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May 1, 2025

William Parham
Director
Centers for Medicare and Medicaid Services
Office of Strategic Operations and Regulatory Affairs
Division of Information Collections and Regulatory Impacts
Attention: CMS-10912

Re: Information Collection Request: Medicare Transaction Facilitator for 2026 and 2027 under Sections 11001 and 11002 of the Inflation Reduction Act (IRA)

Dear Director Parham,

Pfizer, Inc. appreciates the opportunity to provide comments to the Centers for Medicare & Medicaid Services (CMS) on the second round Information Collection Request (ICR) for the *Medicare Transaction Facilitator for 2026 and 2027 under Sections 11001 and 11002 of the Inflation Reduction Act (IRA)*, which CMS released on April 1, 2025. Pfizer Inc. is a research-based, global biopharmaceutical company. We apply science and our global resources to bring therapies to people that extend and significantly improve their lives through the discovery, development and manufacture of medicines and vaccines.

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Detailed Comments

I. MTF ICR Supporting Statement

Issue: CMS has issued a new information collection request (ICR) related to the implementation of the Medicare Drug Price Negotiation Program, which includes mandatory participation for Primary Manufacturers of selected drugs in the Medicare Transaction Facilitator (MTF) system. CMS has estimated total annual burden for Primary Manufacturers across various forms.

Pfizer Comment: Pfizer appreciates CMS's effort to update the burden estimates for Primary Manufacturers to complete the applicable ICR forms based on comments to the initial ICR. However, Pfizer continues to disagree with the total annual burden estimates published in the Supporting Statement. The burden for Primary Manufacturers to complete these forms remains significantly underestimated.

The MFP Effectuation Plan Form will require input from various divisions within each Primary Manufacturer, including multiple staff from the groups identified by CMS, as well as outside legal counsel and consultants. Additionally, given the volume of claims data that selected drug manufacturers will be receiving on a near-daily basis, the Agency's estimate of only two staff dedicated to sampling and analyzing data for the MTF DM payment elements form is inadequate.[1]

Furthermore, the ICR continues to note that "CMS also anticipates some Primary Manufacturers will need to develop novel internal processes to establish their approach to MFP effectuation and engage with the [Medicare Transaction Facilitator (MTF)] system." However, the total annual burden estimates do not adequately reflect the

[1] Table 11

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necessary staff resources and expertise required to develop and implement these significant internal processes. CMS also fails to include adequate burden estimates for the time Primary Manufacturers will need to fully integrate their internal systems with the MTF system in order to gain a thorough understanding of MTF processes and successfully complete the MFP Effectuation Plan Form.

Pfizer would strongly recommend that CMS engage with Primary Manufacturers to develop more realistic estimates of the time and burden costs associated with these requirements.

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

Issue: CMS does not propose to make dispenser information reportable on the enrollment form that will be available to manufactures of selected drugs through the MTF DM portal.

Pfizer Comment: Pfizer recommends that CMS make dispenser information reported on the enrollment form available to manufacturers of selected drugs through the MTF DM portal. This would be like how CMS plans to make manufacturer MFP effectuation plans available to dispensers through the MTF DM portal and would ensure critical information from both dispensers and manufacturers is available to all parties involved in MFP effectuation.

I. Appendix B: Drug Price Negotiation Program MTF DM Primary Manufacturer MFP Effectuation Plan Form

Issue: In General Instructions, CMS proposes that, in the event a Primary Manufacturers holds more than one selected drug with agreed upon MFPs, the manufacturer will no longer be required to submit a separate MFP effectuation plan for each selected drug but rather instructs manufacturers to submit one MFP plan to cover all selected drugs. Alternatively, if the Primary Manufacturer has an effectuation approach that is differentiated across selected drugs, the Primary Manufacturer should indicate such within the details of its Plan, noting which approach is attached to which drug where applicable.

Pfizer Comment: Pfizer appreciates the clarification made by CMS that the MFP Effectuation Plan Form can cover all of a manufacturer's selected drugs as opposed to needing to separately respond for each selected drug.

