U.S. SENATE
COMMITTEE ON HEALTH, EDUCATION, LABOR AND PENSIONS
"PERSPECTIVES ON THE 340B DRUG PRICING PROGRAM"

THURSDAY, MARCH 15, 2018

Questions for the Record – Ms. Sue Veer

Senator Lamar Alexander

1. **The Office of the Assistant Secretary for Planning and Evaluation estimated that Americans spent $457 billion on prescription drugs in 2015.[1] Of that, approximately $12 billion was spent on 340B drugs, which amounts to an estimated $6 billion in savings for hospitals and clinics that participate in the program, according to the Health, Resources, and Services Administration (HRSA). This would mean that the $6 billion in 340B savings represented 1.3 percent of the total purchases of prescription drugs in the United States in 2015. However, it was clear at the hearing, there is not a general consensus around these numbers.**

   How much did Americans spend on prescription drugs in the United States in 2015 and 2016?

   As a representative of my community health center, Carolina Health Centers Inc., as well as a consultant for the National Association of Community Health Centers (NACHC), I can only speak to data that is publicly available as this is data that neither I, nor NACHC, collects or tracks. As is noted above, the Office of the Assistant Secretary for Planning and Evaluation estimated that Americans spent $457 billion on prescription drugs in 2015, which includes $328 billion for retail drugs and $128 billion for non-retail drugs. [2] Similar data was not available for 2016.

   What is the dollar amount of prescription drug sales that were subject to a 340B discount? How much did participating hospitals and clinics collectively spend on 340B drugs in 2015 and 2016?

   Given that this is not data that we track or collect, we point to the same numbers included in the statement above, that "approximately $12 billion was spent on 340B drugs in 2015."[3] This was also referenced by HHS in their notice of Final Rule implementing the 340B Ceiling Price policy and Civil Monetary Policy published in January 2017. The

[1] https://aspe.hhs.gov/pdf-report/observations-trends-prescription-drug-spending
[2] https://aspe.hhs.gov/pdf-report/observations-trends-prescription-drug-spending

FY19 HRSA Budget Justification notes that "In 2016, total sales in the 340B program were approximately $16 billion."[4]

What is the average discount received on a 340B drug relative to the price of a drug with no discount?

I don't think we, as covered entities, are in a position to know the average discount, because there are very diverse purchasing options in the non-340B market. The actual price being paid through non-340B channels is subject to variables such as volume discounts, premium points, rebates, and GPOs; consequently, there is no single definitive data point to which the 340B ceiling price may be compared. The 340B discount can also change dramatically from one quarter to the other if, for example, the manufacturer has raised the price of the drug faster than the rate of inflation and an inflationary penalty is applied[5].

I do, however, strongly believe that the $6 billion in discounts quoted in the first part of your question significantly overstates the actual discounts realized by hospitals, health centers, and other eligible clinics. In its 340B ceiling prices and manufacturer civil monetary penalties rulemaking, using $12B in 340B drug sales in 2015, HRSA stated that "assuming covered entities pay 25 to 50 percent less than non-340B price, HHS calculated the estimated total savings in CY 2015 to be approximately $6 billion." Obviously, the total discounts realized for all 340B drugs purchased depends on the volume of drugs acquired at a price point/discount level. However, applying the same estimate that HHS used (discounts between 25% and 50%) the actual discount (for 2015) would be more than $3 billion (25% of $12B) but likely much less than $6 billion (50% of $12B).

2. **There is agreement that the 340B program serves a valuable role such as by helping low-income patients afford their health care, among other examples. However, there is confusion about the program's purpose and requirements because Congress did not make the program's purpose clear.**

What do you believe is the purpose of the 340B program?

I believe the purpose of the 340B program is to help ensure that the nation has a viable and effective health care safety net. The 340B Program contributes to the effectiveness and viability of that safety net in a number of critical and dynamic ways.

