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Sept. 03, 2025

The Honorable Thomas J. Engels
Administrator
Health Resources and Services Administration
U.S. Department of Health and Human Services
Department of Health and Human Services
5600 Fishers Lane
Rockville, MD 20857

Re: 340B Program Notice: Application Process for the 340B Rebate Model Pilot Program [HRSA-2025 and HRSA–2025–14619]

Administrator Engels,

The National Community Pharmacists Association (NCPA) appreciates the opportunity to provide comments to HRSA on its Request for Public Comment *340B Program Notice: Application Process for the 340B Rebate Model Pilot Program*.

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 205,000 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 community and LTC independent pharmacies.

Concerns with Scope

NCPA has the following concerns regarding the scope of the 340B Rebate Model Pilot program ("Pilot"):

Pilot should be limited to payers and claims in MDPN program. According to the notice, "The scope of this voluntary 340B Rebate Model Pilot Program will be limited to the NDC–11s included on the CMS Medicare Drug Price Negotiation [MDPN] Selected Drug List, regardless of payer." **NCPA asks that HRSA limit the Pilot to only include Medicare Part D payers and claims for the first 10 drugs under the MDPN Program, not all payers/claims covering these 10 drugs, for 2026.** There are many operational, technical, and even legal questions associated with the pilot. For example, it is not clear: 1) whether HRSA, CMS and manufacturers have the legal authority to do 340B price effectuation through a rebate model rather than an upfront discount, and if so, if this rebate model can be applied to all payers, especially for non-Medicaid claims, under the

340B statute; 2) how the rebates will work with respect to contract pharmacies, given that contract pharmacies are not explicitly mentioned as a recipient of the 340B refund in the notice; and, 3) if manufacturers will be able to meet the rebate turnaround times so that covered entities and contract pharmacies can maintain cash flow. Given the many complex questions, operational challenges, and financial risks, NCPA advises that HRSA be deliberate in pursuing this pilot, as there are many potential unintended consequences that could be disastrous for covered entities, the pharmacies that serve them, and the 340B program.

Implementation Concerns

One of the questions that HRSA asked commenters to consider is: "Are there any potential implementation issues not yet sufficiently accounted for in the pilot design (e.g., logistical or administrative burdens)?" **NCPA has the following concerns:**

Concerns with pilot may result in covered entities and contract pharmacies not stocking the ten MDPN program drugs. This rebate model, because of its complicated and unclear mechanisms and delayed payment concerns, may cause covered entities and contract pharmacies to not stock the first ten drugs covered under Part D, , which would in turn hurt the 340B program and harm access of patients to affordable drugs. Under the Medicare Drug Price Negotiation program, contract pharmacies may experience further delays in payment beyond those expected under the negotiation program if manufacturers do not send timely refunds.

Unknown risk for contract pharmacies. **The Pilot as written is not clear on whether contract pharmacies will be holding risk, so NCPA advises that HRSA clarify the role of contract pharmacies before finalizing the Pilot.** Because it is not clear how contract pharmacies will participate in the reimbursement/rebate/claims submission process, and because of the challenges contract pharmacies face in identifying 340B claims, there is a risk contract pharmacies will opt out of the program, thereby limiting the ability of covered entities to use contract pharmacies. This will essentially put the continued participation of contract pharmacies in jeopardy, in turn limiting access for patients.

NCPA interprets the proposed pilot to envision that under the pilot, the manufacturer sends the refunds to the covered entities. However, under the Medicare Drug Price Negotiation program, manufacturers send refunds to pharmacies. **NCPA asks HRSA if under the proposed pilot, can contract pharmacies receive 340B refunds, or can only the covered entities receive 340B refunds?**

Seeking clarity on operationalization of contract pharmacy payment for drugs under the 340B rebate model and the Medicare Drug Price Negotiation Program. Under the proposed rebate model, for drugs in the Medicare Drug Price Negotiation subject to 340B pricing, NCPA believes that the plan/PBM would pay the pharmacy no more than the maximum fair price (MFP) plus any dispensing fee, and that the manufacturer would pay the remainder payment of Wholesale Acquisition Cost (WAC) minus MFP. The manufacturer would then have 14 days to pay the MFP refund after the claim gets to the Medicare Transaction Facilitator Data Module (MTF-DM), which is the minimum amount due for any drug from the manufacturer, including the 340B drug. **NCPA**

