January 31, 2025

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

Submitted Electronically: *IRARebateandNegotiation@cms.hhs.gov*

Re: MTF Agreements Feedback

Dear Mr. Wu:

The National Association of Specialty Pharmacy (NASP) writes in response to the request for pharmacy stakeholder feedback on the draft Medicare Drug Negotiation Program Medicare Transaction Facilitator (MTF) contract agreements released for comment in December 2024 as proposed under the Biden Administration. **NASP urges the Trump Administration to pause any finalization of these MTF agreements and to instead work with the pharmacy/dispensing community to immediately revisit and revise the operational plan for pharmacies/dispensing entities and manufacturers to engage with the new Medicare Transaction Facilitator (MTF) under the Inflation Reduction Act's (IRA) Medicare Drug Negotiation Program. The approach proposed under the Biden Administration to implement in 2026 maximum fair prices (MFPs) and reconcile payments to the pharmacies that dispense the negotiated drugs threatens specialty pharmacies and other pharmacy businesses across the United States. NASP does not believe that the process outlined by CMS accurately interprets the IRA statute and remains extremely concerned the approach proposed will work against any effort to implement the Medicare Drug Negotiation Program. While we are grateful for the CMS career staff's efforts to engage with the pharmacy community, it is paramount that the Trump Administration immediately intervene and work with the pharmacy/dispensing community to reconsider and revise this process.**

As CMS works to implement the IRA, it must first acknowledge and understand the immense amount of financial pressure most pharmacies are already under within the Medicare Part D program. It is paramount that pharmacies' financial and administrative challenges are not further compounded and escalated through implementation of the IRA drug pricing program.

NASP shares the Administration's goal of ensuring beneficiaries have affordable access to the medicines they need. We also believe it is most important that implementation of the IRA law ensures patients will have continued access to the specialty pharmacy of their choice and to the pharmacy-related services that are essential to support beneficiary medication adherence and management, improve health outcomes, and reduce beneficiary, health system, and government costs. This access may be negatively impacted with dire consequences for all if it is not financially feasible for specialty pharmacies to dispense the Medicare negotiated drugs.

Specialty pharmacies provide medications that are typically not dispensed in a community pharmacy but rather by a pharmacy that specializes in and is accredited to manage patients that have chronic diseases and serious medical conditions. The drugs dispensed include biologics, injectables, oncology drugs, and other often high-cost drugs used to treat conditions like cancer, rheumatoid arthritis, organ transplantation, HIV/AIDS, multiple sclerosis, and genetic disorders. These pharmacies manage medications that require special protective packaging, cold chain storage and handling, along with ongoing patient education and 24/7 engagement to support medication management. The complexity of these specialty medications may be due to the drug itself, the way it is administered, the management of its side effect profile and toxicity risk, the disease or condition it is used to treat, and the appropriate way to ensure the drug is not compromised when shipped or sent by courier.

NASP represents the entire spectrum of the specialty pharmacy industry, which includes the nation's leading specialty pharmacies and practicing pharmacists, pharmacy benefit managers (PBMs), pharmaceutical and biotechnology specialty drug manufacturers, group purchasing organizations, wholesalers, distributors, integrated delivery systems, health systems, patient assistance organizations and technology and data management companies, among others. NASP's pharmacy members include specialty pharmacies of all types, including independent (non-affiliated with plan sponsors/PBMs), chain, grocery store, hospital and health system, PBM and health plan owned, and home infusion.

Medicare Transaction Facilitator Requirements for Network Pharmacy Agreements

CMS proposes requiring that Part D Sponsors' include in their network contracts a mandate for pharmacies to enroll in the Medicare Drug Price Negotiation Program's newly designed Medicare Transaction Facilitator Data Module (''MTF DM''). **NASP is alarmed CMS would suggest it intervene in the Part D contracting process to propose such a mandate. NASP finds this effort objectionable and asks that CMS stop pushing this process and engage with pharmacies to establish solutions to the concerns NASP and other pharmacy associations have raised and not proceed with any regulatory mandate on plan sponsor-pharmacy Part D contract agreements or the signing of any MTF DM-pharmacy/dispensing entity contract terms or CMS-pharmacy/dispensing entity contract terms.**

