Testimony of Sue Veer

President and Chief Executive Officer, Carolina Health Centers, Inc.
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Thank you, Chairman Griffith, Ranking Member Castor, Chair McMorris Rodgers and Ranking Member Pallone and members of the committee for the opportunity to appear on the issue of 340B.

My name is Sue Veer, and 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 approximately 26,000 patients in the west central region of South Carolina. I also have the privilege of serving on the Executive Committee of the National Association of Community Health Centers (NACHC) and the Board of Directors for the South Carolina Primary Health Care Association. I am honored to speak with you about the value of the 340B Drug Pricing Program (also referred to as 340B or the 340B Program) for the patients and communities we serve, as well as the over 31 million patients served by Community Health Centers across our nation.

My career in health care spans 40 years and includes working in community hospitals, a major academic medical center, private practices, and now, the community health center world. Though my work environment has varied, the one constant has been my strong commitment to advocating on behalf of patients and their families – ensuring that everyone, regardless of demographic or socio-economic circumstances, has access to appropriate and effective health care delivered with dignity and compassion. When I began working with Community Health Centers in 2001, I found the perfect fit for my commitment to patient and family-centered care and my training in business and organizational development.

I also discovered that, unlike other health care settings where I had worked, the approach to patient care is not episodic or limited to what can be addressed within the walls of a traditional medical practice. Our health centers care for and manage their patients across not just across the continuum of care, but often, the full spectrum of their lives. We provide comprehensive primary and preventive care and address social determinants of health by tackling difficult challenges like homelessness, joblessness, domestic violence, parenting skills, food insecurity, transportation, and so much more. Community Health Centers embody the concept of whole-person care, producing immeasurable value in those patients' lives and across the health care delivery system.

Carolina Health Centers (CHC) is a community based non-profit corporation and Federally Qualified Health Center (FQHC) established in 1977. It is governed by a community-based board of directors, 51% of which are patients of the health center. CHC's primary service area covers 3,708 square miles and includes the seven rural counties of Abbeville, Edgefield, Greenwood, Laurens, McCormick, Newberry, and Saluda.

CHC operates 16 medical practice sites, two community pharmacies, and provides agricultural farmworker health services. CHC's 16 medical practices include nine family medicine practices, two pediatric centers, and one practice site that includes both a family medicine and a pediatric practice. One of the family medicine practices operates as a faith-based practice and is aligned with various community ministries to facilitate referrals. We also serve as a Designated Collaborating Organization for the local mental health agency's Certified Community Behavioral Health Center (CCBHC) and have established primary care practice sites at four of their locations throughout the service area. Agricultural farmworker services are provided year-round at our family practice location in the rural community of Ridge Spring in Saluda County.

CHC has been a pioneer in developing an integrated pediatric medical home model that includes an array of early childhood services. For over 25 years, we have included child development professionals and evidence-based home visitation programs as part of our pediatric model of care.

Behavioral Health and Substance Use Disorder (SUD) services are provided through a combination of in-house behavioral health specialists and collaboration with the Beckman Center for Mental Health Services, the local office of the SC Department of Mental Health. CHC employs six integrated behavioral health professionals, and a Beckman Center counselor is at one of our practice sites.

Meeting the escalating need for Behavioral Health and SUD is a particular challenge due to the lack of adequate 3rd party reimbursement or any other funding source. While the South Carolina Department of Health and Human Services recently adopted new reimbursement guidelines for FQHCs to expand the types of billable providers, in a state that has not expanded Medicaid, few adults have Medicaid coverage. Consequently, these enhanced rules only benefit the pediatric population. We estimate that as high as 80% of our adult behavioral health visits have no source of 3rd party reimbursement. This challenge extends to the need for expanded SUD services.

