



NATIONAL ASSOCIATION OF
Community Health Centers®

July 2025

340B Office Hour

*Part 2 of Epi-Pen/Insulin Terms of Conditions
& Refresher on Sliding Fee Scale*

July 24, 2025



Welcome!

- Today's meeting is being recorded.
- The recording and additional resources will be made available to all registrants.
- A copy of the slides will be sent from regulatoryaffairs@nachc.org after the event.

Housekeeping

Please support **NACHC's commitment to creating a respectful and professional environment** for all webinar participants, including attendees, speakers, and moderators.

To promote a positive experience for everyone, we expect all participants to use the chat and Q&A functions in a respectful and professional manner. Harassment, discrimination, and disruptive or inappropriate behavior of any kind will not be tolerated. Failure to follow these guidelines may result in removal from the webinar at our discretion. **Thank you for your cooperation.**

Overview

340B Federal and Regulatory Updates & Upcoming Events - Elizabeth Linderbaum, NACHC

Insulin and EpiPen Terms and Conditions-
Vacheria Keys, NACHC

Sliding Fee Scale and Deep Dive into Pharmaceutical Operations- Felicity Homsted and Logan Yoho, FQHC 340B Compliance

Q&A - Elizabeth Linderbaum, NACHC

340B Federal and State Updates



See updated 340B Manufacturer Restriction Chart [here](#).

Federal Updates

- Representative Matsui (D-CA) introduced the PATIENTS Act, which will codify 340B providers' ability to use contract pharmacies to dispense 340B discounted drugs
- Representative Buddy Carter (R-GA) will step down as House E&C Health Subcommittee Chair.
 - Representative Morgan Griffith (R-VA) will replace him.

State Updates

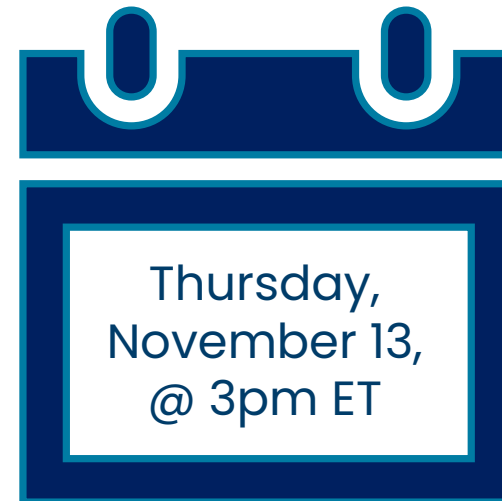
- **Rhode Island** passed their contract pharmacy protection bill, which includes reporting requirements.
- **Ohio** enacted 340B reporting laws in their budget.
- PhRMA is suing **Vermont and Hawaii** over their 340B contract pharmacy protection laws

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



*Join Noddlepod to connect with the 340B community and access previous Office Hour slides and recordings.
Email regulatoryaffairs@nachc.org to get access!*



NATIONAL ASSOCIATION OF
COMMUNITY HEALTH CENTERS®

2025

WORKFORCE CONFERENCE

Formerly FOM/IT

October 21-22 • Caesar's Palace
Las Vegas, NV



Join us in Las Vegas this October for the Workforce Conference!

See the following sessions related to 340B:

Tuesday, October 21

- 11:30 AM – 12:30 PM: **340B for the Finance Team**
- 2:00 PM – 3:00 PM: **Clinic Administered Drugs: To 340B or Not to 340B?**
- 4:00 PM – 5:00 PM: **Opening or Acquiring a 340B Pharmacy to Enhance Sustainable Income**

Wednesday, October 22

- 1:15 PM– 2:15 PM: **Navigating Compliance and Financial Implications of the Inflation Reduction Act for Health Centers**

Registration Link to come.

CMS Releases CY26 Medicare Physician Fee Schedule

CMS released calendar year (CY) 2026 Medicare Physician Fee Schedule (PFS) proposed rule which aims to advance primary care through new quality measures, reduce waste, and introduces a new payment model focused on improving care for chronic disease management. At a glance, the rule proposes to do many things, including the following related to 340B:

Medicare Prescription Drug Inflation Rebate Program:

- Establish a claims-based methodology to remove 340B units from Part D rebate calculations
- Establish a Medicare Part D Claims Data 340B Repository (“340B repository”) for voluntary submissions by covered entities for Part D claims with dates of service on or after January 1, 2026.

