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What To Know As Sen. Cassidy Proposes Changes To 340B

By **Mark Payne**

Law360 (June 30, 2026, 8:50 PM EDT) -- Legislation introduced by the chair of the Senate Health, Education, Labor and Pensions Committee could radically change the scope of the federal 340B drug discount program, including by altering how federally funded providers receive discounts and the reach of provider agreements with outside pharmacies, according to legal experts.

Last week, Sen. Bill Cassidy, R-La., introduced the 340B for Patients Act, which he described as a "comprehensive" set of reforms for an oft-exploited program that hit $81 billion in drug sales in 2024.

"Clearly, there are real transparency and oversight concerns that prevent 340B from translating to better access and lower costs for patients," Cassidy said in a statement.

The 340B drug discount program requires drug manufacturers to sell certain drugs to hospitals and healthcare providers — also known as "covered entities" — contracted with Medicare and Medicaid at significantly discounted prices.

The size of the program has ballooned over the last 15 years, and come under sharp fire for allowing safety-net providers to buy low-cost drugs but collect reimbursements from Medicare, Medicaid or insurers at higher rates without passing all the savings on to patients.

Over the past year, drug manufacturers and industry groups have launched numerous legal battles over parts of the program, seeking changes ranging from how hospitals receive discounts to limits on the number of pharmacies a covered entity can contract with to distribute drugs.

Lucas Morgan, a shareholder at Buchanan Ingersoll & Rooney PC, said Cassidy's legislation suggests the program is under increasing scrutiny from the high levels of the federal government.

"The fact that [Cassidy's] giving it this level of attention shows that the 340B program is definitely under a microscope," he said.

Chanse Jones, a spokesperson for the Pharmaceutical Research and Manufacturers of America, an industry group that lobbies and litigates on behalf of drug manufacturers, welcomed the discussion draft.

"For too long, the program has been exploited by bad actors, driving up costs for patients, taxpayers and employers instead of directly benefiting low-income and uninsured patients," Jones said in a statement.

"We look forward to working with the Committee and stakeholders to advance meaningful reforms

that ensure 340B delivers savings to patients — not profits for hospitals and clinics," Jones added.

Here, Law360 Healthcare Authority looks at some key provisions of the 340B for Patients Act.

Rebates or Discounts?

One of the key bill proposals is focused on how covered entities would receive drug price discounts.

Currently, federally funded hospitals and providers pay 340B program prices up front. That would change under Cassidy's proposed legislation, and give drugmakers far more control over how providers would benefit from 340B pricing.

"A manufacturer may elect to make the ceiling price available to a covered entity through either a discount or rebate," the draft legislation said.

If passed, the legislation would require 340B hospitals and providers to pay full price and then apply for drug rebates.

The rebate model is favored by drugmakers, which argue that an upfront discount model allows significant fraud and abuse.

Johnson & Johnson, Eli Lilly and other major drugmakers have put forward their own 340B rebate models, and sued the U.S. Department of Health and Human Services over claims that it illegally blocked those efforts.

In May 2025, a D.C. federal judge **granted summary judgment** to the federal government, saying that the agency didn't exceed its authority when it said drugmakers must seek approval for their rebate plans.

Last summer, in a twist, the Health Resources and Services Administration, the HHS subagency that oversees the 340B program, introduced its own rebate model, only to face immediate litigation from hospitals and the American Hospital Association.

A district court judge ruled in favor of hospitals last year, issuing a preliminary injunction against HRSA's rebate program. In January, HRSA **dropped its appeal** after discussion with the AHA over any potential program.

HHS is currently considering a rebate pilot program, according to its website, and collecting public comments.

Daphne Kackloudis, a partner at Shumaker Loop & Kendrick LLP, said the rebate model is "incredibly alarming" for covered entities.

"Covered entities believe that not providing the discounts up front will result in a significant cash flow problem," she said.

Contract Pharmacies

The 340B drug discount program has been a boon for rural and low-income providers. But because many don't have the resources to dispense drugs, they contract with outside pharmacies to dispense prescription drugs.

While program rules initially allowed covered entities to contract with one pharmacy, under the Obama administration, HRSA lifted that restriction to allow providers to contract with an unlimited number of pharmacies.

The 340B for Patients Act would significantly curtail that expansion if passed in its current form. The legislation caps the number of contract pharmacies to five and requires the service areas of contract pharmacies to be within the 340B provider's service area.

In the original statute that established the 340B program, the Veterans Health Care Act of 1992, contract pharmacies weren't officially included — HRSA guidance added them in 1996 — but that would change under Cassidy's legislation.

Christopher H. Schott, a partner at Latham & Watkins LLP, told Law360 that officially including contract pharmacies in the law would "mark an unfortunate expansion of the program scope."

However, their inclusion would be balanced by the expansion of "imposing limitations and compliance obligations on contract pharmacies," he said.

These compliance obligations would require covered entities to implement programs that prevent duplicate discounts under 340B and Medicaid, and ensure discounted drugs are going to eligible patients. The proposed regiments would also apply to contract pharmacies, according to Schott.

"This includes imposing penalties for violations directly on the contract pharmacies themselves," he said.

The use of contract pharmacies has garnered the intense ire of drugmakers and led to significant litigation. Drugmakers have sought to impose restrictions on covered entities. In response, numerous states, including Rhode Island, Mississippi and Arkansas, have passed laws blocking drugmakers' restrictions.

Drugmakers have subsequently launched numerous lawsuits challenging those laws, but courts have **mostly sided** with states.

What is a "Patient?"

In April, drugmaker AbbVie Inc. **sued HHS** in D.C. federal court, arguing that the agency is allowing healthcare providers in the 340B program to use an "overly broad" interpretation of the word "patient" to dictate who could get 340B discounted drugs, leading to rampant abuse of the program.

HHS has characterized AbbVie's lawsuit as "an attempt by a highly profitable pharmaceutical company to upend the long-settled operation," among other arguments.

Federal guidelines in place since 1996 state that a covered entity can count a patient when they have "established a relationship with the individual, such that the covered entity maintains records of the individual's health care."

This definition would be narrowed under Cassidy's proposal, which would define "patient" to mean someone who has "received an outpatient health care service at the covered entity within the preceding 2 years."

There would also need to be a record that showed a patient maintained a relationship with a

covered entity for "a period of at least 3 years" or longer if required by another federal or state law.

Latham's Schott said that Cassidy's proposal would make clear that the "prescription of the 340B drug has to result from the outpatient health care service the individual received from the covered entity."

Shumaker's Kackloudis said that a lot of detail will need to be "unpacked" regarding exactly what it means to maintain a relationship with a covered entity. This could lead some covered entities to challenge that part of Cassidy's proposal.

"I imagine … pushback on that component of the definition," she said.

--Editing by Abbie Sarfo and Nick Petruncio.