manufacturer.

  Section 50.1 and Appendix A of the Draft Guidance requires a Primary Manufacturer to submit to CMS "relevant patents," both *expired* and unexpired, that are related to the selected drug.[5] We urge the Agency not to require the submission of expired patents. This requirement creates an undue burden for Primary and/or Secondary Manufacturer(s) given the expansive definition of QSSD and the overly broad request for

[5] Appendix A, Page 210

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patent information. We are also concerned that CMS has not clearly delineated how this information will be used in the "negotiation" process and determination of "MFP".

Additionally, we urge the Agency not to require the submission of non-public patent applications as this forced disclosure of confidential information may hinder industry collaboration. This forced disclosure will disincentivize companies from collaborating, which will hinder the discovery and development of new innovations and ultimately reduce patient choice. As such, we strongly encourage CMS to update its guidance to clarify that the submission of any non-public patent information by a Primary or Secondary Manufacturer should be discretionary.

CMS is also seeking to collect information regarding the selected drug's regulatory exclusivities. We encourage the Agency to clarify that expired regulatory exclusivities are not required for submission. Instead, this information should be disclosed at the discretion of the Primary and/or Secondary Manufacturer. In view of CMS' expansive definition of QSSD, requiring the submission of expired regulatory exclusivities is labor-intensive and burdensome and provides very limited value to CMS in determining the "MFP" as they do not delay or prohibit competition. This onerous requirement is particularly complicated by the fact that expired regulatory exclusivities are not maintained in the course of regular business activities.

Lastly, requiring a Primary and/or Secondary Manufacturer to submit expired regulatory exclusivities disproportionally and negatively impacts small molecule drugs. Unlike biologics, small molecule drugs may be rewarded one or more New Clinical Investigation ("NCI") Exclusivities for developing different innovations relating to new indications to help patients. However, these NCI Exclusivities often run concurrently with a later expiring exclusivity, such as a drug's New Chemical Entity ("NCE") Exclusivity. As a result, many expired NCI exclusivities may never have been material to a product's market share as they expire before, or shortly after, the expiry of the NCE exclusivity. In sum, for all of the above reasons, we strongly encourage CMS to update its guidance to clarify that the submission of any expired regulatory exclusivities by a Primary or Secondary Manufacturer should be discretionary.

- *Market Data and Revenue and Sales Volume Data*
  As outlined in our previous comments, J&J is concerned with the requirements for Primary Manufacturers to submit to CMS market data and revenue and sales volume data for the selected drug to inform the "negotiation" process. These definitions are very broad and often required to be confidential, proprietary information. We ask CMS to remove these data from submission requirements.

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J&J continues to oppose the inclusion of Manufacturer Net Medicare Part D Price in the market data and revenue and sales volume data, which was introduced in manufacturer requirements for IPAY 2027. We are concerned that manufacturer submission of this price could create flawed comparisons with therapeutic alternatives because manufacturers are unable to validate or understand how this information is being used, especially because rebates for therapeutic alternatives are proprietary. We also ask CMS to share with manufacturers of selected drugs the net Medicare Part D price for therapeutic alternatives.

- *Evidence About Alternative Treatments*
  The submission and consideration of evidence about alternative treatments are considered optional in the "negotiation" process. We remain concerned that as currently conceived, there is an inappropriate overemphasis on the non-clinical, manufacturer specific data that bear little to no influence on beneficiary health. J&J continues to believe that the factors which examine the impact to beneficiaries' health and outcomes are the most critical in assessing a drug and should be weighed more heavily than the other factors listed in Appendix A.

  Therapeutic Advance – For this optional evidence, CMS describes its intention to "examine improvements in outcomes to determine the extent to which a selected drug represents a therapeutic advance as compared to its therapeutic alternative(s)". It further notes that for the purposes of "negotiation", the Agency will "consider the extent to which the drug represents a therapeutic advance at the time of consideration based on all available information" available. This definition still lacks the necessary amount of detail and transparency into how the Agency intends to assess a drug's therapeutic advance. Aligned to our previous comments, the definition still does not clarify if this assessment encompasses both safety and efficacy of a drug. We also encourage CMS to consider the characteristics of a drug that impact the therapeutic advancement a drug offers such as the patient experience, mode of administration, adherence to medication regimens, and impact on quality of life.

  Outcomes – CMS defines this optional evidence to include clinical outcomes or outcomes related to the functioning, symptoms, quality of life, or other aspects of a patient's life. J&J asks CMS to further clarify if it also includes cost of care outcomes.

  Unmet Medical Need – J&J recommends that CMS broaden the definition of unmet need beyond the availability of therapies to also include the drug's therapeutic profile correlated to the needs of the disease type and patients and subpopulations, especially those with historically disparate access or outcomes. CMS should take an approach

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that harmonizes the definition in Appendix A with FDA's definition for unmet medical need, and orphan and pediatric regulatory exclusivities codified in other federal statutes.[6]

Off-Label Use – CMS defines off-label use as use of drug that is not approved by the FDA but is included in "evidence-based clinical practice guidelines and the off-label use is a medically-accepted use covered under Part D or Part B".[7] However, we ask CMS to clarify how manufacturers can provide evidence related to off label use that may not be included in evidence-based guidelines.

Improve the Timeline Required of Manufacturers to Submit Manufacturer Data

In Section 40.2, CMS states its intent to require manufacturers to submit required information for the IPAY 2028 by March 1, 2026, noting that manufacturers will not be able to finalize Q4 2025 data until end of January 2026. As outlined in statute, CMS was not required to establish such a short timeline, and we are concerned by the Agency's approach since failure to meet this difficult timeline is under the penalty of excise tax liability. The Agency's proposed approach therefore exceeds authority under the IRA and poses significant and unnecessary administrative and regulatory burden.

Improve the Registration Process for Patient Listening Sessions and Provide Greater Transparency on How the Agency Uses Stakeholder Input to Inform the "Negotiation" Process and Determination of "MFP"

J&J continues to encourage CMS to conduct public engagement events to seek input from patients, caregivers, advocacy organizations and other interested parties in order to gain real perspectives and experiences related to the selected drugs, conditions or diseases treated by the selected drugs, and therapeutic alternatives to the selected drugs. For the patient-focused events and Town Hall, it is critical that CMS continue to make the process to provide patient or caregiver feedback simple and we recommend that CMS minimize any questions requesting personal health information (PHI), which could deter patients and caregivers from providing feedback. Additionally, we recommend that CMS provide greater transparency for how they will use the patient/caregiver focused input. We encourage CMS to provide to manufacturers a summary of findings of the patient/caregiver input and the patient/caregiver listening sessions, including how this information was used in the Agency's assessment of the selected drug prior to the initial offer.

[6] https://www.fda.gov/media/86377/download
[7] Appendix A, page 215

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Enhance Transparency for "MFP" Ceiling Price Calculations, and Calculate "MFP" Ceiling Price at the Lowest Unit of Measure (LUM)

Manufacturers require more transparency around CMS' calculation of the "MFP" ceiling price. We remain concerned that the current calculation is overly complex and lacks the transparency manufacturers need to verify the "MFP" ceiling price. Transparency is essential to enabling manufacturers to validate the accuracy of the "MFP" ceiling calculation and make informed counter-offers during the "negotiation" process.

In Section 60.1 of the Draft Guidance, CMS states that for the purposes of determining a single price included in an initial offer, CMS intends to base the single price on the cost of the selected drug per 30-day equivalent supply. CMS is soliciting comment on whether it should take an alternative approach to negotiating the single price for the selected drug—for example, on a per-unit basis rather than a 30-day equivalent supply basis, or on the basis of days' supply less than 30 days—for drugs for which a 30-days' supply is not representative of the typical use of such drug (for example, drugs that have only one formulation and are indicated for administration once in a course of treatment, or drugs that are typically administered daily for a short period such as two weeks).

Instead of 30-day equivalent supply, J&J strongly advocates for the "MFP" ceiling price to be established based on the lowest unit of measure that is the same (common) across all prices, volumes, dosage forms and strengths for the selected drug. We encourage CMS to adopt this common lowest unit of measure-based approach for drugs selected under both Part B and D. It's important to note that drugs covered under Part B are typically not dispensed in 30-day packages; instead, they are administered—such as through infusion or injection—within a physician's office at varying frequencies that do not align neatly with a 30-day period.

Determining a single "MFP" ceiling price based on a lowest unit of measure offers a more straightforward and transparent method, aligning better with existing claims billing practices throughout the pharmaceutical supply chain and Medicaid. This approach reduces burden and facilitates easy conversion to package size or billing unit type (e.g., MG for Part B or ML for Part D). Once a common billing unit conversion is established (e.g. ML), the prices can be appropriately weighted to derive at a combined single "MFP" ceiling price for both Part B and Part D (e.g. Both Prices converted to a price per/ML). Upon "negotiation" and for "MFP" application purposes, CMS can reconvert the single "MFP" back to the lowest unit of measure according to each program's billing type (e.g., Price per MG for Part B vs. Price per ML for Part D).

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The illustrative example below demonstrates how CMS could implement a lowest unit of measure-based approach for calculating the "MFP" ceiling and the application of "MFP" across dosage forms and strengths for a drug with Part D and Part B utilization.

Example: Part B & D "MFP" Ceiling Calculation at the Lowest Unit of Measure

Step 1: Convert Part B Billing Price Type to a Common Billing Type (e.g. per ML)

In this example, the Part D Billing Price is **$1000 per ML**. For this product, each ML represents 90 MG dosage strength of Part B Billing Units at the lowest unit of measure (1ML=90MG), and each Part B unit price is $8 per MG. To convert the Part B Billing Price to an equivalent price per ML, the price of $8 per MG is multiplied by the number of MG units within 1ML or calculated as $8 X 90 MG, which is equal to **$720 p/ML**.

Original Billing Price before conversion:
Part B = $8 per MG
Part D = $1000 per ML

After the conversion to a common Billing Price per ML:
Part B= $720 per ML (equivalent to $8 per MG X 90 MG that is in each ML)
Part D= $1000 per ML

Step 2: Convert Part B Billing Units to a Common Billing Type (e.g. per ML)

In this example, the total Part D Billing Units equals 200 ML units, and the total Part B Billing Units equaled 31.5K MG units. Since each Part D Billing Unit of 1ML is equal to 90 MG Billing Units, to convert the Part B Billing Units to a common ML Billing Type, divide the total Part B Billing Units of 31.5K MG by 90 MG.

Original Billing Units Before Conversion:
Part B = 31,500 MG Billing Units
Part D = 200 ML Billing Units

After the Conversion to a Common Billing Unit (e.g. ML):
Part B= 350 ML Units (equivalent to 31,500 MG / 90 MG)
Part D=200 ML Units
Total 550ML Combined Part B and Part D Equivalent Billing Units

Step 3: Calculate % Weight of Total Billing Units @ Common LUM by Program

Part B = 64% (350/550ML) Part B common units per ML divided by the total
Part D = 36% (200/550ML) Part D common units per ML divided by the total

Step 4: Calculate a Single "MFP" @ the Common LUM Billing Unit Type (e.g. ML)

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The sum product of Step 1 and Step 3: Part B Billing Price converted at $720 p/ML X the 64% weight + Part D Billing Price $1000 p/ML X 36% weight = $820 Single "MFP" ceiling per/ML LUM.

								Step 1		Step 2	Step 3	Step 4
Medicare Program	NDC 9	Product Description	Billing Type	Billing Unit Type	Billing Units LUM	Pricing Type	**NDC 9** Price Type p/LUM*	**NDC 9** Converted Common price p/LUM	**NDC9** Total Billing Units @ LUM	**NDC9** Total Billing Units @ common LUM	**NDC 9** Common LUM % Weight	**Single "MFP" Ceiling / ML**
Part D	12345-0234	1 ML X 90MG Vial	NCPDP	ML	1	EWA**	$1,000/ML	$1,000/ML	200 ML	200 ML	**36%**	**$821/ML**
Part B	12345-0234	1 ML X 90 MG Vial	HCPCS	MG	90	ASP**	$8/MG	$720/ML	31,500 MG	350 ML	**64%**	

*For NDC-9 with multiple NDC-11s, CMS can calculate a weighted average within the NDC-9 to arrive at a single price per LUM

** EWA = Enrollment Weighted Average; ASP = Manufacturer Calculated Average Sales Price

Example: Application of the "MFP" Across Dosage Forms and Strengths based on Lowest Unit of Measure by program (Part B or D)

If the "MFP" Ceiling of $820 per ML is negotiated to $500 per ML, CMS will need to convert the negotiated price back to the respective programs' billing price type, such as price per MG for Part B or price per ML for Part D.

Step 1: Convert Negotiated Single "MFP" Price per ML to Part B Price per MG LUM

In this example, the $500 per ML is divided by 90 MG units to arrive at $5.56 per MG Part B Billing Price (Note: 90MG = 1ML for this product)

							Step 1
Medicare Program	NDC 9	Product Description	Billing Type	Billing Unit Type	Billing Units LUM	**Negotiated Single "MFP"**	**NDC-9** Conversion to program Price Type p/LUM
Part D	12345-0234	1 ML X 90MG Vial	NCPDP	ML	1	**$ 500/ML**	$500/ ML
Part B	12345-0234	1 ML X 90 MG Vial	HCPCS	MG	90		$5.56 / MG

Further Clarify the Information and Process Needed on Renegotiation Criteria and Timelines

Within Section 130.1 through 130.4 of the Draft Guidance, CMS outlines the methodology it intends to utilize to identify and select "renegotiation-eligible drugs", the data that will be considered, and the process for "renegotiation". As outlined in the Draft Guidance, CMS intends on identifying drugs that have met certain criteria, such as a new FDA-approved indication, experiencing a change in monopoly status, or undergoing a "material change" to

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one of the 1194(e) factors.[8] The Agency also notes a drug would be selected if renegotiation is likely to result in a 15 percent or greater change in the "MFP" and the change in "MFP" would have a significant impact on the Medicare program.

- *Further define material change in factors of the selected drug*

We encourage CMS to further clarify the process by which material changes to the factors under consideration will be assessed, particularly those that are beyond the changes to indication or monopoly status. We recommend that CMS increase the threshold for expected change in the "MFP" to at least 35 percent, aligning with similar percentage change in the non-FAMP applicable percentages between short-monopoly (75 percent) and long-monopoly (40 percent) drugs. This adjustment would support CMS' objective of achieving consistency in defining a "significant change" in the "MFP" when a drug undergoes renegotiation due to new indications or material changes in section 1194(e) factors.

- *Simplify process for data submission and allow manufacturers to update prior ICR*

CMS also provides information on the process by which "renegotiation-eligible drugs" would be considered and the submission of both voluntary and mandatory data submissions. J&J encourages that CMS further clarify and simplify the process for data submission, timelines, and deadlines for manufacturers to ensure compliance. As currently defined, the process outlined carries the risk of further exacerbating the complexities and burdensome nature of data submission required during an initial "negotiation". Section 130.3.2 of the Draft Guidance on Data Collection from Primary Manufacturers and Other Interested Parties for Renegotiation states "once a renegotiation-eligible drug is selected for renegotiation, CMS will collect new information for all section 1194(e)(1) data elements from all Primary Manufacturers with a drug selected for renegotiation". We are concerned that this would be overly burdensome. Instead, we encourage CMS to allow manufacturers to submit updates to original data elements and attest that the ICR responses have not significantly changed since submission of the original data elements.

