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Accountability in the 340B Drug Pricing Program

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Takeaways

- Congress created the 340B Prescription Drug Pricing Program to help safety-net providers stretch limited federal resources, but despite its rapid growth, 340B lacks a system for tracking discounted drug purchases.
- Without a tracking system, drug manufacturers can provide multiple discounts for the same prescription and for prescriptions dispensed to ineligible patients.
- Two proposals would address those problems: a rebate model and a clearinghouse model.
- Under a rebate model, providers would pay full price upfront and receive 340B rebates after submitting claims data to verify eligibility and compliance.

- In a clearinghouse model, providers retain upfront discounts but submit claims data to a third-party clearinghouse for retrospective compliance checks.

The two models have tradeoffs and are a key issue in the debate in Congress and executive action over strengthening 340B accountability.

Every day, patients across the country face significant challenges in accessing care and lifesaving treatments, while many community hospitals struggle to make ends meet and serve vulnerable populations. This is where the 340B Drug Pricing Program comes in.

The idea behind the program was to help safety-net providers stretch scarce federal resources for the vulnerable populations they serve.¹ Congress created the 340B program in 1992 to reverse unintended drug price increases for safety-net providers caused by the 1990 Medicaid Drug Rebate Program.² Its “best price” requirement prompted drugmakers to end voluntary discounts to community health centers and public hospitals, leading Congress to establish 340B to restore access to lower outpatient drug prices.³ While 340B’s narrow mission remains the guiding principle, the program has grown exponentially over several decades as the health care landscape has evolved, with little oversight or clear rules.⁴

One core accountability issue is how 340B and the MDRP overlap in practice. Under the current system, there is no single, consistent way to verify 340B transactions before discounts are provided. This allows providers to claim both a 340B discount and a Medicaid rebate for the same prescription, even though these duplicate discounts are statutorily prohibited.⁵

This problem is further compounded by the Medicare Drug Price Negotiation Program. Beginning in 2026, Medicare pays a negotiated price for certain high-cost drugs, known as the Maximum Fair Price (MFP). Manufacturers must ensure that both the MFP and 340B discount are not dispensed on the same prescription.⁶ However, as with Medicaid drug rebates, the inability to track and verify 340B claims means duplicate discounts

can occur as these programs interact in practice. As more federal drug-pricing policies interact with 340B, the need for timely and reliable claims information becomes more important to ensure program integrity.

As the 340B program continues to grow with limited evidence that patients benefit from the program as Congress intended, policymakers must answer the question: can Congress improve transparency and accountability in 340B in a way that better serves patients and supports the safety-net providers that truly depend on the program?

This report examines the current 340B purchasing system and the tradeoffs of two approaches—rebates and a clearinghouse—that could provide greater transparency and accountability in 340B. We also explore structural reforms Congress could pursue to strengthen the program for the benefit of patients and true safety-net providers.

The Accountability Problem

The basic accountability problem in 340B is that claims associated with 340B eligible purchases are difficult to track and verify, which allows for duplicative discounts on the same prescription and prevents scrutiny over how providers are using 340B savings.⁷ The current system operates primarily through *upfront discounts* and a *replenishment model*. Drug manufacturers that participate in Medicaid are required to sell eligible drugs at a heavily reduced price to 340B providers. These providers then dispense the drugs to eligible patients and are reimbursed by public and private insurers, often at rates well above the discounted price.⁸

However, nothing in our health care system is simple. The mechanics of 340B get more complicated.⁹ In a standard process, a pharmacy dispenses a drug from its inventory then bills the patient's insurer at the full price. The 340B provider later identifies prescriptions it determines as 340B eligible and purchases replacement units at the 340B price to replenish the pharmacy's inventory. The financial benefit for the provider comes from the difference between the reimbursement from payers and patients generated by those prescriptions and the much lower 340B price paid for the replacement drugs. This is referred to as 340B savings, profit, or spread revenue.

The mechanics of pharmacies' roles in the program create another layer of complexity. In pursuit of 340B savings, providers can use an in-house pharmacy or external

pharmacies with which they have an agreement with to dispense 340B prescriptions, known as contract pharmacies.¹⁰ Additionally, providers can either conduct the replenishment through a physical inventory—physically separating drug units based on their 340B eligibility—with a pharmacy or a virtual inventory—which separates transactions in the provider’s billing software based on 340B transactions. A provider can claim and receive a 340B discount through either physical or virtual replenishment.

