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Full Committee Hearing: Perspectives on the 340B Drug Discount Program
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Good morning Chairman Alexander, Ranking Member Murray and Members of the Committee.

My name is Sue Veer. I am the President and CEO of Carolina Health Centers, Inc. (CHC) a Federally Qualified Health Center (FQHC) that serves as the primary care medical home for 27,705 patients in the west central area of South Carolina known as the Lakelands. However, today I am here representing the 1,400 community health center organizations that serve as the primary care medical home for more than 27 million patients at over across 10,000 sites across the country.

Included in my testimony is an overview of the unique characteristics of health centers and how the creation of the 340B Drug Pricing Program (340B program) was critical in enabling many health centers to start providing their patients with access to affordable pharmaceuticals. My testimony continues with an overview of the training and technical assistance work I and others at NACHC have been doing specific to the 340B program, and concludes with four key perspectives on this important program, including how health centers use the program and the resulting savings to expand access to essential primary care and drive improved clinical outcomes.

Thank you for the invitation to serve as a witness at this hearing and to highlight the vital importance of the 340B program to health centers nationwide.

Background on Health Centers and the Creation of the 340B Program

Community Health Centers ensure that underserved patients have access to quality comprehensive primary care

Community Health Centers – also known as health centers, Federally-Qualified Health Centers or FQHCs – are the backbone of our nation's primary care safety net. Our fundamental characteristic is a commitment to ensuring everyone has access to high-quality, comprehensive primary care regardless of demographic, geographic, and socio-economic barriers. By law and by mission, health centers serve areas and populations that the federal government has determined to be medically underserved, and we are required to provide services without regard to a patient's ability to pay. Nationally, almost a quarter of health center patients are

uninsured, and over 70% of them have incomes below the Federal Poverty Level (FPL); for those patients with incomes below the FPL, they pay no more than a nominal fee for the full range of services we provide. An additional twenty percent of patients have incomes between 101% and 200% FPL, these patients are charged discounted rates based on a sliding fee scale.

All health centers provide their patients with access to a comprehensive range of primary and preventive health care services, and many also provide dental, mental health, and substance use disorder services. In addition, health centers provide a wide array of care management, patient education, and assistive services that support access to care, promote enhanced clinical outcomes, and reduce total costs across the health care system. Over two-thirds of health centers serve as Primary Care Medical Homes, which demonstrates health centers' commitment to patient-focused quality and comprehensive care.

Another core characteristic of health centers is how they are governed – namely, by their patients. Each health center organization is an independent, non-profit corporation governed by its own Board of Directors, and a majority of each Board's members must be actual patients of that health center. This structure ensures that each health center remains directly responsive to the unique needs of its patients and community. In an era of increasing consolidation among health care providers, health centers are local, community-based organizations.

The creation of 340B reduced drug prices for health centers and expanded access for their patients

The creation of the 340B program in 1992 played a critical role in health centers' ability to provide affordable care for underserved populations. Prior to that time, the majority of health centers were unable to offer pharmaceutical services for their patients, as the costs of the drugs were often beyond their reach. Thus, the health centers wrote prescriptions for medically necessary drugs that patients often could not afford to fill at commercial pharmacies. As small, community-based providers, health centers lacked the market power to negotiate significant discounts off the sticker price. And while Patient Assistance Programs (PAPs) were available, the amount of paperwork involved and the narrow scope of the programs significantly limited the degree to which health centers could help their patients access the drugs they needed.

This situation was compounded in 1991 upon creation of the Medicaid Drug Rebate Program (MDRP). An unintended consequence of the MDRP resulted in drug manufacturers becoming concerned that selling drugs to non-Medicaid purchasers at discounted prices could increase their exposure to higher Medicaid rebates. That fear caused them to pull back on some of the discounts they had historically provided to safety net providers. In response, Congress created

the 340B program as part of the Veterans Health Care Act of 1992, which also provided similar relief to the VA.

