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Court Strikes Down HRSA Definition of 'Patient' After 340B Audit

By Nina Youngstrom

In a Nov. 3 decision, a federal court voided the definition of “patient” used by the HHS Health Resources and Services Administration (HRSA) in the 340B drug discount program.^[1] The U.S. District Court for the District of South Carolina declared that “the only statutory requirement for 340B eligibility of a person is that the person be a patient of a covered entity.”

The challenge to HRSA’s definition of patient arose in a lawsuit filed by Genesis Health Care Inc., a federally qualified health center in South Carolina, in the wake of a 340B audit.

That was just one of three developments in the same week with big implications for hospitals and other providers that count on 340B drug discounts.

The court said HRSA “failed to prove its patient definition was staying within the four corners of the statute,” noted attorney Andy Ruskin, with K&L Gates in Washington, D.C. Because the court didn’t issue a nationwide injunction on HRSA’s definition, however, covered entities must decide whether to move forward with their own definition of patient while they wait for other decisions supporting this one or for HRSA to withdraw its guidance, he said.

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