- *Clarify deadlines for data submission for selected drugs*

Lastly, we are concerned that the timelines for data submissions remain vague in the Draft Guidance and encourage the Agency to clarify the timelines by which selection will begin and the deadlines to submit data. At present, the guidance simply state that the process would begin approximately 15 months after the end of the "negotiation" period for the drug's IPAY. The guidance lacks information on how long manufacturers will have to review

[8] Section 130.1.4. Page 193 of the Draft Guidance.

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CMS' assessment for renegotiation, submit updated data, or the timelines by which CMS will update the given drugs "MFP". As such, we strongly urge CMS to clarify these timelines in the final guidance.

Requirements to Operationalize "MFP" Effectuation in IPAY 2026 and 2027

Ensure Long Term MTF Support for Operational Feasibility, as No Private Solution Exists

J&J supports an MTF as an end-to-end solution for "MFP" Effectuation. A comprehensive MTF enables CMS to holistically manage the program and provide full visibility, critical for program integrity, and supports program scalability as envisioned by the IRA. A centralized MTF as the end-to-end data and payments facilitator supports a standardized "MFP" effectuation process, limiting pharmacy process variability, providing a central hub to manage manufacturer / pharmacy transactions. An end-to-end "MFP" increases CMS' ability to manage and promote accountability for the program and deduplicating 340B claims, in alignment with statutory requirements. While we recognize the need for flexibility and adaptability as the program evolves, we advise against a decentralized approach that may introduce excessive variability in "MFP" effectuation process, create significant and unsustainable costs for manufacturers, and diminish CMS' ability to maintain oversight. We emphasize that we are aware of *no current private market solutions today* that offer the comprehensive end-to-end functionality envisaged for the MTF.

- *Revise MTF Agreements to reflect CMS' liability for the MTF, remove 180-day termination clause, and offer safe harbors to manufacturers acting in good faith*

We are concerned about CMS' recently finalized MTF Agreements which grant the Agency the right to terminate MTF functionality with only 180 days' notice to manufacturers. Manufacturers are developing systems that are reliant upon the MTF and require long-term support for its functionality. Any significant changes or removal of MTF capabilities would make implementation of "MFP" effectuation impossible. Alternative solutions do not currently exist, and manufacturers would not be able to implement alternative solutions in that timeframe. Such a change would very likely affect patients' access to selected drugs.

Moreover, we stress that we remain concerned that the MTF Agreements require manufacturers to accept the MTF "as is" while broad liability disclaimers shift risk of implementation of the MTF to manufacturers resulting in manufacturers being responsible for MTF operational failures and security and confidentiality risks outside of manufacturers' control. We urge CMS to work with manufacturers to substantially revise these agreements and offer safe harbors for manufacturers acting in good faith.

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We underscore that to enable an operational "MFP" effectuation model, CMS must finalize the MTF build and implementation for IPAY 2026 and beyond. We encourage CMS to refrain from making changes that could compromise program integrity, impede manufacturers' ability to meet statutory obligations, and increase burdens on pharmacies and providers.

Provide Manufacturers with Immediate Clarification on MTF Technical Requirements and Functionality, and a Clear and Accelerated Testing Schedule

Manufacturers' ability to build and implement systems to support "MFP" effectuation and integration with the MTF relies upon having a clear understanding of CMS / MTF technical requirements. In past comments, J&J has recommended that CMS expedite the MTF build and enhance collaboration with manufacturers by implementing a co-development process and sharing comprehensive end-to-end technical requirements with impacted manufacturers by March 1, 2025, to enable manufacturers to meet critical design and build timelines. J&J has continued to advocate for greater transparency regarding the technical requirements and specified our limited capacity to implement any new technical requirements communicated to manufacturers after April 15, 2025, by the go-live deadline of January 1, 2026.

While we appreciate the monthly manufacturer calls and user centered design calls with the MTF DM, we are concerned that manufacturers continue to lack visibility to end-to-end technical requirements for both the MTF DM and PM, and have had no opportunity for engagement with the MTF PM. We are further concerned that the testing schedule is unclear and has been delayed without explanation. We continue to ask for the establishment of a recurring bi-weekly meeting cadence to enable effective solution development and implementation. Direct engagement from CMS and both the MTF DM and PM is crucial to clarify the business requirements and ensure the mutual ability to implement and integrate systems by January 1 for IPAY 2026.

- *Provide clarity and protection from CMPs for scenarios in which manufacturers and Part D plan sponsors require time beyond January 1 to develop and establish a Direct Member Reimbursement (DMR) process*

Additionally, we are concerned that Section 80.1 of the Draft Guidance states that for IPAY 2026 – 2028, access to the "MFP" for an "MFP"-eligible individual that submits a covered DMR request for a selected drug will be facilitated through a reimbursement process established by Primary Manufacturers and Part D plan sponsors. The Draft Guidance does not provide details on this process, including CMS or the MTFs' role in facilitating this process, and the applicability of payment timelines and other requirements outlined in CMS Guidance. J&J is concerned that this process has not yet been established, and development and implementation by January 1, 2026 may not be feasible. Therefore, we

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ask CMS to provide further clarity and protection from CMPs for scenarios in which manufacturers and Part D plan sponsors require time beyond January 1 to develop and establish such a process.

Provide Clarity on Credit / Debit Ledger and Dispute Process, and Ensure Claims Data Transparency for Reversals

J&J requests that CMS provide immediate clarity to manufacturers around the credit / debit ledger. The ledger has significant impact on manufacturer payments and financial flows, and we ask CMS to provide manufacturers with visibility to the credit/debit ledger maintenance protocols, such as reversing and offsetting claims, accounting for negative balances, and credit and debit details.

We note that Section 40.4.3.2 of the Draft Guidance introduces new uncertainty related to the credit/debit ledger by providing contradictory processes for sharing claim reversals with manufacturers. The second paragraph of this section states that "the MTF DM will transmit updated claim-level data elements to the Primary Manufacturer, including the "MTF XRef ICN" (see Table 2) that links an adjustment to the previous MTF ICN." J&J agrees with this approach; however, the fourth paragraph of this section outlines a different process, stating that for claims designated as a full reversal after the "MFP" refund has been transmitted, "the MTF DM will instruct the MTF PM to issue a credit equal to the previously paid "MFP" refund payment. Primary Manufacturers will not need to submit claim-level payment elements back to the MTF DM for full reversals." J&J urges CMS to clarify that the MTF will share with manufacturers any reversal, including full reversals, as an updated claim. It is critical that these claim reversals are always shared with manufacturers once an original claim is shared, regardless of payment status, so that manufacturers can update the accounting and ensure accurate refund funds are available.

In addition, J&J urges CMS to clarify the dispute management process, including compliant management methodology (initiation, escalation, and resolution), the timeframe manufacturers expect to respond and resolve disputes, and how CMS will account for manufacturers' ability to verify discrepancies such as 340B duplicates. We ask CMS to confirm that pharmacy complaint submissions without evidence will not be accepted, that manufacturers have an unspecified amount of time to resolve, submit evidence, and adjust payments where required, and that manufacturers may conduct dispute audits as deemed necessary (including beyond 120 days) when any underlying issue or 340B duplicate is identified. Additionally, we ask for clarification on how manufacturer disputes with MTF related to data accuracy, completeness and transmission impact the 14 day payment period. Specifically, to enable program integrity and help ensure accurate "MFP" payments,

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we ask CMS to clarify that it will "pause" the 14-day payment period without risk of CMPs while the MTF reviews and addresses these data disputes.

Moreover, we underscore the importance of ensuring accuracy for the date stamp included on the manufacturer refund advice (MRA). It is essential for CMS to implement a process that ensures this date is stamped accurately and promptly, as delays can lead to unnecessary complaints and disputes related to the prompt payment window and threatens program integrity.

Implement Solutions to Provide Accessibility and Usability of 340B Claims Data to Manufacturers Seeking to Comply with Statutory Obligations to Effectuate the "MFP"

We urge CMS to implement policies to facilitate accessibility and usability of 340B claims data to manufacturers seeking to comply with statutory obligations to effectuate the "MFP" in IPAY 2026 and future years. In the Draft Guidance, CMS states it is "… considering ways to incorporate asynchronous 340B data into MTF processes in the future." We strongly urge CMS to take immediate action to ensure 340B integrity, especially given the 340B Program's intersection with the IRA and "MFP" Effectuation.

Specifically, J&J recommend CMS require mandatory use of 340B modifiers on all pharmacy and provider claims across all channels, paired with a 340B claims data repository to help ensure all 340B claims are accurately captured and identified for accurate "MFP" effectuation. Use of back-end 340B rebates aligns with this approach and also enables achievement of these goals. This comprehensive 340B solution enables the level of transparency essential to address existing challenges, reduce duplicate claims, and ensure compliance under the IRA.

- *Require 340B modifiers on all pharmacy and provider claims*

In our experience, a very limited number of covered entities (CEs) voluntarily provide the 340B identifier on claims. Mandatory use of 340B claim indicators or modifiers is critical in enabling manufacturers and CMS to accurately identify 340B claims to avoid duplicate discounts, as required by statute. CMS should make clear that CE's obligation to maintain adequate records includes the timely use of modifiers on all pharmacy claims to identify the claim as 340B or non-340B, and that these modifiers must be applied consistently across all channels to help identify and verify 340B prescriptions.

- *Enforce CE compliance with mandatory modifiers*

To enforce CEs' compliance, we recommend that CMS (1) reject Part D claims submitted without required modifiers and (2) conduct periodic audits on their appropriate use. CMS should require CEs to include the appropriate 340B / non-340B modifier on the Part D

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Prescription Drug Event (PDE) record within 72 hours of the prescription being filled at the pharmacy, and prior to the exchange of the PDE data with the MTF DM for "MFP" effectuation. This timeline is feasible, as CMS has acknowledged that TPAs can identify most 340B claims within the 72-hour period following dispense. Because the success of this solution requires CE compliance and accountability for data accuracy, to enforce CEs' compliance with required modifiers, CMS would reject Part D claims submitted without required modifiers, and CMS would conduct periodic audits on their appropriate use.

- *Pair mandatory modifiers with a 340B claims data repository*

Mandatory modifiers, paired with a 340B claims data repository, will help to ensure all 340B claims are accurately captured and identified. Similar to the claims data repository CMS is exploring implementing under the Inflation Rebate Program, the claims data repository would provide a centralized database that contains critical claims level data on 340B units under Part D and B to ensure accurate identification of 340B claims and verification of claims.[9] In establishing the repository, CMS should make clear that CEs must participate as part of their audit obligations. Paired with the use of 340B modifiers on all pharmacy and provider claims that are applied consistently across all channels to help verify 340B claims, the repository will enhance data transparency, program integrity, and compliance with the statutory prohibition on duplicate discounts. As noted, it also enables CMS' compliance with the statutory requirement to remove 340B units from IRA Inflation Rebate Calculations for Part D.

- *Consider manufacturer rebate models as a complementary solution for 340B validation*

We also encourage CMS to consider manufacturers' 340B rebate models as a complementary solution to provide real-time data validation to prevent duplicate discounts that are contrary to law. Such models could solve the issue of de-duplication between the IRA "MFP" and the 340B price for "negotiation" eligible drugs in a manner that does not impact the finances of 340B hospitals or impose undue administrative burdens. Such models allow private-sector innovation to solve, at no cost to the government, some of the 340B / "MFP" duplication challenges.

Establish a CMS Pre-funded "MFP" Discount Pool to Address Pharmacy Cashflow Concerns

CMS has outlined a requirement for Primary Manufacturers to describe their process for mitigating material cashflow concerns for dispensing entities in manufacturer "MFP" Effectuation Plans. J&J acknowledges the financial challenges faced by pharmacies;

[9] 89 FR 97710

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however, it is important to emphasize that manufacturers have limited capacity and no statutory obligation to address these cash flow concerns. Financial reporting obligations under the Sarbanes-Oxley Act require manufacturers to ensure that payments provided to customers or third parties are substantiated and directly linked to specific purchases.[10] Compliance with these legal requirements limits a manufacturer's ability to resolve pharmacy cash flow issues.

J&J continues to urge CMS to leverage its statutory authority to establish a CMS pre-funded "MFP" discount pool to effectively mitigate any pharmacy cashflow concerns and reduce financial and operational burden for pharmacies and all stakeholders. The cashflow magnitude, compliance with fiduciary requirements under Sarbanes Oxley and antikickback statute preclude manufacturers from supporting an "MFP" pre-fund pool. CMS is best positioned to pre-fund an "MFP" discount pool to mitigate untenable financial risk to pharmacies and other stakeholders.

Ensure Manufacturers Acting in Good Faith Receive Protection from Civil Monetary Penalties for Circumstances Outside of their Control, Including Delayed Release of Technical Requirements or MTF Operational Failures

J&J appreciates the ongoing engagement with CMS, including the monthly manufacturer calls and the assignment of dedicated personnel to facilitate quicker responses to manufacturer inquiries. However, given that CMS is leveraging an agile process, the lack of visibility to end-to-end technical specifications, including critical components such as transaction codes and detailed information on the credit ledger process has resulted in a significant ambiguity on the elements needed to accurately develop systems to comply with the program's requirements. J&J has communicated the clarity needed to CMS and has not received the clarity needed, which has forced us to make our own assumptions in finalizing the development of our system build strategy. J&J is documenting these assumptions and will communicate them to CMS including in the submission of our "MFP" effectuation plan on September 1, 2025.

J&J strongly urges CMS to provide adequate protection – such as a hold harmless or safe harbor provision – from civil monetary penalties (CMPs) for manufacturers acting in good faith and who have been engaged in deep partnership with the Agency to develop a workable system, particularly in circumstances beyond their legal and operational control. Such circumstances include delays in CMS' release of technical MTF specifications that

[10] Sarbanes-Oxley Act of 2002; Public Law 107-204

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extend beyond the communicated, requisite manufacturer build timelines, as well as issues related to MTF operations, or if CMS elects to terminate the MTF DM and / or PM.

Manufacturer participation in the CMS MTF-PM clearly indicates a manufacturer's good faith efforts to comply with its statutory obligations to provide access to the "MFP" without duplication with 340B discounts. We ask CMS to leverage its broad statutory authority and significant discretion in implementing the IRA to determine that such good faith efforts are deemed "access" under the law and that manufacturers working in good faith to participate in the MTF-PM, therefore, be deemed as having provided access to the "MFP" and granted a safe harbor from CMPs. This safe harbor would protect manufacturers from CMPs in cases where CMS does not communicate critical requirements for the MTF system, or the MTF has technical issues outside of the manufacturer's control, which may delay payment. J&J urges CMS to establish this safe harbor, especially in the program's first years, to recognize manufacturers' good faith efforts to participate in the MTF-PM option to comply with their statutory obligations.

The Draft Guidance states that CMS will send the Primary Manufacturer a Notification of Potential Noncompliance upon discovery and confirmation of a failure to make the "MFP" available. CMS outlines a process in which Primary Manufacturers will have 10 business days to respond to the Notification to provide additional context, evidence refuting the violation, proof of mitigation of noncompliance, and/or other factors for CMS' consideration. J&J is concerned that 10 business days does not provide enough time for manufacturers to investigate, gather required information and provide it to the MTF, particularly in light of the broad scale of the program, and high volume of claims, including for Secondary Manufacturers. We urge CMS to extend the 10 days to 60 days to allow manufacturers sufficient time to adequately respond to such Notifications.

