

340B Policy & Procedure Manual

340B Procedure Manual

340B.15 – Affordable 340B Insulin & Injectable Epinephrine Access for Low-Income Individuals (EO 14273)

SCOPE: FQHC NAME (hereafter, the health center) adopts this policy for all personnel, including contracted employees.

POLICY: As a Section 330(e) HRSA grant recipient, the health center must comply with the terms and conditions of their award to maintain participation in the HRSA-Funded Health Center Program. The health center has processes in place to ensure compliance with the Notice of Award (NOA) Term 5.

NOA Term 5: “Consistent with Executive Order 14273¹, 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).”

PURPOSE: To ensure the health center’s compliance with Section 330(e) 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.**²

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.

¹ <https://www.federalregister.gov/documents/2025/04/18/2025-06837/lowering-drug-prices-by-once-again-putting-americans-first>

² <https://bphc.hrsa.gov/compliance/compliance-manual/chapter9#footnote9>

PROCEDURE:

The Health Center provides access to insulin and injectable epinephrine at or below the 340B ceiling price, plus a minimal administration fee, to 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.

Eligible Patients

- All *Health Center* 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 program³, 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 Definition⁴ (See Section 340B.03 – 340B Eligibility)

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.

340B EIP Access Locations

- Patient access to 340B EIP is available at:
 - List locations where 340B EIP will be offered. While you are required to provide access to insulin and injectable epinephrine to low-income patients at affordable prices, NOA Term 5 does not mandate that this occurs at all locations providing pharmaceutical services. BPHC has left this decision to the discretion of each health center to determine what is the appropriate method to employ when creating patient access to these life-saving medications.

“High cost-sharing requirement” and “high unmet deductible”

- A patient shall be considered to have a “high cost-sharing requirement” and “high unmet deductible” if their total out-of-pocket cost (including any deductible, copay, coinsurance, or other cost-sharing) for a specific prescription of insulin or injectable

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>

epinephrine exceeds the sum of the discounted price of the designated medication plus the administration fee associated with the 340B EIP.

Adjudication of 340B Injectable Epinephrine and Insulin Pricing (340B EIP)

- NOA Term 5 requires eligible low-income individuals can access these medications at or below the discounted price paid by the health center under the 340B Drug Pricing Program plus a minimal administration fee.
- 340B Price: The OPAIS 340B Pricing Database will serve as the official reference for determining 340B ceiling prices.
- Administration Fee: The minimal administration fee may include any dispensing fee, counseling costs, and any other charges associated with the patient receiving the medication.
 - The administration fee should not create a barrier to low-income health center patients accessing these drugs, and health centers should make every reasonable effort to keep the fee as low as possible. State Medicaid professional dispensing fees may be considered as a reference when determining minimal administration fees.
- Prescription Adjudication: When available, the health center will adjudicate any insurance as part of this process, to determine if the low-income individual meets the “high cost-sharing” or “high unmet deductible” requirements and is eligible to receive discounts under 340B EIP.

340B EIP Pricing Limitation

- NOA Term 5 states “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.
- Because the requirement is to make discounted pricing available to the individual, the health center is not required to charge third-party payors the discounted price.
 - “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.”⁵

⁵ <https://bphc.hrsa.gov/compliance/compliance-manual/chapter16>

POLICY RATIONALE:

NOA Term 5: “Consistent with Executive Order 14273, 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).

Your practices should be incorporated in written policies and supporting procedures that reflect this determination and that define a “high-cost sharing requirement,” a “high unmet deductible,” and “no health care insurance” for this purpose.

You will document on Form 1C: Documents on File in your future Service Area Competition (SAC) applications or Budget Period Progress Reports (BPRs) that you have current practices, supported by written policies/procedures, that demonstrate your compliance with this term of your award, and you will make those documents available for review upon HRSA’s request.

Questions? Contact:

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