CHC Department of Pharmacy includes two entity-owned community pharmacies, both of which are open to the public as well as CHC patients. In compliance with the prohibition against

drug diversion, 340B purchased inventory is used for only established patients of CHC and only for those prescriptions that emanate from CHC's medical practices and HRSA Scope of Project. The 340B Program enables us to offer deeply discounted prescription medication to our patients living at or below 200% of the federal poverty level (FPL) through our income-based sliding fee discount program. Of note, CHC's income based sliding fee discount does not only apply to uninsured patients. For insured patients living at or below 200% of FPL, the sliding fee discount can be applied to help with the burden of high deductibles and copays.

Given our large and very rural service area, the pharmacy operates a daily courier service that delivers prescriptions for established CHC patients to our outlying medical practice sites to ensure access for our patients. Prescriptions are available through mail-order, and we implemented home delivery within a limited range during COVID-19. We also provide prescriptions through several contract pharmacy arrangements, which are necessary due to geographic barriers and limited payer networks, primarily related to specialty drugs. In addition to operating a dispensing pharmacy, clinical pharmacists serve as part of the patient care team, assisting with patient and staff education and medication adherence.

Oral health care is provided through a network of contacted dentists with CHC providing a subsidy for low-income uninsured and underinsured patients.

Like most health centers, CHC provides an array of enabling services to promote patient access and effective utilization of the health center's services. Those enabling services include outreach, patient and community education, transportation support, translation, and referrals to community resources. Our comprehensive Quality and Population Health Department focuses on optimizing our patients' health through care coordination and case management.

According to the HRSA Universal Data System Report, CHC served 26,002 unduplicated patients in 2023. For the current fiscal year (June 1, 2023 - May 31, 2024), CHC projects a total operating budget of $50,420,892, and projected revenue of $52,361,376, for an expected year-end operating margin of 3.7%.

Intent and Value of the 340B Drug Pricing Program:

Early in my 18-year tenure with CHC, I came to understand that pharmacy must be a core component of the health center medical home model to achieve our goals of access, quality, and cost-effectiveness. Before the 1992 enactment of the 340B statute, most health centers did not have the resources necessary to include pharmacy in their scope of services. As a result,

access to affordable prescription medication was limited - particularly for their low-income, uninsured, and underinsured patients. The 340B Drug Pricing Program makes it possible for health centers to provide access to affordable prescription medication for those vulnerable populations. It also enables increased access to primary and preventive care that would otherwise be unfunded or underfunded and, therefore, unavailable in the communities served.

Recognizing the importance of the 340B Drug Pricing Program to the health centers and the communities they serve, I embarked upon developing expertise in health center 340B pharmacy policy and strategic development and have provided related training and technical assistance for health centers all across the country. In 2017, I had the honor of testifying before the United States House Energy and Commerce Committee in support of the integrity and value of health center 340B pharmacy programs. In 2018, I had the additional honor of providing similar testimony before the United States Senate Committee of Health, Education, Labor, and Pensions.

Following my testimony to the Senate HELP Committee in 2018, Senator Lamar Alexander requested that I respond to questions for the record. The first of those questions was: What do you believe is the purpose of the 340B Program? My response to Senator Alexander then, and what I continue to hold as truth today is that the purpose of the 340B Program is to help ensure 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 two very critical and dynamic ways. The first and most obvious is that 340B pricing provides access to affordable prescription medication for low-income, uninsured, and underinsured patients. Access to affordable prescription medication is critical as it is well recognized as one of the key drivers of improved health outcomes. This is not only important in terms of quality for the individual; improved health outcomes also drive cost effectiveness across the entire health care delivery system. Put another way, when health centers can effectively manage acute illness and chronic disease, we keep people out of the emergency room and reduce the use of more costly specialty and inpatient services. Access to affordable prescription medication is a critical piece of that puzzle.

