



Insight

340B Drug Pricing Program: Litigation Supplants Congressional Intent

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Executive Summary

- A recent South Carolina district court ruling opens the door for the 340B Drug Pricing Program to become the largest federal prescription drug program, surpassing Medicare Part D.
- The court ruled that any patient treated by a covered entity (such as hospitals) is 340B eligible and regulatory actions to limit or restrict patient eligibility for covered entities is not in the regulatory agency's rulemaking authority—only Congress can issue such clarification.
- This insight reviews the court's findings and considers the challenges and opportunities policymakers may have in modifying the statute to benefit both patients and taxpayers.

Introduction

The 340B Drug Pricing Program (340B Program) was created in 1992 to “stretch scarce federal resources” 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 drugs would then be reimbursed by insured patients' health plans at a higher price. In turn, the covered entities should, in theory, use the gains from the sale of the drugs to provide uncompensated care to underinsured or uninsured patients.

For deeper dives into the 340B Program please see the American Action Forum's [PRIMER: The 340B Drug Pricing Program](#) and [PRIMER: The 340B Drug Pricing Program – Challenges and Solutions](#).

A recent South Carolina district court [ruling](#) opens the door for the 340B Drug Pricing Program to become the largest federal prescription drug program surpassing [Medicare Part D](#). In anticipation of the court ruling, IQVIA [released](#) a study on expanded 340B patient eligibility, which could see the program double in size. The authors' national modeling found that “estimated sales of branded products would increase by 103.7%...[e]xpressed using 2022 sales, the value of branded, 340B drugs would increase from a baseline of \$93.0 [billion] to \$189.4 [billion], dollarized using wholesale acquisition cost.” Notably, the Congressional Budget Office currently [projects](#) Medicare Part D spending to be [\\$120 billion](#) in 2024. Potentially, prescription drug costs could increase across all payer types as covered entities remain [incentivized](#) to purchase higher-priced branded products over competitively price branded products or generics.

The court [ruled](#) that any patient treated by a covered entity (such as hospitals) is 340B eligible and regulatory actions to limit or restrict patient eligibility for covered entities is not in the regulatory agency's rulemaking authority—only Congress can issue such [clarification](#). Furthermore, the court found that the Health Resources and Services Administration (HRSA) under the Department of Health and Human Services (HHS) does not have the authority to enforce a patient definition in the 340B Drug Pricing Program. The patient definition is essential to determine 340B patient eligibility as a covered entity can dispense a discounted medication and

receive higher reimbursement from an eligible patient's insurance company. Medicaid patients cannot be captured under the 340B Program by statute as Medicaid receives rebates from drug manufacturers through the [Medicaid Drug Rebate Program](#).

This insight reviews the court's findings and considers the challenges and opportunities policymakers may have in modifying the statute to benefit both patients and taxpayers.

The Court Case

Gensis Health Care, Inc. v. Xavier Becerra, as Secretary of the United States Department of Health and Human Services; Carole Johnson, as Administrator of the Health Resources and Services Administration; Emeka Egwim, as Lieutenant Commander in the United States Public Health Service and Director of the Office of Pharmacy Affairs in the Health Resources and Services Administration

Patient Definition

At the center of the case is the HRSA's interpretation of the word "patient" under the [340B statute](#) as well as the agency's attempts to enforce its patient definition on Gensis Health Care. In October 1996 HRSA [published](#) guidelines that included a definition of the term "patient."

Regulatory Background

For a covered entity to provide care to a "patient" as defined by HRSA, the agency required that the entity have a relationship with the patient, maintain records of patient care, and that the patient received care from a health care professional who is employed or contracted with the covered entity. HRSA explicitly stated that covered entity could not simply dispense drugs to a patient to be considered 340B eligible.

In 2015 HRSA issued [further guidance](#) on a patient definition but it was [withdrawn](#) in early 2017.

Ruling

The court found that HRSA's interpretation of the term patient is at odds with congressional intent. The court found that the only statutory requirement for a patient to be eligible under the 340B Program is that the person be a patient of the covered entity regardless of whether the covered entity ordered the patient's prescription.

The court also found that HRSA does not have broad rulemaking authority to implement a patient definition. Moreover, the court declared that all HRSA's earlier patient definition guidelines are unlawful and not enforceable by law.

Conclusion

Following the ruling, the 340B Program is likely to become the largest federal prescription drug program. Without congressional action, covered entities could double their 340B profits without any statutory requirements to provide charitable care or low-cost care to patients. Moreover, HHS and HRSA are limited in their oversight of the program, reducing much needed transparency. Congress must act to return 340B to its original intent and not allow the program to drift into an opaque source of monies for covered entities to use without accountability to either patients or taxpayers.