REBATE VS. REVENUE: THE ACCOUNTABILITY CRISIS THREATENING THE 340B PROGRAM

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THE FAILURE TO REFORM

Covered entities, pharmaceutical manufacturers, trade associations, and lobbyists at both the federal and state levels must recall the foundational goal of the federal **340B Drug Pricing Program**: to address specific healthcare needs while achieving substantial outcomes. The path forward is not about expansion but about **strategic evaluation**.

Viewing the program through a '2026 lens' allows for a much-needed reassessment of its direction and goals. One goal is to test and evaluate the use of rebates in lieu of the program's historical operating model.

The 340B Program originated in 1990, when Congress established the Medicaid Drug Rebate Program to reduce the cost of outpatient pharmaceuticals reimbursed by state Medicaid agencies. The 340B Program was specifically enacted to mitigate the adverse effects of the Medicaid Drug Rebate Program on other non-Medicaid healthcare services by allowing discounts to certain eligible healthcare entities. The rebate program requires drug companies to enter into a rebate agreement with the Secretary of the U.S. Department of Health and Human Services (HHS) as a precondition for Medicaid coverage of their drugs.[1]

The agreement specifies that the manufacturer of each outpatient drug covered by Medicaid must pay a rebate to Medicaid based on the lower of a calculated benchmark or the manufacturer's "best price" for that drug. As a result of the Medicaid rebate law and the "best price" requirement, many pharmaceutical companies discontinued offering deep discounts on their drugs to non-Medicaid purchasers because those discounts required them to pay significant rebates to Medicaid. When manufacturers began raising their prices, the Medicaid savings achieved through the rebate program were offset by increased government spending on drugs bought by non-Medicaid purchasers, such as various federal agencies (*e.g.*, the U.S. Department of Veterans Affairs and the U.S. Department of Defense), state and local governments, and providers receiving federal and/or state support.

Congress enacted Section 340B of the *Public Health Service Act in 1992*[2] and Section 1927(a)(5) of the *Social Security Act* to address these unintended effects.[3] These statutes required pharmaceutical manufacturers participating in the Medicaid program to sign a Pharmaceutical Pricing Agreement (PPA), obliging them to provide discounts on covered outpatient drugs to specified government-supported facilities, referred to as "covered entities," that serve the nation's most medically vulnerable populations. The duty to participate in the 340B Program was extended to manufacturers of drugs covered under Medicare Part B with the *Medicare Modernization Act of 2003*.[4]

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Congress intended for the 340B Program to allow covered entities serving vulnerable populations to "stretch scarce federal resources as far as possible, reaching more eligible patients and providing more comprehensive care."[5] For many years, it worked as intended; however, as with any federal or state law, changes in the healthcare ecosystem necessitate updating the statute and/or administrative regulations to ensure compliance and programmatic success. The 340B Program isn't immune to this reality, as some observers have noted that it has become more focused on providers than on patients.

In March 2025, Congress passed amendments to the Public Health Service Act (Public Law 119-4) as part of the Full-Year Continuing Appropriations and Extensions Act, 2025, yet in doing so, it **squandered a critical and timely opportunity** to substantively enhance access to care for low-income individuals.

The 340B Program is now so expansive and opaque that it **urgently demands comprehensive reform**. Its current unchecked structure is straining the ability of safety-net providers—federally qualified health centers (FQHCs), rural hospitals, and clinics—to deliver essential care to the vulnerable populations they serve.

At its core, the 340B Program requires pharmaceutical manufacturers that participate in Medicaid to offer **substantial discounts** on outpatient drugs to eligible healthcare organizations, known as "covered entities".[6] These entities play a crucial role in delivering care to patients who are disproportionately uninsured, underinsured, or low-income.

For over 33 years, the 340B Program has been a subject of intense controversy. While advocates champion its continued expansion to support marginalized communities, critics highlight its **unchecked growth** and raise alarming concerns about widespread fraud and misallocation of resources. This skepticism was powerfully echoed by a recent, sharp indictment from the Congressional Budget Office (CBO), which warned that if left unaddressed, ongoing waste, fraud, and abuse could **significantly escalate** healthcare costs associated with the 340B Program. Reinforcing this critique, Senator Bill Cassidy, chair of the Senate Committee on Health, Education, Labor & Pensions (HELP), emphasized that any federal program lacking robust **accountability and transparency** is inevitably doomed to failure—a reality to which the 340B Program is not immune.

