

December 2, 2025

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

RE: Implementation of the 340B Rebate Models Pilot Program

Dear Administrator Engels,

The National Rural Health Association (NRHA) is writing to provide additional comments following the Health Resources and Services Administration's (HRSA) recent announcement approving nine drug rebate models under the 340B Rebate Model Pilot Program, set to begin January 1, 2026. 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.

As stated in our <u>previous comment letter</u>, 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. The shift from upfront discounts to rebate-based purchasing introduces significant cash-flow risk and administrative burden that rural safety net providers are uniquely unable to absorb.

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. NRHA continues to have serious concerns that rebate model implementation pushes 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 premise of the program. NRHA reiterates that requiring covered entities to pay the full wholesale acquisition cost upfront and wait for rebate reimbursement breaks with the intended purpose of 340B and is not tenable for rural covered entities. Therefore, NRHA strongly recommends that HRSA not expand the pilot beyond the 9 approved drugs or past 2026 without clear evidence that rebate models did not harm rural providers and patients.

NRHA also urges HRSA to consider at least a 6-month delay to ensure that all impacted stakeholders are ready to participate. HRSA's rebate model has moved quickly, and all stakeholders are not



prepared or equipped to begin complying by January 1, 2026. HRSA released notice regarding the parameters of the program on July 31, required manufacturers to submit their plans by September 15, and HRSA approved or denied these plans just over a month later. Following HRSA's approvals, covered entities, third party administrators, pharmacy benefit managers, contract pharmacies, and other 340B stakeholders have less than 3 months to prepare for this massive change to the implementation of 340B. NRHA members have expressed that the PBMs, TPAs, and independent pharmacies that they works with will not be functional and ready to comply with the rebate model by its start date. An example of this is in Arkansas, where a covered entities in this situation will not receive 340B savings for rebate model drugs and based on 2025 data about 600 patients at this covered entity will lose access to essential medicines.

Thank you for the opportunity to offer additional feedback 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

Chief Executive Officer

National Rural Health Association

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