LEGAL UPDATES

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340B Rebate Pilot Finalized: HRSA Approves Initial Manufacturer Plans, Clarifies Data and Operational Requirements

Services

340B Drug Pricing Program

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The Health Resources and Services Administration (HRSA) finalized the 340B Rebate Model Pilot Program and published FAQs that supplement the August 7, 2025, Federal Register notice. The final materials confirm the pilot takes effect on January 1, 2026, identify the initially approved manufacturers and pharmaceuticals, and clarify what data manufacturers may require from covered entities—now including limited medical claims fields in appropriate cases. HRSA also advises covered entities to reconcile existing accumulations for affected products before the pilot takes effect and outlines how additional manufacturers can join after launch with defined notice and participation conditions.

Approved manufacturers, selected drugs, and service platform

HRSA has initially approved nine manufacturer plans to participate in the pilot effective January 1, 2026. The approved plans are limited to specific drugs. All approved manufacturers intend to utilize Beacon as their service provider/IT platform. All plans must comply with the criteria and safeguards established in the August Federal Register notice.

The following manufacturers and pharmaceuticals were approved:

Bristol Myers Squibb: Eliquis

Immunex Corporation: Enbrel

AstraZeneca AB: Farxiga

Pharmacyclics: Imbruvica

Merck Sharp & Dohme: Januvia

Boehringer Ingelheim: Jardiance

Novo Nordisk Inc.: Novolog; Novolog FlexPen; Novolog PenFill; Fiasp; Fiasp FlexTouch; Fiasp PenFill

Janssen Biotech, Inc.: Stelara

Janssen Pharmaceuticals, Inc.: Xarelto

Manufacturers will issue rebates at the unit level. Covered entities must continue to purchase these drugs through their existing 340B wholesaler accounts, with manufacturers and distributors loading wholesale acquisition cost (WAC) pricing in the 340B account for the affected NDCs and furnishing a 340B ceiling price file through the Beacon platform to support reconciliation, pricing verification, and Medicaid acquisition cost billing. Rebates must be calculated as WAC minus the 340B ceiling price based on the date of service/dispense (not the purchase date).

Data submissions and operational issues

The Federal Register notice restricted requested data to a narrow set of pharmacy claims fields. In its final FAQs and statement regarding approved rebate plans, HRSA confirms it approved collection by manufacturers of limited medical claims data elements similar to the pharmacy claims data fields where appropriate. Manufacturers may only request the HRSA-approved data fields.

HRSA also clarifies rebate timing and oversight expectations: covered entities are to have real-time rebate status visibility, manufacturers are expected to meet the 10-day payment/denial standard, and persistent delays can result in revocation of pilot participation. As noted in the August Federal Register notice, concerns about diversion or duplicate discounts should not be used to deny rebates and must be addressed through audits or administrative dispute resolution (ADR). Both manufacturers and covered entities must maintain auditable records. HRSA will incorporate pilot compliance into audits of both.

Effective date

HRSA advises covered entities to work down and replenish accumulations for affected drugs before the January 1, 2026, effective date, and to consult each manufacturer's notice for handling any unreplenished accumulations that persist after the effective date.

Potential for additional manufacturer participation

Any approvals issued after the initial wave will have effective dates after January 1, 2026. HRSA requires manufacturers to provide covered entities at least 60 days' advance notice after HRSA approval before a rebate plan becomes effective, and all participation remains conditioned on compliance with the August Federal Register criteria. Of the manufacturers with drugs eligible to be included in the pilot, only Novartis and its drug Entresto were not included in the initial approvals. The FAQs note that HRSA could expand the rebate pilot to other drugs in the future.

Key takeaways

The pilot marks a significant shift from upfront discounting to post-dispense rebates for a discrete set of high-impact drugs. For covered entities, the transition will impact cash flow, accumulator strategies, and payer billing at acquisition cost—areas where CFOs, pharmacy leaders, and compliance teams should align now. For manufacturers, adherence to the August Federal Register criteria is required, with heightened expectations on data minimization, prompt rebate adjudication, and transparent claim status reporting. Both sides should document processes for timely submission, reconciliation, dispute handling, and audit readiness ahead of the January 1 launch.

Contact us

If you have any questions about this legal update, please contact Robert Hess, Renee Zerbonia, Kristina Abdalla, or your Husch Blackwell attorney.