COALITION AGAINST SOCIALIZED MEDICINE

a Project of THE CONSERVATIVE POLITICAL ACTION COALITION

To: **Hon. Robert F. Kennedy, Jr, Secretary, US Department of Health and Human Services**
Hon. Thomas Engels, Administrator, Health Resources and Services Administration

From: **Andrew Langer, Executive Director, Coalition Against Socialized Medicine**

Date: **September 8, 2025**

Re: **Comments on the Health Resources and Services Administration of the US Department of Health and Human Services 340B Program Notice: Application Process for the 340B Rebate Model Pilot Program, Docket HRSA-2025-0001, Published in the Federal Register on August 7, 2025**

Below are comments of the Coalition Against Socialized Medicine (hereafter "CASM") to the Health Resources and Services Administration (HRSA) of the Department of Health and Human Services (HHS) in response to the 340B Program Notice: Application Process for the 340B Rebate Model Pilot Program, Docket HRSA-2025-0001, published in the Federal Register on August 7, 2025.

CASM is a coalition of allied free-market, limited-government policy research, education and advocacy organizations, and is led by the Conservative Political Action Coalition (CPAC), a non-profit, non-partisan 501(c)(4) research, education and advocacy organization based in Alexandria, Virginia.

Introduction

The rising cost of prescription drugs is one of the most pressing issues facing American consumers today. Patients rightly expect access to safe, effective, and affordable treatments, whether branded or generic. Yet the policy tools designed to lower costs can, if implemented poorly, lead to unintended consequences—distorting markets, disincentivizing innovation, and undermining patient care. Nowhere is the need for balance more urgent than in the regulation of federal drug pricing programs.

The Coalition Against Socialized Medicine (CASM) believes that real, lasting solutions must thread a careful needle: lowering prices and expanding access without eroding the private sector's capacity to develop, manufacture, and deliver cutting-edge pharmaceutical products. Too often, government interventions in drug pricing—however well-intentioned—have led to

reduced investment in research, supply chain disruption, or bureaucratic inefficiencies that ultimately hurt patients.

That is why CASM approaches regulatory reform with a principled lens. We advocate for policies that reward innovation, promote transparency, and ensure that patients—not middlemen or government agencies—are the true beneficiaries. Our goal is not to shield any sector from accountability, but to ensure that changes to programs like 340B are grounded in data, designed for long-term sustainability, and respectful of the vital role private industry plays in advancing health outcomes.

The 340B Drug Pricing Program sits at the intersection of all these concerns. It is a program originally crafted to support safety-net providers and stretch scarce public health dollars. But over time, it has expanded in scale, complexity, and financial impact—often without clear evidence that patients are benefiting proportionately. Reform is needed, but it must be done in a way that preserves access while correcting course.

To that end, CASM supports HRSA's proposed 340B Rebate Model Pilot Program. As detailed in the following comments, we believe this pilot offers a measured, technically sound, and policy-consistent pathway to restoring transparency and fairness in the 340B ecosystem. It is precisely the kind of reform that strikes the balance the American people expect: protecting consumers while preserving the free-market foundations of pharmaceutical innovation.

Executive Summary

The Coalition Against Socialized Medicine (CASM) strongly supports HRSA's proposed 340B Rebate Model Pilot Program as a critical reform to restore transparency, accountability, and statutory integrity to the 340B Drug Pricing Program.

The proposal offers a voluntary framework for drug manufacturers—specifically for drugs subject to Medicare price negotiation—to provide post-sale rebates to covered entities rather than upfront discounts. This structure directly addresses longstanding issues plaguing the 340B program, including duplicate discounts, diversion, lack of data transparency, and disproportionate financial risk on manufacturers.

The rebate model mirrors rebate systems already used in other federal health programs such as Medicaid and Medicare Part D, while preserving covered entity access and ensuring privacy protections. It introduces standardized claims-based documentation, guaranteed rebate payment timelines, and clear reporting obligations—without adding costs to providers.

