Bristol Myers Squibb™

VIA ELECTRONIC DELIVERY

December 23, 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" (November 25, 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

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] We offer these recommendations to help mitigate against the negative consequences the ICR would have on innovation and, most importantly, patients.

We reiterate our previous comments below as well as provide new comments for consideration.

Summary of Previous BMS Comments

- **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, the lack of transparency in how CMS weighs the data elements submitted continues to be a key point of concern and increases the burdensome nature of the submission. This opacity severely limits the ability to appropriately prepare for the MFP process and puts manufacturers – and other stakeholders – at an extreme disadvantage to provide a meaningful submission. A more transparent methodology that includes a clear, formulaic approach as to how CMS weighs each factor in the establishment of the initial offer provides manufacturers with more predictability and a better understanding of how the Agency adjusts the MFP based on the submitted data. We urge CMS to work and engage with manufacturers to seek learnings that can inform how the Agency can reduce burden and provide more transparency in the future.
- **Inappropriateness of Methodology**: BMS remains concerned that the data requested by CMS does not accurately reflect the true cost of innovation or getting a selected drug to patients –

"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.

[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").

and often, costs associated with drug development and delivery are significantly higher than what the Agency's requested costs portray. As a result, CMS risks undervaluing these medicines as the requested information would lack the data essential to provide a comprehensive, accurate assessment of these costs. Therefore, BMS strongly urges CMS to place less emphasis on factors such as R&D and 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, the BMS urges CMS to considerably de-emphasize the magnitude of adjustment based on manufacturer-specific data. Therefore, we ask that CMS only finalize submission requirements that are essential for operationalizing the MFP process and to do it in the least burdensome manner possible.

- **Evidence About Therapeutic Alternatives**: 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. Furthermore, it is imperative that CMS consider a robust body of information and critical elements to capture the full- and long-term value of a treatments, including health outcomes, both from clinical trials and real-world evidence, medical association guidelines, and Medicare-recognized compendia. 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. 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.

<u>Additional, New BMS Comments</u>

- **Evidence About Therapeutic Alternatives**: BMS appreciates the Agency's revision of the question on therapeutic advance and unmet need (Question 37) to be split into distinct questions, 37a and 37b. However, we are concerned that the Agency has modified the character limit on questions related to the identification of relevant clinical outcome measures CMS should consider in its evaluation of clinical comparative effectiveness (Question 35b) as well as the identification of specific populations and patient experiences (Question 38). Reducing the character limit significantly hinders a manufacturer's ability to provide detailed, comprehensive evidence on a selected drug. Placing undue constraints on responses not only risks increasing the burdensome nature of the ICR dossier submission but inhibits invaluable information sharing between the Agency and manufacturers on the benefit these medicines bring to patients. Therefore, BMS recommends CMS increases the character limits on these questions.

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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 Rachel Licata, Vice President, U.S. Policy & Research, U.S. Policy & Government Affairs, at rachel.licata@bms.com.

Sincerely,

/s/

Rachel Licata
Vice President, U.S. Policy & Research
U.S. Policy & Government Affairs