The 340B program established maximum prices that manufacturers could charge safety net providers for drugs. For those health centers that had the resources to operate their own pharmacies, the creation of 340B was a critical moment in their ability to offer affordable medications to their patients. As discussed below, the ability to realize savings on 340B drugs provided to insured patients also provided resources to expand access to other services for health centers' low-income, medically underserved population.

NACHC Activities to Support Health Centers' 340B Operations and Compliance

My interest in maintaining the scope and integrity of the 340B Drug Pricing Program relates to my dual role as both a health center CEO and a NACHC consultant. As President and CEO of Carolina Health Centers, Inc. (CHC) I provide leadership and oversight for a comprehensive health center program of which pharmacy services are an integral part. CHC opened its first in-house pharmacy, Carolina Community Pharmacy (CCP), in 2005. Our pharmacy program has grown to include two stand-alone community pharmacy locations, daily delivery of prescriptions to our 12 medical practice sites for our patients living in very rural areas, and a new initiative to integrate clinical pharmacists into the patient care teams at our medical practices. My health center made the strategic decision to implement 340B using an in-house model, meaning that we own and operate the pharmacy and manage it under the governance of CHCs' community-based/patient majority Board of Directors. We operate as an "open" pharmacy meaning that prescriptions are filled for both health center patients and the general public, although only prescriptions for CHC patients may be filled using 340B purchased inventory. This "open" model serves as a gateway to engaging people in a primary care medical home, reducing the use of urgent and emergency care, and promoting chronic disease management. Of all prescriptions dispensed through CHCs' sites in 2016, only 33% were covered by a third-party payer and 17% were delivered to outlying rural practice sites where patients have limited access to retail pharmacies.

My individual health center's experience is offered as context for my role as a NACHC consultant. Approximately 5 years ago, NACHC convened a 340B Work Group, in recognition of the importance of pharmacy to health centers' overall model of care, and the vital role of the 340B Drug Pricing Program in enabling health centers to implement pharmacy services. I was honored to be asked to chair the Work Group, which meets face to face twice a year at major NACHC conferences as well as by teleconference on an as needed basis. Since that time, we have also convened a 340B Key Contacts group comprised of at least one representative from each of the state and regional Primary Care Associations (PCA). Together, these two groups

provide tremendous insight into how different health centers across the nation operationalize their 340B program as they work to increase access to care and expand services in response to the needs of the communities they serve. These groups have also helped NACHC to identify best practice models and develop strategies for training and technical assistance (TA) focused on 340B implementation and compliance, as well as identifying challenges health centers encounter in their attempts to optimize the value of the program for their patients.

In 2016, I became an official consultant for NACHC, and my activities since that time have included the following:

- Fourteen state-specific 340B Summits: These Summits, which included health centers covering sixteen states, last from 1-2 days at the discretion of the PCA, and are targeted to both the C-Suite and pharmacy leadership. In advance, I research the state-specific environment, including by surveying the health center membership, to ensure that the material is reflective of their specific situations. To date, we have provided this training for health centers in 16 states, and three more are scheduled for the near future.
- NACHC conferences and trainings: NACHC has incorporated 340B program elements throughout its training curriculum. For example, later this week I will be speaking about the 340B program at two different sessions as part of NACHC's spring conference, and next week I will be presenting on-line as part of NACHC training for Chief Financial Officers. Also, we recently launched a monthly teleconference called "340B Office Hours" which allows the health center 340B community to have a dialogue around operational and compliance questions.
- Health-center-specific sessions at 340B Coalition Conferences: Because of the unique issues that health centers encounter when operating a 340B program, we collaborate with 340B Health – the organization that coordinates the twice-yearly 340B Coalition Conference – to include sessions that are specific to health centers during their semi-annual conferences.
- 340B technical assistance email: We have created an email address for health centers seeking technical assistance with 340B issues. To date, we have responded to hundreds of individual questions and requests for assistance via this email.