CASM's comment outlines widespread expert support for the reform, including from the USC Schaeffer Center, JAMA Health Forum, and former CBO Director Dan Crippen. These sources underscore the 340B program's unsustainable growth and deviation from its original intent. HRSA audits reveal that nearly 70% of covered entities audited are found noncompliant—highlighting the urgent need for reform.

The comment also offers specific recommendations to improve the pilot and support broader implementation:

- Expand the rebate model to all 340B-eligible drugs.
- Standardize claims platforms.

- Offer support for small and rural providers.
- Require public reporting on how 340B savings are used.
- Enforce manufacturer accountability.
- Partner with HHS OIG and CMS on pilot evaluation.

The proposal is not punitive—it is a well-structured, technologically feasible model that enhances compliance while preserving access. CASM urges HRSA to move forward swiftly, evaluate transparently, and codify the model into regulation following a successful pilot.

Overview of HRSA's Proposed Rebate Model Pilot Program

HRSA's recently announced 340B Rebate Model Pilot Program marks a pivotal advancement in the evolution of the 340B Drug Pricing Program. For over three decades, 340B has been one of the most important mechanisms supporting safety-net providers across the country. But while its mission remains essential—ensuring access to affordable drugs for low-income and vulnerable populations—the program's operational reality has drifted far from its original intent.

Published in the Federal Register on August 7, 2025 (Docket No. HRSA–2025–14619), HRSA's pilot proposes a voluntary rebate model that permits manufacturers of certain drugs—specifically, those on the Medicare Drug Price Negotiation Selected Drug List (MDPNP) for 2026—to issue post-sale rebates to 340B covered entities rather than applying discounts upfront. This shift is significant. The model would allow drug manufacturers to reimburse covered entities the difference between the standard acquisition cost (typically the wholesale acquisition cost) and the statutory 340B ceiling price after the sale, based on verified claims-level data submitted through a secure IT platform.

This design directly addresses some of the program's most persistent operational flaws, including:

- The ongoing risk of duplicate discounts, where a manufacturer is forced to provide a 340B discount and a Medicaid rebate for the same unit of a drug;

- Drug diversion, where discounted 340B drugs are dispensed to ineligible patients;

- Lack of transparency, which limits HRSA's oversight and creates financial opportunities that can divert 340B benefits away from patients;

- Unbalanced financial risk, which is borne disproportionately by manufacturers due to limited visibility into claim adjudication.

To participate, manufacturers must submit detailed plans that meet HRSA's criteria for IT infrastructure, data protection, reporting, rebate timing, and covered entity support. Covered entities will be required to submit a limited set of claims data to manufacturers within 45 days of drug dispensation. Manufacturers must issue rebates—or formally deny them with documentation—within 10 days of receiving the data. Importantly, rebate denial based on alleged diversion or duplicate discounts cannot be used as a pretext to avoid payment; instead, manufacturers must escalate such concerns through HRSA's existing mechanisms, such as audits or administrative dispute resolution.

The Original Purpose of 340B—and Why Reform Is Urgent

The 340B program was created by Congress in 1992 as part of the Veterans Health Care Act, with the explicit goal of enabling covered entities to "stretch scarce federal resources as far as possible, reaching more eligible patients and providing more comprehensive services." At its core, the program was meant to provide safety-net hospitals, community health centers, and specialized clinics with discounts on outpatient prescription drugs so they could continue serving uninsured and underinsured patients.

But over the past 30 years, the program has experienced explosive growth in scale and complexity:

- In 1997, 340B purchases totaled less than $1 billion.
- By 2021, that number had skyrocketed to over $44 billion.

Much of this growth is driven by large health systems and the contract pharmacy model, which allows covered entities to dispense 340B drugs through thousands of affiliated retail pharmacies—many of which serve commercially insured patients.

This growth has triggered increasing concern from policymakers, watchdog agencies, and researchers. A 2024 policy analysis by the USC Schaeffer Center highlighted that while the number of covered entities has grown dramatically, there are no requirements for how savings must be used, nor are there consistent reporting mechanisms to verify patient impact. In many cases, hospitals generate significant margins by purchasing drugs at 340B prices and billing insurers at full rates, with little transparency about whether savings are passed on to patients or used for community benefit.

