HEALTHCARE

BRG

April
2026

340B Patient Definition and Implications for Duplicate Replenishment

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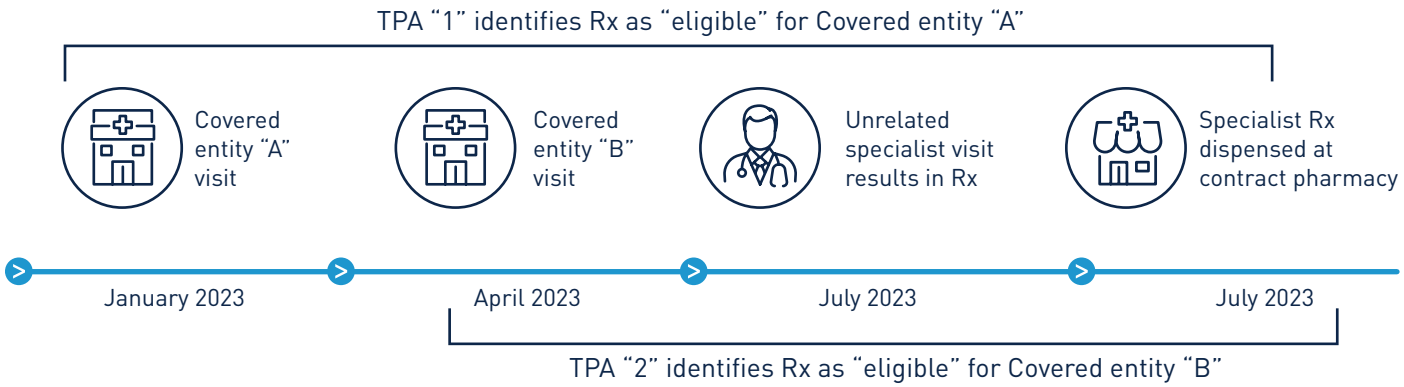
In November 2023, the US District Court for the District of South Carolina issued a decision in a lawsuit involving the federally qualified health clinic (FQHC) Genesis HealthCare, a "covered entity" eligible to purchase significantly discounted drugs under the 340B Drug Pricing Program. The court agreed with Genesis that the 340B statute does not require 340B prescriptions to originate in 340B-eligible locations if the prescriptions are for a covered entity's "patients." In commenting on potential definitions for the term "patient" in this context, the court cited as one possible framework an American Medical Association definition that defines an established patient as one who has received care within the past three years.[1]

This decision may have encouraged covered entities to take a broader view of which patients and prescriptions are 340B eligible, as noted in a prior issue brief. As a result, two or more covered entities may consider the same individual to be their "patient" at a given time. If an individual fills a prescription at a pharmacy that is eligible to receive shipments of 340B-priced drugs on behalf of two or more of those covered entities, more than one covered entity potentially could seek 340B pricing for the prescription by placing a "replenishment" order with their wholesaler.

In the illustrative example below, a patient makes an initial visit at covered entity "A," subsequently visits covered entity "B," and then sees a specialist for a concern unrelated to their visits to covered entities "A" and "B." The specialist then writes a prescription that is filled at a contract pharmacy that has an arrangement with both covered entities "A" and "B." Each covered entity's third-party administrator (TPA) separately determines that the prescription is for a patient of the covered entity, potentially triggering two separate orders of 340B replenishment units.[2]



The 340B prime vendor Apexus addresses this situation, noting that "to the extent that an individual qualifies as a patient of both covered entities, HRSA expects the entities to resolve the issue in good faith. In cases where a covered entity purchased and dispensed a 340B drug to an individual, no other covered entity is permitted to replenish or otherwise assert credit. Covered entities that utilize replenishment are required to ensure that only one covered entity receives a 340B discount on a particular patient transaction."[3]

1 *Genesis v. Becerra*, Order, 4:19-cv-01531-RBH, US District Court, District of South Carolina, Florence Division (November 3, 2023).

2 TPAs review pharmacy claims data on behalf of covered entities, identify claims for potential 340B replenishment, and coordinate with wholesalers to place replenishment orders.

