

## **Comment Letter: 340B Rebate Model**

We, the undersigned patient advocates and patient advocacy organizations from across the United States, write in response to the Health Resources and Services Administration's (HRSA) Request for Information regarding the potential implementation of a rebate model within the 340B Drug Pricing Program.

We represent thousands of patients, caregivers, and families navigating a wide range of acute, chronic, and complex health conditions. While our individual experiences vary, we are united in a shared concern: **today's 340B program lacks sufficient transparency, accountability, and demonstrable patient benefit.**

We are specifically responding to HRSA's request for input on how a potential rebate model may impact patient access, transparency, and program integrity and how the agency can ensure that any future model delivers meaningful benefit to patients.

### **Patients Are Too Often Invisible in the 340B Program**

The 340B program was established to support vulnerable patients by allowing covered entities to stretch scarce resources. However, in practice, many patients remain unaware that they are part of the program at all.

Patients are NOT told:

- When their medications are purchased under the 340B program
- How the program is intended to benefit them and their community
- Whether any savings are being passed through to support their care

This lack of transparency leaves patients disconnected from a program that depends directly on their treatment and prescriptions.

### **Patients Have a Right to Know and a Right to Understand Their Role**

If a patient's prescription is generating revenue within one of the largest federal drug pricing programs in the country, that patient should not be left in the dark.

Patients should be informed when their medications are part of the 340B program and understand whether and how they are personally benefiting from any associated discounts.

Transparency is a baseline expectation, not an added feature. Without it, patients cannot make informed decisions about their care or fully understand the financial dynamics surrounding their treatment.

## **Patient Experience Raises Serious Concerns About Financial Harm**

Through our work with patients and caregivers, we are increasingly seeing situations where individuals receiving care at 340B-participating hospitals and health systems are still facing significant financial hardship.

Patients report:

- Being billed aggressively for care, even after treatment at 340B-covered entities
- Being sent to collections for medical bills they cannot afford
- Accumulating substantial medical debt tied to hospital care
- In some cases, facing financial distress that contributes to bankruptcy

These experiences raise serious questions about whether the financial benefits generated through the 340B program are reaching patients in a meaningful way.

If a program is intended to support vulnerable patients, it should not coexist with patients struggling under the weight of medical bills tied to that same system.

At a minimum, there must be a clear and measurable connection between program participation and reduced financial burden for patients.

## **Considerations for a Potential Rebate Model**

As HRSA evaluates whether to implement a rebate model, it is critical that patient impact remains central to the analysis. Any rebate-based approach should be carefully evaluated for:

- Impact on patient access to medications, particularly if changes introduce delays, denials, or new barriers to care
- Financial implications for patients, including whether savings are passed through or retained within the system
- Transparency at the point of care, ensuring patients understand when their treatment is part of the 340B program

- Program integrity, including whether changes improve accountability without creating administrative complexity that affects patient care
- Opportunities to improve both transparency and program efficiency through simple, real-time solutions. For example, existing pharmacy systems could provide a clear notification on a patient's receipt or at the point of sale when a prescription is processed under the 340B program. This type of notification can be implemented without delaying care and would ensure patients are aware, in real time, when their treatment is part of the program. At the same time, rebate processing can be structured to allow timely or provisional reimbursement to covered entities, with reconciliation occurring later. This supports both patient awareness and efficient program operation.

Without clear safeguards, structural changes risk further distancing patients from the intended benefits of the program.

## **Patient Safeguards Must Be Non-Negotiable**

As HRSA evaluates a potential rebate model, it is essential that operational and structural changes do not come at the expense of patients.

Any reform, including a rebate-based model, must be implemented in a way that **maintains or improves timely patient access to medically necessary medications**, without introducing delays, denials, or new barriers to care.

Specifically:

- Patients should not experience delays in accessing medications due to rebate processing, claims validation, or administrative changes
- Continuity of care must be preserved, and patients who are stable on treatment should not face interruptions due to programmatic or financial model changes
- Treatment decisions must remain between patients and their licensed healthcare providers, free from non-clinical interference related to administrative or financial structures
- Transparency must extend beyond institutional reporting and be meaningful at the point of care
- Any savings generated through the program should result in clear, direct financial benefit to patients
- Data collection and reporting requirements must protect patient privacy and be designed to minimize administrative burden, without disrupting provider workflow or timely care delivery

Transparency between institutions is not enough. Patients must be able to see, understand, and benefit from the program built around their care.

## **A Clear Standard: Measurable Patient Benefit**

As HRSA considers whether to implement a rebate model or other changes to the program, we urge the agency to anchor its decision-making in a clear and patient-centered standard:

### **Does the 340B program measurably benefit patients?**

Any future model rebate or otherwise must be evaluated based on its ability to deliver direct, transparent, and meaningful benefit to patients while preserving access, continuity of care, and clinical decision-making.

## **Key Principles for Any 340B Reform**

We respectfully recommend that HRSA incorporate the following principles into 340B framework:

1. **Transparency to Patients:** Patients should be informed when they are receiving care or medications through the 340B program.
2. **Demonstrable Patient Benefit:** Covered entities should be able to show how 340B-generated savings are used to benefit patients directly, including reducing financial burden.
3. **Accountability and Reporting:** Reporting requirements should ensure program integrity while minimizing administrative burden and avoiding disruption to patient care.
4. **Patient-Centered Program Design and Access Protection:** Any rebate model or structural change should be evaluated based on its real-world impact on patient access, affordability, continuity of care, and clinical autonomy.

## **Patients Must Be Part of the Process**

For too long, discussions about the 340B program have been dominated by institutional stakeholders. Patients, the individuals whose care makes the program possible, have too often been left out.

Patients do not experience healthcare policy in theory. They experience it in access to medications, affordability, and financial stability.

Ensuring that patients are informed participants and not invisible ones is essential to creating trust and accountability in the program. Right now we have a bloated program, with no accountability to the people generating the revenue.

## Conclusion

The 340B program plays a significant role in our healthcare system and with that role comes responsibility.

To maintain its credibility and fulfill its original purpose, it must clearly and consistently serve patients and the communities it is intended to support.

Patients should not be invisible participants in a program built around their care. They should be informed, included, and meaningfully supported.

Together, we respectfully urge HRSA to implement the 340B Rebate Pilot Program with clear patient protections and to ensure that transparency, accountability, and measurable patient benefit are the standard for this and all future 340B policy decisions.

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## Signatories

This letter reflects the voices of thousands of patients and caregivers across the country, brought together through individual advocates and patient advocacy organizations to ensure the patient perspective is heard in this process.

Together, we respectfully urge HRSA to implement the 340B Rebate Pilot in a way that protects patients and ensures they are informed, included, and meaningfully benefit from the program and to make transparency, accountability, and measurable patient benefit the standard for all future 340B policy decisions.

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