



NATIONAL ASSOCIATION OF
Community Health Centers®

April 2026 Regulatory Affairs Office Hour

340B Rebate RFI

April 2, 2026



Welcome!

- Today's meeting is being recorded.
- The recording and additional resources will be made available to all registrants.
- AI note-takers are not permitted and will be removed from the call.
- 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.**

Noddlepod Replacement: Higher Logic

Higher Logic is now fully connected to your NACHC account. Here is a [step-by-step guide](#) on how to login/create a NACHC account. Once you have a NACHC account, you can:

- Login into [Higher Logic](#) with your NACHC account username and password
- Go to the [communities](#) page and request to join which communities you would like to join. For example, you may want to join the 340B Advocacy or the FQHC Pharmacy Operations communities.
- Allow 3-4 days for NACHC to approve your request. If you have any issues, reach out to regulatoryaffairs@nachc.org.
- Begin posting and interacting with the group!

If any information on your Higher Logic profile is incorrect, please update the information on your [NACHC profile](#) and it will be updated to Higher Logic automatically.

Overview

4th Circuit Court Ruling Update- FQHC 340B
Compliance

Overview of 340B Rebate RFI and templates-
Elizabeth Linderbaum, NACHC

Calculator and Data Elements- FQHC 340B
Compliance

A CHC perspective of framing the letter: Lisa
Nelson, Chief Pharmacy Officer, Unity Care
Northwest

Q&A and Upcoming Events - Elizabeth
Linderbaum, NACHC

4th Circuit Court Ruling

Fourth Circuit Blocks West Virginia 340B Delivery Law

Court: U.S. Court of Appeals for the Fourth Circuit

Decision Date: March 31, 2026

Case: PhRMA et al. v. McCuskey.

Issue: Whether state laws can impose delivery and data-sharing mandates on 340B drug manufacturers

Holding: West Virginia's law is likely preempted by federal 340B statute

What WV S.B. 325 Tried to Do

West Virginia S.B. 325

- Required manufacturers to:
 - Deliver 340B drugs to any contract pharmacy designated by a covered entity
 - Prohibited limits on contract pharmacy networks
- Prohibited manufacturers from:
 - Requiring claims or utilization data as a condition of 340B drug delivery
- Enforcement:
 - \$50,000 per violation
 - Enforced by state AG, Board of Pharmacy, and Insurance Commissioner

The Court's Bottom Line

The court affirmed a preliminary injunction

Found manufacturers are likely to succeed on the merits

Key conclusion:

- States cannot add conditions to the federal 340B program that Congress did not include

Result:

- West Virginia cannot enforce S.B. 325 while litigation continues

340B as a Federal “Spending-Power Bargain”

Congress
created a federal
bargain:

Manufacturers receive access to Medicaid markets
In exchange, they provide statutorily defined discounts

States:

Are not parties to this bargain
May not rewrite or expand it

The court
emphasized:

340B sets price terms only
Delivery and distribution conditions are not mandated by statute

Federal Supremacy & Uniformity

S.B. 325:

- Applies only to manufacturers participating in 340B
- Targets conduct that exists solely because of federal law

The court found:

- Congress ousted states from this field
- HHS is the exclusive enforcer of 340B

States cannot:

- Do indirectly what HHS cannot require directly

Operational Interference

State law interferes with:

- HHS enforcement authority
- Manufacturer audits (needed to prevent diversion & duplicate discounts)
- National uniformity of the 340B program

Prohibiting data requirements:

- Undermines manufacturers' ability to establish reasonable cause for audits
- Disrupts federal ADR and compliance mechanisms

Implications for 340B Policy Nationwide

Strengthens manufacturer challenges to:

- State 340B delivery mandates
- State restrictions on audit-related data access

Deepens a national circuit split:

- 4th Circuit: State delivery laws likely preempted
- 5th & 8th Circuits: Similar laws upheld

Increases likelihood of:

- Supreme Court review
- Congressional intervention

Key takeaway:

- 340B rules must come from Congress or HHS — not individual states

340B Rebate RFI

NACHC's Key Arguments

Rebate model brings interrelated risks that could significantly destabilize CHC operations.

Limited Patient Access

CHCs may be forced to limit inventory, delay access to high-cost medications, or scale back sliding fee scale programs that rely on 340B savings without the upfront discounts.

Manufacturer Control Without Guardrails

Manufacturers determine the approval/denial of 340B rebates, as well as the timing of the required payments. With limited federal enforcement mechanisms (HRSA), **CHCs could see a rise in denied or delayed rebates, which could place them in financial peril.**

Financial Instability

Upfront WAC purchasing creates significant liquidity risk and the uncertainty of payment timing disrupts payroll, vendor payments, and pharmacy operations.

Operational and Administrative Burden

New requirements for claims submission, reconciliation, dispute resolution, IT system upgrades, and vendor contracts places a large burden on CHCs.

