

**Testimony of Sue Veer**

President and Chief Executive Officer, Carolina Health Centers, Inc.  
House Energy and Commerce, Subcommittee on Oversight and Investigations  
Hearing on “Examining How Covered Entities Utilize the 340B Drug Pricing Program”  
October 11, 2017

Good morning Chairman Murphy, Ranking Member DeGette and Members of the Subcommittee.

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 26,952 patients in the west central area of South Carolina known as the Lakelands.

At the request of Subcommittee staff, I am providing the following executive summary. My testimony continues with an overview of Carolina Health Centers and specifically our 340B program. Thank you for the invitation to serve as a witness at this hearing and to highlight the vital importance of the 340B program to CHC and to health centers nationwide.

**Executive Summary**

Carolina Health Centers, Inc. (CHC) is a non-profit primary care corporation established in 1977, now comprised of 13 primary care medical practices, a program focused on serving migrant farmworkers, and two community pharmacies. CHC serves as the primary care medical home for 26,952 distinct and unduplicated patients in the west central area of South Carolina known as the Lakelands – an area which encompasses 7 counties and over 3,700 square miles, and which the U.S. Department of Health and Human Services has determined to be medically underserved.

## Carolina Health Centers, Inc.

### Written Statement

Sue Veer MBA, President and CEO

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As a Federally-Qualified Health Center (FQHC) – also known as a community health center - CHC is committed to ensuring all members of our community have access to a high-quality, comprehensive primary care medical home regardless of demographic, geographic, or socio-economic barriers. Like all FQHCs, by law and by mission, we never turn a patient away due to inability to pay. Patients with incomes below the poverty level pay no more than a nominal fee for the full range of services we provide, and those between 101-200 FPL pay discounted rates based on a sliding fee scale.

In addition to providing comprehensive primary and preventive health care services, community health centers such as CHC provide a wide array of care management, patient education and support, and assistive services that support access to care, promote enhanced clinical outcomes, and reduce total costs across the health care delivery system. And like all community health centers, we are governed by a community based Board of Directors, a majority of whose members are patients of the health center. This structure ensures that we remain directly responsive to the unique needs of our patients and the community.

Like the roughly 1,400 HRSA-funded community health centers, CHC is subject to intensive and on-going oversight from the United States Department of Health and Human Services Health Resource and Services Administration (HRSA). The HRSA requirements with which we 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<sup>1</sup>. HRSA consistently oversees and enforces compliance with all these requirements through a variety of mechanisms including on-site compliance reviews, frequent interactions with project officers,

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<sup>1</sup> A summary of HRSA's program requirements for Community Health Centers is included in Appendix A. For a complete listing of all requirements, see the 92-page Compliance Manual available at: <https://bphc.hrsa.gov/programrequirements/pdf/healthcentercompliancemanual.pdf>

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and regularly-scheduled reporting obligations. HRSA also approves what is called our “Scope of Project”, meaning those primary care delivery sites, services, and providers that are considered part of the health center’s program operations, and therefore are subject all the requirements I’ve just described.

Carolina Health Centers is registered with the Office of Pharmacy Affairs Information System (OPAIS) as a 340B entity with one main site (referred to as “parent sites” in OPAIS nomenclature) and 15 satellite medical practice sites (referred to as “child sites” in OPAIS nomenclature), 2 of which have been terminated, leaving 13 active child sites. **These child sites represent primary care medical practices from which 340B eligible prescriptions may be generated.** Each child site was added to our health center’s Scope of Project before becoming eligible for the 340B program. As previously mentioned, adding a site to our Scope of Project requires proving to HRSA that the new site can meet all their requirements. This includes demonstrating that CHC can provide all patients at the new site – and their family members – with access to the full range of services and discounts provided at all other CHC sites, without reducing access or raising costs at any existing sites. Thus, when determining whether to add a child site, we must, and do, consider costs and commitments that go far beyond access to 340B priced drugs.

The 340B profile for CHC in the OPAIS also lists multiple contract pharmacy arrangements; however, those contracts were terminated before implementation and are so noted in the OPAIS.

