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Submitted VIA Regulations.gov
April 20, 2026
Re: HHS Docket No. HRSA-2026-03042
Request for Information: 340B Rebate Model Pilot Program

I. Introduction
The Craneware Group appreciates the opportunity to comment on the Health Resources and Services Administration's ("HRSA") Request for Information regarding a potential 340B Rebate Model Pilot Program.

The Craneware Group provides financial, compliance, and operational infrastructure solutions to hospitals and health systems nationwide. Our systems support covered entities participating in the 340B Drug Pricing Program through eligibility determination, transaction-level reconciliation, audit readiness, contract pharmacy oversight, duplicate discount prevention, and cross-program reporting.

To assess the real-world operational and financial implications of the proposed rebate model, The Craneware Group analyzed 2025 activity across a representative subset of customers using our solutions. Within this subset, approximately 169 covered entities processed roughly 17 million 340B-related prescription and medical transactions associated with IPAY 2026 and 2027-designated drugs that would be directly impacted by a rebate-based model. Within this subset alone, the modeled financial exposure associated with a shift to wholesale acquisition cost ("WAC") purchasing and rebate recovery exceeds $700 million annually.

Based on this level of operational visibility, we view the proposed rebate model as a structural shift in program design rather than a procedural refinement. Transitioning from an upfront statutory discount model to a post-adjudication rebate model would materially alter working capital dynamics, compliance workflows, data exchange requirements, and dispute resolution processes across covered entities.

Hospitals collectively provide more than $40 billion annually in uncompensated care based on American Hospital Association survey data. At the same time, many hospitals — particularly rural and safety-net providers — operate at or near breakeven margins, reflecting sustained

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financial pressure across the field.[1] In this environment, the 340B Program serves as a critical financial stabilizer supporting patient access in vulnerable communities. Policy changes that introduce payment timing uncertainty or expand administrative complexity should be evaluated in the context of these existing constraints.
A rebate-based model does not simply adjust reimbursement mechanics; it reallocates financial and operational timing responsibilities in ways that carry measurable implications for program scalability, predictability, and sustainability.

Taken together, these considerations reflect a consistent pattern: the proposed rebate model introduces new financial exposure, expands administrative complexity, and relies on data infrastructure that remains fragmented and difficult to standardize in practice. These dynamics compound rather than operate independently, creating system-level risk across covered entities.

With consideration for the operational, financial, and structural considerations outlined below, we have significant concerns that a rebate-based model may introduce risks that would be difficult to reverse once implemented at scale. These risks include disruption to hospital cash flow, increased administrative fragmentation, and potential erosion of the program's ability to support patient access.

Accordingly, we believe a rebate-based model represents a fundamental departure from the longstanding design of the 340B Program and should not be advanced absent clear evidence that it can be implemented without destabilizing covered entities.

If HRSA elects to proceed with a pilot despite these concerns, it should be implemented in a limited, controlled environment with transparent administration across a defined subset of covered entities. This approach is necessary to enable rigorous evaluation of operational, financial, and compliance impacts before any broader implementation is considered.

Our comments are offered to support that evaluation and to help ensure that operational sustainability, financial stability, and patient access remain central to any proposed modernization consistent with the intent of the 340B statute.

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[1] American Hospital Association reporting indicates hospitals provided approximately $41.4 billion in uncompensated care in 2023 and that many rural hospitals continue to face significant operating margin pressure.

II. Structural Distinction Between Upfront Discounts and Rebates

For more than three decades, the 340B Program has operated as an upfront discount model. Under this structure:

- Statutory ceiling prices are applied at the time of purchase
- Covered entities realize discounted pricing at the point of acquisition
- Administrative activities focus on eligibility verification, diversion prevention, and statutory duplicate discount safeguards—not claims-based reimbursement recovery or post-transaction reconciliation

A rebate-based model is not a procedural refinement; it is an architectural shift. Under a rebate model:

- Covered entities would purchase drugs at a higher initial price, such as wholesale acquisition cost (“WAC”)
- Claims-level data would be compiled and submitted to manufacturers for validation
- Manufacturers would adjudicate rebate eligibility
- Payment timing, denial protocols, and reconciliation processes would expand materially

This approach converts the program from a price-at-purchase structure into a post-adjudication claims model, fundamentally altering how value is realized within the program.

