July 2, 2024

The Honorable Chiquita Brooks-LaSure
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
200 Independence Ave., SW
Washington, DC 20201

The Honorable Meena Seshamani, MD, Ph.D.
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Centers for Medicare & Medicaid Services
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Submitted Electronically: IRARebateandNegotiation@cms.hhs.gov

Re: "Medicare Drug Price Negotiation Program Draft Guidance" – Implementation of Sections 1191-1198 of the Social Security Act for Initial Price Applicability Year 2027, and Manufacturer Effectuation of the Maximum Fair Price (MFP) in 2026 and 2027

Dear Administrator Brooks-LaSure and Deputy Administrator Seshamani:

The National Association of Specialty Pharmacy (NASP) appreciates the opportunity to comment on CMS' Medicare Drug Price Negotiation Program Draft Guidance. On May 3, 2024, CMS issued the program draft guidance to address the implementation of sections 11001 and 11002 of the Inflation Reduction Act (IRA)[1] which describes how CMS intends to implement the Negotiation Program for initial price applicability year 2027 and clarifies policies for manufacturer effectuation of the MFP in 2026 and 2027, specifying requirements that will be applicable to manufacturers of drugs that are selected for negotiation and procedures that may be applicable to drug manufacturers, Medicare Part D plan sponsors (PDPs and MA-PD Plans), pharmacies, mail order services and other dispensing entities that dispense drugs covered under Medicare Part D.

As CMS works to implement the IRA drug pricing reform sections of the law, it must first acknowledge and understand the immense amount of pressure pharmacies are already under within the Medicare Part D program. CMS must ensure that the implementation of the IRA's Part D provisions, particularly the effectuation of the Maximum Fair Price (MFP), does not exacerbate the financial difficulties already faced by pharmacies. For years, pharmacies have been subject to draconian payment reductions after the point-of-sale through pharmacy direct and indirect remuneration (DIR) and other cuts, and those

[1] These Sections of the Inflation Reduction Act created Part E under Title XI of the Act (Sections 1191-1198).

cuts have persisted this year as a carryover from 2023 contract agreements. Pharmacies have experienced even worse upfront cuts at the point-of-sale ("negotiated price") through 2024 contract terms. Despite CMS implementing new Part D regulations in January 2024 that amended the definition of negotiated price to capture all price concessions at the point of sale, specialty pharmacies and the broader pharmacy community have faced significant financial uncertainty, resulting in many forced pharmacy acquisitions and closures at an alarming rate. Today, Part D reimbursement across drugs dispensed is too often far less than a pharmacy's actual acquisition cost of the drugs, and pharmacy dispensing fees are not nearly adequate to buffer the payment reductions or to afford the cost of the requisite high-touch pharmacy services needed to cover plan and/or manufacturer requirements to support a patient on a specialty drug. Some Part D sponsors and their PBMs have initiated contract practices for this calendar year that pharmacies believe are in violation of the new 2024 Medicare Part D rules, and some Plans/PBMs continue to grossly undermine the Medicare Any Willing Pharmacy statute. Congress has been working to address these concerns, but CMS also has it within its own authority to enforce existing law that is intended to ensure payments to pharmacies are reasonable. Doing so is critically important especially now, as CMS seeks to implement the IRA drug pricing reform provisions, which will most certainly result in significant additional Medicare Part D financial pressures on and processes for specialty pharmacies and the broader pharmacy community.

NASP shares the Administration's priority of ensuring patients must have affordable access to the medicines they need. With this priority, we also believe it is most important to ensure that implementation of the IRA law and CMS' related regulations and guidance ensure that patients have continued access to the specialty pharmacy of their choice and to the pharmacy-related services that are essential to support patient medication adherence and management, improve health outcomes, and reduce patient, health system, and government costs. Our comments, specifically on Guidance Sections 40, 90, and 110, seek to address implementation of the law's provisions while ensuring these specific priorities are protected for specialty pharmacies and the patients they serve.

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 manufacturers of specialty drugs, group purchasing organizations, wholesalers, distributors, integrated delivery systems, health systems, 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, health plan owned, and home infusion.

NASP COMMENTS ON MEDICARE DRUG PRICE NEGOTIATION PROGRAM DRAFT GUIDANCE

Section 40 – Requirements for Manufacturers of Selected Drugs

This Section requires that for the initial price applicability year 2027, the Primary Manufacturer of a selected drug is the entity that is responsible for a number of requirements, including those with implications for specialty pharmacy patients and specialty pharmacies, as follows:

- Ensuring the MFP is made available to all MFP-eligible individuals (beneficiaries) and to pharmacies and others that dispense the selected drug to those individuals;
- Responding to CMS requests within specified timeframes with documentation demonstrating compliance and remedial actions, as applicable, pursuant to reports of noncompliance or other CMS compliance and oversight activities and pays any civil monetary penalties (CMPs) for violations.

