June 6, 2024

House Energy & Commerce Oversight and Investigations Subcommittee Holds Hearing on the 340B Drug Pricing Program

On Tuesday (June 4), the House Energy and Commerce Committee's Oversight and Investigations Subcommittee held a hearing on "Oversight of 340B Drug Pricing Program." Lawmakers on the Subcommittee heard from a panel of witnesses representing a county-run safety-net hospital, community health centers, disproportionate share hospitals (DSH), and policy analysts. During the hearing, there was broad bipartisan support for the 340B program, as well as bipartisan agreement that legislative changes could improve the integrity of the program. Some of the most discussed policies included increasing transparency around 340B dollars, clarifying the definition of a 340B patient, giving patients the flexibility to choose where they receive discounted drugs, tightening covered entity eligibility, and increasing the Health Resources and Services Administration's (HRSA) ability to oversee the program.

During the hearing, Reps. Earl "Buddy" Carter (R-GA), Larry Buschon (R-IN), and Diana Harshbarger (R-TN) also asked witnesses about their recently introduced bill, the 340B Affording Care for Communities and Ensuring a Strong Safety-Net Act (340B ACCESS Act). While most of the witnesses spoke favorably about the bill serving as a good first step to improving the 340B program, one witness raised concerns about the reporting requirements for covered entities and said it could provide a distorted view of entities' 340B programs and the benefits they provide.

- *For more information*: https://energycommerce.house.gov/events/oversight-and-investigations-subcommittee-hearing-oversight-of-340-b-drug-pricing-program

Opening statements

Subcommittee Chairman Morgan Griffith (R-VA): In his statement, Chairman Griffith said, "The 340B program was established by Congress to allow certain covered entities that provide care to a large number of underserved patients to purchase drugs at significant discounts from manufacturers." However, he said covered entities have no mandate to disclose how 340B drug discounts are used, calling the program a "black box." While he said he supports the "overall 340B program" and hospitals that "appropriately" use 340B dollars, he is concerned by the rapid growth in the program, which he said now accounts for almost $54 billion in annual discounted sales, and "reports about entities taking advantage of the system." He said, "I believe creating more transparency in the program so we can see where the dollars are flowing and ensuring the program is not being taken advantage of is the first step." Full Statement.

Ranking Member Kathy Castor (D-FL): In her statement, Ranking Member Castor said the 340B Drug Discount Program provides real savings to millions of Americans by redirecting a small portion of the "enormous profits of

pharmaceutical companies to hospitals and clinics that primarily serve vulnerable patients." She said she believes Republicans and Democrats can work together to improve the program but added that the program's growth should not be cited as evidence it is not working. Instead, she pointed to increases in the cost of drugs, particularly specialty drugs, to explain increased 340B program costs. She said drug companies have fought the 340B program for years, while drug prices for consumers continue to rise. She said as lawmakers talk about 340B oversight and reforms they must be clear on the benefits of the discounts for patients. Full Statement.

Full Committee Chair Cathy McMorris Rodgers (R-WA): In her statement, Committee Chair McMorris Rodgers said, "This hearing is an opportunity for us to evaluate recent trends and developments in the health care system that impact the 340B Drug Discount Program." She noted that 340B savings are "critical" to community health centers, high disproportionate share hospitals, and rural providers. She said, "In some cases, savings from the 340B Program are helping keep the lights on at what may be the only hospital in a rural community." However, she expressed concerns that the "program is being co-opted by larger, more profitable health care systems," which can increase costs for everyone. She cited evidence suggesting hospitals favored more expensive brand name drugs over lower cost alternatives in order to gain larger 340B savings, as well as a study suggesting the program incentivized hospital system acquisitions of independent oncology practices. She spoke in support of increased transparency to better understand how covered entities use the 340B program. Full Statement.

Full Committee Ranking Member Frank Pallone (D-NJ): In his statement, Committee Ranking Member Pallone said, "The 340B Drug Pricing Program is incredibly important to the ability of hospitals, community health centers, and specialized clinics to provide comprehensive, quality health care to underserved populations across the country." He noted, "Without these discounts, some providers with the slimmest fiscal margins would be forced to significantly pare back the care they provide, or worse, close their doors altogether." He touted Democrats' passage of the Inflation Reduction Act and provisions to lower drug costs. While he praised the Subcommittee's efforts to ensure covered entities are using 340B savings appropriately, he raised concerns that the hearing will not allow for a balanced discussion about 340B and its future, noting that Republicans did not invite drug manufacturers or HRSA to serve as witnesses. He concluded saying, "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." Full Statement.

