

Inside Health Policy

E&C Panel Looks Into 340B As Legislative Efforts Increase In Congress

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Lawmakers are aiming for swift action to improve the federal program meant to provide prescription drugs at discounted prices to low-income and underserved communities but haven't yet agreed on an approach. At least three legislative proposals to address a variety of operational concerns were introduced this year and are circulating on Capitol Hill, with mixed reactions from program stakeholders.

The House Energy & Commerce oversight subcommittee met Tuesday (June 4) to hear from academic and health care industry experts on whether the 340B drug discount program is operating in a manner that best supports its mission to serve low-income, underserved and rural patient populations with access to affordable medications-- and, if not, what policy changes are in order to realign the program with its initial intent.

More than a year since the full committee advanced a bill that would require 340B hospitals to report their total program savings and other key metrics to the Health Resources and Services Administration (HRSA) annually, partisan division on the issue remains, with Republicans pushing to update the 340B program with additional requirements and clarified language while some Democrats worry such changes would hinder patient access.

"I am a supporter of the overall 340B program. There are many hospitals, including in my district, who are appropriately using the 340B dollars to keep their doors open and heavily rely on this program. Yet, we see reports about entities taking advantage of the system," E&C oversight subcommittee Chair Morgan Griffith (R-VA) said in his opening statement.

The hearing comes after Republican E&C committee member Larry Bucshon (IN), lead sponsor for the bill passed last year, introduced the "340B Affording Care for Communities and Ensuring a Strong Safety-Net (ACCESS) Act" in May along with Reps. Buddy Carter (R-GA) and Diane Harshbarger (R-TN). The bill seeks to clarify 340B statute to ensure savings produced by the 340B program are used to benefit patients. The bill would clarify the intent of the 340B program, address where low-income and uninsured patients can receive their prescriptions at 340B prices, codify the definitions of a 340B "patient" and "contract pharmacy," and establish new eligibility criteria for hospitals.

Another House bill introduced earlier this year is the "340B Pharmaceutical Access to Invest in Essential, Needed Treatments & Support (PATIENTS) Act," sponsored by Rep. Doris Matsui (D-CA). It aims to clarify participating drug companies are required to provide discounted drugs to covered entities through community and specialty

pharmacies, and to prohibit the enforcement of any restrictions or barriers on 340B pricing access by drug makers.

Also, a bipartisan group of senators released a discussion draft for the yet-to-be finalized "Supporting Underserved and Strengthening Transparency, Accountability, and Integrity Now and for the Future of 340B (SUSTAIN 340B) Act." The proposed Senate bill aims to address a myriad of issues different 340B participants have with the program, such as addressing contract pharmacy restrictions, cementing an official 340B patient definition and implementing child-site location registration requirements.

In recent years, lawmakers increasingly scrutinized 340B hospitals for a lack of transparency on how drug savings are spent and whether savings are being exploited for other operations. While lawmakers like Bucshon, Griffith and E&C full committee Chair Cathy McMorris Rodgers (R-WA) are supportive of the 340B program and don't wish to end or restart the program from scratch, they say more transparency and better oversight is needed to alleviate those concerns.

However, the full committee's ranking Democrat, Rep. Frank Pallone (NJ), is worried proposals to significantly rework 340B statute will not reduce prescription drug costs or help ensure that patients have access to affordable medicines. Pallone also opposed the Bucshon bill passed by E&C last year.

"Restricting 340B does not save taxpayer money or lower health care costs for patients. In fact, undermining 340B would severely weaken the health care safety net, creating greater obstacles for people who already struggle to receive accessible, affordable care," Pallone said at the hearing Tuesday.

Pallone also expressed doubt about whether the hearing would offer a balanced discussion on the 340B and its future, given that committee only heard from academic experts and representatives for a South Carolina community health center and an Ohio hospital. Pallone called out Republicans for not inviting witnesses to represent the perspective of drug companies or HRSA.

340B hospitals share Pallone's concerns. Hospitals say legislative proposals that aim to enforce additional reporting or eligibility requirements for hospitals would impede upon the program's mission and prevent them from providing proper care to their communities. Hospitals are also [against proposals to establish](#) a concrete definition for a 340B patient or child-site registration requirements.

Matthew Perry, president and CEO of Genesis HealthCare System, told lawmakers during the subcommittee hearing that the 340B program works well as it is because the statute does not impose any restrictions on how covered entities must use their savings from drug discounts to care for patients.

"Rather, it grants us the flexibility to direct resources toward the areas where our patients need them the most. That is the way Congress designed 340B. It is critical that

340B continues to provide this level of flexibility so we can continue addressing our communities' greatest needs," Perry said.

Perry added that proposals to update or clarify 340B statute would shrink the scope of 340B, significantly limit hospitals' ability to provide basic services to individuals and communities with low incomes, or possibly put 340B hospitals out of business.

Community health centers and drug makers are more receptive to the idea of updating the 340B statute. Carolina Health Centers CEO Sue Veer testified that participation in the 340B program makes it possible for community health centers to offer increased access to primary and preventive care that would otherwise be unfunded or underfunded and, therefore, unavailable in the communities served. But she said clarification of the law is still necessary.

Veer said lack of clarity in the law negatively impacts the ability of all 340B-covered entities and drug makers to develop and maintain partnerships. It's led to at least 29 drug makers imposing conditions on the drugs they provide at 340B discounted prices and to the emergence of business models that are not consistent with the program's mission, Veer added.

Veer encouraged lawmakers to consider ways to amend 340B statute in a manner that preserves the ability of covered entities to carry out the program's mission. Any legislation considered for passage must include provisions to define what a 340B patient is, identify prescription eligibility, codify the appropriate use of contract pharmacies, protect against third-party discriminatory contracting and fee structures, and command transparency and accountability that demonstrates how all 340B-covered entities are using program revenues and savings to the benefit of patients.

"340B is essential for many providers, including community health centers and rural hospitals, to ensure low-income and uninsured patients have access to affordable medications and health care services. Despite astounding growth in recent years, we know the 340B program is not always benefiting the patients who need it most," Thomas Johnson, executive director of the coalition ASAP 340B, said in a statement Tuesday.

"In fact, the numerous concerning reports of misuse beg the question: where are all the savings going?" Johnson asked.

ASAP 340B is a coalition of drug industry representatives, community health centers and other stakeholders open to reforming the 340B program. While hospitals are against provisions included in the new 340B ACCESS Act and would prefer lawmakers pass the 340B PATIENTS Act, ASAP 340B is in favor of the Republican-led bill and say it broadly aligns with the vision its members have for making changes to the program.

Stephen Ubl, president and CEO of the Pharmaceutical Research and Manufacturers of America (PhRMA), which is a member of the ASAP 340B coalition, says the 340B

ACCESS Act is a “major milestone in the longstanding effort to fix the 340B program so that it works better for patients and true safety-net providers.” -- *Gabrielle Wanneh* (gwanneh@iwpnews.com)