40.4 – Providing Access to the MFP in 2026 and 2027

After a Primary Manufacturer of a selected drug for negotiation enters into an MFP agreement with CMS, according to the guidance, each manufacturer for each selected drug must provide access to the MFP to MFP-eligible individuals[2] and to pharmacies/dispensing entities with respect to such MFP-eligible individuals who are dispensed a selected drug under Medicare Part D or an MA-PD plan under Medicare Part C, for all dosage forms[3] of that drug. CMS defines "providing access to the MFP" to dispensers as ensuring that the net amount paid by the pharmacy/dispensing entity for the selected drug is no greater than the MFP.

CMS also explains in the guidance that the IRA law states that the negotiated prices used in payment by each Part D plan sponsor for each selected drug must not exceed the applicable MFP plus any dispensing fees for such drug. CMS explains that this requirement ensures that Part D MFP-eligible individuals will have access to the MFP at the point-of-sale, as intended by Congress. Requiring MFP-eligible individuals have access to the MFP ensures their cost sharing will be based on the applicable MFP – a price negotiated by Medicare with manufacturers intended to reduce the drug's costs significantly and therefore improve the affordability of the drug for a beneficiary.

NASP urges CMS to interpret the MFP for the select drugs as equal to the "lowest possible reimbursement" definition of "negotiated price" as set forth in the final Part D regulation issued by CMS that went into effect in January 2024.[4] It is clear in the IRA statute that Congress directed manufacturers to provide pharmacies access to the MFP for the selected drugs and CMS, through its proposed guidance, is seeking to establish a process to ensure pharmacies pay no more than the MFP when acquiring a drug. It stands to reason that if Congress intended for pharmacies to have access to the MFP, that the MFP (plus dispensing fees) would also be considered the negotiated price at the point of sale. To permit a plan sponsor to apply further price concessions to a Medicare negotiated drug, reducing a pharmacy's point-of-sale reimbursement below the MFP would most certainly put a pharmacy underwater on the ingredient cost of the drug alone. Such unreasonable reimbursement

[2] Defined in section 1191(c)(2)(A) of the Inflation Reduction Act.
[3] Including the list of NDC-9s and NDC 11s.
[4] Centers for Medicare & Medicaid Services (CMS), Department of Health and Human Services (HHS); Medicare Program; Contract Year 2023 Policy and Technical Changes to the Medicare Advantage and Medicare Prescription Drug Benefit Programs; Policy and Regulatory Revisions in Response to the COVID-19 Public Health Emergency; Additional Policy and Regulatory Revisions in Response to the COVID-19 Public Health Emergency; published May 9, 2022.

would be in violation of the Any Willing Pharmacy statute,[5] and CMS must enforce the law to ensure payment to pharmacy is reasonable to permit a pharmacy to participate in network.

NASP urges CMS to explicitly prohibit any post-sale pharmacy price concessions for select drugs with an MFP to safeguard pharmacies from further financial instability. Any post-sale concessions would fail to result in a reduction to a MFP-eligible individual's cost sharing, meaning that these individuals would never benefit from post-sale concessions applied to the selected drugs, and such post-sale concessions only serve to threaten the financial viability of pharmacies, their ability to dispense certain drugs, and their continued ability to participate in pharmacy networks. While reducing beneficiary out-of-pocket drug costs is a significant goal of the IRA reforms, in implementing the law, it is critically important that CMS also seek to protect beneficiary access to their pharmacies, and as such, prohibit post-sale pharmacy price concessions (post-sale pharmacy DIR fees).

The IRA statute is clear that pharmacies are to receive a dispensing fee[6] though it did not stipulate any amounts for such fees. However, as acknowledged repeatedly by CMS in the draft guidance, all pharmacies are expected to have an increase in their operating costs to manage the new MFP process, including but not limited to: management of inventory, any reporting and reconciliation of payments through the MTF, and potentially many different manufacturer payment process requirements, etc. **NASP requests that as part of its oversight responsibilities in implementing the IRA law, CMS monitor and audit Part D plan/MA-PD dispensing fee arrangements to ensure that Plans are recognizing and covering new pharmacy operating cost requirements associated with the MFP for select drugs in addition to respecting and affording dispensing costs specialty pharmacies incur compared to their retail pharmacy counterparts, due to the extensive patient service requirements both manufacturers and plans require from specialty pharmacies.**

- ***40.4.1 – Medicare Transaction Facilitator (MTF) Data Facilitation***

The IRA statute mandates that Primary Manufacturers make the MFP for selected drugs available to both MFP-eligible individuals and pharmacies/dispensing entities. When a pharmacy/dispensing entity is not purchasing the selected drug at MFP, pharmacies/dispensing entities will need a refund from the Primary Manufacturer administered through a retroactive process. CMS acknowledges that the following data exchange elements be in place to administer such a process: 1) verification that the selected drug was dispensed to a MFP-eligible individual via certain claim-level data elements and identifying which pharmacy/dispensing entity dispensed the select drug; 2) to initiate the 14-day prompt MFP payment window for effectuating the MFP refund for each claim for each selected drug to each pharmacy/dispensing entity; and 3) to collect payment-related data for each claim for a selected drug from Primary Manufacturers to indicate when a refund was paid and the amount of the refund paid. These requirements necessitate the coordination and reconciliation of several disparate data elements, including, but not limited to:

- Part D Verification to determine patient and drug MFP eligibility;
- Identifying 340B transactions that would not be MFP-eligible;
- Calculating MFP refunds; and

[5] Section 1860D-4(b)(1)(A) of the Social Security Act.
[6] Defined in section 1198(b)(3)(D) of the Inflation Reduction Act.