Section 1: Primary Manufacturer's Description of Participation in the MTF PM

Issue: In Question 2C, CMS proposes to verify primary manufacturer banking information by requiring Primary Manufacturers to upload a voided check or a letter from a bank. If uploading a letter from a bank, the letter must be on bank letterhead and include the account holder's name, the account number, routing number, signature from a bank representative and the representative's contact information for verification purposes.

Pfizer Comment: Pfizer urges CMS to implement a streamlined process for verifying bank account information for manufacturers participating in the MTF PM. It is more efficient for manufacturers to complete an electronic funds transfer (EFT) authorization form instead of providing a voided check or bank letter. This approach has been used successfully in other CMS programs, including the prior Medicare Part D Coverage Gap Discount Program (CGDP). Pfizer believes CMS should adopt a comparable approach for MFP effectuation.

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Section 2: Managing Relationships with Dispensing Entities

Issue: In Question 4, CMS proposes to provide Primary Manufacturers with a list of dispensing entities that have self-identified as having material cashflow concerns at the start of a price applicability period. Primary Manufacturers would also be required to provide information describing their process for mitigating material cash flow concerns for dispensing entities and any qualifying criteria a dispensing entity needs to participate in this process.

Pfizer Comment: Pfizer is opposed to the requirement to develop mitigation plans for dispensers with material cashflow concerns. We share the agency's goal of ensuring prompt payment for dispensers, which under CMS' current approach to effectuation has become problematic for many pharmacies. This is one of the many reasons why Pfizer, and the broader pharmaceutical industry, has advocated for CMS to utilize an implementation model like that which has been used for many years in the Part D CGDP. This would involve pre-funding MFP refund amounts to dispensers on behalf of manufacturers at the time of claim adjudication, with manufacturers invoiced later. This should be paired with a claims data repository to deduplicate 340B and MFP claims, as noted below in our response to Question 6.

Furthermore, we also have significant concerns that the requirement for manufacturers to develop mitigation plans was not included by CMS in the draft guidance for MFP effectuation in 2026 and 2027. By introducing this new concept solely in the Final Guidance, CMS deprived stakeholders, including manufacturers, of the opportunity to provide comment and input.

If CMS declines to adopt a CGDP-like model with pre-funded MFP refunds, we strongly encourage the agency to provide more transparency about the types of mitigation plans it expects. While we appreciate the ability of manufacturers to develop their own qualifying criteria, the lack of clarity from CMS on acceptable mitigation plans presents significant uncertainty and compliance burden.

We also ask that CMS monitor Part D plan sponsor and dispenser actions surrounding the mitigation plans, as we are concerned about potential unintended outcomes from different manufacturers developing varying approaches, including disruptions to patient access to their prescribed medications.

Finally, in the lead-in to Question 4, Pfizer seeks clarity about the timing of when Primary Manufacturers will be provided with a list of dispensing entities that have self-identified as having material cashflow concerns. As written, we believe this lead-in statement could be interpreted as Primary Manufacturers not receiving this list until the start of the price applicability year, which would be too late for manufacturers to take the dispenser status into account in advance of manufacturer MFP effectuation plans being finalized. Pfizer recommends that CMS clarify this statement.

Section 3: Information Requested of Primary Manufacturers Declining Use of the MTF PM

Issue: In Question 5, CMS proposes to collect information about a Primary Manufacturer declining to use the MTF PM's process for effectuating MFP. CMS also asks Primary Manufacturers to describe their process for contacting, reimbursing, and responding to dispensing entities to effectuate the MFP.

Pfizer Comment: Pfizer urges CMS to clarify that Primary Manufacturers can respond to Question 5 by providing information that is aggregated across dispensers or types of dispensers. We believe reporting at the aggregate level will still provide CMS with the information required from manufacturers choosing not to participate in the MTF PM but will help to minimize the burden on Primary Manufacturers.

