



340B Insulin & Injectable Epinephrine Access for Low-Income Individuals Resource Sheet

Press Release: HRSA Announces Action to Lower Out-of-Pocket Costs for Life-Saving Medications at Health Centers Nationwide: <https://www.hrsa.gov/about/news/affordable-medications>

Federal Register: Lowering Drug Prices by Once Again Putting Americans First
<https://www.federalregister.gov/documents/2025/04/18/2025-06837/lowering-drug-prices-by-once-again-putting-americans-first>

Sec. 7. *Access to Affordable Life-Saving Medications.* Within 90 days of the date of this order, as appropriate and consistent with applicable law, the Secretary shall take action to ensure future grants available under section 330(e) of the Public Health Service Act, as amended, 42 U.S.C. 254b(e), are conditioned upon health centers establishing practices to make insulin and injectable epinephrine available at or below the discounted price paid by the health center grantee or sub-grantee under the 340B Prescription Drug 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 healthcare insurance.

Electronic Handbook: Notice of Award Terms and Conditions: Grant Specific Terms

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.

Federal Register: Implementation of Executive Order on Access to Affordable Life-Saving Medications (12/23/2020 HHS Rule, rescinded on 11/1/2021)
<https://www.federalregister.gov/documents/2020/12/23/2020-28483/implementation-of-executive-order-on-access-to-affordable-life-saving-medications>

Medicare Benefit Policy Manual Chapter 13: Rural Health Clinic (RHC) and Federally Qualified Health Center (FQHC) Services (3/20/2025) <https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/bp102c13.pdf>

90.1 – “Charges and Waivers (Rev. 220, Issued: 01-15-16, Effective: 02-01-16, Implementation: 02-01-16) Charges for services furnished to Medicare beneficiaries must be the same as the charges for non-Medicare beneficiaries. FQHCs may waive collection of all or part of the copayment, depending on the beneficiary’s ability to pay.”

90.2 – “Sliding Fee Scale (Rev. 239, Issued: 01-09-18, Effective: 1-22-18, Implementation: 1-22-18) FQHCs that are approved by HRSA are required to establish a sliding fee scale in accordance with statutory and HRSA requirements.”

Health Center Program Compliance: Manual Chapter 9: Sliding Fee Discount Program

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

- k. "Health center patients who are eligible for sliding fee discounts and have third-party coverage are charged no more for any out-of-pocket costs than they would have paid under the applicable SFDS discount pay class.⁹ Such discounts are subject to potential legal and contractual restrictions."¹⁰

⁹ For example, an insured patient receives a health center service for which the health center has established a fee of \$80 per its fee schedule. Based on the patient's insurance plan, the co-pay would be \$60 for this service. The health center also has determined, through an assessment of income and family size, that the patient's income is 150% of the FPG and thus qualifies for the health center's SFDS. Under the SFDS, a patient with an income at 150% of the FPG would receive a 50% discount of the \$80 fee, resulting in a charge of \$40 for this service. Rather than the \$60 co-pay, the health center would charge the patient no more than \$40 out-of-pocket, consistent with its SFDS, as long as this is not precluded or prohibited by the applicable insurance contract.

¹⁰ Such limitations may be specified by applicable Federal or state programs, or private payor contracts.

Health Center Program Compliance Manual: Chapter 16: Billing and Collections

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

- "The health center must make and continue to make every reasonable effort to collect appropriate reimbursement for its costs on the basis of the full amount of fees and payments for health center services without application of any discount when providing health services to persons who are entitled to:
 - Medicare coverage under title XVIII of the SSA [42 U.S.C. 1395 et seq.];
 - Medicaid coverage under a State plan approved under title XIX of the SSA [42 U.S.C.1396 et seq.]; or
 - Assistance for medical expenses under any other public assistance program (for example, CHIP), grant program, or private health insurance or benefit program.
- 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."