- Determining total pharmacy payment across responsible entities: patients, Part D plans and manufacturers

CMS has determined that it will engage a MTF to provide a myriad of services with some of these services being mandatory to allow for the exchange of data with manufacturers and for CMS to verify data from manufacturers to ensure compliance with the law.

CMS states that a Primary Manufacturer may choose to contract with one or more third parties to perform the data exchange operations with the MTF. **NASP urges that CMS mandate a single, standardized approach for data exchange and payment processes, regardless of the involvement of third parties, to streamline operations and reduce administrative burdens on pharmacies. Otherwise, pharmacies would have to configure their operations to meet the individual needs of several manufacturers as well as potentially multiple verification systems in order to ensure they are ultimately paid correctly for the MFP.**

Effectuating the MFP should not be directly or indirectly left to the pharmacies to figure out and manage, diverting pharmacy time and resources away from serving its patients and adding significant financial and administrative burden to pharmacies that, as mentioned, are already facing numerous financial pressures within the Part D program in the absence of sufficient financial support to cover their business costs.

While NASP is pleased that CMS intends to prohibit manufacturers and any manufacturer-contracted partner from charging pharmacies fees for the retrospective MFP data/payment processes, this does not fully insulate pharmacy risk, nor does this account for the potential costs and significant burden of the many ancillary activities pharmacies may have to perform to support manufacturers with MFP effectuation outside of a required data exchange process managed by the MTF. CMS states in the guidance that it "intends to leverage existing Part D claims data in this data exchange and does not envision dispensing entities separately transmitting claims data to Primary Manufacturers." NASP asks that CMS formally establish requirements and protections for pharmacies to ensure the burden of this data exchange process is not in any way placed on pharmacies. Pharmacies simply need more assurance beyond CMS intent in guidance. Pharmacies cannot be placed at any financial risk in order for the IRA law's requirements to be carried out. Congress clearly did not intend for pharmacies to shoulder the burden of MFP effectuation.

CMS states that requiring Primary Manufacturers to exchange data with the MTF will be necessary to administer a uniform approach to the start of the 14-day prompt MFP payment window for each claim to a pharmacy/dispensing entity and to the MTF for verification purposes, saying that any failure to meet this process will be considered a violation and risk the Primary Manufacturer being subjected to civil monetary penalties (CMPs) as permitted by the statute. **CMS does not address what happens to effectuation of the MFP for a pharmacy/dispensing entity should this occur, and the Primary Manufacturer is (or opts to be) subjected to CMPs instead of participating and carrying through the data exchange process. NASP must reiterate that pharmacies cannot be left at financial risk if manufacturers do not follow through on the requirement to effectuate the MFP. Pharmacies must receive assurance and commitment from CMS that in these circumstances, the MTF will work with CMS to leverage the existing Part D claims data process to effectuate the MFP for pharmacies.**

Data Transmission, Access and Timing – An Alternative Approach

NASP is providing comments on the process CMS has proposed to effectuate the MFP to pharmacies through its proposed guidance, but NASP strongly believes an alternative approach is likely needed in the absence of addressing pharmacies' concerns. NASP strongly encourages CMS to seek not to completely "reinvent the wheel" in terms of designing a new process to ensure manufacturers are able to meet statutory MFP requirements, but rather follow to the greatest extent possible, the existing claims process system that has proven to be efficient, effective, transparent and timely for all parts of the pharmaceutical channel (all contracted entities) in the transfer of claims data for verification and payment.

The existing Part D claims management process, including the facilitation of the existing Coverage Gap Discount Process (CGDP) under Medicare Part D that largely seems to facilitate a data exchange process that, with few alterations to better support increased transparency to pharmacies, could otherwise be mirrored to support manufacturer effectuation of the MFP as required under the IRA law. Indeed, NASP understands that Congress sought to model the MFP effectuation statutory requirement after the statute that established the CGDP[7] 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.

CMS has indicated that the CGDP model will be used to operationalize the new Manufacturer Discount Program (MDP) that IRA law replaced it with, saying that the MDP will be effective under the new Part D benefit starting in 2025. CMS should strongly consider the potential overlapping needs and functions necessary to also effectuate the manufacturer MFP (drug discount) refund. 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, NASP recommends that another contracted entity rather than a Plan Sponsor/PBM should 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

[7] 42 U.S. Code § 1395w–114a.

pharmacy's administrative and financial risk of no MFP retroactive payment or delayed retroactive payments.

