

# CAROLINA HEALTH CENTERS, INC. POLICY

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**TITLE:** Provision of Pharmacy Services

**CATEGORY:** Pharmacy Services

**NUMBER:**

**EFFECTIVE DATE:** January 31, 2013

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**POLICY:**

In support of its mission to promote access to affordable high-quality primary care services and improve the health of the communities served, Carolina Health Centers, Inc. (CHC) provides pharmacy services that are available to both medical patients of CHC and the community at large.

CHC pharmacies are duly licensed and operated in compliance with all local, state, and federal laws and regulations.

Core services available to all patients include dispensing of prescription medications, patient and family counseling, health education, and medication therapy management (MTM) to achieve both optimal clinical outcomes and cost effectiveness.

The Chief Pharmacy Officer will administer a robust quality assurance and improvement program and report to the Corporate Quality Improvement Committee.

**SECTION I:**

**PHARMACY SERVICES FOR THE GENERAL PUBLIC**

**(SERVICES PROVIDED TO INDIVIDUALS WHO ARE NOT MEDICAL PATIENTS OF CHC)**

The Bureau of Primary Health Care (BPHC) of the Health Resources and Services Administration (HRSA) of the United States Department of Health and Human Services (HHS) has established that Federally Qualified Health Centers (FQHC), otherwise known as community health centers – are expected to provide pharmacy services as appropriate for the patient and communities they serve. Carolina Health Centers, Inc. provides pharmacy services to the general public in order to promote access to appropriate health care services and improve the health and well-being for all residents of the communities served. Policies specific to services provided to the general public (individuals who are a pharmacy patient only and are not established as a patient with one of CHC’s medical home locations) include:

- Prescriptions dispensed for individuals not qualifying as a patient as defined by the 340B Drug Discount Program will be filled using alternate inventory purchased at a non-340B price.

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- The general public may be eligible for discounted pricing as long as such discounts are not in violation of third party payer agreements or in violation of local, state, or federal regulations.
- The general public will be eligible for all available services (with the exception of 340B discount pricing) including patient counseling, health education, and MTM.

### SECTION II: 340B DISCOUNT DRUG PRICING PROGRAM (SERVICES AVAILABLE TO MEDICAL PATIENTS OF CHC)

#### BACKGROUND ON THE 340B DISCOUNT DRUG PRICING PROGRAM:

[Section 340B of the Public Health Service Act \(1992\)](#) requires drug manufacturers participating in the Medicaid Drug Rebate Program to sign an agreement with the Secretary of Health and Human Services. This agreement limits the price manufacturers may charge certain [covered entities](#) for covered outpatient drugs. The resulting program is called the 340B Program. The program is administered by the Office of Pharmacy Affairs (OPA), a part of the federal Health Resources and Services Administration/Department of Health and Human Services.

Upon registration on the OPA database as a participant in the 340B Program, entities agree to abide by specific statutory requirements and prohibitions.

#### POLICIES SPECIFIC TO 340B PHARMACY SERVICES:

Carolina Health Centers, Inc. participates in the 340B Drug Pricing Program in order to expand access to affordable prescription medications for its eligible patients, and to generate savings that support expanded and enhanced services for the medically underserved patients in our service area.

As a participant in the 340B Drug Pricing Program, Carolina Health Centers, Inc. (CHC) policies are:

- CHC uses any savings generated from 340B in accordance with 340B Program intent
- CHC meets all 340B Program eligibility requirements.
  - CHC is registered as a covered entity in the Office of Pharmacy Affairs (OPA) Database and that listing is complete, accurate, and correct.
  - CHC receives a grant or designation consistent with that conferring 340B eligibility.

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- CHC complies with all requirements and restrictions of Section 340B of the Public Health Service Act and any accompanying regulations or guidelines including, but not limited to, the prohibition against duplicate discounts/rebates under Medicaid, and the prohibition against transferring drugs purchased under 340B to anyone other than a patient of the entity. [REFERENCE: [Public Law 102-585, Section 602](#), [340B Guidelines](#), [340B Policy Releases](#)]
- CHC maintains auditable records demonstrating compliance with the 340B requirement described in the preceding bullet.
- CHC identifies eligible prescriptions to be those in which:
  - a.) the patient's primary care provider is employed or under contractual or other arrangements with CHC;
  - b.) the individual receives a health care service (within the scope of grant/designation for which 340B status was conferred) from this professional such that the responsibility for care remains with the health center;
  - c.) CHC maintains records of the individual's health care; and
  - d.) The prescription emanates from that care, which is provided at a medical site registered in the OPAIS or as a result of other services in CHC's HRSA approved Scope of Project<sup>1</sup>
- CHC uses 340B purchased inventory for all clinic administered drugs including those administered to Medicaid beneficiaries and maintains information consistent to this in the OPA Medicaid Exclusion Database.
- CHC does not use 340B purchased inventory for prescriptions dispensed by Carolina Community Pharmacy to Medicaid fee-for-service (FFS) beneficiaries; however, 340B purchased inventory is used for prescriptions dispensed from Carolina Community Pharmacy to patients enrolled in Medicaid Managed Care plans. Consistent with instructions from South Carolina Department of Health and Human Services (SCDHHS) CHC outlines these billing practices, including the billing NPI numbers, in writing on an annual basis and at the time of any changes.
- CHC has systems/mechanisms and internal controls in place to reasonably ensure ongoing compliance with all 340B requirements, which are detailed in the Department of Pharmacy Policy and Procedure Manual.