NASP appreciates CMS' effort to establish a neutral third-party entity to help pharmacies and other dispensing entities access "maximum fair prices (MFPs)" from drug manufacturers under the new Medicare Drug Negotiation Program. Additionally, we recognize the goal of streamlining data exchange to ensure accurate payment processing between manufacturers and pharmacies. However, the proposed 2026 implementation timeline, coupled with the absence of system modeling or testing, raises serious concerns about the viability of this approach and the potentially devastating consequences for both patients and pharmacies if it proves ineffective. **NASP remains frustrated that CMS has not prioritized the creation of a single, seamless system to manage both data and transaction payments between manufacturers and pharmacies/dispensing entities. Without this integration, the entire process will likely be unworkable and unsustainable for pharmacies/dispensing entities.**

CMS faces multiple immediate risks it must address before it should be working to finalize any contract terms for dispensing entities and manufacturers with the agency or with the MTF DM:

- Pharmacies/dispensing entities do not have the ability to reconfigure their internal claims systems to support varied and not-yet-understood manufacturer processes for effectuating the maximum fair price to pharmacies/dispensing entities for January 1, 2026 and to also plan for any cash flow concerns when manufacturers are not required by CMS to outline their planned payment processes until September 2025. CMS is requiring manufacturers to establish their own MFP effectuation plans for every Medicare negotiated medication they manufacture, and NASP is concerned that there is no clarity on what these plans will look like, how they will work with specialty pharmacies, or what they will require of specialty pharmacies.
- Under CMS' requirements, pharmacies and their technology providers will only have 122 days to establish systems and processes to work with manufacturer effectuation plans, which is grossly insufficient, especially if the manufacturer plans all require different internal procedures to be in place.
- Manufacturers have the option of whether or not to use the MTF PM to pay pharmacies/dispensing entities the difference between their acquisition cost and the Medicare negotiated drugs' maximum fair prices. If manufacturers opt to set up their own system of payment and their own way of establishing pharmacy acquisition costs that differs from CMS' recommended standard default rate (Wholesale Acquisition Cost), manufacturers will only have three months (September-December 2025) to figure out how to ensure their system of payment works with all of the pharmacies they will need to pay.
- Pharmacies/dispensing entities are not typically paid by manufacturers today. As a result, pharmacies will need to establish new payment reconciliation processes and estimate the "maximum fair price" refund amounts they will receive from manufacturers across different drugs.

- Pharmacies/dispensing entities will need to develop financial tracking and reconciliation processes across all claims for the negotiated price drugs they dispense.
- Pharmacies/dispensing entities will not understand when PDE transmission occurs and Part D claims for negotiated drugs are provided to the DDPS and if there are any PDE rejections that prohibit claims from then going forward to the manufacturer, nor the impact this process and timing will have adding onto the 14-day prompt payment standard required of the manufacturers.

Repeatedly, through numerous meetings and comment letters, NASP, other pharmacy associations and individual pharmacies have tried to impress upon CMS their concerns about CMS' proposed data management and payment systems for negotiated drugs, emphasizing the devastating impact CMS' current plan will have on pharmacy cash flow. The MTF data module alone will take at least 21 days. If a claim is rejected, the MTF data module could take longer. CMS is requiring manufacturers to issue payments within 14 days after receipt of the claim, but by the time this payment is issued, the pharmacy may have waited for nearly 40 days or longer (if there is a claim dispute), given the potential length of the entire process. This will not be sustainable, particularly for a specialty pharmacy that only dispenses limited types of drugs to support patients with certain conditions. As the negotiation program grows each year, for some of these specialty pharmacies, the only drugs they dispense may be negotiated drugs.