Main Argument: CHCs should be exempt from any 340B rebate model

The rebate structure is fundamentally incompatible with the CHC care delivery and financing model. It undermines the statutory intent of the 340B program, which was designed to enable safety-net providers to stretch limited resources and expand access to care.



The “problem” that the rebate model seeks to address, could be solved without restructuring the program. **NACHC has been a leader in support of a neutral, third-party claims clearinghouse that would maintain the upfront discount structure and minimize administrative burden.**



Patient access and safety-net sustainability is the core issue. The rebate model introduces major risks that could reduce access to medications and weaken the financial stability of CHCs nationwide.

NACHC’s Regulatory Affairs team, in collaboration with FQHC 340B Compliance, K&L Gates, and the PCA Hub, have drafted two template comment letters for PCAs and CHCs to amplify their concerns about a 340B Rebate Model to HRSA. **Comments are due April 20th**

Templates:

- **340B Rebate RFI Long Template**
- **340B Rebate RFI Short Template**

340B Rebate Comment Letter Data Elements



Filed UDS Report Fields

Uninsured
Patients

Medicaid
Patients

Medicare
Patients

Commercially
Insured
Patients

Total Patient
Count

Pharmacy
Administrative
Costs

Pharmaceutical
Costs

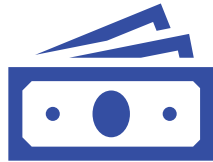
Sliding Fee
Discounts
Provided

Staffing



340B Compliance Staff

Internal auditing
TPA oversight/maintenance
Manufacturer restriction management
MFP reconciliations



Finance Staff

Monthly/annual booking and reporting
TPA reconciliations
MFP reconciliations



Quality/Compliance Staff

Internal auditing

Consultant Costs



What vendors do you use?

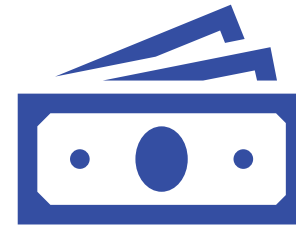
Annual Auditor

Legal Counsel

340B Consultant/Program Management

Referral Capture

Medicaid Billing



What costs did you incur in 2025?