Finalize Proposal Related to Claims with Drug Data Processing System (DDPS) Edits

In the Draft Guidance, CMS provides a list of DDPS edits that directly relate to the determination and verification of "MFP" eligibility. CMS states the MTF will not transmit "MFP" claims to manufacturers when those claims have open DDPS edits included on this list. J&J underscores that manufacturers must receive clean claims from the MTF DM in order to initiate the 14-day payment period. Therefore, we are aligned to and support the process outlined in Draft Guidance to ensure that claims with open DDPS edits impacting the determination and verification of "MFP" eligibility should not be transmitted to manufacturers until such edits are cleared and resolved.

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Continue Formulary Inclusion Exceptions for All Future IPAY Periods

For IPAY 2026-2028, CMS has maintained its exception for formulary inclusion for Part D selected drugs. In Section 110.1, the Agency specifically notes that this policy has been in place due to concern on a selected drugs formulary placement and potential risk for patient access. We share in this concern and therefore urge CMS to ensure selected drugs maintain their formulary placement in all future years and should extend beyond 2028 as a critical means to ensure consistency in the program and stability in patient access. Further, maintaining a consistent approach for all future years reduces regulatory burden, simplifies the Program's administration on an annual basis, and provides the necessary predictability for patients, providers, and manufacturers.

J&J Recommendations for "MFP" Effectuation under Part B

J&J appreciates the opportunity to provide input on CMS' development of an "MFP" effectuation model for Part B drugs for IPAY 2028. A workable "MFP" effectuation approach under Part B requires CMS to adopt and facilitate a data-driven retrospective discount model facilitated by an MTF. Similar to Part D, J&J supports a centralized MTF approach for data exchange and payment facilitation for "MFP" effectuation under Part B to enable operational feasibility and minimize the risk of unwieldy variability while better enabling CMS to maintain appropriate levels of oversight for the Program. A standardized approach enhances operational efficiency, improves transparency and promotes program integrity by ensuring CMS is able to manage the program end-to-end.

Aligned to our mutual goal of program integrity, we support claims level transparency, and a retrospective refund and claims data transparency to enable claims validation prior to payment. A retrospective model reduces program integrity risk and increases program compliance. Additionally, we urge CMS to ensure that "MFP" effectuation does not impose substantial financial risks on Part B providers that could hinder beneficiaries' access to Part B drugs subject to "negotiation".

Consider Key Differences for "MFP" Effectuation for Part B from the Process Established for Part D

While we recognize that certain aspects of the Part D "MFP" Effectuation model may be applicable to Part B, there are distinct challenges for "MFP" effectuation under Part B. It is important to note the significant differences between these two programs, which introduce unique operational challenges that must be accounted for as CMS considers "MFP" effectuation policies for IPAY 2028. J&J seeks to partner with CMS and serve as a resource as the Agency considers and develops these policies.

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In the Draft Guidance, CMS is seeking feedback on how "MFP" refund payments for drugs payable under Part B may differ from the process established for Part D. Some key differences are summarized below:

- **Diversity of Providers:** There is significantly larger number of providers under Part B compared to the number of dispensing entities in Part D. These Part B providers include hospital outpatient departments, physician offices, infusion clinics, etc., each with their own distinct operational considerations. The staggering provider volume and variety of provider setups will undoubtedly add layers of administrative and operational complexity related to claims, transactions, and disputes, which must be accounted in "MFP" effectuation policies for IPAY 2028 for to enable operational feasibility.
- **Extended Payment Period for Claims:** To align with the existing Medicare Part B claims processing timelines, the manufacturer payment period for eligible "MFP" claims in Part B should be a minimum of 30 days rather than the 14 days currently required by CMS for "MFP" effectuation under Part D. Part B claims involve additional complexities not present in Part D that require additional processing time, such as deriving the NDC-11 from the Healthcare Common Procedure Coding System (HCPCS) Code, and processing necessary billing unit of measure conversions. For instance, while Part B claims are typically submitted in units of measure (such as MG) described by the HCPCS code, they can also be submitted in the NCPDP standard, such as ML, necessitating conversions. Furthermore, Part B claims must be checked for duplication resulting from claims in which a specialty pharmacy sends a patient's medication directly to a healthcare facility for administration (aka "white bag" claims), as they often overlap with the service codes submitted alongside the drug HCPCS Code (J-Code). Given these concerns, we recommend extending the reimbursement timeline to 30 days to align with industry standards.
- **Claims Processing Variability:** Unlike Part D, where all claims are processed through the Drug Data Processing System (DDPS) that shares data with the MTF DM for "MFP" effectuation, Part B claims are processed by multiple Medicare Administrative Contractors (MACs). This increases the number of sources exchanging data with the MTF, necessitating increased coordination and data validation to ensure manufacturers consistently receive standardized, accurate and complete data.
- **Role of Group Purchasing Organizations (GPOs):** GPOs typically negotiate discounts and purchase drugs under Part B, and this dynamic will impact provider acquisition costs for Part B drugs.
- **Avoiding Duplicate Discounts with Discarded Drug Refund Program:** It is imperative for CMS to account for the discounts that have already been provided under the

Discarded Drug Program in Part B. This will ensure that manufacturers are not subjected to duplicate discounts on the portions that have either already been refunded or will be refunded through the program.

- **Enhancing Data Transparency:** CMS must establish policies to address the current lack of data transparency related to Medicare Advantage claims for "MFP" effectuation under Part B.
- **Identifying NDC-11s for Accurate Claims Processing:** For some Part B drugs, a single HCPCS code may correspond to multiple qualifying single-source drugs. To address this and ensure accurate identification of "MFP"-eligible claims and calculation of "MFP" discount amounts, CMS must establish a requirement for Part B providers to identify NDC-11s on Part B drug claims.
- **Comprehensive 340B Solution:** Similar to Part D, there is a need for a comprehensive 340B data transparency solution to help identify 340B claims and avoid duplicate discounts in accordance with the statute.

Provide Visibility to Manufacturer Required Claims Data for Part B "MFP" Effectuation

Aligned to a data-driven approach, manufacturers require critical claims data that enable verification of "MFP" eligible claims and refund amounts without duplication with 340B. Manufacturers must be provided with access to standardized, accurate and complete claims level data at time of invoice, scrubbed by the MTF for accuracy and completeness, to enable validation required for compliance with our fiduciary responsibilities arising under Sarbanes Oxley.

J&J supports the claims level data that CMS intends to provide to manufacturers for "MFP" effectuation under Part D outlined in Table 2 in the Draft Guidance. Manufacturers continue to require those fields for Part B "MFP" effectuation. In addition to the critical data elements outlined in Table 2, there are additional data required by manufacturers for "MFP" effectuation under Part B. These *additional or new* data elements for Part B are outlined in the table below:

Table: Additional Manufacturer Required Data for Part B Effectuation

Field Name	Field Description / Notes
Plan Name	Name of the health plan that provides insurance coverage for the patient (ex: field 11C on HCFA 1500 form). This is particularly important for Medicare Advantage Plans.

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Plan ID Code	Identifier of the health plan that provides insurance coverage for the patient (with explicit crosswalk to Name). This is particularly important for Medicare Advantage Plans.
HCPCS Code (aka: "J-Code" / Q-Code)	The HCPCS code utilized by the billing provider to indicate the drug that was administered (ex: field 24D on HCFA 1500 form)
NDC-11	The 11-digit National Drug Code that indicates the drug that was administered
Service Provider NPI	National Provider Identifier (NPI) for physician that administered the drug to the patient (ex: field 24J on the HCFA 1500 form)
NPI of Billing Provider	National Provider Identifier (NPI) for entity that billed the drug being administered to the patient (ex: field 33A on HCFA 1500 form)
Billed HCPCS Quantity	The number of HCPCS units that were billed by the service provider (ex: field 24G on the HCFA 1500 form). This field helps with validation to identify duplicate claims, and aberrant quantities.
NDC Unit Quantity	The quantity of administered drug (in NDC units). This field is needed to support manufacturer conversions from HCPCS quantities into NDC quantities.
Service Location State	State abbreviation indicating the state in which the drug was administered
Place of Service Code	Place of Service Code as described in Schedule / Exhibit (ex: field 24B on HCFA 1500 form; e.g,: 11 = Office)
Primary Diagnosis Code	Indicates patient's primary diagnosis code (standard ICD-10 Code format) (ex: field 24E on HCFA 1500 form)
Allowable Cost of Drug	The allowable charges for covered drug based on the negotiated fee the provider agrees to accept from the payer to provide this drug. This data element will assist manufacturers in preventing duplicate discounts between buy-and-bill and specialty dispense.
Encrypted Patient ID Code	A patient-level identifier that remains fixed when multiple claims are billed across different dates of service and across different invoices for the same patient. This field helps to identify duplicate claims and abnormal claim activity.

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Claim Number (assigned by billing provider)	The claim number / identifier assigned by the billing provider
Claim Number (assigned by plan)	The claim number / identifier assigned by the plan
HCPCS Modifiers 1, 2, 3, 4	Modifier Codes 1, 2, 3, and 4 designated by billing provider (ex: field 24D on HCFA 1500 form, regardless of presence) (includes JW, JZ, JG, TB, UD, JA, JB)

Additional rationale is provided below to support manufacturer requirements for the additional critical claim level data for Part B outlined in the table above:

- **NPI of Billing Provider Required to Enable Payment Efficiencies Under Part B:** Given the large number of Part B providers, wide variety and frequent changes in provider set ups and provider / facility relationships, it is important that CMS facilitate payment of "MFP" refunds at the facility level and for credit / debit ledger management. To enable this, manufacturers must have access to the NPI of the billing provider.
- **HCPCS Codes, NDC-11s and Modifiers Are Required to Effectuate Part B "MFP" Claims:** As Part B drugs are billed using HCPCS codes, it is critical for Part B "MFP" Effectuation that manufacturers receive the HCPCS code used by the provider to bill for the drug on each "MFP" eligible claim. We note that the HCPCS codes might not accurately reflect specific drugs administered, especially when multiple drugs share a HCPCS code. To determine the accurate "MFP" refund amount, manufacturers must identify the drug's NDC, which is not required on Part B claims. *Therefore, we urge CMS to require the submission of NDC-11 codes for reimbursement under Part B FFS and on MA claims*. To enforce NDC-11 reporting, claims submitted without this information should be rejected. Manufacturers must also receive all J-Code modifiers used on "MFP" eligible claims, including modifiers used to identify units under the discarded drug refund program, route of administration, and 340B units.
- **Data Required to Support 340B Deduplication:** Under section 1193(d)(2) of the Act, manufacturers are required to provide access to the "MFP" on eligible claims in a nonduplicated amount to the 340B ceiling price. As noted in the Draft Guidance, as CMS is currently declining to assume responsibility for deduplicating claims, manufacturers must adopt processes to identify and deduplicate 340B claims. In order to do this, it is critical that manufacturers receive the critical data elements outlined in

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the table above, including 340B modifiers (JG, TB, UD), as well as Prescriber NPI, Service Provider NPI, and NPI of Billing Provider with Date of Service, and Claim Number (assigned by billing provider).

We are concerned that 340B modifiers may be unreliable if they are not accurately used. Additionally, we note that the 340B modifiers are not required under Medicare Advantage. Therefore, manufacturers require additional data to validate and more accurately identify and deduplicate 340B claims. We strongly urge CMS to require MA plans to mandate 340B covered entities' use of mandatory 340B modifiers on claims to improve transparency and better identify 340B-eligible claims. In addition, we are aligned to PhRMA's comments urging CMS to adopt and require an additional modifier for "non-340B" claims, similar to the JZ modifier implemented under the Discarded Drug Refund Program. A non-340B modifier would improve transparency and support clearer and more accurate identification of 340B claims.

J&J notes that a comprehensive solution to 340B transparency is required to support transparency and program integrity for both Part D and B. As outlined in our comments above, we support the mandatory use of 340B modifiers on all claims across all channels, paired with a 340B Claims Data Repository to help ensure all 340B claims are accurately captured and identified for accurate "MFP" effectuation. Use of back-end 340B rebates aligns with this approach and also enables achievement of these goals.

Adopt a Standard Default Refund Amount (SDRA) Under Part B Based on Average Sales Price

J&J supports the establishment of an SDRA for selected drugs under Part B to provide predictable provider reimbursement and reduce disruptions in patient access to selected drugs that may arise from uncertainty and financial risks faced by providers. J&J encourages CMS to adopt Average Sales Price (ASP) as the basis for the calculation of the SDRA for "MFP" eligible claims under Part B. The calculation should account for the provider add-on payment (for example, ASP + 6% - "MFP" + 6%). J&J does not support a WAC based calculation, as acquisition cost is often lower than WAC because of discounted pricing available to providers through GPO contracting. An ASP-based calculation minimizes risk of provider disruption, as providers are familiar with ASP as the basis for reimbursement under Medicare Part B, but also Medicare Advantage and some commercial plans. However, as described in more detail below, it is critical that in implementing this SDRA calculation, CMS ensure "MFP" is excluded from manufacturer calculation of ASP to prevent significant financial loss for providers administering selected drugs and access issues for patients.

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Exclude "MFP" from the Calculation of ASP to Minimize Access Risks for Patients under "MFP" Effectuation and for Accurate Calculation on Inflation Rebates

The IRA stipulates provider reimbursement for selected drugs under Part B be based on "MFP", rather than ASP. This statutory change is expected to significantly reduce provider reimbursement for selected drugs, with a significant impact to oncology providers.[11] J&J is concerned about the potential ramifications for provider practices and the consequent loss in patient access to selected drugs that may result from this reduced reimbursement. To avoid further financial strain on providers and help to safeguard patient access to selected drugs, *it is critical that CMS clarify that the "MFP" should be excluded from the calculation of ASP.*

Inclusion of "MFP" in the calculation of ASP would rapidly erode ASP, leading to even greater impact to provider reimbursement, as ASP is the basis of reimbursement for drugs under Medicare Part B, but also Medicare Advantage and some commercial plans. Importantly, the law does not require CMS to include "MFP" in the calculation of ASP, and therefore CMS has the authority under the law to make this clarification to avert significant financial consequences for providers and potential access challenges for Americans.

Furthermore, the law specifically excludes "MFP" from the calculation of Average Manufacturer Price (AMP). Under the Inflation Rebate Program, AMP is used to calculate inflation rebates that manufacturers owe for Part D drugs with price increases greater than the rate of inflation, while ASP is applied for Part B drugs. To achieve program integrity and consistency in how rebates are determined across the Inflation Rebate Programs, CMS should adopt a uniform approach regarding the treatment of "MFP" in these two price points and maintain similar "MFP" exclusion for the determination of inflation rebates.

We further note that including "MFP" in ASP can artificially trigger inflation rebates when there are no pricing changes for a drug. For instance, if a drug ceases to be a selected drug, its ASP may rise once the "MFP" is no longer in effect and phases out of the ASP calculation. As a result, manufacturers would be liable for an inflation penalty despite taking no pricing actions. Therefore, to ensure the accuracy of inflation rebate penalties, it is critical that CMS confirm that "MFP" is excluded from the calculation of ASP.