The Regulatory Affairs team will be hosting an Office Hour on Thursday, August 7 from 4-5PM ET and drafting comments on the proposal. Register for the office hour [here](#). Review CMS' [press release](#) and [fact sheet](#). View the CY26 PFS proposed rule [here](#).

Sliding Fee Scale Recap

Health Center Sliding Fee Program Requirements

- Bureau of Primary Health Care (BPHC) Health Center Compliance Manual:
- Chapter 9: Sliding Fee Discount Program
- The health center must operate in a manner such that **no patient shall be denied service due to an individual's inability to pay.**
- The health center must prepare a **schedule of fees or payments for the provision of its services** consistent with locally prevailing rates or charges and designed to cover its reasonable costs of operation and must prepare a **corresponding schedule of discounts** (sliding fee discount schedule) to be applied to the payment of such fees or payments, by which **discounts are adjusted on the basis of the patient's ability to pay.**
- The health center's schedule of discounts must provide for:
 - A full discount to individuals with incomes at or below Federal Poverty Guidelines (FPG) [100% of FPG], except nominal charges for service
 - No discount to individuals with incomes greater than twice FPG [200% of the FPG].

Health Center Sliding Fee Program Requirements

Bureau of Primary Health Care (BPHC) Health Center Compliance Manual:

Chapter 16: Billing and Collections

- If a health center elects to provide its patients access to **supplies or equipment** (for example, eyeglasses, prescription **drugs**, dentures) that are related to, but not included in, the service itself as part of prevailing standards of care, the **health center determines how to charge its patients for such supplies or equipment** (for example, flat discounts, at cost, sliding fee discounts).
- Footnote 3. See Chapter 9: Sliding Fee Discount Program for more information on the sliding fee discount schedule.

Health Center Sliding Fee Program Requirements

Bureau of Primary Health Care (BPHC) Health Center Compliance Manual:

Chapter 9: Sliding Fee Discount Program

- 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.
 - Footnote 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.



Medicare Sliding Fee Requirements

Chapter 13 of the Medicare Benefit Policy Manual:

- 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.
- FQHCs that are approved by HRSA are **required to establish a sliding fee scale in accordance with statutory and HRSA requirements**.

<https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Internet-Only-Manuals-IOMs-Items/CMS012673>

<https://www.cms.gov/regulations-and-guidance/guidance/manuals/downloads/bp102c13.pdf>

Sample Sliding Fee Scales

Traditional Model:

	Dispensing Fee (Service)	+	Ingredient Costs (Supply)	Minimum Charge
Level A: < 100% FPL	\$4	+	AAC	\$5
Level B: 101% to 200% FPL	\$8		AAC	\$9
Level C: > 200% FPL			U&C	

Flat Fee Model:

	Flat Fee
Level A: < 100% FPL	\$10
Level B: 101% to 200% FPL	\$20
Level C: > 200% FPL	U&C

OSV Review of Sliding Fee Scale

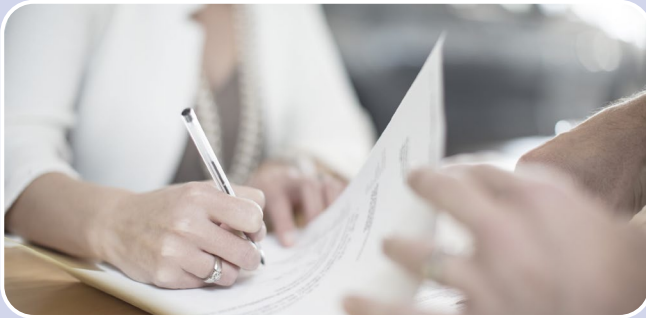
Element C: Sliding Fee for Column I Services For services provided directly by the health center (Form 5A: Services Provided, Column I), the health center's SFDS(s) is structured consistent with its policy and provides discounts as follows:

- A full discount is provided for individuals and families with annual incomes at or below 100 percent of the current FPG, unless a health center elects to have a nominal charge, which would be less than the fee paid by a patient in the first sliding fee discount pay class above 100 percent of the FPG.
- Partial discounts are provided for individuals and families with incomes above 100 percent of the current FPG and at or below 200 percent of the current FPG, and those discounts adjust based on gradations in income levels and include at least three discount pay classes.
- No discounts are provided to individuals and families with annual incomes above 200 percent of the current FPG.