In the absence of a CGDP-like pre-funded option, under the approach outlined by CMS in the guidance, NASP believes pharmacies will be essentially pre-funding retrospective MFP adjustments themselves and then having to pursue and track any and all MFP refund payments under potentially varied manufacturer approaches. This is unacceptable and not what Congress intended when passing the IRA law.

NASP is extremely concerned that with the various options under consideration by CMS in the proposed guidance, payment to pharmacies under a retroactive process would amount to MFP payment effectuation taking as long as 60 days or more for each claim for a dispensed selected drug. This despite the fact that the statute envisioned that pharmacies would be paid the MFP (plus dispensing fees) within a 14-day prompt payment period. This is because once claims data has been verified by the Part D plan sponsor, and the pharmacy has already received payment, CMS envisions having the plan sponsor submit complete prescription drug event (PDE) records to the Drug Data Processing System (DDPS) for secondary verification before that data is then sent to the MTF and then the MTF sends data information to the manufacturer for response. Today, in the absence of any MFP effectuation requirements, Part D plan sponsors have 30 days to submit complete PDE records to DDPS. This window of time is extremely unworkable if CMS is to require a secondary validation of Medicare Part D claims by the DDPS before data is made available to the MTF for the MTF to provide to manufacturers. **CMS states it is evaluating whether the current 30-day PDE data transfer window should be shortened to seven days to support pharmacies receiving timely MFP refunds. NASP must emphasize that is critically important that CMS shorten this window and would suggest the time window for submission of PDE records to the DDPS by plan sponsors be conducted in less than seven days, with CMS considering how this data exchange can be done in real time on a daily basis and function to capture all claims, reversals, and rebills. Under the CMS model proposed, there should likewise be very limited timing requirements for the claim-level data elements on each dispense of an NDC of a select drug to be transmitted from the MTF to Primary Manufacturers, with this also functioning in real time and on a daily basis.**

In addition to enforcing the IRA law's 14-day prompt MFP payment requirement from the Primary Manufacturer to the dispensing pharmacy, CMS is proposing to also require a Primary Manufacturer to transmit claim-level payment elements in its report with any payment-related data or information on no refunds provided to the MTF within the 14-day prompt MFP payment window. CMS explains this is to ensure CMS can appropriately administer the MFP program and to monitor compliance with the requirements of the program. CMS has outlined the following payment elements must be included in this transmission: the MFP refund transaction date; confirmation of the MFP refund to the dispensing entity; the method for determining the MFP discount/refund amount (including whether it was at the standard refund amount of WAC-MFP or another refund amount); the NPI of the entity receiving the MFP refund; the quantity of the selected drug; and the amount of payment sent as the MFP refund; whether no refund was paid (e.g., 340B claims); no refund was paid despite attempts to pay (no pharmacy response) or no refund paid (e.g., prospective access to the MFP was made to the pharmacy, etc.).

CMS states that it is also considering having the MTF generate an electronic remittance advice to the pharmacy/dispensing entity for purposes of reconciling manufacturer retrospective MFP refunds. **NASP urges CMS to have the MTF provide for electronic remittance advice with at least the same information that will be required from the Primary Manufacturers to the MTF. NASP asks that CMS ensure this information is provided electronically with payments under the 14-day prompt standard to support pharmacies in reconciling retroactive payment adjustments for all MFP selected drugs that are dispensed.**

NASP has specific concerns about the MFP payment process when there are circumstances that result in a drug being dispensed but never received by the MFP-eligible individual (e.g., a patient opts not to receive the medication due to cost, and it goes back into a pharmacy's stock); and other claim reversals and adjustments. A process under the model CMS has proposed would need to allow for a credit or at least a reasonable reversal process to be in place, if a pharmacy was in receipt of the MFP for a drug that has a claim that is ultimately reversed or not completed. The process would need to allow for information to be reported to and captured by the MTF to moderate a payment adjustment between the pharmacy and manufacturer in a non-burdensome and timely manner. NASP is discussing this issue further with its members who represent the entire channel of specialty pharmacy to understand recommendations it can offer to support a fair and non-burdensome process to address claim adjustments and reversals that occur after the pharmacy has been paid a retroactive MFP.

- ***40.4.2 – Nonduplication with 340B Ceiling Price***

The IRA law states that the Primary Manufacturer of a select drug is not required to provide access to the MFP for a select drug to MFP-eligible individuals who are eligible to be dispensed a drug subject to a 340B ceiling price under statute if the 340B ceiling price is lower than the select drug's MFP. Primary Manufacturers are required to provide access to the MFP to 340B covered entities in a nonduplicated amount to the 340B ceiling price if the MFP for the select drug is lower than the 340B ceiling price.

