HRSA 340B REBATE MODEL PILOT PROGRAM

Summary of the Revised July 31, 2026 Announcement

KEY FINDING: The revised pilot contains no categorical exemption for Critical Access Hospitals, FQHCs, rural hospitals, Rural Referral Centers, Sole Community Hospitals, children's hospitals, cancer hospitals, DSH hospitals, or other 340B covered-entity classes. Once an approved manufacturer plan applies to a selected drug, the rebate process is intended to apply across covered-entity types.

Program Overview

HRSA action and status. The Health Resources and Services Administration (HRSA) issued the revised program as a Federal Register *Notice*, not as a proposed rule or notice of proposed rulemaking. The notice is scheduled for publication on August 3, 2026 and states that it is effective immediately upon publication, unless revised by a future notice. It does not open a new public-comment period.

Purpose. The pilot allows qualifying drug manufacturers, with prior HHS approval, to use rebates rather than upfront 340B discounts for a limited group of drugs. The covered drugs are the NDC-11s of drugs selected under the Medicare Drug Price Negotiation Program for initial price applicability years 2026 and 2027, during each drug's applicable negotiated-price period. The model applies regardless of payer or indication.

Participation. Manufacturer participation is voluntary and requires HRSA/HHS approval, but covered entities do not receive a general option to remain under the upfront-discount method for an approved manufacturer-drug combination. Approved manufacturers must participate for at least one year and may not implement a rebate plan before receiving HHS approval.

How the Rebate Model Would Operate

- **Acquisition and rebate amount:** Covered entities would generally obtain covered products through existing distribution channels with wholesale acquisition cost (WAC) loaded, then seek a rebate equal to WAC minus the 340B ceiling price on the date of dispense.
- **Claims submission:** Covered entities must be allowed at least 45 calendar days from the date of dispense to submit the required claims-level data, with allowances for extenuating circumstances and claim-status adjustments.
- **Payment deadline:** Manufacturers must pay the rebate, or issue a documented denial, within 10 calendar days after a completed data submission. If a submission is incomplete, the 10-day clock restarts when the missing information is supplied.
- **Technology and data:** The manufacturer must pay all costs of the required submission platform. The platform must support all applicable covered entities, provide real-time claim-status reconciliation, limit collection to required data, provide technical assistance, and protect PHI and other personally identifiable information consistent with applicable law, including HIPAA.
- **Advance notice:** Approved plans must provide covered entities and other affected parties at least 90 calendar days of implementation notice, including registration and operational instructions.

No Categorical Exemptions

HRSA specifically rejected carving up or phasing in the pilot according to covered-entity category. The notice acknowledges that Critical Access Hospitals, rural hospitals, FQHCs, and larger health systems raised different financial and operational concerns. Nevertheless, HRSA concluded that differences between the average hospital and the average FQHC do not justify excluding particular classes. It further states that the duplicate-discount and nonduplication risks are drug-specific and apply to all covered entities, rather than only to particular provider categories.

Individualized exceptions may be possible, but are not guaranteed. A manufacturer plan must describe any non-broad exception and communicate it to HRSA and affected providers. Examples include entities without TPA access, rural hospitals, or health centers. Any accommodation depends on

the manufacturer plan and HRSA approval; it is not automatic protection for CAHs, FQHCs, or rural providers.

Implementation Timeline

Date	Milestone
August 3, 2026	Scheduled Federal Register publication; the notice becomes effective immediately upon publication.
August 24, 2026	Deadline for eligible manufacturers to submit rebate-model plans to HRSA.
By September 24, 2026	HRSA states that approvals, if any, will be made by this date.
Fall 2026	Approved manufacturers must provide at least 90 days of notice and implementation instructions to covered entities and other affected parties.
January 1, 2027	Operational effective date for approved plans involving selected drugs for the 2026 and 2027 initial price applicability years.
By April 30, 2028	HRSA plans to publish an evaluation of the pilot, using public and aggregated information to the extent practicable and lawful.

Public Comment and Legal Form of the Action

No new comment period. The July 31 announcement does not request comments and provides no deadline for public comments on the revised pilot. HRSA treats the stakeholder-input process as already completed. It reports that it reviewed 2,449 public comments and 26 nonpublic submissions—2,475 total—submitted in response to the February 17, 2026 Request for Information. The RFI comment period closed April 20, 2026. A separate Paperwork Reduction Act process addressed the information-collection burden and had a 30-day comment deadline of July 15, 2026; that was not a new comment period on the underlying pilot policy.

Not a proposed rule. The document is labeled "ACTION: Notice," includes no proposed regulatory text, and does not propose an amendment to the Code of Federal Regulations. HRSA is therefore implementing the program through an operative notice rather than first publishing an NPRM and receiving another round of comments. This procedural choice may remain subject to Administrative Procedure Act litigation; describing the document as a notice does not, by itself, resolve whether a court could view the policy as a substantive rule requiring notice-and-comment rulemaking.

Most Important Implications for Covered Entities

- CAHs, FQHCs, rural hospitals, and other safety-net providers should plan on inclusion. Organizations seeking hardship relief should press for plan-specific exceptions based on lack of TPA access, rural status, liquidity constraints, or limited operational capacity.
- Providers should identify the affected 2026 and 2027 negotiated drugs, assess WAC and cash-flow exposure, and confirm systems can submit claims within 45 days and reconcile manufacturer action within 10 days.
- Covered entities should monitor HRSA's publication of approved plans because those documents will determine the covered drugs, platform instructions, individualized exceptions, and operational details effective January 1, 2027.

Official Sources

Revised notice: Federal Register Public Inspection Document, FR Doc. 2026-15633. Prior RFI: 91 FR 7287 (Feb. 17, 2026).