Recommendations

- **Require manufacturer participation in the CMS-designed MTF payment module (PM) for negotiated drugs instead of forcing pharmacies to potentially manage a different claims process for engagement with every individual manufacturer of a Medicare negotiated drug and pilot test these systems in advance with different types of pharmacies/dispensing entities (including independent specialty pharmacies) to give manufacturers and pharmacies/dispensing entities assurance that the tested system is viable for broad operation.**
- **Require Plan Sponsors or their PBMs to provide financial or administrative support to pharmacies for administration of the claims process for negotiated drugs and to address the burden and complexity of reconciled claims payments on negotiated drugs.**
- **Leverage existing NCPDP data to automate pharmacy enrollment in the MTF DM and MTF PM as much as possible to lessen burden on pharmacies/dispensing entities and as an alternative to contractual mandates on pharmacies.**

Rather than mandate that specialty and other pharmacies/dispensing entities participate in a system that is destined to fail, we implore the Administration to hear pharmacies' concerns and design a workable payment system for pharmacies/dispensing entities under the Medicare Drug Negotiation Program.

If these efforts are not achievable, another recommended alternative would be for CMS to rely on a model of claims administration and payment that has already existed. The Coverage Gap Discount Process (CGDP) under Medicare Part D could be mirrored to support manufacturer effectuation of the MFP as required under the IRA law. We do not see any legal reason why CMS could not require manufacturers to pre-fund MFP effectuation payments, as the IRA provides no such prohibition. Indeed, NASP understands that Congress sought to model the MFP effectuation statutory requirement after the statute that established the CGDP[1] in an effort to follow past precedent for a discount program under Part D.

CMS effectuates CGDP discounts through contracted third-party entities with the Part D plans serving as payment facilitators. In the CGDP, manufacturers are required to provide CGDP-eligible individuals discounted prices for drugs at the point of sale. Part D plans include the manufacturer-required discount amount as part of the Plan's payment obligation. The pharmacy knows its full compensation amount for related claims in real time and within the claims workflow, and payments are made within a 14-day prompt payment standard. Manufacturers repay Part D plans through the CGDP contractor. CMS, Part D plans, and manufacturers reconcile financial transactions independently without disrupting patient access or pharmacy economics. Such a financing model would allow manufacturers to seamlessly pay MFP refund amounts to pharmacies at the point of sale.

If the CGDP was to serve as the model for MFP effectuation, the MTF DM could potentially serve as the data facilitator to manage access to 340B data and to also ensure trust and protect the competitive interests of pharmacies and manufacturers in relation to acquisition-related data. The CGDP includes a pre-funded account approach to managing reconciled payments to pharmacies to meet statutory payment obligations in a timely manner. Under a CGDP-like approach, CMS should have direct oversight of the MFP effectuation process as well as govern the necessary data and financial flows. CMS should also consider alternative pre-funding pathways that ultimately could reduce a manufacturer's risk and a pharmacy's administrative and financial risk of no MFP retroactive payment or delayed retroactive payments.

Legal Concerns with CMS-Proposed Contract Agreements

NASP is advising that the Administration put a hold on moving forward with its proposed CMS-dispensing entity agreement, CMS-manufacturer agreement, MTF DM-dispensing entity agreement, and MTF-manufacturer agreement until improvements are made to change processes to effectuate the MFP to pharmacies/dispensing entities and address pressing cash flow concerns. It is essential that the Trump Administration engage specialty pharmacy and the broader pharmacy/dispensing entity communities to address these concerns first before proceeding with contract agreements between entities. That said, as plans continue to move

[1] 42 U.S. Code § 1395w–114a.

forward, NASP wants to share some specific legal questions and issues of significant concern regarding the terms of the CMS contracts that were presented for comment, affecting pharmacies/dispensing entities:

CMS and Dispensing Entity and MTF DM and Dispensing Entity Agreements:

II. DISPENSING ENTITY'S RESPONSIBILITIES

(c) Dispensing Entity ***shall*** enroll in the MTF DM… [emphasis added]

NASP Comment: Through this agreement, CMS would require pharmacies to join the MTF DM as a condition for participation in Medicare Part D, which there is no statutory requirement under the IRA for pharmacies to do. Pharmacies do not support a mandate to be under this contract agreement or a mandate to participate in the MTM DM.

II. DISPENSING ENTITY'S RESPONSIBILITIES

(f) Dispensing Entity shall make records available upon request to CMS and its agents, designees or contractors, or any other authorized representatives of the United States Government, or their designees or contractors, at such times, places, and in such manner as such entities may reasonably request for the purposes of audits, verifications, inspections, and examinations upon request.