CHC’s pharmacy program is exclusively “in-house” - defined as owned and operated by the health center regardless of location. As such, CHC operates 2 community pharmacy sites that serve both health center patients non-health center patients. Eligible prescriptions for health center patients only are filled with 340B purchased inventory and all non-health center patient

prescriptions are filled with non-340B purchased inventory. Using calendar year 2016 as a sample, 142,045 or 43.1% of the 329,679 prescriptions dispensed at CHC's two pharmacies were filled with 340B purchased inventory for eligible patients. Of those prescriptions filled with 340B, 68% were not covered by a third-party payer and classified as uninsured.

The health center statute requires all FQHCs to use all 340B savings for purposes that advance their HRSA approved Scope of Project – in other words, for activities that increase access to high-quality, affordable care for medically underserved populations. While every health center may use their 340B savings differently, these funds are commonly used to support sliding fee discounts, clinical pharmacy programs, and provider salaries. In the case of CHC, our total 340B savings for 2016 – calculated as the net margin after the sale of the drug - \$561,620. These savings enable the health center to provide deeply discounted pharmacy services to those patients eligible for the income-based sliding fee program, offer medication therapy management to promote clinical and cost effective care, and assist patients with qualifying for manufacturer Patient Assistance Programs. 340B savings also directly support the following otherwise unfunded services designed to expand access to essential primary care services:

- Daily delivery of health center patient prescriptions to CHC medical practices in outlying rural communities with limited or no access to affordable pharmacy services. This service makes over 20,000 affordable prescriptions accessible to low-income and underserved persons each year. 2016 cost of this service = \$163,124.
- Oral health services – both preventive and restorative - provided to uninsured and sliding fee eligible through a network of contract dentists. 2016 cost of this service = \$57,737.
- Behavioral health counseling provided on-site to CHC patients who would either not qualify for, or have long delays in receiving care from the local mental health agency. 2016 cost of this service = \$35,000.

In addition, the 340B savings contribute to our ability at CHC to ensure continued access to primary care and preventive care at certain of our medical practice sites in rural communities

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that are operating with a negative margin and would otherwise be at risk of closing. The total cost of maintaining primary care access at those sites in 2016 was \$1,812,581.

CHC defines “charity care” as the value of services provided for which all or part of the charges are uncompensated. Organization-wide in 2016, CHC provided \$4,753,211 in charity care which represents 21% of total patient revenue.

### **Overview of Carolina Health Centers, Inc.<sup>2</sup>**

Carolina Health Centers, Inc. (CHC) is a non-profit primary care corporation established in 1977, now comprised of 13 primary care medical practices, a program focused on serving migrant farmworkers, and two community pharmacies. CHC serves as the primary care medical home for 26,952 distinct and unduplicated patients in the west central area of South Carolina known as the Lakelands – an area which encompasses 7 counties and over 3,700 square miles, and which the U.S. Department of Health and Human Services has determined to be medically underserved.

As a Federally-Qualified Health Center– also known as a community health center - CHC is committed to ensuring everyone has access to a high-quality, comprehensive primary care medical home regardless of demographic, geographic, and socio-economic barriers. By law and by mission, we never turn a patient away due to inability to pay; patients with incomes below the poverty level pay no more than a nominal fee for the full range of services we provide, and those between 101-200 FPL pay discounted rates based on a sliding fee scale.

In addition to providing comprehensive primary and preventive health care services, community health centers such as CHC provide a wide array of care management, patient education and support, and assistive services that support access to care, promote enhanced clinical outcomes, and reduce total costs across the health care system. And like all community

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<sup>2</sup> Data source: 2016 HRSA Uniform Data System Report (required of all FQHC and FQHC Look-Alikes)

health centers, we are governed by a community based Board of Directors, a majority of whose members are patients of the health center. This structure ensures that we remain directly responsive to the unique needs of our patients and the community.

Community health centers are subject to intensive and on-going oversight from the United States Department of Health and Human Services Health Resource and Services Administration (HRSA). The HRSA requirements with which we must comply are spelled out in a 92-page manual and are grouped into 18 major categories, including – but not limited to – clinical quality, financial management, ensuring access, and collaboration with other local providers. HRSA consistently oversees and enforces compliance with all 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 what is called our “Scope of Project”, meaning those primary care delivery sites, services, and providers that are considered part of the health center program – and therefore, to which all the requirements I just mentioned apply.

CHC directly provides primary and preventive health care services at 10 family medicine practice sites, 2 pediatric practices, 1 school-based clinic, a farmworker health program, and 2 community pharmacy locations<sup>3</sup>. In addition, CHC’s comprehensive pediatric medical home model includes 3 evidence-based home visitation programs.

