

Insulin and EpiPen Terms and Conditions: Frequently Asked Questions

The Executive Order (EO) "[Lowering Drug Prices by Once Again Putting Americans First](#)" requires health centers to establish practices to make insulin and injectable epinephrine affordable to individuals with low incomes under the 340B program. On June 24, 2025, health centers received new notice of awards (NOAs) and were notified of the new Terms and Conditions to implement the EO.

1. Does this policy apply to just health center patients or any individual?

These are the Terms and Conditions of your health center's 330 funding, and they only apply to health centers and their patients. Additionally, the Executive Order¹ states "consistent with applicable law" which includes compliance with 340B statutory and regulatory requirements to not resell or otherwise transfer 340B drug to a person who is not a patient of the entity.²

2. When do health centers need to implement this change?

The new 340B Terms and Conditions do not explicitly include an implementation date. However, health centers are required to make their policies and procedures available upon HRSA's request, including during an Official Site Visit (OSV). This information will be included in Form 1C: Documents on File³ in your Future Service Area Competition (SAC) application or upcoming Budget Period Progress Report.

3. What steps should health centers take to implement the new Terms and Conditions?

Health centers should first evaluate existing policies and procedures related to making medications affordable. Based on existing policies and procedures, the leadership team can develop new ones or amend existing ones to incorporate the Terms and Conditions. Once the health center has drafted policies and procedures to reflect the new Terms and Conditions requirements, the next step is to focus on implementation at the entity-owned pharmacy, contract pharmacies, or provider dispensed medications, where applicable.

4. Does this apply to ALL Insulin? What about GLP-1s?

This applies to all insulin products purchased under the 340B program. The policy only applies to injectable epinephrine (e.g. EpiPen[®]) and insulin, not other medications used to treat diabetes or other forms of epinephrine. GLP-1s (Glucagon-Like Peptides) like Ozempic[®] & Trulicity[®] are not insulins and thus not included.

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

² <https://www.hrsa.gov/sites/default/files/hrsa/rural-health/phs-act-section-340b.pdf>

³ <https://bphc.hrsa.gov/sites/default/files/bphc/funding/form-1c.pdf>

5. How does HRSA define “low-income”?

The Terms and Conditions define low-income as being an individual living in a household with an income level at or below 200 percent of the Federal Poverty Guidelines. Health centers are required to make the specified medications available to low-income patients 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.

6. Does this apply to FQHC Look-A-Likes?

As written, the Executive Order does not apply to Look-A-Likes. Per the EO, 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...”

7. Does this apply to both contract pharmacies and in-house pharmacies, or can we apply it only to the in-house pharmacy?

The requirement is to have established practices for making insulin and injectable epinephrine available at or below the 340B price plus a minimal administration fee. Health centers have the flexibility to choose where this access is created. Creating access to these medications at either entity-owned or contract pharmacies, or both, will support compliance with the new terms and conditions. It is up to the health center to select which pharmacies can make insulin and injectable epinephrine available at or below the 340B price for health center patients. Health centers may also elect to make these medications available through provider dispensing at their clinic locations in compliance with state and federal law.

8. What if my health center only uses contract pharmacies?

Since 2020, drug manufacturers have restricted access to insulin products at the 340B price at contract pharmacies. Health centers have the ability to use the designation process to select one contract pharmacy, per health center site, to receive “restricted” drugs at the 340B price. Your health center should make a good-faith effort to be compliant with the new 340B Terms and Conditions in your Notice of Award.

If the health center is unable to access medications at 340B prices, then they are unable to extend the discount as it is not available. Per the EO, “health centers establishing practices to make insulin and injectable epinephrine available at or below the discounted price **paid...**”

9. Are there any specific requirements for patient education regarding the Insulin and injectable epinephrine discounts, especially if FQHC has a contract pharmacy arrangement?

There are no specific requirements to educate patients about these discounts, but just like health centers have always been doing, you'll want to share with your patients where they can access these medications at an affordable price.

10. How should health centers define “minimal administration fee?”

Specific administration fee limits are not defined/prescribed; this is another area that is left for the health center to best determine what constitutes a "minimal administration fee". You can look up your state's Medicaid professional dispensing fee or cost of dispensing survey to help guide your administration fee. Apexus, the 340B Prime Vendor, [340B Medicaid Profiles by State / Territory Tool](#)⁴ provides a resource for identifying state Medicaid requirements including Medicaid professional dispensing fees.

11. We adhere to this order in our current Sliding Fee Scale (SFS) policy. Can we add to our SFS policy, or should it be a stand-alone policy?

The health center should determine where to add this language, based on what route is best for them. This does not need to be a stand-alone policy, but some health centers may elect to make it so.

If a health center's current policy is already in compliance with the new Terms and Conditions (currently providing low-income patients with high cost-sharing requirements; high unmet deductibles; or have no health care insurance access to insulin and injectable epinephrine at 340B pricing plus a minimal dispensing fee), then it is reasonable to make any necessary updates to the policy that already exists.

It is important to note that the new terms and conditions added additional expectations for creating access for individuals with low incomes. Specifically, health centers are instructed to add new definitions to their policies and procedures defining “high cost sharing requirement,” a “high unmet deductible,” and “no health care insurance.” If creating stand-alone policy, it is recommended that the health center reference the existing income determination policy utilized by the health center.

⁴ <https://www.340bpvp.com/resource-center/medicaid>

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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.

Executive Order 14273: 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.

