Bristol Myers Squibb™

VIA ELECTRONIC DELIVERY

May 1, 2025

Office of Management and Budget (OMB)
725 17th Street NW
Washington, DC 20503
Attention: OMB Desk Officer

Re: Medicare Transaction Facilitator for 2026 and 2027 under Sections 11001 and 11002 of the Inflation Reduction Act (CMS-10912)

Bristol Myers Squibb (BMS) appreciates the opportunity to comment on the Centers for Medicare & Medicaid Services (CMS) *Medicare Transaction Facilitator for 2026 and 2027 under Sections 11001 and 11002 of the Inflation Reduction Act Information Collection Request* ("MTF 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]

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

[1] CMS, "Medicare Transaction Facilitator for 2026 and 2027 under Sections 11001 and 11002 of the Inflation Reduction Act (IRA)" (Apr. 1, 2025), *available at* https://www.cms.gov/medicare/regulations-guidance/legislation/paperwork-reduction-act-1995/pra-listing/cms-10912.

[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's 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.

consideration of and response to stakeholder feedback on its proposals, particularly as the Agency updates its approach for effectuating the MFP for selected medicines in Initial Price Applicability Years ("IPAYs") 2026 and 2027.

While BMS thanks CMS for the opportunity to provide additional comments on the MTF ICR, we are disappointed that CMS did not incorporate our feedback from the previous *Medicare Transaction Facilitator for 2026 and 2027 under Sections 11001 and 11002 of the Inflation Reduction Act (IRA)* comment opportunity.[3] We intend for our input previously and here to help CMS to improve transparency and clarity of IRA implementation, and our recommendations 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] However, we reiterate that an ICR is not an adequate mechanism for providing public input and dialogue on establishing important processes for how manufacturers must provide access to the MFP to MFP-eligible individuals and entities, as well as data and payment elements. We continue to note our concerns with CMS' approach due to various operational complexities, which are informed by BMS's significant expertise with transaction processing. We hope to work with the Agency to ensure operational success, but in the absence of additional Agency action to remedy these serious concerns, CMS should provide flexibility for manufacturers to establish the appropriate data sets, timeframes, and processes to support compliance and ensure efficient operationalization of the MFP, particularly in the early IPAYs.

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

- **Financial and Operational Burden on Manufacturers**: Despite CMS' proposals, BMS notes our significant financial and operational concerns with the MTF. We are generally supportive of the MTF becoming a "platform" for carrying out critical front-and-back-end functions of MFP effectuation, including the necessary ability to communicate with stakeholders directly involved in the MTF process. Although we recognize the potential of the MTF process to ease the burden on all stakeholders, including manufacturers, BMS notes that in its current state, the MTF would fall short of this goal. MFP effectuation will come at a significant financial and operational cost to manufacturers, particularly for high-volume, high-value products. In the absence of additional Agency action to remedy these serious concerns in advance of January 1, 2026, and to help ensure a transparent and administratively efficient operationalization of the MFP, we continue to ask that CMS provide flexibility for manufacturers to establish the appropriate data sets, timeframes, and processes to support compliance. Given the many operational concerns we have highlighted in past comments, BMS notes that it will be very challenging, if not impossible, for manufacturers to submit a plan by September 1, 2025. We ask CMS to give manufacturers additional flexibility, either with the elements of the effectuation plan, the timeline, or both, in addition to keeping MFP Effectuation Plans confidential. BMS appreciates the additional clarification from CMS on the aspects of the Effectuation Plan that will be provided to MTF DM participants and may be shared with other interested stakeholders. However, we emphasize the importance of protecting manufacturers' proprietary information throughout the process of MFP effectuation; therefore, CMS should limit the distribution of a manufacturer's plan to stakeholders (e.g., dispensing entities) on a need-to-know basis and only in a form and manner that preserves the confidentiality of the manufacturer's proprietary information. To the extent possible, CMS should provide manufacturers with an opportunity to review the redacted versions of their effectuation plans to ensure no confidential information is being released, as well as mandate the MTF to share all dispensing

[3] CMS "Medicare Transaction Facilitator for 2026 and 2027 under Sections 11001 and 11002 of the Inflation Reduction Act (IRA)" (Oct. 28, 2024), *available at* https://www.cms.gov/medicare/regulations-guidance/legislation/paperwork-reduction-act-1995/pra-listing/cms-10912.
[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.

entity information (Appendix A) with manufacturers to allow for improved communication between participating stakeholders in an effort to facilitate a more transparent, compliant MFP effectuation process.