The proposed guidance makes clear that CMS will not assume responsibility for "deduplicating" discounts and instead expects manufacturers to assume that responsibility themselves. Supplying claims data is to be voluntary by a dispensing entity while CMS works to establish a process to identify applicable 340B eligible claims through the reporting of payment elements to the MTF. **For those dispensing entities that opt to provide this information, NASP believes the effort would be immensely burdensome as dispensers seek to work with individual manufacturers through their separate data submission processes.**

CMS proposes that when a 340B price is lower than MFP, 340B entities append a modifier on the claim to identify the claim as 340B, which CMS believes would allow the manufacturer to avoid making the default payment for those claims. Yet, CMS acknowledges that most covered entities and their contract pharmacies cannot identify 340B claims at the point of sale, and likely not until days later, after the claim is submitted. **NASP believes it would be unworkable to expect pharmacies to use a separate physical inventory of 340B drugs.**

NASP is concerned that contract pharmacies for 340B covered entities will be in a very difficult situation regarding MFP implementation. Many contract pharmacies use a replenishment model,

receiving drugs from the covered entity after they have been validated as 340B eligible. This process can take over 20 days after a 340B-eligible drug has been dispensed.

CMS should develop a methodology that would enable covered entities to retrospectively submit 340B claims data to the MTF and require that the MTF use the data to identify 340B claims that should be withheld from being submitted to the manufacturer.

Absent CMS guidelines and criteria for the manufacturers' nonduplication plans, a manufacturer could require covered entities to submit large volumes of data to the manufacturer or its contractor in order to receive the 340B price or MFP as a refund. However, this would be at odds with the longstanding practice of covered entities accessing the 340B discount as a purchase price and would be highly disruptive to how hospitals manage their 340B programs. Outside of a very narrow exception for AIDS Drug Assistance Programs, HRSA has never authorized manufacturers to offer 340B discounts as refunds instead of purchase prices.

NASP strongly encourages CMS to work with stakeholders to find more viable alternatives to ensure covered entities can purchase drugs at the 340B price and support efforts to address MFP refunds through a process that works with hospital and contract pharmacy processes to manage 340B drugs.

- ***40.4.3 – Retrospective Refund Amount to Effectuate the Maximum Fair Price (MFP)***

As addressed earlier in these comments, **NASP is concerned that separating the MFP financial transaction from the real-time claims processing system to be managed by the manufacturer under Part D could result in significant payment delays and disruptions for pharmacies. The best way to facilitate a retrospective MFP approach would be to create an automated, standardized, transparent, and predictable process, modeled after the Coverage Gap Discount Program (CGDP) that is aligned with current Part D claims processing systems in order to ensure timely MFP payments. Such an approach would reduce administrative burdens on pharmacies and manufacturers as well as financial risk and support a 14-day payment standard.**

For Primary Manufacturers to meet their statutory obligation under the IRA to make the MFP available to pharmacies, if on a retrospective basis, CMS has proposed a Standard Default Refund Amount that reflects the difference between the selected drug's WAC and the MFP. However, CMS is also proposing to let manufacturers opt for an alternative refund formula instead of the Standard Default Refund Amount to effectuate the MFP for a pharmacy.

NASP believes use of WAC would allow for a fair standard metric to approximate a pharmacy's acquisition costs as it is generally accepted that specialty drugs are acquired at this benchmark. NASP urges CMS to require use of this standardized metric across manufacturers for determining retrospective payments in order to allow for predictability and replication across the pharmaceutical channel to support the pharmacy refund amount. Since WAC and MFP are both publicly available data they would easily allow for an auditable MFP refund amount for all stakeholders, including pharmacies, manufacturers, and Medicare.

Permitting a variety of metrics for determining pharmacy acquisition costs would be administratively burdensome for pharmacies as pharmacies seek to reconcile their payments for selected drugs across

many manufacturers. NASP also urges CMS to prohibit manufacturers from requiring pharmacies to individually report their acquisition costs, as there are likely thousands of different acquisition costs for the same drugs as each pharmacy in the United States has different contract terms with entities in pharmaceutical channel, and sharing such information would allow proprietary pharmacy acquisition costs to be shared with others in the channel that are not privy to this information. Allowing a multitude of refund formulas could also lead to the risk of unreasonable metrics that are falsely assumed to model pharmacy acquisition costs.
The use of unreasonable metrics to address pharmacy acquisition costs in the absence of any CMS guardrails and agency oversight would only further undercut pharmacy reimbursement under Part D, contributing to the financial strain many pharmacies are already facing today.

CMS needs to provide greater oversight and a formal approval process for manufacturers if it opts not to require WAC as the standard pricing metric to be used by all Primary Manufacturers. CMS must provide information on how it will determine whether and what type of alternative pricing metrics (not WAC) ensure reasonable reconciliation payments to pharmacies that are sufficient for Primary Manufacturers to meet their obligations to make the MFP available under the terms of the law. CMS must also explain and set requirements as to how a pharmacy would be made aware of any Primary Manufacturer's decision to use an alternative metric to WAC and be provided information on that metric in advance of its use with an opportunity to appeal for reconsideration of the metric and alert CMS to its concerns.

- ***40.4.4 – Options for Medicare Transaction Facilitator (MTF) Payment Facilitation***

CMS states it has received immense stakeholder feedback that MTF payment facilitation is important to support manufacturer effectuation of the MFP. While the agency interprets the IRA law to say it is the sole responsibility of the Primary Manufacturer to provide access to the MFP and that CMS has no express role to support manufacturer effectuation of the MFP, CMS is considering how the MTF could offer some form of a voluntary payment facilitation functionality that connects the Primary Manufacturer to the dispensing entity for the purpose of providing a retrospective refund to the dispensing entity within a 14-day prompt MFP payment window.

