Bristol Myers Squibb™

VIA ELECTRONIC DELIVERY

December 23, 2024

Office of Management and Budget (OMB)
725 17th Street NW
Washington, DC 20503
Attention: 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 (ICR) (CMS-10849, OMB 0938-1452)

Bristol Myers Squibb (BMS) appreciates the opportunity to comment on the Centers for Medicare & Medicaid Services (CMS) *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) ("Negotiation Data Elements 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]

[1] CMS, "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)" (Nov. 25, 2024), *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) 2027.

While BMS appreciates the opportunity to provide comments on the Negotiation Data Elements ICR, we are disappointed that CMS did not incorporate any of our feedback from the most recent *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)* comment opportunity.[3] Just as CMS has learned from the IPAY 2026 process, so too have stakeholders, including manufacturers—and it is critical for CMS to apply those learnings to IPAY 2027 and make meaningful, positive changes.

We have continued to share 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,[4] and we offer these comments to help mitigate against the negative consequences the ICR would have on innovation and, most importantly, patients. In general, an ICR is not an adequate mechanism for providing public input and dialogue on the important process of establishing the wide range of data and metrics that CMS will use in MFP-decision making. We continue to note, however, that the current process is not sufficient to address (to the extent possible under the IRA) the full value of a selected medicine. For factors that are not tied to the value a selected medicine offers to patients, caregivers, providers, and the Medicare program, we strongly urge CMS to only collect essential information for setting the MFP and to do so in the most effective and accurate way possible. And importantly, we continue to ask the Agency for the maximum level of flexibility and transparency in implementing this process, especially in the early IPAYs. BMS also strongly supports CMS' efforts to directly and actively solicit focused input from patients, beneficiaries, caregivers, and consumer and patient organizations, but CMS must make significant improvements in order for the process to be more meaningful, comprehensive, transparent, deliberative, and relevant to understanding a medicine's value.

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

Summary of Previous BMS Comments

- **Scope and Burden of Information:** BMS remains concerned with both the scope and burden of information CMS will require as part of the ICR submission. For example, manufacturers will have exceedingly short timeframes for completing and submitting the data submission—which could require multiple individuals compiling complex data sources and then submitting in a form acceptable to CMS for submission. This process can be even more burdensome than CMS had outlined. Even for the appropriate data elements that manufacturers can provide, the breadth of information coupled with the strict timelines will make the burden exceptionally high. And without clear instructions and guidance from CMS on how to answer intricate questions, manufacturers may make reasonable assumptions with their submissions, but risk making such assumptions that are not consistent

[3] CMS, "Negotiation Data Elements and Drug Price Negotiation Process for Initial Price Applicability Year 2027 under Sections 11001 and 11002" (July 2, 2024), *available at* https://www.cms.gov/regulations-and-guidance/legislation/paperworkreductionactof1995/pra-listing/cms-10849.
[4] 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 2027 and Manufacturer Effectuation of the Maximum Fair Price (MFP) in 2026 and 2027" Draft Guidance, released on May 3, 2024 (hereinafter referred to as the "IPAY 2027 comments") and other corresponding IRA comment letters.

with how other manufacturers may interpret their obligation, thus creating an inequity in how CMS views this information to establish an MFP. There may also be information to which manufacturers do not reasonably have access or cannot provide with reasonable efforts, further driving inequities across data submissions and subsequent evaluations. And many of the requested data, such as government price reporting information, are already available to CMS, while others are publicly available, creating additional and unnecessary burden on manufacturers.

