



NATIONAL ASSOCIATION OF
Community Health Centers®

March 2026 340B Office Hour

340B Rebate RFI

March 12, 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 in to [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

340B Review and Current Events – Elizabeth Linderbaum, NACHC

A CHC perspective of framing the letter: Sue Barnhart, 340B Program Director, Keystone Health

Template Letter Overview

Q&A, Upcoming Events – Elizabeth Linderbaum, NACHC

340B State Updates

Contract Pharmacy Bills:

- **Introduced in 2026:** Arizona, Iowa, Florida, New York, Washington
- **Still active from 2025:** California, Georgia, Ohio, Massachusetts, Michigan, New York, Illinois

Other:

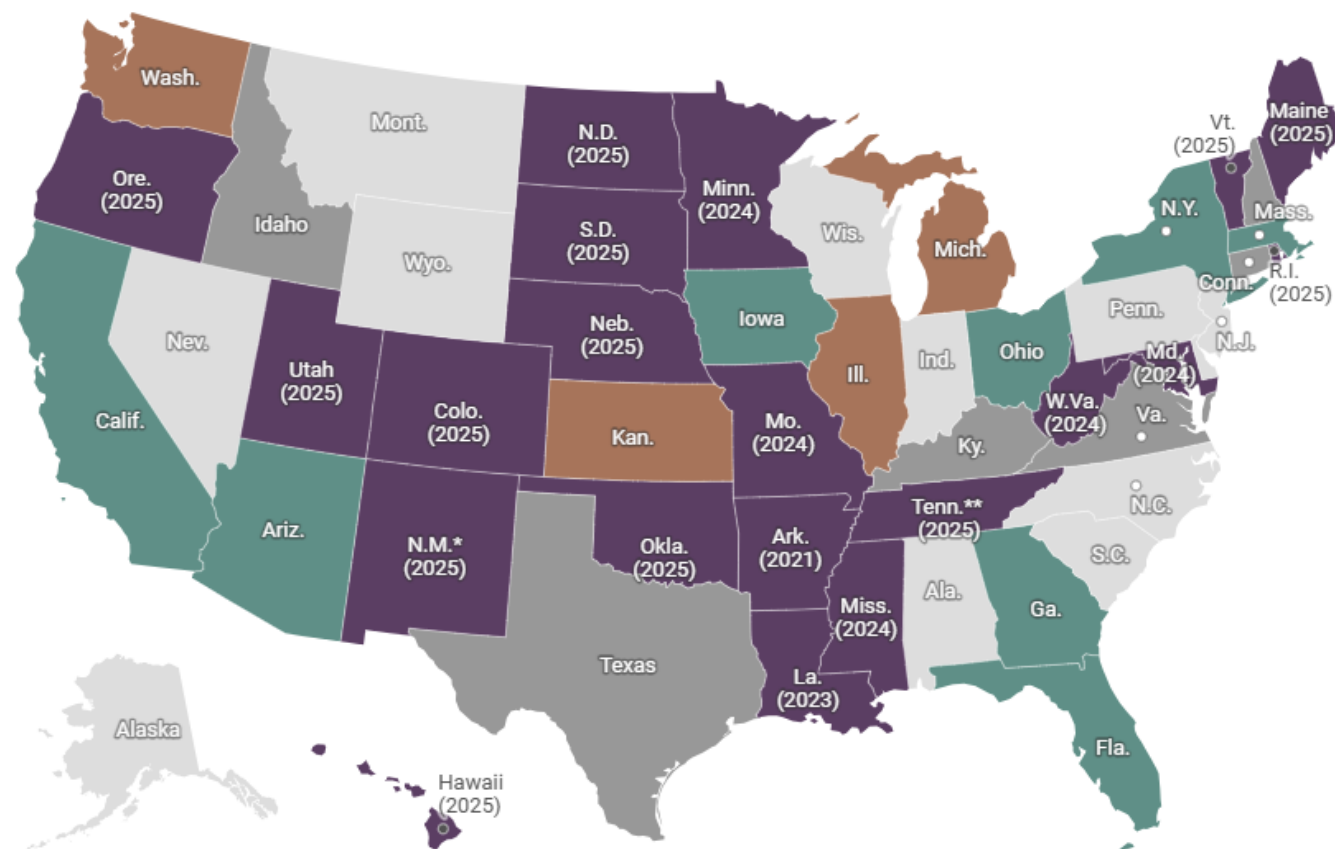
- Virginia SB 278 passes both chambers, with Governor for signature by the end of week