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<sup>1</sup> Form 5C of the HRSA approved Scope of Projects may include services that are not provided at a distinct and unchanging physical location or are, as in the case of inpatient hospital coverage, are not provided at a location owned and operated by the health center covered entity. Therefore, the care provided establishes patient eligibility, the location where that care is provided is unable to be registered in the OPAIS.

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- CHC conducts routine compliance audits under the direction of the Chief Pharmacy Officer. Audit results are regularly reviewed with the Pharmacy Oversight Committee (see below) and any major findings are reported to the Corporate Compliance Officer.
- CHC provides comprehensive orientation to the 340B program for new pharmacy staff and conducts regular and ongoing updates and continuing education.
- CHC conducts corporate wide training on the 340B program to maximize the value to patients served at all medical sites.
- CHC has procedures in place to protect the patient's right to use the pharmacy of their choice.
- CHC also utilizes contract pharmacy services. The contract pharmacy arrangements are performed in accordance with OPA requirements and guidelines including, but not limited to:
  - CHC obtains sufficient information from the contractor to ensure compliance with applicable policy and legal requirements, and CHC utilizes an appropriate methodology to ensure compliance including an annual independent audit of contract pharmacies .
  - Signed Contract Pharmacy Services Agreement(s) complies with 12 contract pharmacy essential compliance elements  
<http://www.hrsa.gov/opa/programrequirements/federalregisternotices/contractpharmacyservices030510.pdf>
- CHC acknowledges its responsibility to contact OPA as soon as reasonably possible if there is any change in 340B eligibility or material breach by the CHC of any of the foregoing policies.
- CHC acknowledges that if there is a breach of the 340B requirements, CHC may be liable to the manufacturer of the covered outpatient drug that is the subject of the violation, and depending upon the circumstances, may be subject to the payment of interest and/or removal from the list of eligible 340B entities.
- CHC elects to receive information about the 340B Program from trusted sources, including, but not limited to:
  - [The Office of Pharmacy Affairs \(OPA\)](#)
  - [The 340B Prime Vendor Program, managed by Apexus](#)
  - Any OPA contractors

### SCOPE:

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These policies apply to all CHC pharmacy services including those provided at primary medical sites and community pharmacy locations.

### **RESPONSIBILITY:**

#### Pharmacy Oversight Committee:

- The Pharmacy Oversight Committee (POC) is a standing committee comprised of the Senior Leadership Team of the organization, the Department of Pharmacy Leadership Team, and the Financial Analyst/340B Compliance Manager.
- The POC is charged with strategic planning, operations and compliance of pharmacy services within the organization.
- The POC is granted the authority to:
  - Develop and implement clinical protocols and operating procedures consistent with this Board approved policy;
  - Develop and implement pharmacy service enhancements consistent with standards of practice, scope of project, and the organization's mission, vision, and goals;
  - Develop and recommend major expansions of the pharmacy to the Board of Directors; and
  - Regularly review and respond to performance and compliance measures, providing regular reports to the Board of Directors and ensuring that the Board is updated at least annually on the value of the program as it relates to expanded access and enhanced services in the communities served.

#### 340B Compliance Responsibilities:

The following CHC Staff are engaged with 340B program compliance.

##### A. Chief Executive Officer

- Responsible as the authorizing official in charge for the compliance and administration of the program.
- Responsible for attesting to the compliance of the program in form of recertification.

##### B. Chief Financial Officer

- Responsible for financial management and allocation of savings to support the non-profit mission of CHC

##### C. Chief Pharmacy Officer

- Accountable agent for 340B compliance

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- Agent of the CEO responsible to administer the 340B program to fully implement and optimize appropriate savings and ensure current policy statements and procedures are in place to maintain program compliance

### D. Pharmacy Operations Manager

- Oversees the daily audit functions within the pharmacy operation

### E. Financial Analyst/340B Compliance Manager

- Collaborates with the Chief Pharmacy Officer on the internal audit plan of the 340B program
- Provides analytics to support compliance
- Manages the contract pharmacy arrangements and audit functions, including liaising with any Third Party Administrator(s)
- Includes information on 340B program compliance as part of the quarterly report to the CHC Board of Directors

### F. Chief Operations Officer

- Ensure workflow for clinic administered drugs and devices is implemented and maintained to enable the tracking of 340B purchased drugs and devices at the NDC level from purchase to patient
- Information Technology Staff support the Pharmacy software selection of tracking software to manage the 340B program
- Assist as needed in defining the process and access to data for compliant identification of eligible patients
- Archive the data so as to be available to auditors when audited

### PROCEDURES:

The Board of Directors authorizes the Pharmacy Oversight Committee to develop and approve detailed procedures supporting this policy which will be maintained in the Department of Pharmacy Operations Manual.

Board Approval: 1/31/13

Board Approved Revision: 3/24/14

Board Review/No Revisions: 3/30/15

2018 Board Review and Approval of Revisions: 8/20/18

2019 Board Review and Approval of Revisions: