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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 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

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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

Jacqueline Roche
Head, Payment and Delivery Policy
Johnson & Johnson

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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;
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.

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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."*[1]

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 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

[1] 5 C.F.R. § 1320.5(d)(1)(i)-(iii)

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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".

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.

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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, 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.

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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 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.

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

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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

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".

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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
  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

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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 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.

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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

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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,

Jacqueline Roche
Head, Payment and Delivery Policy & Global Policy Institute
Johnson & Johnson Worldwide Government Affairs & Policy