May 1, 2025

VIA ELECTRONIC SUBMISSION

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William N. Parham, III
Director
Office of Strategic Operations and Regulatory Affairs
Centers for Medicare & Medicaid Services
7500 Security Boulevard
Baltimore, Maryland 21244

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

Dear Director Parham,

Eli Lilly and Company (Lilly) appreciates the opportunity to provide comments on the Medicare Transaction Facilitator Information Collection Request (ICR). Lilly is one of the country's leading innovation-driven, research-based pharmaceutical and biotechnology corporations. Our company is devoted to seeking answers for some of the world's most urgent medical needs through discovery and development of breakthrough medicines and technologies and through the health information we offer. Ultimately, our goal is to develop products that save and improve patients' lives.

As a member of both the Pharmaceutical Researchers and Manufacturers Association of America (PhRMA) and the Biotechnology Innovation Organization (BIO), Lilly largely joins those groups in their comments on this Proposed Rule and encourages CMS to carefully consider the input of those organizations. That said, Lilly would like to offer the following comments to highlight certain topics and Lilly-specific positions.

Comments can be summarized as follows:

I. The Dispensing Entity Enrollment Form Should Include Certification Prompt for Dispensing Entities Providing Data to Manufacturers.
II. The 14-Day Payment Window Should Have the Option to be "Paused" Upon the Submission of a Dispute or Complaint to Ensure Fair and Feasible Processing.
III. Clearly Define the Timelines and Processes for Complaint and Dispute Resolution, Including CMS Review Structure, Personnel Involved, and Criteria for Evaluating Information.
IV. CMS' Purported Requirement that Manufacturers Must Mitigate Pharmacy Cashflow Concerns is Unlawful.
V. CMS' Proposed Approaches to Addressing 340B Duplicate Discounts Must Be Strengthened.
VI. CMS Should Define that MFP Refunds Cannot Exceed the SDRA.

I. The Dispensing Entity Enrollment Form Should Include Certification Prompt for Dispensing Entities Providing Data to Manufacturers.

Effectuating the "Maximum Fair Price" (MFP) is inherently a multi-party process and any "requirement" as to one party should be a requirement as to all parties. Consider a made-up pharmacy, call it the "ABC Pharmacy," that does not want to sign up with the Medicare Transaction Facilitator (MTF). This provider would need to find a different way to receive an MFP refund payment from a manufacturer, even though the pharmacy may not be willing to share all of the information required to accurately effectuate an MFP. Requiring only the Primary Manufacturer to transmit and receive specific data elements places a disproportionate burden on these entities and decreases the likelihood that any data sharing efforts will meet the requirements to accurately effectuate MFP.

To prevent these data disruptions, the dispensing entity enrollment form should include a certification prompt for dispensing entities to affirm their role in providing data to manufacturers. An example of this certification is provided below.

> ***Section 6: Data Sharing Certification***
> *I hereby certify, to the best of my knowledge, that the dispensing entity will share applicable data elements with manufacturers to meet the requirements to accurately effectuate MFP. The information being sent to manufacturers is complete and accurate, prepared in good faith and after reasonable efforts. I understand that the shared information is essential for administering the Negotiation Program.*
> ***[ ] Acknowledge and Agree***

II. The 14-Day Payment Window Should Have the Option to be "Paused" Upon the Submission of a Dispute or Complaint to Ensure Fair and Feasible Processing.

The payment elements form reiterates that primary manufacturers are required to submit claim level payment details within 14 calendar days of receipt. Primary manufacturers should be afforded the ability to "pause" this window in the event of an outstanding complaint or dispute. Given the tight turnaround, the optionality of a pause would be beneficial in ensuring the right payments are made to the right parties at an accurate time.

In lieu of this "pause", the Primary Manufacturer Payment Elements Form should include space to track or explain any credits, similar to the Coverage Gap Discount Program. Tracking these details is essential for resolving complaints and maintaining an uninterrupted payment system.

III. Clearly Define the Timelines and Processes for Complaint and Dispute Resolution, Including CMS Review Structure, Personnel Involved, and Criteria for Evaluating Information.