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Section 4: MFP Effectuation

Issue: In Question 6, CMS proposes information that Primary Manufacturers will be required to provide to describe the process for effectuating nonduplication of claims that are 340B eligible and not subject to MFP availability.

Pfizer Comment: Pfizer remains highly concerned about the continued lack of a role for CMS in identifying and deduplicating 340B claims, with CMS stating in the Final Guidance for the Medicare Drug Price Negotiation Program (Final Guidance)[2] that the Agency "will not, at this time, assume responsibility for deduplicating discounts between the 340B ceiling price and MFP."[3]

Manufacturers have limited insight into which Part D units are subject to 340B pricing. While the addition of the Prescriber ID data field to the data elements shared through the MTF Data Module is appreciated, the National Provider Identifier (NPI) alone is generally not sufficient evidence that a claim was 340B-eligible, as noted in the Final Guidance. Without a requirement for covered entities to identify 340B units and share appropriate information with manufacturers, there is a high risk of paying duplicate MFP and 340B discounts, which is prohibited under the IRA.[4]

The Final Guidance encourages manufacturers to work with dispensing entities, covered entities, and their 340B third-party administrators to facilitate access to the lower of the MFP and 340B ceiling price.[5] However, certain state laws prohibit manufacturers from requiring 340B claim-level data from covered entities or their contract pharmacies, and HRSA has rejected reasonable business solutions that could help manufacturers address 340B and MFP duplicate discount risks through 340B rebate models.[6] Given the prohibitive state laws and HRSA's rejection of viable business solutions, it is impractical for manufacturers to depend on claims data submission processes for 340B identification.

Pfizer urges CMS and HRSA to implement a coordinated, comprehensive approach to achieve the IRA's statutory requirement that prohibits manufacturers from having to provide duplicate 340B/MFP discounts. This could include utilizing the claims data repository described in the CY 2025 Medicare Physician Fee Schedule Final Rule[7] for the Part D inflation rebate program, accompanied by clear requirements for covered entities to timely and accurately report claims data with HHS oversight and enforcement.

Issue: In Questions 8-9, CMS proposes information that Primary Manufacturers will provide in its MFP Effectuation Plan to describe its plan for calculating the MFP refund amount if using a retrospective reimbursement model, whether using the dispensing entity's actual acquisition cost or a reasonable proxy such as the Standard Default Refund Amount (SDRA), or if the manufacturer does not intend to effectuate the MFP retrospectively.

Pfizer Comment: Pfizer has significant concerns with the Agency's statement in the Final Guidance that the "SDRA may not be universally appropriate or sufficient to effectuate the MFP."[8] Based on conversations that pharmaceutical manufacturers have had with supply chain experts, we believe the extra charges above WAC are

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[2] Medicare Drug Price Negotiation Program: Final 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. *See* https://www.cms.gov/files/document/medicare-drug-price-negotiation-final-guidance-ipay-2027-and-manufacturer-effectuation-mfp-2026-2027.pdf

[3] Final Guidance, p. 55.

[4] Social Security Act (SSA) § 1193(d).

[5] Final Guidance, p. 232.

[6] See, e.g., Eli Lilly and Co. v. Becerra, No. 1:24-cv-03220 (D.D.C. Nov. 14, 2024); Johnson & Johnson Health Care Sys. Inc. v. Becerra, No. 1:24-cv-03188 (D.D.C. Nov. 12, 2024); Kalderos v. United States, No. 1:21-cv-02608 (D.D.C. Oct. 6, 2021).

