National Home Infusion Association

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January 31, 2025

Jeff Wu
Acting Administrator
Centers for Medicare & Medicaid Services
U.S. Department of Health and Human Services
7500 Security Boulevard
Baltimore, MD 21244-1850

RE: Draft Medicare Transaction Facilitator Agreements

Dear Acting Administrator Wu:

The National Home Infusion Association (NHIA) appreciates the opportunity to submit comments on the Draft Medicare Transaction Facilitator (MTF) Agreements ("Draft MTF Agreements") that were posted on the CMS website for public feedback.[1] 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 Agreements related to dispensing entities. These include the Draft MTF Agreement between CMS and dispensing entities (Draft Dispensing Entity MTF Agreement)[2] and the Draft MTF Agreement between dispensing entities and the MTF Data Module Contractors (Draft Data Module Contractor MTF Agreement)[3], collectively referred to as the Draft Dispensing Entity MTF Agreements.

In implementing the Inflation Reduction Act's (IRA) Medicare Drug Price Negotiation Program, CMS is utilizing a MTF to facilitate the effectuation of negotiated prices for relevant drugs under the program. NHIA is concerned with the effects on dispensing entities of some of CMS' operational policies for MFP effectuation. In broad terms, the Draft Dispensing Entity MTF

[1] https://www.cms.gov/inflation-reduction-act-and-medicare/medicare-drug-price-negotiation

[2] https://www.cms.gov/files/document/dispensing-entity-cms-mtf-program-agreement.pdf
[3] https://www.cms.gov/files/document/dispensing-entity-mtf-data-module-contractor-agreement.pdf

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Agreements do not adequately protect dispensing entities, as CMS disclaims all warranties and protections for dispensing entities and can modify the agreements unilaterally. In addition, the audit and notice requirements for dispensing entity termination are unduly burdensome.

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. We believe that CMS' solution to allow dispensing entities to self-identify, during enrollment with the MTF Data Module Contactor, that they "anticipate having material cashflow concerns at the start of the initial price applicability year due to the reliance on retrospective MFP refunds within the 14-day prompt MFP payment window" is insufficient to provide dispensing entities with relief from the burden of operating at a cashflow deficit. CMS' guidance merely requires manufacturers to have a process for mitigating dispensing entities' material cashflow concerns in their MFP effectuation plans. There is no requirement that the process that a manufacturer develops be discussed or reviewed by the dispensing entity to determine if the mitigation process will actually be effective.

Administrative Burden from Variable Manufacturer Processes

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. In addition, while CMS is requiring manufacturers to have a process for mitigating cashflow concerns of dispensing entities that self-identify that retrospective MFP refunds likely will cause them material cashflow concerns, there is no standard for such processes.

NHIA recommends that CMS require manufacturers to utilize a standard payment process, which will enable dispensing entities to track MFP refunds in a less burdensome manner. If CMS continues to allow each manufacturer to have a unique payment arrangement, NHIA asks that CMS disallow manufacturers from changing such payment arrangements once established and approved by CMS.

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Participation in Part D Plan Networks

CMS is considering requiring dispensing entities – as a condition of participation in Part D sponsors' networks – to be enrolled with the MTF Data Module contractor. As discussed above, NHIA believes that the Draft Dispensing Entity MTF Agreements are unfairly biased against dispensing entities, and we do not believe that enrollment with the MTF Data Module Contractor should be a condition of participation in Medicare Part D.

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 the SDRA should be the default standard for MFP refund amounts, and that if a manufacturer chooses an alternative amount, the manufacturer should be required to disclose to dispensing entities the supporting documentation required by CMS.

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