As both my written and oral testimony to the Committee emphasized, access to affordable prescription medication is one of the primary drivers of improved individual

[4] https://www.hrsa.gov/sites/default/files/hrsa/about/budget/budget-justification-fy2019.pdf
[5] See 42 U.S. C.

and population health. The 340B program plays a significant role in ensuring access to affordable medication, thereby increasing the effectiveness of the care provided by safety net providers such as Carolina Health Centers and all the other community health centers in the country, which provide all services – including pharmacy services – to low-income, uninsured and underinsured individuals on the basis of an income-based sliding fee. This directly improves health outcomes for individual patients and contributes to cost-effectiveness throughout the health care delivery system through improvements in population health and reduced use of other, more costly settings of care.

I believe Congress was clear in its intentions for the 340B Program when it enacted the statute in 1992. It is important to remember that the genesis of the 340B program was manufacturers reducing voluntary discounts to safety-net providers (who became covered entities) in the wake of the Medicaid drug rebate statute. These safety-net providers relied heavily on federal financial assistance, as well as other sources of community support, and the loss of those voluntary discounts posed a real threat to their viability. Consequently, as stated in the House Report that accompanied the Veterans Health Care Act of 1992, which created the 340B program, the 340B program was intended to "enable [covered] entities to stretch scarce Federal resources as far as possible, reaching more eligible patients and providing more comprehensive services."

As I note above, the 340B program allows health centers to provide patients with access to affordable pharmaceuticals; however, consistent with the stated intent of the statute, the program also enables health centers to use the savings that we would otherwise spend on more expensive drugs to provide more comprehensive services, leading to improved patient health outcomes, and ultimately, driving improved cost-effectiveness across the health care delivery system. The following examples of how those savings are used at my health center clearly demonstrate how the 340B Program has a positive impact on the viability of the safety net:

- Delivery of prescriptions to health center patients in outlying rural areas with little or no access to pharmacy services;
- Care management, care coordination, and medication reconciliation services;
- Oral health services (including preventive care) for low-income, uninsured, and sliding-fee eligible adults;
- Behavioral health counseling services for low-income, uninsured, and underinsured health center patients whose mental health/behavioral health symptoms do not reach the level of severity required for eligibility in the state's community mental health system;
- Continued provision of essential primary health care in communities with a disproportionate number of uninsured/underinsured patients, and/or high need for social support services resulting in uncompensated care for which the health center federal grant is not sufficient; and
- Otherwise uncompensated care such as bad debt and 3rd party denied services.

Without the 340B program, the scope of service provided at health centers like Carolina Health Centers would be compromised, which in turn, would compromise the strength of the nation's health care safety net.

Do you currently track how you spend money generated through participation in the 340B program?

Yes, all revenue generated by our health center, including that which is generated by our pharmacy services and our 340B discounts, is projected, tracked, and reported to our community-based, patient majority Board of Directors through our planning, budgeting, and financial reporting system. While this is not a line item transfer of funds in the accounting system, we are able to determine what the net margin is for each service or service delivery and determine what otherwise unfunded patient and community services are covered by that margin.

What percentage of your 340B savings goes directly towards lowering the cost of prescription drugs for patients? If 340B savings are not being used for this purpose, how are you using these savings?

The breakdown of percentage of savings allocated towards offsetting the cost of drugs and providing health center services varies from health center to health center according to community need, patient mix, income levels, and variations in prices of drugs. What is clear is that all of the savings are going to both lowering the cost of prescription drugs dispensed to uninsured and underinsured low-income patients and providing more comprehensive primary and preventive care services for all patients.

As I referenced in both my written and oral testimony, HRSA requires all health centers to reinvest all program income generated from all sources into activities that promote the non-profit mission and HRSA approved scope of project for the health center. My response to the first part of Question # 2 outlines some of the appropriate use of savings at my health center and I would be happy to compile examples from other health centers I have worked with across the country if that information would be useful.

Should there be requirements for how hospitals and clinics participating in the 340B program can use savings generated from the program?

