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HRSA's 340B Rebate Pilot Returns with New Rules and Renewed Litigation

Key Updates

- HRSA has approved implementation plans for 10 manufacturers participating in its revised 340B Rebate Model Pilot Program, scheduled to begin Jan. 1, 2027. The revised pilot faces a new legal challenge seeking to halt implementation before the launch date.

Why It Matters

- The pilot shifts covered entities from upfront 340B discounts to post-purchase rebates, increasing cash-flow exposure and administrative burdens. Although the approved plans share common requirements, manufacturer-specific differences in rebate eligibility, Medicare Maximum Fair Price coordination and contract pharmacy restrictions add operational complexity.

Next Steps

- Covered entities should prepare for Beacon implementation, review manufacturer-specific requirements, assess cash-flow exposure and establish processes for managing rebate claims and resolving payment delays before the Jan. 1, 2027, launch.

The Health Resources and Services Administration (HRSA) has approved controversial implementation plans for 10 manufacturers participating in the revised 340B Rebate Model Pilot Program (Rebate Pilot), scheduled to begin Jan. 1, 2027. Under the approved plans, covered entities (CEs) generally will purchase affected drugs at wholesale acquisition cost (WAC), submit claims-level data after dispensing or administration and receive a rebate equal to the difference between WAC and the applicable 340B ceiling price. HRSA's Rebate Pilot will have significant economic and non-economic impacts on CEs and is subject to new legal challenges.

This alert examines the revised Rebate Pilot's requirements, key differences among the approved manufacturer plans and practical steps covered entities can take to prepare for

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The 340B Rebate Pilot's History and Renewed Legal Challenges

HRSA's current Rebate Pilot is its second attempt to shift payment for certain 340B drugs from an upfront discount to a back-end rebate model. HRSA withdrew its prior pilot after the U.S. District Court for the District of Maine entered a nationwide preliminary injunction, finding that HRSA likely had not adequately considered CEs' reliance on upfront discounts and the financial and administrative burdens associated with a rebate model. In a separate proceeding, the D.C. Circuit affirmed HHS's position that the 340B statute permits rebate models, while also concluding that manufacturers may not impose such models without prior HHS approval.

HRSA published the revised Rebate Pilot on Aug. 3 after receiving nearly 2,500 comments from CEs and other stakeholders. The basic premise is the same as before: CEs must purchase drugs at WAC and recover the 340B discount after the fact. This shifts financial exposure and operational responsibility to CEs, which must submit complete claims data, monitor the rebate platform, correct errors, reconcile payments and pursue delayed or denied rebates.

As a result, on Oct. 9, the American Hospital Association (AHA), the Maine Hospital Association and four hospitals filed suit in the U.S. District Court for the District of Maine challenging the revised Rebate Pilot and approved manufacturer plans. The plaintiffs allege that HRSA violated the Administrative Procedure Act by understating financial and administrative burdens, overstating potential benefits and failing to adequately consider CEs' reliance on upfront discounts and less burdensome alternatives. They also requested a temporary restraining order and postponement of the Rebate Pilot and approved plans before the Jan. 1, 2027, launch.

How the Revised 340B Rebate Pilot Will Work

The approved manufacturer plans establish common requirements for rebate administration, claims submission and payment, including:

- **Standardized rebate administration and pricing.** The approved manufacturer plans are notably standardized. All 10 manufacturers will use Beacon to administer rebate submissions and payments. CEs will continue ordering drugs through existing 340B wholesaler accounts, with WAC rather than the 340B ceiling price loaded for affected products. Rebate amounts will equal the difference between WAC and the applicable 340B ceiling price and generally will be calculated at the unit level.
- **Claims submission and payment deadlines.** CEs generally will have 45 calendar days from the date of dispense or administration to submit rebate claims. Manufacturers must pay or deny a complete rebate request within 10 calendar days. If a submission is incomplete, however, the 10-day period restarts after the CE corrects and resubmits the claim. HRSA also limits manufacturers to specified pharmacy and medical claims fields and does not permit manufacturers to require purchasing or encounter-level data.
- **Limited transition accommodation.** The approved plans include a limited transition accommodation for CEs with pending 340B accumulations when the Rebate Pilot begins. During the first 15 calendar days after Jan. 1, 2027, CEs may seek rebates for up to two package-size accumulations generated by pre-January 1 dispensing that had not yet been replenished under the existing upfront-discount model, provided the underlying claims otherwise meet applicable submission deadlines.