Because 340B eligibility is determined retrospectively, and claims information is fragmented across the program, it can be difficult for government officials and stakeholders to verify whether each transaction meets 340B requirements before the discount is provided.

Another accountability concern is how providers use the savings from the program. The current model allows providers to keep the 340B savings as profit. Current law does not require providers to disclose how they use the savings, but the public purpose of 340B is to let providers use the savings to reinvest in uncompensated care and expand services for the patients that allow the 340B hospital to qualify for discounts.¹¹

Notably, not all 340B providers face the same financial pressures. Large health systems have significantly increased their participation in the program and have taken full advantage of the program’s drug savings. They are often not strapped for funds in the same way as smaller, more financially vulnerable safety-net hospitals, which struggle to keep their doors open and often see proportionately see less 340B discounts.¹²

The current replenishment model has a basic tradeoff: immediate cash flow for true safety-net providers comes with a limited ability to verify that discounts are claimed appropriately and whether savings are connected to the patients the program is meant to serve. Currently, there is only one main mechanism that attempts to account for money flowing through the program: HRSA audits and HRSA-approved manufacturers.

The Health Resources and Services Administration (HRSA) has authority to conduct audits of the program. However, it conducts only about 200 covered entity audits per fiscal year (less than 1% of covered entities participating in the program).¹³ Of the covered entities that are audited, roughly half each year are found to have two or more adverse findings. Given the sheer number of covered entities and savings generated—over \$100 billion in 340B drug purchases across a large network of registered providers

in 2025—it is nearly impossible for HRSA to monitor compliance across the program, leaving the full scope of inappropriate use of the program unknown.¹⁴

As a result, the current system and the lack of clear rules around eligibility and patient benefits leave gaps in the government’s ability to prevent duplicate discounts, ensure discounts are provided only for drugs associated with care for 340B-eligible patients, and ensure that savings benefit the patients 340B is meant to serve.¹⁵

Accounting for 340B Savings

There are two main approaches in front of lawmakers in Washington to close this transparency and accountability gap, allowing the government to better verify discounts: a clearinghouse model and a rebate model. Both would rely on standardized claims information to verify compliance, though they would do so at different points in the payment process. The clearinghouse would continue upfront discounts with delayed verification, while a rebate model can review a claim before a 340B discount is administered. Each approach comes with different tradeoffs that lawmakers must consider, and both would need to be paired with additional reforms to address how 340B savings are used to directly benefit patients.

Clearinghouse Model

One method to increase transparency and accountability under the current upfront discount model is to create a clearinghouse to verify claims.¹⁶ Under this approach, an independent third-party clearinghouse would collect and examine detailed claims information from providers and manufacturers retrospectively. The financial mechanics and timing would be similar to the current upfront discount model, but accountability would rely on identifying the improper claim after the drugs have been dispensed. Further, timing requirements for when providers submit claims and third parties verify them must be tight to ensure no delay or non-compliance from providers or manufacturers. That would bring a clearinghouse model closer to the way other drug rebates happen.

The key change would be new claims information submission requirements so that the clearinghouse could verify that 340B transactions comply with program rules. If a

transaction does not comply, providers would be required to return improper discounts. A third-party administrator would administer the clearinghouse and have enforcement authority—ideally in conjunction with HRSA—to ensure participants follow program rules.

Accountability Through Claims Data. In a clearinghouse model, standardized and detailed claims information would create a clearer record of which transactions qualify for 340B pricing, which patients are eligible, and where duplicate discounts or other improper claims occur. If a provider violates program rules, the clearinghouse could identify the improper transaction and inform HRSA to require the provider to reimburse the drug manufacturer accordingly and in a timely manner.

To further increase accountability, a clearinghouse should be structured to allow all participants in the program—providers, manufacturers, payers, and others—to have access to the claims data so that they can check each other for compliance.

Preserving Upfront Discounts. A clearinghouse would allow providers to continue to receive upfront discounts while still allowing improper claims to be identified and reimbursed. This would be especially beneficial to small, independent safety-net providers who rely on upfront savings to keep their doors open and continue to serve their communities.