Moreover, HRSA's limited oversight capacity has contributed to weak program integrity. In 2025, HRSA audited only 0.33% of covered entities, yet found compliance violations in roughly 70% of those audits. These included violations related to diversion, duplicate discounts, and improper eligibility documentation.

It is clear that reform is not only warranted—it is long overdue.

The Case for a Rebate Model: Addressing Structural Flaws Without Undermining Access

HRSA's rebate model represents a pragmatic and well-designed effort to restore transparency and accountability without disrupting patient access or imposing unreasonable burdens on covered entities.

A rebate-based structure is already standard in other federal health programs. Medicaid and Medicare Part D both utilize post-sale rebates as a pricing mechanism. TRICARE does the same. In the commercial sector, rebates are a fixture of pharmacy benefit manager (PBM) contracts. The concept is not new or untested. What HRSA is proposing is to apply a similar structure to a subset of 340B transactions in a way that protects manufacturers from duplicate discounts, improves data flow, and increases transparency for regulators.

Here are some of the specific benefits of the model:

1. Duplicate Discount Prevention: By requiring submission of specific claims-level data—such as service date, NDC, prescriber ID, quantity dispensed, and BIN/PCN information—manufacturers can reconcile claims with Medicaid rebate submissions and avoid being charged twice for the same unit. This not only protects manufacturers, but also reduces erroneous spending from state Medicaid programs and federal payers.

2. Rebate Timeliness and Predictability: Covered entities will know in advance what data is required, when it must be submitted, and when rebates will be paid. Under the existing 340B replenishment model, reimbursement timelines are opaque and vary widely. This pilot introduces predictability into the process, allowing covered entities to better manage cash flow and inventory.

3. Claims Integrity and Compliance: The model creates a data trail. If a covered entity receives a rebate, there is evidence to support that the drug was dispensed to an eligible patient. If a rebate is denied, the manufacturer must provide documentation. HRSA retains the ability to audit and review these interactions. This is a critical improvement over the current system, where HRSA relies largely on covered entity self-reporting.

4. Enhanced Data Security and Patient Privacy: All manufacturer platforms used in the pilot must meet HIPAA and other applicable data security standards. Claims data is limited to fields that are necessary to verify eligibility and pricing compliance. No clinical data or personally identifying information beyond the transactional level is collected. These protections are clearly stated in the proposal and should satisfy any concerns about patient privacy.

5. No Added Cost to Covered Entities: Manufacturers bear the cost of implementing the rebate platforms and supporting systems. HRSA explicitly prohibits passing on administrative fees or IT costs to covered entities. Furthermore, entities are not required to change wholesalers or disrupt existing distribution mechanisms. The model is designed to overlay onto existing operations, not replace them.

Expert Support and Health Policy Consensus

The proposed 340B rebate model doesn't exist in a vacuum—it reflects years of recommendations from bipartisan experts, oversight agencies, and academic institutions that have tracked the program's evolution and recognized its drift from original legislative intent. Among the clearest endorsements of reform come from the **USC Schaeffer Center for Health Policy & Economics**, whose researchers have consistently highlighted the need for increased transparency and structural safeguards within the 340B framework. In their 2024 report, *The 340B Drug Pricing Program: Background, Ongoing Challenges, and Recent Developments*, the authors note that 340B has shifted from a targeted safety-net program into a sprawling financial tool often leveraged by health systems in ways that are disconnected from patient benefit.

They cite three critical issues:

1. **Lack of mandatory reinvestment**: Covered entities are not required to reinvest savings in patient care, and few do so in a transparent way.

2. **Unmonitored profit extraction**: Some hospital systems use contract pharmacy arrangements to generate significant profits off commercially insured patients.
3. **Insufficient accountability**: The absence of reporting requirements or a centralized data infrastructure enables misuse, and HRSA's audit authority is underutilized and under-resourced.

