



The 340B Drug Discount Program: Confusion Driving Reform and Litigation

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Executive Summary

- The 340B drug discount program has long suffered from a lack of congressional clarity on the intent of the ever-expanding program.
- In the absence of such clarity, frequent litigation and state policy actions will continue to disrupt the 340B program and confuse program participants.
- This insight reviews recent developments in litigation and state policy actions and what they will mean for the 340B program going forward.

Introduction

The [340B drug pricing program](#) (340B program) was created in 1992 to “stretch scarce federal resources”^[1] by allowing covered entities, such as hospitals, to purchase physician-administered and out-patient drugs at a discount (typically 25 percent) from those manufacturers participating in the Medicaid program. The drug would then be reimbursed by an insured patient’s health plan at a higher price. In turn, the covered entity should, in theory, use the gains from the sale of the drug to provide uncompensated care to underinsured or uninsured patients.

Yet the 340B program suffers from a lack of congressional clarity on the intent of the ever-expanding program, leading to confusion among its participants. Specifically, lawmakers never specified the target population of the program, nor have they required that discounts be shared with patients. Thus, the amount by which patients actually benefit from the 340B program may be quite limited.^[2] The lack of clarity regarding the goals of the 340B program has often invited litigation and state-level action. For example, to reduce federal spending, the Department of Health and Human Services (HHS) attempted to cut reimbursement to hospitals for outpatient drugs in the 340B program – yet the Supreme Court ruled in 2022 that HHS must restore approximately \$1.6 billion in funds for 2018 and 2019. Similarly, New York state is carving out [Medicaid managed care beneficiaries](#) onto a single drug plan, effectively absorbing for itself 340B funds and excluding covered entities from directly participating in the program.^[3]

The American Action Forum has extensively covered the [340B drug pricing program](#) and identified the many issues that arise from its lack of statutory purpose. Without congressional leadership, litigation around the 340B program will continue to escalate, as will state activity with further attempts to expand the population the program serves. This insight reviews recent developments in litigation and state policy actions and what they will mean for the 340B program going forward.

Three Legal Cases

Case One: Distribution of Drug Manufacturer Discounts

Background: The Affordable Care Act expanded the number of contract pharmacies a covered entity could partner with to capture as many insured patients as possible.[4] In 2020, however, six drug manufacturers [stopped offering 340B program discounts](#) to an unlimited number of contract pharmacies over concerns of duplicative discounts, which occur when a drug is eligible for two separate discounts, first under the 340B program and again under Medicaid.[5] In 2021, the Health Resources and Services Administration (HRSA), which oversees the 340B program, sent a [letter](#) to the drug manufacturers in response to the limited distribution of their discounts, rejecting their concerns over duplicative discounts and holding that drug manufacturers must offer discounts to all pharmacies contracted by covered entities.

Ruling: In January 2023, the U.S. Court of Appeals for the Third Circuit disagreed with HRSA. The court [found](#) that no language in the statute of the 340B program required drug manufacturers to provide discounts to every contract pharmacy.

Why It Matters: Further legal action is likely inevitable as HRSA has issued non-compliance letters to manufacturers that have continued to limit their distribution to pharmacies.

Case Two: State Oversight

Background: The Arkansas General Assembly passed a law that expands the definition of a covered entity to include all pharmacies and requires drug manufacturers to offer discounts to [any pharmacy](#) that contracts with a covered entity in the state. The law also provides the state with the authority to regulate drug distribution systems. Following the passage of the law, PhRMA (the trade association representing drug manufacturers) sought an [injunction](#) against its implementation.

Ruling: The U.S. District Court for the Eastern District of Arkansas found in favor of [this law](#). The American Hospital Association, among others, released [amici curiae](#) in support of the district court's ruling.

Why It Matters: Pharmacies that contract with covered entities are likely to support the enactment of state laws to protect their access to drug manufacturer discounts. Without clear guidance from HRSA around program participants, states are likely to require drug manufacturers to offer 340B program discounts to even more types of entities, most notably pharmacies.

Case Three: Definition of a 340B Patient

Background: In 2017, HRSA conducted an audit into Genesis Healthcare, a holding company with subsidiaries that provide health care services, and found that 340B drugs were dispensed to ineligible patients. Consequently, HRSA required that Genesis Healthcare submit a corrective action plan to reimburse drug manufacturers for these erroneous discounts. HRSA also terminated, and subsequently reinstated, Genesis Healthcare in a complex series of actions. Genesis Healthcare sued HHS over HRSA's narrow definition of eligible patients.[6] A district court ruled in favor of HRSA's argument that the lawsuit was rendered moot by HRSA's reinstatement of the company into the program. Genesis Healthcare appealed this decision.

Ruling: The U.S. Court of Appeals for the Fourth Circuit [disagreed](#) with the district court's "ruling of mootness," [7]

as the problems relating to patient definition in 340B persist. The case was remanded for further proceedings.

Why It Matters: If the court finds in favor of Genesis Healthcare and invalidates the current definition of a 340B patient, covered entities would be able to capture significantly more patients under the program. Expanding the number of patients eligible for 340B would increase reimbursement for covered entities and the pharmacies that distribute the drugs.

Overall, litigation around the intentions of the 340B program will continue at both the state and federal level as a lack of clarity over whether HRSA's regulatory guidance reflects congressional intent. Only legislative action in Congress will solve this problem.

Medicare Part B Reimbursement

Background: As an insurer, the Medicare program was paying market price for drugs provided at a discount to covered entities. For a significant time, HHS attempted to cut reimbursement in Medicare Part B for 340B outpatient drugs. Starting in 2017, HHS announced its intention to reduce payments to the [drug's average sales price by -22.5 percent](#) – slashing reimbursement to hospitals by approximately \$1.6 billion per year.[8] Several legal challenges followed with conflicting decisions issued by lower courts while HHS reimbursed hospitals at the reduced amount.

