August 28, 2025

Public Comment on the 340B Rebate Model Pilot Program
Submitted by: The Craneware Group
Docket No.: HRSA-2025-14998

To Whom It May Concern:
The Craneware Group appreciates the opportunity to submit comments on HRSA's proposed 340B **Rebate Model Pilot Program** (hereafter, the "Rebate Pilot").

As a long-standing partner to safety-net hospitals, community health centers, and other covered entities participating in the 340B Drug Pricing Program, we work alongside providers who rely on 340B benefits to stretch scarce resources, improve access to care, and sustain essential community services. Any changes to the program must first and foremost protect these patient-focused outcomes.

While we recognize HRSA's efforts to invite stakeholder input, we are deeply concerned that the Rebate Pilot, as currently drafted, is operationally unworkable and may leave hospitals and the communities that depend on them financially at risk and unable to fully meet their mission. We urge HRSA to take additional time to carefully evaluate the potential consequences and make necessary adjustments before finalizing any rebate guidance.

The Craneware Group's Evaluation of the 340B Rebate Model Pilot Program
The following analysis reflects The Craneware Group's experience supporting operational, financial, and compliance workflows across a broad spectrum of U.S. healthcare organizations.

To assess the practical implications of the Rebate Pilot, we analyzed data from a representative sample of 17 provider organizations, encompassing 81 covered entities, 573 pharmacies, and 908 contract pharmacy relationships. The dataset covers the period January 1 through June 30, 2025, and focuses on the ten drugs proposed for inclusion in the pilot.

- **Unique prescriptions reviewed:** 95,499
- **Total prescription claims (including refills):** 160,675
- **Listed WAC pricing:** $430,457,141
- **Actual spend under traditional 340B discounting:** $81,758,922.11

Key Findings
If these same transactions were processed under the rebate model, Covered Entities in this sample would be required to pay WAC pricing upfront at more than five times higher than current 340B acquisition costs. **That represents a $348.7**

million increase in short-term cash outlay that providers would need to float while awaiting reimbursement, even under best-case rebate processing timelines.

This model risks straining provider cash flow, particularly among safety-net hospitals, rural health centers, and other vulnerable entities. **While manufacturers benefit from deferred payout and interest accrual, the financial exposure for covered entities is substantial and deeply concerning.**

Recommendations

Considering these findings, The Craneware Group respectfully offers the following feedback for HRSA's consideration:

- **Preserving Operational Continuity and Minimizing Disruption**
  Address the real-world implications of delayed reimbursement, pricing visibility, and cash flow instability introduced by the rebate model.

- **Promoting Standards and Interoperability**
  Ensure the pilot integrates with existing 340B, EHR, and revenue cycle systems, supporting broader national goals of healthcare interoperability.

- **Safeguarding Data Privacy and Streamlining Requirements**
  Limit data demands to what is essential, avoiding unnecessary complexity or duplication that strains provider resources.

- **Supporting Fair Dispute Resolution and Transparency**
  Mandate clear justification for any rebate denial and ensure a timely, transparent resolution process that providers can trust.

- **Preparing for a Dual-Model Environment**
  Anticipate the administrative complexity of managing both rebate-based and traditional 340B discounts simultaneously and provide mitigation strategies to reduce compliance risk and burden.

The sections that follow expand on each of these points in detail:

1. Preserving Operational Continuity and Minimizing Disruption

The introduction of a rebate-based pricing mechanism — while narrow in scope today — represents a fundamental shift from how the 340B Program has functioned for more than 30 years. Covered entities accustomed to upfront discounts will face new timing, reconciliation, and reporting burdens that directly threaten the patient benefits 340B participation makes possible. For many safety-net providers, these benefits fund healthcare services, medication access, patient assistance programs, and essential community services.

A critical operational concern is the absence of the 340B price through wholesaler account price catalogs under the rebate model along with the lack of bulk access to 340B ceiling prices. Without visible 340B pricing flags, covered entities and their third-party administrators (TPAs) cannot confirm drug eligibility in real time. Because the 340B ceiling price is not available to TPAs, providers would be unable to validate purchases, ensure compliance, or reconcile rebate payments accurately — increasing compliance risk and delaying or eliminating savings that support vulnerable patients and communities.

