

# CAROLINA FAMILY HEALTH CENTERS, INC. POLICY

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**TITLE:** PHR-101 Affordable 340B Insulin and Injectable Epinephrine Access

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**EFFECTIVE DATE:** October 28, 2025

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**SECTION:** Pharmacy

**REFERENCE PROCEDURE:** PHR-101.01 Affordable 340B Insulin and Injectable Epinephrine Access

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**RESPONSIBLE CHIEF OF STAFF:** Chief Pharmacy Officer

**RESPONSIBLE COMMITTEE:** Pharmacy & Therapeutics CIT

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**REVIEWED:**

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## I. PURPOSE

The purpose of this policy is to ensure Carolina Family Health Centers, Inc. (CFHC, Inc.) compliance with Section 330(e) Notice of Award (NoA) Term 5 requirement to provide affordable access to insulin and injectable epinephrine to low-income individuals with high-cost sharing requirements, high unmet deductibles, or no health insurance by extending 340B pricing plus a minimal administration fee, so long as in compliance with state and federal law and not precluded or prohibited by applicable insurance contracts.<sup>1</sup>

## II. POLICY

As a Section 330(e) HRSA grant recipient, CFHC, Inc. must comply with the terms and conditions of the award to maintain participation in the HRSA-Funded Health Center Program. As such, CFHC, Inc. has processes in place to ensure compliance with the NoA Term 5, which states:

“Consistent with Executive Order 14273<sup>2</sup>, the recipient of a grant under section 330(e) of the Public Health Service Act (42 U.S.C. 254b(e)) must have established practices to make insulin and injectable epinephrine available at or below the discounted price paid by the health center grantee (award recipient) or sub-grantee (subrecipient) under the 340B Drug Pricing Program (plus a minimal administration fee) to individuals with low incomes, as determined by the Secretary, who: (a) have a high cost-sharing requirement for either insulin or injectable epinephrine; (b) have a high unmet deductible; or (c) have no health care insurance. For this purpose, a “low-income individual” is an individual living in a household with an income level at or below 200 percent of the Federal Poverty Guidelines (see 42 CFR 51c.303(f), Poverty Guidelines | ASPE).”

### Eligible Patients

CFHC, Inc. patients with incomes below 200% of the Federal Poverty Guidelines who have a high cost-sharing requirement for either insulin or injectable epinephrine, have a high unmet deductible, or have no health care insurance, are eligible for 340B injectable epinephrine and insulin pricing (340B EIP).

To ensure compliance with Federal requirements of the 340B program<sup>3</sup>, in order to be eligible to receive 340B medications, an individual must be a patient of the health center and meet patient eligibility criteria described in HRSA 1996 Patient Definition.<sup>4</sup> CFHC, Inc. prescribes,

dispenses, and/or administers 340B medications only to individuals eligible to receive 340B medications. *Refer to PHR-100 Pharmacy Program Compliance.*

Income determination is made through patient application to the Sliding Fee Discount Program and is based on household size and annual income. Patients must have an active, unexpired Sliding Fee Discount Program Application to be eligible for the 340B EIP. *Refer to FIN-116 Sliding Fee Discount Program.*

Determination of high cost-sharing and high unmet deductible is made through pharmacy adjudication of the prescription claim through the pharmacy software any applicable third-party payor. Because the requirement is to make discounted pricing available to the individual, CFHC, Inc. will not charge third-party payors the discounted price. According to the Health Center Program Compliance Manual, Chapter 16:

“The health center must make and continue to make every reasonable effort to secure payment for services from patients, in accordance with health center fee schedules and the corresponding schedule of discounts.”<sup>5</sup>

### **Eligible Drugs**

The health center maintains a formulary of affordable insulin and injectable epinephrine products for access at 340B EIP. This formulary is reviewed and updated quarterly, in line with 340B pricing updates.

### **Eligible Locations**

Patient access to 340B EIP is available at all CFHC, Inc. pharmacy locations: Wilson Community Health Center Pharmacy, Harvest Family Health Center Pharmacy, and Freedom Hill Community Health Center Pharmacy.

### **340B EIP Pricing**

For all prescriptions meeting the above eligibility requirements, the patient responsibility shall be limited to a maximum of the actual acquisition cost plus a minimal administrative fee equivalent to the Tier 4 pharmacy dispensing fee. *Refer to FIN-116 Sliding Fee Discount Program.*

## **III. DEFINITIONS**

- **High cost-sharing requirement:** Total out-of-pocket cost (including copay, coinsurance, or other non-deductible cost-sharing) for a specific prescription of insulin or injectable epinephrine that exceeds the sum of the discounted price of the designated medication plus the administration fee associated with the 340B EIP.
- **High unmet deductible:** Total out-of-pocket cost due to unmet deductible for a specific prescription of insulin or injectable epinephrine that exceeds the sum of the discounted price of the designated medication plus the administration fee associated with the 340B EIP.
- **Low-income individual:** An individual living in a household with an income level at or below 200 percent of the Federal Poverty Guidelines.

- **Minimal administration fee:** Minimal administration fee may include any dispensing costs, counseling costs, and any other charges associated with the patient receiving the medication.
- **No health care insurance:** An individual who, for a given period, does not have any form of prescription coverage through employer-based insurance, direct purchase, Medicaid, Medicare, military or VA coverage, or other government programs.

#### IV. REFERENCES

1. <https://bphc.hrsa.gov/compliance/compliance-manual/chapter9#footnote9>
2. <https://www.federalregister.gov/documents/2025/04/18/2025-06837/lowering-drug-prices-by-once-again-putting-americans-first>
3. <https://www.hrsa.gov/sites/default/files/hrsa/rural-health/phs-act-section-340b.pdf>
4. <https://www.hrsa.gov/sites/default/files/hrsa/opa/patient-entity-eligibility-10-24-96.pdf>
5. <https://bphc.hrsa.gov/compliance/compliance-manual/chapter16>