HHS Says It Appropriately Certified Clinics for Drug Discounts

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Summary by Bloomberg AI

- A federal health agency is opposing a court challenge from drugmakers over whether it lawfully allowed certain clinics to obtain discounted medicines through a government pricing program.
- The US Health Resources and Services Administration argues it established appropriate procedures to certify clinics under Sagebrush Health Services for participation in the 340B Drug Pricing Program.
- The agency says vacating the current certification process would force Sagebrush and other health entities that provide services to vulnerable communities out of the 340B program.

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Eli Lilly & Co., Amgen Inc., and UCB Inc.'s "claims are misplaced," the government said in a **motion for summary judgment** filed April 24 to the US District Court for the District of Columbia.

"HRSA's compliance check removed more than forty Sagebrush sites from the 340B program and subjected HRSA to protracted litigation," the agency said. "HRSA's method for compiling a list of covered entities and collecting historical 340B purchases is also reasonable."

The 340B program allows covered entities such as qualifying safety-net hospitals, clinics, and other health providers to buy outpatient drugs at steeply discounted prices from manufacturers participating in Medicaid. HRSA, an agency within the US Department of Health and Human Services, oversees the program.

Congress requires HRSA to annually certify and recertify the eligibility of clinics for the program, including clinics that treat sexually transmitted diseases.

The drugmakers **allege** the agency failed to lawfully perform that task and acted arbitrarily and capriciously when it greenlit certain clinics. They ask the court to set aside the actions and order the agency to develop a process with transparent criteria for certifying clinics.

But HRSA "did not neglect its statutory duties," the government argued. Instead the agency said it found more efficient and reliable ways to compile a list of covered entities by state and collect relevant historical purchase data of 340B discount drugs that still meets the intent of the statutory requirements, it said.

The agency also argued how vacating the current certification process would force Sagebrush and other health entities that provide services to vulnerable communities out of the 340B program.

"This case is a collective strategy by a group of large and highly profitable prescription drug manufacturers to unilaterally upend the long-settled operation of the statutory 340B program that provides discounted medication to healthcare providers and their patients," the government said.

The manufacturers survived some of the government's **claims** to dismiss the case over lack of subject matter jurisdiction and failure to exhaust regulatory administrative remedies before initiating the lawsuit. A federal judge last year ruled that the drugmakers didn't need to exhaust administrative remedies.

Arnold & Porter Kaye Scholer LLP represents Lilly and UCB. Hogan Lovells US LLP represents Amgen.

The case is **Amgen Inc., v. Kennedy**, D.D.C., No. 1:24-cv-03571, motion for summary judgment 4/24/26.