Witness Testimony

Anthony DiGiorgio, Neurosurgeon, University of California San Francisco (UCSF) Health. In his statement, Dr. DiGiorgio, who works as a neurosurgeon at the California-based safety-net hospital Zuckerberg San Francisco General, spoke about abuses of the 340B program and potential areas for reform. He said today the program includes many large, consolidated hospital systems that use the 340B program to increase revenue, as well as newer entrants who are expanding into more affluent communities where they can sell discounted drugs at a profit. He said these abuses by larger hospital systems have prompted drug companies to increase list prices and restrict contract pharmacies and have led to increased consolidation among health care providers. He highlighted several areas for 340B reform including: increasing the DSH percentage required for eligibility and ensuring the DSH calculation includes outpatient visits; increasing transparency among 340B covered entities in a

straightforward manner as to not increase the burden on safety-net hospitals; defining eligibility criteria for patients; ensuring child sites meet program requirements limiting contract pharmacies to a hospital's referral region; and ensuring the 340B benefit can follow the patient. Full Statement

Sue Veer, President and CEO, Carolina Health Center. In her testimony, Ms. Veer, who leads a federally qualified health center, said the 340B program is "critical" for the patients they serve, enabling them to access lower-cost drugs and underfunded health care services, such as early childhood services. She raised concerns that the stability of the 340B program is at risk, noting that drug manufacturers view the program as a liability and growth in the program has further divided drug manufacturers and covered entities. Further, she said lack of clarity in the 340B statute has enabled manufacturers and courts to set conditions and restrictions on the program that are forcing some providers to close. She noted that her organization experiences a $667,000 loss annually due to manufacturer data submission requirements. Further, she said the lack of clarity has enabled some bad actors to flourish and those bad actors garner far more attention than the majority of covered entities who wish to uphold the program's mission. She praised the 340B Access Act and the Senate 340B Bipartisan Working Group's SUSTAIN Act Discussion Draft as good first steps and said Congress and stakeholders must work to find a workable solution. Full Statement

William (Bill) Smith, Senior Fellow and Director of Pioneer Life Sciences Initiative, Pioneer Institute. In his statement, Dr. Smith raised concerns that many of the 340B program's resources are being captured by vendors, including for-profit pharmacy chains and pharmacy benefit managers (PBMs), and some 340B hospitals are focusing on more affluent communities to increase revenues. He noted that there is no statutory requirement that uninsured or underinsured patients receive their drugs at the 340B discounted price and said taxpayers bear the burden when 340B covered entities purchase a 340B discounted drug but charge Medicare the full Part B rate and employers bear the burden when their health plans are charged full price for 340B drugs. Further, he said the program has led to rapid consolidation between hospitals and independent physician practices. He spoke in favor of increased transparency to provide more insight into how much revenue hospitals get from the 340B program and how much is spent on charity care. Full Statement

Matthew Perry, President and CEO, Genesis Healthcare System. In his statement, Mr. Perry said the Genesis Healthcare System is the largest care provider serving rural, southeastern Ohio and that it has a Medicare DSH percentage of 17.05% enabling it to qualify for the 340B program. He said the 340B program is a "lifeline" for Gensis and that fills the gap for federal insurance programs that "chronically" underfund care. He said Genesis saves about $56 million a year through 340B discounted drugs and is the difference between "operating at a razor-thin positive margin or an unsustainable negative margin." He said Genesis fully invests all revenue from 340B discounted drugs for insured patients back into patient care. For example, he said they reduce or provide no-cost prescriptions to eligible patients and fund specialized services, including the region's only trauma center. He spoke critically of proposals to restrict 340B discounts to low-income or uninsured patients or base them on provider levels of charity care, saying they could put Gensis out of business reducing access to care for rural Ohio residents. Full Statement.

Q&A

Subcommittee Chairman Griffith asked a series of questions to Dr. Smith on how hospitals are reimbursed through the 340B program during which he clarified that 340B covered entities are able to purchase discounted

340B drugs and bill Medicare and commercial insurance for their full coverage rates to generate revenue to invest in care for underserved patients. Dr. Smith said in most cases Medicare patients pay the 20% copay on the full price of the drug as opposed to the 340B discounted rate and that hospitals with larger shares of commercial patients are able to generate the largest 340B savings.

