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Insights

Government Shutdown Does Not Slow HRSA's 340B Rebate Pilot Program

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Despite the ongoing government shutdown, the Health Resources and Services Administration ("HRSA") has approved eight drug manufacturer plans for participation in its 340B rebate pilot program, which is set to launch on January 1, 2026. Under this pilot model, 340B covered entities must purchase select drugs at the wholesale acquisition cost ("WAC") and may only access the 340B discount by submitting rebate requests directly to the manufacturers. This rebate-based approach applies exclusively to the drugs and plans approved by HRSA for the pilot.

HRSA has approved rebate plans submitted by the following manufacturers and select drugs described in HRSA's approval:

- Bristol Myers Squibb
- Immunex Corporation
- AstraZeneca AB
- Pharmacyclics
- Merck Sharp & Dohme
- Boehringer Ingelheim
- Novo Nordisk Inc.
- Janssen Biotech, Inc.
- Janssen Pharmaceuticals, Inc.

Each plan utilizes the Beacon Platform for data exchange and rebate processing. Covered entities should expect communications from participating manufacturers in the coming days, along with registration instructions from Beacon to facilitate rebate submissions. Covered Entities should carefully review this information and HRSA's FAQs describing the 340B rebate program.

The timing of the 340B pilot program coincides with the implementation of drug pricing provisions under the Inflation Reduction Act ("IRA"), also effective January 1, 2026. Covered entities are encouraged to closely evaluate the IRA's impact on their 340B discounts, as the legislation is expected to reduce the value of those discounts.

Please contact Brandon W. Shirley if you have any questions about this alert or your organization's 340B program.

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