The second and more far-reaching role of the 340B Drug Pricing Program is that it enables covered entities like Community Health Centers to increase access to comprehensive primary and preventive that would otherwise be unfunded and unavailable, particularly for low-income, uninsured, and underinsured patients. 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 noted 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 any margin remaining after covering operational costs to provide more comprehensive services, leading to improved patient health outcomes, and ultimately, driving cost-effectiveness across the entire health care delivery system.

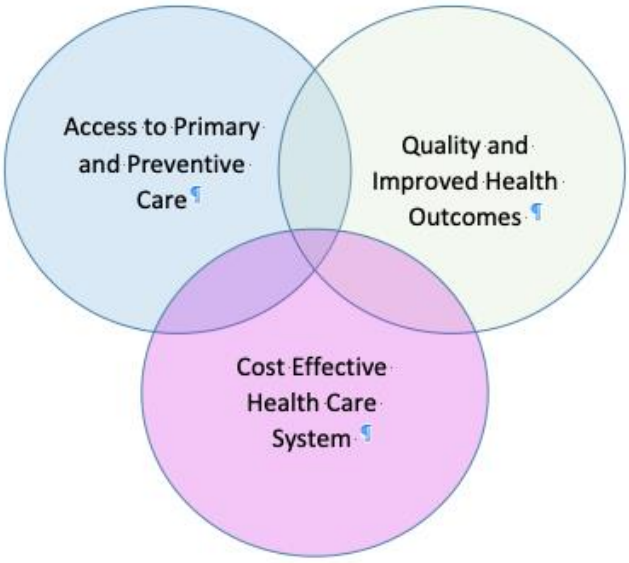
At Carolina Health Centers, that 340B contribution to our operating margin supports the following programs and services that would otherwise not be available in an equitable manner for the patients and communities we serve:

- Delivery of medically necessary prescriptions to patients at our medical sites in rural and remote locations;
- Prescription medication provided at or below cost for low-income, uninsured, and underinsured patients when even the 340B cost of that medication is prohibitive;
- Integrated behavioral health counselors that treat patients who are uninsured, not eligible for, or have long waits to access the public mental health system;
- Otherwise, unfunded treatment of substance use disorder;
- Early Childhood Services and parenting education programs for families who do not meet the eligibility criteria for our four evidence-based programs that are funded under the federal Maternal Infant Early Childhood Home Visitation program;
- Enabling services that address social determinants of health and work to improve health equity:
    - Outreach and care coordination to bring vulnerable populations into a primary care medical home and reduce the use of the emergency department for routine primary care;
    - Quality and population health specialists that work directly with patients to ensure that they are receiving recommended primary and preventive care and screenings and work with complex patients to connect them to needed specialty care and social services;

- A voucher program that subsidizes oral health care services provided by a network of private dentists for our low-income, uninsured, and underinsured patients; and
- The viability of primary care practice sites in communities with a disproportionate uninsured population.

These are programs and services that directly impact the clinical outcomes and cost effectiveness of the care provided to Carolina Health Centers patients. All of these are supported in part by the contribution 340B makes to our operating margin.

In summary, as the diagram below illustrates, the value of the 340B Drug Pricing Program lies at the intersection of Access, Quality, and Cost Effectiveness. Access to comprehensive primary and preventive health care results in improved health outcomes for individual patients, as well as improved population health. This, in turn, reduces the need for and use of more costly services, impacting the cost-effectiveness of the entire health care delivery system.



Developments Impacting the Value of the 340B Drug Pricing Program:

In recent years, and to an increasingly alarming degree, 340B covered entities and pharmaceutical manufactures have begun treating each other like adversaries rather than the partners that they are intended to be in this vitally important safety net program. I believe this is in large part driven by three primary intertwined factors.

First, the 340B Program brings together a variety of stakeholders with vastly different – perhaps even polarized - purposes and priorities, which create the lens through which they view the program. For example, to pharmaceutical manufacturers, the 340B Program represents a liability, while for a covered entity like my health center, 340B is an asset. Unfortunately, each stakeholder tends to be myopic, only seeing through their lens rather than from the vantage point of mutuality.