asks clarification from HRSA that if the 340B covered entity applies for a rebate on an MFP drug after the MFP refund has been paid to the pharmacy, how will this be operationalized in the MTF-DM and the Medicare Transaction Facilitator Payment Module (MTF-PM)? NCPA believes that the manufacturer at a minimum owes an MFP rebate if the 340B contract price is lower than MFP. NCPA also seeks clarification from HRSA if the manufacturer will send an additional refund to the pharmacy under the proposed rebate model if the 340B price is lower? Or will the manufacturer reverse the previous payment to the pharmacy and then send the entire WAC-340B refund to the covered entity? NCPA notes that the term "contract pharmacy" does not appear in the 340B rebate model guidance.

NCPA believes that payment to contract pharmacies under the rebate model will occur in either of these two scenarios. **NCPA asks HRSA to confirm if our assumptions below are correct:**

Scenario 1: If the MFP is lower than the 340B price:

- The contract pharmacy fills the prescription for the selected drug;
- The PBM/health plan pays the contract pharmacy no more than MFP plus any professional dispensing fee;
- The PBM/health plan sends the claim to DDPS, which in turn sends the claim to the MTF-DM, which finally sends the claim to the manufacturer;
- The manufacturer pays the MFP refund claim (which is likely WAC-MFP) within 14 days to the contract pharmacy;
- The claim is determined later to be 340B;
- The covered entity cannot seek a refund because the MFP is lower than the 340B ceiling price;
- Therefore, the total payment goes to the contract pharmacy.

Scenario 2: If the 340B price is lower than the MFP:

- The contract pharmacy fills the prescription for the selected drug;
- The PBM/health plan pays the contract pharmacy no more than MFP plus any professional dispensing fee;
- The PBM/health plan sends the claim to DDPS, which in turn sends the claim to the MTF-DM, which finally sends the claim to the manufacturer;
- The manufacturer pays the MFP refund claim (which is likely WAC-MFP) within 14 days to the contract pharmacy;
- The claim is determined later to be 340B;
- Either:
    - 1) The manufacturer owes an additional refund to the contract pharmacy to provide the difference between the MFP and the 340B price, OR
    - 2) the manufacturer reverses the WAC-MFP refund payment to the contract pharmacy, the manufacturer gets a credit in the credit/debit ledger system, and then the manufacturer provides the WAC-340B refund to the covered entity for the 340B claim.

NCPA stresses that it is very important that HRSA and CMS clarify these scenarios so that contract pharmacies understand the flow of payment. HRSA should work with CMS to better describe the flow of payments. This is important with respect to the contractual relationships that contract pharmacies have with covered entities. This will also affect the replenishment model which has operated for many years in reducing contract pharmacy outlays for drug product purchases for prescriptions filled for patients of the covered entity. Elimination of the replenishment approach for these drugs will increase pharmacy cost of goods and add to financial pressures.

Variability in pilot programs will create significant administrative burden for contract pharmacies. **NCPA is also concerned with the variability in the rebate models, as manufacturers will be submitting their own unique rebate proposals.** The variability will result in significant administrative burden to pharmacies, which adds to the existing administrative burden on pharmacies having to deal with multiple manufacturer effectuation programs under the Medicare Drug Price Negotiation program.

Contract pharmacies must have reasonable notice. NCPA seeks clarification on when and how pharmacies will receive notice; this request for public comment merely states that the manufacturer's plan "…should allow for 60 calendar days' notice to covered entities and other impacted stakeholders before implementation of a rebate model, with instructions for registering for any IT platforms." **NCPA requests that HRSA stipulate that at the same time the manufacturers are alerting the covered entities, the manufacturers and/or the covered entities are in turn required to inform the contract pharmacies within the same timeframe of notice of covered entities, i.e., 60 calendar days**. **Additionally, NCPA requests clarification of the form of notice, i.e., is an e-mail sufficient, or should the notice be delivered in certified mail, and who receives the notice.**

Manufacturers and plans/PBMs must not impose arbitrary restrictions on the 340B program. In any 340B rebate model, to promote beneficiary access to the pharmacies of their choice, NCPA opposes:

- Arbitrary manufacturer restrictions on the 340B program, which include manufacturers limiting the number of contract pharmacies that can participate in the program;
- PBM and plans arbitrarily limiting access for contract pharmacy, including in the following schemes:
    - Reimbursing 340B covered entities and contract pharmacies at a lower rate than other entities not participating in the program;
    - Imposing differing terms (such as fees, charge-backs, or audits) on 340B participants;
    - Interfering with an individual's choice to receive drugs from a 340B participant;
    - Requiring 340B participants to identify which drugs fall within the program;
    - Refusing to contract with a 340B participant on the basis that they utilize the program;

- Arbitrarily re-classifying pharmacies as ineligible to provide 340B if they cannot submit N1 transactions, or for other reasons; or
- Denying coverage of drug because it is a 340B drug.

