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# Court guts 340B program 'patient' definition, opening door to more 340B use

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On November 3, a federal district court issued a monumental decision[1] endorsing an expansive view of who is a "patient" of a 340B program covered entity eligible to receive a 340B drug. In *Genesis Healthcare, Inc. v. Becerra*, a judge in the federal district court for the district of South Carolina overturned part of the government's definition of a 340B-eligible patient, ruling in favor of a covered entity challenging a Health Resources and Services Administration (HRSA) audit finding that the entity violated the 340B statute's prohibition against diversion.

In so doing, the court endorsed a 340B patient definition that is significantly broader than the definition historically used by HRSA and would allow covered entities to use 340B drugs for prescriptions that originated outside the covered entity. The decision has the potential to upend 340B program operations, allow broader use of 340B drugs, raise questions about HRSA's ability to oversee the program and invite further calls for Congress to provide HRSA with authority to limit 340B use.

## Genesis lawsuit challenging HRSA's narrow patient definition

At issue in *Genesis* is a 2018 lawsuit filed by a federally qualified health center (FQHC) covered entity challenging an HRSA audit finding that Genesis violated the 340B statute by using 340B drugs for ineligible patients. The statute prohibits covered entities from transferring or reselling a 340B drug to a "person who is not a patient of the entity."

The definition of a 340B-eligible patient is critical to a covered entity's ability to benefit from 340B participation because covered entities can generate 340B savings by purchasing outpatient drugs at discounted prices, administering or dispensing them to eligible patients, and receiving payer reimbursement. The scope of the 340B patient definition dictates how widely covered entities can use 340B drugs and generate 340B savings.

The statute does not define the term "patient," and HRSA interpreted the statutory term in 1996 guidance. HRSA's guidance did not limit 340B use based on where a prescription is initiated, but over the years, HRSA audit enforcement has focused on the prescription's origination. In the Genesis audit, HRSA found Genesis committed diversion by using 340B drugs for prescriptions that the covered entity did not initiate (i.e., were written by outside providers at outside locations unrelated to a covered entity encounter).

Genesis argued that HRSA's definition of a 340B-eligible patient is inconsistent with the 340B statute because individuals are patients of a covered entity so long as they have received services from the covered entity. As such, covered entities can use 340B drugs to fill any prescription originating from any source, as long as the individual receiving the prescription has separately received services from the covered entity.

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After Genesis filed its initial lawsuit, HRSA reversed the audit finding, and the district court in South Carolina dismissed the case as moot. Genesis appealed, and the Fourth Circuit Court of Appeals reversed, finding that a legal controversy still existed because HRSA could issue a new audit finding against Genesis using the same interpretation of a 340B-eligible patient. The Fourth Circuit remanded the case to the district court to evaluate the legality of HRSA's interpretation, as outlined in the Genesis audit report.

## The court's broad definition of 340B-eligible patient and open questions

The court found that the 340B statute and congressional intent behind the 340B program require a broad definition of a 340B-eligible patient, and a covered entity does not need to initiate a prescription for it to be filled with a 340B drug.

The court endorsed a broad patient definition as follows:

- The only statutory requirement for 340B patient eligibility is that the person be a patient of the covered entity.
- The 340B statute does not require the covered entity to have initiated the healthcare service resulting in the prescription.

- The covered entity must have an "ongoing relationship" with the individual, but the statute does not require that the individual have an encounter at the covered entity within a specific period of time.

The court emphasized that the question of whether an encounter must have occurred within a specific period of time was not at issue before the court, and the court noted that HRSA did not provide suggestions for a "reasonable temporal requirement." However, the court acknowledged that Genesis "voluntarily" adopted a two-year limit, and the American Medical Association's definition of an "established patient" requires receipt of a healthcare service within the last three years.

The court also did not define what it means for a covered entity to have an "ongoing relationship" with an individual. The court noted that "it is reasonable to conclude that Congress intended patient to have its plain and ordinary meaning: 'an individual awaiting or under medical care and treatment.'" An open question is whether the individual must receive a healthcare service from the covered entity beyond a drug dispense.

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The court acknowledged HRSA's requirement in the 1996 patient definition guidance that individuals receive more than the dispensing of a drug from a covered entity to qualify for 340B but did not address the requirement, perhaps because the 1996 guidance was not at issue in the case. At issue was the position taken by HRSA in the Genesis audit regarding prescription origination, which was not articulated in the 1996 guidance.

## Implications for 340B use and the future of the 340B program

### Applicability

The court limited the scope of its review to the interpretation of a 340B patient used by HRSA in the Genesis audit, specifically HRSA's statement that, for an individual to qualify for 340B, the covered entity "must have initiated the healthcare service resulting in the prescription, regardless if the patient had an unrelated billable [covered entity] encounter."

The court did not review or weigh in on the legality of HRSA's 1996 patient definition guidance, which did not include the statement in the Genesis audit linking the prescription's origin to patient definition.

The court enjoined HRSA from enforcing the interpretation of a 340B patient used in the Genesis audit but only against Genesis. However, the court also found the interpretation to be in contradiction to the statute and, therefore, unenforceable. As such, HRSA may be precluded from taking the same position in a future audit of other covered entities.

The reach of any limits on HRSA enforcement is not yet known, including whether HRSA's position would be unenforceable in areas of the country outside the Fourth Circuit, which covers Maryland, North Carolina, South Carolina, Virginia, and West Virginia. The federal government could also appeal the decision to the Fourth Circuit, which could have implications for applicability and next steps.

