National Home Infusion Association

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May 1, 2025

Mehmet Oz, MD
Administrator
Centers for Medicare & Medicaid Services
ATTN: CMS-10912
7500 Security Boulevard
Baltimore, MD 21244-1850

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

Dear Administrator Oz:

The National Home Infusion Association (NHIA) appreciates the opportunity to submit comments on the Information Collection Request (ICR) submitted by the Centers for Medicare & Medicaid Services (CMS) to the Office of Management and Budget (OMB) regarding the Medicare Transaction Facilitator (MTF) for 2026 and 2027.[1] The ICR includes several forms, including those related to dispensing entity enrollment, manufacturer maximum fair price (MFP) effectuation plans, manufacturer payment elements, and complaint and dispute intake (collectively, "Draft MTF Forms"). NHIA is a trade association representing companies providing infusion therapy to patients in their homes, as well as manufacturers and suppliers of infusion and specialty pharmacy products. As the leading voice for the home and alternate infusion community, we write to share our feedback regarding the Draft MTF Forms.

In implementing the Inflation Reduction Act's (IRA) Medicare Drug Price Negotiation (MDPN) Program, CMS is utilizing a MTF to facilitate the effectuation of negotiated prices for negotiated drugs under the program. The MTF system will include two modules: the MTF Data Module (DM) – which manufacturers participating in the MDPN Program will be required to participate in – and the MTF Payment Module (PM) – which is optional for manufacturers. Of note, CMS recently finalized a requirement that Part D sponsors' participating network agreements with

[1] 90 Fed. Reg. 14373 (April 1, 2025)

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pharmacies require that such pharmacies enroll in the MTF Data Module, making participation a requirement for dispensing entities as well.[2]

NHIA is concerned with the effects on dispensing entities of some of CMS' operational policies for MFP effectuation. Our comments are outlined below.

MTF Data Module Mandatory Participation

In Appendix A – Drug Price Negotiation Program MTF DM Dispensing Entity and Third-Party Support Entity Enrollment Form ("Enrollment Form") – CMS stated that it had proposed in rulemaking a requirement that Part D sponsors require in their agreements with pharmacies that dispensing entities be enrolled in the MTF DM. Indeed, as mentioned above, CMS already has finalized this requirement, which NHIA strongly opposes. First, pharmacies should not be required to enroll in the MTF DM before they know the details of manufacturers' Effectuation Plans. Under CMS' timeline, pharmacies would be required to enroll in the MTF DM in June, but manufacturers would not have to submit their Effectuation Plans for another three months. In addition, under polices imposed by CMS, pharmacies will be saddled with below cost reimbursements from pharmacy benefit managers (PBMs) under the MDPN Program, along with administrative burdens. Enrollment with the MTF Data Module Contractor should not be a condition of participation in Medicare Part D for pharmacies.

Financial Burdens from Retrospective MFP Refund Payments

NHIA believes that CMS' process for payment to dispensing entities under the Medicare Drug Price Negotiation Program will be financially and administratively burdensome for dispensing entities, as they will have to purchase selected drugs at a price higher than the MFP to stock them and "float" payments for selected drugs dispensed to Medicare beneficiaries. This will cause dispensing entities to operate at a cashflow deficit while they wait for MFP refund payments from multiple manufacturers using varying methods.

The draft Enrollment Form asks dispensing entities to self-identify as having "material cashflow concerns" at the start of the initial price applicability year due to the shift in payment from Part D sponsors to a combination of Part D sponsor payment and potentially lagged MFP refund payments. CMS stated its expectation that "certain types of dispensing entities" may have material cashflow concerns related to MFP effectuation. CMS identified sole proprietor rural and

[2] 90 Fed. Reg. 15792 (April 15, 2025)

urban pharmacies that dispense a high volume of Medicare Part D drugs and "pharmacies who predominantly rely on prescription revenue to maintain business operations" among the dispensing entities that may have material concerns about cashflow related to MFP effectuation. NHIA notes that virtually all pharmacies "predominantly rely on prescription revenue to maintain business operations" and therefore will have material concerns about cashflow. Thus, CMS should not require pharmacies to self-identify and should deem all pharmacies as having material cash flow concerns that allow them to work with manufacturers to mitigate cashflow concerns. NHIA is concerned that while CMS will require manufacturers to have a process for mitigating cashflow concerns of dispensing entities with material cashflow concerns, there is no standard for such processes, leading to administrative burdens on pharmacies.