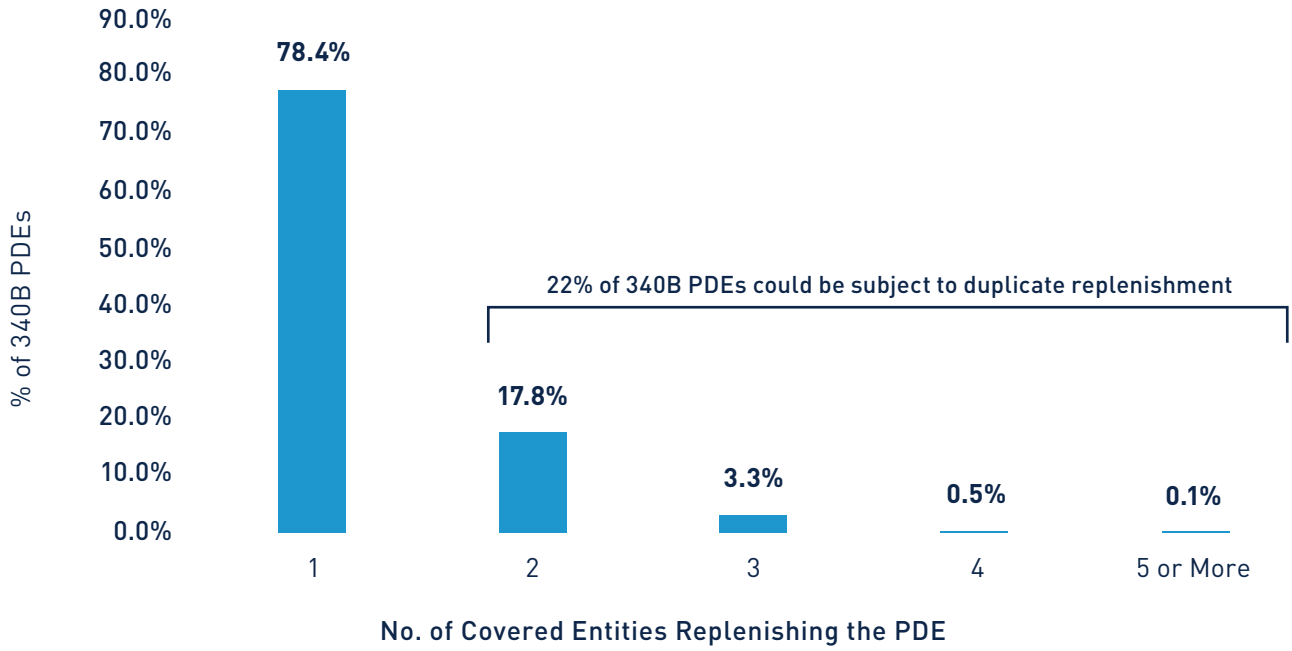
3 FAQ ID: 1599, 340B Prime Vendor Program, https://www.340bpvp.com/search#q=1599&tab=faq.

In practice, a covered entity may be unaware that it is replenishing the same claim as another covered entity unless the two utilize the same TPA. Even then, the prioritization logic to resolve duplication is not clear. HRSA's stance as indicated above does not clarify how an HRSA auditor reviewing an individual covered entity could determine that the same dispense was replenished by another covered entity. As such, HRSA has no distinct way to monitor compliance with its own guidance.

Analysis of Medicare Part D Prescription Drug Event (PDE) data for 2024 indicates that, if all covered entities used a three-year test to define "patient," as suggested by the court in *Genesis*, 28 percent of brand drug PDEs could be replenished by at least one covered entity.[4]

More than 20 percent of PDEs replenished at least once are at risk of replenishment by more than one covered entity. While most of these could be replenished by only two covered entities, a small number could be replenished by more than five. Four percent of 340B PDEs could be replenished by both a hospital and an FQHC. This represents 36 percent of PDEs that could be replenished by an FQHC.

FIGURE 1: SHARE OF 2024 340B PDES BY COUNT OF REPLENISHING COVERED ENTITIES



A lack of comprehensive 340B claims data reporting confounds HRSA's ability to enforce its own prohibition on duplicate replenishment. Comprehensive claims collection could identify instances of noncompliance, but enforcement would be challenging given the cumbersome nature of the administrative dispute resolution (ADR) process and limited visibility into 340B reversals. By linking effectuation of the 340B price one-to-one with the provision of claims data, a 340B rebate model would ensure the transparency needed for monitoring and enforcement.

4 Analysis is limited to PDEs where the beneficiary was enrolled continuously in Medicare Part A and B for the three calendar years preceding the PDE dispense date. Each PDE is appended with the Medicare Provider Number(s) associated with any 340B hospitals and/or FQHCs for which the dispensing pharmacy served as an in-house or contract pharmacy in 2024. If the beneficiary has at least one inpatient or outpatient claim associated with an appended covered entity in the three years preceding the dispense date, that covered entity is assumed to have replenished the PDE. For reporting purposes, a "covered entity" is defined as a distinct Medicare Provider Number in the case of hospitals and a distinct grant number in the case of FQHCs.

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