



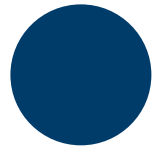
NATIONAL ASSOCIATION OF  
Community Health Centers®

# New 340B Terms and Conditions: What's Next?

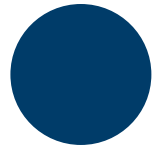
July 2nd, 2025



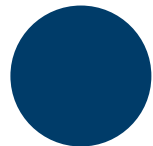
# Today's Agenda



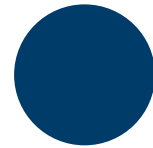
NACHC Resources



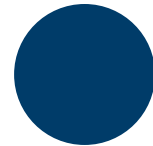
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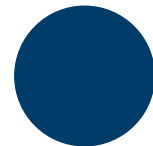
Implementation Timeline



The Facts & Next Steps



Sample Policy & Procedure  
Overview



Q&A

**THIS IS FINE**





# NACHC Resources

01

Sample Policies & Procedures

02

FAQs

03

340B Office Hours-  
Operations Deep Dive

# Trump Executive Order on Lowering Drug Prices

Executive Order was Released on April 15th Based on First Term Action

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.

# New 340B Terms and Conditions

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.**

# Implementation Timeline

HRSA does not require an explicit implementation date. However, you must have written policies and procedures available for review, depending on the upcoming deadlines for the requirements below for your health center. Make a reasonable effort!