HRSA’s evaluation should account for the systemic implications of this transformation, including changes in payment timing, reliance on manufacturer adjudication, and the introduction of new administrative processes that increase operational burden and create variability in financial outcomes.

These changes introduce delayed revenue realization, expanded dispute cycles, and increased administrative complexity—each of which carries implications for the financial stability and operational predictability of covered entities.

III. Current Administrative Infrastructure

The Craneware Group’s experience across supported 340B organizations reflects a highly complex and increasingly fragmented administrative environment. Covered entities operate across diverse care settings, payer structures, and, in many cases, multiple state regulatory models, each with distinct Medicaid policies, billing requirements, and reporting expectations.

Under the current upfront discount model, administrative operations extend well beyond basic program participation and include:

- Eligibility validation across multiple care locations and provider types
- Accumulator management across in-house and contract pharmacy dispensing
- Contract pharmacy reconciliation across geographically distributed networks
- Audit documentation and compliance readiness across federal and manufacturer requirements
- Medicaid carve-in and carve-out coordination, often varying by state and payer type

For multi-state health systems, these processes must be executed across non-uniform Medicaid policies, differing managed care structures, and state-specific reporting requirements, requiring significant system configuration, operational oversight, and continuous monitoring.

Administrative requirements associated with 340B participation have expanded materially in recent years due to manufacturer-imposed reporting conditions, platform-specific submission mandates, and increased audit scrutiny. These requirements are not standardized and frequently vary by manufacturer, resulting in parallel processes across multiple third-party platforms and submission systems.

A. System-Level Administrative Saturation

The current 340B administrative environment no longer functions as a single-program workflow. It operates as a multi-system, multi-party coordination model requiring alignment across:

- Covered entities
- Contract pharmacies
- Wholesalers
- Manufacturers
- State Medicaid agencies
- Managed care organizations
- Third-party reporting platforms (e.g., ESP, Beacon, Kalderos)

These systems operate with non-uniform data standards, varying submission timelines, and differing adjudication expectations. As a result, covered entities must maintain parallel processes to meet compliance obligations across multiple, unaligned models.

Administrative capacity is therefore constrained not by participation volume alone, but by the cumulative complexity of overlapping, non-standardized, and frequently evolving requirements.

B. Implications for Rebate Model Evaluation

Any evaluation of a rebate-based model must account for this existing system-level saturation. A rebate model would not be introduced into a neutral administrative environment; it would be layered onto an already fragmented and capacity-constrained system.

Absent meaningful standardization and reduction of existing administrative burden, a rebate model would compound fragmentation, increase operational strain, and introduce additional points of failure across already complex, multi-state healthcare delivery systems.

IV. Contract Pharmacy Restrictions and Program Balance

In addition to administrative complexity, existing distribution constraints further shape how 340B operations function in practice.

In recent years, manufacturer-imposed contract pharmacy distribution conditions and expanded data reporting requirements have materially reshaped 340B operations for covered entities. These actions have introduced significant administrative complexity and have been associated with measurable financial impacts, as covered entities experience reduced access to 340B pricing in contract pharmacy arrangements while continuing to serve eligible patient populations.

Based on observed utilization patterns across a representative sample of covered entities, certain high-impact drug categories alone represented more than $700 million in 340B program value in 2025. This underscores the scale of financial exposure that would become subject to rebate timing variability under a post-adjudication model.

If a 340B Rebate Model Pilot Program is structured to provide manufacturers with standardized, claims-level transparency sufficient to address duplicate discount concerns, the operational basis for maintaining certain contract pharmacy restrictions is materially weakened.

A rebate-based model designed to enhance transactional transparency would alter the conditions under which current distribution limitations have been justified. Maintaining both expanded rebate infrastructure and restrictive contract pharmacy limitations would compound administrative burden while perpetuating financial asymmetry between manufacturers and covered entities, without corresponding gains in program integrity.

