National Rural Health Association

September 8, 2025

Tom Engels
Administrator
Health Resources and Services Administration
5600 Fishers Lane
Rockville, MD 20857

RE: 340B Program Notice: Application Process for the 340B Rebate Model Pilot Program

Submitted electronically via regulations.gov.

Dear Administrator Engels,

The National Rural Health Association (NRHA) is pleased to offer comments on the Health Resources and Services Administration's (HRSA) notice regarding the application process for the 340B Rebate Model Pilot Program.

NRHA is a non-profit membership organization with more than 21,000 members nationwide that provides leadership on rural health issues. Our membership includes nearly every component of rural America's health care, including rural community hospitals, critical access hospitals, long-term care providers, doctors, nurses, and patients. We work to improve rural America's health needs through government advocacy, communications, education, and research.

We appreciate HRSA's continued commitment to the needs of the more than 60 million Americans that reside in rural areas, and we look forward to our continued collaboration to improve health care access throughout rural America.

Rebate Model Pilot Program Criteria.

A rebate model represents a significant departure from how the 340B program has functioned since its inception. Upfront discounts have allowed rural covered entities to participate in 340B and effectuate the program's purpose of stretching scarce federal resources and expanding access to care. NRHA is extremely concerned that rebate models push the financial risk onto covered entities that operate with thin margins, add further administrative burden, and ultimately disincentivize rural covered entities from staying in the program. While we understand that HRSA must take action on rebate models following recent litigation, NRHA contends that rebate models are misaligned with the reality of operating a covered entity in a rural area and the purpose of 340B. NRHA does not support the implementation of a rebate model pilot program, however we offer comment on opportunities to protect rural safety net providers within the current proposal.

NRHA raises the following issues that are not fully addressed in HRSA's notice:

Rural exemption. NRHA urges HRSA to consider adding a rural exemption to the program. Rural sole community hospitals (SCHs), critical access hospitals, and federally qualified health centers must be allowed to opt out of this model and continue to receive upfront discounts in the program.

Additional notice and program parameters. NRHA appreciates the criteria put forth in this notice, but we contend that more guardrails and information are needed. Also, there are 15 days between the end of the comment period for this notice and the deadline for manufacturers to submit plan

proposals. NRHA is concerned that HRSA will not have sufficient time to modify the criteria for plans in this notice.

In recently published frequently asked questions (FAQs) HRSA indicates that it is "under no obligation to respond to or act on the comments."[1] We strongly urge the agency to take stakeholder comments seriously and publish an additional notice that addresses any new issues raised by stakeholders.

Enforcement. First, we urge HRSA to pursue all enforcement actions allowed under the 340B statute to rectify improperly denied rebates or other manufacturer abuses of the rebate model. HRSA should utilize its authority to impose civil monetary penalties on manufacturers in addition to its stated ability to terminate manufacturers' rebate model agreements.

Additionally, NRHA is particularly concerned that covered entities will not have an efficient and timely process for seeking relief for improperly denied rebates or other issues that may arise out of participating in a rebate model. HRSA notes that manufacturers may use existing statutory processes, including 340B Administrative Dispute Resolution (ADR), for diversion and duplicate discount concerns. HRSA then states that covered entities are also "afforded opportunities to raise concerns with OPA […]." **NRHA requests clarification on how covered entities may raise their concerns** as HRSA does not explicitly state that they must use the ADR process.

NRHA acknowledges that the ADR process is the only avenue available through the statute for covered entities to seek relief for any issues in the 340B program. However, we are aware of covered entities that have had ADR claims pending for multiple years and therefore **are extremely concerned that ADR is not efficient enough for covered entities to obtain relief for improperly denied rebates.** This will particularly be an issue for rural covered entities that cannot afford to wait months or years for rebates given that they generally have less cash available and operate with thin margins. Simply put, the ADR process is not appropriate for resolving disputes regarding improperly denied claims.