Couple that tendency toward a myopic view of the 340B Program with the exponential growth of the Program, and you have the second factor driving us toward an adversarial stance. Manufacturers naturally view the growth of the Program as their liability increasing at an unsustainable rate; while a covered entity such as my health center (and me as a patient advocate) sees growth in terms of our ability to serve more patients with more comprehensive health care services.

While I acknowledge that the 340B Program has grown significantly, it is important to acknowledge there may be factors artificially inflating the true measure of growth. The growth of the 340B Program is almost exclusively referenced only in terms of overall spend without correlating it with unit volume. Consequently, the rhetoric around the growth of the Program does not adjust for the impact of increased unit price in the growth equation. An additional factor contributing to the growth of the 340B Program is the aging of our population and the proportionally greater number of prescription medications used by older adults. This is not to suggest that I do not recognize there has been growth in the Program, but to point out that, in fairness to all parties, it is important to look at the growth equation in its totality.

Lack of clarity in the 340B statute is the third, and most dominant factor that is negatively impacting the ability of all categories of 340B covered entities and pharmaceutical manufacturers to develop and maintain a partnership – one that is true in both spirit and function – to ensure that the 340B Program achieves its goal and intent of enhanced health access to more comprehensive health care services and ultimately, with greater health equity and a healthier population.

Lack of clarity has left the door open for manufacturers to arbitrarily impose conditions and restrictions on the purchase of drugs using 340B pricing – conditions and restrictions that have been impactful on all health centers and nothing short of devastating for many. Health centers across the country are facing tough decisions such as scaling back services or hours of operation, closing practice sites, and laying off staff – all because the contribution their

pharmacy brings to the operating margin has been decimated by the restrictions arbitrarily placed on the use of the well-established contract pharmacy model. Even health centers – CHC included - that have agreed to the data sharing conditions imposed by manufacturers to allow some modified use of contract pharmacy are experiencing impactful loss of contribution to their operating margin due to the administrative burden of operationalizing and supporting the data submission requirements. There is also increased cost associated with the work of the clinical team to evaluate and adjust treatment plans when a patient is no longer able to receive a certain manufacturer's product at the health center's contract pharmacy they are established with.

Carolina Health Centers has the benefit of an entity owned (in-house) health center pharmacy; however, many of our patients still depend on our contract pharmacy partners due to geographic barriers or limited payor networks. Even with a substantial portion of our patients' prescriptions being filled in-house and our agreement to comply with the data submission requirements of three manufacturers, our Chief Pharmacy Officer last year estimated the reduction in contribution to our operating margin to be $667,000 annually. In addition, we estimate an additional .6 FTE of workforce time is necessary to manage the added burden of administration and care coordination. Without factoring in the increased operational cost, this represents an estimated $667,000 annually that is no longer available to support the health care services outlined earlier in my testimony. For many health centers, especially an estimated 40% without an entity owned pharmacy, both the loss of resources and increased operational costs are exponentially increased.

Lack of clarity in the statute has also enabled the emergence of business models that are not consistent with the intent of the statute and safety net purpose of the 340B Program. This in turn has further motivated the manufacturers' interest in and efforts to contain the growth of the Program by imposing conditions and restrictions. In my experience, which has been primarily with community health centers, the vast majority of covered entities function as good stewards of the Program. Like my health center, they have significant controls in place to ensure that only those patients with whom they have an established direct patient care relationship are eligible for drugs filled with 340B purchased inventory. By both mission and mandate (HRSA Health Center Program Expectations) income based sliding fee discount programs are required for all services and patients are not refused any service based on an inability to pay. Health centers demonstrate their good stewardship by being transparent about how all resources are used to increase access to health care programs and services that benefit their patients and the communities served. Finally, as is the case with Carolina Health Centers, a robust compliance plan – including extensive internal self-auditing – is standard practice.

