

October 6, 2026

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

RE: Implementation of the 340B Rebate Model Pilot Program

Dear Administrator Engels,

The National Rural Health Association (NRHA) is writing regarding the Health Resources and Services Administration's (HRSA) [recent announcement](#) to pilot a rebate mechanism for certain drugs under the 340B Rebate Model Pilot Program, set to begin January 1, 2027. 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 sustained 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, clinics, FQHCs, doctors, nurses, and patients. We work to improve rural America's health needs through government advocacy, communications, education, and research.

As stated in [previous comment letters](#), the 340B Program is essential to meeting the health care needs of rural communities. Rural hospitals and clinics operate on narrow financial margins and rely on 340B savings to maintain core services, purchase essential medications, and provide care to uninsured and underinsured rural patients. NRHA reiterates its concern that a rebate model represents a substantial 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 at the point of purchase. NRHA appreciates the analysis shared in the announcement notice but continues to believe the shift from upfront discounts to rebate-based purchasing introduces significant cash-flow risk and administrative burden that the smallest, rural safety net providers may be uniquely unable to absorb.

NRHA contends that rebate models are misaligned with the reality of operating a covered entity in a rural area and the premise of the 340B program. We continue to urge HRSA to exempt small rural hospitals and clinics from rebate requirements, allowing these covered entities to retain upfront discount pricing as the default mechanism. Alternatively, accommodation such as delayed effective date or simplified claims submission pathway for Critical Access Hospitals, Sole Community Hospitals, rural DSH hospitals, Federally Qualified Health Centers, and other low-volume rural covered entities are warranted.

Insofar as HRSA must pursue rebate models for the 340B program, NRHA recognizes that the pilot's design reflects meaningful efforts to minimize impacts on covered entities and urges HRSA to consider the following recommendations as additional opportunities to protect rural safety net providers within the pilot program.

Pilot Rebate Program Requirements

NRHA supports HRSA's plan to require all IT platform costs to be borne by the manufacturer, with technical assistance available to covered entities as needed. Manufacturers must take responsibility for any costs of data submission, and HRSA should ensure that no additional administrative costs may be passed onto covered entities.

Further, NRHA supports allowance of covered entity's ability to continue ordering selected drugs through existing distribution mechanisms, such as 340B wholesaler accounts with WAC prices loaded, so purchases flow through existing infrastructure rather than duplicative new workflows.

Data Collection and Reporting Requirements

Despite building on the existing program infrastructure, NRHA continues to have concerns about the administrative cost borne by small rural covered entities. 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, a number consistent with HRSA's own estimates of \$34,320 per entity for claims process changes. This included hiring third parties to upgrade or align IT systems and otherwise ensuring rural covered entities were ready to comply. NRHA asks HRSA to further consider opportunities to simplify and streamline process to relieve burden on safety-net covered entities. One such opportunity is the establishment of a central repository for processing claims rather than individual manufacturer platforms.

Rebate Payment Timing and Potential Cash-Flow Impacts for Covered Entities

As mentioned above, rural covered entities are not in a financial position to absorb upfront costs and wait for rebates. NRHA recognizes HRSA's efforts to minimize cashflow impacts for covered entities through requirements around 10-day prompt payment, allowance of unit level rebate options, and transitional inventory allowances.

NRHA calls on HRSA to closely monitor manufacture compliance with these policies and take appropriate enforcement action where delays occur. We ask HRSA to establish strict guidelines for manufacturer documentation of claim denials and to make information on rebate denials and disputes publicly available as noted in the FRN notice. Further, NRHA continues to encourage HRSA to explore its statutory authority to implement an appropriate channel for resolving disputes regarding improperly denied claims beyond the existing Administrative Dispute Resolution (ADR) process.

Additionally, NRHA strongly recommends that HRSA not expand the pilot beyond those on the CMS Medicare Drug Price Negotiation Program [Selected Drug List](#) or past 2027 without clear evidence that rebate models did not harm rural providers and patients.

Data

NRHA recognizes HRSA for the pilot's reliance on a defined set of standardized pharmacy and medical claims data elements that are commonly available and already maintained by covered entities or their vendors in the ordinary course of billing and dispensing operations. To the extent that covered entities must report data in order to receive rebates, HRSA must prohibit manufacturers from choosing 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.



Thank you for your consideration of our feedback. Please refer to [NRHA's comments on the HRSA Request for Information](#) regarding the Rebate Model Pilot program for further detail on many of these items. If you would like additional information, please contact Carrie Cochran-McClain, NRHA's Chief Policy Officer, at ccochran@ruralhealth.us.

Sincerely,

A handwritten signature in black ink, appearing to read "Alan Morgan". The signature is fluid and cursive, with a long horizontal stroke extending to the right.

Alan Morgan
Chief Executive Officer
National Rural Health Association