Similarly, a **2024 article in the JAMA Health Forum** points to growing fragmentation in 340B operations and the widening gap between program design and actual health equity outcomes. It notes that while the number of 340B-eligible prescriptions continues to grow, there is no consistent evidence that patients benefit from reduced out-of-pocket costs or expanded services. The article calls for the establishment of more data-driven mechanisms to ensure that the program functions as Congress intended—and cites a rebate-based model as a promising reform.

Together, these respected sources reinforce that the rebate model is not a radical change—it is a rational response to a system that has become too large, too complex, and too opaque to manage through its original design.

The Current 340B Model Is Financially Unsustainable

Without intervention, the 340B program will continue to expand in ways that undermine pricing integrity in the pharmaceutical supply chain.

In 2024, former Congressional Budget Office Director **Dan Crippen** wrote a memo for AIR340B.org outlining how the unchecked growth of the program distorts federal budgets and drives up costs. He noted that because 340B discounts are not capped or means-tested—and because the program lacks reinvestment requirements—it creates financial incentives that can:

- Encourage over-utilization of expensive branded drugs.
- Drive providers toward volume-based prescribing.
- Inflate Medicare Part B reimbursements, increasing taxpayer burden.
- Reduce federal and state tax revenues due to the charitable status of many large 340B hospitals.

This isn't merely an academic concern. The Government Accountability Office and the HHS Office of Inspector General have each warned that duplicate discounts are costing Medicaid and Medicare billions in unnecessary spending. In some cases, a manufacturer may be forced to provide a 340B discount to a hospital and a Medicaid rebate to a PBM on the same prescription. Because there's no shared claims database, neither side has visibility. This is both wasteful and unfair.

The rebate model proposed by HRSA begins to resolve this. By requiring covered entities to submit basic transactional data (such as NDC codes, prescriber identifiers, and claim-level pharmacy info), the model empowers manufacturers to validate that:

- The covered entity is eligible.
- The drug is eligible.
- The patient encounter qualifies.
- No other 340B entity or Medicaid plan has already been reimbursed.

This validation prevents "stacked discounts," reduces federal waste, and restores fairness to manufacturers—many of whom are required by statute to participate in 340B in exchange for access to Medicaid markets.

The Rebate Model Does Not Undermine Access or Equity

Critics of reform often warn that adding complexity to 340B could harm access to care. But that concern misunderstands how the rebate model is designed—and how most covered entities already operate.

The truth is, most hospitals and health centers already use a **replenishment model**: they dispense a drug at full price, then retrospectively apply 340B pricing once they identify qualifying prescriptions. The HRSA rebate model mirrors this operational logic, with two key improvements:

1. **Rebate payments are guaranteed within 10 days**, creating faster cash flow than current replenishment timelines.
2. **Covered entities are protected from administrative fees**, as manufacturers must fund the rebate infrastructure.

Covered entities do not need to alter their pharmacy networks, distributors, or patient engagement models. Nor must they provide excessive data. HRSA has limited required fields to basic pharmacy claim information and included guardrails to ensure that data is stored securely in compliance with HIPAA and related privacy laws.

Moreover, covered entities have **45 days to submit data** after dispensing, with extensions allowed for extenuating circumstances. This is a generous window, particularly compared to other federal reimbursement programs.

The model actually increases operational certainty for covered entities while reducing legal exposure for manufacturers.

Current Audit Data Paints a Troubling Picture

Another important rationale for adopting the rebate model is the overwhelming evidence of noncompliance across the 340B landscape.

In 2025, HRSA published an internal audit summary showing that of the 0.33% of covered entities audited annually:

- 70% had at least one material finding.
- Common violations included diversion, inadequate documentation, and billing overlap with Medicaid.
- Many entities failed to correct errors until prompted by HRSA auditors.

The low audit frequency and high violation rate create a troubling asymmetry: bad actors can game the system with relatively little risk, while honest providers operate in good faith with limited guidance.