OSV

Your next operational site visit, a reviewer can request to review your P&Ps

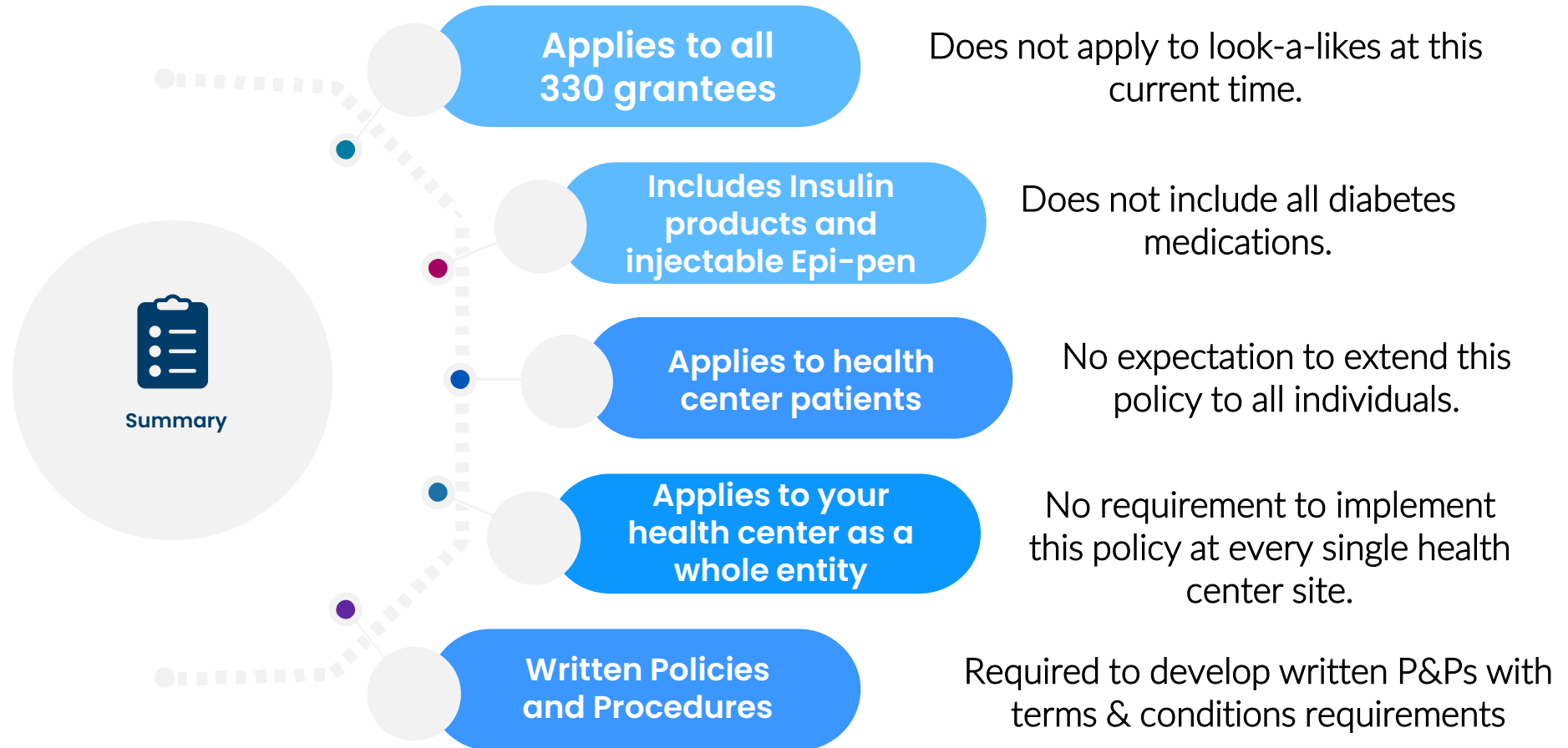
SAC

Information should be included in Form 1C: Documents on File in your future Service Area Competition application.

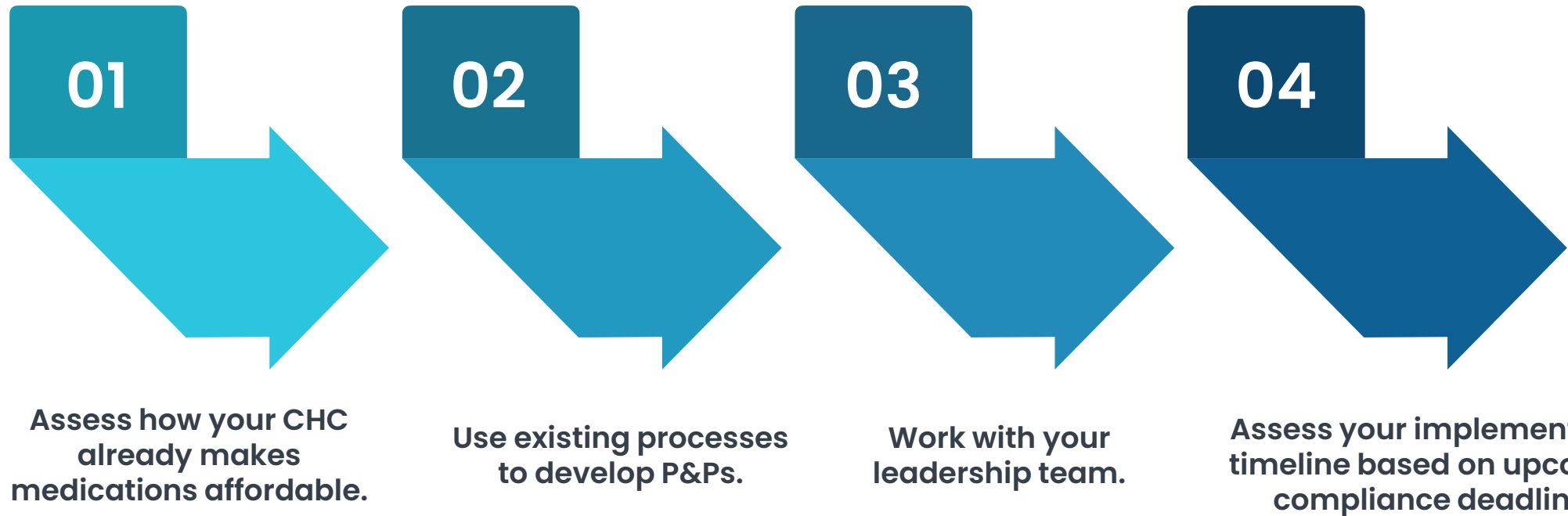
BPR

The Budget Period Progress Report is required for non-competing continuation of Health Center Program (H80) awards.

# The Facts



# Where Do I Start?



# Sample P&P: 340B Injectable Epinephrine & Insulin Pricing (340B EIP)

## 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.

## 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.**

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

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

<https://www.hrsa.gov/sites/default/files/hrsa/opa/patient-entity-eligibility-10-24-96.pdf>

<https://www.340bpvp.com/Documents/Public/340B%20Tools/sample-policy-and-procedure-manual-community-health-centers.docx>

# Sample P&P: 340B EIP Policy 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 Sample P&P: 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.

