



Weekly Checkup

Verdict: Congress Must Act

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A district court in South Carolina [recently ruled](#) on the Health Resources and Services Administration's (HRSA) ability to define a qualifying patient for the [340B Drug Pricing Program](#). Luckily, American Action Forum's Director of Health Care Policy Laura Hobbs recently published an overview of the case. Let's dive into her takeaways as well as what this development may mean for 340B reform going forward.

First, some background on the case. Genesis Health Care, Inc. was audited by HRSA in 2017, and as a result was deemed ineligible for the 340B Program because it was distributing drugs to ineligible patients and failed to maintain auditable records. HRSA defined an eligible patient as an individual with an established relationship with a 340B covered entity (CE) that kept that individual's records, and who received services from the CE. Notably, HRSA explicitly stated that an individual is considered ineligible if their only interaction with the CE was the dispensing of drugs. Essentially, for a patient's drugs to qualify for a 340B discount, the dispensing CE has to be the one providing the services leading to the prescription. Upon being removed from the 340B Program, Genesis sued, and that led to the district court ruling. As Hobbs states, 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." More to the point, **the court also found that HRSA does not have broad rulemaking authority to implement a patient definition and that all prior patient definitions are illegitimate and unenforceable by law.**

This author is not a lawyer, and thus will avoid dwelling on the legal specifics of the court's ruling. I will instead focus on the effects. **While the HRSA definition was already quite broad, this latest ruling could significantly increase the number of patients eligible for 340B drugs and thus potentially drastically expand the size of the 340B Program.** For comparison, Medicare Part D, the largest federal drug program, is currently [projected](#) to spend around \$120 billion in 2024. An [IQVIA study](#) looking at the potential effects of this ruling estimates that the "sales of branded products would increase by 103.7%...from a baseline of \$93.0 [billion] to \$189.4 [billion]."

With this district court ruling, the 340B Program, already the second-largest federal drug program in terms of spending, could become the largest—surpassing Medicare Part D. As a reminder, 340B [was intended](#) to "stretch scarce federal resources as far as possible, reaching more eligible patients and providing more comprehensive services." Clearly, the program has [strayed far](#) from this intended purpose and requires reform to return it to its original aim. **The ruling highlights that reform cannot come through HRSA – Congress must act. Failure to do so would mean that this already unaccountable program – which has a variety of [negative effects](#) on our health care system – will grow ever larger and further drift beyond its purpose.**