

Rebate Model Road Map

A federal district court upholds HRSA's authority to require approval prior to drugmakers' imposition of 340B rebate models.

May and June 2025

HRSA approves manufacturers for the pilot program.

October 2025

A federal district court stops the pilot from taking effect on January 1, finding that HRSA failed to consider the pilot's impact on covered entities and did not provide a reasonable explanation for changing its longstanding policy of requiring upfront 340B discounts.

December 29, 2025

Parties agree to dismiss the case with an understanding that HRSA will reissue a new model; expectation is that HRSA will attempt to remedy APA issues.

January 12, 2026

Responses to request for information due to HRSA.

March 19, 2026

**Late 2024
Early 2025**

Several drug manufacturers sue HRSA to challenge HRSA's authority to require approval prior to drugmakers' imposition of 340B rebate models.

July 2025

HRSA announces a voluntary 340B rebate model pilot program that will start on January 1, 2026 and be limited to the first ten drugs subject to Medicare Part D price caps.

December 1, 2025

A group of hospitals and hospital associations sue HRSA to block the agency's pilot program, arguing that the agency did not comply with the Administrative Procedure Act's (APA) rulemaking requirements.

January 7, 2026

A federal appellate court upholds the district court's decision.

February 17, 2026

HRSA publishes request for information seeking input on a possible 340B rebate program.



340B Rebate Overview

Since the 340B program was established in 1992, the overwhelming majority of covered entities have accessed 340B ceiling prices as upfront 340B discounts. Over the last couple years, some pharmaceutical manufacturers have advocated for a 340B rebate model, under which drugmakers would provide 340B ceiling prices as post-purchase rebates instead of upfront discounts.

The Health Resources & Services Administration (HRSA), which oversees the 340B program, has not permitted manufacturers to unilaterally institute 340B rebate models.

Last year though, HRSA announced its own 340B rebate model pilot program that would start on January 1, 2026 and would be limited to the first ten drugs subject to Medicare Part D price caps.

A group of hospital associations and hospitals legally challenged the pilot, and the federal court hearing the case granted the hospitals a nationwide preliminary injunction that prevented HRSA from starting the pilot at the beginning of this year. The federal government is now engaged in discussions with the hospital plaintiffs about HRSA reconsidering the pilot, and 340B stakeholders are waiting to see what steps HRSA takes next.

Covered entities continue to have substantial concerns about the impact of a rebate model on patient care, finances, and operations. More specifically, entities are concerned that a rebate model would:



Undermine covered entities' ability to provide discounts on drugs to patients at the point of sale because of delayed access to 340B ceiling prices and uncertainty over whether a manufacturer will provide a 340B rebate,



Require covered entities with already limited financial resources to float significant costs for an extended period of time, and



Force covered entities to invest time, money, and energy into designing, implementing, and managing a system to track rebate requests at a time when they already face significant funding and budgetary pressures.

For more information about this issue, contact **Peggy Tighe**,
Legislative Counsel at Peggy.Tighe@PowersLaw.com.