To ensure the effective processing of disputes and complaints, it is imperative to clearly define the timelines and processes involved. Currently, the Drug Price Negotiation Program Complaint and Dispute Intake Form collects necessary information from Primary Manufacturers, dispensing entities, beneficiaries, and other interested parties to submit a complaint or dispute related to effectuating the MFP. We encourage CMS to provide more clarity on the complaints and disputes process, including more specificity for the complaints and disputes processes and more clarity about CMS' role. To guarantee an effective process, it is imperative to adhere to best practices, which encompass:

Due Process. The process should be conducted in a reasonable timeframe to prevent unnecessary delays and ensure that parties can move forward with resolution or enforcement of the decision. This encompasses providing access to claims-level data, a fair and orderly presentation of evidence, and ensuring genuine opportunities to contest any inaccuracies in the claims.

Objectivity and Freedom from Conflicts of Interest. The individuals tasked with evaluating dispute claims should not be part of the same group responsible for the design and execution of the program. Such individuals may potentially possess biases, positions, or other objectives that extend beyond the specific facts of the dispute in question. The entity administering the MTF must not have a vested financial interest based on whether more or fewer eligible claims for manufacturer refunds are honored.

Non-Delegation. The MTF should not be permitted to impose, through "program administration rules" *de facto* regulations that alter the rights and obligations of stakeholders. CMS must ensure that any "rulemaking" related to the MFP program come directly from the agency and that these rules are implemented through appropriate administrative procedures.

Ability, Training, and Efficiency. The individuals responsible for determining the result should be trained with skillsets designed to resolve administrative disputes fairly and professionally.

Efficiency. Those responsible for responding to disputes should be a fully dedicated resource, not one appointed on an *ad hoc* basis. Moreover, they must apply the same routine over and over and able to handle procedural matters more expeditiously.

Transparency. The outcome and the process leading to a decision should be transparent, providing a clear understanding of the rationale behind the

ultimate determination. These determinations should be summarized in a file identifying the result of the dispute and when the funds were returned to the manufacturer in a file format that is easily accessible.

Confidentiality. In some cases, it may be important to maintain the confidentiality of certain information. This can help protect sensitive information.

Finality. The dispute resolution process must have clear timeframes for resolving conflicts so that these disputes do not remain unresolved.

Additionally, while CMS notes supporting documentation will expedite resolution, there is no clear indication of the timeline for resolution. To prevent these complaints or disputes from going un-resolved, a timeline for resolution should be indicated. We propose that CMS use the same resolution deadlines as the Coverage Gap Discount Program: sixty (60) calendar days after the dispute submission deadline date.

IV. CMS' Purported Requirement that Manufacturers Must Mitigate Pharmacy Cashflow Concerns is Unlawful.

The requirement to fix pharmacy cashflow issues goes well beyond the statutory command. Manufacturers are required to "provide access to" the MFP. CMS cannot require manufacturers to financially support retail pharmacies or other providers under the guise of "providing access to" MFP programs. Many pharmacies face profitability issues due to factors unrelated to MFPs, such as inadequate reimbursement from large health insurers or liabilities from opioid-related litigation. How will a manufacturer – or the government – know if the pharmacy's request for liquidity genuinely is caused by the MFP program as opposed to other business problems that a pharmacy may be facing and how is this a manufacturer's responsibility to resolve?

It is important to recognize that more than 90% of independent pharmacies indicated they may not sell Medicare Part D prescription drugs selected for price negotiation due to the lack of protocol ensuring fair reimbursement by pharmacy benefit managers and insurers once the negotiated prices take effect.[1] The issue was clear, or should have been, when the IRA passed, but it was rushed through Congress without hearings or stakeholder input, leading to unintended consequences.

Against this legislative, administrative, and legal backdrop, CMS maintains in this ICR, which effectively enshrines and expands the decision to make manufacturers – rather than the government – the stopgap financier. CMS should not add additional requirements on manufacturers, especially obligations to address cashflow concerns that are not supported by the IRA statute.

[1] National Community Pharmacists Association (NCPA). Report for Fall Survey of Independent Pharmacy Owners/Managers. October 15, 2024. Available: https://ncpa.org/sites/default/files/2024-10/NCPA-FallSurvey2024-ExecSummary.pdf.

V. CMS' Proposed Approaches to Addressing 340B Duplicate Discounts Must Be Strengthened.

CMS has set forth expectations for manufacturers to develop comprehensive plans to address 340B duplication, ensuring that the MFP is effectuated correctly. This includes submitting detailed information on how they will manage data exchange with the MTF and comply with the 14-day prompt MFP payment window.

Manufacturers are required to ensure that the MFP is accessible to 340B covered entities when it is lower than the 340B ceiling price for a given medicine. However, CMS view that manufacturers are also be responsible for "deduplicating" these discounts is concerning given the lack of statutory requirement for such responsibility and the absolute opacity in the 340B system.