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[11] https://advisory.avalerehealth.com/insights/commercial-spillover-impact-of-part-b-negotiations-on-physicians

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J&J appreciates the opportunity to submit comments in response to the Draft Guidance. Given the short timeline, we strongly recommend CMS work with manufacturers of selected products and other stakeholders to urgently address operational concerns and ensure readiness for IPAY 2026. Aligned with the Agency's stated objectives, we also encourage CMS to carefully consider areas in which the Medicare Drug Price "Negotiation" Program could benefit from improved and streamlined approaches and definitions, in service of ensuring the highest value and health for Medicare beneficiaries. For questions, please contact jroche8@its.jnj.com.

Sincerely,

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General Comment

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MASSBIO

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August 29, 2025

Submitted electronically

William N. Parham, III
Director
Centers for Medicare & Medicaid Services, Office of Strategic Operations and Regulatory Affairs
Division of Regulations Development
Attention: CMS-10912/OMB Control Number 0938-NEW
Room C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

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 Mr. Parham:

The Massachusetts Biotechnology Council ("MassBio") appreciates this opportunity to submit Comments to the Centers for Medicare & Medicaid Services (CMS) on the above-referenced Negotiation Data Elements (NDE) Information Collection Request (ICR) for Initial Price Applicability Year (IPAY) 2028 under the Medicare Drug Price Negotiation Program (MDPNP) created by the Inflation Reduction Act (IRA). In particular, MassBio has significant concerns with a change to the ICR that may significantly distort reporting on research and development (R&D) costs of a selected drug, by failing to include costs involved in acquiring a product from another manufacturer in considering research and development costs. Such acquisitions are a common pathway for commercialization of innovative drugs, and accurately accounting for the research and development costs represented in such an acquisition is essential to CMS' ability to consider research and development costs as directed by statute. Below, MassBio makes several recommendations for how to provide an opportunity for manufacturers to report these costs accurately.

MassBio represents the premier global life sciences and healthcare hub of Massachusetts, which has a vibrant biomedical research and development community that is a global leader for medical discovery and innovation. MassBio's 1,700+ member organizations are dedicated to preventing, treating, and curing diseases through transformative science and technology that brings value and hope to patients. MassBio's mission is to advance Massachusetts' leadership in the life sciences to grow the industry, add value to the healthcare system, and improve patient lives.

In general, MassBio appreciates CMS's efforts to simplify reporting and reduce burden in the ICR, including removing unnecessary questions and combining reporting where feasible. The process of assembling data for submission to CMS via the ICR can be extremely burdensome, and simplification and burden reduction are important goals.

However, the most important goal of the negotiation data elements ICR should be gathering accurate data for CMS to consider in applying the negotiation factors it is directed to consider by statute, including

"[r]esearch and development costs of the manufacturer for the drug and the extent to which the manufacturer has recouped research and development costs."[1]

In both the IPAY 2026 and IPAY 2027 NDE ICRs, CMS included a question within the section of the ICR regarding R&D that specifically asked manufacturers to provide "acquisition costs incurred by the Primary Manufacturer for the selected drug," meaning either the costs for acquiring the selected drug from another manufacturer or the share of the cost of acquiring another manufacturer that could be attributed to the selected drug.[2] In the draft 2028 NDE ICR, however, CMS has removed that question, without providing any explanation in the IPAY 2028 draft guidance. In the new ICR, there is no place for a manufacturer that acquired the selected drug from another manufacturer to report those costs—R&D costs as defined in the draft 2028 NDE ICR are limited only to R&D costs of the Primary Manufacturer.

By excluding acquisition costs of a selected drug, for a drug that has been acquired by the Primary Manufacturer from another manufacturer, CMS may be excluding a significant amount, or even almost all, of the R&D costs of a selected drug. It is a common practice in the pharmaceutical industry for smaller pharmaceutical companies to develop a drug in its early stages, bringing the drug through, for instance, Phase 1 or Phase 1 and Phase 2 trials. At that point, the drug may hold significant commercial promise, but the costs of bringing the drug all the way to FDA approval and to patients—e.g., through the costs of the much larger Phase 3 trials, as well as costs of scaling up manufacturing and other expenses involved in commercialization—are much more easily borne by a larger manufacturer that acquires the drug from a smaller manufacturer, or acquires the entire smaller manufacturer itself. This dynamic is important to supporting the market-based pharmaceutical innovation ecosystem in the United States. It is simply not practical in most cases for a small pharmaceutical firm to bring a drug all the way to market, so the prospect of an acquisition of a promising drug or the entire company is essential to the business model of small, innovative pharmaceutical companies. For many MassBio members developing innovative drugs, acquisition of the drug or the whole company by a larger pharmaceutical company is the only pathway available to bring a drug to patients.

Removing the ability of a Primary Manufacturer to present the costs of acquiring a drug that has already gone through substantial R&D investment as R&D investment has several potential harms: First, it provides an incomplete picture of the R&D costs that a Primary Manufacturer has incurred, failing to provide an opportunity for CMS to appropriately consider, as the IRA statutory text directs, to consider the R&D costs for a selected drug. Second, it may even have unintended consequences on the pharmaceutical R&D ecosystem, by disincentivizing large manufacturers from purchasing promising investigational drugs and bringing them to market—with the risk that some of these products may never make it to market at all. Disrupting this common pathway for bringing innovative drugs to market works at cross-purposes with CMS' efforts to implement the IRA in ways that minimize its negative impact on pharmaceutical innovation, a goal directed by the President's April executive order on drug pricing, to "minimize any negative impacts of the maximum fair price on pharmaceutical innovation within the United States."[3]

There are multiple options for address this shortcoming in the current draft ICR. First, CMS could and should simply revert to including the question about acquisition costs that it included in the IPAY 2026 and IPAY 2027 ICRs. This solution would not only allow manufacturers to report R&D costs accurately, but would also minimize burden on manufacturers who have already developed methodologies and systems for reporting on R&D and acquisition costs over the past two negotiation cycles. Minimizing

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[1] Social Security Act Sec. 1194(e)(1)(A) (42 U.S.C. § 1320f-3(e)(1)(A)).

[2] Part A, Question 1 in the IPAY 2026 and 2027 final NDE ICRs.

[3] Section 3(a), Executive Order 14273 (Apr. 15, 2025), available at: https://www.whitehouse.gov/presidential-actions/2025/04/lowering-drug-prices-by-once-again-putting-americans-first/.

burden and providing predictability would help address concerns raised in the President's April executive order that the IRA negotiation process has been "administratively complex and expensive"[4]—reporting on acquisition costs as part of R&D spending is a straightforward and simple way for a manufacturer to present this information to CMS.

If CMS does not wish to revert to the prior question structure, it remains important for manufacturers that acquired a selected drug from another manufacturer to report the cost of that acquisition attributed to the selected drug as part of their R&D investments, and the current draft NDE ICR offers no way to do so. If CMS is concerned that the question in the 2026 and 2027 ICRs may have permitted manufacturers to report acquisition costs that exceeded the costs that can reasonably be attributed to R&D, a better solution would be to include a form of the question regarding acquisition costs within the calculation of R&D costs, but request that manufacturers calculate only the costs of the acquisition that can be attributed to R&D. This would be administratively complex, because manufacturers may not have easy access to the financial information necessary to make such a calculation, but it would provide a way for manufacturers to present their full R&D costs for a selected drug and avoid non-R&D acquisition costs from being counted in R&D.

MassBio supports efforts by CMS to simplify reporting of data through the ICR, but strongly objects to the removal of acquisition costs as an element in considering R&D costs. Without addressing this issue, for drugs that have been acquired by one company for another, CMS will have an incomplete and inaccurate picture of the research and development costs it is directed to consider by statute, and risks inadvertently affecting market-based decisions that companies make to bring innovative drugs to market.

MassBio thanks CMS for your consideration of our comments on this issue. Please don't hesitate to contact me at (617)-674-5148 or kendalle.oconnell@massbio.org..if you have any questions or would like any additional information to consider our comments.

Sincerely,

Kendalle Burlin O'Connell
President & CEO
Massachusetts Biotechnology Council (MassBio)

[4] Section 1, Executive Order 14273.

PUBLIC SUBMISSION

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General Comment

This comment contains two parts. Part 1 delineates my recommendation to require manufacturers to lower the prices at the touch point of the care provider in addition to the beneficiaries to maintain stable financial operations. The second part requests targeted healthcare professional review (from care providers at health systems, rather than managed care organizations, FDA, manufacturers, etc.) of the clinical evidence for therapeutic criteria and alternatives.

I love the concept of lowering drug costs for beneficiaries and for taxpayers. I want to also do so in a way that does not sacrifice the care we provide or the access to care.

Most importantly, I want to do so in a way that does not cause an unsustainable shift that could massively shift the healthcare system, which comprises 17.6% of the US GDP.

Part 1

In the past, many programs that have been designed to save have created a cost differential "revenue leak" within health-systems. While that may sound okay, health-systems are truly not-for-profit entities and cannot sustain withholding payment reductions in an environment with increased costs.

I have seen this effect of tightening at all levels of every healthcare organization I have worked for for several years, and I have worked in enough market segments to know that this is unlike any other business I have ever worked in. For example, when Starbucks closes stores, I see that widely broadcasted, but I do not know many people who know that over 155 hospitals in rural areas have closed or reduced services in the last 20 years (conservative underestimate).

In portions of my home state, you have to drive for hours to get to a hospital (very literally--multiple hours). Any

medical complication that could normally be treated routinely (although not fun for patients to experience) could be a death sentence (literally) if you wait an additional hour. Heart attacks, strokes, large cuts causing massive bleeds, even falls, and that is just to name a few. Those were all daily occurrences at my job in the ER, and I really feel for the people in rural Texas and other rural areas who have been unknowing victims to systems that do not allow hospitals to provide their care in a financially sustainable way.

I highly recommend that a system be developed that protects health-systems providing care to patients by assuring the cost reductions fall on those who set the prices and control the manufacturing process where cost reductions are more readily reduceable.

Part 2

I would highly recommend that the opinion of practicing clinicians in a CMS Care Provider with no conflicts of interest from manufacturers, health plans, pharmacy benefit managers, or others, provide input on clinical information.

While I can appreciate that the public has an option to provide commentary and find that valuable, I (as a healthcare provider/practitioner) often feel that these programs are to the detriment of an already unsustainable care provision ecosystem.

As someone who sees the patients, manages (some) money, and is highly stringent about budget, I also feel I lack the flexibility to advise the care team to proceed with what is best for the patient and our system, and too often, I worry that we have learned to provide care at the direction of payors and manufacturers instead of patients and care providers.

For some of these higher cost drugs, I would highly recommend (and I am sure it is happening) to perform a widesweeping pharmacoeconomic evaluation of the life of that beneficiary in the US healthcare system. Average spend per patient on drug over a 10 year period for example.

In many cases, these drugs help to improve outcomes for the long term in chronic disease management, and primarily CV risk.

What I as a care provider worry about is that heart attacks, diabetes, kidney disease, and many of the things GLP-1RAs lower risk for (even excluding obesity), greatly reduce the risk for heart failure with reduced ejection fraction, which once decompensated is very difficult to reverse without heart transplantation, expensive cardiac devices, or even new technology (e.g. BiVACOR, which was a brilliant innovation I was ecstatic to work around in my last job).

These therapies, yes, are costly, but most importantly, they are investments in our patients when targeted to the right individuals. We have so much data to show their benefit in cardiac risk prevention which I fear, if we reduce coverage too soon, will not allow us to capture the data in Phase IV/post-marketing FDA evaluation that is needed to evaluate if these therapies truly help reduce over all cost over the patient's life.

NATIONAL HEALTH COUNCIL

August 29, 2025

Mehmet Oz, MD, MBA
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
7500 Security Boulevard
Baltimore, MD 21244

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 Administrator Oz:

The National Health Council (NHC) appreciates the opportunity to comment in response to the 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 (the ICR).

Created by and for patient organizations over 100 years ago, the NHC convenes organizations from across the health ecosystem to forge consensus and drive patient-centered health policy. We promote increased access to affordable, high-value, comprehensive, accessible, and sustainable health care. Made up of more than 180 national health-related organizations and businesses, the NHC's core membership includes the nation's leading patient organizations. Other members include health-related associations and nonprofit organizations including the provider, research, and family caregiver communities; and businesses and organizations representing biopharmaceuticals, devices, diagnostics, generics, and payers.

General Comments

The NHC acknowledges CMS' efforts to design a fair and transparent data collection process that facilitates patient-centered drug price negotiations. It is imperative that the forms and accompanying instructions reflect a balance between completeness, consistency, and administrative feasibility. The process must be sufficiently rigorous to ensure meaningful and reliable data collection, while retaining the flexibility necessary to accommodate a broad range of stakeholders, including patients, caregivers, manufacturers, and researchers.

The NHC emphasizes three overarching principles applicable across all sections of the ICR:

1. Transparency is essential to public confidence. Patients and taxpayers must be able to understand how data are used and how decisions are made.[1]
2. Consistency in reporting is critical to supporting valid comparisons across products, mitigating administrative burden, and improving the reliability of negotiated outcomes.[2]
3. Patient-centeredness must remain the central objective. Every data element—whether related to manufacturer costs, clinical alternatives, or revenue—should ultimately serve the goal of ensuring that Medicare beneficiaries are able to access clinically appropriate therapies without undue financial burden.[3]

The NHC acknowledges the statutory timelines and operational complexity inherent in this multi-stakeholder process and encourages CMS to adopt strategies that reduce unnecessary burden, facilitate participation from a broad range of contributors, and provide clarity regarding how each data element will be used in price determinations. A transparent and predictable framework will enhance stakeholder trust and support the program's long-term credibility and success.

Section-By-Section Comments

The following technical and policy-focused recommendations are intended to help CMS refine the ICR in alignment with statutory intent, patient-centered objectives, and the program's broader commitment to affordability, sustainability, and innovation. Each section comment is designed to improve clarity, consistency, and operational feasibility, while ensuring that the data collection framework reflects the perspectives and needs of all stakeholders, including patients, caregivers, providers, manufacturers, payers, and the broader health system.

Section A: Selected Drug Information

The NHC acknowledges CMS' decision to prepopulate Section A with National Drug Codes (NDC-11s) and associated identifiers, recognizing this as an important measure to improve consistency and reduce variation across manufacturer submissions. However, the accuracy of this prepopulation process is of paramount importance, as discrepancies or omissions may result in downstream consequences that adversely affect patient access. Specifically, errors in the NDC list may lead to reimbursement inconsistencies, inappropriate claims denials, or delays in therapy initiation.[4]

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[1] Sarosh Nagar, Leah Z. Rand, and Aaron S. Kesselheim, "What Should US Policymakers Learn From International Drug Pricing Transparency Strategies?" *AMA Journal of Ethics* 24, no. 11 (2022): E1083–1090, https://doi.org/10.1001/amajethics.2022.1083.