Contract pharmacies often extend dispensing access in rural and underserved communities. These arrangements are particularly important where pharmacy access is otherwise limited and where 340B savings help sustain essential services. To preserve program balance and patient access, HRSA should consider whether participation in a rebate pilot should require reassessment of manufacturer-imposed limitations premised on duplicate discount concerns.

While HRSA has previously noted limitations in its authority over contract pharmacy arrangements, the design and implementation of a rebate pilot program falls squarely within HRSA's authority. Accordingly, the interaction between rebate mechanisms and existing distribution limitations should be addressed as a defined condition of the pilot's rules of engagement.

Evaluating rebate implementation and contract pharmacy restrictions in isolation risks perpetuating asymmetric administrative and financial burden across covered entities. If enhanced data transparency meaningfully addresses manufacturer visibility concerns, alignment between pricing mechanics and distribution practices should be incorporated into a comprehensive and balanced pilot design.

V. Systems and Data Infrastructure Requirements

Beyond program structure, the feasibility of a rebate model depends on the underlying data and systems infrastructure required to support it.

A rebate-based model would require the development or modification of significant data and systems infrastructure, including:

- Timely claims-level data transmission capability
- Standardized manufacturer submission formats

- Secure patient-level data transmission protocols
- Cross-system reconciliation among:
  - Wholesalers
  - Contract pharmacies
  - Medicaid systems
  - Medicare Maximum Fair Price (MFP) program data
  - Manufacturer rebate adjudication systems

These requirements necessitate coordinated data exchange across multiple stakeholders operating on non-uniform systems, with varying data standards, submission timelines, and reconciliation processes.

Across the covered entities supported by our systems, customers report extensive operational effort and resource allocation to comply with existing manufacturer-imposed rebate and reporting models, including those associated with the Medicare Drug Price Negotiation Program (MFP). Despite these investments, organizations continue to experience persistent challenges achieving accurate and consistent reconciliation. These challenges are driven by non-standardized data requirements, evolving submission expectations, and fragmented system interactions across stakeholders.

This experience demonstrates that even with significant investment and focused operational effort, rebate-based data exchange and reconciliation processes remain difficult to standardize and execute reliably in practice.

Introducing a 340B rebate model would extend these same structural challenges across a broader set of transactions and participants, increasing the risk of data inconsistency, reconciliation delays, and administrative burden across already complex, multi-system environments.

VI. Cash Flow and Payment Timing Considerations

These operational and data dependencies translate directly into financial implications for covered entities and are consistent across both aggregate system-level analysis and individual provider-level modeling.

Under the current upfront discount model, covered entities realize the statutory ceiling price at the time of purchase. With recent national reporting showing median hospital operating margins

generally in the 1% to 3% range, many providers remain financially constrained, particularly rural and safety-net hospitals.[2] By contrast, manufacturers in the pharmaceutical sector operate with significantly higher margins, and changes that delay or alter the realization of 340B pricing shift additional financial and timing advantages toward manufacturers.

A rebate model introduces receivable exposure and adjudication variability. Even if rebate payments are required within ten (10) calendar days:

- Payment lag alters working capital dynamics
- Denial and dispute cycles introduce revenue uncertainty
- Revenue timing becomes dependent on manufacturer adjudication processes
- Contract pharmacy arrangements further complicate revenue allocation

For margin-constrained, rural, and safety-net providers, variability in receivable realization has disproportionate operational consequences. Administrative expansion that diverts resources toward rebate adjudication rather than pharmacy or clinical operations indirectly affects patient access to medications.

If HRSA pursues a rebate pilot, binding payment timelines, enforceable compliance standards, standardized denial protocols, and appropriate remediation mechanisms will be essential to mitigate destabilization risk.

A. Case Study: Financial Impact of a Rebate Model on a High-Performing Community Hospital

A high-performing, independent community hospital with an investment-grade credit profile and strong liquidity metrics was evaluated to assess the potential impact of a 340B rebate-based reimbursement model.

The organization operates with approximately $310 million in annual operating expenses and maintains financial stability despite ongoing sector-wide margin pressures typical across not-for-profit hospitals.