[7] See https://public-inspection.federalregister.gov/2024-25382.pdf

[8] Final Guidance, p. 69.

not due to manufacturer prices, but instead additional charges by other supply chain entities (such as wholesalers). In other words, manufacturers have very limited control of pricing in the supply chain beyond WAC. We believe the Final Guidance as written could undermine the integrity of the Drug Price Negotiation Program (DPNP) by creating perverse incentives for dispensers and others in the pharmaceutical supply chain to improperly increase profits through arrangements that artificially increase MFP refund amounts. This is a direct contradiction of the President's stated goals in the recent Executive Order *Lowering Drug Prices By Once Again Putting Americans First* to promote a more competitive, efficient, transparent, and resilient pharmaceutical value chain that delivers lower drug prices for Americans.[9]

This concern is not hypothetical. Past experience has shown how supply chain stakeholders can manipulate prices to increase their own profits at the expense of the system. For example, until CMS prohibited the practice, Part D plan sponsors would sometimes enter arrangements with pharmacies that inflated the negotiated price, leading to higher government costs, manufacturer discounts, and beneficiary cost-sharing.[10] Similarly, vertical integration in Medicare Advantage has enabled plans to shift profits between related entities to circumvent medical loss ratio requirements.[11]

Basing manufacturer refund obligations on acquisition costs above WAC would also be a unique approach, diverging from other federal drug pricing programs like 340B, which use WAC as the baseline. CMS should not be assessing MFP access based on prices set by entities other than the manufacturer, as manufacturers do not control the prices at which dispensers acquire drugs from wholesalers and other intermediaries.

For these reasons, Pfizer strongly urges CMS to specify in future guidance that MFP refunds should be no larger than the SDRA (WAC minus the MFP). We also recommend CMS closely monitor the impact of SDRA-based refunds on pharmacy reimbursement in Part D to ensure Part D plans are not clawing back payments because pharmacies typically acquire single source brand drugs for prices about 4% below WAC.[12] Maintaining the integrity of the DPNP requires aligning manufacturer obligations with their actual pricing and limiting opportunities for supply chain manipulation.

Issue: In Questions 12-13, CMS proposes to collect information that Primary Manufacturers will provide in its MFP Effectuation Plan necessary to document alternative purchasing or reimbursement arrangements, such as prospective purchasing, that a Primary Manufacturer and dispensing entity may have entered into outside of the MTF PM.

Pfizer Comment: Pfizer recommends that CMS provide manufacturers who utilize alternative purchasing or reimbursement arrangements outside the MTF PM with access to the credit/debit ledger system. Even though these manufacturers will still be reporting claims-level payment information to the MTF DM, these data could be used to populate a simple, non-dynamic record of payments within the MTF system. While we understand this ledger system could not be used to alter payments for manufacturers with alternative arrangements, it would still serve as a useful centralized record for them.

[9] Lowering Drug Prices by Once Again Putting Americans First – The White House
[10] CMS. Medicare Program; Contract Year 2023 Policy and Technical Changes to the Medicare Advantage and Medicare Prescription Drug Benefit Programs; Policy and Regulatory Revisions in Response to the COVID–19 Public Health Emergency; Additional Policy and Regulatory Revisions in Response to the COVID–19 Public Health Emergency. Final Rule. May 9, 2022. Available at: https://public-inspection.federalregister.gov/2022-09375.pdf
[11] Ibid.
[12] Myers and Stauffer. NADAC Equivalency Metrics. Last Updated September 20, 2024. Available at: https://www.medicaid.gov/medicaid/prescription-drugs/downloads/retail-price-survey/nadac-equiv-metrics.pdf

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More broadly, Pfizer is concerned about CMS's interpretation of the IRA statute as placing the "sole responsibility" on manufacturers to provide access to the MFP, while also imposing strict requirements if they choose to use an approach outside the MTF PM. For example, CMS is maintaining a requirement for a 14-day timeline for manufacturers to transmit payments to dispensers, even if a pharmacy and manufacturer have agreed to a different timeline under an alternative arrangement. Additionally, CMS notes in Question 13 that it may request copies of private pharmacy-manufacturer contracts without limitation. Given CMS's stated position that the responsibility lies solely with manufacturers, the agency should defer to the terms governing any private agreements for arrangements outside the MTF PM, rather than imposing additional requirements.

Issue: In Questions 16-20, CMS proposes to collect information regarding MFP effectuation with Secondary Manufacturers of a selected drug. CMS clarifies that CMS will not enroll Secondary Manufacturers in the MTF, that it will be up to the Primary Manufacturer to register a use from the Secondary Manufacturer as deemed appropriate, and that where access it provided the Secondary Manufacturer can act as an authorized user to participate in the Primary Manufacturer's MTF DM Account.

