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December 19, 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: 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 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; 30-day 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.

There have been limited changes since the initial IPAY 2026 Negotiations Data Elements ICR, and we continue to be concerned with the significant volume of data and related submission burden. Consistent with the Administration's stated goals to reduce regulatory burden that stifles American businesses and ingenuity, we continue to 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

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beneficiaries. We further ask CMS to provide transparency into how the submitted elements are weighted and used to inform CMS' initial offer.

We recommend CMS adopt J&J's recommendations submitted on August 28, 2025 in response to the 60-day ICR, which are summarized at a high level below.

Simplify and improve the process for reporting "Research & Development Cost and Recoupment."

- Maintain that the calculation of the "costs for failed and abandoned" drugs not be limited by mechanism of action
- Include acquisition costs in the calculation of drug development costs and recoupment.
- Allow for cost of capital and inflation adjustments in calculation of manufacturer's recoupment.

Leverage CMS' discretion to more adequately consider the clinical profile of the drug and ensure a transparent process in doing so.

- 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 are arbitrary and hinder the quality of information available to the Agency.

In addition to the recommendations above, we recommend CMS adopt the following changes to new modifications made in the 30-day ICR.

Remove Reporting Requirements for Average Sales Price for Quarters that Do Not Affect 2025 Payment

J&J acknowledges that Questions 14 and 15 under Section G were added for reporting of ASP in order to account for Part B selected drugs in IPAY 2028. Question 14 requires submission of ASP, ASP unit, and total units sold for the last two sales quarters of calendar year 2025 (ending December 31, 2025) and J&J urges CMS to remove this question requiring Q3 and Q4 2025 ASP reporting from the IPAY 2028 ICR, as these quarters do not impact reimbursement in 2025. There is a two-quarter lag between the time that sales used

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in the ASP calculation take place and the effective date of the payment limits.[1] For example, Q4 2025 ASP reported in Q1 2026 does not affect payments until Q2 2026 and therefore could not have influenced reimbursement at the ICR submission deadline. For these reasons, CMS should not require inclusion of Q3 or Q4 2025 ASP in the ICR.

Remove Addition of Average Sales Price (ASP) Other Questions Under Section G that Are Already Available to CMS

As with other data points required under Section G, manufacturer-reported ASP is already available to CMS, and CMS should not require duplicative reporting of information already available to federal agencies (Best Price, Federal Supply Schedule (FSS) price, Big Four price). Question 14 is unduly burdensome because Q4 2025 ASP is calculated and reported during Q1 2026. Mandating duplicative Q4 2025 pricing submissions while manufacturers are still performing statutory calculations (such as unit rebate amount (URA) validation and 340B calculations) for the March 2026 IPAY 2028 ICR deadline and during the first quarter of IPAY 2026 MFP effectuation is unnecessarily burdensome.

We ask CMS to relieve manufacturers of the significant unnecessary burden imposed by the required reporting of duplicative data that are already reported to federal agencies (including ASP, Best Price, Federal Supply Schedule (FSS) price, Big Four price).

Remove Existing and Newly Reduced Character Limitations

In the 30-day ICR, we are concerned that CMS is further restricting existing character limitations for questions under Section I which seek patient or caregiver (to 6,000 from 36,000), clinical (18,000 from 36,000), health research (18,000 from 36,000), and manufacturer-focused input (6,000 from 36,000). We ask CMS to remove these arbitrary and unnecessary character limitations which may challenge the ability for stakeholders to provide complete responses.

J&J opposes the character limits in the ICR, as such limits impose an undue burden on manufacturers by requiring them to truncate complete responses, restricting the ability of manufacturers to provide complete information. As a result of character limitations, manufacturers may need to make reasonable assumptions, which is not recognized in the Certification Statement. Considering the significant ramifications of providing incomplete or inaccurate information, including the risk of civil monetary penalties, manufacturers should have the ability to provide as much detail as needed in the ICR form in order to

[1] https://www.cms.gov/files/document/frequently-asked-questions-faqs-asp-data-collection.pdf

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provide complete and accurate information. Therefore, we urge CMS to remove word limitations throughout the ICR form.

Support for Removal of Requirement to Identify "Composition of Matter" Patents

J&J supports CMS' removal of the requirement for manufacturers to identify "composition of matter" patents because 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. We agree that all patents covering a medicine should be considered equally.

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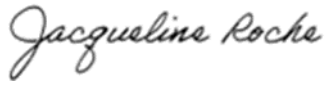
J&J appreciates the opportunity to submit comments in response to the Drug Price Negotiation for Initial Price Applicability Year 2028 under Sections 11001 and 11002 of the Inflation Reduction Act (IRA) Information Collection Request (ICR) Forms (CMS-10849, OMB 0938-1452). We urge CMS to revise the ICR 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 A

August 28, 2025

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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

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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.

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.[2] 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."[3]

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

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[2] 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*
[3] 5 C.F.R. § 1320.5(d)(1)(i)-(iii)

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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*
- *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 outlined 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

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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.
- *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.

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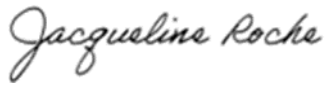
While the cost-related factors are required, CMS should use its discretion to more adequately consider the clinical profile of the drug and ensure a transparent process in doing so. We urge CMS:

- 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.

***

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,



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