Under a modeled scenario, limited to IPAY 2026 and 2027 drugs, the hospital would experience:

- $11.0 million in incremental drug acquisition cost

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[2] Kaufman Hall, *National Hospital Flash Report* (2025). National median hospital operating margins reported at 1.7% year-to-dat[2]e through July 2025 and 2.9% year-to-date through September 2025.

- A 3.55% increase in total operating expenses

Hospital operating expenses represent the ongoing cost of providing patient care and maintaining operations, including salaries and benefits, medications, supplies, information systems, utilities, and facility support. As a result, increases in operating expense can directly constrain resources available for care delivery and community access.

While a 3.55% increase may appear modest in isolation, this level of cost growth is material in the context of hospital operating margins, which often range between 1–3% for similar organizations. In this scenario, the modeled increase would fully erode operating margin and result in negative financial performance.

Importantly, this analysis reflects a limited subset of drugs, not full program exposure. Expansion of a rebate-based model across additional drug categories would proportionally increase financial impact.

In addition to margin compression, the rebate model introduces:

- Working capital strain due to higher upfront acquisition costs at wholesale acquisition cost (WAC)
- Dependence on manufacturer adjudication for revenue realization
- Expanded administrative requirements for claims submission, tracking, and dispute resolution

These factors collectively represent a structural shift in financial risk from manufacturers to providers.

Notably, this modeled impact applies to an organization with strong financial fundamentals and credit stability. For smaller, rural, or margin-constrained providers, similar reimbursement shifts have disproportionate and potentially destabilizing effects on operations and patient access.

This analysis demonstrates that even limited implementation of a rebate-based model introduces financial and operational risks that extend beyond administrative complexity and into core organizational sustainability.

VII. Rebate Denials and Dispute Resolution

To prevent rebate adjudication from becoming inconsistent or discretionary, a pilot model should establish clear, enforceable standards governing denial practices. At a minimum, the model should require:

- Explicitly limited and defined grounds for denial
- Mandatory written rationale with supporting documentation for each denial
- Standardized denial codes applied consistently across manufacturers
- Defined appeal processes with clear timelines for review and resolution
- Escalation pathways subject to HRSA oversight

Absent these guardrails, denial variability would introduce significant administrative burden, increase dispute volume, and create financial unpredictability for covered entities.

VIII. Duplicate Discounts and MDPNP Coordination

We recognize the statutory nonduplication provisions associated with the Medicare Drug Price Negotiation Program (MDPNP) and the coordination complexity faced by manufacturers.

However, based on operational experience, a rebate-based structure does not inherently resolve cross-program data coordination challenges. Accurate duplicate discount prevention requires timely, complete, and interoperable data across multiple stakeholders, including covered entities, state Medicaid programs, managed care organizations, and manufacturers.

A rebate model, operating retrospectively, continues to rely on post-transaction data matching and reconciliation processes that remain subject to data latency, inconsistency, and variation in data standards across programs. As a result, a rebate model shifts the timing of reconciliation but does not eliminate the underlying data fragmentation that drives duplicate discount risk.

Rather than layering a rebate-based model onto existing systems, HRSA should evaluate standardized data harmonization mechanisms designed to address nonduplication objectives without expanding administrative burden.

One such approach would be the use of an independent, neutral clearinghouse model to facilitate secure, standardized claims-level validation across stakeholders. A clearinghouse-based approach would support real-time or near-real-time validation, improve data consistency, and reduce reliance on retrospective reconciliation, while preserving the statutory upfront discount structure.

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IX. Conditions Necessary for a Viable Pilot

If HRSA elects to pursue a 340B Rebate Model Pilot Program, the following elements are necessary to support operational feasibility, minimize unintended consequences, and enable meaningful evaluation.