Note that NACHC consults with Apexus–the 340B Prime Vendor – to ensure that all training and technical assistance activities are aligned. I serve as faculty for the Apexus' in-person trainings (called "340B University") and serve on one of its Advisory Councils. Apexus also serves as a first line of response when addressing individual TA requests, and has recently created a special version of 340B University to specifically address health centers' unique circumstances.

What follows are four observations related to health center participation in the 340B Drug Pricing Program -- notably, the value it brings to patients and communities served.

Four Health Center Perspectives on the 340B Program

1. **Health centers are good stewards of the 340B program.**
   The health center mission and model of care are consistent with the congressional intent of the 340B Drug Pricing Program – "to stretch scarce federal resources as far as possible, reaching more eligible patients and providing more comprehensive services." As such, since its establishment in 1992, health centers have worked hard to ensure that they are good stewards of the 340B program. To that end, health centers ensure that vulnerable patients can afford their medications; reinvest 340B savings toward purposes that advance health centers' safety net mission of expanding access for underserved populations; and adhere to extensive reporting and oversight requirements to demonstrate that health centers are increasing access to affordable primary health care.

   - **Health centers work to ensure that low-income uninsured and underinsured patients can afford to access their medications purchased through 340B.** As discussed above, a fundamental characteristic shared by all health centers is the commitment to ensure that patients can access appropriate medical care, regardless of their insurance status or ability to pay. As a result of this commitment, health centers use 340B savings to ensure that low-income patients can afford their medications. Specifically, health centers use 340B savings both to offset the cost of providing prescriptions to uninsured and underinsured patients on an income-based sliding fee scale, and to finance the considerable resources necessary to leverage PAPs on behalf of their patients.

   - **Health centers must reinvest all 340B savings into activities that advance their HHS-approved mission of expanding access for underserved populations**
     As the Committee is aware, the 340B statute does not specify how providers should use the savings they accrue under 340B. However, the authorizing statute for the health center program – Section 330 of the Public Health Service Act requires in Subsection330(e)(5)(D) – that health centers must reinvest all 340B savings into activities that further the goals of the health center project and enable the health center to provide high quality, affordable care to medically underserved populations. Later, I will discuss some of the many ways in which health centers use 340B savings to expand access and improve outcomes for their patients.

   - **Health centers are subject to extensive federal oversight and reporting requirements**
     Each of the more than 1,400 health center organizations are subject to extensive and on-going oversight from the United States Department of Health and Human Services (HHS) Health Resources and Services Administration (HRSA).

- The HRSA requirements with which health centers must comply are spelled out in a 92-page manual and are grouped into 18 major categories, including – but not limited to – clinical quality, governance structure, financial management and accountability, ensuring access, and collaboration with other local providers[1].
- HRSA consistently oversees and enforces compliance with all of these requirements through a variety of mechanisms, including: on-site compliance reviews, frequent interactions with project officers, and regularly-scheduled reporting obligations.
- HRSA also approves health centers' "Scope of Project", meaning those primary care delivery sites, services, and providers that are considered part of the health center's program operations. Only those approved delivery sites and services that have undergone HRSA scrutiny and are subject to HRSA's ongoing oversight are eligible to participate in the 340B program – and 340B savings can only be used to support activities which are consistent with and advance our health center project.
- Each year, health centers must submit extensive data to HRSA on a wide range of measures, including but not limited to: patient characteristics, payer mix, services, costs, and clinical outcomes. The manual with instructions for how to compile this data is 200 pages long, and each health center's data is posted publicly on the HRSA website.

2. The 340B program is essential to each health centers' ability to achieve their congressionally-mandated mission of providing affordable access to care for underserved populations.

Access to affordable prescription medications is recognized by most medical providers as one of the primary drivers of improved health outcomes. This point was made emphatically by the Chief Medical Officer of my health center when he stated: "To diagnose and not be able to treat the patient effectively is always an exercise in futility and sometimes a death sentence." Health centers serve as patient-centered medical homes and are responsible for the overall management of the health of their patients; however, if patients cannot afford their prescriptions, health centers will be limited in their ability to treat acute conditions, manage chronic disease, and optimize their patients' health outcomes.

