Senate HELP Committee's 340B Hearing Mixes Calls for Increased Oversight with Bipartisan Program Support

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Scrutiny of 340B hospital oversight, bipartisan efforts to reform the drug pricing program and health care issues tied to the federal government shutdown took center stage on Capitol Hill Thursday as a key Senate panel held its first hearing on the 340B program in the 119th Congress.

Despite being led by Chairman U.S. Sen. Bill Cassidy (R-La.), an outspoken critic of the 340B program, the Senate Health, Education, Labor and Pensions (HELP) Committee's two-hour-long Capitol Hill hearing featured many instances of bipartisan support for the drug discount program and often veered off topic. Still, lawmakers in both parties appeared supportive of increased program oversight, particularly for 340B hospitals.

Some Republican members spent much of the Capitol Hill event taking issue with hospitals' use of 340B savings and calling for greater 340B program transparency—while others defended the program and criticized the drug industry. Meanwhile, many Democrats called for broader health care reforms and urged Congress to address the impasse over extending Affordable Care Act tax credits and remedying big Medicaid cuts—two issues at the center of the ongoing federal government shutdown. Some Democrats also voiced support for greater 340B program transparency.

Committee members also noted the expected 340B program changes that will come under the Health Resources and Services Administration's (HRSA) 340B rebate pilot model, which is set to go live in early 2026. However, implementation of that program—which responds to drugmakers' efforts to convert 340B from an upfront discount to a backend rebate—could be delayed due to the federal shutdown.

The hearing featured testimony from: Aditi Sen, the Congressional Budget Office's (CBO) health policy studies unit chief; Michelle Rosenberg, the Government Accountability Office's (GAO) health care director; and William Feldman, a Los Angeles-based physician and health policy researcher, who's authored several studies about the 340B program.

Opening Remarks

Cassidy, who released a series of reform recommendations this spring, echoed common drug industry criticisms of 340B in his opening remarks. Specifically, he pointed to a recent National Pharmaceutical Council (NPC) studyon 340B's effects on employer-sponsored insurance premiums—a report he previously referenced during a <u>July 31</u> HELP Committee hearing on healthcare affordability.

Provider advocates have panned the findings of the NPC—a nonprofit health research organization funded by 20 large pharmaceutical companies.

Cassidy further argued that participation in the 340B program has "ballooned with limited oversight, raising questions about how the revenue is used and whether it is actually directly benefiting low-income patients."

He added that "if this committee is serious about making health care more affordable, about making drugs more affordable, about improving commercial insurance and helping the patient, we need to reform 340B and put patients first."

U.S. Sen. Tammy Baldwin (D-Wisc.), a member of the bipartisan group of six senators working on 340B legislation, provided the opening statement for Democrats in lieu of HELP Committee Ranking Member U.S. Sen. Bernie Sanders (I-Vt.), who did not attend the hearing.

She criticized congressional Republicans for refusing to negotiate with Democrats over the ongoing federal government shutdown. Baldwin also touted her bipartisan 340B legislative work, arguing that the 340B program is "not without its problems" but must continue to support safety-net providers.

"Our working group wants to increase transparency and ensure appropriate oversight, as well as work towards a strong patient definition and address contract pharmacies, child sites and duplicate discounts," she said. "The best approach is to be comprehensive and bipartisan, so we can ensure that 340B continues to support our safety net as Congress intended it to be."

Witness Testimony

CBO's Sen overviewed the nonpartisan agency's recent report on 340B growth, which Cassidy and U.S. House GOP leaders had requested. She specifically listed the ways that CBO concluded that the 340B program could

increase federal spending, including the prescription of more and higherpriced drugs, the expansion of services and the integration of hospitals and off-site clinics.

CBO's claims about the 340B program's impact on federal spending has prompted strong pushback from 340B provider advocates, who've argued that the program reduces costs for taxpayers and improves access to care for low-income patients.

GAO's Rosenberg and Sen also both noted that the 340B statute does not have explicit guidelines for how covered entities can use 340B services.

Meanwhile, Feldman, the Democrat's witness, recommended multiple reforms to the program: increased transparency on how about much revenue is generated by the 340B program and how it's spent; new funding for HRSA to conduct audits; limits on child cites and contract pharmacies to ensure they're located in areas that serve disadvantaged populations. He further urged the committee to consider "restrictions on aggressive debt collection" and more assistance to help cover out-of-pocket costs.

"These reforms, if carefully targeted and implemented, could improve 340B without compromising the ability of community health centers and safety-net hospitals to provide care," he said. "However, and we should be very clear about this, ill-crafted reforms could jeopardize facilities that depend on 340B for their function and even their survival."

Feldman added that "340B reform alone will not reduce drug costs sufficiently." He recommended that lawmakers also look at "protecting and expanding price negotiation under the Inflation Reduction Act" and "addressing patent abuses by pharmaceutical companies."

Several Committee Members Praise Program

U.S. Sen. Tommy Tuberville (R-Ala.), who has not historically been active on 340B matters, began the questioning by arguing that 340B "is the only health care program that does not cost the taxpayers money."