NRHA asks that HRSA explore its statutory authority to implement a separate process for resolving rebate covered entities' rebate disputes. This process must prioritize timely, expedited review of disputes.

Contract pharmacy. Manufacturer restrictions on contract pharmacy arrangements have eroded the benefit of the program for rural covered entities and added significant administrative complexity. HRSA does not address manufacturers' ability to deny claims because covered entities did not comply with contract pharmacy conditions. As discussed further below, HRSA explicitly states that rebate claims cannot be denied due to duplicate discount or diversion concerns. **Similarly, HRSA must make clear that manufacturers cannot deny rebates for contract pharmacy claims that do not comply with manufacturer restrictions.** This is not the appropriate avenue to resolve contract pharmacy disputes and withhold savings from covered entities. We are concerned that if this is a legitimate basis for denying rebate claims, it will be misused by manufacturers.

Insofar as HRSA must pursue rebate models for the 340B program, NRHA provides the following comments and recommendations on HRSA's criteria:

[1] https://www.hrsa.gov/opa/340b-model-pilot-program#:~:text=press%20release.-,FAQs,-Following%20are%20some

General Requirements

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.

Ideally, NRHA would like to see HRSA establish a centralized repository for processing rebate model claims. The model is limited to drugs selected for on the Centers for Medicare and Medicaid Services' (CMS) Drug Price Negotiation Program (MDPNP) Selected Drug List; however, that encompasses ten drugs and nine different manufacturers. This means that rural covered entities could be required to register for and use nine different IT platforms, which will be a significant challenge given their limited staff and resources.

However, if HRSA must move forward with allowing manufacturers to use their own unique IT platforms, **NRHA urges HRSA to ensure that covered entities' data submission to manufacturers will not impose additional costs on covered entities.** We are pleased to see explicit language that manufacturers must take responsibility for any costs of data submission, and that no additional administrative costs may be passed onto covered entities. Increasing complexity in the 340B program generally, like contract pharmacy restrictions, have eroded rural covered entities' savings and increased administrative burden that takes away from patient care. Manufacturers must not be allowed to compound these difficulties by passing along costs of data submission and associated platforms to covered entities.

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.

NRHA supports this criterion. Rural covered entities must have adequate notice before rebate models begin in order to prepare for this change and familiarize themselves with the IT platforms.

However, we urge HRSA to finalize a new, delayed start date. Implementing rebate programs beginning January 1st will put an immense burden on rural covered entities. HRSA should delay the start date until June 1, 2026, to give covered entities more adequate time to prepare.

Reporting Requirements

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.

NRHA agrees that rural covered entities need adequate time to submit and report the required data. Many rural providers participating in 340B have one or two-person pharmacy or billing teams who already juggle compliance with Medicaid carve-outs, payer rules, and manufacturer restrictions. As such, rural covered entities need a reasonable timeline for reporting. **NRHA agrees with HRSA that manufacturers should allow 45 days for data submission from the date of dispense.**

HRSA states that manufacturers must allow any "extenuating circumstances and other exceptions" when it comes to late data submissions. NRHA requests more detailed guidelines around "extenuating circumstances and other exceptions" or clarity on covered entities ability to appeal manufacturers decisions around this. We are concerned that without prescriptive language around what manufacturers may consider "extenuating circumstances and other exceptions" that covered entities will not be afforded true exceptions when they are needed.

9. Plan should ensure that the IT platform will have the capability to provide real-time reconciliation reports for covered entities to be informed of the rebate status of submitted claims.

NRHA supports this requirement. Rebate models must be transparent for rural covered entities. Many rural covered entities are concerned about rebate models because they do not have ample cash on hand to absorb paying the full wholesale acquisition cost and waiting for a rebate. They should be equipped with transparent, real-time data about the status of their rebate claims.

Rebate Requirements

12. Plan should ensure that all rebates are paid to the covered entity (or denied, with documentation in support) within 10 calendar days of data submission.

