DEPARTMENT OF HEALTH & HUMAN SERVICES

Centers for Medicare & Medicaid Services

Administrator
Washington, DC 20201

June 23, 2025

The Honorable Earl L. "Buddy" Carter
U.S. House of Representatives
Washington, DC 20515

Dear Representative Carter:

Thank you for your letter to Secretary Kennedy and me expressing your concern regarding implementation of the Inflation Reduction Act's (IRA) Medicare Drug Price Negotiation Program ("Negotiation Program") and the impacts on patients and pharmacies. We appreciate hearing your concerns and your commitment to pharmacies as critical players in the health care system that provide access to selected drugs for Medicare beneficiaries.

On April 15, President Trump signed Executive Order 14273, "Lowering Drug Prices by Once Again Putting Americans First"[1] (EO). Among other things, section 3 of the EO directs the Secretary of Health and Human Services to take steps to improve the IRA. Specifically, section 3 directs the Secretary to propose and seek comment on guidance for the Negotiation Program for initial price applicability year 2028 and manufacturer effectuation of maximum fair price (MFPs) under the program in 2026, 2027, and 2028. The guidance is intended to improve the transparency of the Negotiation Program, including to minimize any negative impacts of the maximum fair price on pharmaceutical innovation within the United States.

On May 12, in accordance with the EO's directive to the Secretary, the Centers for Medicare & Medicaid Services (CMS) issued Draft Guidance on Medicare Drug Negotiation Program[2] for the third cycle of negotiation and manufacturer effectuation of negotiated MFPs in 2026-2028 (May 12 draft guidance). This guidance describes requirements and parameters for the third cycle of negotiations and the first cycle of renegotiations for the Negotiation Program. In addition to soliciting comment on ways to increase transparency in the Negotiation Program, the May 12 draft guidance also solicits feedback to improve implementation of the IRA's requirement that drug manufacturers provide access to the MFP for selected drugs to pharmacies, mail order services, and other dispensing entities, including alternative solutions for sharing verified data or for routing refund payments from manufacturers to dispensing entities. The comment period for the May 2025 draft guidance closes June 26, 2025.

Regarding your specific concerns about Part D plan reimbursement for selected drugs and potential impact on pharmacy revenue, under section 1860D-2(d)(1)(D) of the Social Security Act (the "Act"), as amended by section 11001(b) of the IRA, Part D plan payment for a selected drug during its price applicability period must not exceed the applicable MFP, plus any dispensing fees. CMS encourages Part D plan sponsors to work with pharmacies to ensure

[1] https://www.govinfo.gov/content/pkg/FR-2025-04-18/pdf/2025-06837.pdf
[2] https://www.cms.gov/files/document/ipay-2028-draft-guidance.pdf

adequate and fair compensation for dispensing selected drugs. As noted in CMS's October 2, 2024, Medicare Drug Price Negotiation Program Final Guidance[3] for the second cycle of negotiation and manufacturer effectuation of negotiated MFPs in 2026 and 2027 (October 2024 final guidance), the agency shares concerns regarding the potential impact on pharmacy revenue upon availability of MFPs. CMS will work to ensure plans engage in sustainable and fair reimbursement practices with all pharmacies to ensure access to selected drugs for individuals with Part D and will closely monitor whether further programmatic adjustments are needed to address any contrary practices that emerge. Depending on findings from CMS's monitoring of plan reimbursement for selected drugs, CMS may take immediate steps to ensure adequate reimbursement for, and access to, selected drugs as needed.

Section 1193(a) of the Act specifies the manufacturer's responsibility to provide access to the MFP to MFP-eligible individuals, pharmacies, mail order services, and other dispensing entities. As stated in section 40.4 of the October 2024 final guidance and reaffirmed in section 40.4 of the May 12 draft guidance, a manufacturer must provide access to the MFP either prospectively or retrospectively. Due to concerns from a range of interested parties about the need for a mechanism for manufacturers and dispensing entities to engage in data exchange and facilitate payment exchanges to support MFP effectuation, CMS established the Medicare Transaction Facilitator (MTF). Since the statute does not provide CMS with an express role in effectuating the MFP, CMS intends for the MTF to serve in a ministerial, facilitating role that would assist Primary Manufacturers in meeting their statutory obligation by sharing Part D claims data with such manufacturers and passing through participating manufacturers' MFP refund payments to dispensing entities.

