May 1, 2025

Submitted Electronically

William N. Parham, III
Director
Centers for Medicare & Medicaid Services, Office of Strategic Operations and Regulatory Affairs
Division of Regulations Development
Attention: CMS-10912/OMB Control Number 0938-NEW
Room C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

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

Dear Director Parham:

AstraZeneca appreciates this opportunity to provide comments to the Centers for Medicare & Medicaid Services (CMS) on the proposed, revised Information Collection Requests (ICRs) for the implementation of Maximum Fair Price (MFP) and the Medicare Transaction Facilitator (MTF) for 2026 and 2027.[1]

AstraZeneca is a global, science-led biopharmaceutical company that focuses on the discovery, development and commercialization of prescription medicines, primarily for the treatment of diseases in three therapy areas: Oncology, Cardiovascular, Renal & Metabolism (CVRM) and Respiratory & Immunology. We are also working to solve the challenges for rare disease patients through Alexion, AstraZeneca Rare Disease. AstraZeneca operates in over 100 countries and its innovative medicines are used by millions of patients worldwide. AstraZeneca is the primary manufacturer for two selected drugs: FARXIGA (dapagliflozin), selected for initial price applicability year (IPAY) 2026; and CALQUENCE (acalabrutinib), selected for IPAY 2027.

AstraZeneca appreciates CMS' efforts in providing the ICRs for public comment through two rounds and for the areas where CMS has provided some additional clarity in the revised ICRs. However, AstraZeneca remains concerned that the agency has not yet provided enough information for relevant private sector partners, including AstraZeneca and the entities that dispense our selected drugs, to prepare plans for MFP effectuation for 2026 and beyond.

Effectuating MFP for Medicare beneficiaries beginning January 1, 2026, will be one of the most complex implementation efforts undertaken by CMS in decades, on par with the efforts to roll out elements of the Affordable Care Act and the Medicare Part D program. AstraZeneca recognizes the challenges inherent in this effort, and emphasizes that the only path to

[1] https://www.cms.gov/medicare/regulations-guidance/legislation/paperwork-reduction-act-1995/pra-listing/cms-10912.

successfully delivering Medicare beneficiaries access to the MFP for selected drugs starting in January involves ongoing close cooperation between the agency and its private sector partners.

These challenges and the associated uncertainty are not only facing manufacturers, but also dispensing entities. AstraZeneca wants to emphasize that significant concerns have been raised about effectuation by dispensing entities, especially independent pharmacies, not only in their communications with CMS but also through ongoing communication between AstraZeneca and dispensing entities. Successful effectuation of MFP for Medicare beneficiaries will not be possible without more detailed and more frequent communication from CMS to both manufacturers and dispensing entities.

Our comments, organized below by the four separate ICRs released, focus on ongoing areas of concern specific to the ICR forms and do not represent the full spectrum of AstraZeneca's potential concerns with the Medicare Drug Price Negotiation Program and its MFP effectuation process. AstraZeneca urges CMS to provide additional information, as soon as possible, to guide the effectuation plans manufacturers will submit to CMS, as well as both manufacturers' and dispensing entities' efforts to effectuate MFP.

Appendix A: Dispensing Entity Enrollment (Drug Price Negotiation Program MTF DM Dispensing Entity and Third-Party Support Entity Enrollment Form)

As we noted in our comments on the 60-day ICRs, the dispensing-entity enrollment ICR requests that dispensing entities provide their National Council for Prescription Drug Programs (NCPDP) identification numbers, as well as information that is ordinarily provided in NCPDP format, but without specifying that this information be provided in NCPDP format.

For ease of transmitting and processing the information included in this ICR to manufacturers, we recommend that this information be transmitted to the Data Module (DM) of the MTF in NCPDP format, and then transmitted from the DM to manufacturers **(**or the manufacturer's declared effectuation vendor as identified in our submitted Manufacturer Effectuation Plan due 9/1**)** in the same format. These types of claims-level data exchanges currently rely on NCPDP format, and it would be helpful for CMS to specify in the MTF ICR that the data will be provided by dispensing entities and then to manufacturers in this format.

