PUBLICATION

HRSA Seeks Stakeholder Input on 340B Rebate Model Pilot Program

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Following successful litigation by the American Hospital Association (AHA) that blocked its original 340B rebate pilot program from taking effect on January 1, 2026, the Health Resources and Services Administration (HRSA) has issued a Request for Information (RFI) seeking input from interested parties regarding the potential implementation of a rebate model under the 340B Drug Pricing Program. Published in the *Federal Register* on February 17, 2026, the RFI solicits comments on whether HRSA should implement a rebate model and, if so, how best to operationalize such a framework for all stakeholders. Comments are due by March 19, 2026.

The 340B Drug Pricing Program has traditionally operated as an upfront discount program, meaning covered entities receive the discounted 340B drug price at the time of purchase. Under a rebate model, covered entities would instead buy the drugs at a higher market-rate price and later receive a rebate equal to the difference between that initial price and the 340B ceiling price. This fundamental shift in program structure has significant implications for covered entities' operations, cash flow, and compliance infrastructure.

The RFI comes after HRSA received inquiries from drug manufacturers in 2024 seeking to unilaterally implement rebate models, primarily to address the nonduplication provision under the Medicare Drug Price Negotiation Program (MDPNP) and facilitate the prevention of 340B-Medicaid duplicate discounts. HRSA made clear that implementing a rebate model without prior Secretarial approval would violate section 340B(a)(1) of the Public Health Service Act.

Key Issues for Comment

HRSA describes this RFI as part of a "methodical and deliberate approach to assess whether to implement a potential 340B Rebate Model Pilot Program consistent with its statutory authority." The agency has committed to "analyzing the comments received prior to pursuing the implementation of a potential 340B rebate model pilot program." HRSA is seeking input across several targeted areas:

Costs to Covered Entities: The RFI asks covered entities to describe their current administrative costs related to 340B operations and compliance, and to estimate the incremental administrative and operational costs they would incur under a rebate model. HRSA seeks information on both one-time program startup costs and ongoing costs, as well as the methodology used to develop these estimates.

Cash Flow Impacts on Covered Entities: Any rebate program would require covered entities to pay higher drug prices upfront and then later seek to recover the 340B discount from the pharmaceutical manufacturer. The RFI specifically requests information on how a rebate model would affect covered entities' cash flow, including working capital requirements, access to credit, and potential downstream effects on patient care and services. This is a critical concern for safety-net providers that operate on thin margins.

Reliance Interests: Since the inception of the 340B program in 1992, covered entities have received the drug discount at the time of purchase. The RFI asks stakeholders to address reliance interests in continuing to obtain 340B ceiling prices through upfront discounts and whether such interests are "reasonable in light of the

[HHS] Secretary's express statutory authority to provide for discounts via 'rebate or discount.'" This question appears to anticipate potential legal arguments that covered entities may raise in future litigation.

Rebate Processing and Denials: HRSA seeks recommendations on appropriate timelines for rebate processing, standards that should govern rebate denials, and appeal processes to ensure denials are limited to appropriate circumstances. The RFI asks about standard process elements that should be required, including template forms and timelines for adjudicating improper denials. This may also include safeguards to prevent improper denials to avoid the cost and burden of pursuing an appeal process.

Data Collection and Privacy: The RFI asks stakeholders to describe current data collection practices related to 340B participation and whether a rebate model would change those activities. HRSA also seeks recommendations for ensuring appropriate privacy and security safeguards for patient information and data submission.

Duplicate Discount Prevention: The RFI solicits information on covered entities' and manufacturers' current practices for avoiding duplicate discounts under 340B and Medicaid, as well as challenges encountered in identifying potential duplicates. HRSA is interested in whether a rebate model could assist in preventing duplicate discounts and improving program integrity.

Program Integrity and Benefits: HRSA asks stakeholders to explain whether and how a rebate model would affect program integrity, reduce diversion or improper claims, and increase pricing transparency. Stakeholders are also asked to describe any other potential benefits and whether those benefits would outweigh costs.

Practical Considerations for Stakeholders

Covered entities considering submitting comments should assess and document their current 340B operations and compliance costs, model the potential cash flow and administrative impacts of a rebate model on their organization, and identify specific concerns about the timing and reliability of rebate payments. Organizations should also consider what safeguards and standards would be necessary to protect their interests if a rebate model is implemented.

What This Means for You

This RFI represents a significant moment for the 340B Program. While HRSA has committed to analyzing comments before pursuing implementation of any pilot program, the agency's issuance of this RFI – following the withdrawal of the original pilot and agreement to new procedural guardrails – suggests continued interest in testing rebate-based approaches despite the AHA's successful legal challenge to the initial pilot program. Notably, some observers have suggested that the RFI seems to both provide HRSA some cover for not moving forward with a rebate program while also signaling that HRSA has not yet dismissed the notion of using a rebate approach to enhance the agency's ability to crack down on duplicate discounts. The 30-day comment period (compared to the 39 days provided for the original pilot proposal) has also drawn attention regarding whether future notices will follow similarly expedited timelines. Covered entities and other stakeholders who wish to influence the design of any potential pilot program, who believe a rebate model should not be implemented, or who have concerns regarding its implementation – including operational feasibility and impact – should consider submitting detailed comments outlining their concerns about a potential rebate program and addressing the specific questions posed in the RFI.

Comments must be received by **March 19, 2026**, and should be submitted electronically through the Federal eRulemaking Portal.

For additional information on the current state of affairs for the 340B Program, please contact Greg Fliszar, Alissa Fleming, Katherine Denney, or any member of the Baker Donelson Health Law Team.