All of CHC’s service delivery sites are located in Medically Underserved Areas and/or in communities designated as having Medically Underserved Populations. The percentage of patients served at each site that are uninsured, under-insured, and low income varies dramatically among the practice locations based upon the socio-economic demographics of the community.

In addition to those services provided directly, CHC provides other statutorily-required services through contracts and affiliation agreements with community partners. When our

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<sup>3</sup> A list of service delivery sites is included as Appendix B.

## Carolina Health Centers, Inc.

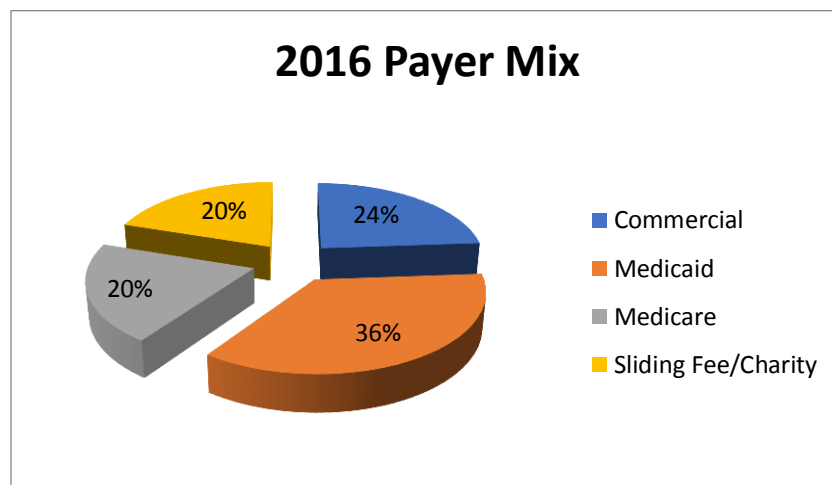
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patients are hospitalized, rounding services are provided through the hospitalist service at local hospitals; behavioral health and substance abuse services are provided through affiliation with the local mental health and substance abuse agencies; and oral health services are provided through contracts with private practice dentists with CHC providing a subsidy for the care provided to sliding-fee discount eligible patients with incomes below 200% FPL

At its direct delivery sites, CHC provided 105,433 medical visits for 26,952 unduplicated patients during calendar year 2016. Following is a breakdown of the payer-mix for 91,610 encounters that represent billable visits:



Carolina Health Centers, Inc. (CHC) staff totals 231.20 full time equivalent (FTE) employees.

The direct patient care staff includes:

- Medical providers = 25.8 FTEs
- Clinical support staff = 63 FTEs
- Enabling staff (case managers, care coordinators, outreach workers, etc.) = 18.2 FTEs
- Patient Service representatives = 48.5 FTEs
- Pharmacy personnel = 45.40 FTEs

In 2016, CHC had an operating budget of \$28,292,993 and received \$4,291,355 in Bureau of Primary Health Care Section 330 grant funding. Other grant funding includes: \$1,879,656 in state funding provided through the Maternal and Infant Early Childhood Home Visiting (MIECHV) program, which supports the three evidence-based home visitation programs integrated into CHC's pediatric medical home model; \$110,717 in state funds allocated to FQHCs for participation in the state's Healthy Outcomes Program; \$102,650 in EHR Incentive payments; and \$176,823 in private grants and contracts restricted to support of the home visitation programs.

#### **Carolina Health Centers Pharmacy Program**

Carolina Health Centers, Inc. (CHC) opened its first in-house pharmacy, Carolina Community Pharmacy (CCP), in 2005. The pharmacy was initially located in CHC's largest pediatric practice site and was opened as a "closed" pharmacy meaning prescriptions could only be filled for health center patients and the pharmacy had only 340B purchased inventory. Within a few months CHC leadership made the decision to convert to an "open" pharmacy meaning that prescriptions could be filled for both health center patients and the general public, thereby requiring that the pharmacy maintain separate inventories for 340B eligible and non-340B eligible prescriptions. This decision was driven in large part by family members of health center patients requesting to fill their prescriptions at CCP as a matter of convenience. Many of the prescriptions filled for non-health center patients were noted as being generated in emergency departments and urgent care centers, indicating the potential lack of access to a primary care medical home. As a result, **an additional benefit CHC's "open" pharmacy model has brought to the community is that it 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.**