By embedding compliance into the rebate process, HRSA can eliminate this mismatch. Claims must meet minimum standards to be eligible for rebate. If there is a conflict—such as another covered entity submitting a claim for the same drug—the platform will flag it. This creates passive enforcement, improving integrity without requiring new enforcement staff.

Covered Entities Remain Free to Serve Patients

A key virtue of HRSA's model is that it does not place unnecessary restrictions on who covered entities can serve or how they dispense medications. The rebate model does not limit contract pharmacy use, restrict drug formularies, or impose prior authorizations. It simply asks that entities validate 340B eligibility through basic claims fields.

Covered entities can continue to serve insured, uninsured, or Medicaid patients as they choose. What changes is the accountability built into the system. Rebate payments now require traceable evidence.

This tradeoff—modest data submission in exchange for sustained financial benefit—is not just reasonable, it is essential.

Recommendations to Strengthen and Expand the Pilot

While HRSA's rebate model pilot is a smart and much-needed reform, its success will ultimately hinge on how it is implemented, evaluated, and scaled. Below are several concrete recommendations to enhance the model's impact, ensure its integrity, and enable expansion beyond the initial limited scope.

1. Expand to All 340B-Eligible Drugs

Limiting the rebate model to drugs on the Medicare Drug Price Negotiation Selected Drug List is a strategic starting point—but not a sufficient end state. Once the pilot is proven effective, HRSA should expand the rebate structure across all outpatient drugs eligible under the 340B statute. By applying the model universally, HRSA would:

- Close loopholes that allow entities to exploit differences in drug eligibility status;
- Simplify processes for manufacturers, who otherwise face a fragmented pricing and claims ecosystem;
- Prevent prescriber or pharmacy behavior that might shift based on where rebates are required vs. where they are not;
- Drive more consistent compliance across the entire pharmaceutical landscape.

2. Standardize Claims Submission Platforms

To streamline operations and reduce administrative friction, HRSA should work with CMS and stakeholders to create or certify standardized IT platforms for rebate claims submission. This would:

- Minimize redundant infrastructure investments;
- Reduce confusion for covered entities working with multiple manufacturers;
- Ensure uniform data formats and validation logic;
- Lower technical barriers for smaller, rural providers.

Standardization also lays the groundwork for a national clearinghouse or data repository, which could serve as a long-term compliance and audit tool.

3. Create Financial Support for Small or Rural Providers

While large hospital systems have extensive administrative resources, smaller covered entities—especially rural hospitals, Ryan White clinics, and critical access hospitals—may face challenges in adapting to new systems.

HRSA should:

- Offer transition grants or technical assistance funds;
- Allow phased adoption timelines for small providers;
- Provide shared service options or platform access through regional hubs;
- Host regular trainings and compliance bootcamps in partnership with provider associations.

This ensures equity in implementation and avoids unintended access disruptions in underserved communities.

4. Mandate Public Reporting of 340B Savings Usage

The rebate model introduces greater transparency in pricing. HRSA should pair this with increased transparency in how covered entities use 340B savings.

Covered entities should be required to submit annual reports describing:

- The total amount of 340B-related revenue and savings;
- How those funds were used to expand services, subsidize care, or improve patient access;
- The number of patients served through 340B-funded initiatives.

This data can be made publicly available in aggregated form, allowing the public and policymakers to assess whether the program is achieving its intended outcomes.

5. Strengthen Manufacturer Accountability

While the rebate model protects manufacturers from duplicate discounts, it must not become a shield against fulfilling statutory obligations. HRSA should make clear that:

- Manufacturers cannot arbitrarily delay or deny rebates;
- Rebates must be paid within 10 calendar days, as specified;
- All denials must include a documented, legitimate reason;
- Repeated noncompliance by manufacturers can trigger formal review or audit by HRSA.

Manufacturers participating in the pilot must play by the rules with the same discipline required of covered entities.

6. Collaborate with HHS OIG and CMS on Pilot Evaluation

The evaluation of this pilot is not just important—it's a potential inflection point for the future of 340B.

