

September 8, 2025

Honorable Thomas J. Engels
Administrator
Health Resources and Services Administration
Department of Health and Human Services
5600 Fishers Lane
Rockville, MD 20852

Re: Application Process for the 340B Rebate Model Pilot Program (HRSA-2025-14998)

Dear Administrator Engels,

On behalf of our hospitals and health systems, we appreciate the opportunity to comment on the Health Resources and Services Administration's (HRSA) notice of the 340B Rebate Model Pilot Program. We are concerned with the adoption of rebate model in any form, as it would, to use HRSA's own language, "fundamentally shift how the 340B program has operated for over 30 years." However, if the model must move forward, we would like to put forth several vital factors to consider in developing the program.

We believe that any rebate model would undermine the intent of the 340B Program, nullifying its original purpose to provide upfront discounts to safety-net providers and shifting financial and operational burdens from manufacturers back on to providers. Paying full drug prices upfront and then waiting for rebates would create unsustainable cash flow gaps, presenting a severe financial burden for covered entities, especially rural hospitals and small providers with thin margins.

We share the concern of other covered entities that the proposed rebate model will increase administrative complexity and would divert resources from patient care. The rebate model effectuates the development of new IT systems, data tracking, claim reconciliation, and staff training requirements, all without clear requirements for standardization. We believe that this would place undue financial and administrative burdens on providers, as it would require them to balance using multiple different manufacturer-specific platforms at once. If rebates are implemented, it is important to apply enforcement mechanisms and standardized data formats to allow for timely rebate payments and lesser implementation hurdles for covered entities.

The potential data security and privacy risks are also troubling and must be addressed before any rebate is put into effect. Submitting sensitive patient data to third-party platforms that are not accountable under the Health Insurance Portability and Accountability Act (HIPAA) could put private patient information at risk. Additionally, the proposed allowable data sharing includes patient-identifiable information, such as RX number, Fill Number, Prescriber ID, and Service Provider ID, which means that providing such information places covered entities at risk of violating HIPAA. At a minimum, HRSA must execute manufacturer liability requirements for breaches as well as secure vetting of IT platforms.

Finally, under the proposed model, HRSA must clarify that drug companies cannot deny rebates and denial documentation must provide a thorough explanation for why a rebate will not be paid as well as clearly address how disputes will be handled. We have grave concern that without staunch requirements for denials, manufacturers will develop creative ways to deny payment to covered entities. The current proposal requires the parties participating in the rebate transaction to resolve disputes in a good faith manner and manufacturers will be removed from the rebate model if they delay payments repeatedly. The proposed penalty for repeated delayed payments is not sufficient for those manufacturers who act in bad faith, nor does it protect 340B covered entities from financial harm that is the consequence of delayed rebates. Special attention should also be paid to maintaining contract pharmacy agreements and not allow

manufacturers to employ methods through a rebate model to deny payment to drugs disbursed in this manner.

We urge HRSA to examine these issues and consider the harm to covered entities in implementing any rebate program. At a minimum, HRSA should delay the implementation of a rebate model until the concerns identified above and in the other many comments submitted on behalf of 340B covered entities are adequately addressed. This would safeguard patient information and lessen the administrative and financial burden such a model would place on covered entities.

We appreciate your careful consideration.

Sincerely,

Baptist Health
Kentucky and Indiana

Henry Ford Health System
Michigan

Legacy Health
Oregon and Washington

Marshfield Clinic Health System
Wisconsin and Michigan

Methodist Le Bonheur Healthcare
Tennessee and Mississippi

OSF Health Care
Illinois and Michigan

Piedmont Healthcare
Georgia

Presbyterian Healthcare
New Mexico

Sanford Health
South Dakota

University of Kansas Health System
Kansas