As an alternative, to mitigate the potential cashflow crisis for pharmacies, NHIA asks CMS to consider advancing payment of the expected MFP refund to pharmacies at the beginning of each month. Under such an approach, pharmacies would communicate to manufacturers the expected number of price-negotiated prescription drugs likely to be dispended to MFP-eligible individuals, based on claims-level data, and manufacturers would issue payment at the beginning of the month. Payments could be adjusted quarterly to account for overpayments or underpayments.

CMS will utilize Appendix B – Drug Price Negotiation Program MFP DM Primary Manufacturer MFP Effectuation Plan Form ("MFP Effectuation Plan Form") – to collect necessary information from manufacturers related to their MFP Effectuation Plans. The MFP Effectuation Plan Form states that "Primary Manufacturers are required to transmit their claim-level payment elements within 14 days of receiving claim-level data elements from the MTF DM." NHIA requests that CMS clarify that pharmacies need to be paid within 14 days of claim adjudication – not based on when the data is transmitted to the manufacturer. If CMS bases the requirement on the date of data submission, it should require Part D plans to submit the data daily, instead of weekly. CMS should minimize the amount of time that pharmacies are forced to operate at a cashflow deficit.

Administrative Burden from Variable Manufacturer Processes

CMS will use the MFP Effectuation Plan Form to collect necessary information from manufacturers related to their MFP Effectuation Plans. CMS' guidance allows manufacturers to utilize the MTF or their own processes for providing dispensing entities with MFP refunds. As a result, dispensing entities will have to manage and interact with multiple different payment arrangements, which will be operationally burdensome and costly. NHIA believes that CMS should require all manufacturers participating in the MDPN Program to utilize a consistent

process for MFP effectuation. Specifically, NHIA disagrees with CMS' decision to make participation in the MTF Payment Module voluntary for manufacturers. We believe this will lead to unnecessary confusion and administrative burdens for dispensing entities and potentially will lead to difficulties accessing drugs for which pharmacies do not have a direct relationship with the manufacturer. It also will be difficult to monitor for compliance and track MFP refunds if the MTF effectuation is done outside of the Payment Module.

MFP Refund Amounts

Under CMS' guidance, manufacturers have the option to provide MFP refunds to dispensing entities at the Standard Default Refund Amount (SDRA) – the difference between the Wholesale Acquisition Cost (WAC) and MFP – or at an alternate amount if a manufacturer determines an alternate amount is appropriate to effectuate the MFP and has supporting documentation that demonstrates why MFP refunds were provided at an amount different from the SDRA.

NHIA believes that CMS should require manufacturers to use WAC to calculate the MFP refund amount – that is that the SDRA should be the default standard for MFP refund amounts. It is critical that pharmacies be protected from manufacturers arbitrarily imposing refund amounts different from the SDRA that do not appropriately effectuate the MFP.

Complaint and Dispute Resolution

Appendix D – the Drug Price Negotiation Program Complaint and Dispute Intake Form ("Dispute Intake Form") – will be used to collect information from dispensing entities, manufacturers, and beneficiaries for submission of a complaint or dispute regarding MFP effectuation. The Dispute Intake Form provides very few details about the dispute process, and NHIA believes that a more defined process is needed to protect pharmacies. Consistent with the cashflow concerns discussed earlier, we believe that disputes between manufacturers and dispensers should be resolved within seven calendar days of receipt. In addition, NHIA disagrees with the statement on the Dispute Intake Form that "Complaints related to a lack of MFP availability may not always require a specific resolution." NHIA believes that the requirement of MFP effectuation always will need to be resolved, and that there will be heightened concerns if CMS does not require utilization of the SDRA as discussed above.

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Thank you for your consideration of these recommendations. Please contact me if you have questions at connie.sullivan@nhia.org.

Sincerely,

Connie Sullivan, B.S. Pharm
President and Chief Executive Officer