AstraZeneca appreciates CMS' proposal, now finalized in the Contract Year (CY) 2026 Part D rule, to require dispensing entities contracting with Part D plans to participate in the MTF DM, as well to shorten the time period for initial submission of Part D Event (PDE) records within seven days.[2]

Appendix B: Manufacturer Effectuation Plan ("Drug Price Negotiation Program MTF DM Primary Manufacturer MFP Effectuation Plan Form")

AstraZeneca notes, as we did in comments on the 60-day ICR, that the timeframes for the submission of manufacturers' plans for MFP effectuation leave very little time to address potential concerns from CMS regarding the plans. AstraZeneca appreciates that submitting these plans in September 2025 for IPAY 2026 will provide maximum time for manufacturers to develop these plans and for CMS to refine requirements and expectations, but the short time

[2] 89 Fed. Reg. 99,340 (Dec. 10, 2024) (proposed);

frame between submission of these plans and the MFP's effective date will require CMS to be as responsive as possible to any concerns during that time frame.

In addition, generally speaking, it remains very difficult for AstraZeneca to develop an effectuation plan because so little detail is available regarding the MTF itself. Providing more information regarding the functioning of the MTF PM well before the deadline for manufacturers to submit such plans is essential to the development of meaningful and thoughtful plans by manufacturers.

It similarly remains difficult to assess CMS' burden estimate without more specific information about the MTF. AstraZeneca appreciates that CMS has added to this ICR a recognition that MFP effectuation plans for different drugs will vary, for manufacturers with multiple selected drugs in IPAY 2026 and 2027, but the need for effectuation plans to take into account different drugs only underscores the urgent need for more details about the MTF's functionality.

Question 3: This question requests information from manufacturers regarding their process for contacting, receiving, and responding to inquiries from dispensing entities regarding MFP effectuation. There remain several areas where more clarity would be helpful to understanding the burden involved in resolving disputes and complaints, and planning AstraZeneca's process for intake and handling of such issues, including:

- Whether manufacturers are obliged to respond to inquiries.
- Whether CMS is considering requiring a minimum response time.
- Whether the MTF PM will play a role in communication with dispensing entities if the manufacturer is using the PM.

Question 4: AstraZeneca appreciates that the ICR continues to suggest that manufacturers will have discretion to verify whether a dispensing entity has material cashflow concerns, and is not bound to a dispensing entities self-identification as having such concerns. (AstraZeneca notes that this discretion is also implied in CMS' revision from the 60-day ICR for dispensing entities in Appendix A, Question 3, that information identifying cashflow concerns "will be treated as confidential and shared with Primary Manufacturers for purposes of informing Primary Manufacturer's development of their MFP Effectuation Plan only.")

However, it is worth reemphasizing that manufacturers that plan to rely on the MTF PM may be limited in their ability to describe their plans for mitigating material cashflow concerns from dispensing entities while operational details regarding the MTF PM remain uncertain.

Further, AstraZeneca notes that there are likely to be significant differences between the cashflow concerns posed for dispensing entities by different selected drugs. AstraZeneca appreciates CMS' clarification in that MFP effectuation plans may vary across a manufacturer's different selected drugs, but would further appreciate recognition that plans for addressing material cashflow concerns also should vary across different drugs.

Similarly, the cashflow concerns cited by dispensing entities are likely to evolve over time, and CMS should recognize that manufacturers' plans for addressing such concerns likely will have flexibility to evolve as dispensing entities adjust to MFP effectuation.

Finally, Primary Manufacturers cannot be practically accountable for Secondary Manufacturers' choices regarding MFP implementation and mitigation material cashflow concerns. CMS should

clarify that Primary Manufacturers' plans for addressing material cashflow concerns need not encompass efforts by a Secondary Manufacturer.

Question 6: Regarding manufacturer plans for nonduplication of 340B discounts and the MFP, AstraZeneca reiterates that it intends to comply with CMS' stated expectations for a nonduplication process, and it remains our assumption that manufacturers need not separately seek approval from the HHS entity regulating compliance with the 340B program as part of this process.

We note again that some of the elements requested of manufacturers in the ICRs may not be necessary for the manufacturer to provide where a manufacturer is using the MTF PM for payment processing. In the interest of reducing burden and increasing clarity, CMS should clarify how the information expected would be different for manufacturers using the PM versus manufacturers using their own payment facilitator. AstraZeneca also continues to encourage CMS to consider what role the MTF PM could play in communication with dispensing entities in relation to possible duplicate discounts.