CHC is registered with the Office of Pharmacy Affairs Information System (OPAIS) as a 340B entity with one main site (referred to as “parent sites” in OPAIS nomenclature) and 15 satellite medical practice sites (referred to as “child sites” in OPAIS nomenclature), 2 of which have been terminated, leaving 13 active child sites. **These child sites represent primary care medical practices from which 340B eligible prescriptions may be generated.** Each child site was added to CHC’s Scope of Project before becoming eligible for 340B. As previously mentioned, adding a site to our Scope of Project requires proving to HRSA that the new site can meet all their requirements. This includes demonstrating that CHC can provide all patients at the new site – and their family members – with access to the full range of services and discounts provided at all other CHC sites, without reducing access or raising costs at any existing sites. Thus, when determining whether to add a child site, CHC must consider costs and commitments that go far beyond access to 340B priced drugs.

As previously noted, CHC serves 7 rural counties with primary care medical sites widely dispersed over 3,708 square miles. In 2006 leadership recognized that only health center patients in close proximity to CCP were able to access affordable prescription medication through CHC’s 340B pharmacy program. In order to ensure that CHC patients in these rural communities had access to affordable prescription medication, CHC initiated a daily delivery service to its outlying medical practices. In compliance with provisions in the South Carolina Pharmacy Practice Act, and under strict quality control procedures, prescriptions for health center patients received (via fax, telephone, or e-scribed) from medical providers at CHC’s outlying practice sites are dispensed from CCP and delivered to the practice site where they are distributed to the patient by licensed personnel. Today, that **delivery service provides over 20,000 prescriptions each year to health center patients in rural communities - patients who in many cases would otherwise have no access to affordable prescription medication<sup>4</sup>.** In

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<sup>4</sup> Appendix C: Prescriptions Dispensed provides the number of prescriptions delivered to patients in the outlying rural communities for a 5-year period.

**the words of one of CHC most senior medical providers: *“To diagnose when the patient has no access to affordable medication is always an exercise in futility ... and in some cases just the announcement of a death sentence.”***

CHC opened a second pharmacy location in 2009 as a stand-alone community pharmacy doing business as Carolina Community Pharmacy Northwest. In 2012 CHC moved the original pharmacy from The Children’s Center into a second stand-alone site doing business as Carolina Community Pharmacy at The Village. Both of these pharmacies are in close proximity to the CHC medical practices in the Greenwood community and in 2016 CHC opened a co-located medical practice in CCP at The Village.

CHC entered into a contract pharmacy arrangement in 2013; however, that agreement was terminated in 2015 without being implemented. Abandoning the idea of expanding access through contract arrangements was based on CHC’s capacity to operate in-house pharmacies, and a **strategic decision made in collaboration with CHC’s medical staff leadership to focus on greater integration of the clinical pharmacy into the primary care medical home model.** CHC pharmacists at both pharmacy locations have direct access to the health center patient’s electronic medical record and the ability to send messages to the medical providers through the EHR system. The Director of Pharmacy is considered a member of the Medical Leadership Team, along with the Chief Medical Officer, Director of Family Medicine, and Director of Pediatrics, which enables a high level of collaboration between the prescribing providers and dispensing pharmacies. Beginning in 2016 CHC is focusing on increased clinical integration including rotation of clinical pharmacists at medical practice sites and participation of clinical pharmacists on interdisciplinary treatment teams.

Currently, CHC’s pharmacy program includes two community pharmacies, both of which operate as “open” pharmacies, meaning that they provide pharmacy services to both health center patients and the general retail public. However, only health center patients are eligible to have prescriptions filled with 340B purchased inventory, and CHC performs daily audits to protect against diversion of 340B drugs to non-eligible patients. In 2016, the 2 pharmacy sites

dispensed a total of 329,679 prescriptions inclusive of those delivered to the outlying medical practices. Of the total dispensed 142,045 prescriptions were filled for health center patients using 340B purchased inventory, which represents 43.09% of total dispensed. Of the prescriptions dispensed using 340B purchased inventory, 95,590 or 67.3% were not covered by a third-party payer and 23,823 or 16.77% were delivered to outlying practice sites.<sup>5</sup>