[2] Sean R. Tunis et al., "Use of Real-World Evidence in the Medicare Drug Price Negotiation Program: A Checklist for the Centers for Medicare and Medicaid Services and Manufacturers," *Health Affairs Scholar* 3, no. 3 (March 21, 2025): qxaf030, https://doi.org/10.1093/haschl/qxaf030

[3] National Health Council, *Amplifying the Patient Voice: Reflections and Recommendations from the Second Cycle of CMS Patient Engagement* (August 2025), https://nationalhealthcouncil.org/wp-content/uploads/2025/08/Amplifying-the-Patient-Voice-Reflections-and-Recommendations-from-second-cycle.pdf.

To mitigate these risks, CMS should consider establishing a transparent and time-bound error correction protocol that clearly outlines the process by which manufacturers may dispute or supplement CMS-populated data. This process should include defined timelines for review and adjudication and should be publicly documented to ensure predictability. The absence of such a mechanism could shift the burden of administrative inaccuracies onto patients and providers.

Further clarification is warranted regarding the treatment of discontinued NDCs, sample packages, and private-label distributions. Although manufacturers are required to report these data, the implications for Maximum Fair Price (MFP) calculations remain unclear. For example, the inclusion of discontinued NDCs may create uncertainty for providers regarding reimbursement status and coverage eligibility. To address these concerns, CMS should issue explicit interpretive guidance, supplemented by illustrative examples, to promote consistent treatment across Medicare Administrative Contractors.

Finally, the NHC encourages CMS to provide beneficiaries and caregivers with a plain-language explanation of the NDC selection methodology. Transparent communication regarding which product formulations are subject to the MFP—and why certain versions are excluded—will be critical to preventing confusion at the point of care, whether at the pharmacy counter or in a clinical setting. Improved patient-facing transparency will be essential as Medicare beneficiaries navigate the implementation of this new pricing framework.

Section B: Non-FAMP Data Collection

The NHC recognizes that the collection of non-Federal Average Manufacturer Price (non-FAMP) data is a statutory requirement under the IRA and acknowledges its value as a baseline metric for evaluating manufacturer pricing behavior. However, non-FAMP figures, in isolation, offer limited insight into the actual financial impact experienced by Medicare beneficiaries.[5] The prices patients encounter at the pharmacy counter or point of care are shaped by a complex interplay of factors, including formulary tiering, coinsurance levels, utilization management policies, and site-of-care billing structures.[6]

Accordingly, the NHC urges CMS to clearly articulate the role non-FAMP data will play in negotiation determinations, particularly in relation to other data sources that reflect real-world access and affordability. CMS should ensure that its interpretation of non-FAMP is contextualized within this broader framework. Clarification on how these values will be weighed—particularly in relation to patient cost-sharing and access barriers—will enhance the integrity and credibility of the negotiation process.

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[4] Justin Lo, Michelle Long, Rayna Wallace, and Kaye Pestaina, "Claims Denials and Appeals in ACA Marketplace Plans in 2023," *KFF*, January 27, 2025, https://www.kff.org/private-insurance/claims-denials-and-appeals-in-aca-marketplace-plans-in-2023/

[5] Steven M. Lieberman and Paul B. Ginsburg, "Knowing Actual Prices Will Help HHS Set the Maximum Fair Price Under the Inflation Reduction Act," *Health Affairs Forefront*, February 16, 2024, https://doi.org/10.1377/forefront.20240212.193706

[6] National Academies of Sciences, Engineering, and Medicine, *Making Medicines Affordable: A National Imperative*, ed. SJ Nass, G. Madhavan, and NR Augustine (Washington, DC: National Academies Press, 2017), chap. 3, "Factors Influencing Affordability," https://www.ncbi.nlm.nih.gov/books/NBK493090/

Furthermore, the reliability of non-FAMP data may vary across product types. For therapies introduced after 2021, or those with non-continuous NDC marketing histories, reported non-FAMP values may be limited in scope or influenced by anomalous pricing periods.[7] Estimates may also vary depending on whether data are derived from direct sales or public pricing reports.[8] To bolster analytical rigor and stakeholder confidence, CMS should consider implementing a review process that compares reported non-FAMP values to additional pricing benchmarks where appropriate—such as Wholesale Acquisition Cost (WAC), Average Sales Price (ASP), or commercial net pricing data, when available. CMS could further improve transparency by publishing anonymized, aggregated summaries of how these comparisons informed the agency's evaluation.

Finally, the NHC underscores the importance of addressing discrepancies between Primary and Secondary Manufacturer data submissions. Variances between these sources may introduce uncertainty into the negotiation process and pose administrative challenges for downstream stakeholders, including providers and pharmacies. CMS should develop reconciliation protocols to resolve such inconsistencies, including specific timelines and criteria for determining the authoritative data source. Technical guidance to manufacturers on expected standards for non-FAMP reporting would also help promote consistency and reduce the risk of access delays for beneficiaries.

Section C: Research and Development (R&D) Costs and Recoupment

The NHC acknowledges that R&D cost and recoupment analyses can contribute valuable context to drug price negotiations. However, the NHC emphasizes that such data must not displace considerations that center on the patient experience, including affordability and timely access to clinically appropriate treatments. Methodologies for estimating R&D expenditures differ widely across companies, and attributing development costs to a single therapy—particularly when research is shared across platforms, therapeutic areas, or programs—presents significant methodological challenges.[9]

To enhance transparency and consistency, the NHC recommends that CMS request manufacturers to include a general description of the methodologies and key assumptions used in allocating R&D costs, consistent with industry norms and proprietary protections. CMS should also publish de-identified, aggregated summaries of these disclosures to provide stakeholders with insight into the agency's approach. Doing so would help avoid undue emphasis on opaque or non-standardized accounting

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[7] Matthew J. Martin et al., *Prescription Drug Price Measures to Inform Upper Payment Limits: Guidance for State Prescription Drug Affordability Boards*, PORTAL (Harvard Medical School and Brigham and Women's Hospital), December 13, 2024, https://eadn-wc03-8290287.nxedge.io/wp-content/uploads/2025/01/PORTAL_Price-Measures-for-UPLs-Memo_Final.pdf

[8] Inmaculada Hernandez, Nathan Gabriel, and Sean Dickson, "Nonfederal Average Manufacturer Price to Estimate Savings Generated by Minimum Discounts under the Inflation Reduction Act," *Journal of Managed Care & Specialty Pharmacy* 29, no. 11 (2023): 1261–63, https://pmc.ncbi.nlm.nih.gov/articles/PMC10609926/

[9] Steven Simoens and Isabelle Huys, "R&D Costs of New Medicines: A Landscape Analysis," *Frontiers in Medicine* 8 (October 25, 2021), https://doi.org/10.3389/fmed.2021.760762.

practices, which may vary by company size, portfolio structure, or internal reporting policies.

Recoupment analyses should also be carefully balanced against the IRA's overarching goal of ensuring affordable access to high-value therapies. Policies that rely excessively on manufacturer-reported cost recovery risk disincentivizing future investment in areas with high scientific or operational risk, including treatments for rare diseases, pediatric conditions, or less commercially attractive therapeutic areas.[10] CMS should therefore evaluate recoupment data in conjunction with other patient-centered inputs—such as measures of clinical benefit, patient-reported outcomes, adherence patterns, and improvements in quality of life.

Where public funds have supported the development of a therapy—through direct grants, tax incentives, or public-private partnerships—CMS should consider this investment in a manner that recognizes the shared value created by such collaborations. Public contributions to R&D have helped catalyze transformative innovations, and it is appropriate that pricing decisions reflect both the public's investment and the importance of preserving incentives for future research. CMS should adopt a standardized approach for assessing the role of prior federal support in drug development, ensuring that this factor is applied transparently and consistently across products.

Question 1: Costs Related to the Selected Drug. The NHC supports CMS' effort to collect detailed information on pre-clinical research, post-Investigational New Drug development, and other allowable R&D expenditures. However, to ensure comparability across products and manufacturers, companies should be required to document their methodologies for allocating indirect costs, clearly delineate direct costs, and provide sufficient justification for proportional or other allocation methods. Where indirect costs are distributed across multiple products or divisions, the total pool and rationale for allocation should be disclosed. Similarly, inflation adjustments should be based on a transparent, standardized methodology, with manufacturers identifying the indices used, detailing any assumptions, and providing sufficient information to support external validation. While this information may provide useful background for negotiation, it should remain one of several considerations, subordinate to patient-centered factors such as unmet need, real-world impact, and affordability.

Question 2: Costs of Failed or Abandoned Products. The NHC recognizes that investment in failed or abandoned products is an intrinsic aspect of pharmaceutical innovation and supports CMS' inclusion of this information in the ICR. To enhance the interpretability of these data, manufacturers should be asked to explain the connection between these abandoned programs and the selected drug, including the stage of development, therapeutic target, and reasons for termination. This level of detail can help illuminate research trajectories and portfolio management strategies. However, CMS should exercise caution in applying these figures during negotiation. While relevant to understanding the broader investment landscape, they do not represent direct costs associated with bringing a single therapy to market and may risk distorting

[10] Mujaheed Shaikh, Pietro Del Giudice, and Dimitrios Kourouklis, "Revisiting the Relationship Between Price Regulation and Pharmaceutical Research and Development (R&D) Intensity," *Health Economics* (2020), https://doi.org/10.1007/s40258-020-00601-9

value assessments if given disproportionate weight. The primary use of these disclosures should be to inform CMS' understanding of development risk and market dynamics, rather than as a standalone justification for pricing outcomes.

Question 3: Global and U.S. Net Revenue for the Selected Drug. The NHC supports the collection of both U.S. and global net revenue data, as this information is essential to contextualizing cost recovery and informing price negotiation. To promote uniformity and reliability, CMS should require manufacturers to specify the methodologies used to calculate net revenue, including the treatment of chargebacks, discounts, rebates, returns, and other commercial arrangements. Particular care should be taken to distinguish between cash and non-cash transactions. U.S. net revenue should serve as the primary data point in Medicare negotiations, with global revenue providing supplemental context. CMS should also request disclosure of relevant exchange rates, inflation adjustments, and reporting timeframes to ensure cross-manufacturer consistency. Where appropriate, CMS may wish to publish anonymized, aggregated summaries of revenue data to demonstrate how these inputs align with broader statutory objectives of sustainability, value, and beneficiary access.

Section D: Current Unit Costs of Production and Distribution

CMS' inclusion of questions related to the current unit costs of producing and distributing selected drugs reflects the need for greater transparency into the underlying economic drivers of pricing. While unit cost data alone do not capture the full complexity of pharmaceutical pricing, they are a necessary input for evaluating whether the price of a product is reasonably aligned with its manufacturing and supply chain expenditures. To ensure that these data support meaningful comparisons across products and therapeutic areas, CMS must establish clear definitions, promote consistency in reporting, and account for factors that may introduce variability—such as batch size, formulation differences, or distribution models. The following comments are intended to support the integrity and interpretability of this section.

Question 4: Per Unit Production and Distribution Costs. The NHC supports CMS' collection of per-unit production and distribution costs for each NDC-11 associated with a selected drug. When collected and applied appropriately, this data can serve as a useful reference point to assess whether pricing claims reasonably reflect underlying cost structures. However, production cost data must be gathered and analyzed in a manner that ensures consistency, transparency, and comparability across manufacturers and dosage forms. Without standardized methodologies, cost submissions may vary significantly depending on internal accounting practices, rendering cross-manufacturer comparisons unreliable.

To that end, CMS should consider requiring manufacturers to use a consistent framework for calculating per-unit costs, including clear definitions of cost categories and allocation principles. Particular attention should be paid to how shared or indirect expenses—such as administrative overhead, facility operations, depreciation, and other fixed costs—are attributed across product lines and NDCs. These inputs should be described in a manner that allows CMS to determine whether allocations are reasonable and whether costs have been overstated in ways that could distort price justification.

The inclusion of discontinued NDCs and sample packages may also provide useful insight into a product's lifecycle and historical pricing practices. However, CMS should clarify how such data will be factored into pricing determinations. Without clear guidance, ambiguity around the treatment of these units could introduce unnecessary administrative burdens or delay claims processing. While production and distribution cost data are important for understanding market dynamics, they do not represent the price patients ultimately face. CMS should therefore treat this information as a contextual reference—useful in detecting implausible or inflated cost assertions—but not as a primary determinant of negotiated price. Affordability, access, and clinical value must remain the guiding principles.

Question 5: Explanation of Calculation of Per Unit Production and Distribution Costs. The NHC underscores that the contextual narrative accompanying per-unit cost data is equally essential to interpreting the figures accurately and meaningfully. To support transparency and comparability, CMS should require manufacturers to provide a detailed explanation of how production and distribution costs were calculated. This should include a breakdown of direct inputs—such as raw materials, labor, quality assurance, logistics, packaging, and labeling—as well as any indirect costs attributed to the product. Where indirect costs are allocated across NDCs or product lines, the methodology for allocation should be clearly described and justified.

In addition, manufacturers should specify whether production and distribution costs were incurred domestically or internationally, distinguishing between the two in reporting. Capital expenses—including facilities and equipment—should be identified and accompanied by the depreciation methodology used. For sample units, manufacturers should describe their production process and cost basis, including whether these units were manufactured on dedicated lines or as part of general production.

To promote consistency, CMS may wish to establish uniform standards for inflation adjustment and cost indexing. Requiring manufacturers to cite the indices used and to explain any assumptions will improve the reliability of the data. Where feasible, CMS should also consider publishing anonymized, aggregated descriptions of submitted methodologies. This would allow stakeholders to better understand industry practices without compromising proprietary business information.

In all cases, the NHC reiterates that production and distribution costs should be treated as one of many contextual factors in the negotiation process. While relevant to assessing reasonableness, these figures should not serve as a standalone basis for determining the MFP. Ultimately, what matters is whether beneficiaries can obtain medically necessary therapies at a cost that does not undermine adherence, outcomes, or financial stability.

Section E: Prior Federal Financial Support

Understanding the extent of prior federal financial support for the development of selected drugs is critical to assessing public investment in innovation. This includes not

only direct grant funding but also indirect forms of support such as federally funded research infrastructure, public-private partnerships, and regulatory assistance. Transparent reporting in this section can help CMS determine whether taxpayer-funded contributions played a substantive role in the drug's discovery, development, or commercialization. To ensure accurate and consistent responses, CMS should provide clear guidance on what qualifies as relevant federal support and require sufficient detail to contextualize the public's role in advancing the therapy.

Question 6: Federal Funding Support Amount. The NHC supports CMS' inclusion of prior federal financial support as a required data element in the negotiation process. Transparency regarding these contributions—such as grants from the National Institutes of Health, Biomedical Advanced Research and Development Authority contracts, and Orphan Drug tax credits— ensures that the public's role in enabling drug development is appropriately reflected in price-setting decisions. The framework should incorporate these data in a manner that strengthens accountability while preserving incentives for continued investment in therapies that address unmet medical needs.

To improve fairness and interpretability, CMS should require manufacturers to report material forms of federal support—such as direct grants, cooperative agreements, tax credits, and federal contracts—associated with the development of the selected product. Where feasible, manufacturers should also disclose significant in-kind support, including access to federal laboratories or technical expertise, and provide explanatory context. To promote consistency and accuracy, CMS should clarify whether disclosures must be limited to support directly tied to the marketed product or whether broader R&D contributions should be included, particularly in cases where shared infrastructure or platform research was involved.