Site Visit Findings: Notes:

- **Do not review discounts for supplies and equipment** that are related to but NOT included in the service itself as part of prevailing standards of care (for example, eyeglasses, **prescription drugs**, dentures). **These supplies and equipment are not considered services and are not subject to Health Center Program SFDP requirements.** (Pg 45)

Pharmacy OSV Focus



EHB Scope Form 5A

- Examples of issues have ranged from being told to remove CRx from Column II to adding it to Column III, in addition to Column II.



Contract Credentialing

- Example of issue was site reviewer requesting documentation of credentialing of contract pharmacy pharmacists.



Sliding Fee Scales

- Example of issue include OSV reviewer stating that slides are required on the cost of the dispensing fee (service cost).



Terms & Conditions Recap

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; AND**
- (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 IC: 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**

BPHC encourages health centers to begin implementing these updated award terms immediately to ensure full compliance.

NACHC Resources and Next Steps

Outstanding questions we are assessing:

- What recourse do CHCs have if they are unable to procure 340B priced drugs at contract pharmacies due to manufacturer restrictions?
- What criteria should CHCs use to define low income?
- What role will PBMs play with the implementation of the EO?
- How do health centers verify a patient's remaining deductible at the pharmacy counter?

Review the [slides](#), [recording](#), [FAQ](#), and [sample policy](#) from NACHC's 7/2 webinar.

If you don't receive our emails, reach out to your IT department to whitelist 'regulatoryaffairs@nachc.org'

Insulin & Injectable Epinephrine EO Timeline

1st Insulin & Epi EO: July 24, 2020



2nd Insulin & Epi EO: April 15, 2025



1st Insulin & Epi Rule Published 12/23/2020



1st Insulin & Epi EO Rule
Rescinded: Nov 1, 2021

<https://www.federalregister.gov/documents/2020/07/29/2020-16623/access-to-affordable-life-saving-medications>

<https://www.federalregister.gov/documents/2020/12/23/2020-28483/implementation-of-executive-order-on-access-to-affordable-life-saving-medications>

<https://www.federalregister.gov/documents/2021/10/01/2021-21457/implementation-of-executive-order-on-access-to-affordable-life-saving-medications-rescission-of>

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

The EO Applies to:

330 Grantees

- Does not apply to FQHC Look-alikes or CHCs not participating in 340B

Insulin & Injectable Epinephrine

- Not all forms of epinephrine & not all diabetic medications

Individuals Eligible for 340B

- The EO states “consistent with applicable law”, including 340B

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.**

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:

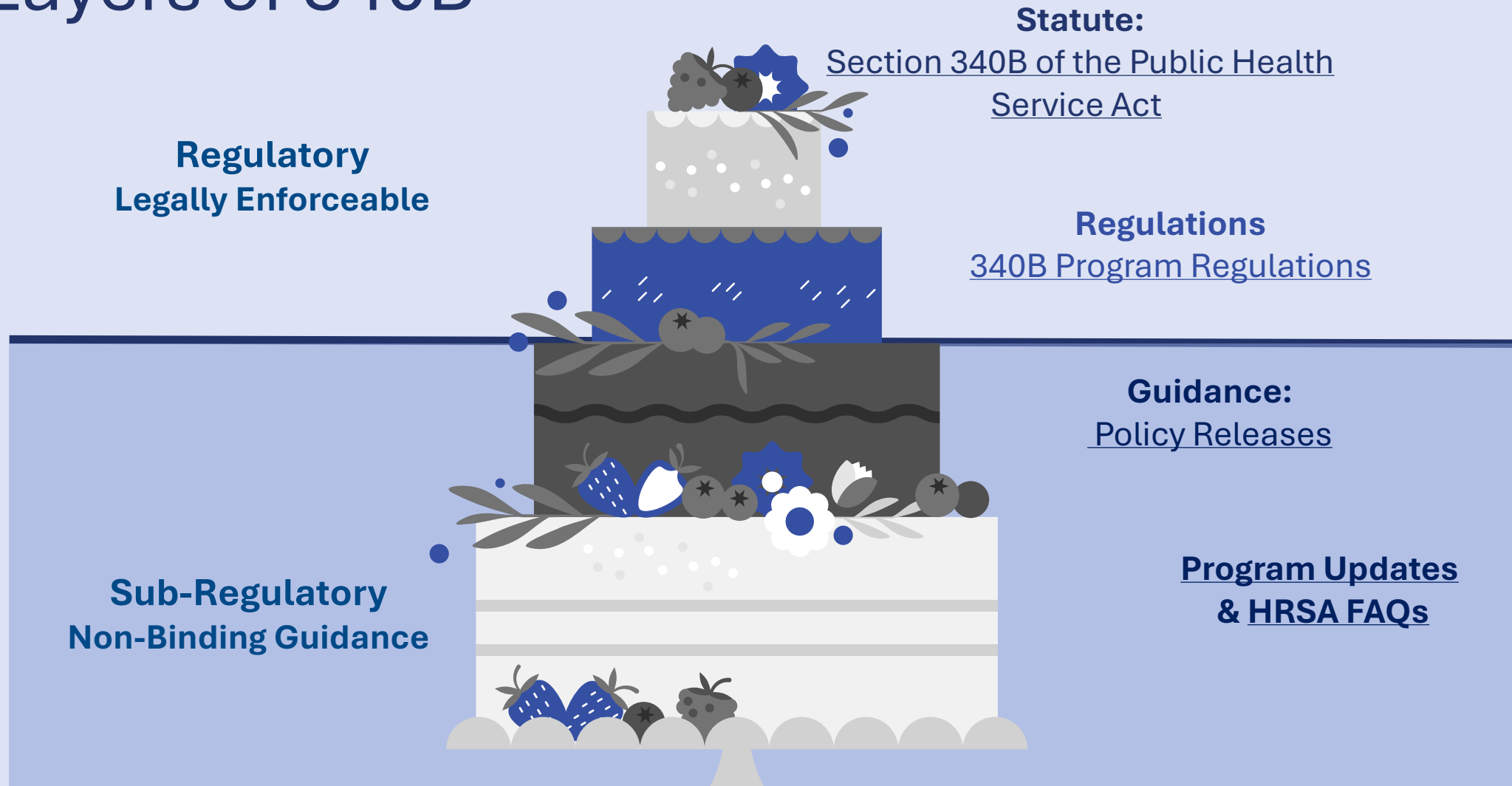
- **Eligible Patients:** All *Health Center* patients with incomes below 200% of the Federal Poverty Guidelines who have a high cost-sharing requirement for either insulin or injectable epinephrine, have a high unmet deductible, or have no health care insurance, are eligible for 340B injectable epinephrine 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...**
 - **Example: Entity Owned Pharmacy, Contract Pharmacy, Physician Dispensed**

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.”