Pfizer Comment: Pfizer has significant concerns regarding the CMS proposal to collect information on MFP effectuation from Secondary Manufacturers of a selected drug. Pfizer maintains that the CMS approach of holding Primary Manufacturers responsible for discounts made available by separate corporate entities (Secondary Manufacturers) is unworkable and not supported by statute.

The Inflation Reduction Act (IRA) does not authorize CMS to impose requirements or liability on a legal entity that maintains a distinct corporate identity from the Primary Manufacturer. Imposing such requirements exceeds CMS' authority, as it is not "necessary for purposes of administering the program and monitoring compliance."[13]

Pfizer believes CMS could more effectively monitor manufacturer compliance by requiring separate effectuation plans and entering into separate agreements with Primary and Secondary Manufacturers, rather than the current construct. Pfizer has previously explained in comments to the Agency why the CMS approach runs counter to fundamental corporate law principles[14].

Pfizer continues to urge CMS to abandon the Primary and Secondary Manufacturer construct in future guidance, as it is unworkable and not supported by the statutory framework.

Other Issues

Issue: In discussing the confidentiality of manufacturer MFP effectuation Plans, CMS clarifies which portions of MFP effectuation plans will be made available through the MTF DM vs. which portions will be redacted to protect proprietary information. Specifically, CMS plans to make Section 1, Question 1; Section 2, in its entirety; and Section 3, in its entirety, available within the MTF DM, while Section 1, Question 2; and Sections 4 – 6, in their entirety, will be redacted and collected solely for CMS' use to ensure effectuation of the MFP.

Pfizer Comment: Pfizer appreciates the change made by CMS in the Final Guidance to limit distribution of the MFP effectuation plans to dispensers through the MTF DM. We also appreciate CMS further clarifying in this second ICR which sections and questions will be available within the MTF DM vs. which will be redacted. However, we are concerned about protecting the confidentiality of proprietary information that may be included in the MFP effectuation plans. We recommend CMS add a field to the MFP effectuation plan form that would enable Primary

[13] SSA § 1193(a)(5)
[14] Medicare Drug Price Negotiation Program: Public Submissions

Manufacturers to indicate which information is proprietary and would need to be redacted upon distribution to dispensers through the MTF DM.

In addition, prior to effectuation plans being distributed, CMS must ensure that Primary Manufacturers are provided with an opportunity to object to the distribution of any confidential commercial information, as required by HHS' FOIA procedures in 45 C.F.R. Part 5, Subpart D. Despite CMS' clarity that responses to questions in Section 2 will be made available to dispensing entities without redactions, manufacturers may find that to fully address questions raised in Section 2 they may need to include some proprietary information. We ask that CMS maintain flexibility in this scenario for IPAY 2026 and work with manufacturers to understand if portions of responses need to be redacted.

Issue: In discussing the issue of document uploads, CMS updated what must be submitted electronically in the MTF DM interface and what can be submitted via a downloadable, fillable PDF. Specifically, CMS specifies that Sections 2-6 of the MFP effectuation plan must be completed by entering the required information into the fillable PDF and then uploaded to the MTF user interface for submission.

Pfizer Comment: Pfizer appreciates the change to allow Primary Manufacturers to upload documents for a broader number of questions. We further urge CMS to ensure that this change will give Primary Manufacturers the ability to include a schematic or other visual that may help to clarify written explanations in the fillable PDF. Alternatively, CMS could also provide the option to upload documents at the end of the form, and Primary Manufacturers could reference those attachments in their answers to individual questions.

II. Appendix C: Medicare Drug Price Negotiation Program Primary Manufacturer Payment Elements Form

Issue: CMS proposes that Primary Manufacturers will be required to transmit specified claim-level payment elements back to the MTF DM for every set of claim-level data elements transmitted to the Primary Manufacturer by the MTF DM. Pfizer offers the following payment element-specific comments.