Moreover, CMS's decision to not require covered entities to take any steps to identify 340B/MFP prescriptions creates an operational void. There are currently no systems, incentives, or penalties for fraud compelling covered entities to voluntarily identify these dispenses, which puts manufacturers at significant risk of extending duplicate discounts on drugs that fall under both MFP and 340B categories. Manufacturers also lack audit rights on 340B/MFP duplication, and there are no administrative or judicial appeal options under the statute, so front-end protections are the only avenue available to ensure manufacturers are not subject to illegal duplicate discounts. Other provisions in the IRA, specifically the Part B and Part D inflation rebates, also prohibit duplicate discounts, yet CMS continues to evade responsibility for ensuring compliance by dispensing entities. It is imperative that CMS and HRSA promptly and collaboratively develop a holistic approach to address these issues. At a minimum, CMS should recognize – and endorse – recent manufacturer efforts to implement 340B prices through retroactive rebate or cash replenishment.[2] These programs, which do not harm covered entity 340B cashflow, will provide manufacturers the data necessary to avoid duplicate discounts and manage MFP/340B pricing dynamics.

If CMS and HRSA do not endorse manufacturer rebate programs, then, at a minimum, CMS should couple a requirement for 340B claims modifiers with the establishment of a clearinghouse-type entity. This approach is already being explored by CMS in the context of inflation rebates, to offer better certainty that all prescriptions subject to 340B agreements are appropriately identified across all claims billed to Medicare and Medicaid. The 340B clearinghouse would act as a claims verifier, reviewing data submitted by 340B covered entities (or entities acting on their behalf) to determine the likelihood that a claim is subject to a 340B agreement, similar to the role played by 340B third-party administrators (TPAs) and split-billing vendors today but with transparency for the government and manufacturers' funding the 340B program. Units marked as subject to 340B agreements on either the claim or by the 340B clearinghouse would be excluded from MFP. Further, any clearinghouse contract must be a neutral entity. For example, the chosen clearinghouse

[2] *See e.g.,* Nyah Phengsitthy, *J&J, Bristol Myers Turn to Drug Rebates in Fight Over Price* Cuts, BLOOMBERG LAW (Dec. 4, 2024).

should not be owned or overseen by covered entities. The selected clearinghouse should have demonstrated expertise in adjudicating claims in real-time for retail medicines and provider-administered medicines. This would enable a single clearinghouse to serve for claims across the government programs, simplifying the operational process.

VI. CMS Should Define that MFP Refunds Cannot Exceed the Standard Default Rebate Amount (SDRA).

The form provides an opportunity for manufacturers to indicate whether they will use the dispensing entity's actual acquisition cost (AAC) or a reasonable proxy for calculating the MFP refund amount. The SDRA set forth in the final guidance relies on the notion that manufacturers must cover the mark ups charged by others in the supply chain which creates serious concerns. First, this concept creates incentives for gaming by encouraging middlemen, dispensers and other entities within the pharmaceutical supply chain to "jack up" prices because they know the manufacturer will come along and pay for these inflated costs. The argument might be that this would not occur because someone would have to "float" the inflated acquisition price, but as we have seen in other programs, there is no end to creativity intermediaries will deploy.

This problem is exacerbated by the fact that manufacturers lack influence over the prices dispensers pay to supply chain intermediaries, such as wholesalers. If CMS was the party at risk to such gamesmanship, we have no doubt the agency would take steps to prevent the misallocation of taxpayer dollars. But as the Department of Justice recently recognized in a similar situation, "it is arguably worse for the government to play fast and loose with others' (drugmakers') money on the line."[3] To prevent the possibility of artificially increased MFP reimbursements, CMS should define that that MFP refunds cannot exceed the SDRA (i.e., WAC minus the MFP).

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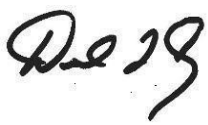
Lilly is appreciative for the opportunity to respond to the ICR. We sincerely appreciate your thoughtful consideration of the issues discussed in this letter and look forward to working with you in the future on these topics. Please do not hesitate to contact Derek Asay at Asay_Derek_L@Lilly.com with any questions.

Sincerely,



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[3] Reply Mem. (Doc. 24) at p. 17, *Albany Med. Health Sys. v. HRSA*, No. 23-3252 (D.D.C. Apr. 19, 2024).