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HRSA Announces 340B Pilot Program

On July 31, the Health Resources and Services Administration (HRSA) announced a voluntary 340B Rebate Model Pilot Program that would be available for the 10 drugs on the CMS Medicare Drug Price Negotiation Selected Drug list for year 2026.

This follows multiple drug companies having tried to force HRSA, using litigation, to approve their plans to transition 340B discounts to covered entities to a much broader rebate program. WHA has joined an amicus briefing in defense of HRSA, maintaining that HRSA, and not individual drug companies, has the authority to approve, deny or set other parameters regarding the lawful use of rebates in the 340B program.

Under HRSA's pilot program, 340B hospitals would be required to purchase these 10 drugs at wholesale acquisition cost, submit certain data elements to drug companies and receive a rebate within 10 calendar days of data being submitted. Drug companies would also have to apply for participation in the program by September 15, with approvals from HRSA by Oct. 15.

Drug companies would be required to submit specific plans in 1,000 words or less detailing their use of a rebate model and would be required to ensure they are not passing along costs associated with data submission or other administrative costs to 340B hospitals.

WHA intends to provide comments to HRSA on this proposal in advance of the Aug. 31 deadline. HRSA is looking for feedback in four areas, including:

1. Flexibilities needed to maximize efficiency and efficacy of the pilot.
2. Safeguards to mitigate adverse, unintended impacts for covered entities.
3. Additional data or reporting elements that could improve implementation and evaluation.
4. Logistical or administrative burdens imposed by the pilot design.

Contact WHA Vice President of Federal and State Relations Jon Hoelter with questions or comments.



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- CMS Issues 2026 IPPS Final Rule
- Only One More Week to Submit Your Nomination for the 2025 Global Vision Community Partnership Award

EDUCATION EVENTS

Aug. 26, 2025

Infection Prevention and Antibiotic Stewardship

Sep. 17, 2025

2025 Annual Wisconsin Organization of Nurse Leaders Conference

Sep. 23, 2025

Inpatient Dialysis in Rural Health