A. Sub-Issue: In the description of Payment Element 3, CMS states that "[c]odes should be based on the final disposition of a refund." Additionally, CMS also states that "Code 7 should be used when the refund amount transmitted was adjusted by a credit amount on a manufacturer-maintained credit ledger."

   Pfizer Comment: Pfizer requests that CMS clarify these two statements. Specifically, regarding the former, did CMS mean to indicate that the code a manufacturer enters should account for any credits or debits?

   Additionally, regarding the latter, is this statement referring to the debit/credit ledger that will be maintained by the MTF PM? If not, would manufacturers utilize Code 2 for refund amounts that have been adjusted based on the MTF PM-maintained credit/debit ledger?

B. Sub-Issue: CMS proposes that Primary Manufacturers will populate Payment Element 3 with one of several pre-identified justification codes to indicate whether the MFP refund payment was at the SDRA, a different amount, or the reason an MFP refund was not provided.

   Pfizer Comment: Under current CMS guidance, Code 4 only addresses scenarios where a selected drug's 340B ceiling price is lower than the MFP. However, a drug's 340B ceiling price can also be equal to the MFP or, under certain circumstances, higher than the MFP. Pfizer urges CMS to:

- Expand the existing Code 4 to include scenarios where the 340B ceiling price is equal to the MFP. Currently, Code 4 only addresses situations where the 340B ceiling price is lower than the MFP. However, the 340B ceiling price can also be equal to the MFP, and manufacturers need a clear mechanism to address these situations and avoid duplicate discounts. If a manufacturer can utilize Code 4 both where the 340B ceiling price is equal to or lower than the MFP refund, the manufacturer can continue to provide access to the 340B price while avoiding a duplicate 340B/MFP discount. We believe the expansion of Code 4 to include the scenario of the 340B ceiling price being equal to the MFP would be consistent with the combined meaning of sections 1193(d)(1) and 1193(d)(2) of the Social Security Act (the Act).

- Add a new payment element code to address the scenario where the 340B ceiling price is higher than the MFP by allowing manufacturers to calculate the MFP refund as the difference between the higher 340B ceiling price and the MFP. Section 1193(d)(2) of the Act states that a manufacturer of a selected drug "shall be required to provide access to the maximum fair price to such covered entity with respect to maximum fair price eligible individuals… at such ceiling price in a *nonduplicated amount to the ceiling price* if such maximum fair price is below the ceiling price for such selected drug" (emphasis added). But the existing payment element codes established by CMS do not seem to contemplate this scenario. In such cases, we believe manufacturers should be able to pay the difference between the higher 340B ceiling price and the lower MFP as the MFP refund amount. If manufacturers can provide access to the MFP by paying the difference between the higher 340B ceiling price and a lower MFP, while still providing the 340B covered entity with access to the 340B price, this will prevent a duplicate discount (discussed below).

- Clarify that manufacturers utilizing the MTF PM should also be able to use the credit/debit ledger system to make these adjustments for claims identified as 340B outside of the 14-day prompt MFP payment window.

As discussed in our comments on Appendix B, Pfizer remains highly concerned about CMS' position not to assume any responsibility for deduplicating discounts between the 340B ceiling price and MFP.[15] Under the current 340B replenishment model used by covered entities, manufacturers in many cases have very limited insight into which Part D units are subject to 340B pricing, which creates a significant risk of duplicate 340B and MFP discounts despite the IRA's statutory prohibition. Given these overarching concerns about the risk of duplicate discounts at a minimum we ask that CMS allow manufacturers to have a clear way to address 340B/MFP duplicate discounts by taking steps outlined above.

C. Sub-Issue: In the description of Payment Element 4, CMS notes that in cases "where the payment elements represent a claim that was adjusted or reversed, the Primary Manufacturer will indicate the new number of units of the selected drug included in the adjusted MFP refund paid or reversed as a *positive value*" (emphasis added).