Implementation and Infrastructure. Because no such entity exists, the Department of Health and Human Services (HHS) would need time to establish a third-party clearinghouse before it could start evaluating claims. This effort would also require dedicated financial resources to ensure it ran efficiently.

Enforcement Challenges. Because providers would still receive discounts before claims are verified, providers that abuse the system could continue those practices or delay efforts to reimburse improper claims. Improper transactions may be identified only after a discount has already been provided. Historically, oversight and enforcement to prevent duplicative discounts has proven to be difficult. Therefore, for a clearinghouse to provide meaningful accountability, the model would need strict oversight and enforcement mechanisms from both government and the clearinghouse authorities to deter any ongoing abuse.

Rebate Model

Another way to strengthen transparency and accountability in the 340B program is to shift from the current upfront discount/replenishment model to a rebate model, an approach used by most federal drug pricing programs and commercial health plans.¹⁷ Under this model, providers would acquire drugs at the higher, non-340B price, dispense them to eligible patients, and purchase replacement drugs from the drug manufacturer at the standard commercial price, and then submit a claim to a neutral third party, which would be specified in legislation, with information showing that the transaction meets 340B requirements. Once the rebate claim is approved, the provider would receive a 340B rebate from the drug manufacturer for the difference between the standard price and the 340B price. This model determines eligibility for the discount before a 340B provider makes revenues from the sale of the discounted drug.

To avoid allowing repetitive claims and a verification process that could be abused, an efficient rebate model should establish strict rules, firm timelines to make corrections, prompt dispute resolution, and a clear distinction between responsibilities.

An example of this model can be seen in Ryan White AIDS clinics, which use a rebate model through the AIDS Drugs Assistance Programs (ADAP). This program provides heavily discounted drugs to working-class patients living with HIV/AIDS.¹⁸ After paying for the full cost of an eligible drug, clinics submit a claim to receive a 340B price via a rebate. This helps the clinics provide vulnerable patients with access to costly, lifesaving drugs while accounting for claims-level transparency into the 340B pricing that ADAPs receive.

Notably, this rebate model is not mandatory. However, in 2023, 75% of ADAP programs—whom have small staff sizes and tight operating budgets—elected to use the rebate models to receive 340B pricing.¹⁹ This demonstrates that an effective rebate model must be built from assurances that all parties participate in good faith, includes strong oversight mechanisms, and violators face meaningful penalties should they misuse the program. This will help the program hold to guiding principles: ensuring lifesaving drugs and high-quality care reach vulnerable patients.

Ryan White AIDS Clinics are not the only program that operates through rebates. Rebates are also commonly used to account for discounts and ensure accountability in

programs such as Medicaid, Medicare Part D, and TRICARE.²⁰

Positive Impact on Transparency. A rebate model increases transparency into individual transactions because a provider must submit claims information before receiving the 340B price.²¹ The data would give the government and manufacturers more information to prevent duplicate discounts and verify that transactions comply with program rules before claims are paid. This model would help ensure a reliable solution to program integrity challenges and dispute resolutions.

Real-Time Accountability. Given that discounts would not be issued through the rebate until after the claim is verified, misuse and improper claims would be caught before resources are allocated.

Cash Flow Concerns. While a rebate model could provide greater accountability for transactions, it could also create cash flow concerns for providers—especially the essential, rural, and independent hospitals that rely on immediate 340B savings to make ends meet—if not held to a tight time frame. Under the current model, providers receive savings when the drug unit is dispensed and replenished. Under a rebate model, they would have to wait for the drug to be dispensed, their rebate claim to be approved, and for the manufacturer to pay the rebate.

For small, independent hospitals with only a few months of cash on hand, as is the case for almost 10% of hospitals, a delay could have a significant impact on their ability to serve patients.²² However, for large hospital systems with substantial operating revenue and reliable private insurance reimbursements, the impact would be far smaller, if felt at all. However, regardless of size and operating budget, a well-run and well-timed rebate model—such as one with a 10-to-30-day turnaround time—would have the same financing cost as the current replenishment model.²³

To avoid inadvertently sending small hospitals closer to the red—or even forcing them to close their doors entirely—a rebate model would need to be structured so that claims can be processed, approved, and paid within a tight time frame, with targeted protections for genuinely vulnerable hospitals.²⁴ This would preserve access in underserved communities while still bringing stronger accountability to the program as a whole.