- **Cashflow Concerns**: While the financial strain on dispensing entities is undoubtably an unfortunate outcome of the IRA and one that manufacturers have flagged often for CMS to fix, we do not believe it to be a manufacturer's responsibility to establish a process for remedying potential cashflow concerns, as manufacturers will also be experiencing significant financial strain to effectuate and operationalize MFP payments to dispensing entities. Just as dispensing entities will be financially impacted, so too will manufacturers, not only by the cost of effectuating MFP, but by significant market shifts as a function of the IRA. It is both unrealistic and impossible for manufacturers to take on the responsibility of validating legitimate cashflow concerns and potentially remedying them. Additionally, BMS is concerned that if CMS does not address dispensing entity concerns, we could see significant patient impacts due to new financial incentives which could result in downstream actors' steering patients towards other, non-MFP medicines. We strongly urge CMS to remove manufacturers from the process of resolving any cashflow issues and work with Congress to remedy dispensing entity cashflow concerns in advance of January 1, 2026.

- **MFP/340B Non-Duplication**: BMS understands that CMS does not have the appropriate data inputs to fully operationalize the MFP/340B non-duplication provision, and we implore the Health Resources and Services Administration to work with CMS to provide adequate specificity to effectuate this provision in advance of January 1, 2026. In the absence of this Agency collaboration, however, the burden continues to be put on the manufacturers to create a valid and reliable process for identifying 340B-eligible claims. Given CMS' position that manufacturers must resolve these issues independently, but with the challenges if not the impossibility of doing so now, BMS urges CMS and more broadly the Secretary of Health and Human Services to acknowledge that a 340B rebate model is an appropriate and viable solution and would help both manufacturers and CMS implement MFP effectuation. In the absence of Agency action, and in light of the vast complexity of the 340B program, CMS should expressly acknowledge that manufacturers may establish, receive, review, and, as necessary, audit MFP validation data to ensure manufacturers have provided MFP access in accordance with the statute.
    - Manufacturer Payment Elements: To facilitate accurate refund payments for 340B claims that are also MFP eligible, BMS requests that additional reason codes be included to address the following scenarios:
        - When the MFP equals the ceiling price, and no MFP refund will be issued.
        - When the 340B ceiling price is higher than the MFP, manufacturers may pay the difference between the 340B ceiling price and the MFP.

      For claims identified outside of the 14-day window that are 340B eligible, BMS requests to use the credit/debit ledger to make appropriate adjustments using the relevant reason codes.

- **Payment Timelines**: Based on our significant experience with transaction processing, we again reiterate our compliance concerns related to verifying claims data within this timeline due to the new processes that need to be developed to facilitate compliant MFP effectuation, including the additional 340B program complexity and short timeframe for developing an MFP effectuation plan. Therefore, we ask CMS to lengthen the 14-day prompt payment window or, at a minimum, allow manufacturers who do not utilize the MTF payment facilitation process to agree with dispensers on an acceptable and compliant payment timeline. CMS could also consider starting the 14-day prompt payment window only when the manufacturer obtains all of the data necessary to validate MFP eligibility, including whether the unit is a 340B unit.

- **Payment Elements Examples**: To benefit both Agency and manufacturer compliance, we ask CMS to create numeric/strawmen examples in support of Appendix C, similar to the user-friendly mathematical guides CMS created to support the implementation of the Medicare Prescription Payment Plan. We believe having these examples will not only aid in transparency in oversight, but perhaps uncover unique circumstances related to dollar amounts and refunds that may not fit neatly into CMS' pre-determined payment elements, which might warrant additional refinements to Appendix C in advance of January 1, 2026. Should CMS choose not to issue these examples in coordination with the next ICR, we urge the Agency to provide and work through these examples during the monthly manufacturer MTF calls.

- **Complaints and Disputes**: We ask CMS to further refine this complaint and dispute functionality to ensure sufficient procedural protections, including by establishing a formal appeals process for disputes to provide guardrails and recourse for manufacturers. Additionally, we ask CMS to clarify that if a claim is going through the dispute process that the obligation for manufacturers would be essentially "frozen" until after CMS makes a determination – and relatedly, that once CMS makes a determination, the 14-day prompt payment window would then restart. Finally, CMS must ensure that dispensers/other stakeholders engage in good faith efforts with manufacturers to resolve MFP disputes prior to submitting complaints through CMS' formal process.

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BMS appreciates the opportunity to comment on the MTF 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 and Communications, at katie.verb@bms.com

Sincerely,

/s/

Katie Verb
Executive Director, Policy & Reimbursement and Strategic Alliances
U.S. Policy & Government Affairs and Communications