We urge HRSA to:

- **Require that 340B pricing remain visible** in wholesaler account price catalogs for rebate-eligible drugs during the pilot or grant access to the full 340B ceiling price data-set through exports to allow systematic validation of 340B prices and rebate payment.
- **Restrict advance WAC purchase requirement** allowing WAC purchase to occur at anytime in relation to service date rather than requiring a WAC purchase to have occurred prior to the 340B claim being dispensed.
- **Allow 340B adjudication to occur prior to Medicare Part D (MFP) rebates** sustaining maximum 340B benefit to Covered Entities and operational efficiencies.
- **Preserve operational efficiency** by ensuring rebate platforms align with the systems providers already use, such as claims data feeds, TPA connections, or wholesaler account structures, to avoid duplicative work and manual reconciliation.
- **Monitor cash flow and workload impacts** on pharmacy and finance teams, with particular attention to Disproportionate Share Hospitals (DSH), rural hospitals, and Federally Qualified Health Centers (FQHCs).
- **Provide implementation support or grants** for rural and resource-constrained entities.
- **Issue timely contract pharmacy guidance** and clarify whether contract pharmacies will retain access under the pilot. Clarification is required as to whether manufacturers must allow multiple contract pharmacies, which are currently denied through unilateral manufacturer contract pharmacy restriction policies.
- **Address the cash flow crunch** created by wholesale acquisition cost (WAC) purchasing. For example:
    - **Establish an interim payment or rebate prepayment model to limit provider exposure to prolonged reimbursement delays.** This mimics how interim payments or draw-downs are used in other CMS programs and would keep providers from carrying 100% of the financial risk.
    - **Mandate that rebates be paid within a defined, enforceable timeframe with interest penalties for delay.** Create a defined standard that ensures manufacturers process rebates with urgency, just as providers are expected to dispense and report on tight deadlines.
    - **Include manufacturer reporting requirements that disclose the average float period and cash impact on covered entities.** We believe HRSA should see in black-and-white that providers will be floating millions of dollars for much longer than 10 days.
    - **Provide technical assistance, risk modeling tools, and targeted financial support for small and rural providers facing disproportionate cash flow exposure.** Some providers may need bridge support or at least structured forecasts to prevent disruption of patient care due to cash flow issues.
- **The most significant hidden cost of the rebate model for covered entities is the time value of money — the financial impact of advancing millions in drug spend while waiting for reimbursement.** HRSA should make clear that manufacturers must compensate providers for this burden, consistent with the regulation's stated intent that no administrative costs be passed on to covered entities.

Even short delays in receiving rebates reduce the resources available for patient care. For a rural hospital with limited staff and tight margins, a 30-day delay can mean postponing medication purchases, scaling back covered entity patient assistance programs, or cutting uncompensated care. These outcomes run counter to the mission of the 340B Program and jeopardize the stability of our nation's healthcare safety net.

2. Promoting Standards and Interoperability

We support the requirement that manufacturers bear all IT and administrative costs related to the rebate model. However, to truly reduce provider burden and variability, and to protect patient access, HRSA should:

- Establish baseline data standards and technical specifications for the required IT platforms at the outset of the pilot, not after implementation.
- Require systems to integrate with existing 340B tools and revenue cycle systems to enable seamless execution and avoid undoing years of progress toward national interoperability and value-based care:
    - **Avoid shifting the cost of operational system changes onto covered entities.** Most providers have already configured their EHRs, revenue cycle systems, and 340B platforms to comply with existing standards and workflows. Supporting the rebate model may require significant reconfiguration, system customization, or third-party integration; yet the guidance does not specify how covered entities will be reimbursed for these expenses. HRSA should require manufacturers to cover these costs, consistent with the stated intent that providers bear no costs under the pilot.
    - **Align with national policy goals**. The shift toward a value-based healthcare economy depends on connected, data-driven systems that reduce administrative burden and improve care coordination.
    - **Prevent workflow disruption**. Lack of integration would force providers into duplicative or manual processes, recognizing indirect costs but having no clarity on how these costs will be borne by manufacturers, exposing them to increasing compliance risk, delayed rebate payments, and potentially limiting funds for patient services.
    - **Support scalability and vendor choice**. Integration ensures providers can continue using trusted technology partners rather than being locked into manufacturer-selected platforms.
- Develop a vendor-neutral reporting framework to ensure transparency, scalability, and provider choice across different covered entity types and sizes.

Without common standards and interoperability from day one, providers will face increased administrative complexity, higher compliance costs, and greater risk of error. These outcomes directly counter to the pilot's stated goals. The result would not just be operational inefficiency; it could mean delayed patient care and diminished access to lifesaving medications. Interoperability is not optional. It is foundational to success.

Past federal initiatives, such as the initial stages of the EHR Incentive Programs ("Meaningful Use"), demonstrated that delaying interoperability standards until after rollout significantly increases provider burden, implementation costs, and the time required to realize intended program benefits — lessons that should inform the 340B rebate pilot from the start.

3. Safeguarding Data Privacy and Streamlining Requirements

We appreciate HRSA's guardrails on data privacy and limiting the required fields for rebate submission. However, there is growing ambiguity between the original 340B rebate guidance, which clearly identifies a maximum of 11 data fields, and the HRSA FAQ, which permits manufacturers to request additional fields in their individual pilot plans with justification. This introduces significant risk. If each manufacturer requests a different set of fields or formats, covered entities will be forced to build multiple custom processes and technologies to comply — a costly and time-intensive undertaking. **This complexity cannot be implemented in 60 days, particularly for providers managing limited resources and multiple vendor integrations.**

In addition, even standardized fields (such as RX number, NDC, and prescriber ID) vary across systems and provider types. If manufacturers enforce rigid formatting or deny rebates based on non-substantive discrepancies in these fields, covered entities may experience avoidable delays and claim denials, creating downstream financial gaps and operational inefficiencies.

