

Submitted electronically to IRARebateandNegotiation@cms.hhs.gov

September 18, 2026

Mehmet Oz, M.D.
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
7500 Security Boulevard
Baltimore, MD 21244–1850

Re: Medicare Drug Price Negotiation Program: [Draft Guidance, Manufacturer Effectuation of the Maximum Fair Price in 2028](#)

Administrator Oz,

The National Community Pharmacists Association (NCPA) appreciates the opportunity to provide comments to the Centers for Medicare and Medicaid Services' (CMS') *Draft Guidance - Manufacturer Effectuation of the Maximum Fair Price in 2028*.

NCPA represents America's community pharmacists, including 18,900 independent community pharmacies. Almost half of all community pharmacies provide long-term care services and play a critical role in ensuring patients have immediate access to medications in both community and long-term care (LTC) settings. Together, our members employ 235,000 individuals, and provide an expanding set of healthcare services to millions of patients every day. Our members are small business owners who are among America's most accessible healthcare providers. NCPA submits these comments on behalf of both independently-owned community and long-term care pharmacies.

NCPA has the following comments on the draft IPAY 2028 guidance for the Medicare Drug Price Negotiation Program.

Manufacturers Should Reimburse Authorized Generics at the SDRA, or an Otherwise Transparent Amount

NCPA's members have indicated that for authorized generics that have MFPs, manufacturers are not providing MFP refunds under the MDPNP at the same amount as the brand equivalent of the drug, despite manufacturers pledging to do so in their effectuation plans. To remedy this issue, NCPA is working to ensure that manufacturers are reimbursing authorized generics the same, at the Standard Default Refund Amount (SDRA). **We prefer that CMS mandate that manufacturers must reimburse authorized generics at the SDRA. However, if manufacturers reimburse at the pharmacy's contract purchase price for the authorized generics, NCPA requests that CMS**

mandate that manufactures clarify that point in effectuation plans, in a manner that can be visible to pharmacies, including how their refund amount is calculated.

For example, in CMS' proposed Appendix B: Medicare Drug Price Negotiation Program MTF DM Primary Manufacturer MFP Effectuation Plan Form, the manufacturer can opt to select "Option 3" which occurs when "[t]he Primary Manufacturer generally plans to use a proxy for acquisition cost other than the applicable SDRA to calculate and make the retrospective MFP refund payments to dispensing entities and/or Part B providers. If selecting this option, [the manufacturer must] provide the proxy measure(s) the Primary Manufacturer intends to use in the space provided."¹ **NCPA seeks clarity from CMS and manufacturers which amount the manufacturers will use as a proxy under Option 3, and if it applies to some pharmacies and not others. NCPA requests clarification from CMS and manufacturers as to what tiering system is applied to the SDRA, to which pharmacies, and how CMS and manufacturers are defining various types of pharmacies under this system.**

Manufacturer MFP Effectuation Plans Should Be More Transparent

NCPA and its members have been thankful for CMS making manufacturers' effectuation plans public, but notes that it is difficult for pharmacies to interpret these plans as they are highly redacted. For example, pharmacies often do not know precisely how much they will be paid by manufacturers for the MFP refund amount, and how timely they will be paid by manufacturers. This makes Part D plan contracting challenging for pharmacies, who are trying to negotiate with plans and PBMs for payment of the MDPN drugs. NCPA is thankful that CMS is considering making such details "...available to dispensing entities, Part B providers, and possibly other stakeholders upon request without redactions....,"² although this clarity will only be available beginning in 2028. We ask that this information be made available now to pharmacies for IPAY 2027, as CMS has all that information already from the manufacturers.

Manufacturers Should Provide More Support for Pharmacies with Material Cashflow Concerns

CMS states that during the MTF DM enrollment, CMS will ask dispensing entities and/or Part B providers to self-identify whether they are a dispensing entity and/or Part B provider that anticipates 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.³ NCPA notes that while our members continue to self-identify as having material cashflow concerns, we are not seeing differences in how manufacturers are treating pharmacies that self-identify. NCPA seeks greater clarity from CMS on what manufacturers should offer

¹ [Medicare Transaction Facilitator for 2028 under Sections 11001 and 11002 of the Inflation Reduction Act \(IRA\)](#), Appendix B: Medicare Drug Price Negotiation Program MTF DM Primary Manufacturer MFP Effectuation Plan Form, page 7. July 24, 2026. CMS.