THE CASE FOR A REBATE MODEL: REASSESSING THE 340B FRAMEWORK

Against this backdrop of controversy, a transformative solution has gained traction. In October 2020, the data infrastructure and analytics company Kalderos proposed a pivotal enhancement to the 340B Program: a transition to a marketplace-standard **rebate model**, as detailed in their policy paper, "The Kalderos 340B Rebate Model in Action – Ensuring a Thriving and Sustainable 340B Program".[7]

Six years later, this innovative idea has compelled government oversight. In 2024, major pharmaceutical manufacturers—including Johnson & Johnson, Eli Lilly, Sanofi, and Bristol-Myers Squibb—announced they would offer discounted drug prices through a rebate system rather than upfront price reductions. This action led the Health Resources and Services Administration (HRSA) to approve the **340B Rebate Model Pilot Program**.[8] Reaction, however, has been sharply polarized: manufacturers have welcomed the policy, while hospital advocates and other covered entities have aggressively attacked it.

Crucially, patient advocacy groups, such as ADAP Advocacy, Health Education Advocacy and Learning Collaboration (HEAL), and the Autoimmune Association, have **embraced the rebate model**, as it demands greater accountability and tangible benefits for patients. These organizations contend that without comprehensive reform to enforce oversight and transparency, hospitals may prioritize their own **economic self-interest over patient needs**.

ADAP Advocacy warned HRSA in a written comment that its approach to the pilot program would expose the agency to a legal challenge for violating the Administrative Procedure Act. The American Hospital Association (AHA) and the Maine Hospital Association (MHA) did just that and won in the U.S. District Court for the District of Maine, which issued a nationwide preliminary injunction of the 340B Rebate Model Pilot Program.[9]

The victory lap to kill the rebate model was short-lived.

HRSA issued a request for information (RFI) seeking feedback from stakeholders and the public on whether and how this model should be developed for 340B. This time, HRSA doesn't appear positioned to repeat the mistakes it made during its first attempt to implement the rebate model, no doubt emboldened by the hospital special interests that embarrassed it in federal court.[10]

ENHANCING OVERSIGHT AND FINANCIAL ACCOUNTABILITY

The shift from upfront 340B discounts to a retrospective rebate system promises significantly improved oversight. Under this approach, requests by covered entities to pharmaceutical manufacturers for 340B pricing must be accompanied by data confirming the appropriate use of drugs for eligible patients. This request process is essential, as alarming evidence suggests that **very few patients** utilizing 340B receive any demonstrable assistance with their out-of-pocket costs at the counter.

The **340B Rebate Model** is a key mechanism for clarity and control. It is a measured solution designed with accountability and flexibility, ensuring covered entities gain **clear visibility** into manufacturer price concessions and the subsequent allocation of rebate dollars. This transparency allows entities to verify correct pricing and, in turn, provides manufacturers with confidence against duplicate discounts or diversion schemes. For states without statutory language prohibiting duplicate discounts.[11]The model helps safeguard Medicaid payments and preserve vital resources for indigent and disabled populations, an improvement that is even more significant given recent funding cuts, such as those authorized by the *One Big Beautiful Bill Act (BBB)*.

A **vitally crucial patient-centric aspect** of the rebate model is its ability to empower patients to determine whether they are benefiting from 340B pricing. By enabling the real-time identification of eligible patients, it establishes a foundation for proactively informing them about potential savings.

THE STAGGERING FINANCIAL DISPARITY

The necessity for this overhaul is underscored by the program's explosive, untracked growth:[12]

Scale of Purchases

According to IQVIA, 340B purchases totaled a staggering **$147.8 billion** at list price last year, a 16.7% year-over-year increase. Since 2018, 340B purchases have surged by **174.6%**, compared to only 53.3% growth for non-340B purchases.[13]

The Unaccounted Spread

Dr. Adam Fein of the Drug Channels Institute noted that discounted 340B purchases totaled around **$80 billion**, leaving a **$68 billion gross-to-net gap**. He stated: "That's a massive spread. Yet despite the scale, there's still no transparency into how billions in discounts and spreads are allocated or used".[14]

Entity Growth

The number of covered entities and their registered sites has exploded from 1,000 in 1992 to **over 53,000 sites today**. The count of 340B-eligible contract pharmacies has increased by over **2,400%** in the last 15 years.[15] The core question remains whether this massive programmatic expansion has resulted in **tangible benefits for patients** at the pharmacy counter or elsewhere.[16]

PATIENT CARE VS. HOSPITAL REVENUE

The *Affordable Care Act* (ACA) attempted to strengthen the 340B Program by requiring participating hospitals to provide charity care, including financial aid for free or discounted services. Yet, the data paints a troubling picture:

- A Robert Wood Johnson Foundation report reveals nearly **75% of adults with medical debt owe at least part of it to hospitals**
- The Urban Institute reports that Black and Hispanic communities are **39% more likely** to have debt collection judgments.