Despite my positive experience, I acknowledge that the lack of clarity in the statute, particularly as it relates to requiring what I have outlined as standard practice for good stewards of the 340B Program, has resulted in business models and operational practices that are inconsistent with the Program intent and have been referred to as abuse of the Program. Unsurprisingly, the few "bad actors" have garnered far more attention than the thousands of covered entities that are good stewards of the Program. It is also not surprising that this has fueled and accelerated the work of the manufactures to curtail the growth of the Program and even scale back its availability – even to those good stewards who are committed to integrity, health equity, and increased access to essential health care programs and services.

The intersection and continued escalating impact of these three factors create an urgent need for a solution that creates a sustainable and patient focused 340B Program now and into the future.

Solutions for a Sustainable 340B Program in the Future:

It is critical that diverse covered entities and drug manufacturers find a path back to being partners and not adversaries in the 340B Program. The current state is extracting a heavy toll on the community health centers and more importantly the communities that depend upon us.

That path must be lined with clearly defined guardrails to protect against arbitrary conditions and restrictions and abusive business models. At the same time, it is critical for that path to have points of access that recognize and accommodate the scope of responsibility for patient specific to the different 340B covered entities in the health care delivery system.

With all due respect and consideration of Carolina Health Centers' manufacturer partners and other 340B covered entity types, I suggest two overarching guidelines for moving forward.

First, the solution must be comprehensive and address the multiple areas in which the current statute lacks clarity and has failed to establish appropriate authority for and oversight of the Program. Incrementally addressing the deficits in 340B Program rules and oversight does not promote collaboration among the partners and fails to establish all of the guardrails necessary to promote the integrity of the Program.

In addition, to have long term viability, the solution cannot be single stakeholder centric. It must be derived from a diverse multi-stakeholder commitment to work toward a consensus model that protects the value of 340B with patient care at the center of the dialogue. A comprehensive

solution can only come about when the diverse stakeholders work together to develop the art of mutuality. In recent months we have seen a movement toward mutuality in the introduction of the "340B Affording Care for Communities and Ensuring a Strong Safety Net Act (340B Access Act), as well as the Discussion Draft entitled "Supporting Underserved and Supporting Transparency and Integrity for the Future of 340B (SUSTAIN Act) recently circulated by the Senate Gang of Six. It is critical that we continue working through these proposals in order to achieve optimal consensus.

We at Carolina Health Centers believe that the following are the most critical elements to be included in any proposal intended to sustain the 340B Program for the benefit of our patients now and into the future:

1. A foundational Statement of Intent that establishes into perpetuity that the 340B Program is intended to provide access to affordable medication and support the work of health care safety to increase access to comprehensive health care.
2. A patient definition with a clear and unwavering threshold that establishes patient 340B eligibility based upon a direct patient care relationship between the patient and the covered entity.
3. Prescription eligibility that aligns directly with the scope of care provided by the specific covered entity type. Eligibility should recognize pharmacy as a core component of a primary care medical home and, for those covered entities functioning as a medical home, accommodate that scope of care and responsibility across the health care continuum.
4. The use of contract pharmacy must be codified with provisions that accommodate limited payer networks, patient geographic mobility, and the challenge of pharmacy deserts.
5. Protection against 3rd party discriminatory contracting and fee structures.
6. Transparency and accountability for demonstrating how the covered entity ensures patient affordability and uses the 340B contribution to operating margin to promote health equity and enhance access to comprehensive health care programs and services.
7. HRSA authority and accountability for program integrity, supported by an independent clearinghouse to support the necessary data exchange and analysis.

Again, thank you, Chairman Griffith, Ranking Member DeGette, Chair McMorris Rodgers, and Ranking Member Pallone, for your attention to this critical issue. I am heartened that this program, which is so vitally important to community health centers, is the subject of this hearing, and I encourage you to begin considering comprehensive legislation to reform it.