NASP agrees that MTF payment facilitation under the model proposed by CMS in the guidance would be essential to effectuate the MFP. NASP also thinks the MTF is needed if CMS opts to support access to the MFP through an alternative approach that models the Coverage Gap Discount Program (CGDP).

NASP strongly disagrees with CMS' determination that it has no express role to support manufacturer effectuation of the MFP. CMS oversight, guardrails and review of the MTF payment facilitation process will be essential to ensure that all players in the pharmacy channel appropriately address the ultimate process CMS puts in place. At a minimum, CMS' role in this effort should include:

- **Defining roles and responsibilities for key activities and transactions in the MFP effectuation process (e.g., Part D plan required to verify MFP eligibility; MTF to assess WAC values; Primary Manufacturer to not set unreasonable acquisition metrics; pharmacy to verify accuracy of MFP payment);**

- **Clarifying which entities can play a role in effectuating the MFP based on required capabilities (e.g., only Health Insurance Portability and Accountability Act (HIPAA) covered entities are able to manage claims-based level transactions);**
- **Defining minimum data standards for core transactions (e.g., refund request must include claim number, NDC, units dispensed, etc.)**
- **Ensuring financial accountability across channel stakeholders to oversee against and mitigate against any cost shifting to pharmacies.**

In the proposed guidance, CMS solicits comment on two distinct payment facilitation options that would be voluntary to the for both Primary Manufacturers and pharmacies:

1. The MTF collecting banking information from participating pharmacies/dispensing entities and providing that information to Primary Manufacturers who want to receive that information in order to provide payments.
2. The MTF receiving aggregated refund amounts from participating Primary Manufacturers and passing through the refunds to participating pharmacies/dispensing entities.

Technical specifications for both options have not yet been provided by CMS.

NASP believes that if CMS opts to not amend its approach to facilitate payment through existing claims processing systems similar to the CGDP, then it needs to allow for a MTF process that supports a standardized, accurate and expedited process for issuing fair and appropriate MFP payments to pharmacies. While it is difficult to completely evaluate the two options provided by CMS, NASP pharmacy members would likely be most interested in Option 2 given that, as explained in the guidance, the MTF would provide payment confirmation to both the dispensing entity and the Primary Manufacturer to demonstrate effectuation of the payment and close out the transaction while also maintaining a record of the execution of payment within the 14-day prompt MFP payment window for each transaction facilitated, which could assist in any dispute and complaint resolution process between the pharmacy and a manufacturer.

As raised previously in these comments under Section 40.4.1, CMS does not provide for any process to ensure effectuation of the MFP for a pharmacy/dispensing entity if a Primary Manufacturer is found to not meet its 14-day payment statutory requirement (intentionally or unintentionally) and is subjected to CMPs. **NASP must reiterate that pharmacies cannot be left at financial risk if manufacturers do not follow through on the statutory requirement to effectuate the MFP. Pharmacies must receive assurance and commitment from CMS that in these circumstances, the MTF will work with CMS to leverage the existing Part D claims data process and/or structure a pre-payment account with Primary Manufacturers similar to the model used in the CGDP in order to effectuate the MFP for pharmacies and protect pharmacies from financial risk.**

- ***40.4.5 – Medicare Transaction Facilitator (MTF) Dispensing Entity Participation Requirements***

The MTF is required to be used by Primary Manufacturers for data exchange as outlined in section 40.4.1; however, use of the MTF for facilitation of retrospective refund payments is at the option of both Primary Manufacturers and pharmacies as outlined in section 40.4.4. If not utilized for payment

facilitation, payments to pharmacies would be provided through a separate process agreed to by the Primary Manufacturers and pharmacies.

NASP is pleased that CMS makes clear in this section that neither Primary Manufacturers nor their contracted entities shall charge pharmacies/dispensing entities any transaction or other fees for the data exchanges facilitated through the MTF. However, such assurances are insufficient. NASP remains extremely concerned about the financial uncertainty and cash flow challenge pharmacies will face if the transaction process across all Primary Manufacturers of selected drugs and pharmacies is not uniform, standardized and seamless. Pharmacies having to manage a multitude of different payment systems among manufacturers would be untenable. CMS must require that a uniform payment transaction system be utilized regardless of whether it is administered by the MTF or administered by manufacturers and/or their contractors.

