



April 20, 2026

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

RE: HRSA-2026-03042; Request for Information – 340B Rebate Model Pilot Program

Submitted electronically via regulations.gov.

Dear Administrator Engels,

The National Rural Health Association (NRHA) is pleased to respond to the Health Resources and Services Administration's (HRSA) request for information (RFI) on a 340B Rebate Model Pilot Program. 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.

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.

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 effectuate the program's purpose of stretching scarce federal resources and expanding access to care. NRHA does not support the implementation of a rebate model pilot program. Insofar as HRSA must pursue rebate models for the 340B program, NRHA provides the following comments on HRSA's criteria and offer recommendations on opportunities to protect rural safety net providers within the current proposal.

NRHA urges HRSA to consider an exemption for critical access hospitals, sole community hospitals, federally qualified health centers, and other covered entities located in rural areas.

We urge HRSA to use the [Federal Office of Rural Health Policy definition of rural](#) to define rural areas. This would include nonmetropolitan counties, outlying metropolitan counties with no population from an urban area of 50,000 or more people, Census tracts with RUCA codes 4-10 in metropolitan counties, and other sparsely populated areas located in metropolitan counties. 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. NRHA contends that rebate models are misaligned with the reality of operating a covered entity in a rural area and the purpose of 340B.

Cost to Covered Entities

The rebate model has the potential to add multiple layers of complexity and significant costs for rural covered entities. Generally, rural covered entities expect to experience increased costs in order to comply with rebate models. Prior to HRSA's rescission of its original rebate model announced in 2025, rural hospitals reported investing tens of thousands of dollars in preparation during the pre-implementation period. This included hiring third parties to upgrade or align IT systems and otherwise ensuring rural covered entities were ready to comply.

To streamline some administrative burden and costs, **NRHA asks HRSA to establish a centralized repository for processing rebate model claims.** Depending on the number of drugs and manufacturers eligible for a rebate model, rural covered entities could be required to register for and use several different IT platforms, which will be a significant challenge given their limited staff and resources. Increasing complexity in the 340B program has 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.

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 supported the past proposal in HRSA's August 2025 notice of its now rescinded rebate model that manufacturers must take responsibility for any costs of data submission, and that no additional administrative costs may be passed onto covered entities.¹

Last, **NRHA does not support expanding a rebate model to all drugs under the 340B program.** While NRHA previously supported HRSA's proposal to limit its rebate model to MDPNP selected drugs, we urged the agency to limit the program to the court mandated set of drugs given the expected costs associated. Limiting the scope of 340B drugs subject to rebate models will make the process less administratively difficult for rural covered entities as they often lack the staff or infrastructure to manage any additional administrative workload.

Payment Timing and Potential Cash Flow Impacts for Covered Entities

In its August 2025 notice, HRSA planned to **require manufacturers to pay rebates within 10 calendar days.**² **NRHA supports retaining this timeline in any future rebate model.** 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.

Rebate Denials

As part of a future rebate model, HRSA must **explore its statutory authority to implement an appropriate channel for resolving disputes regarding improperly denied claims.** NRHA is

¹ 90 Fed. Reg. 36163, 36164 (Aug. 1, 2025).

² 90 Fed. Reg. 36165.

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. The 340B Administrative Dispute Resolution (ADR) process is currently the only avenue available for covered entities to seek relief for any issues in the 340B program, but we do not believe it is the appropriate mechanism for rebate model disputes. 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.

Further, we ask HRSA to pursue all enforcement actions allowed under the 340B statute to rectify improperly denied rebates or other manufacturer abuses of the rebate model. 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. HRSA should utilize its authority to impose civil monetary penalties on manufacturers and exercise authority to terminate manufacturers' rebate model agreements under appropriate circumstances.

When manufacturers deny rebates, NRHA requests strict guidelines for documentation. Manufacturers should provide "documentation in support" of a denial and such documentation must provide clear, timely information. Documentation must provide a specific reason for the denial along with a narrative justification, including an explanation of how covered entities can rectify the denial and, if possible, resubmit data to receive a rebate.

HRSA's prior rebate model explicitly stated that rebate claims cannot be denied due to duplicate discount or diversion concerns. This should be built into a future rebate model and further, **HRSA must make clear that manufacturers cannot deny rebates for contract pharmacy claims that do not comply with manufacturer restrictions.** Manufacturer restrictions on contract pharmacy arrangements have eroded the benefit of the program for rural covered entities and added significant administrative complexity. A future rebate model 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.

Data Collection by Covered Entities

In general, **NRHA encourages limited program reporting and supports data collection** only insofar as it is data that covered entities are already reporting in another federal program. Rural covered entities do not have the administrative capacity to comply with additional unfunded mandates for reporting. To the extent that covered entities must report data in order to receive rebates, HRSA must outline clear and specific data elements to be reported. Additionally, manufacturers must not be able to choose their own data elements or add data elements to any HRSA-defined list. This would insert more complexity and uncertainty, especially considering that covered entities may have to submit claims to several different manufacturers. A limited, uniform set of data elements will help moderate the burden of submitting claims on small, rural covered entities.

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 suggests allowing at least 45



days for covered entities to submit data, as outlined in HRSA’s prior rebate model. Additionally, NRHA requests detailed guidelines around when covered entities may receive an exception or extension for data submission. Manufacturers must have clear guidance from HRSA that delineates this process in order to avoid arbitrary decision making.

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

Sincerely,

A handwritten signature in black ink, appearing to read "Alan Morgan", is written over a light grey dotted background.

Alan Morgan
Chief Executive Officer
National Rural Health Association