Ranking Member Castor noted that each of the witnesses expressed support for the 340B program and finding ways to strengthen and support the program. Mr. Perry said Genesis uses their estimated $55 million in annual 340B savings to care to their patient populations and invest in programs that are chronically underfunded. For example, he mentioned the funds are used to support their Cancer Care Center. Ms. Veer said she is supportive of proposals to better define patient eligibility and increase transparency into how 340B savings are used but believes covered entities must retain the flexibility to decide how to reinvest those savings to best serve their communities.

Chair McMorris Rodgers asked about hospital reporting and metrics to increase transparency. In response, Mr. Perry said covered entities have a tremendous amount of transparency already, noting they put together an annual 340B calculator report highlighting savings and investments. Ms. Veer said her entity reports 340B data to their board and complies with federal reporting requirements. She said she supports measures to report the populations served, including both uninsured and underinsured, and programs and services that are supported by 340B savings. Chair Rodgers also asked about the similarities between site-neutrality, 340B and provider consolidation. Dr. DiGiorgio said larger 340B entities have a competitive advantage over smaller independent practices that may not be 340B eligible, which can drive independent practices out of business or lead them to be acquired. When asked about whether there is value in allowing employers to review acquisition cost data, Dr. Smith said yes.

Committee Ranking Member Pallone spoke about the beneficial ways covered entities use 340B savings. Mr. Perry said without the 340B program to cover the gap in Medicare, Medicaid, and Tricare, Genesis would not remain in business. Ms. Veer said her organization also relies heavily on 340B and noted that not all HRSA-required FQHC services are reimbursable and 340B helps them meet those requirements. Ranking Member Pallone said the Committee's efforts "should be focused on enhancing 340B to provide the greatest patient benefit" and criticized efforts to reduce the program's size and increase complexity.

Rep. Jan Schakowsky (D-IL) raised concerns that some pharmaceutical company restrictions affect consumers' access to drugs and negatively impact safety-net providers. Mr. Perry said contract pharmacy restrictions have resulted in large financial losses for covered entities and that the specialty pharmacies allowed can be hundreds of miles away, which impacts hospitals' ability to invest in patient care. Ms. Veer said 340B funding can help support food insecurity issues that contribute to obesity and hypertension.

Rep. Michael Burgess (R-TX) asked about the locations of contract pharmacies in relation to covered entities, noting that he discovered some Texas patients are required to use Massachusetts pharmacies. Dr. Smith said "the most confusing aspect" of 340B is the location of the contract pharmacy. Dr. Smith explained that prior to March 2020 hospitals without an in-house pharmacy could contract with a single pharmacy in the community, but noted that HRSA expanded that to an unlimited number of pharmacies and data suggest hospitals are contracting with pharmacies hundreds of miles from their locations.

Rep. Jeff Duncan (R-SC) asked Ms. Veer to talk about innovative ways Carolina Health Center uses 340B savings. Ms. Veer spoke the ability to create and maintain a primary medical home in the community for patients who were using the emergency department for primary care needs. She said those patients are able to get affordable medications through 340B and they are able to offset some of the cost of the center, which serves a large portion of uninsured and underinsured patients. Rep. Duncan also asked about ways to improve the integrity of the 340B program to which Dr. DiGiorgio said increased transparency to show where 340B drugs are being purchased, who they're being purchased for, who's paying for the drug, and what the covered entity's revenue from the drug is.

Rep. Paul Tonko (D-NY) spoke in favor of the 340B program and safety-net providers who serve vulnerable patient populations and asked Mr. Perry how 340B enables Genesis to serve patients in a predominantly rural area. Mr. Perry said it enables them to provide high-quality care and support underfunded programs. When asked about the impact of eliminating or reducing 340B, Mr. Perry said it is good that more entities that meet the requirements are enrolling in 340B.

Rep. Debbie Lesko (R-AZ) spoke in favor of the 340B Drug Pricing Program and the 340B covered entities in her district. When asked whether increasing the 340B covered entity eligibility percentage would benefit patients, Dr. DiGiorgio said it would ensure the discount is going to hospitals that take care of disproportionate share patients and crack down on hospitals that may be abusing the program. He said he believes patients should be able to control how they access discounted drugs. Dr. DiGiorgio also said he does not believe increasing the hospital eligibility threshold would impact low-income patients' access to affordable care, noting that he believes outpatient services should be included in the program. When asked about the roll of contract pharmacies, Dr. DiGiorgio said if the DSH percentage is adjusted and the discount is allowed to follow the patient the only limit on contract pharmacies should be that they are used within a hospital's referral region.

