Bristol Myers Squibb™

VIA ELECTRONIC DELIVERY

July 14, 2025

Chris Klomp
CMS Deputy Administrator, Director of the Center for Medicare
Centers for Medicare & Medicaid Services
200 Independence Avenue SW
Washington, DC 20201

Re: Negotiation Program Drug Selection for Initial Price Applicability Year 2028 under Sections 11001 and 11002 of the Inflation Reduction Act (IRA) Information Collection Request (ICR)

Bristol Myers Squibb (BMS) appreciates the opportunity to comment on the Centers for Medicare & Medicaid Services (CMS) *Negotiation Program Drug Selection for Initial Price Applicability Year 2028 under Sections 11001 and 11002 of the Inflation Reduction Act Information Collection Request ("Drug Selection ICR" or "ICR")*.[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, Negotiation Program Drug Selection for Initial Price Applicability Year 2028 under Sections 11001 and 11002 of the Inflation Reduction Act Information Collection Request" (May 13, 2025), *available at* https://www.cms.gov/regulations-and-guidance/legislation/paperworkreductionactof1995/pra-listing/cms-10844.

[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 Selection 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.

We thank CMS for the opportunity to provide input on the "Identification and Selection of Renegotiation-Eligible Drugs ICR Form" (Renegotiation ICR). As we discussed in our comments on the IPAY 2028 guidance, transparency in the renegotiation process will be crucial. BMS appreciates the voluntary nature of this Renegotiation ICR allowing manufacturers the opportunity to provide the Agency with data on selected drugs to inform the eligibility and selection of previously selected drugs for renegotiation. However, we emphasize the importance of transparency and clear communication from CMS on this process. Given there are certain instances where selection for renegotiation is at the discretion of the Agency, specifically circumstances where a selected drug has a new indication or has a material change to one of the section 1194(e) factors, it is vital that CMS is clear in their methodology and process for how they determine which drugs are selected for renegotiation. Moreover, CMS should provide clear explanations as to how they weigh data elements for the renegotiation process. Without this clarity from the Agency, it significantly limits manufacturers' ability to adequately prepare for this process and provide data that would be truly influential in CMS' determination of eligibility or selection for renegotiation. BMS continues to ask the Agency for the maximum level of flexibility and transparency in implementing this new renegotiation process, especially in the early IPAYs.

In light of ongoing efforts to increase efficiency and reduce low-value expenditures across the US government, BMS encourages CMS to consider the full cost of renegotiating previously agreed upon MFPs. As HHS continues to restructure and streamline operations, there may be other priorities of greater importance than renegotiation—a process that may or may not produce new savings. GAO found that CMS obligated $49.8 million on average annually to implement drug price "negotiation" in Medicare FY2022-FY2024.[4] Looking forward, CMS expects to obligate $301 million each year for the program, from FY2025-FY2033.[5] Going back to renegotiate previously agreed upon MFPs would greatly increase these costs and would likely divert resources from negotiating newly selected drugs. Indiscriminate use of the renegotiation processes would add new inefficiencies to an already-

[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").

[4] GAO. April 28, 2025. "Initial Implementation of Medicare Drug Pricing Provisions." https://www.gao.gov/products/gao-25-106996

[5] *Ibid.*

burdensome process for all parties, and would undermine future "negotiation" efforts for drugs more generally.

Key comments include:

- **Transparency and Clarity**: The lack of transparency and clarity into how the Agency will utilize the data submitted in the Renegotiation ICR to inform CMS' determination of eligibility and selection for renegotiation is highly concerning. As manufacturers are voluntarily submitting additional data to CMS, it is important that there is a clear, consistent, and transparent methodology being used by the Agency to make this determination. Therefore, CMS should provide more clarity as to how the submitted data impacts or influences the Agency's determinations. This will give manufacturers more predictability and allow for more meaningful data submissions to CMS on the selected drug as there would be a greater understanding of how data elements factor into the Agency's decision-making.
- **Inappropriateness of Methodology**: There are multiple instances in this ICR where CMS is requesting or considering data that does not accurately portray the cost of innovation or reflect the cost of bringing a selected drug to patients – and oftentimes, drug development and delivery are significantly more costly than what CMS' requested costs portray. To the extent possible, we encourage CMS to provide an opportunity for manufacturers to submit data that offers a more complete view of the drug development and delivery process.