HRSA should:

- Define transparent, public-facing performance metrics before the pilot concludes;
- Work with the HHS Office of Inspector General (OIG) to design safeguards and audit sampling protocols;
- Engage CMS, which already manages large-scale rebate operations under Medicaid and Medicare Part D, to align infrastructure and learn from existing systems;
- Solicit structured feedback from both manufacturers and covered entities at scheduled intervals;
- Publish a post-pilot report summarizing findings, best practices, areas for improvement, and recommendations for full-scale implementation.

The more inclusive and methodical this evaluation is, the more defensible and scalable the rebate model becomes.

Addressing Concerns from Covered Entities and Critics

As with any major change, HRSA's rebate pilot has faced pushback from some stakeholder groups. These concerns are not without merit, but most are based on either misunderstanding or overstatement. Let's address them directly.

"It's too administratively burdensome."
Most covered entities already maintain claims-level data for reimbursement, reporting, or internal compliance. The fields required under the rebate model—service date, NDC, prescriber ID, etc.—are standard pharmacy claims information.

Further, the model gives 45 days to submit this data and allows for exceptions when needed. Manufacturer-funded IT platforms reduce financial and operational barriers. For most providers, this will not require major process changes.

"It slows down access to discounts."
Not true. Covered entities will receive rebate payments within 10 days—often faster than current replenishment payment cycles. Moreover, because the rebate is tied to validated claims, entities gain greater assurance of eligibility and payment, which improves budgeting and forecasting.

"It risks exposing patient data."
The model was explicitly designed with HIPAA and privacy compliance in mind. No clinical or personally identifying information is collected. The only data fields used are those already required for drug reimbursement. In fact, the rebate platform provides better data protection than the patchwork spreadsheets and manual systems currently in use.

"It will drive entities out of the 340B program."
If a covered entity cannot demonstrate that a patient encounter was eligible for 340B, then that rebate should not be paid. This isn't exclusion—it's enforcement of the law. Honest providers have nothing to fear from accountability. The rebate model may deter bad actors, but it protects the integrity of the program and the legitimacy of those who operate within it.

Why HRSA Should Codify the Rebate Model into Regulation

Once the pilot concludes and demonstrates success, HRSA should not wait years to act. The rebate model should be formalized through rulemaking and made available to all manufacturers and drugs.

Doing so would:

- Institutionalize transparency as a core feature of 340B;
- Provide legal clarity for stakeholders;
- Deter opportunistic litigation or state-level interference;
- Encourage alignment with CMS, state Medicaid plans, and other federal pricing policies;
- Signal to Congress that HRSA is taking proactive steps to strengthen program integrity.

Formal rulemaking also gives stakeholders another opportunity to provide input and refine the model for long-term durability.

Conclusion: Why This Pilot Is the Right Step at the Right Time

The 340B program remains one of the most powerful tools in the federal government's healthcare access arsenal. But power without oversight invites misuse. For years, audits, reports, and investigations have shown that the program lacks basic transparency. The rebate model proposed by HRSA is the clearest, most achievable path toward correcting that.

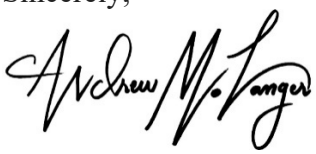
It aligns with how drugs are priced in nearly every other federal program. It leverages existing provider workflows. It introduces compliance as a natural feature of operations, not an afterthought. And it does all of this without limiting access or undermining the original mission of 340B. We urge HRSA to:

- **Proceed confidently with this pilot;**
- **Expand its scope upon successful evaluation;**
- **Codify its features through regulation;**
- **Partner with other federal agencies for robust monitoring;**
- **And continue listening to stakeholders across the spectrum.**

This is what principled reform looks like: data-driven, stakeholder-informed, and mission-aligned.

We commend HRSA for its leadership and strongly support the proposed 340B Rebate Model Pilot Program.

Sincerely,



Andrew M. Langer
Director
CPAC Foundation Center for Regulatory Freedom