AstraZeneca remains strongly supportive of the proposal outlined by CMS in publishing the CY 2025 Physician Fee Schedule final rule, to "explore establishing a Medicare Part D claims data repository to comply with the statutory obligation for removal of 340B units from Part D drug inflation rebate calculations."[3] A central source for this information will make a significant difference in manufacturers' ability to address concerns around duplicate discounts. A potential clearinghouse may also inform manufacturers' responses to Question 21 of the ICR, which concerns manufacturers' "approach for completing internal auditing to ensure all transactions effectuate MFP in compliance with the final guidance and Negotiation Program requirements." Avoiding duplication of MFP and 340B discounts will be a significant challenge in any scenario, but a Part D claims repository as contemplated by CMS would be a significant aid to this effort and meaningfully reduce the risk of operational issues that affect manufacturers' ability to provide access to MFP.

Appendix C: Manufacturer PM Form ("Medicare Drug Price Negotiation Program Primary Manufacturer Payment Elements Form")

AstraZeneca appreciates the steps toward further details that CMS provides in the revised Manufacturer PM form. For instance, CMS has clarified that, in some cases, "MFP refund amounts transmitted to dispensing entities may differ from the amount directed by the claim-level payment elements in situations such as adjustment by the application of credits," and then spells out how manufacturers may use this functionality (for instance, that "[i]n cases where the payment elements represent a claim that was adjusted or reversed," the manufacturer can still use the selected drug units field to "indicate the new number of units of the selected drug included in the adjusted MFP refund paid").

However, this clarification on the treatment of adjusted or reversed refunds simply underscores the complexity of the process that will be undertaken by the MTF, manufacturers, and dispensing entities, which is still difficult to plan for without more tangible detail on the MTF PM itself.

[3] https://www.cms.gov/newsroom/fact-sheets/calendar-year-cy-2025-medicare-physician-fee-schedule-final-rule

Appendix D: Disputes and Complaints ("Drug Price Negotiation Program Complaint and Dispute Intake Form")

In the overview of the dispute and complaint process, CMS states that complaints and disputes "must be submitted to CMS no later than 120 calendar days from the date of the subject of the complaint or dispute." As AstraZeneca noted in its comments on the 60-day ICR, more clarity is needed in order to ensure that complaints and disputes comply with this requirement: If a dispensing entity does not receive a retrospective refund and submits a complaint regarding this issue, would the "subject of the complaint or dispute" be the date on which the drug was dispensed, the date on which the dispensing entity conveyed the PDE record to the MTF DM, or the date on which the refund would have been due? To maximize clarity, AstraZeneca recommends that CMS begin the 120-day period from the date on which the complaining entity first directly raised the complaint or dispute with the entity against which the complaint or dispute has been raised, which would be a verifiable date for all entities involved.

The agency also does not provide detail on how quickly the complaint or dispute will be provided by the system to manufacturers (or other parties). In order for the complaint and dispute functionality to be useful for all entities involved, including dispensing entities, CMS should set an expectation for a timeframe for the dissemination of complaints and disputes, and the timeframe expected for responses. Given that CMS has provided 120 days provided for the initiator of the complaint or dispute to submit the matter to the complaint/dispute function, the agency should consider using the same, 120-day timeframe for the initial response by the entity against which the complaint or dispute has been raised.

Further, AstraZeneca reiterates its concern from the 60-day ICR comments that complaints or disputes lodged against manufacturers or other entities may contain proprietary information or other information that should not be made public. CMS can and should state clearly—as it has provided additional details regarding confidentiality of PM elements manufacturers submit to the ICR—that the agency intends to ensure any complaints or disputes filed will be kept confidential given the sensitivity of the information involved and, if possible, provide details on how it plans to ensure such complaints and disputes are kept confidential.

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Thank you for considering and incorporating AstraZeneca's comments. AstraZeneca appreciates CMS' commitment to cooperative efforts with manufacturers and dispensing entities to ensure successful implementation of MFP for the sake of Medicare beneficiaries, and AstraZeneca is ready to provide feedback on CMS' plans as they continue to evolve.

If you have any questions or would like additional information, please contact me at sarah.arbes@astrazeneca.com.

Sincerely,

Sarah C. Arbes
Head of Federal Affairs and Policy