This level of detail will help CMS and other stakeholders understand the scope and relevance of public contributions to the selected drug's development, while promoting fair outcomes for Medicare beneficiaries and the broader public.

Question 7: Explanation of Calculation of Federal Financial Support. The NHC emphasizes that narrative explanations accompanying reported federal support figures are essential to establishing their relevance, accuracy, and comparability. Manufacturers should be expected to provide disaggregated reporting by source of funding, including award numbers, dates, and associated programmatic details when available. Such transparency would allow validation against publicly available federal databases and provide greater assurance that reported figures accurately reflect the federal government's contributions.

Where indirect costs or shared research infrastructure were supported by federal funds, the methodology for apportioning these costs to the selected product should be clearly described. Similarly, for in-kind support or cooperative agreements, CMS should require a description of the valuation methods used, including assumptions and allocation principles. While Section E does not require inflation adjustments for Question 6, CMS may wish to request that manufacturers indicate whether inflation-adjusted figures are included in Question 7 to support consistent interpretation across submissions.

These measures would strengthen the integrity of the negotiation process by ensuring that federal support is not only disclosed but also contextualized appropriately within manufacturers' pricing justifications.

Question 8: Agreements Between Primary Manufacturer and Federal Government. The NHC supports the requirement that manufacturers disclose any relevant agreements with federal agencies, including those related to licensing, purchasing, pricing, and other negotiated terms. These agreements may include preferential pricing arrangements, volume-based purchase commitments, or negotiated terms under programs such as the Federal Supply Schedule. Transparent disclosure of such agreements can help ensure that Medicare beneficiaries are not disadvantaged relative to other federally supported programs.

To support this goal, manufacturers should be required to describe the key terms of these agreements, including exclusivity provisions, applicable price or volume thresholds, effective dates, and expiration timelines. In cases where an agreement encompasses platform technologies, multi-drug pipelines, or broader supply arrangements, manufacturers should explain how the selected drug fits within the scope of such contracts. Additionally, CMS should clarify whether pricing or purchasing terms that apply to other federal programs are also relevant in the context of Medicare negotiations.

To balance transparency with protection of proprietary business information, CMS could consider publishing anonymized, aggregate summaries of the nature and scope of disclosed agreements. This would reinforce public trust that federal contributions are appropriately factored into pricing determinations while preserving the integrity of confidential contractual arrangements.

Section F: Patents, Exclusivities, and Approvals

Patent protections and regulatory exclusivities can significantly influence drug pricing and availability. This section addresses the intellectual property and market exclusivity landscape surrounding the selected drug, as well as the presence or absence of generic or biosimilar competition. A clear understanding of these elements is essential for evaluating the manufacturer's pricing leverage, market dynamics, and the duration of monopoly pricing. CMS should ensure that the questions in this section elicit precise, well-documented information on patent scope, expiration dates, exclusivity types, and any current or anticipated generic entry, so that negotiation decisions are grounded in a full understanding of competitive context.

Questions 9A and 9B: Patents and Patent Applications. The NHC supports CMS' collection of detailed information on both granted patents and pending patent applications related to selected drugs. Patent protections are a central determinant of market exclusivity and the timing of generic or biosimilar competition—factors that have a direct and often prolonged impact on patient access and affordability. A clear and comprehensive understanding of the patent landscape is essential to ensure that pricing negotiations are grounded in an accurate representation of market barriers.
CMS should require manufacturers to list all granted patents and publicly available patent applications associated with the selected drug and to categorize them by type

(e.g., composition of matter, method of use, formulation, delivery device). This structured classification will help CMS better understand the nature and scope of exclusivity protections while allowing for consistency across manufacturer submissions.

While certain secondary patents may reflect meaningful therapeutic enhancements—such as improved safety, tolerability, or patient adherence—others may have more limited implications for clinical benefit. To support a balanced and informed negotiation process, CMS should consider requiring manufacturers to disclose relevant patent ownership information, particularly in cases involving joint ventures, licensing arrangements, or technologies arising from federally supported research. Increased transparency in this area would help ensure that the role of public investment in innovation is appropriately recognized.

In addition, CMS should examine the role of pending patent applications in shaping future market dynamics. Although such applications are often confidential, manufacturers should be expected to disclose the general subject matter, intended therapeutic benefit, and potential market implications of active filings. This information may assist CMS in assessing whether the timing of potential generic or biosimilar entry is likely to be affected by unresolved patent protections.

Question 10: Exclusivity Periods. The NHC agrees with CMS that exclusivity periods conferred by the FDA represent an important component of the overall pricing landscape. Statutory exclusivities—including those granted under Hatch-Waxman, the Biologics Price Competition and Innovation Act (BPCIA), and the Orphan Drug Act—play a legitimate role in incentivizing innovation, particularly for rare conditions or populations with limited treatment options. Overlapping or sequential exclusivity periods may provide important assurances that help justify investment in high-risk or low-return therapeutic areas.

However, the cumulative effect of these protections—particularly when combined with other forms of intellectual property protection—may result in extended periods of market exclusivity. While such exclusivity can serve an important role in encouraging private investment and supporting the development of innovative therapies, particularly in high-risk or underserved areas, it is also important to ensure that these protections do not unnecessarily delay the entry of generics or biosimilars. CMS should evaluate how the interaction of exclusivity provisions and intellectual property protections may affect competition over time and consider whether the resulting timelines appropriately balance incentives for innovation with timely and affordable access for patients.

CMS should request that manufacturers disaggregate exclusivity periods by type and duration and clarify how each interacts with the patent landscape. For example, when a drug holds both Orphan Drug Exclusivity and a method-of-use patent, it would be useful to understand how those protections function together to affect the availability of generics or biosimilars. CMS may also wish to require disclosure of whether exclusivity protections apply to the core indication or only to supplemental approvals, as this distinction has implications for both pricing and patient access.

By encouraging greater transparency regarding the structure and duration of exclusivity protections, CMS can better assess whether these mechanisms are serving their intended purposes to support timely access to affordable therapies.

Question 11: Active and Pending FDA Applications and Approvals. The NHC supports CMS' proposal to collect information on active and pending FDA applications related to selected drugs, as these data can provide important insight into lifecycle management activities that may influence pricing and exclusivity. CMS should distinguish between applications that offer clinically meaningful improvements—such as enhanced safety, expanded indications for underserved populations, or improved adherence—and those that involve more limited changes, including packaging modifications or minor dosing adjustments. Manufacturers should also be asked to indicate whether pending applications are expected to trigger new exclusivity protections or extend existing ones, particularly when filings occur near the expiration of exclusivity or patent rights. Greater transparency in this area will help ensure that pricing negotiations remain focused on clinical value and patient benefit, rather than regulatory actions that may delay competition without advancing therapeutic outcomes.

Section G: Market Data and Revenue and Sales Volume Data

This section seeks to contextualize a drug's market performance by gathering information on list and net pricing, sales volumes, and revenue across public and private payers. These data elements are central to understanding real-world utilization patterns, pricing behavior, and how the financial burden is distributed across the health care system. CMS must ensure that the information collected under this section is detailed enough to inform negotiation, while also structured to enable meaningful comparisons across drugs, payers, and patient populations. Accurate reporting and careful interpretation of this data can help distinguish between payer savings and patient affordability, reinforcing the program's intent to lower costs for Medicare beneficiaries.

Questions 12 & 13: Wholesale Acquisition Cost (WAC). The NHC supports CMS' collection of WAC data as a foundational benchmark in evaluating pricing dynamics. While WAC does not reflect negotiated discounts or rebates, it remains a central factor in determining patient cost-sharing obligations, particularly for individuals with coinsurance linked to list prices. As such, WAC should not be interpreted solely as a proxy for manufacturer pricing strategy, but rather as a reference point that shapes patient financial exposure at the point of care.

To enhance transparency and utility, CMS could compare manufacturer-reported WAC data against publicly available sources such as First Databank, Medi-Span, or RED BOOK. Any discrepancies should be assessed in terms of their impact on patients, including variations in out-of-pocket costs or coverage determinations. Clear documentation of how WAC values align—or diverge—from other pricing benchmarks would provide additional clarity for stakeholders, including patient organizations and plan sponsors.

Questions 14 & 15: Medicaid Best Price. The NHC affirms the importance of the Medicaid Best Price requirement as a safeguard for preserving affordability for low-

income beneficiaries. CMS' continued collection and review of best price data is essential to ensuring that the statutory rebate framework operates as intended. Given the complexity of pharmaceutical contracting, the agency should evaluate whether current reporting captures the full range of price concessions, including those offered through bundled sales, value-based arrangements, and specialty pharmacy networks.

Where discrepancies arise between reported best prices and underlying transaction-level data, CMS should take appropriate steps to verify accuracy and ensure that Medicaid beneficiaries fully benefit from statutory pricing protections. Maintaining integrity in best price reporting is especially critical for high-cost specialty drugs, which represent a growing share of Medicaid prescription spending and may pose significant access barriers if rebate mechanisms are weakened or circumvented.

Questions 16 & 17: Federal Supply Schedule (FSS) Price. The FSS price represents a deeply discounted federal procurement rate, often lower than commercial prices due to statutory discounting requirements. While not directly tied to patient out-of-pocket costs, the FSS price offers a useful reference point for understanding the range of prices manufacturers are willing to accept in other contexts. CMS' review of FSS data can provide insight into broader pricing practices and inform assessments of value in Medicare negotiations.

Where notable gaps exist between FSS and commercial net prices, CMS could explore whether such differences reflect market segmentation, supply chain dynamics, or contracting terms with unique federal obligations. Understanding these distinctions may help contextualize how pricing decisions affect affordability for non-federal populations without conflating separate statutory frameworks.

Questions 18 & 19: Big Four Price. The "Big Four" federal purchasers—the Department of Veterans Affairs, Department of Defense, Public Health Service, and Coast Guard—often secure the most favorable pharmaceutical pricing in the United States through statutory formulas and direct negotiation. CMS' collection of Big Four pricing data offers a valuable comparative lens for examining pricing variability across public programs.

While acknowledging the distinct statutory authorities that govern each federal purchaser, CMS may assess how negotiated prices for the Big Four compare to net prices in Medicare and commercial markets. Where consistent patterns emerge, these comparisons may inform future efforts to strengthen pricing consistency while preserving program-specific statutory protections.

Questions 20 & 21: Manufacturer U.S. Commercial Average Net Unit Price. Commercial net pricing reflects a complex array of negotiated discounts, formulary placement incentives, and access arrangements. While such mechanisms can lower overall payer expenditures, the benefit to patients is often indirect, particularly when cost-sharing is based on undiscounted list prices. CMS' collection of commercial net price data is therefore essential to understanding how payer-facing savings translate—or fail to translate—into patient-level affordability.

The NHC encourages CMS to request disaggregated data on how rebates, copay assistance, and patient support programs contribute to net price calculations. While patient assistance programs offer temporary relief, they should not substitute for sustainable, systemwide affordability. To evaluate real-world patient impact, CMS should also consider comparing commercial net prices with actual patient out-of-pocket costs across plan designs. Such analysis would support more targeted interventions that improve transparency and fairness in cost sharing.

Questions 22 & 23: Medicare Part D Net Average Unit Price. Medicare Part D net pricing plays a central role in shaping beneficiary access and affordability, particularly for those managing high-cost chronic conditions on fixed incomes. Differences between "net average unit price" and "net best price" within Part D can obscure underlying variations in manufacturer discounts, especially when program-specific mechanisms such as coverage gap discounts or Manufacturer Discount Program obligations are applied.

To improve visibility, CMS should request additional clarity on how these concessions are structured and whether they result in lower patient spending or merely shift costs among program stakeholders. The NHC urges CMS to interpret Part D net price data with a focus on patient outcomes, particularly whether negotiated discounts reduce actual pharmacy counter costs or are absorbed elsewhere in the system without beneficiary benefit.

Question 24: Proprietary Information Designation. The NHC strongly supports transparency in the price negotiation process and cautions against overbroad classification of market data as proprietary. While the protection of commercially sensitive information is appropriate in limited circumstances, overly broad redaction risks undermining public confidence in the negotiation process and obscuring the very dynamics it seeks to improve.

CMS should narrowly define the scope of proprietary information to exclude only those data elements whose disclosure would result in demonstrable competitive harm. Aggregated data—such as average net prices by payer segment, unit sales volumes, WAC and list prices, and ranges of rebates or discounts—should be made publicly available, with clear explanations of methodology. CMS should also consider a mechanism for patient and consumer groups to comment on published summaries, ensuring that the program remains anchored in its statutory purpose of improving affordability and access for beneficiaries.

Section I: Evidence About Alternative Treatments

This section is designed to capture information about the clinical and experiential value of therapeutic alternatives to the selected drug, drawing on perspectives from patients, caregivers, clinicians, researchers, manufacturers, and the broader public. Understanding the availability, effectiveness, and accessibility of these alternatives is essential to evaluating a drug's comparative benefit and identifying unmet needs. CMS should ensure that the structure and content of this section accommodate a wide range of inputs—both qualitative and quantitative—while maintaining transparency and

methodological rigor. Facilitating robust engagement across respondent types will help ensure that the full context of therapeutic value is incorporated into price negotiations.

Question 25: Respondent Information. Collecting information on respondent type and organizational affiliation is essential to interpreting submitted data. To further enhance transparency, CMS should consider requiring the disclosure of relevant financial relationships with manufacturers of the selected drug or its comparators, including indirect support. Clear guidance should be provided for respondents with multiple roles—such as patient organizations that also conduct research or engage in industry collaboration—so they can accurately represent their perspective. Patient organizations in particular warrant recognition as a distinct category given their unique role in representing the lived experiences of patients.

Questions 26–31: Patient- and Caregiver-Focused Input. Patient and caregiver perspectives are indispensable to assessing therapeutic value. The NHC commends CMS for including targeted questions in this section. To increase accessibility, CMS could offer structured prompts—such as checkboxes or rating scales—in addition to open-text fields. This approach may reduce barriers for respondents with limited time, English proficiency, or health literacy. These questions should also explicitly invite input on non-clinical challenges that affect patient experience, such as affordability, coverage restrictions, or geographic access limitations. Respondents should be encouraged, though not required, to include demographic or contextual information—such as disability status or rural residence—to inform accurate interpretation of access barriers.

Questions 32–37: Manufacturer-Focused Input. Manufacturers play an important role in contributing comparative evidence and contextualizing unmet need. CMS should consider developing a standardized template to guide manufacturer responses, with clearly defined parameters for cost, prevalence, and utilization estimates. While manufacturers may choose to submit detailed dossiers, a core data template would promote consistency and reduce potential disparities between large and small companies. All submissions should be accompanied by methodological disclosures, including funding sources and known limitations, to support appropriate interpretation.

Questions 38–43: Clinical-Focused Input. Clinician perspectives offer valuable insights into treatment paradigms, clinical utility, and real-world challenges. CMS should consider requesting that clinicians describe observed differences in treatment access, including among individuals living in rural areas, people with disabilities, and others who may experience reduced access due to geographic, socioeconomic, or functional factors. Submissions should also address relevant patient-centered outcomes—including adherence, tolerability, and quality of life—in addition to traditional clinical endpoints. Clarifying the role of non-clinical influences, such as formulary placement or cost-sharing, would further strengthen the utility of these submissions.

