



Court Pauses Controversial 340B Rebate Pilot Program: What Happens Now?

On December 29, a federal judge in Maine issued an order granting a preliminary injunction that effectively paused the implementation of the controversial 340B Rebate Pilot Program that the Health Resources and Services Administration (HRSA) was attempting to implement January 1, 2026. The court reasoned that the “paucity of the administrative record” in developing and implementing the program likely violates the Administrative Procedures Act, which requires agency actions to be both reasonable and reasonably explained. HRSA appealed the decision to the U.S. Court of Appeals for the First Circuit and also requested a stay from the district court to allow the 340B Rebate Pilot Program to be implemented on January 1 while the case is being appealed. The judge refused to grant a stay on the injunction during HRSA’s appeal to the First Circuit.

Though the First Circuit could still remove the preliminary injunction on appeal – allowing for the delayed implementation of the 340B Rebate Pilot Program – on December 31, the First Circuit declined to do so on an emergency basis. In other words, the courts are maintaining the status quo for now and the 340B Rebate Pilot Program will not go into effect January 1.

For nonprofit, safety-net health care providers that qualify as 340B covered entities, this means continuing to order pharmaceutical products at the discounted 340B price instead of having to outlay for product at manufacturer list prices (known as WAC), submit data, and wait for a rebate payment to get to the 340B price. This was welcome news to 340B stakeholders that were reeling from the scope and speed of the change HRSA was attempting. But there are a number of other factors for 340B stakeholders to keep in mind for 2026.

First, this case is not over. The First Circuit could reverse the lower court decision on appeal. All 340B stakeholders would be well advised to monitor developments closely and ensure they are ready to implement the 340B Rebate Pilot Program in response to a ruling by the First Circuit.

Second, the rebate pilot was paused because the administrative record for developing the 340B Rebate Pilot Program was remarkably thin for a change with such a massive impact on the stakeholders. The record also included an admission that HRSA hadn't actually finished its examination of the administrative costs to stakeholders for the pilot. This anemic administrative record led the judge to say that HRSA "cannot fly the plane before they build it." But, for 340B stakeholders, what that means is that if HRSA does properly "build the plane," there is nothing in the record suggesting HRSA cannot implement this or a similar rebate-style program. In fact, the court asserted that Congress clearly gave HRSA the option to implement a rebate program. It is not reasonable to expect that manufacturers are going to let this rebate concept go with a shrug, especially considering the investments they've made to get it off the ground. We should expect a rework.

Third, what that rework may look like is an open question. If HRSA really wants to get something moving, an easy path would be scaling the scope back to 340B covered entities that volunteer to be part of the pilot. Now that there are numerous 340B covered entities that were set up to operate on a rebate basis, there is a large pool of potential volunteers to test the rebate concept. HRSA could even test on paper in parallel with the existing up-front discount structure if they are really interested in understanding the challenges 340B covered entities might face, without actually disrupting their finances or operations.

Fourth, the primary issue that HRSA offered as the rationale behind the 340B Rebate Pilot Program was ensuring that manufacturers are not paying duplicate discounts between the 340B program and the new negotiated maximum fair price (MFP) refunds that take effect on January 1, 2026, for 10 expensive and commonly prescribed products under the Inflation Reduction Act. Under the law, Medicare only has to pay the dispenser the MFP for a product, plus a cost-based dispensing fee, which means the dispenser has to be able to buy that product at or less than the MFP or it will lose money on the dispense. But, since the pricing only applies to Medicare, manufacturers are not required to discount their products for purchases

for dispenses to other payers.

To facilitate payments to dispensers, the Centers for Medicare & Medicaid Services (CMS) introduced a refund model that will be facilitated through a data exchange in a new Medicare Transaction Facilitator (MTF). In essence, when dispensers purchase any of the 10 products that have an MFP, and those products are dispensed to Medicare patients, they can get a refund for the difference between the price they paid and the MFP if the MFP is lower.

But, for dispenses of MFP products that are eligible for 340B and are paid by Medicare, manufacturers are not required to stack the MFP refund and the 340B discount. Instead, they are required to sell to 340B covered entities at the lesser of the two prices. But, when the 340B covered entity is working with a contract pharmacy for dispensing, the dispenser and 340B covered entity are not the same, adding another layer of complexity that has not been addressed.

Since the 340B Rebate Pilot Program was expected to give manufacturers the data they need to ensure there is no stacking of MFP refunds and 340B discounts, with the program on hold, the potential for duplication looms large.

Fifth, regardless of whether the 340B Rebate Pilot Program had moved forward on January 1, 340B contract pharmacies face substantial uncertainty and financial risk if they are dispensing MFP products purchased at full price to Medicare beneficiaries at the MFP price, but their refund is disrupted over questions of whether the dispense was also eligible for 340B. One of the nation's largest pharmacy chains recently notified thousands of 340B covered entities that it was carving MFP products out of its contract pharmacy arrangements in the 340B program until it is confident its systems can handle the complexities.

Finally, regardless of whether the 340B Rebate Pilot Program moved forward on January 1, 340B covered entities are facing a financial shift in 340B revenues as the dispensing margins shrink for MFP products, pricing and pricing model changes ripple through the industry, and Medicaid enrollment and ACA plan enrollment continue to adjust to legal and market changes. While it is a relief for 340B covered entities not to compound these challenges with the vagaries of the 340B Rebate Pilot Program, there is still much to consider heading into 2026.

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