Monthly

Annual

Retainer

Episodic

Increased fees to manage manufacturer restrictions and/or MFP

340B Dispense and Administration Data

TPA Reports

EHR Reports

Pharmacy System
Reports

Manufacturer
Restriction Impact
Reports

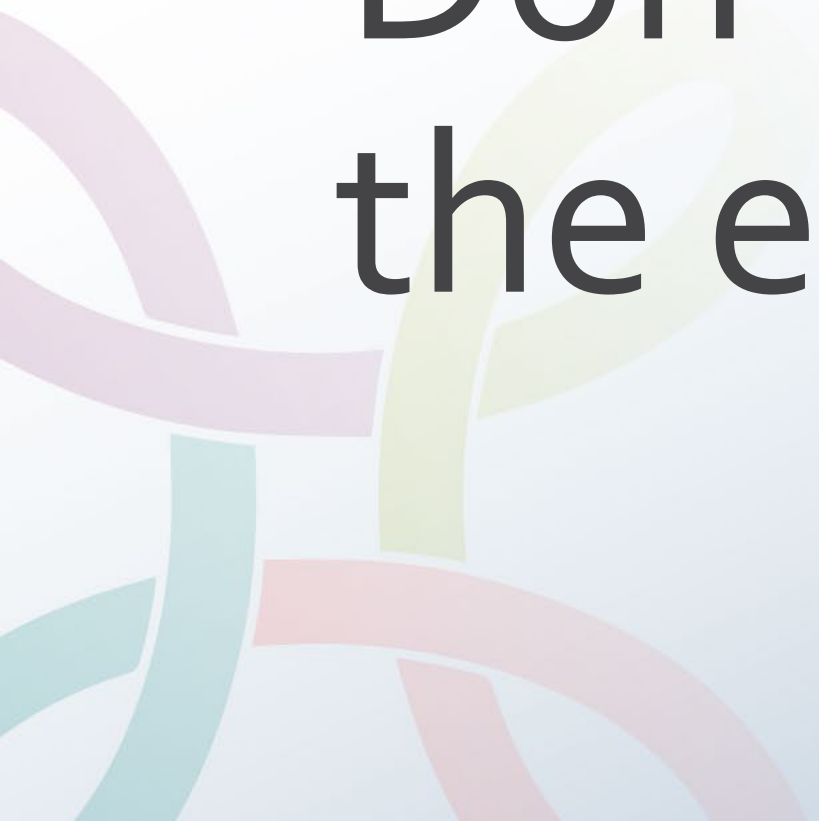
Clinic Administered
Drug Module Costs

RFI Response: HRSA 340B Rebate Model Pilot Program

Lisa Nelson, PharmD, 340B ACE

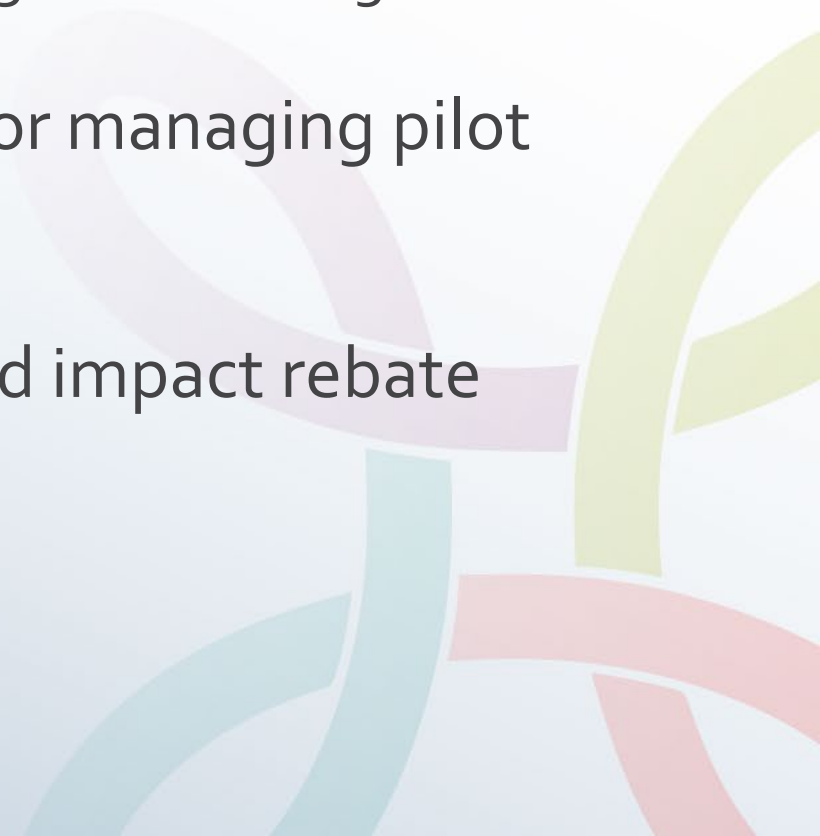
Chief Pharmacy Officer

Unity Care Northwest



Don't let perfect be
the enemy of good.


Key Data Points to Address

- Financial status of health center and impact 340B Rebate Model Pilot on cash flow
 - Understand wholesaler payment terms and the timing of when drugs are paid for and when rebates are received
 - Impact on operational and administrative costs for managing pilot
 - Current costs for managing program
 - Estimate of increase in costs under rebate pilot
 - How 340B revenue is used to support patients and impact rebate pilot will have on patients
 - Medication access
 - Services
- 

Unity Care Northwest RFI Response

- Prescription Drug Sliding Fee Discount Program Impact
- Medicaid billing requirements
- Increased administrative burden
- Cash flow impacts
 - Visuals to demonstrate timing of drug ordering, drug payment, rebate submission, and rebate payment

Impacts to Cash Flow – Scenario One

Sunday	Monday	Tuesday	Wednesday	Thursday	Friday	Saturday
	Invoice	Invoice	Invoice 	Invoice	Invoice	
		Prescription Filled	Rebate Submitted		Payment Due	
					Prescription Returned to Stock	Rebate Payment Received
	Rebate Reversal Submitted					

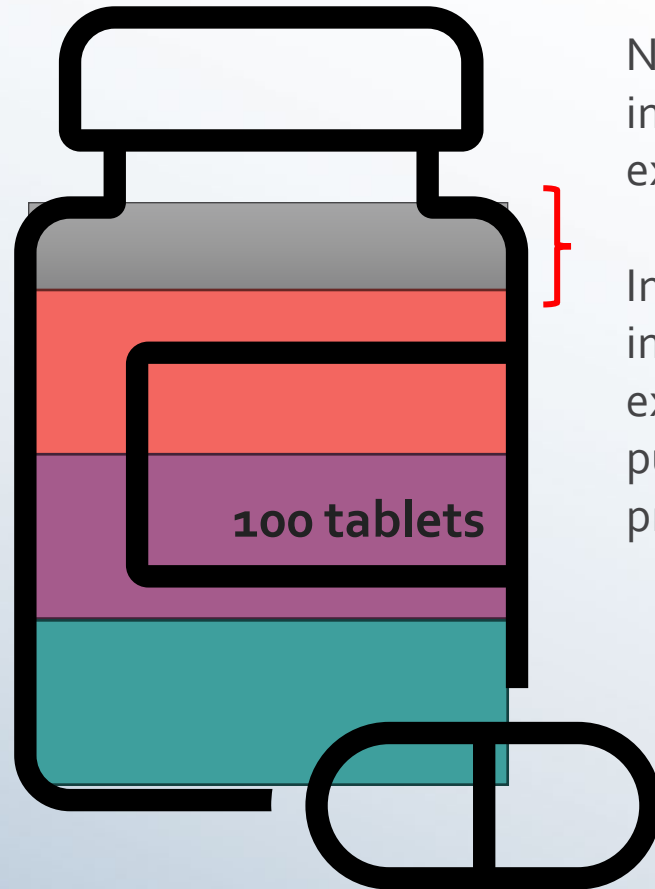
Scenario for 340B physical inventory model with rebate submission occurring after prescription filled and before sold. If returned to stock, administrative burden is increased.