Questions 44–50: Research-Focused Input. Input from researchers and advocacy organizations can enhance understanding of patient-centered outcomes and disease burden. CMS should prioritize evidence from studies that incorporate real-world data, caregiver impact research, and patient-reported outcomes. While economic

evaluations can provide relevant context, their use should be calibrated to avoid reinforcing models that risk undervaluing the lives of individuals with chronic conditions or disabilities. Emphasis should be placed on meaningful patient-reported outcomes, including quality of life, symptom burden, and treatment preferences. As in other sections, methodological transparency is essential to ensure utility and interpretability.

Questions 51–53: Other Public Input. This section offers an important pathway for broader societal perspectives. CMS should clarify that responses may include information from community-based organizations, health systems, or other civic institutions that experience indirect effects of therapeutic value, such as impacts on the caregiving workforce or public health infrastructure. This section may also be used to identify areas where evidence is lacking, particularly for conditions that are less common or for groups that face practical challenges in accessing care.

Questions 54–55: Visual Representations and Citations. The NHC supports CMS' inclusion of dedicated space for visual materials and citations. However, the current limits—20 visuals and 250 citations—may be unduly restrictive for certain submitters. CMS should clarify whether these limits apply per drug or per respondent and allow flexibility where justified. Importantly, formal citation requirements should not be imposed on patient or caregiver respondents, whose testimony remains critical even when unsupported by peer-reviewed sources. In contrast, manufacturers and researchers should be held to appropriate standards of documentation and citation.

Question 56: Proprietary Information. The NHC encourages CMS to adopt a cautious approach to proprietary designations. Transparency is critical to the legitimacy of the negotiation process. Redactions should be narrowly limited to trade secrets or information demonstrably likely to cause competitive harm if disclosed. CMS should also publish anonymized, aggregate summaries of all responses—especially patient and caregiver submissions—to ensure that their contributions remain visible and impactful throughout the decision-making process.

Part 2: Drug Price Negotiation and Renegotiation Process Counteroffer ICR Form

The NHC recognizes that the counteroffer ICR process is primarily directed to manufacturers and governs the mechanics of their statutory and renegotiation submissions. While the NHC does not directly participate in this process, it is essential that counteroffers be managed in a manner that maintains trust in the program and upholds patient-centered objectives. As CMS evaluates counteroffers, the agency should remain guided by the statutory goals of the IRA: improving affordability, ensuring fairness, and promoting long-term sustainability. The structure and timing of the 30-day response window should also strike an appropriate balance between timeliness and fairness, allowing manufacturers sufficient opportunity to submit complete and accurate information while supporting the efficient progression of negotiations. Minimizing uncertainty throughout this process is critical for the patients who depend on these therapies.

To strengthen transparency and public confidence in the negotiation process, CMS should publish aggregated, de-identified summaries of manufacturer justifications submitted through the counteroffer process. These summaries would demonstrate that

counteroffers are subject to rigorous and consistent review, reinforcing the integrity of the program while protecting sensitive commercial information. Public access to such information would also help stakeholders understand the factors considered during negotiations and provide assurance that the process remains aligned with statutory objectives and patient-centered principles.

The NHC also appreciates CMS' continued commitment to excluding Quality-Adjusted Life Years (QALYs) from the negotiation process, as required by statute and reiterated in recent guidance. Valuing life differently based on disability status, age, or other characteristics is inappropriate, and the exclusion of QALYs is essential to preserving fairness in Medicare drug price negotiations.[11] However, the NHC remains concerned about the potential for QALY-related data to influence analysis through secondary sources. We encourage CMS to provide additional clarity on how such metrics are identified and excluded in practice, and to indicate when QALY-based information has been removed from manufacturer submissions or internal justification documentation. More broadly, therapeutic value assessments should reflect the full range of patient experiences, not a single summary metric. The NHC recommends that CMS incorporate multiple sources of evidence to capture outcomes patients consider meaningful, such as daily functioning, treatment burden, quality of life, and financial impact. This multidimensional approach will help ensure that negotiation decisions remain aligned with patient priorities and statutory intent.

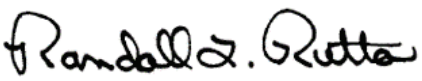
Taken together, these refinements would ensure that the counteroffer ICR process supports fair and effective Medicare drug price negotiations while reinforcing patient trust in the program.

Conclusion

The NHC values the opportunity to engage with CMS on this important process and remains committed to working together to ensure that Medicare beneficiaries have access to affordable, high-value care.

Thank you again for the opportunity to provide input to CMS on this ICR. Please do not hesitate to contact Kimberly Beer, Senior Vice President, Policy & External Affairs at kbeer@nhcouncil.org or Shion Chang, Senior Director, Policy & Regulatory Affairs at schang@nhcouncil.org, if you or your staff would like to discuss these comments in greater detail.

Sincerely,



Randall L. Rutta
Chief Executive Officer

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[11] National Council on Disability. *Quality-Adjusted Life Years and the Devaluation of Life with Disability*. Washington, DC: National Council on Disability, November 6, 2019. https://www.ncd.gov/assets/uploads/reports/2019/ncd_quality_adjusted_life_report_508.pdf#:~:text=Adjusted%20Life%20Year%20,in%20countries%20where%20QALYs%20are

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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

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[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,

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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,***

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[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.

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[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.

PIPC Partnership to Improve Patient Care

August 11, 2025

Honorable Mehmet Oz, MD, MBA
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
7500 Security Boulevard
Baltimore, MD 21244

Dear Administrator Oz:

Thank you for this opportunity to comment on the Information Collection Request for IPAY 2028. Since passage of the Inflation Reduction Act, we have worked collaboratively with organizations representing patients and people with disabilities to amplify the perspectives of those with lived experience in the implementation of the Medicare Drug Price Negotiation Program. As communicated by over 100 organizations representing patients and people with disabilities in the attached Open Letter, we want to reiterate our concerns about the agency's use of data that devalues people with disabilities and serious chronic conditions as well as older adults.[1]

The Partnership to Improve Patient Care (PIPC) has long advocated for policies that put patients and people with disabilities at the center of healthcare. PIPC is a unique coalition that focuses its efforts on ensuring the evidence used to make health care decisions does not devalue people with disabilities and serious chronic conditions and lead to challenges for accessing care that will improve their quality of life, as well as their families. PIPC supports the development and use of patient-centered comparative clinical effectiveness research to drive informed health care decisions – and opposes reliance on discriminatory value assessments and cost effectiveness analyses that devalue subpopulations most at risk for disease and disability to cut costs at the expense of long-term health and wellness.

As we have stated in the past, the new IPAY 2028 guidance does not adequately reflect statutory limitations on the use of quality-adjusted life years (QALYs) and similar measures given the revised approach proposed for IPAY 2028 that would no longer require submitters to clarify whether such measures are included in their evidence.[2] While we appreciate the footnote stating QALYs will not be used, we are very disappointed that the Information Collection Request does not reflect our concern about the need for disclosure of the use of such measures in light of the QALY-based studies referenced in the Explanatory Statements published last December.[3] If referenced even indirectly, the United States is at risk of the

[1] See https://files.constantcontact.com/e7a90be4701/2e199106-a152-4598-838b-1b08dce510c2.pdf
[2] See https://www.pipcpatients.org/uploads/1/2/9/0/12902828/pipc_ipay_2028_comment_letter.pdf
[3] See https://aesara.com/wp-content/uploads/2025/05/10-Poster-Is-the-IRA-Drug-Price.pdf

associated rationing of care for which QALYs were created to achieve and as we see in other countries that rely on these measures of cost effectiveness to determine who is worthy of care. Instead, we urge CMS to avoid use of one-size fits all value metrics that fail to reflect how our nation values every American life. No patient is average, and no measure of value should assume so.

As you know, federal law bars the use of QALYs and similar measures in making Medicare reimbursement and coverage decisions.[4] The first Trump administration took significant steps forward to recognize the value of all lives in fighting state-based Crisis Standards of Care that would have put people with disabilities at the back of the line for care in a shortage. President Trump's administration publicly expressed concerns that such policies were based on bias and stereotypes about people with disabilities. While the explanations for determining Maximum Fair Prices (MFP) for IPAY 2026 included reference to QALY-based studies, going forward, we want to work with the Trump administration to improve MFP decisions and ensure they no longer rely on value judgments as to the relative worth of one human being versus another, based on the presence or absence of disability. We know now that disclosure of the use of QALYs and similar measures already barred from Medicare's consideration is a necessary step to keep these value judgments out of Medicare decision-making as intended by the law.

Make America Healthy Again (MAHA) is aligned with efforts to ensure policymakers and payers do not undermine the informed decisions of providers and patients seeking to optimize their quality of life. We agree that the success of our nation's health care programs should be measured by the impact on health and wellness. We look forward to working with you and the new administration on identifying strategies to align incentives in our health care system to promote preventative healthcare, as well as high quality health care decision-making for people living with disabilities and chronic conditions.

Thank you for your consideration.

Sincerely,

Tony Coelho
Chairman
Partnership to Improve Patient Care

[4] 42 USC Sec 1320e

REJECT HEALTH POLICIES THAT DEVALUE AND RATION CARE FOR ANY AMERICAN

All lives are valuable, and our health care policy should adhere to this fundamental American belief.

We strongly urge policymakers to reject policies that would devalue and ration care for any American whether modeled after foreign or domestic value assessment methodologies.

As organizations representing patients, people with disabilities, older adults, healthcare professionals, children and family caregivers, we strongly oppose policies that rely on discriminatory, one-size-fits-all value metrics such as the Quality-Adjusted Life Year, or QALY. The reason is simple: value assessments that use QALYs or similar metrics don't just value treatment. They assign a financial value to the group of people for whom a given treatment is intended based on their health status. In practice, treatments for a group of people that are sicker, older, or disabled, may be assessed as less valuable. Health policies based on these methods justify public and private payers restricting access by not covering them or using benefit management techniques that effectively ration access. **Instead, policies should drive equal access to quality healthcare for every American.**

Therefore, we are eager to work productively with policymakers to improve the health of Americans. We agree people should not be denied or face barriers to medical care on the basis of stereotypes, assessments of quality of life, or judgments about a person's relative "worth" based on the presence or absence of disabilities or age. There is a long history of robust, bipartisan opposition to QALY-based policies in Medicare and Medicaid that underscores America's core belief that the lives of individuals with disabilities, older adults and infants are worth just as much as any other person.

A wide range of organizations and leaders across the political spectrum and health care landscape have echoed our concerns. And the National Council on Disability has repeatedly warned Congress against enacting policies that reference QALY-based metrics and has explicitly recommended that CMS refrain from pursuing policies to reduce Medicare and Medicaid prescription drug costs that utilize pricing models from foreign countries relying heavily on QALYs and similar measures. **We are concerned about policies that would prioritize cost savings by, in effect, both dictating and rationing care based on assessing the perceived value of those receiving care.**

We are committed to collaborating with the administration, Congress and states on common sense health reforms that address affordability while also preserving equal access to care. We will work across the aisle to ensure the implementation of solutions that allow America's patients, families, and their healthcare professionals to decide the best care for them.

ADAP Advocacy Association
Aimed Alliance
Alliance for Aging Research
Alliance for Patient Access
ALS Association
American Academy of Nursing
American Association of People with Disabilities
American Association on Health and Disability
American Behcet's Disease Association
American College of Family Medicine
American Music Therapy Association
American Spinal Injury Association
Appalachian Learning Initiative
Association of Academic Physiatrists
Association of University Centers on Disabilities
Autistic Self Advocacy Network
Axis Advocates
Biomarker Collaborative
Blue Ridge Independent Living Center
Buscher Consulting
Cancer*Care*
Cancer Support Community
Caring Ambassadors
Center for Autism and Related Disorders
Child Neurology Foundation
Christ Medicus Foundation
Clinician Task Force
Coalition of State Rheumatology Organizations
Color of Gastrointestinal Illnesses
Community Access National Network
Conquering CHD
Crohn's & Colitis Foundation
Davis Phinney Foundation for Parkinson's
Depression and Bipolar Support Alliance (DBSA)
Diabetes Leadership Council
Diabetes Patient Advocacy Coalition
Disability Belongs
Disability Equity Collaborative
Disability Rights Education and Defense Fund (DREDF)
Dravet Syndrome Foundation
Epilepsy Alliance America
Epilepsy Foundation of America
Exon 20 Group
Friedreich's Ataxia Research Alliance
Genetic Alliance
Global Coalition on Aging Alliance for Health Innovation
Global Liver Institute
GO2 for Lung Cancer
Health Hats
HealthHIV
Healthy Men Inc.
HIV+Hepatitis Policy Institute
Hydrocephalus Association
Hypertrophic Cardiomyopathy Association
ICAN, International Cancer Advocacy Network
Infusion Access Foundation
Lakeshore Foundation
Lane Independent Living Alliance (LILA)
Little People of America (LPA)
Lupus and Allied Diseases Association, Inc.
Lupus Foundation of America
Maryland Statewide Independent Living Council
Massachusetts Family Institute
MLD Foundation
Monica Weldon Consulting LLC
Multiple Sclerosis Foundation
National Alliance on Mental Illness
National Association for the Advancement of Orthotics and Prosthetics
National Coalition for LGBTQ Health
National Council on Independent Living
National Disability Rights Network (NDRN)
National Down Syndrome Society
National Fabry Disease Foundation
National Psoriasis Foundation
National Right to Life
NBIA Disorders Association
New Jersey Statewide Independent Living Council
Northwest Parkinson's Foundation
Not Dead Yet
Partnership to Improve Patient Care
Patients for Patient Safety
Patients Rights Action Fund
PDL1 Amplifieds
PlusInc
RAMP Disability Resources and Services
Rehabilitation Engineering and Assistive Technology Society of North America
RetireSafe
Rural Advocates for Independent Living, Inc.
Second Thoughts MA
The Arc of the United States
The Bonnell Foundation: Living with cystic fibrosis
The Headache and Migraine Policy Forum
The Matrix Consulting, LLC
The Statewide Independent Living Council of Illinois
Tourette Association of America
United Spinal Association
US Hereditary Angioedema Association
Washington Civil & Disability Advocate
WeMatter Organization

August 29, 2025

VIA Electronic Filing – *IRARebateandNegotiation@cms.hhs.gov*

Dr. Mehmet Oz
Administrator
Centers for Medicare & Medicaid Services
U.S. Department of Health and Human Services
7500 Security Boulevard
Baltimore, MD 21244-8016

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 Dr. Oz,

Takeda Pharmaceuticals America, Inc. (Takeda) appreciates the opportunity to submit comments to the Centers for Medicare & Medicaid Services (CMS) regarding the *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] Takeda is a global, values-based, R&D-driven biopharmaceutical company focused on creating better health for people and a brighter future for the world. We aim to discover and deliver life-transforming treatments in our core therapeutic and business areas, including gastrointestinal and inflammation, rare diseases, plasma-derived therapies, oncology, neuroscience and vaccines.

As detailed further below, we have four recommendations regarding the ICR. CMS should:

1) Take additional steps to reduce unnecessary data submission burdens associated with the ICR;
2) Avoid using net Part D prices when establishing a Part B MFP;
3) Revise its definition of an "affiliate" to ensure stakeholders who comment on the ICR are not "affiliated" with the manufacturer of a selected drug merely because the manufacturer asks the stakeholder to respond to the ICR; and

[1] Available at: https://www.federalregister.gov/documents/2025/06/30/2025-11979/agency-information-collection-activities-proposed-collection-comment-request.

