

Federal Court Broadens Definition of Patient Under 340B Program

Healthcare Law Update

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Keith Roberts
Member & Chair, Litigation

Shannon Carroll
Member, Healthcare

Paul DeMartino, Jr.
Associate, Healthcare

BRACH | EICHLER^{LLC}
Counsellors at Law

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On November 3, 2023, a federal district court issued a monumental decision endorsing an expansive view of who qualifies as a “patient” of a 340B program “covered entity” facility eligible to receive a drug under the federal 340B Drug Pricing Program. The federal 340B Drug Pricing Program is intended to help safety-net health care providers stretch their financial resources to reach more financially vulnerable patients and allows qualifying facilities that treat low-income and uninsured patients to buy outpatient prescription drugs at a discount of 25 to 50 percent. The federal court in *Genesis Healthcare, Inc. v. Becerra* overturned part of the government’s definition of what is a 340B-eligible patient, ruling in favor of a covered entity that challenged a Health Resources and Services Administration (HRSA) audit that found that the facility violated the 340B statute’s prohibition against diversion, which prohibits a drug from being provided to an individual who is not an eligible outpatient of that facility.

In its decision, the court found that the HRSA’s more restrictive definition of a 340B-eligible patient, which required a covered entity to initiate the services resulting in the relevant prescription in order to claim them as a patient, was inconsistent with the 340B statute. Instead, the court found that the intent of the statute required a broad reading of the definition of who is an eligible patient under the 340B Drug Pricing Program, allowing covered entities to use 340B drugs for prescriptions that originated outside of the facility. The court’s ruling also established that a covered entity must have an ongoing relationship with an individual to meet the broad definition of a 340B-eligible patient, notwithstanding that the statute does not establish any specific periods of time in order to establish a patient relationship.

For more information, contact:

Keith Roberts | 973.364.5201 | kroberts@bracheichler.com

Shannon Carroll | 973.403.3126 | scarroll@bracheichler.com

Paul DeMartino, Jr. | 973.364.5228 | pdemartino@bracheichler.com