Ruling: In June 2022, the U.S. Supreme Court [ruled](#) against HHS. The court stated that “we do not agree with HHS’ interpretation of the statute. We conclude that, absent a survey of hospitals’ acquisition costs, HHS may not vary the reimbursement rates for 340B hospitals. HHS’ 2018 and 2019 reimbursement rates for 340B hospitals were therefore contrary to the statute and unlawful.” HHS must now pay hospitals through the Centers for Medicare and Medicaid Services (CMS) to adequately reimburse them for 2018 and 2019.

Why It Matters: HHS is likely to release [a final payment remedy](#) to hospitals following the Supreme Court decision. Yet unanswered [questions](#) persist around the HHS secretary’s authority to reduce Medicare reimbursement as litigation continues. One potential ramification of the ruling is that HHS, via CMS, may have to take monies from elsewhere in its budget. According to [one source](#), the ruling could reduce payments to hospitals for “non-drug services,” potentially including “all outpatient hospitals and not just 340B sites.”[9]

Medicare Part B spending is spiraling out of control. One study [projected](#) that by 2031, Part B will account for more than half of total Medicare spending. These recent court cases demonstrate HHS’ limited ability to either set the terms of program participation or control costs without congressional action.

New York State and Medicaid Carve-out

In New York, controversial reforms to Medicaid now allow the state to manage pharmacy benefits directly for beneficiaries. The state returned to an [expensive fee-for-service pharmacy model](#) – which no longer allows hospitals and other entities to bill health plans for “340B-purchased drugs at a higher negotiated rate,” but rather for only the cost the pharmacy paid to acquire the drug.[10] This new pricing model reduces the ability of hospitals and other covered entities to generate monies in the 340B program.

Although New York has [budgeted \\$705 million](#) to make hospitals and other covered entities whole for funds lost from the 340B program, it is likely not enough. One study projected that New York’s state is likely to experience an increase in costs of an “estimated \$154 million during the first year of implementation and \$1.5

billion over five years.” These reforms could dramatically reduce funds hospitals and other covered entities receive in the state.[11]

Hospitals concerned about the loss of 340B funds from Medicaid have [sued](#) New York over fears of long-term gaps in reimbursement. Additional lawsuits are likely to follow as concerns around New York’s ability to fund covered entities adequately through a single budget. Moreover, a [compromise bill](#) is before the New York Senate to reverse part of the controversial reform, restoring covered entities’ ability to generate funds directly from the 340B program.

Policymakers should be watching to see if reforms to the Medicaid pharmacy benefit in New York increase rather than decrease the overall health care spending. The inability of covered entities to generate additional funds through the 340B program is likely to exacerbate pressure on the state budget.[12]

Conclusion

Without clear congressional leadership to address the core design failures of 340B, frequent litigation and state policy actions will continue to disrupt the program and confuse program participants. Federal attempts to reduce Medicare spending in the 340B program have failed in court. State activity, such as New York’s attempt to expand the purpose of the 340B program, may push the program further away from its intended purpose. The 340B program has become defined by piecemeal case law, and Congress should act to clarify the intent and purpose of the federal program

[1] The Commonwealth Fund, “[340B Drug Discount Program: Why More Transparency Will Help Low-Income Communities](#)” 2018.

[2] For example, the [Commonwealth Fund](#) found that “...one-quarter of 340B providers spent less than 2.6 percent of their budget on uncompensated care.” Moreover, [a study in 2022](#) found no difference in the amount of uncompensated care provided based on a hospital’s participation status.

[3] Rachel Silberstein “[Safety-net groups fear ‘Armageddon’ if federal funds access lost](#)” 2023.

[4] As covered entities, even those with pharmacies, have been able to contract with an unlimited number of pharmacies to capture a 340B claim.

[5] [42 USC 256b\(a\)\(5\)\(A\)\(i\)](#) “prohibits duplicate discounts; that is, manufacturers are not required to provide a discounted 340B price and a Medicaid drug rebate for the same drug. Covered entities must have mechanisms in place to prevent duplicate discounts.”

[6] According to the Judge’s [opinion](#) “HRSA was enforcing “[p]atient eligibility requirements . . . defined in guidelines (61 Fed. Reg. 55156 (Oct. 24, 1996)).”

[7] A ruling of mootness would mean that the respective court did not have the power to issue a ruling on the issue.

[8] ECG Management Consultants “[SCOTUS Sides with 340B Hospitals in \\$1.6 Billion Ruling](#)” 2022. The

authors found that these “...HHS payment policies reduced impacted hospital reimbursement for outpatient drugs by approximately 30 percent and are valued at \$1.6 billion total over the period in question.”

[9]20-1114 [American Hospital Assn. v. Becerra \(06/15/2022\)](#) Justice Kavanaugh writes “... HHS’ argument that Congress could not have intended for the agency to “overpay” 340B hospitals for prescription drugs ignores the fact that Congress, when enacting the statute, was well aware that 340B hospitals paid less for covered prescription drugs. It may be that the reimbursement payments were intended to offset the considerable costs of providing healthcare to the uninsured and underinsured in low-income and rural communities.”

[10] New York carved out [Medicaid beneficiaries](#) onto a new single drug plan[10]as [pharmacists in the state have been vocal](#) about their under reimbursement from PBMs for several years. Therefore, moving New York’s Medicaid population, the [second-largest in the U.S.](#), would be financially beneficial for independent pharmacists.

[12] It is important to [highlight](#) that California’s carve-out “...included funds invested into a safety net pool—this pool, however, only covers community health centers, not 340B hospitals.”