Layers of 340B



Layers of 330

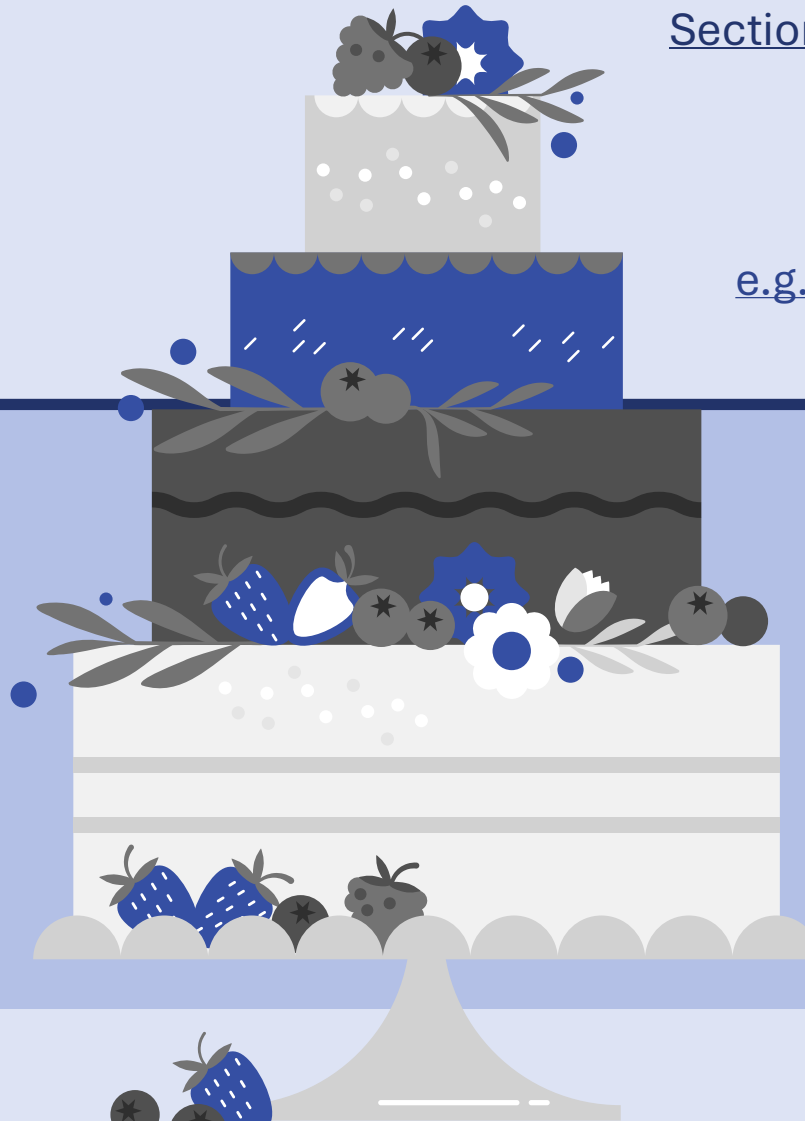
Regulatory
Legally Enforceable

Statute:
Section 330 of the Public Health
Service Act

Regulations:
e.g. Physician Fee Schedule (PFS)

Sub-Regulatory

Guidance & Policies:
Health Center Program
Compliance Manual
&
Policy Information Notices
(PINs) and Program
Assistance Letters (PALs)



42 USC § 254b (k)(3)(G) - “330 Statute”

(3) Requirements

(G) the center-

(i) has prepared a schedule of fees or payments for the provision of its services consistent with locally prevailing rates or charges and designed to cover its reasonable costs of operation and has prepared a corresponding schedule of discounts to be applied to the payment of such fees or payments, which discounts are adjusted on the basis of the patient's ability to pay;

(ii) has made and will continue to make every reasonable effort-

(I) to secure from patients payment for services in accordance with such schedules; and

(II) to collect reimbursement for health services to persons described in subparagraph (F) on the basis of the full amount of fees and payments for such services without application of any discount;

(iii)(I) will assure that no patient will be denied health care services due to an individual's inability to pay for such services; and

(II) will assure that any fees or payments required by the center for such services will be reduced or waived to enable the center to fulfill the assurance described in subclause (I); and

(iv) has submitted to the Secretary such reports as the Secretary may require to determine compliance with this subparagraph;

PBM Payer Contract Language

Network Provider agrees that it **shall collect the full Copayment from Members**, and that the Copayment is **not changed or waived unless required by law**...Unless prohibited by law, the collection of the Copayment must occur **prior to dispensing** each medication...Failure to collect the Member Copayment is also a **material breach** of Network Provider's obligations and may result in **immediate termination**...Network Provider understands that any claim for which Network Provider cannot establish the collection of the Copayment may be subject to **full recoupment by PBM**, in its sole discretion.

PBM Payer Contract Language



In accordance with U.S. Department of Health & Human Service, Health Resource Services Administration (“HRSA”) rules and requirements, Network Pharmacy Providers owned by or contracted with a **340B Participating Entity** may **discount or waive the Cost-Sharing Amounts** owed by Members for reasons of genuine financial need.

Operationalizing Secondary Discounts



Entity-Owned Pharmacy Software

Secondary Plans

- Some software vendors will allow a secondary plan that is billed after an insurance
- Removes any staff judgement calls on how much to charge
- Sometimes there are limitations in the calculation (e.g. may not be able to take AAC into consideration) and must apply a flat charge
- Sometimes this will, incorrectly, show up as revenue and financial reports must be adjusted

A/R Accounts

- These are easier to implement, simply charge the remainder to the A/R Account
- A/R accounts require the staff at POS to make a judgement call on what price to charge eligible patients
- In the case of EIP, you cannot seek repayment or bill patient for the discount
- Staff will need to regularly reconcile A/R accounts

Contract Pharmacy Cash Cards



- Currently most TPAs report contract pharmacy cash cards as being designed to run as a primary benefit only.
 - Reminder that your contract pharmacies have requirements follow state & federal law and applicable insurance contract requirements.

Thank You For Joining July's 340B Office Hours

Questions?

Email:
regulatoryaffairs@nachc.org