# Sample P&P: 340B Injectable Epinephrine & Insulin Pricing (340B EIP)

## PROCEDURE:

- **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 program, 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.
- **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 the pharmacies listed** in Addendum A.

# Sample P&P: 340B Injectable Epinephrine & Insulin Pricing (340B EIP)

## PROCEDURE:

- **Adjudication of 340B Injectable Epinephrine and Insulin Pricing (340B EIP):** 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:** Because the NOA 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.”

# Questions?

# Mark Your Calendars!



**NACHC Policy Pulse – July 9**

**Open to All**

<https://bit.ly/3e9a7CI>



**F.A.S.T. Call – July 23**

**Open to All**

<https://bit.ly/NACHCFASTcallregistration>



**F.A.S.T. Deep Dive – September 24**

**NACHC Members Only**

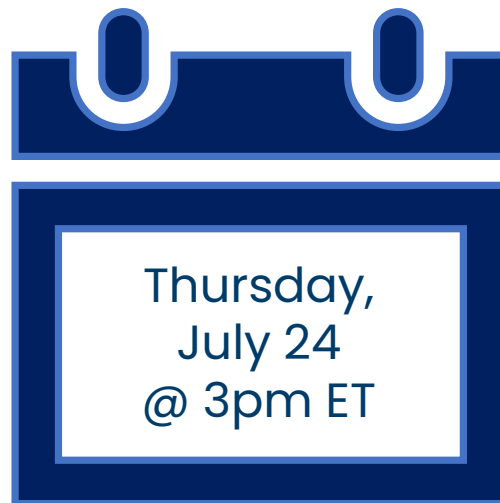
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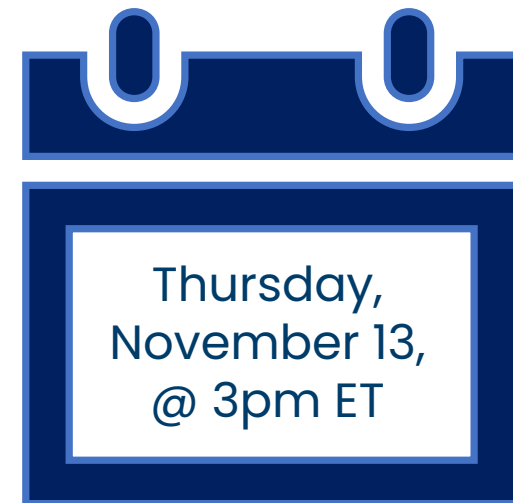
# Upcoming 340B Office Hours

During each 340B office hours, we discuss the most recent federal, state, and operational updates.  
**There will be no August 340B Office Hours due to CHI!**

Register [here](#) to attend the upcoming 340B Office Hours



*Focus topic: Refresher on IRA  
101 & Part 2 of Epi-Pen/Insulin  
Terms of Conditions*



Join Noddlepod to connect with the 340B community and access previous Office Hour slides and recordings.  
Email [regulatoryaffairs@nachc.org](mailto:regulatoryaffairs@nachc.org) to get access!

# Advocacy Updates

- Find current advocacy campaigns in [NACHC's action center](#)
- **Call-in Campaign during House Vote**
  - Action Alert email will go out the morning of July 2
  - Full court press for advocates to make phone calls
  - NACHC will share on social media, so please amplify
- Bipartisan **CHC Caucus Campaign**
  - We have reached **33 Members—with a goal of 50!**
  - Share the campaign: <https://bit.ly/Join-CHC-Caucus>

**Thank you for your partnership!**



The "One Big Beautiful Bill" puts millions of Americans at risk of losing their health coverage, including patients of Community Health Centers (CHCs). CHCs provide high-quality and cost-effective primary and preventive health care to over 16 million patients insured through Medicaid. Medicaid funding is vital, and changes of this magnitude will have an immediate and devastating impact on CHC patients and the financial stability of CHCs. We strongly urge the House to reject this legislation.

*Follow the link to read our full statement.*

**NACHC STATEMENT REGARDING SENATE PASSAGE OF THE ONE BIG BEAUTIFUL BILL**

**[Read Full Statement](#)**

# THANK YOU!

Contact us at  
[RegulatoryAffairs@nachc.org](mailto:RegulatoryAffairs@nachc.org)



NATIONAL ASSOCIATION OF  
Community Health Centers®

PLEASE VISIT US ONLINE

[nachc.org](http://nachc.org)