- ***40.5 – Compliance with Administrative Actions and Monitoring of the Drug Price Negotiation Program***

CMS states in the guidance that it is required by the IRA law to establish a robust program for monitoring compliance with the Negotiation Program. However, **NASP is concerned that CMS states it "may" audit any data related to the Primary Manufacturer providing access to the MFP, including where the selected drug is provided by a Secondary Manufacturer. NASP wants to emphasize the importance of CMS overseeing and requiring compliance with the process for data exchange to effectuate the MFP, and reiterate that CMS should go further to require standardization and uniformity around payments to pharmacies with CMS oversight and protections to ensure that pharmacies are not put at any financial risk for the requirements of the law addressing MFP payments. The process for the exchange of information between manufacturers and pharmacists must be part of a mandatory audit by CMS.**

Section 90 – Manufacturer Compliance and Oversight

- ***90.2 – Monitoring of Access to the MFP in 2026 and 2027***

This section of the draft guidance reiterates statutory requirements that Primary Manufacturers must meet, providing pharmacies and other dispensing entities and MFP-eligible individuals access to the MFP, and that this requirement applies to all sales of the selected drugs, including when there are Secondary Manufacturers. CMS states that if it determines through audits, investigations, and complaints from pharmacies or other market participants that Primary Manufacturers have not fulfilled their MFP obligations to make the MFP available within the 14-day prompt MFP payment window, CMS will first encourage payment discrepancies to be addressed and may then issue CMPs.

NASP would appreciate clarity from CMS on the frequency in which it will proactively audit manufacturer compliance and whether it will commit to interviewing participating pharmacies that are dispensing MFP drugs to understand concerns and options for how to address these concerns for pharmacies.

CMS states that when claims are paid at a refund amount other than the Standard Default Refund Amount (WAC), Primary Manufacturers will be required to maintain documentation demonstrating why MFP refunds were provided to an amount other than the Standard Default Refund Amount or were not provided for applicable claims.

- ***90.2.1 – Manufacturer Plans for Effectuating MFP***

Under this Section, CMS states that it will require Primary Manufacturers to submit their plans for making the MFP available, including their process for deduplicating 340B covered units for the selected drug, in writing to CMS at least seven months before the start of the first initial price applicability year for the selected drug (June 1, 2025). CMS believes this will allow the agency sufficient time to conduct outreach to Primary Manufacturers to review their plans, conducting a risk assessment for each submission. CMS also clarifies that manufacturers' plans must include description(s) of the types of documentation and data they would collect, maintain and deliver to CMS. CMS plans to publish the manufacturer plans on the CMS IRA website, making all non-proprietary information accessible to pharmacies and others.

CMS states that all Primary Manufacturer plans will be assessed for their consistency with the requirements outlined in sections 40.4-40.4.5 of this draft guidance and must include:

- Information on the plan to meet the 14-day prompt MFP payment window for reimbursing pharmacies regardless of whether the manufacturer is using the potential MTF functionality to administer payment or its own mechanism to administer payment;
- Policies and procedures for determining the methodology it will use to calculate the amount of each reimbursement due to the dispensing entity (WAC, actual acquisition cost, or otherwise); and
- Confirmation it will submit verification of reimbursement to the MTF via the requested report with payment-related data for meeting the 14-day requirement.
- Information on whether it will participate in the potential MTF payment facilitation functionality.

CMS also states that it will conduct a risk assessment for each plan submission, and when plans are identified by CMS as having a greater risk of failing in making the MFP consistently available, subject such manufacturers to increased scrutiny through CMS' monitoring and oversight activities.

CMS also states that if a Primary Manufacturer decides to make a change from proactively effectuating the MFP at the point of sale or makes any other changes to its MFP methodology, it must inform CMS within 90 days or as soon as practical.

NASP supports CMS efforts to establish an earlier deadline for manufacturer plans to be made available and agrees that this plan information should be made available to pharmacies/dispensing entities in advance of the MFP process going into effect. To support transparency and clarity of process, it is essential that pharmacies understand the process manufacturers will use to effectuate the MFP and what processes CMS will be undertaking to ensure compliance.

NASP wants to reiterate and emphasize strongly its concern about all manufacturers setting their own operational plans, requiring pharmacies to then understand and potentially set up different processes

to manage numerous manufacturer processes for a multitude of drugs as the drug negotiation program continues to grow. This would be untenable for pharmacies to manage administratively and afford. CMS also addresses directly that it will conduct a risk assessment of manufacturer plans, assuming some may be at risk of failing. This acknowledgement furthers our point on the need for standardization, uniformity and consistent oversight. We urge CMS to use its authority to enforce the law's requirements by standardizing a process. Information from the manufacturers on how they foresee managing the process should first be collected by CMS, and then a formal process outlined that all must follow.

For those plans identified by CMS to have risk, NASP would like to better understand what CMS's process to rectify concerns will be put in place, and what engagement pharmacies would have in this process, since it is pharmacies that are the ones subject to significant financial risk as any manufacturer plan is put in place.

NASP is extremely concerned about CMS' vague proposed oversight standard of a manufacturer being able to inform CMS as soon as practical of any planned change in its payment of the MFP. There is nothing in the guidance that speaks to when a pharmacy/dispensing entity would be required to be informed of any change in the payment of the MFP, and manufacturers are given flexibility to report or not report any change to CMS. The lack of a standard for manufacturer reporting of changes in effectuating the MFP to CMS and no standard requirement for manufacturers to inform pharmacies of these changes could have significant negative consequences for pharmacies to raise a complaint, dispute or appeal lack of payment or incorrect payment amounts to either CMS or the manufacturers and to have these addressed and addressed in a timely manner.