NRHA supports HRSA's call for manufacturers to pay rebates within 10 calendar days. As mentioned above, rural covered entities are not in a financial position to absorb upfront costs and wait for rebates. Rural covered entities rely upon 340B program savings to help stretch scarce federal resources and provide critical services to their patients, as is the intent of the program. Small rural providers who operate on razor-thin margins with limited reserves may experience delayed access to savings which compromises payroll, medication access, and operational continuity. Manufacturers must provide timely rebates to covered entities and avoid creating any cashflow issues for rural covered entities.

NRHA requests stricter guidelines around rebate denials. We appreciate that HRSA includes a requirement for manufacturers to provide "documentation in support" of a denial but we remain concerned that this is not enough. Manufacturers must provide clear, timely information on any rebate claim denials. Manufacturers must provide a specific reason for the denial along with a narrative justification. This should also include an explanation of how covered entities can rectify the denial and, if possible, resubmit data to receive a rebate.

13. Plan should ensure that 340B rebates are not denied based on compliance concerns with diversion or Medicaid duplicate discounts […] manufacturer should raise those concerns directly with OPA or utilize the 340B statutory mechanisms, such as audits and administrative dispute resolution (ADR), for addressing such issues. Covered entities are also afforded opportunities to raise concerns with OPA if there are issues with rebate delays and denials, or any other administrative or logistical issues emerging through implementation of the rebate model.

NRHA strongly supports HRSA's guideline that manufacturers cannot deny rebate claims based on diversion or duplicate discount concerns. Again, we stress that concerns, or need for clarity, on contract pharmacy compliance cannot be a legitimate reason for manufacturers to deny claims and HRSA must issue guidance on this.

The rebate model has the potential to add multiple layers of complexity for rural covered entities. HRSA must ensure that the pilot program adds as little additional burden to participants as possible. We reiterate that information included along with a denial must explain directly why the claim was denied and how covered entities can rectify the denial and, if possible, resubmit to receive a rebate.

Rebate disputes that may result in unrecovered savings means real financial consequences for rural covered entities that have historically relied upon 340B savings to keep services and medications available to patients. NRHA urges HRSA to monitor closely any issues with denied rebates. We encourage the agency to use its authority to terminate manufacturers' rebate models, and additionally impose civil monetary penalties, if they are not complying with the criteria outlined in their plans and in HRSA's guidance.

14. Plan should ensure that 340B rebates are only paid on sales of drugs selected under the MDPNP, regardless of payer.

HRSA's Rebate Model is limited to drugs selected for MDPNP. This means that the only manufacturers eligible for the pilot are those with Medicare Drug Price Negotiation Program contracts. **NRHA fully supports this provision of the program.** We believe that limiting the scope of 340B drugs subject to rebate models will make the process less administratively difficult for rural covered entities. Rural covered entities often lack the staff or infrastructure to manage any additional administrative workload.

HRSA notes that it may call for plans from manufacturers for future years beyond 2026 at a later date. **Future iterations of the rebate model should remain limited in scope. NRHA does not support expanding any rebate models to all 340B drugs.**

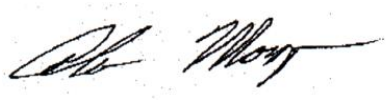
15. All data requested as part of the Plan should be limited to only the following readily available pharmacy claim fields […].

NRHA supports limiting data collection from covered entities to those listed in the notice. We have major concerns with language in the FAQs that says manufacturers "may request to collect additional data, but must provide compelling supporting information on why the additional data elements are needed."

We believe that manufacturers should not be able to choose their own data elements and insert more complexity, especially considering that covered entities may have to submit claims to up to nine different manufacturers. A limited, uniform set of data elements will help moderate the burden of submitting claims on small, rural safety-net providers.

Thank you for the chance to offer comments on this pilot program and for your consideration of our comments. If you would like additional information, please contact NRHA's Government Affairs and Policy Director Alexa McKinley Abel at amckinley@ruralhealth.us.

Sincerely,



Alan Morgan
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