Every effort is made to ensure that uninsured and low-income patients are able afford their prescriptions. As mentioned earlier, one of HRSA's expectations of community health centers is that they have a sliding fee discount policy that applies to all patients with incomes at or below 200% of the federal poverty guidelines (FPL). HRSA requires that the sliding fee discount policy be applicable to all services included in the health center's HSRA approved Scope of Project, including pharmacy services. As a component of CHC's sliding fee policy, the benefit of the 340B discount price is passed on to patients with incomes below 200% of FPL. There are times when, even at these discounted rates, patients are not able to afford much needed prescriptions. In these cases, CHC will assist the patient in securing their medication through a manufacturer Prescription Assistance Program whenever possible. When no other options are available, CHC has a Benevolence Fund, supported by employee donations that may be accessed to assist patients with payment for

CHC does not participate in a pharmaceutical group purchasing organization (GPO) but purchases all drugs from Smith Drug Company, a wholesaler headquartered in Spartanburg, SC. CHC purchases under separate 340B and non-340B accounts for each pharmacy in order to effectively maintain separate inventories. CHC operates with an open formulary – i.e. stock not limited to a predetermined list of approved drugs and devices – purchases include a large number of NDCs (National Drug Codes)<sup>6</sup>. When categorized by therapeutic class 85% of

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<sup>5</sup> Appendix C: Prescriptions Dispensed provides detailed information on the prescriptions dispensed over the five year period of 2012-2016.

<sup>6</sup> Appendix D1 provides a list of all NDCs purchased in 2016.

purchases are related to the management of chronic disease including co-existing behavioral health issues prevalent among the patients served by the community health center<sup>7</sup>

According to the previously referenced 2016 Uniform Data System Report, CHC's pharmacy program employs 45.40 FTEs. Because CHC operates an open pharmacy serving both 340B and non-340B patients, only a proportional amount of the personnel resources is specifically attributable to the 340B program. The staff is comprised of:

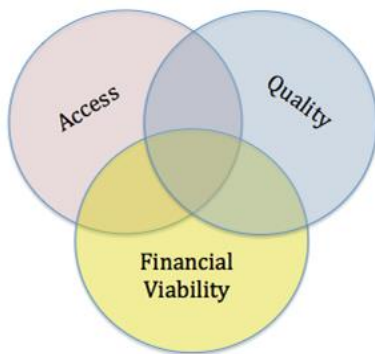
- 1 FTE Director of Pharmacy
- 1 FTE Pharmacy Operations Manager
- 1 FTE Clinical Coordinator
- 7 FTEs Staff Pharmacists
- 16 FTEs Registered Pharmacy Technicians
- 25.40 Patient Service Representatives

All pharmacy staff attend CHC New Employee Orientation, which includes a training segment on the history, purpose, and compliance framework for the 340B Drug Pricing Program. CHC encourages and supports all registered and licensed staff to complete the Apexus 340B University (either online or in person) and requires each member of the 3-person pharmacy leadership team to attend a live 340B University at least every three years. CHC's President and CEO, as well as Director of Pharmacy regularly attend 340B specific training offered by the National Association of Community Health Centers. Licensure and certification of all professional staff is maintained by CHC's Credentialing and Contract Management Specialist.

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<sup>7</sup> Appendix D: Drugs Purchased provides detailed information on drugs purchased over the five year period of 2012-2016 with a breakdown by therapeutic class for drugs purchased in 2016.

Participation in the 340B Drug Pricing Program is strategically important to Carolina Health Centers (CHC) and the patients it serves. The graphic below illustrates what CHC leadership has adopted as their strategic imperative to protect and optimize that benefit:



Access to affordable prescription medication and integration of the clinical pharmacy with the primary care medical home is one of the greatest drivers of improved individual and population health outcomes; and Improved individual and population health outcomes position CHC favorably in a value based reimbursement environment and positively bend the cost curve for the health care delivery system.

Participation in the 340B Drug Pricing Program is also critically important in achieving CHC's mission to remove barriers that limit access to primary and preventive care.

CHC is grateful for the resources that have been made available through HRSA's Office of Pharmacy Affairs and the HRSA Prime Vendor Program currently administered by Apexus. The availability and continued evolution of these resources has enabled CHC and pharmacy leadership to develop a solid framework for an effective and compliant 340B pharmacy program.

### **Conclusion**

As my testimony demonstrates, the 340B program is vital to CHC and 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.