General Renegotiation Instructions

- Transparency, Clarity, and Burden: BMS believes the lack of methodology and transparency in how data elements will be weighted is a significant limiting factor in this process that does not allow manufacturers to adequately prepare for renegotiation. If the Agency does not create a meaningful, clear process for how CMS determines eligibility and selection for renegotiation, then manufacturers are at an extreme disadvantage to provide a meaningful, substantive submission. For example, a manufacturer may be motivated to submit the ICR to share new evidence, such as a new study read-out that may not have been mature during the initial negotiation process for the selected drug. While the ICR is voluntary, it is important CMS recognizes the substantial amount of time and preparation required for manufacturers to submit data and evidence to inform the Agency's determinations on eligibility and selection for renegotiation. Without clarity from CMS as to how the various data elements in the ICR are weighted or the Agency's process for establishing the renegotiated MFP, this could lead to inefficiencies and discourage manufacturers from participating in this aspect of renegotiation process. Therefore, we urge the Agency to provide a more transparent methodology with detailed explanations as to how these data submissions influence CMS' determinations in order to improve the overall renegotiation process. This should also include more clarity into the "holistic inquiry" outlined in the IPAY 2028 guidance that CMS proposed to use to inform selection for renegotiation and provide insight into all of the factors CMS considered in their determination of drugs that are eligible and selected for renegotiation. This will give manufacturers more transparency and predictability in the process and inform future submissions for the ICR. Furthermore, we are concerned with the lack of clear instructions and guidance from CMS on how to answer intricate questions, making this process more burdensome than the Agency has outlined. Manufacturers may make reasonable assumptions with their submission, but risk making such assumptions that are not consistent with how other manufacturers may interpret these questions. Thus, creating an inequity in how CMS views this information to make a determination regarding renegotiation. Additionally, we are concerned CMS has not provided a clear timeline in the Renegotiation ICR instructions nor in the IPAY 2028

Guidance for the submission of this ICR to the Agency. It is crucial that this timeline does not make the submission process more burdensome for manufacturers and provides ample time for submissions to truly influence CMS' decision-making process. Therefore, we encourage CMS to provide a reasonable, flexible timeline that reduces the potential burden of submission while allowing for true engagement between manufacturers and the Agency.

- Instructions for Submission of Previously Reported Data: CMS states that manufacturers should not "report any data or costs that were previously reported to CMS under a previous data submission" and "should only include data not previously reported to CMS".[6] BMS disagrees with this assertion as CMS has provided this ICR as an opportunity for manufacturers to provide information to the Agency that informs CMS' determinations for eligibility and selection for renegotiation. If there was data in the initial negotiation process that was undervalued by the Agency then the manufacturer should have the ability to report the previously-submitted data as information that should factor into CMS' determination. Therefore, we recommend that CMS allow for manufacturers to report any data they deem influential to the Agency's determination for renegotiation, regardless of whether that data had previously been reported to CMS.

Section 1: Research and Development Costs and Recoupment

BMS is concerned with the data elements on research and development (R&D) that CMS will use to determine eligibility and selection for renegotiation as they do not adequately capture the value and benefit of a drug to patients and the broader health care system. Therefore, BMS encourages CMS to consider metrics that more adequately represent the selected drug's therapeutic and clinical attributes, which would provide a more complete picture of the drug development and commercialization process to contextualize broader investment and innovation.

BMS is strongly opposed to CMS' consideration of global net revenue to determine whether manufacturers have recouped R&D costs for selected drugs. This would include net sales information from countries outside of the U.S. and has no place in influencing CMS' decision-making for eligible and selected drugs for renegotiation, a U.S. specific policy change for the U.S. market. There is no need for CMS to review or consider global sales data to make a determination regarding a U.S. market specific policy, thereby making it wholly inappropriate for CMS to incorporate it into this process.