"We should be expanding this, not reforming it," Tuberville said.

He was not the only Republican to offer support for the 340B program.

U.S. Sen. Susan Collins (R-Maine), said the 340B program "made the difference between a positive operating margin and a negative operating margin" for many Maine hospitals.

"If we were to limit or eliminate altogether the 340B benefit without other policy changes, we would wipe out the ability of these hospitals to operate," she said.

U.S. Sen. Lisa Murkowski (R-Alaska) concurred with Collins' remarks about 340B's importance and argued that there needs to be a mechanism to ensure 340B savings are passed on directly to patients. She further defended the use of 340B contract pharmacies and telehealth arrangements and asked witnesses about the impact of manufacturer 340B contract pharmacy restrictions.

"Contract pharmacies and telepharmacy services are critically important for us, connecting patients to critical pharmacies," Murkowski said, asking how contract pharmacies could be "preserved and strengthened" to help rural communities.

Feldman said his research has found that some covered entities have been expanding their contract pharmacies to more affluent areas. Sen referred to CBO's research attributing the growth of the 340B program, in part, to expanded use of 340B contract pharmacies, adding that CBO had not specifically investigated where these contract pharmacies were located.

340B Program Skeptics

Meanwhile, U.S. Sen. Roger Marshall (R-Kans.), a longtime critic of the 340B program, argued that the 340B program "began as a wonderful program," but has since been abused by "big monopolistic hospital systems." He called for the committee to advance 340B program legislation in the coming months.

"Before we leave for Christmas, I hope that we have legislation passed through committee and marked up," he said. "It's time to quit thinking about it."

Cassidy, who earlier this year hinted at plans to introduce his own 340B legislation, also appeared supportive of the HELP Committee marking up a bill, potentially the bipartisan working group's long-awaited legislation, after Marshall's comments.

"There may be a product for us to look at," he said.

U.S. Sen. Jon Husted (R-Ohio), who previously criticized hospitals' use of the 340B program during an August HELP Committee hearing, said he supports the drug discount program but believes it's "in desperate need of reform." He argued that while some covered entities "are truly serving low-income patients," others "are running Super Bowl ads and have huge CEO salaries."

NYU Langone Health faced initial congressional scrutiny in February after the nonprofit health system aired a Super Bowl ad in its local market area featuring former New York Giants receiver Victor Cruz. However, U.S. Rep. Greg Murphy (R-N.C.) ended up praising the system's "prudent financial management" after speaking with NYU Langone officials.

Husted said he hoped the hearing will help ensure 340B savings are targeted "toward the places that are in need of those resources to help drive down the cost for consumers."

U.S. Sen. Josh Hawley (R-Mo.), who opposed Medicaid cuts in the GOP-backed federal reconciliation law before ultimately endorsing the measure, spent most of his questioning criticizing "big pharma" and did not specifically mention the 340B program.

Other Committee Questions

Meanwhile, Democrats largely defended the program while appearing supportive of increased 340B oversight measures. They also spent most or all of their questioning criticizing Republicans for Medicaid cuts included in the recently enacted reconciliation law and for GOP leaders' role in the government shutdown.

Baldwin argued that the HRSA's 340B rebate pilot program could disrupt covered entities' finances and "threaten their ability to continue to provide their current level of care and services." She said a Wisconsin health center told her that the pilot proposal would significantly raise its upfront drug costs, adding that other state providers had shared similar concerns.

Baldwin also asked Feldman to explain how the rebate pilot, which providers have strongly opposed, could affect the 340B program, and whether Feldman recommended alternatives. Feldman offered that a third-party clearinghouse would ensure neutrality.

U.S. Sen. Tim Kaine (D-Va.), who along with Baldwin is a member of the group of six senators, said the working group was "making real progress" He also called for any 340B legislative efforts to prioritize federally qualified health centers (FQHCs), noting they rely on a "financial three-legged stool."

"First, funding through HRSA for community health centers; second, reimbursement for services provided to patients that have [federal] health

insurance...and then third, 340B savings," Kaine said. "These are the three pillars."

U.S. Sen. John Hickenlooper (D-Colo.), another member of the bipartisan SUSTAIN 340B Act working group, asked about strengthening HRSA's authority and ensuring the best entity is responsible for oversight of any reforms.

He offered that "this committee has a checkered history in terms of foxes in henhouses and making sure that we have the right people making the decisions relative to their own self interests."

U.S. Sen. Maggie Hassan (D-N.H.), asked witnesses what additional steps lawmakers could take to ensure 340B savings are used to improve patient access and argued that "big pharma" is responsible for raising prescription drug costs.

Meanwhile, U.S. Sen. Andy Kim (D-N.J.), who echoed other Democrats in criticizing Medicaid cuts in the recent reconciliation law, argued that many 340B providers are facing significant financial pressures as a result of that spending legislation. He also expressed concerns that 340B hospitals did not have explicit requirements for how they use their 340B savings.