NASP Comment: This audit, inspection and examination requirement on pharmacies is grossly overreaching. It is broad and extensive, requiring that a pharmacy provide any of its records at any time essentially to any entity, including potential competitors in the channel if they are considered as meeting the terms of this section of the agreement.

II. DISPENSING ENTITY'S RESPONSIBILITIES

(g) Dispensing Entity shall cooperate with all compliance activities in which CMS shall engage pursuant to applicable guidance and regulations and this Agreement, including but not limited to any audits carried out by CMS pursuant to section V of this Agreement.

NASP Comment: This requirement would allow CMS to establish any new "compliance activities" without promulgating a formal rule for notice and comment. A pharmacy would have no notion of what it would be agreeing to under this requirement.

(1) Termination by the Dispensing Entity. Dispensing Entity may terminate this Agreement subject to the requirements set forth in subparagraphs (i)-(ii).

The Dispensing Entity acknowledges that termination of this Agreement by the Dispensing Entity may result in non-compliance with applicable contractual obligation(s) with any applicable Part D plan sponsor(s) requiring the Dispensing Entity to be enrolled in the MTF DM.

A. Notice. If the Dispensing Entity decides to terminate this Agreement, the Dispensing Entity shall notify CMS of its intent to terminate this Agreement and specify the reasons for termination in the notice. Within thirty (30) calendar days of receiving the Dispensing Entity's notice, CMS shall send an acknowledgment of receipt to the Dispensing Entity of its notice and notify any applicable Part D plan sponsor(s) and participating manufacturers in writing. Unless otherwise expressly provided in writing by CMS in response to the Dispensing Entity's termination notice, the effective date of termination shall be 180 calendar days following CMS' acknowledgment of receipt.

B. Attestation. In order to terminate this Agreement, the Dispensing Entity shall attest, in a form and manner determined by CMS, that the Dispensing Entity does not participate or no longer participates in any Part D plan sponsor network or will no longer be participating in any Part D plan sponsor network as of the effective date of termination of this Agreement. As part of the attestation, the Dispensing Entity shall agree that it will re-enroll in the MTF DM if the Dispensing Entity contracts with a Part D plan sponsor to be a network pharmacy in the future by executing a new MTF Program Agreement and MTF Data Module Contractor Agreement and by providing all necessary information required for re-enrollment in the MTF DM.

NASP Comment: Pharmacies are not required to dispense MFP drugs; therefore, a pharmacy cannot be mandated to enroll with the MTF DM nor would a pharmacy be violating its agreement to participate in Medicare Part D by terminating this MTF DM agreement. The clauses above appear to mandate that the dispenser must furnish all MFP drugs in order to participate in the Medicare Part D program, which is by no means a statutory requirement.

IX. DISCLAIMERS

NASP COMMENT: CMS disclaims too broad of liability with the disclaimers. CMS mandates participation in the MTF DM while simultaneously disclaiming all liability for the MTF DM.

XI. SIGNATURES

NASP COMMENT: The requirements in this section, much like the requirements throughout the agreement incorporate current and future sub-regulatory requirements outside of this document with terms that remain undefined. A pharmacy/dispensing entity would never

truly understand what it is agreeing to in this contract agreement, as CMS could alter the terms at any time. There are associated penalties on a pharmacy/dispensing entity for non-compliance with any term CMS determines to put in place at any time it chooses to do so. Requiring dispensing entities sign an agreement that allows the other party to unilaterally modify the agreement would seem to create an invalid contract promise and no contract formation.

Conclusion

The Trump Administration must stop and revisit efforts to comply with the IRA and effectuate the MFP for pharmacies/dispensing entities under the Medicare Drug Negotiation Program. Pharmacies cannot be placed at any financial risk in order for the law's requirements to be carried out. NASP looks forward to working with the Trump Administration to address these concerns. For further information, please contact me at Sheila.Arquette@naspnet.org.

Sincerely,

Sheila Arquette, RPh.

President and CEO