Rep. Scott Peters (D-CA) spoke in favor of the 340B program but raised concerns that some covered entities may be misusing the program to support more affluent populations and spoke in favor of policies to clarify the definition of a patient under the program. He noted the need for consensus on ways to reform the 340B program to ensure it is not dictated by courts. In response to a question on potential reforms, Ms. Veer said there is consensus around the intent of the program and there is some consensus around clarifying the definition of patient eligibility and prescription eligibility. She said it is important that those definitions be built on direct patient care relationships, and said if you get the patient definition right it should not matter where prescriptions are filled.

Rep. Dan Crenshaw (R-TX) spoke in favor the 340B program but also the need to ensure the discounts reach the intended patient population. He asked witnesses about whether better defining a 340B patient or creating a new patient ID would improve program integrity. Mr. Perry said he isn't sure how a patient ID system would work but noted his health system tracks every 340B patient to comply with HRSA and statute. Dr. DiGiorgio said it could be helpful to understand where patients receive the majority of their care and spoke in favor of basing covered entity eligibility on the DSH metric, raising concerns that other metrics like uncompensated care, charity care, or hospital prices could be gamed. When asked about greater transparency around duplicative discounts, Dr. DiGiorgio and Ms. Veer spoke in favor of increasing transparency into duplicative discounts, with Ms. Veer speaking about proposals that leverage independent clearing houses to identify the duplicative discounts.

Rep. Rick Allen (R-GA) spoke in favor of the 340B program but also the need to ensure discounts go to low-income and rural patients. Ms. Veer spoke to the need for increased transparency and accountability and the need to accurately report the patient population served, but said there is disagreement on the metric to use. Mr. Perry spoke about how Genesis uses 340B savings to track and monitor patients and invest in underfunded programs that support patient care.

Rep. Larry Bucshon (R-IN) said the 340B program is critical but that existing statute has created ambiguity and recent court cases have created uncertainty around the future of the program. He said that HRSA doesn't have the authority needed to oversee the program and noted that his bill, the 340B Access Act, clarifies key definitions and increases transparency around the program. He specifically spoke about the need to increase transparency reporting requirements for DSH hospitals.

Rep. John Joyce (R-PA) spoke in favor of the 340B program but raised concerns about the rapid growth and the potential to incentivize consolidation. He asked whether requiring 340B covered entities to spend savings directly on patients would curb hospital abuses and ways to better define a 340B patient. Dr. DiGiorgio said that requirement alone is unlikely to address the issues because of disparities in hospital prices and noted that any definition of a patient should include having established ongoing care with the covered entity.

Rep. Diana Harshbarger (R-TN) spoke about the growth in 340B covered entities and the impact on consolidation, rising health care prices and federal spending on health care. Dr. DiGiorgio agreed with the correlation. She asked whether tax-exempt hospitals participating in 340B should have additional requirements and trends of some 340B covered entities shifting toward more affluent communities. Separately, she discussed the 340B Access Act, noting it would reform the 340B program and increase transparency and allow certain hospitals to have unlimited contract pharmacies. Ms. Veer said the bill would help rural and critical access hospitals maintain their independence. In response to a question, Ms. Veer noted that drug manufacturers' restrictions on covered entities' use of contract pharmacies can limit rural providers' ability to serve patients who live thousands of miles from the hospital.

Rep. Gus Bilirakis (R-FL) spoke in favor of the 340B program but also for reforms to improve program integrity. He spoke critically of the Biden administration's interpretation of 1115 waiver guidelines and uncompensated care and the impact on 340B hospitals in Florida and Texas. Dr. DiGiorgio said there are many ways to improve uncompensated care without relying on 340B.

Rep. Earl 'Buddy' Carter (R-GA) asked Mr. Perry if he opposed the 340B Access Act, which aims to address misaligned incentives that increase consolidation in health care. Mr. Perry spoke against the transparency provisions, raising concerns that the bill "cherry picks" metrics that could be used to provide a distorted view of how organizations are using the 340B program. As an example, he raised concerns about reporting charity care. Dr. DiGiorgio separately said transparency can help improve the program by showing who purchased the drug, who reimbursed the drug, which patient the drug went to, and how much revenue was made off the drug. Dr. DiGiorgio and Ms. Veer called Carter's bill a good start to help sustain the program.

If you have questions, please contact Heather Meade or Heather Bell.

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