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2026 340B Program Update – 340B Rebate Model RFI Comments Due and Manufacturers Continue Restricting 340B Pricing

Key Takeaways

- HRSA has extended the deadline for comments on its proposed 340B rebate model pilot program to April 20, 2026. Covered entities have a limited window to submit detailed feedback on how the model would affect operations and patient care.
- The proposed rebate model and new manufacturer data submission policies increase administrative burden and create risk of pricing denials and cash flow disruption. These changes could significantly expand compliance obligations and force providers into frequent disputes to recover 340B savings.
- Covered entities should submit detailed RFI comments and actively monitor 340B pricing access and denials. Providers should also begin tracking data, documenting losses and preparing for potential ADR filings and manufacturer engagement.

The 340B program is experiencing rapid changes that could have a substantial impact on covered entities' (CEs) operations, cash flow and compliance obligations. Below, we discuss two key developments that require CEs' attention. CEs should respond to the Health Resources and Services Administration's (HRSA) Request for Information (RFI) by the April 20, 2026 deadline and CEs should monitor 340B price denials by Eli Lilly and Novo Nordisk as discussed below.

HRSA has extended the deadline for its initial Request for Information (RFI) related to the 340B rebate model pilot program to April 20. To avoid the financial and operational implications of HRSA's proposed changes, covered entities should submit comments by April 20 detailing how the program will impact their 340B operations and patient care.

Specificity is critical. This is an opportunity for CEs to show the immense effort and expense that goes into running a compliant 340B program and how the rebate program will exponentially increase that complexity and investment.

Also, two manufacturers, Eli Lilly and Novo Nordisk, have implemented policies that now require covered entities to submit dispensing data for all 340B drugs within 45 days of dispense. These policies introduce new administrative considerations and may affect access to 340B drug pricing in the in-house setting. It is essential for providers to verify

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Related Capabilities

- Health Care
- 340B Drug Pricing Program

they are still receiving 340B pricing, track all dispensed 340B drugs and note any instances where 340B pricing is denied, as there may be opportunities to recover potential losses.

Building an Effective RFI Submission

It is extremely important for CEs to act now and submit information to HRSA demonstrating why a 340B rebate program would be detrimental to CEs and access to patient care if implemented.

If a 340B rebate model takes hold, CEs will experience significant cash flow challenges, operational disruptions and new compliance burdens, given the immense data involved. The RFI responses should contain as much detail as possible to emphasize the burden a 340B rebate model will have on CEs. Without input from CEs, HRSA will again have free rein to implement a rebate model that does more harm than good. CEs also need to continue going on record to remind HRSA that the 340B program is a discount program — not a rebate program as stated in the statute.

A rebate program would impact thousands of individual dispenses by a CE. Rebate denials are virtually guaranteed, whether due to inadvertent mistakes given the sheer volume of claims each manufacturer must review (via their rebate data vendor) or due to disagreements concerning 340B parameters, such as HRSA's patient definition.

Once rebate denials occur, HRSA's Administrative Dispute Resolution (ADR) process will be the only recourse available to CEs that isn't directly influenced by the manufacturers. CEs will have to continuously track rebate denials and file corresponding ADR claims. This tracking and resulting ADR filings will result in substantial time and litigation expenses. CEs should estimate this time and expense and include the same in responses to the RFI.

To help mitigate these risks, we strongly encourage providers:

- Submit comments to HRSA before the April 20 deadline
- Gather / estimate data points on the administrative and financial burdens a 340B rebate program would impose
- Include advocacy elements that properly frame the illegality of a rebate model

Monitoring 340B Pricing Denials and Preparing for ADR Claims

As of April 1st, both the Eli Lilly (went into effect February 1, 2026) and Novo Nordisk policies requiring in-house claim-level data are in effect. At the earliest, providers may start noticing lack of access to 340B pricing 45 days after the effective dates of the policies if data is not submitted.

Currently, some CEs have reported losing access to 340B pricing for Lilly products. All CEs should closely monitor changes to their pricing and document any inability to access 340B prices. If a CE is denied access to a 340B drug price, it may file an ADR with HRSA to recover the lost funds, but CEs must act promptly. We have heard anecdotally that HRSA is aware of the denials and is monitoring the matter via ADR filings.

Next Steps

Covered entities should take the following steps to protect 340B pricing access and position themselves to recover any denied savings.

- Monitor drugs at issue and confirm access to 340B pricing.

- Gather data for all drugs where 340B pricing is restricted to prepare ADR filing
- Begin good faith communications with Eli Lilly and Novo Nordisk in anticipation of filing an ADR claim
- Draft ADR complaint and prepare supporting data

Should you have questions regarding the information discussed, please reach out to Kyle Vasquez, Jessica Andrade, Eleanor Brown, Mary Canavan, Deja Williams or your preferred Polsinelli attorney.