Pfizer Comment: Pfizer appreciates the proposed data fields provided by the MTF to Primary Manufacturers, especially the addition of fields to support claim adjustments. However, we believe there could be scenarios where the new number of units is zero, and zero is neither positive nor negative value. As such, we ask that CMS clarify this statement to allow for zero values.

[15] Medicare Drug Price Negotiation Program: Final 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. *See* https://www.cms.gov/files/document/medicare-drug-price-negotiation-final-guidance-ipay-2027-and-manufacturer-effectuation-mfp-2026-2027.pdf

Additionally, as stated in our IPAY 2027 comments, while we appreciate CMS's concern about privacy risks, we urge CMS to reconsider providing a deidentified beneficiary ID to Primary Manufacturers. This would allow us to better identify duplicate claims while protecting against privacy risks. While both the DDPS and Part D plan sponsor will have verified the MFP eligibility of beneficiaries, under the Guidance neither of these entities appear to be scrubbing the claim-level data for duplicate claims across channels or within the invoicing data itself or for other types of invalid claims.

If a deidentified beneficiary ID is not provided, CMS should require the MTF to perform an additional data scrub to eliminate duplicate claims and catch obvious errors. This will help avoid disputes and allow Primary Manufacturers to make MFP refund payments more efficiently. We also urge CMS to consider conducting regular audits and reviews of claims submitted to the MTF, and the ability to request additional data fields from supply chain participants.

D. Sub-Issue: CMS does not specify whether Primary Manufacturers will be permitted to transmit batched claim-level payment elements back to the MTF.

   Pfizer Comment: Pfizer urges CMS to clarify whether manufacturers may submit batched payment element forms. For example, could payment element form information be batched by dispensing entity such as through a common ownership or chain code?

E. Sub-Issue: CMS does not adequately describe the credit/ledger system.

   Pfizer Comment: Beyond our specific comments on the use of the ledger system for Payment Element 3, Codes 3-4, Pfizer broadly encourages CMS to provide further information regarding the operations of the credit/debit ledger system that will be managed by the MTF PM for participating manufacturers. There is considerable uncertainty surrounding the credit/debit ledger system, particularly in terms of how the ledger will interact with the payment elements reported by manufacturers. We request that the Agency furnish additional details, including examples with illustrative claims.

III. Drug Price Negotiation Program Complaint Information Collection Request (ICR) Form for Non-MTF Users

Issue: CMS has included an information collection form for non-MTF users stating that CMS will engage a "compliance contractor" that will "support the successful administration of the Negotiation Program by collecting and investigating (as needed) complaints and disputes from dispensers, pharmacies, mail order services, manufacturers and other interested parties," including complaints "related to lack of access to the maximum fair price, or lack of access to accurate cost-sharing."

Pfizer Comment: Pfizer has concerns about the lack of detail provided regarding the role and authority of the "compliance contractor" that will be responsible for collecting and investigating complaints and disputes from various stakeholders. Without more specific information on how the contractor will perform these functions and the extent of their decision-making authority, it is challenging for Pfizer to comment effectively on the proposed approach.

To ensure compliance with federal acquisition regulations and to maintain the integrity of the investigation process, Pfizer recommends that CMS clarify that the contractor will not have final decision-making authority over the outcome or final fact-finding of any investigation. This would help to prevent the contractor from performing

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inherently governmental functions, which is prohibited in regulation, and ensure that the process remains transparent and impartial.

Pfizer encourages CMS to provide additional details on the proposed complaint and dispute resolution mechanism to allow stakeholders to provide more meaningful feedback and input on the implementation of the Drug Price Negotiation Program.

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Pfizer appreciates the opportunity to comment on the second round Information Collection Request (ICR) for the *Medicare Transaction Facilitator for 2026 and 2027 under Sections 11001 and 11002 of the Inflation Reduction Act (IRA)*. If you have any questions, please contact me at Margaret.Davis@Pfizer.com.

Sincerely,

Margaret Davis-Cerone
Senior Director, Head of Federal Policy
Corporate Affairs
US Policy & Government Relations