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# The Ongoing Saga of Patient Definition, or Lack Thereof, in the 340B Program: The Federal Courts Jump in

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Patient definition in the 340B program has been a vexing issue throughout the thirty plus years of the program. It has become even more complicated after the *Genesis Healthcare, Inc. v. Becerra* court decision on November 3rd, 2023, in the Federal District Court of South Carolina. This decision has called into question the very language of "**Patient Definition**" in the 340B statute and how the Health Resources and Services Administration (HRSA) has applied it in recent audits. The court ruled in favor of a Covered Entity that challenged a HRSA audit's finding that the entity violated the 340B statute's prohibition against diversion, based upon HRSA's position on what constitutes an "eligible patient" in a 340B setting.[1]

## What is the 340B Program & the Patient Definition?

HRSA and the Office of Pharmacy Affairs (OPA) within HRSA administer the 340B Drug Pricing Program. Drug manufacturers sign a pharmaceutical pricing agreement (PPA) which requires the manufacturer to charge a price for covered outpatient drugs that will not exceed an amount determined under the statute, or the 340B ceiling price.[2] Covered Entities in the program are clinics and other qualified organizations that meet HRSA requirements and are eligible to purchase covered drugs at the 340B discount price.[3] The mission of the 340B Program is to allow Covered Entities to "stretch scarce federal resources"[4] and to provide drugs at a significant discount to patients served by the Covered Entity. Hence, the importance of Patient Definition. In the Medicaid Program, an individual qualifies for Medicaid benefits based upon their eligibility in a particular state, with the State Medicaid Agency essentially becoming their health benefit provider. The 340B program is not based upon a particular individual's eligibility but upon the area serviced by the Covered Entity, such as a disproportionally low-income area. Therefore, the "Patient" is someone who enters the facility seeking medical care, including prescription drugs, regardless of whether they are covered by Medicaid, a private insurer, or have no insurance. Given the importance of this topic, the following provides an outline of the existing guidance on Patient Definition.[5]

1. *The covered entity has established a relationship with the individual, such that the covered entity maintains records of the individual's healthcare; and*
2. *The individual receives healthcare services from a healthcare professional who is either employed by the Covered Entity or provides healthcare under contractual or other arrangements (e.g., referral for consultation) such that responsibility for the care provided remain with the Covered Entity; and*
3. *The individual receives a healthcare service or range of services from the Covered Entity which is consistent with the service or range of services for which grant funding or federally qualified health center look-alike status.*

[1] *GENESIS HEALTH CARE INC. v. Becerra, Civ. No. 4: 19-cv-01531-RBH (D.S.C. Jan. 5, 2023).*
[2] https://www.hrsa.gov/opa/manufacturers
[3] https://www.hrsa.gov/opa/eligibility-and-registratio
[4] https://www.hrsa.gov/opa#:~:text=The%20340B%20Program%20enables%20covered,entities%20at%20significantly%20reduced%20prices.
[5] https://www.govinfo.gov/content/pkg/FR-1996-10-24/html/96-27344.htm

**History of the Patient Definition**

In 2015, HRSA proposed to narrow the Patient Definition to require that the specific prescription for the product must result from a medical service provided by the Covered Entity. This proposed change was never finalized, in large part due to HRSA's limited ability and authority to promulgate regulations and guidance. Many in the industry were anticipating what we then called the "mega-rule," which we thought would include the narrower patient definition and help bring the program more in line with what we felt was its mission: to be a safety net program that provides critical benefits to the uninsured and under-insured in this country. I, like many, felt that the current Patient Definition was being applied too broadly. At the time, individuals with private insurance could enter an eligible clinic and have a drug dispensed to them. The Covered Entity would dispense drugs purchased at the 340B price, and the individual would still receive private insurance reimbursement. The 340B program does not allow government 'double dipping,' meaning that Covered Entities cannot provide 340B purchased drugs to a Medicaid patient and get Medicaid reimbursement from the state. However, HRSA cannot restrict the double dipping of 340B drugs with private health insurance. I was at the congressional hearing in July of 2015 where Congress reviewed HRSA's oversight of the 340B program.[6] A key topic in that hearing was discussing what Covered Entities were doing with the significant, in my opinion, revenue or savings from the reimbursement from private health insurance. The Director of the Program, then Captain Pedley, stated that "the statute is silent as to whether a patient is insured or uninsured. They just have to meet our patient eligibility guidance… The statute is silent again on how the savings are used."[7]

Fast forward to today, the industry did not get the tighter Patient Definition they were hoping for, meaning that Covered Entities could universally apply a loose definition and seek even more revenue, or "savings." The 304B program's total sales grew to $43.9 billion in 2021, a 15.6% increase over 2020 sales and more than 3.5 times above total sales in 2015 ($12.1 billion).[8]

**HRSA Audits**

HRSA started performing audits of Covered Entities, including the 2018 audit of Genesis Healthcare which found that Genesis violated the 340B statute by using 340B drugs for ineligible patients. In that audit, HRSA stated that "the prescription for the 340B drug must originate from a healthcare encounter with Genesis or one of its contract healthcare providers." The key to the HRSA audit was around the prescription's origination. Genesis disagreed with HRSA, arguing that HRSA's interpretation of the term "patient" is contrary to the plain wording of the statute and that Genesis may resell 340B drugs to its patients even if the prescription did not originate from Genesis or one of its contract providers. This small difference in the interpretation of the statute may have an impact in billions of dollars.

**Opinion on the Future**

So, what does this all mean for the future of the program? In my opinion, the 1996 HRSA guidance around Patient Definition is too broad and leaves an opening for Covered Entities to see significant revenue through such a general definition. With this court finding, the situation may become more dire, opening the floodgates for other Covered Entities to apply this new "Patient Definition Plus." There may be few opportunities for HRSA to provide additional regulation or guidance regarding the proposed Patient Definition in 2015, particularly since the decision in *Genesis Healthcare, Inc. v. Becerra* potentially established a de facto definition or interpretation of the statute's language moving forward.

[6] https://www.congress.gov/event/115th-congress/house-event/106269/text
[7] https://www.govinfo.gov/content/pkg/CHRG-115hhrg26929/html/CHRG-115hhrg26929.htm
[8] https://340breport.com/federal-data-show-340b-sales-hit-43-9-billion-in-2021-drug-industry-consultant-reports/