Impacts to Cash Flow – Scenario One

Sunday	Monday	Tuesday	Wednesday	Thursday	Friday	Saturday
	Invoice	Invoice	Invoice 	Invoice	Invoice	
		Prescription Filled			Payment Due	
	Prescription Picked Up	Rebate Submitted				
					Rebate Payment Received	

Scenario for 340B physical inventory model with rebate submission occurring after prescriptions is sold to decrease administrative burden

Damaged / Expired Medication



No opportunity to rebate when inventory is damaged or expires.

In current physical 340B inventory model, damaged or expired medication are purchased up front at 340B price

Emailing Congress Members RFI Response



Including key, salient points in body of email

Questions?



Submitting a letter for the first time or need a refresher?

After customizing your letter,

1. Complete Your Internal Review Process

- Before submitting your comments, follow your organization's internal approval process
- Ensure at least one additional person reviews the letter
- Approval processes vary by organization, but reviewing for accuracy and clarity is critical

2. Submit Your Comment

- Return to the [original Federal Register notice](#) and select **"View Comment Instructions."** and **upload your comments as a PDF**

Be sure to submit your comment by **April 20**

3. Amplify Your Message

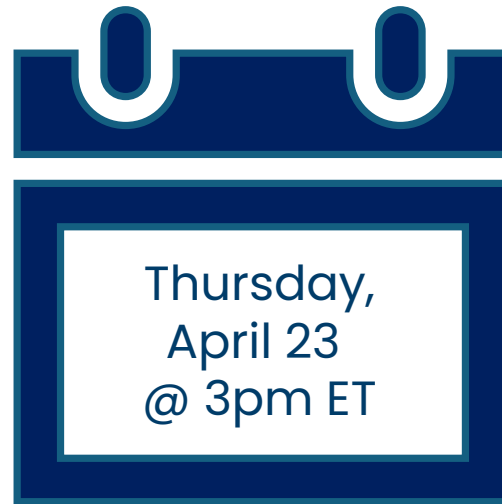
After submitting your comment, consider ways to extend its impact:

- Share it on your **organization's website**
- Coordinate with your **communications team**
- Send it to **policymakers or partners**

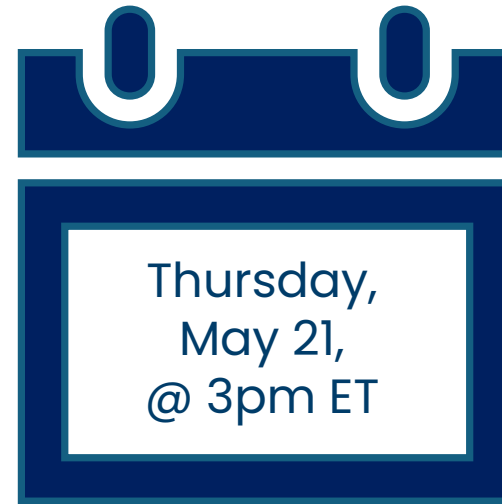
Upcoming 340B Office Hours

During each 340B office hours, we discuss the most recent federal, state, and operational updates.

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



*Focus topic: OSV
Changes and Express
Scripts FTC Settlement
Update*



Focus topic: TBD

Join us at Workforce in April!

April 28–29, Caesars Palace. [Register here.](#)



Wednesday, April 29:

1:15 PM – 2:15 PM PT: **"Strengthening 340B Compliance: Effective Self-Audits and Peer Review Strategies"**

2:45 PM – 3:45 PM PT: **"Rebates, Revenue, and Reality: Updates from Implementing the 340B Rebate Model Pilot"**

We Want to Hear From You!

Join one of NACHC's upcoming focus groups to share your experience with our advocacy programs and resources. Whether you're a seasoned advocate, brand-new, or just curious, your feedback will help us strengthen tools that support the Health Center Movement.

Your voice shapes what comes next — we hope you'll join us!



*Learn more details
and register today!*



Thank You For Joining
April's RA Office Hours

Questions?

Email:
regulatoryaffairs@nachc.org