[1] For a complete listing of all requirements, see the 92-page Compliance Manual available at: https://bphc.hrsa.gov/programrequirements/pdf/healthcentercompliancemanual.pdf

Beyond ensuring access to affordable pharmaceuticals, health centers use 340B savings to support other activities that increase access and improve outcomes. Here are some examples of ways in which health centers use 340B savings to increase access to high-quality, affordable care for their patients:

- Implementing delivery systems and mail order pharmacy programs to ensure access to affordable prescription medication for health center patients in outlying rural communities with limited or no access to affordable pharmacy resources. One such service makes over 25,000 affordable prescriptions accessible to low-income and underserved persons.
- Establishing multidisciplinary Care Transition Teams providing care management for patients at high risk for repeat hospital admissions. The model for this program resulted in savings to their local health care delivery system of over $1.4 million in the first year of the program.
- Subsidizing the cost of behavioral health counseling provided by a local partnering agency on-site at the health center to low income, uninsured, and underinsured patients who would either not qualify for, or have long delays in receiving care from the local mental health agency.
- Establishing a pharmacist led interdisciplinary controlled substance review process with the goal of decreasing inappropriate prescribing of opioids and the associated patient morbidity and mortality. This initiative resulted in a 66.2% reduction of patients on chronic opioids and cut premature deaths in half over a 3-year period.
- Covering the cost of uncompensated care provided to patients in communities with high rates of poverty for which the health center's Section 330 grant funds are inadequate.
- Maintaining health center operations in sites where mitigating circumstances result in higher cost and subsequent operational losses. Examples of mitigating circumstances are disproportionate need for unfunded enabling services such as social work, translation, transportation, and care coordination or increased cost of provider staffing in difficult to recruit to rural and frontier areas.

3. The contract pharmacy model enables health centers to expand access to affordable prescription medications.

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 until it reaches a break-even point. Further, providing access to medications after

clinic hours and on weekends may present an additional drain on limited health center resources.

The ability to contract with more than one pharmacy further improves health centers' ability to provide for their patients and ensure access to affordable medications. 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 have longer hours than an in-house pharmacy can provide.

Based on my experience with health centers across the country, there are three primary drivers of a health center decision to implement 340B using a contract pharmacy arrangement:

- Lack of capital and operational resources, as well as the organizational capacity to support the implementation and ramp-up to a financial viable pharmacy operation;
- Geographic dispersion of the health center's patient population in small rural areas unable to support a full-scale pharmacy operation within the health center site; and
- Potential disruption to small, locally-owned independent pharmacies, as it would pull away too many customers for them to remain economically viable, especially in rural areas.

It is worth noting that savings that health centers achieve though a 340B contract pharmacy arrangement may provide the resources necessary to implement an in-house pharmacy program moving forward, which, in my experience, appears to be an evolving trend.

4. A "one size fits all" approach to program changes could have unintended consequences.

At present, approximately 15 types of health care providers are eligible to participate in 340B. From an administrative perspective, it might seem simpler to implement a single set of rules that apply equally to all 15 types of eligible providers. However, a "one-size-fits-all" approach when making changes to the 340B program could potentially have unintended consequences for one entity and even further unintended consequences for another type of entity.

For example, health centers do not provide "charity care" in the generally understood manner of a designated, and perhaps limited, charity care fund. All FQHCs, by law and by mission, are required to see all patients, regardless of ability to pay. If health centers were required to report the amount of "charity care" provided, the broader concept of

community benefit would be a more appropriate measure, though not likely comparable to other covered entity types.

For this reason, when considering any potential 340B changes, we encourage policymakers to work with health centers to best understand the responsibilities and requirements that are unique to health centers and the patients we serve.

Conclusion

As my testimony demonstrates, the 340B program is vital to the nation's community health centers, our ability to provide our patients with access to affordable prescriptions, as well as to support needed services for our low income and underserved patients. Thank you for the opportunity to testify before you today and for recognizing the importance of the 340B program for health centers and the patients we serve.