Contract pharmacies should not be required to identify 340B claims. **In any rebate model, NCPA supports CMS not requiring pharmacies to identify 340B claims, and re-emphasizes the infeasibility of 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*.

Additional Comments

Additionally, NCPA has the following comments on the Rebate Model Pilot Program Criteria General Requirements as proposed by HRSA:

"1. Plan should include assurances that all costs for data submission through an Information Technology (IT) platform be borne by the manufacturer and no additional administrative costs of running the rebate model shall be passed onto the covered entities." **NCPA asks HRSA to expressly add that no additional administrative costs of running the rebate model shall be passed onto covered entities or contract pharmacies.**

"2. Plan should allow for 60 calendar days' notice to covered entities and other impacted stakeholders before implementation of a rebate model, with instructions for registering for any IT platforms." **As stated above, NCPA seeks clarification on when and how pharmacies will receive notice. NCPA requests that HRSA stipulate that at the same time the manufacturers are alerting the covered entities, the manufacturers and/or the covered entities are in turn required to inform the contract pharmacies within the same timeframe of notice of covered entities, i.e., 60 calendar days. Additionally, NCPA requests clarification of the form of notice, i.e., is an e-mail sufficient, or should the notice be delivered in certified mail, and who receives the notice.**

[…]

"4. Plan should provide a technical assistance/customer service component and ensure that opportunities to engage with the manufacturer in good faith regarding questions or concerns are made available to covered entities through both the IT platform and a point of contact at the manufacturer." **NCPA asks that HRSA requires manufacturers to provide this technical assistance/customer service component to contract pharmacies as well.**

"5. Plan should ensure that the IT platform has assurances in place to ensure that the data is secure and protected and collection of the data is limited to the elements listed below that are necessary for providing 340B rebates pursuant to section 340B(a)(1) of the PHSA." **NCPA advises that HRSA should make it clear that PBMs and health plans will not receive 340B related information on claims.** NCPA is concerned that PBMs and health plans would use this information to discriminate through payments or contracting with pharmacies based on 340B utilization.

[...]

"7. Plan should ensure that covered entities are allowed to submit and report data (as detailed below) for up to 45 calendar days from date of dispense, with allowances for extenuating circumstances and other exceptions, including adjustments when a 340B status change occurs on a claim." **As stated above, NCPA advises that HRSA should make it clear that PBMs and health plans will not receive 340B related information on claims.** NCPA is concerned that PBMs and health plans would use this information to discriminate through payments or contracting with pharmacies based on 340B utilization.

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Rebates

[…]

"14. Plan should ensure that 340B rebates are only paid on sales of drugs selected under the MDPNP, regardless of payer." **As stated above, NCPA asks that HRSA limit the Pilot to only include Medicare Part D payers and claims for the first 10 drugs under the MDPN Program, not all payers/claims covering these 10 drugs.** For example, HRSA does not have authority to regulate duplicate discounts outside of Medicaid.[1]

Data

"All data requested [by the manufacturers] as part of the Plan should be limited to only the following readily available pharmacy claim fields: Date of Service; Date Prescribed; RX number; Fill Number; 11 Digit National Drug Code (NDC); Quantity Dispensed; Prescriber ID; Service Provider ID; 340B ID; Rx Bank Identification Number (BIN); and Rx Processor Control Number (PCN)." **As stated above, NCPA advises that HRSA should make it clear that PBMs and health plans will not receive 340B related information on claims. If a 340B Third Party Administrator (TPA) is making the request for the covered entity for a rebate from the manufacturer, the TPA cannot use any info captured in its other lines of business.** NCPA is concerned that PBMs and health plans and administrators would use this information to discriminate through payments or contracting with pharmacies based on 340B utilization.

[1] See 42 USC 256b(a)(5)(A)(i).

Conclusion

NCPA appreciates the opportunity to share with HRSA our comments and suggestions. 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,

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