A. Governance and Scope

- Clear articulation of statutory authority, scope, and limitations of the pilot program
- Voluntary participation for both covered entities and manufacturers
- Limitation of the pilot to a defined subset of drugs, covered entities, and/or claim types to enable controlled evaluation
- Defined duration with formal evaluation checkpoints prior to any expansion

B. Manufacturer Participation and Accountability

- Defined and consistent manufacturer participation standards
- Binding rebate payment timelines with enforceable penalties for noncompliance
- Standardized denial codes and adjudication criteria applied uniformly across manufacturers
- Requirement for detailed, claim-level denial rationale to support provider reconciliation and appeal

C. Data Standards and Interoperability

- Uniform national data submission templates and formatting standards
- Alignment of data definitions across manufacturers, HRSA, and state Medicaid programs
- Elimination of duplicative or misaligned data submission timing requirements that do not reflect provider workflows
- Flexibility for covered entities to utilize existing systems and select their own technology or vendor partners, without mandated platforms

D. Duplicate Discount and Medicaid Coordination

- Formal coordination model with state Medicaid agencies to ensure alignment on 340B eligibility reporting and rebate processing
- Defined process to revisit and reconcile manufacturer rebate denials for claims in which covered entities have reported 340B eligibility to the state
- Standardized approaches for managing distinctions between Managed Medicaid and Fee-for-Service programs

E. Financial Protections and Cash Flow Stability

- Cash-flow mitigation safeguards to address delays inherent in rebate-based reimbursement

- Interim payment mechanisms or advance credit structures, where appropriate
- Clear timelines for dispute resolution and financial reconciliation

F. Contract Pharmacy and Distribution Alignment

- Evaluation of the interaction between rebate implementation and existing contract pharmacy restrictions
- Requirement that participation in the pilot include reassessment of distribution limitations tied to duplicate discount concerns

G. Patient Definition and Compliance Standards

- Recognition that patient eligibility determinations are governed by covered entity policies and procedures, consistent with statutory guidance
- Explicit limitations on denial practices that reinterpret or override covered entity patient definitions
- Clear compliance standards applied consistently across manufacturers and programs

H. Administrative Burden and Operational Feasibility

- Assessment and minimization of incremental administrative burden introduced by rebate processes
- Avoidance of duplicative reporting requirements across multiple platforms or entities
- Alignment with existing provider workflows, billing systems, and revenue cycle operations

I. Transparency and Evaluation

- Predefined, transparent evaluation metrics established prior to pilot initiation
- Measurement of:
    - Administrative burden
    - Financial impact on covered entities
    - Impact on patient access
    - Accuracy and effectiveness of duplicate discount prevention
- Public reporting of pilot outcomes to inform future policy decisions

Even when limited in scope, however, a rebate pilot would operate within shared infrastructure and workflows, meaning that operational complexity and financial exposure are not confined to the pilot population alone, as shared infrastructure and workflows extend operational and financial effects beyond the defined pilot scope.

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X. Conclusion

The question presented in this RFI is not whether a rebate model is statutorily permissible, but whether it is operationally sustainable across thousands of covered entities operating under diverse financial and administrative constraints.

A rebate-based model converts the 340B Program from a price-at-purchase structure into a claims-adjudication model. This transformation carries measurable implications for staffing, systems, cash flow, and dispute resolution. Absent clearly defined guardrails and mitigation mechanisms, it introduces the risk of operational destabilization that reduces financial predictability and, in turn, affects patient access, particularly among rural and safety-net providers operating under thin margins.

We recognize HRSA's interest in gathering empirical data and evaluating potential program integrity enhancements. Should HRSA pursue a pilot, careful scope limitation, enforceable payment standards, standardized data protocols, and transparent evaluation metrics will be essential to ensure that the program's core purpose — enabling covered entities to stretch scarce federal resources — remains intact.

However, once implemented, a rebate-based model may be operationally difficult to unwind, even if unintended consequences emerge. For this reason, any pilot must be approached with clear structural safeguards, defined boundaries, and a rigorous evaluation model prior to any broader adoption.

The considerations outlined in this response are not theoretical — they reflect current operating conditions across covered entities and observed performance of similar rebate-based frameworks in practice. The Craneware Group remains committed to supporting customers through evolving regulatory environments and appreciates HRSA's deliberate and data-driven approach. If HRSA would find it helpful, The Craneware Group would welcome the opportunity to discuss these comments further and provide additional operational or data-informed perspective.

Respectfully submitted,

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