4) Give more weight to section 1194(e)(2) factors than section 1194(e)(1) factors while maintaining flexibility in how it weights the factors within 1194(e)(2).

I. Despite Efforts to Streamline the ICR, It Remains Overly Burdensome

Takeda strongly supports the Administration's goals of unleashing the capabilities of U.S. private sector companies by cutting regulatory excess and government-imposed inefficiencies.[2] Accordingly, we appreciate that CMS has attempted to streamline the ICR in some respects. Nevertheless, the Administration can do more to cut the ICR's burdens; the ICR continues to place a significant and unnecessary burden on manufacturers. This burden is inconsistent with the Administration's deregulatory goals as well as the requirements of the Paperwork Reduction Act. Much of the data required of manufacturers under the ICR has no clear utility to CMS in setting maximum fair prices (MFPs) and is difficult for manufacturers to compile at all or (at a minimum) to report in the manner CMS requests. The Research and Development (R&D) data sought by the ICR is a good example of these problems. As in the past, the ICR divides R&D into several subcategories and requests data from manufacturers on these distinct subcategories of R&D: subcategories that often do not reflect R&D categories that manufacturers typically collect and retain in the ordinary course of business, and accordingly that are difficult or infeasible to reconstruct and submit to CMS, particularly over a compressed period of time. Further, there is no clear benefit to CMS from imposing this excess data submission on manufacturers. This data-intensive approach is not mandated by the statute. Moreover, CMS has yet to clarify the benefits of mandating the submission of these subcategories rather than a single R&D figure for a selected drug, despite requests from manufacturers for further explanation.

We believe that CMS could streamline the ICR by articulating its goals clearly and limiting the data sought from manufacturers to data authorized by the IRA that CMS specifically intends to use in setting MFPs; by doing so, CMS could reduce needless burdens to CMS reviewers as well as manufacturers and other data-submitters. Takeda encourages CMS to adopt this approach, which is central to the Administration's deregulatory endeavors.

II. CMS Should Not Use Net Part D Prices when Establishing a Part B MFP

As previously shared, Takeda interprets the statute as directing CMS to treat products covered under both Medicare Part B and Part D as distinct products—one for each Part. According to this interpretation, CMS should negotiate and apply an MFP for a Part B selected drug only with respect to Part B, and similarly, negotiate and apply an MFP for a Part D selected drug only with respect to Part D. This approach aligns with the statutory language of the IRA and would also remove a significant amount of the confusion and complexity created by attempting to develop and apply a single MFP to both Part B and Part D.

[2] See, e.g., Executive Order 14192, Unleashing Prosperity Through Deregulation, January 31, 2025.

Furthermore, using "net Part D prices," which include statutory manufacturer discounts specific to Part D, as a basis for setting MFPs in Part B when drugs are utilized in both programs is inappropriate. Integrating Part D manufacturer discounts into Part B MFPs would inappropriately extend discounts created by Congress for the Part D program into the Part B framework.

III. Asking a Stakeholder to Respond to the ICR Should Not Constitute an Affiliation Between the Manufacturer and That Stakeholder

In question 25 of the ICR regarding Respondent Information (a question respondents are required to answer), CMS asks: "Are you or your organization affiliated with the manufacturer of the selected drug or its therapeutic alternative(s)?" CMS then specifies that "[f]or the purpose of this ICR, an individual or organization is 'affiliated with the manufacturer' if the individual or organization receives or has received funding from the manufacturer for research, speaking, or other engagements, and/or any other purpose related to the drug or its potential therapeutic alternative(s) or if the individual or organization has been asked by the manufacturer to respond to this ICR."[3]

This "affiliate" definition could cause confusion, as a manufacturer could inform stakeholders, such as a patient advocacy organization or medical professional society, about the ICR without meaning to ask them to respond to the ICR; but a stakeholder could misunderstand the information and think the manufacturer may be asking them to respond to the ICR. Thus, without any intent to do so, a manufacturer could inadvertently create an "affiliation" with a stakeholder under this unorthodox concept of affiliation. We are concerned that a stakeholder may then be discouraged from responding to the ICR—which involves a considerable amount of work—if it thinks its input may be written off or viewed skeptically as coming from a "manufacturer affiliate." This works against CMS' interest in obtaining robust input on selected drugs from a broad array of stakeholders.

Additionally, we cannot see how asking a stakeholder to respond to an ICR could somehow create an "affiliation" between the manufacturer and stakeholder, irrespective of whether the stakeholder receives any funding from the manufacturer or has any connection to the manufacturer of any type. This concept of an "affiliate" is overly broad and does not reflect the ordinary meaning of an "affiliate."[4] Accordingly, CMS should revise the ICR's definition of an affiliate to remove affiliation based on a manufacturer asking a stakeholder to respond to the ICR.

IV. CMS Should Weigh Section 1194(e)(2) Factors More Heavily Than Section 1194(e)(1) Factors

Section 1194(e) of the Social Security Act specifies the factors that CMS shall consider "as the basis for determining the offers and counteroffers" for a selected drug's MFP. The statute is silent on how CMS

[3] ICR at 47 n.38 (emphasis added).
[4] See, e.g., https://www.oxfordlearnersdictionaries.com/us/definition/american_english/affiliate, defining the noun "affiliate" as "a company, an organization, etc. that is connected with or controlled by another, larger one."

should weight these factors. Takeda has two key recommendations on weighting the factors specified in the statute:

1) CMS should weigh the section 1194(e)(2) factors more heavily than the section 1194(e)(1) factors, recognizing the critical importance of promoting access to drugs with the greatest clinical benefits, especially to patient subpopulations with urgent and unmet needs; and
2) CMS should maintain flexibility in how it weights the factors within section 1194(e)(2), recognizing that the statute does not direct it to prioritize particular factors within 1194(e)(2) and that their relative importance should vary across different selected drugs.

Takeda further recommends that CMS determine the weight of these factors by taking into account the disease area, the relative unmet needs of the Medicare patient population, and the outcomes that are most important to Medicare patients, healthcare providers, and other key stakeholders. Maintaining this type of flexibility will enable CMS to consider the unique needs of each population, including sub-populations with varying disease severity, treatment experience and treatment goals.

With the need for this type of flexibility in mind, however, Takeda also believes it would be helpful for CMS to develop more predictable methodologies to use in evaluating the section 1194(e)(2) factors, especially in identifying therapeutic alternatives to a selected drug. Enhancing transparency on these issues would be useful both to manufacturers of selected drugs and to other stakeholders that submit comments (or that participate in CMS forums on selected drugs). As an example of how CMS could provide greater clarity on the evaluation of the section 1194(e)(2) factors, CMS could specify that in identifying therapeutic alternatives to an indication for a selected drug it would begin with products recommended or preferred by evidence-based clinical practice guidelines and newly launched products with unique treatment profiles but that may not yet have a well-established market position. CMS could specify that it would only depart from specific guidelines along these lines in exceptional circumstances in which it explained the reasons for the departure in its initial offer. More specificity on these points—coupled with appropriate flexibility, as discussed above—could help all stakeholders to focus their comments to CMS and improve the transparency of this critically important process.

* * *

Thank you for considering our comments as you seek to refine the IPAY process for 2028. If you have any questions, please feel free to contact me at Lorena.Ferrara@takeda.com.

Sincerely,

Lorena Ferrara
Senior Director, Public Policy & Reimbursement
U.S. Public Affairs
Takeda Pharmaceuticals America, Inc.

Inspired by patients.
Driven by science.

VIA ELECTRONIC FILING TO: www.regulations.gov

Mr. Chris Klomp
CMS Deputy Administrator and Director of the Center for Medicare
Centers for Medicare & Medicaid Services
7500 Security Boulevard
Baltimore, Maryland 21244-1850

August 28, 2025

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 Mr. Klomp:

UCB, Inc. (UCB) is a global biopharmaceutical company focused on innovating new medicines to treat chronic, severe diseases in neurology and immunology. We are more than 9,000 people globally, inspired by patients and driven by science. Our foundational commitment to crafting sustainable solutions and delivering medicines that aim to improve lives is at the core of all that we do, as we live our purpose each day. Since 1928, we have brought together the expertise, talent, tools, and scientific ingenuity needed to pursue what's right for people living with severe disease and society. UCB is committed to ensuring that all patients have affordable access to the right medicine at the right time, regardless of age, ethnicity, geography, or economic circumstance. Patients are at the heart of everything we do at UCB, from where we invest our research dollars to how we engage with other stakeholders to bring new therapies to market. Every day, we work to ensure that patients have the best individual experience while promoting access to high-quality, coordinated, affordable care and equitable access to medicines for all patients.

UCB appreciates this opportunity to provide comments to the Centers for Medicare & Medicaid Services (CMS) regarding the 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.[1] We acknowledge CMS's efforts to streamline reporting for manufacturers of selected drugs in some areas of the IPAY 2028 ICR and support continued efforts to further enhance and improve information collection. Changes to the ICR, however, should not only strive to reduce reporting burden but also ensure that CMS is collecting data that is accurate and meaningful. Importantly, these changes should not preclude the submission of potentially important and relevant data. As discussed further below, UCB is concerned that some of the proposed changes to the ICR oversimplify assumptions about R&D

[1] Centers for Medicare & Medicaid Services. 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. June 30, 2025, https://www.cms.gov/files/zip/cms-10849.zip

investments and could ultimately lead to inaccurate estimation of manufacturer costs. Specifically, UCB makes the following recommendations to CMS, which are described further herein:

I. Continue to collect information on acquisition costs and consider them within the context of R&D cost and recoupment.
II. Continue to exclude forward-looking market data.
III. Continue to improve its process for selecting and evaluating therapeutic alternatives.

I. CMS should continue to collect information on acquisition costs and consider them within the context of R&D cost and recoupment.

UCB appreciates CMS's efforts to streamline data reporting in the ICR, however, we are concerned that changes to Section C ("Research and Development (R&D) Costs and Recoupment") may lead to the exclusion of relevant cost information. In particular, we oppose the removal of questions related to acquisition costs from Section C and are troubled that the reporting of acquisition costs is completely disallowed. We strongly disagree with CMS's rationale outlined in the IPAY 2028 draft guidance that "acquisition costs are not driven by R&D."[2] On the contrary, R&D investments made by the acquired entity are an inherent factor in valuing and determining acquisition costs. We are concerned that CMS may be basing its decision on an oversimplified and generalized assumption about how acquisition costs may be derived and ignoring a potentially large strategic R&D investment made by manufacturers.

Acquisitions involving unapproved products represent a major risk for manufacturers. Acquiring companies are paying for the costs of R&D already invested in those products without knowing whether those products will be successfully brought to market, a risk that is amplified for manufacturers acquiring early-stage products. Moreover, the complete exclusion of acquisition costs altogether incorrectly assumes that no R&D investments were made prior to the point of acquisition and would effectively amount to a penalty against manufacturers who invested in and successfully launched acquired products.

Acquisitions are also complex, and costs can be difficult to report depending on the nature of the deals, which can often involve licensing arrangements, multiple products at various stages of development, or acquisitions of whole companies. As such, these costs should not be treated as a standardized input or wholly excluded because they are difficult to parse. UCB strongly urges CMS to reincorporate information collection related to acquisition costs into the ICR. In particular, we recommend a return to the approach CMS employed in previous negotiation cycles in which manufacturers reported both total acquisition costs and total acquisition costs of the selected drug, as well as explanations of the allocation methodology. This approach aligns with other fields in the ICR that require manufacturers of selected

[2] Memorandum from Chris Klomp, CMS Deputy Administrator and Director of the Center for Medicare to Interested Parties (May 12, 2025), https://www.cms.gov/files/document/ipay-2028-draft-guidance.pdf.

products to report a numerical amount and then provide a narrative explaining the methodology for the calculation.

II. CMS should continue to exclude forward-looking market data.

UCB is pleased that CMS did not include forward-looking market data as part of the information collection request. As we noted in our comment letter on the IPAY 2028 draft guidance, speculative information is not factual information, and no manufacturer can predict the future. Considering such information would inject inherent uncertainty and inaccuracy into the MFP determination process. In addition, the legislative history of the IRA makes clear that Congress chose not to include forward-looking market data in the manufacturer-specific factors CMS would consider as part of the MFP-setting process. For these reasons, compelling manufacturers to provide such information would not have been consistent with the statute.

III. CMS should continue to improve its process for selecting and evaluating therapeutic alternatives.

UCB commends CMS for taking a holistic approach to gathering data on the availability and use of pharmaceutical-only therapeutic alternatives, as evidenced by the various stakeholder-oriented questions outlined in Section I ("Evidence on Alternative Treatments"). We agree with CMS that soliciting input from patients and other stakeholders can uncover valuable information that will ultimately enhance the totality of data informing the negotiation process; however, we encourage CMS to continue to improve the process by which this data is collected, and how therapeutic alternatives are selected, reviewed, and communicated with manufacturers. In particular, we note that CMS does not disclose to manufacturers the therapeutic alternatives under consideration until after the negotiation process has begun. This timing precludes manufacturers from weighing in on the appropriateness of the selected therapeutic alternatives prior to the initial meetings with CMS and may also result in a missed opportunity for manufacturers to submit relevant clinical, economic, or patient-focused information in a timely manner.

At a minimum, UCB recommends that CMS provide manufacturers with the therapeutic alternatives under consideration, including potential weighting of indications, before the manufacturer meets with CMS to discuss its ICR submission. Providing this information before the initial offer is determined will allow the manufacturer to provide feedback on the appropriateness of therapeutic alternatives, and how each indication should be weighted, before negotiation meetings begin. This change will allow for a more productive negotiation process and aligns with the "Lowering Drug Prices by Once Again Putting Americans First" Executive Order (issued April 15, 2025), which calls for CMS to increase the transparency of the Medicare Drug Price Negotiation Program in the IPAY 2028 Guidance.[3]

[3] The White House. Executive Order 14273. Lowering Drug Prices By Once Again Putting Americans First. (April 15, 2025), https://www.whitehouse.gov/presidential-actions/2025/04/lowering-drug-prices-by-once-again-putting-americans-first/.

In addition, the availability of therapeutic alternatives can vary widely by condition or disease, which means that the number of comparators for each selected drug and volume of data may also vary widely. To ensure the greatest consistency and clinical appropriateness in the selection of therapeutic alternatives, UCB strongly recommends that therapeutic alternatives have the same FDA-approved indication(s) (including the specific level of disease severity) as the selected drug, rather than broadly treat the same disease or condition. For instance, for indications where a product is indicated for a severe form of the disease, CMS should not consider drugs that treat non-severe forms of the disease.

* * *

UCB appreciates the opportunity to provide input on CMS's initial ICR forms. We respectfully urge CMS to meaningfully consider the feedback submitted herein to help ensure continued drug innovation and that patient interests are upheld during IRA implementation. If you have any questions, please feel free to contact Christine Liow, U.S. Public Policy Lead, at Christine.Liow@ucb.com.

Sincerely,

Patty Fritz
Vice-President, U.S. Corporate Affairs
UCB, Inc.