What Neither Model Solves

Both the clearinghouse and rebate models would create an administrative and financial burden for program participants, who would need to provide detailed claims and patient data, referral information, and information on discounts. Much of the required information, however, is already collected through routine pharmacy claims, billing, and compliance systems.²⁵ Policymakers would need to weigh that burden against the value of more complete and consistent information about 340B transactions that can help prevent prohibited duplicate discounts.

More importantly, both models could improve transparency of 340B claims, but neither would ensure that the savings providers generate ultimately benefit patients. Separate reforms would still be needed to ensure this is met.

The Path to Reform

Reforming the 340B program—including improving transparency and accountability—has long been discussed in Washington. More recently, lawmakers and HRSA have put forward several proposals to address concerns about program integrity.

- **HRSA rebate pilot:** In 2025, HRSA announced a pilot rebate program for entities participating in the 340B program.²⁶ This model would require providers to submit rebate claims after drugs are dispensed to eligible patients. Approved claims would then be paid through rebates from manufacturers within 10 days, among other mechanics to address cash flow concerns from providers. This pilot program faced legal challenges from providers, prompting HRSA to revise the model. The revised pilot is now slated to take effect in January 2027.²⁷ It has a limited scope—only involving certain, selected drugs with a maximum fair price (MFP)—and is only set for one calendar year.
- **SECURE 340B Act:** The *SECURE 340B Act* from Representatives Scott Peters (D-CA) and John Joyce (R-PA) would create an independent clearinghouse to collect and analyze claims data in order to identify potential violations and track the use of 340B savings.²⁸ The bill would also establish additional guardrails in the program, including requirements for patient definition, child site eligibility standards, and require providers to report their use of 340B savings.

- **340B ACCESS Act: Representatives** Buddy Carter (R-GA) and Diana Harshberger (R-TN) introduced the 340B ACCESS Act, which would create an independent clearinghouse to monitor and verify 340B claims, specifically working to prevent duplicate discounts from being administered.²⁹ Similar to other proposals, this bill includes program integrity guardrails like patient affordability standards and eligibility standards for child sites.
- **340B for Patients Act (Cassidy Discussion Draft):** Senator Bill Cassidy (R-LA) released a discussion draft of his *340B for Patients Act*, which includes provisions to improve accountability for 340B savings.³⁰ Under the proposal, manufacturers could choose to offer 340B ceiling prices through a rebate, track claims through a clearinghouse, or continue providing upfront discounts. Covered entities would have similar flexibility in how they access 340B pricing, so long as those savings are passed along to 340B patients. The proposal also includes enforcement mechanisms and penalties to ensure participants comply with program rules.
- **SUSTAIN 340B Act:** The Senate bipartisan 340B working group, led by Senators Jerry Moran (R-KS) and Tammy Baldwin (D-WI), introduced the *SUSTAIN 340B Act*.³¹ This bill would sunset any 340B rebate model implemented by the Department of Health and Human Services (HHS) and replace it with a third-party clearinghouse to process claims data, with a focus on preventing duplicate discounts and other program violations. It would also make reforms related to patient affordability benefits, reporting requirements, and patient definition.

While the path for all these proposals remains uncertain, they reflect growing bipartisan agreement that stronger transparency and accountability is needed to ensure the 340B program is benefiting patients and adhering to program integrity standards.

Conclusion

The 340B program has an important mission: helping patients access and afford care while supporting safety-net providers that serve vulnerable communities. That mission is especially important at a time when health care remains inaccessible or unaffordable for too many 340B patients. But a program this large should also have clear rules to ensure discounts are properly claimed and program revenue benefit the patients and communities 340B was created to serve.

Congress should start by improving the mechanisms through which 340B discounts are administered and tracked. Rebate and clearinghouse models offer two possible paths to improve transparency and accountability for 340B transactions, better verify patient eligibility, and prevent duplicate discounts. But neither approach can ensure on its own that 340B savings are used to benefit patients. Congress will need to pair stronger transaction-level transparency and accountability with broader reforms that keep the program focused on the patients it was created to serve.

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