² [Medicare Transaction Facilitator for 2028 under Sections 11001 and 11002 of the Inflation Reduction Act \(IRA\)](#), Appendix B: Medicare Drug Price Negotiation Program MTF DM Primary Manufacturer MFP Effectuation Plan Form, page 1. July 24, 2026. CMS.

³ [Draft Guidance on Manufacturer Effectuation of the Maximum Fair Price in 2028 under the Medicare Drug Price Negotiation Program](#), page 49. July 16, 2026. CMS.

pharmacies that self-identify as having material cashflow concerns. After CMS' experience to date with manufacturers IPAY 2026 effectuation plans, we urge CMS to create specific standards by which the agency will evaluate whether the manufacturers' cash flow mitigation plans for IPAY 2027 will make a meaningful difference in improving the financial situation of community pharmacies.

340B Concerns

Contract pharmacies should not be required to identify 340B claims for the MFP program. The draft guidance states that a dispensing entity may voluntarily apply indicators to a Part D claim to indicate the claim is being billed for a 340B drug.⁴ **NCPA supports CMS not requiring contract pharmacies to identify 340B claims, and re-emphasizes the infeasibility of contract pharmacies identifying those claims either proactively or retroactively.** NCPA has found that the N1 transaction is not feasible as it is not adopted by pharmacy information systems. For details of NCPA's position, see our [July 2024 comments](#) to CMS' *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*, as well as our [March 2023 comments](#) to CMS' *Medicare Part D Drug Inflation Rebates Paid by Manufacturers: Initial Memorandum, Implementation of Section 1860D-14B of Social Security Act, and Solicitation of Comments*.

340B interaction with MDPNP. An issue that our members continue to face is in regard to the interaction between the MDPNP and the 340B program. Pharmacies have alerted NCPA that Beacon MFP, acting on behalf of the manufacturers of MDPNP selected drugs, is inappropriately rejecting MFP refund claims due to the assumption that the drugs are 340B drugs and that the pharmacy is a contract pharmacy. They are subsequently denying good faith inquiries (GFI) by pharmacies that have no contract pharmacy relationships or have reasonable belief that a claim is not 340B-eligible. Lacking a contract pharmacy agreement, these pharmacies are not replenished with inventory purchased by the covered entity, nor trued up financially thus they are owed a refund from the manufacturer to effectuate MFP. Additionally, members that do have contract pharmacy agreements also report inappropriately rejected MFP refund claims due to 340B status and also report dissatisfaction with the GFI process.

NCPA is advising our members to access their 835 remittance advice available in the Medicare Transaction Facilitator and review lines with Remittance Advice Remark Code (RARC) = N907 No refund because this claim has been identified as 340B-eligible with a ceiling price lower than the maximum fair price to identify any rejected MFP refunds. NCPA is also telling members that all the manufacturers with an MFP drug in 2026 use Beacon MFP to handle GFIs from pharmacies, but that they need to sign in or enroll to open a GFI. NCPA advises members that the first step to correct this is to use the Beacon MFP GFI process. If using the Beacon MFP GFI process does not correct MFP refund payment, NCPA is advising its members to use CMS' dispute form in the MTF.

⁴ Page 32.

That being said, this issue remains a long-standing and unresolved matter, and NCPA requests CMS to develop a permanent solution. NCPA members are waiting weeks on end for refunds that may not come, while having to constantly submit and monitor complaints. It's very burdensome and a major cashflow concern that the agency has told us it's working to address for months. Again, NCPA requests CMS to develop a permanent solution and make that solution public. We also urge the agency to work with pharmacies and other stakeholders on the 340B rebate pilot model should that be implemented in January 2027 for the IPAY 2026 and IPAY 2027 drugs. This pilot may help mitigate the 340B issues with the MFP program, but we ask the agency to work with us over the next few months on assuring smooth implementation.

NCPA thanks CMS for the opportunity to provide feedback, and we stand ready to work with the agency to offer possible solutions and ideas. Please let us know how we can assist further, and should you have any questions or concerns, please feel free to contact me at steve.postal@ncpa.org or (703) 600-1178.

Sincerely,

A handwritten signature in black ink, appearing to read 'Steve Postal', with a stylized flourish extending from the end.

Steve Postal, JD
Senior Director, Policy & Regulatory Affairs
National Community Pharmacists Association