For multiple questions, CMS includes instructions regarding adjustments for inflation to dollar amounts. BMS is concerned with this, as CMS is requesting inflation adjustments for costs that are neither traditionally adjusted for inflation nor aligned with U.S. Generally Accepted Accounting Principles (GAAP) standards. Most reporting financial frameworks, such as U.S. GAAP, require financial statements to be prepared on a historical cost basis known as "nominal reporting". This means transactions are recorded at their original value at the time of occurrence, without adjustment for inflation. Historical cost accounting ensures that the reported figures are based on actual transactions and verifiable documentation. Inflation adjustments introduce estimates and assumptions, which reduce the objectivity and reliability of financial information. Additionally, there is no inclusion of a standard for measuring the rate of inflation which introduces subjectivity and complexity to providing data to these questions. Inflation rates vary depending on the index (e.g., CPI-U, CPI-W, C-CPI-U, etc.) and the methodology used. Therefore, not having a standard for inflation adjustment will introduce inconsistency across manufacturers and across submissions. We request that CMS not adjust these figures for inflation to preserve consistency with U.S. GAAP and comparability across manufacturers.

[6] CMS, Drug Selection ICR, p. 20.

Section 2: Current Unit Costs of Production and Distribution

BMS is concerned that the Current Costs of Production and Distribution framework is too narrow in scope and does not accurately reflect the realities of bringing a selected medicine to market. Additionally, we note that there could be legitimate business transactions necessitated by patient access concerns that result in manufacturers incurring transfer prices. Therefore, we request CMS consider a broader view of costs of production and distribution related to patient access to medicines.

Section 3: Prior Federal Financial Support

In CMS' consideration of data related to prior federal financial support, the only relevant data 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 narrow this definition.

Section 4: Patents and Exclusivities

BMS supports the protection of intellectual property (IP) rights and believes that an effective 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 information CMS is considering could contradict this framework that was intended to protect and encourage innovation. Additionally, CMS' requests for patent information relating to the selected drug are overly broad and ambiguous. This ambiguity is further complicated by the 300-word limit on the Explanation of Patents (Expired and Non-Expired) and Patent Applications (Question 9).

Section 5: Market and Revenue and Sales Volume Data

For the Manufacturer U.S. Commercial Average Net Unit Price and the Manufacturer U.S. Commercial Average Net Unit Price- Best (Question 12), CMS requests that manufacturers submit total unit volumes. However, these two price points are likely offered on completely different sets of volumes (i.e., the Manufacturer U.S. Commercial Average Net Unit Price-Best is often offered to a very limited set of customers, likely no more than one, and therefore applies to a very limited volume of units). Therefore, CMS could erroneously interpret the data and correlate the best price with the total commercial unit volume. The appropriate approach would be for CMS to remove the commercial-best price, at a minimum, CMS should separate the total unit volumes between the Manufacturer U.S. Commercial Average Net Unit Price and the Manufacturer U.S. Commercial Average Net Unit Price-Best.

Section 6: New Indications and Evidence About Therapeutic Alternatives

We continue to encourage 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 go 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. We appreciate CMS providing the opportunity for manufacturers to submit data that reflects and speaks to the added value the selected drug brings to patients. However, CMS significantly inhibits this provision of data with the 3,000 word count limit for both questions. Manufacturers have limited opportunity to

share evidence about therapeutic alternatives and it is difficult to provide complete, comprehensive evidence across indications with these constrained limits. For example, a drug with 20 indications could have no more than 150 words for each indication making it near impossible to provide detailed and thorough evidence within the proposed word limit currently imposed in the form. Therefore, we request CMS increase the word limit and allow for the submission of supporting exhibits (i.e., charts, graphs, etc.).

Additionally, we continue to caution CMS on the consideration of off-label therapeutic alternatives, as well as those in different pharmacologic classes, unless supported in either one or more of the compendia or in peer-reviewed medical literature. It is important that CMS prioritize and consider the most appropriate therapeutic alternatives in their determination of eligibility and selection for renegotiation.

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BMS appreciates the opportunity to comment on the Drug Selection 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/

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