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ISSUE ALERTS

FEDERAL COURT REJECTS NARROW DEFINITION OF A 340B-ELIGIBLE "PATIENT" PREVIOUSLY USED BY HRSA

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In late 2023, the United States District Court for the District of South Carolina issued a significant opinion (*Genesis Health Care, Inc. v. Becerra*, No. 4:19-CV-01531-RBH, 2023 WL 7549156 (D.S.C. Nov. 3, 2023)) concerning the definition of the term "patient" under the federal 340B prescription drug program, which is administered by the Health Resources and Services Administration (HRSA). In its decision, the court ruled that 340B-covered entities may treat prescription drugs as 340B-eligible if those drugs are administered to individuals who are patients of the covered entity, under the plain meaning of the term "patient," regardless of whether the patient's prescription at issue arose from a service that was actually performed by the covered entity.

BACKGROUND

The 340B program was created by statute in 1992 (42 U.S.C. § 256b), and it enables various "covered entities" — including critical access hospitals, federally qualified health centers (FQHCs), children's hospitals, and certain other "safety-net" facilities that provide healthcare services to indigent or underserved populations — to purchase drugs from manufacturers at a reduced rate, allowing those entities to retain a profit when the drugs are administered to the covered entity's "patients." Congress made clear at the time of enactment that the purpose of the 340B program was to allow these covered entities — all of which receive substantial federal funding — to "stretch scarce Federal resources as far as possible, reaching more eligible patients and providing more comprehensive services." By permitting covered entities to purchase prescription drugs at a reduced price and receive non-reduced reimbursement from patients and third-party payors, then, the 340B program provides a significant financial benefit to covered entities, which is precisely what Congress intended the program to do.

Although various other terms related to the 340B program are specifically defined by statute, Congress chose not to provide a specific definition of the term "patient." Identifying 340B-eligible "patients" is one of the most crucial aspects of any covered entity's 340B-program participation. If the term "patient" is narrowly construed, the covered

entity will administer fewer prescription drugs through the 340B program, which will, of course, reduce the program's financial benefit to the covered entity.

Federal regulators responded to Congress's decision to leave the term "patient" without a specific statutory definition by issuing various and inconsistent guidance regarding who qualifies as a 340B-eligible "patient." In 1996, the federal Department of Health and Human Services (HHS) issued a notice that adopted a "flexible" definition of the term "patient" that could reach a broad swath of individuals for whom the covered entity has provided, or may provide, treatment. In 2015, however, HRSA proposed guidance embracing a narrower definition of the term "patient" indicating that an individual could only qualify as a 340B-eligible "patient" if the prescription at issue arose from treatment provided by the covered entity. That 2015 proposed guidance was ultimately withdrawn, and HRSA has not published definitive guidance on the topic.

COURT OPINION

In the *Genesis Healthcare* opinion, the court ruled that a narrow interpretation of the term "patient" under the 340B program — an interpretation that made the definition of the word "patient" contingent on whether the prescription drugs administered result from care that the covered entity itself provided — was inconsistent with the statute, and it enjoined HRSA from enforcing that interpretation against the plaintiff covered entity.

The covered entity involved in the case, GHI, is an FQHC that, in 2018, HRSA determined was ineligible to participate in the 340B program after finding that it had failed to keep required records related to its 340B program and that it had "dispensed 340B drugs to ineligible patients." As part of the suspension, HRSA issued a letter to GHI in 2019 in which it opined that "in order for an individual to qualify as a 340B patient, GHI must have initiated the healthcare service resulting in the prescription" at issue. In June 2018, GHI initiated a lawsuit to set aside HRSA's decision to remove it from the 340B program. While the lawsuit was pending, HRSA reinstated GHI and enabled it to resume participation in the 340B program, but it did not repudiate the "ineligible patients" analysis in its 2019 letter to GHI. The court determined that the question was not moot as HRSA's enforcement of the term "patients" could create "uncertainty as to the viability of Genesis's business model as well as the services that it is able to provide."

In its ruling, the court summarized the legislative history and other available evidence of legislative intent, and it concluded that Congress intended the term "patient" to have a significantly broader meaning than the definition HRSA utilized in its 2019 letter to GHI. The court noted that Congress could have added, and indeed did consider adding as a prerequisite for 340B eligibility, that the covered entity actually provides the care that leads to the prescription, but Congress chose not to incorporate any such prerequisite. Instead, Congress left the term "patient" undefined while emphasizing that the purpose of the 340B program was to provide a significant financial benefit to covered entities that would enable them to maximize the services they offer. Given this statutory framework and clear Congressional intent, the court concluded that the narrow reading of the term "patient" in HRSA's 2019 letter to GHI was inconsistent with the plain meaning of the statute and could not be enforced against GHI.

TAKEAWAYS

The U.S. District Court's ruling in *Genesis* is a significant victory for 340B-covered entities and may provide some covered entities an opportunity to reevaluate how they identify 340B-eligible "patients." Covered entities and other 340B stakeholders may find opportunities to increase the financial benefits they derive from the 340B program by implementing a broader view of who qualifies as a 340B-eligible "patient" in accordance with the *Genesis* court's opinion.

The court's opinion raises several significant questions about the 340B program that have yet to be answered. Although the court rejected the narrow definition HRSA previously used against GHI, it did not specifically define

what constitutes a 340B-eligible “patient” in all circumstances. Furthermore, the court’s opinion casts some doubt on other HRSA-issued guidance and on HRSA’s general process for issuing and implementing guidance. Covered entities and other 340B stakeholders should stay tuned for additional court cases, new regulatory guidance, and even statutory amendments that may affect how 340B-program restrictions are interpreted and enforced in the future.

FOR MORE INFORMATION

If you have questions or want more information regarding the court ruling's impact on the definition of a 340B-eligible "patient," contact your legal counsel. If you do not have regular counsel for such matters, Foulston Siefkin LLP would welcome the opportunity to work with you to meet your specific needs. For more information, contact Brooke Bennett Aziere at 316.291.9768 or baziere@foulston.com or Alex Schulte at 913.253.2155 or aschulte@foulston.com. For more information on the firm, please visit our website at www.foulston.com.

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