CMS recently finalized a requirement in the Contract Year 2026 Medicare Advantage and Part D Final Rule[4] that Part D sponsors' network participation agreements with contracting pharmacies, including any contracts with any first tier, downstream, and related entities, require such pharmacies to be enrolled in the MTF Data Module. Enrolling in and using the MTF is free for pharmacies and does not place any requirement on them to actually dispense selected drugs under the Part D program. The purpose of the MTF is to give dispensing entities an effective tool to ensure continued access to selected drugs that are covered under Part D for beneficiaries and dispensing entities and help maintain the accuracy of Part D claims information and payment.

With respect to the concerns related to the timing of MFP refund payments, CMS has taken steps to help pharmacies in ensuring they receive timely payment from manufacturers for retrospective access to the MFP through refund payments. As detailed in sections 40.4 in the final guidance for MFPs in 2026-2027 and the May 12 draft guidance, these steps include, but are not limited to, CMS requiring Primary Manufacturers to transmit payment of an amount that provides access to the MFP to pharmacies, mail order services, and other dispensing entities within 14 days of when the MTF sends data that verify the selected drug was dispensed to an MFP-eligible individual to the Primary Manufacturer. As outlined in October 2024 final guidance, if a

[3] https://www.cms.gov/files/document/medicare-drug-price-negotiation-final-guidance-ipay-2027-and-manufacturer-effectuation-mfp-2026-2027.pdf

[4] https://www.federalregister.gov/documents/2025/04/15/2025-06008/medicare-and-medicaid-programs-contract-year-2026-policy-and-technical-changes-to-the-medicare

pharmacy believes it has not received a retrospective refund that effectuates the MFP, CMS recommends the dispensing entity remediate with the manufacturer directly. If remediation between the parties cannot be reached, pharmacies are encouraged to use the complaints process, within the established MFP complaint and dispute process, to report and address MFP access issues. CMS will also monitor manufacturer compliance with MFP effectuation requirements. The May 12 draft guidance outlines additional steps CMS will take to ensure that manufacturers fulfill their obligation to make the MFP available to dispensing entities, including fact-specific assessments that account for various factors such as whether a retrospective refund amount paid by the manufacturer is sufficient to account for commercially reasonable costs the dispensing entity is likely to encounter in the supply chain, the invoice amount from the dispensing entity, and agreements or communications between the dispensing entity and the manufacturer regarding the availability of the MFP to the dispensing entity. CMS is soliciting comments on these factors and other considerations CMS should take into account when assessing whether MFP was made available to the dispensing entity.

Another step CMS took in the October 2024 final guidance to address pharmacies' cashflow concerns is a requirement that manufacturers include a process for mitigating material cashflow concerns for pharmacies in their MFP effectuation plan. During enrollment in the MTF, pharmacies will be asked to self-identify whether they anticipate having material cashflow concerns at the start of an initial price applicability year due to the reliance on retrospective MFP refunds within the 14-day prompt MFP payment window. CMS will make the list of the self-identified dispensing entities available to Primary Manufacturers in the MTF and will provide updates to the list on an ongoing basis as other dispensing entities enroll in the MTF and self-identify as anticipating having material cashflow concerns or as dispensing entities update their self-identification over time. This information will be provided to manufacturers to assist in the development of their MFP effectuation plans. CMS expects that the requirement that manufacturers establish mitigation processes for addressing these material cashflow challenges will better enable them to work with pharmacies to ensure continued beneficiary access to their selected drugs. Examples of processes to mitigate material cashflow concerns for identified pharmacies may include, but are not limited to, prospective purchasing agreements or accelerated MFP refund timelines.

Thank you again for bringing your concerns about the Negotiation Program implementation to our attention. I value your feedback and look forward to continuing to work with you to support pharmacies in dispensing selected drugs and to ensure Medicare beneficiaries have access to the medications they need. If you have any additional questions or concerns, please have your staff contact the CMS Office of Legislation.

Sincerely,

Dr. Mehmet Oz

cc:

Hon. Jake Auchincloss
Hon. James Comer
Hon. Richard Hudson
Hon. John Joyce, M.D.
Hon. Diana Harshbarger, Pharm.D.
Hon. Thomas H. Kean, Jr.
Hon. Nicole Malliotakis
Hon. Mariannette J. Miller-Meeks, M.D.
Hon. Cliff Bentz
Hon. Austin Scott
Hon. Eleanor Holmes Norton
Hon. Raja Krishnamoorthi
Hon. Sanford D. Bishop, Jr.
Hon. Michael Cloud
Hon. Dan Crenshaw
Hon. Vicente Gonzalez
Hon. Tim Moore
Hon. Terri A. Sewell
Hon. Carol D. Miller
Hon. John H. Rutherford
Hon. Joe Wilson
Hon. Claudia Tenney
Hon. French Hill
Hon. Jefferson Van Drew
Hon. Derek Schmidt