We recommend:

- **Clarifying that only the 11 fields defined in the regulation are required** for all manufacturers, unless HRSA specifically approves additional elements for **all** pilot participants.
- **Requiring uniform formatting standards and validation logic** across manufacturers to prevent fragmentation and reduce the burden on covered entities.
- **Ensuring that any additional fields proposed by manufacturers are subject to HRSA review and public comment**, and that providers are given adequate time and technical guidance to implement changes.
- **Providing a standardized, HRSA-approved data guide**, including submission, adjudication, and reconciliation specifications to promote consistency and minimize delays.

Every additional data requirement takes time and attention away from patient care. Unnecessary variation across manufacturer requirements will result in avoidable claim rejections, delayed rebates, and added administrative overhead — all of which undermine the 340B Program's mission to stretch scarce resources in support of vulnerable patients.

4. Supporting Fair Dispute Resolution and Transparency

The Rebate Pilot's explicit restrictions on rebate denials for diversion or duplicate discount concerns are a strong foundation. To ensure these protections translate into uninterrupted patient care, HRSA must require:

- **Detailed, standardized denial documentation.** Manufacturers should provide written notice for any denied rebate, citing a specific reason from a defined list of allowable grounds, and offer a time-bound appeals process. This will allow covered entities to act swiftly, resolve disputes, and protect patient services.
- **Real-time rebate status visibility.** The rebate IT platform must include real-time financial tracking and reconciliation capabilities. Providers need to know when and how rebate funds are flowing because those dollars support direct care, not overhead.
- **Clear guidance on impacted patient programs.** If a rebate is denied, HRSA must clarify how providers should continue operating 340B-funded medication access or patient assistance programs. Without such guidance, safety-net providers may be forced to reduce services mid-treatment due to reimbursement uncertainty.

When rebates are delayed or denied without cause, the result is not just an administrative burden -- it's fewer medications, fewer outreach programs, and fewer care options for patients in need.

To safeguard fairness and transparency, HRSA should implement a robust oversight and accountability framework that includes:

- **Consequences for delayed payments.** Providers must not absorb the financial burden of late or missing rebates. Timely payments should be mandatory, with penalties for delays, consistent with existing 340B civil monetary penalties.
- **Required manufacturer reporting.** HRSA should mandate transparent reporting from manufacturers, including:
    - Total rebates paid and rejected, by covered entity
    - Rejection categories with reason codes
    - Average days to payment
    - Number of unresolved disputes
- **Enforceable penalties for non-compliance.** Rebates that are wrongfully withheld should carry meaningful consequences, just as traditional 340B overcharges do.
- **A neutral, HRSA-led dispute resolution process.** When internal appeals fail, providers must have access to a timely, binding third-party resolution mechanism. Without this, manufacturers retain unchecked control over the flow of rebate funds.

5. Preparing for a Dual-Model Environment

During the Rebate Pilot, covered entities will likely operate under both the traditional 340B discount model and the rebate-based model simultaneously, introducing risk of confusion, administrative burden, and compliance exposure.

We urge HRSA to:

- **Issue clear guidance on managing dual models**, including how covered entities can track rebate eligibility across purchasing channels.
- **Clarify whether manufacturers may apply their own contract pharmacy restrictions under the Rebate Pilot**, recognizing that such restrictions further limit patient access, especially in rural and underserved communities.
- **Evaluate scaling the rebate model to other drug classes only after robust performance metrics, stakeholder feedback, and unintended consequences are fully reviewed**. Operating under two models will increase complexity and compliance risk. Without clear, practical guidance, well-intentioned providers could face audit findings or penalties, jeopardizing their ability to participate in the program and maintain access for their patients.

In closing, The Craneware Group is committed to supporting the healthcare providers who rely on the 340B Program to sustain access, affordability, and care delivery in vulnerable communities across the US. As a technology partner with deep experience in compliance and operational integration, we will do everything we can to help our customers understand and adapt to these proposed changes.

That said, we must be clear: the current structure of the 340B Rebate Model Pilot presents significant challenges. The implementation timeline is too short, key components remain undefined, and the burden on covered entities is disproportionate. Without greater specificity, reasonable lead time, and enforceable guardrails on manufacturer behavior, this pilot undermines the very outcomes the 340B Program was designed to protect.

We urge HRSA to provide additional clarity, extend the timeline for implementation, and include stronger protections to ensure manufacturers are held accountable. These steps are critical to ensuring that any transition to a rebate model is feasible, fair, and aligned with the mission of the 340B Program.

Sincerely,

Lidia Rodriguez-Hupp
Chief Customer Officer
The Craneware Group