Health centers already are subject to such requirements. In Section 330(e)(5)(D) of the Public Health Service Act, health centers are required to reinvest all 340B savings into activities that are approved under their HRSA/ Bureau of Primary Health Care (BPHC) Scope of Project or that otherwise promote the purposes of the approved project and advance their charitable mission. Further, health centers are subject to detailed and intense oversight as conducted by HRSA/BPHC, and are required to report detailed information on their operations to HRSA/BPHC.

Senator Bill Cassidy

1. **How many of your members have joint ventures with for-profit care facilities?**

   To clarify, my employer – Carolina Health Centers, Inc. is a sole non-profit community health center corporation and does not have members. However, in my work as a consultant for NACHC, which has afforded me a great deal of interaction with their members, I would say that it is not typical for health centers to enter into joint ventures.

   Based on an understanding of joint ventures as characterized by shared ownership and shared governance, among other things, the requirements of health centers to be governed by a patient majority board and to grow/expand based on a community need, do not necessarily align with the joint venture model. While health centers often contract with other providers and resources, this is based on meeting an identified community need. Further, due to requirements under Section 330 of the Public Health Service Act, federal fraud and abuse laws (e.g. Stark and anti-kickback), and federal tax exemption rules, these contracts typically are based on compensation at fair market value for services rendered and not on the division of revenue as is customary in a joint venture model.

Senator Patty Murray

1. **Spending on 340B drugs has increased over the past few years, but such spending still represents a small fraction of drug sales. Between 2012 and 2015, the U.S. drug market grew from about $318 billion to $425 billion. Meanwhile, the 340B market grew by about $5 billion – increasing its share of the total drug market by less than 1 percent.**

   How has the 340B program helped your entities offset the rising cost of prescription drugs and continue providing comprehensive services needed by patients?

   As I note above, the 340B program allows health centers to provide patients with access to affordable pharmaceuticals and consistent with the stated intent of the statute, the program enables health centers to use the savings that we would otherwise spend on more expensive drugs to provide more comprehensive services. The following examples of how those savings are used at my health center clearly demonstrate how the 340B Program has a positive impact on the viability of the safety net:

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Based on my experience and observations, participation in the 340B program has the effect of offsetting the rising cost of prescription drugs in two ways. First, for our health center and many others I have consulted with, education about and participation in the 340B program has created a culture of cost-consciousness that significantly impacts prescribing patterns. By that I mean our provider team works very hard to ensure that patients have access to the most affordable effective treatment. Secondly, by ensuring that patients have access to affordable medication, we are able to more effectively manage their chronic disease and reduce the need for additional, and likely more expensive medication, thereby positively impacting the cost curve as it relates to the cost of prescription medication

The expansion of contract pharmacies over the past few years has caught the attention of many stakeholders. In fact, 60 percent of rural hospitals rely on contract pharmacies for more than half of their overall 340B benefit. There are many rural health settings within my home state of Washington that participate in 340B.

What role do contract pharmacies play in 340B, including to improve the continuity of care and drug adherence for eligible patients in rural communities?

As I noted in my testimony, while most health centers likely would prefer to implement the 340B program using an in-house pharmacy, operating an in-house pharmacy can be daunting and sometimes presents insurmountable barriers. Health centers might lack space, technology, ability to recruit professional staff and availability of operating capital to sustain the in-house pharmacy operation. Further, providing access to medications outside of clinic hours may present an additional drain on limited health center resources.

The flexibility to contract with more than one pharmacy improves health centers' ability to provide for their patients and ensure access to affordable medications. Even health centers with in-house pharmacies often find contract pharmacies to be useful tools to expand patient access, as patients have more pharmacies to choose from, including those that are closer to their home or work, and that have longer hours than an in-house pharmacy can provide.

This is particularly important in rural areas, where patients potentially have to drive tens to hundreds of miles to reach their health center; having access to a contract pharmacy increases the likelihood that patients will both obtain, and maintain adherence to, their prescriptions, thereby effectively managing their chronic diseases and other treatment regimens. It is also important to note that contract arrangements, particularly with independent pharmacies in these rural communities, may service to promote effective community relations.