### Possible changes to audit enforcement

The potential impact of the court's decision on HRSA audit enforcement is difficult to predict, in part because HRSA does not publish its audit protocol and HRSA's audit enforcement standards have been unclear and shifting.

Industry observations in recent years have suggested HRSA may have already stopped taking the position used in the Genesis audit, at least to some extent, which has resulted in fewer diversion findings. However, it is possible that HRSA could make further updates to its audit protocols to conform to the court's decision, perhaps allowing broader 340B use and resulting in even fewer audit findings.

For example, prior to 2019, HRSA's default position in audits appeared to be that a covered entity could not use 340B drugs to fill a prescription that originated outside the covered entity unless the covered entity met a narrow exception for referrals that began with a covered entity encounter.

In 2019, HRSA announced a reevaluation of its audit enforcement authority. Afterward, industry observations of audits suggested HRSA may have started allowing 340B use for prescriptions originating outside the covered entity on a case-by-case basis if the covered entity could demonstrate that the individual was a patient of the covered entity.

If HRSA were to implement a broader patient definition consistent with the court's decision, it is possible HRSA could allow 340B use for prescriptions written by outside specialists and other providers unrelated to care rendered by the covered entity, even in cases where there is no referral relationship.

The decision also calls into question HRSA's enforcement of a hospital child site registration notice issued on October 27, which ended a COVID-19 "waiver" and announced that, after a 90-day grace period ends, hospitals would be unable to use 340B drugs in provider-based hospital locations that do not appear on a reimbursable line of the hospital's most recently filed Medicare cost report.[2]

The court did not address HRSA's policy on what locations are eligible parts of a covered entity and whether individuals treated in provider-based locations not yet on the cost report are 340B-eligible patients.

### Drug manufacturer restrictions

As program stakeholders have been awaiting the court's decision in *Genesis*, drug manufacturers have continued to implement

restrictions on the ability of covered entities to access 340B pricing for drugs dispensed through contract pharmacies. These restrictions are also the subject of federal litigation, with the Third Circuit Court of Appeals issuing a decision in January 2023 allowing such restrictions and two more circuit court decisions pending.[3]

Although related to different statutory provisions, the *Genesis* decision is consistent with the Third Circuit's decision with respect to HRSA's ability to enforce statutory interpretations. The Third Circuit found that HRSA's position that the 340B statute prohibits contract pharmacy restrictions was unlawful because the statute is silent on contract pharmacy use and HRSA was attempting to enforce a requirement that was not expressed in the statute.

Similarly, the court in *Genesis* found HRSA cannot tie patient eligibility to prescription origination because, although the statute limits 340B use to "patients," the statute does not include a limitation to patient eligibility based on prescription origination.

Stakeholders should monitor how drug manufacturers react to the *Genesis* decision. On the one hand, the court's endorsement of a broad patient definition may make it more difficult for manufacturers to unilaterally impose restrictions on 340B use based on their own narrow interpretation of patient eligibility. On the other hand, the court's general position on HRSA's ability to take enforcement action may have implications for HRSA's ability to stop contract pharmacy restrictions.

## 340B program purpose

The court used strong language describing the purpose of 340B, consistent with how covered entities view the program, which could support covered entities in their advocacy to protect the program. The court said the purpose of 340B was "to provide a means to make 340B entities profitable in order for those 340B entities to 'stretch scarce Federal resources as far as possible'" (referring to language used by Congress during the debate over the creation of 340B in 1992).

The court found that a broad patient definition was consistent with this purpose, noting that "the more patients a 'covered entity' can sell discounted 340B drugs to, the greater the 'covered entity's' profit margin, and the greater the ability of the 'covered entity' to provide services to the indigent and achieve the purpose of the 340B statute."

## HRSA's authority to administer 340B

The decision is likely to raise questions about HRSA's ability to oversee the program. Although HRSA does not have the authority to issue regulations on the definition of a patient, the court acknowledged that HRSA has the authority to implement statutory interpretations through guidance, including an interpretation of the term "patient."

However, such interpretations must be consistent with the statute, and they must have the "power to persuade," which is a more difficult standard to meet than the standard courts use when reviewing the legality of agency regulations. Drug manufacturers have repeatedly called for limits on the patient definition test to rein in the volume of 340B purchases.

The court's declaration that HRSA cannot impose restrictions on patient definition beyond the language in the statute suggests that HRSA's role in placing guardrails on patient definition is limited.

The court hinted at calls to restrict 340B and highlighted the need for Congress to take such actions. The court noted: "If there is a desire to restrict the 340B Program and limit the ability of 'covered entities' to remain profitable in the face of prescription drug price increases, Congress is the appropriate entity to take the necessary action."

The court went on to say: "It is not the role of HRSA to legislate and limit the 340B program by restricting the definition of the term 'patient,' thereby frustrating the ability of the 340B statute to accomplish its purpose."

Such statements and the court's overall opinion are likely to result in additional calls for Congress to amend the 340B statute to define key terms and provide HRSA with the authority to administer the program through regulations.

## Notes

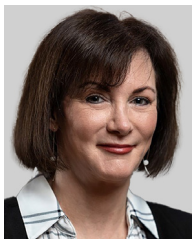
[1] https://bit.ly/3ugs2ip

[2] See here for Bass, Berry & Sims' alert on the notice: https://bit.ly/47sxZY8

[3] See here for Bass, Berry & Sims' alert on the Third Circuit decision: https://bit.ly/3QBxtjP

## About the authors



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