Where Manufacturer 340B Rebate Plans Differ

The most significant variation between approved manufacturer plans relates to MFP coordination. Because some drugs subject to the Rebate Pilot may also be subject to the MFP for Medicare beneficiaries, manufacturers must account for situations in which the same drug transaction could otherwise receive both the 340B price and an MFP-related refund.

Several manufacturers, including Merck, Pfizer, Teva and Amgen, intend to preserve the 340B rebate and address potential duplication through the MFP refund process. By contrast, AbbVie, AstraZeneca and Bristol Myers Squibb expressly contemplate denying a 340B rebate in certain circumstances where the MFP is lower than the applicable 340B ceiling price. GSK initially plans to address duplication through the MFP process but reserves the right to change that approach after an initial observability period.

Regarding contract pharmacy restriction policies, Merck expressly incorporates aspects of its existing policy restrictions into rebate eligibility, while Teva states that its current policy restrictions will remain in effect. These approaches provide even greater traction and validation of the restrictions that CEs initially viewed as unlawful.

Several plans also provide that, when multiple CEs submit claims associated with the same utilization, the first conforming submission will be treated as valid. That may create attribution and timing issues for CEs using contract pharmacies, third-party administrators (TPAs) or overlapping accumulator arrangements. Other notable variations include GSK's exclusion of certain AIDS Drug Assistance Programs already receiving 340B discounts through existing rebate arrangements and Astellas's detailed criteria for exceptions to the 45-day filing deadline.

How Covered Entities Should Prepare for the 340B Rebate Pilot

With the revised Rebate Pilot scheduled to take effect Jan. 1, 2027, CEs should begin preparing for the operational and financial implications of the approved manufacturer plans, including the following steps:

- **Prepare for Beacon implementation.** CEs should address registration, including a legal/risk review of terms, banking and ACH setup, TPA connectivity, claims feeds, internal reconciliation and responsibility for exception handling before January 1.
- **Identify manufacturer-specific requirements.** CEs should identify the manufacturers and drugs impacting their operations and identify the relevant rules, exceptions and procedures for each applicable manufacturer.
- **Assess and document cash-flow exposure.** CEs should run the cost of purchasing affected drugs at WAC and account for potential delays caused by incomplete or denied claims. For high-cost drugs, even short payment delays may create significant financial exposure. Likewise, given the significant volume of transactions that Beacon will need to adjudicate, it's likely that CEs may never fully recover all discounts that would have otherwise been accessible under the historical 340B upfront discount model.
- **Review contract pharmacy and TPA workflows and ensure access to technology and reporting necessary to comply with the rebate policies.** CEs should confirm whether manufacturer-specific contract pharmacy restrictions apply and ensure that claims attribution processes minimize competing submissions for the same utilization.
- **Replenish existing accumulations before January 1 where possible.** The transition accommodation is narrow and should not be viewed as a substitute for implementation planning.
- **Develop a process for delayed or denied rebates.** CEs should establish internal procedures for tracking the 10-calendar-day payment-or-denial deadline, identifying

overdue rebate claims and promptly escalating unresolved issues with the manufacturer and Beacon. CEs should also designate responsibility for documenting payment delays, preserving supporting records and reporting persistent reimbursement issues to HRSA where appropriate.

Polsinelli's national 340B team advises numerous health systems on manufacturer restrictions and data submission policies, including contracting, manufacturer disputes and litigation.