



## **12/29/2025 – District Court Halts Rebate Pilot for all Covered Entities**

Today, Chief Judge Lance E. Walker from the U.S. District Court for the District of Maine issued an order temporarily blocking the Health Resources & Services Administration (HRSA) from implementing the 340B rebate pilot program (rebate pilot) for all covered entities prior to its planned January 1, 2026, start date. The Court issued this injunction in response to a complaint filed by the American Hospital Association, the Maine Hospital Association, and four hospitals (plaintiffs) on December 1, 2025.

Notably, the decision applies to all covered entities, including grantees.

The Court found that the plaintiffs proved that 1) HRSA violated the Administrative Procedures Act (APA) by developing the rebate pilot without following APA procedures, 2) irreparable harm would likely occur without an injunction, and 3) the “balance of equities” and public interest weigh in favor of temporarily halting the rebate pilot.

The decision states that HRSA violated the APA by failing to: 1) consider that covered entities had relied on an up-front discount program for the history of the 340B program and the costs to covered entities, 2) adequately respond to public comments, 3) reasonably explain the reason for the rebate pilot, and 4) otherwise act within APA parameters. The Court summarized the requirements of the APA as “minimal requirements” that the “agency action be reasonable and reasonably explained.” In this case, the Court held that HRSA did not follow those standards and therefore “cannot fly the plane before they build it.”

The decision pointed to the millions of dollars hospitals were to spend in compliance costs, the downstream effect of which would potentially cause them to cut services and suspend partnerships with drug distributors. The Court also pointed out that the plaintiffs were ineligible to recover any damages from the rebate pilot should it later be invalidated. The Court stated that the injunction would preserve the status quo and protect the reach of covered entities to continue serving the public’s significant interest in receiving critical medical services.

The Court had previously denied the request of several manufacturers and PhRMA to intervene in the case. The Court allowed manufacturers and PhRMA to submit amicus

briefs supporting the rebate pilot. Several covered entity allies filed an amicus brief in support of the temporary restraining order.

The decision is a temporary measure that maintains the status quo until the Court can hear the merits of the case, which is unlikely before January 1, 2026. It is possible that HRSA will appeal the decision to the First Circuit. We anticipate that HRSA will issue some guidance on its website in response to the ruling. Until then, covered entities should anticipate that they will be allowed to receive up-front 340B discounts on the drugs that were subject to the rebate pilot. HRSA can issue a new rebate model in the future, and it would presumably follow the procedures of the APA more carefully if it did so.

Powers will continue to monitor activity surrounding the rebate pilot. Please contact Powers' drug pricing team, or your lead Powers attorney, if you have any questions.

**UPDATE 12/30/2025:**

HHS has filed an appeal to the First Circuit of the District Court's decision to temporarily halt the 340B rebate pilot program. HHS has also asked the District Court to put its decision on hold, pending review of its appeal by the First Circuit. HHS stated that if the District Court does not rule in its favor by 6pm today on its request to put the decision on hold, HHS will submit a request to the First Circuit to put the decision on hold. Presumably, if the District Court decision is put on hold, the AHA and hospital plaintiffs will appeal that decision to the First Circuit.

The District Court on the afternoon of December 30<sup>th</sup> denied the request of HHS for a stay pending the appeal to the First Circuit.

Look out for further updates.