- ***90.2.2 – Negotiation Program Complaints and Disputes***

CMS states that it will establish a centralized intake system for receiving reports on complaints and disputes related to access to the MFP with respect to eligible individuals (beneficiaries) and pharmacies/dispensing entities that provide selected drugs to MFP-eligible individuals. It describes this process to have different tracks and to focus on technical issues and data matters, making clear that the MTF intake process for addressing such concerns will under no circumstances determine whether a Primary Manufacturer has provided access to the MFP or met its legal obligations (e.g., payment to pharmacies within 14-days). CMS states that the agency itself would be responsible for these issues not the MTF, and that it is still exploring options for collecting appeals/complaints and addressing them. CMS specifically states that it is still exploring the limits on the scope of disputes and complaints that the agency may remediate in the context of otherwise private transactions between Primary Manufacturers and dispensing entities.

CMS must establish a clear process for addressing any financial transaction disputes between manufacturers and pharmacies, ensuring that pharmacies have a reliable mechanism for reporting and resolving issues. It is unclear how CMS would ever be able to comply with the law's requirements to impose CMPs on manufacturers that do not effectuate the MFP for eligible individuals or pharmacies/dispensing entities if it is not able to appropriately consider proactive financial-related

complaints/disputes received or act on them. NASP would again reiterate that the law needs to be enforced by CMS, and that a standardized and required process for payment under Medicare Part D, rather than an optional and private payment process, is essential to effectuating the MFP. The amount of pressure on the channel to accurately provide access to the MFP is immense, and to establish a free-for-all system where manufacturers have carte blanche to design their own payment systems will create chaos for pharmacies and result in significant payment errors. This puts both pharmacies and manufacturers at extreme financial risk – as there is no guarantee of payment to a pharmacy, and manufacturers may be subjected to CMPs. NASP again recommends that CMS reconsider its approach entirely and instead rely on the existing claims process including the CGDP in order to support access to the MFP for pharmacies and ensure a streamlined process for all entities in the channel.

Section 100.1 – Failure of Manufacturer to Ensure Access to a Price Less Than or Equal to the MFP

CMS states that upon discovery and confirmation of a failure to make the MFP available, CMS will send the Primary Manufacturer Notice of Potential Noncompliance and establish an "informal" process allowing the Primary Manufacturer 10 business days to respond to the notice. CMS will then consider the materials and make a decision regarding manufacturer liability and any CMPs.

NASP is alarmed that such a process to assess compliance with the law's requirements is being presented as an informal process. The law requires that the MFP terms be met and met within a specifically defined window of 14-days. CMS' informal process as suggested, would allow for well over 10 days before any decision is reached on manufacturer compliance with effectuating the MFP. As this process rolls out, pharmacy payment remains non-existent, and CMS does not address what happens when the MFP is not effectuated, effectively leaving pharmacies to "hold the bag." This is a significant concern and must be addressed by CMS. CMS should establish a formal, expedited process for addressing non-compliance with MFP requirements, ensuring resolution within the already defined 14-day payment window to prevent any financial risk to pharmacies.

Section 110 – Part D Formulary Inclusion of Selected Drugs

CMS states that Medicare Part D plans must include each covered Part D drug that is a selected drug on Part D formularies during contract year 2026 (and 2027) if a MFP is in effect for that drug that year and during each subsequent year that a MFP for the selected drug. However, CMS states it does not have sufficient information to determine whether changes to the formulary inclusion policies are warranted given that it does not yet have information on plan formularies for Contract Year 2025 nor for Contract Year 2026 – the first year the law goes into effect. CMS says it intends to monitor Part D plans' compliance with formulary requirements and treatment of selected drugs and may possibly address formulary policies in the future. CMS also says that it will not implement explicit tier placement or utilization management requirements at this time. CMS does express concern that Part D sponsors may be incentivized in certain circumstances to disadvantage selected drugs by placing selected drugs on less favorable tiers compared to non-selected drugs, or by applying utilization management that is not based

on medical appropriateness to steer Part D beneficiaries away from selected drugs in favor of non-selected drugs.

NASP is concerned about specialty patient access to the selected drugs whether for new patients or for those on current selected drug therapies, where a change in drug formulary could be extremely detrimental to their treatment. It is a very valid concern that Part D sponsors may make significant formulary changes as a result of the law, and CMS oversight and enforcement will be essential to protecting patient access to their needed specialty medications. NASP urges CMS to implement monitoring and enforcement mechanisms that ensure Part D sponsors cannot make formulary changes that disadvantage selected drugs and harm patient access.

Conclusion

NASP looks forward to continued opportunities to work with CMS as it implements the Medicare Negotiation Program. To address questions about our comments or for further information, please contact me at Sheila.Arquette@naspnet.org.

Sincerely,

Sheila Arquette, RPh.
President and CEO