This raises a critical ethical question: How many individuals burdened by medical debt could have been assisted with the billions in unaccounted 340B revenue generated by eligible hospitals?

CONCERNS AND COUNTERARGUMENTS

Hospital representatives, led by the American Hospital Association (AHA), argue that the rebate model will cause "predictable and considerable adverse effects," citing financial strains, limited cash flow, and immense administrative burdens.[17] The AHA estimates compliance would require **"nearly 4,160 hours across two full-time employees per year per hospital,"** totaling 11.2 million burden hours systemwide. This objection ignores the program's history. As the AHA argues, the disparity in estimated administrative burden between covered entities and manufacturers "does not justify the pilot".

However, this position demonstrates an apparent **refusal to acknowledge** that the 340B Program, like any 30-year-old federal initiative, requires periodic change to ensure transparency.

The **Ryan White Clinics for 340B Access (RWC-340B)**, while not entirely opposed, also voice concerns over financial and administrative burdens, estimating the need for an additional **$100,000 in cash** to cover upfront drug costs, which could hamper their ability to offer upfront patient discounts. Addressing these concerns, ADAP Advocacy has proposed that drug manufacturers provide an upfront "draw" payment to smaller covered entities to mitigate the initial rollout.

These concerns are effectively refuted by the nearly three decades of experience of State AIDS Drug Assistance Programs (ADAPs). ADAPs, among the original covered entities, predominantly use a claims-based rebate mechanism widely regarded as the gold standard for accountability.

THE ADAP GOLD STANDARD

These concerns are **effectively refuted** by the nearly three decades of experience of **State AIDS Drug Assistance Programs (ADAPs)**. ADAPs, among the original covered entities, predominantly use a claims-based rebate mechanism widely regarded as the **gold standard for accountability**. This retrospective model establishes the necessary systems and data frameworks to prevent diversion and duplicate discounts while ensuring patients receive life-saving medications at no cost.

The success is quantifiable:

- ADAPs now serve **87.4% more clients** than in Fiscal Year 2000.
- Drug manufacturer rebates constitute **50% of the ADAP budget**, up from just 7% twenty-five years ago, proving the rebate model can be a robust funding mechanism that supports expansion.

CLOSING: THE UNAVOIDABLE MANDATE FOR TRANSPARENCY

In any democratic society, the government's obligation to its citizens is perhaps nowhere more profound than in the provision of healthcare. When taxpayer dollars or corporate mandates finance that care, the ethical and administrative imperative for **absolute transparency** becomes non-negotiable. Opaque systems, where costs, quality metrics, and decision-making processes remain hidden, **fundamentally erode public trust, breed systemic inefficiency, and ultimately compromise the well-being of the marginalized populations** the programs, like the federal 340B Drug Pricing Program, were designed to serve.

A path forward, represented by the rebate model, offers a **meaningful, balanced solution** to realign the 340B Program with its original legislative intent: **expanding access to care and treatment for low-income patients**. While change presents logistical challenges, the **340B Rebate Model** is a crucial, high-stakes endeavor. Its value lies not just in its operations but also in its mandate to **educate and inform** the White House, Congress, and state-level elected officials. The pilot will definitely show *why* the current system is failing, and *who* and *how* a modernized, transparent model will finally succeed.

A 340B pilot program will allow Congress and the Administration to determine whether a rebate program can work effectively. The General Accounting Office, a nonpartisan government entity, should be asked to evaluate the impact of the 340B rebate pilot program. In doing so, both proponents and opponents can be assured of fair and accurate assessment.

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ENDNOTES

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2 Codified at 42 U.S.C. § 256(b).

3 Codified at 42 U.S.C. § 1396r-8(a)(5).

4 See Medicare Prescription Drug Improvement and Modernization Act of 2003, Pub. L. No. 108-173, codified at 42 U.S.C. § 1396r- 8(a).

5 H.R. Rep. No. 102–384, 102d Cong., 2d Sess., pt. 2, at 12 (1992).

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