- **Inappropriateness of Methodology:** Importantly, CMS' requested costs do not accurately portray the cost of innovation or reflect the cost of getting a selected drug to patients—and oftentimes, drug development and delivery are significantly more costly than what CMS' requested costs portray. For example, no other health technology assessment (HTA) process in the world includes supply side factors (*e.g.*, R&D costs, public funding) to determine the value of a product and/or to inform price considerations. BMS strongly urges CMS to place a lesser emphasis on factors such as R&D recoupment and more emphasis on the selected drug's therapeutic and clinical attributes, which is the true measure of innovation. The manufacturer-specific data elements are also not reflective of the realities of supplying product to the market, as channel complexities, access, and additional costs are not accounted for in the submission. To the extent possible, we urge CMS to account for these measures by providing an opportunity 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 also asserts that 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). And practically speaking, only information that is currently available via standard price reporting conventions should be included in the manufacturer's submission. The IRA statute only refers to the submission of a manufacturer's non-FAMP, and not the other pricing metrics in the current ICR, and BMS urges CMS to remove these extraneous reporting requirements. We also ask CMS to only finalize submission requirements that are essential for operationalizing the MFP process and do so in the least burdensome way possible.

- **Evidence About Alternative Treatments:** While we have been encouraged that CMS appears receptive to a broad and holistic view of value, we remain deeply concerned with the difficulty for manufacturers to respond with constrained limits and provide comprehensive evidence on un-specified therapeutic alternatives across multiple indications, particularly in complex disease states where medicines are used in combination and/or across multiple lines of therapy. The burden associated with this is tremendous, and the Agency could alleviate some of this burden by creating scoping discussions to improve efficiency for both manufacturers and CMS.

- **Patient and Stakeholder Input:** BMS supports CMS' efforts to directly and actively solicit focused input from patients, beneficiaries, caregivers, and consumer and patient organizations as it implements IPAY 2027. It is critical for CMS to consider a variety of perspectives throughout the data submission and review process, and we are pleased to see that CMS is improving the data collection process with information more closely aligned to respondents' area of expertise. We applaud CMS for proposing to approach different stakeholders uniquely and provide a more appropriate forum and method for stakeholders to deliver the information relevant to their areas of expertise, as opposed to a one-size-fits-all ICR submission. While this is a good first step, BMS recommends the Agency adopt a structured consultation process where relevant stakeholders are permitted to provide input in a format most suited to their expertise; this type of tailored approach could underscore the importance and value of stakeholders' submissions and involvement and ultimately encourage more participation. We also urge CMS to make the stakeholder input process as user-friendly as possible.

Additional, New BMS Comments

- **Dollar Amounts Inflation Adjustments:** BMS is concerned with how CMS introduces additional instructions regarding adjustments for inflation to dollar amounts in the updated ICR. The document includes a contradictory directive that creates confusion: it initially advises against adjusting dollar amounts for inflation but then requires inflation adjustments for historical costs that are neither traditionally adjusted for inflation nor aligned with U.S. Generally Accepted Accounting Principles (GAAP) standards. This inconsistency undermines the clarity and practical application of the guidance, which could leave manufacturers uncertain about how to proceed with the data submission and also inconsistently report information across submissions.

  Specifically, when requesting global, total lifetime net revenues for the selected drug (Question 6a), CMS states to "*not* make adjustments for inflation" (emphasis added).[5] However, in the same section, the Agency later requests manufacturers to "report the global, total lifetime net revenue for the selected drug for the global, total lifetime net revenue period *after* making adjustments for inflation and explain the methodology used to make such adjustments for inflation" (emphasis added).[6] A similar inconsistency is observed in Questions 9: Federal Funding Support Amount and 10: Explanation of Calculation of Federal Financial Support.[7]

  Most financial reporting 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. Therefore, adjusting total lifetime net revenues would deviate from this standard and make the financial information submitted inconsistent with U.S. GAAP.

  Additionally, the guidance introduces subjectivity and complexity by not establishing a standard for measuring the rate of inflation. 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. BMS requests that the Agency not adjust these figures for inflation to preserve consistency with U.S. GAAP and comparability across manufacturers.

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BMS appreciates the opportunity to comment on the Negotiation Data Elements ICR. Should you have any questions or concerns, please contact Caroline Tucker, Director, Executive Branch Strategy, at caroline.tucker@bms.com.

Sincerely,

/s/

Katie Verb
Senior Director, Federal Policy & Reimbursement
U.S. Policy & Government Affairs and U.S. Policy Communications

[5] CMS, Negotiation Data Elements ICR, p. 20.
[6] *Id.*
[7] *Id.* at pp. 25-26.