Lawsuit Action:

- DOJ and HHS file amicus briefs in Colorado and Rhode Island cases against 340B contract pharmacy laws
- TN Judge dismissed AbbVie's lawsuit

340B REPORT State 340B Contract Pharmacy Access Laws and Bills

● Contract pharmacy law enacted ● Contract pharmacy bill introduced in 2025-2026 session ● Contract pharmacy bill cleared first legislative chamber ● Contract pharmacy bill died



* New Mexico's law only applies to community health centers.

**Tennessee's bill only applies to drugmaker 340B restrictions placed after July 1, 2025.

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Map: updated as of March. 5, 2026 • Created with [Datawrapper](#)

Congressional 340B Updates

- Reps. Doris Matsui (D-CA), Dusty Johnson (R-SD), Debbie Dingell (D-MI), and Tracey Mann (R-KS) are leading a House letter to block FY27 funds from being used for a 340B Rebate Model. [NACHC supports this letter.](#)
- Reps. Jack Bergman (R-MI) and Jake Auchincloss (D-MA)- led bill to exempt CHCs from 340B rebate models is now up to 42 co-sponsors ([H.R.7391](#))
- HRSA may soon schedule a Congressional briefing on the impact of the 340B rebate model on patients' access to medication, as required by the [Consolidated Appropriations Act, 2026.](#)



Share Your Experience with the IRA and MTF

Please use the poll and chat function of the webinar to share your experience with the Inflation Reduction Act (IRA) and the Medicare Transaction Facilitator (MTF).



Please reach out to regulatoryaffairs@nachc.org if you want to share more about your experience or need assistance.

340B Rebate RFI & Calls

On February 13, HRSA released a request for information on the potential use of rebates in the 340B program. This comes after the failed attempt to launch a 340B rebate model pilot last year, which was halted by the courts due to a lack of an administrative record. **Comments are due April 20th**

March 12, 3-4:30 pm ET



340B Office Hours

Hear from health center experts about how they plan to utilize data to bolster their arguments. We encourage people to also bring questions about their draft templates, data inputs, and specific scenarios
[Register here.](#)

April 2, 3-4pm ET



Regulatory Affairs Office Hours

Working session with FQHC 340B Compliance and NACHC's Regulatory Affairs team, where people can come with specific questions on data, framing arguments, and more. [Register here](#)

[NACHC 340B Rebate Website](#)

Find the calculator, instructions, webinar recordings, and more!



Health Center Perspective of 340B Rebate Model

Sue Barnhart, 340B Program
Director, Keystone Health

Keystone Rural Health Center

- Founded in 1986 to provide health care to migrant farm workers; in 1992 received status of FQHC
- Serves more than 65,000 unique patients annually
- Two entity-owned pharmacies
 - 61 contract pharmacies

Family Medicine (2)

Behavioral Health (2)

Chiropractic

Dental Care (2)

Pediatric Dental

Women's Care

Podiatry (2)

Pediatrics (2)

Pediatrics High School Clinic

Community Health Services

Infectious Diseases

Internal Medicine (3)

Urgent Care (2)

Pediatric Development Center

Pharmacy (2)

Agricultural Worker Program (4)





Our Health Center's Perspective of a Rebate Model

- What is the true reason for a rebate model – transparency or control?
 - According to the number of HRSA audits with no/minimal findings, compliance is not the problem.
- Transparency:
 - Even with the claims data we are currently providing, manufacturers still insist on a rebate model.
 - Claims data provides the information they need to prevent duplicate discounts.
- Control:
 - With a rebate model, it will give control to the manufacturers in choosing to approve or deny rebates.
 - Without this control, they rely on getting approval for a HRSA audit, then still deal with a covered entity's refusal to pay. Denying a rebate payment will relinquish HRSA control and turn it over to the manufacturers.



Payer Group vs Patient Care

- ▶ Medicaid and ADAP are set up as a rebate model on adjudicated claims
 - ▶ Payers are not providing up-front patient care and can sustain rebate costs.
- ▶ Community Health Centers provide patient care and require up-front discounts
 - ▶ In 2025, our 340B discount contributed nearly \$2,000,000 to our reduced fee uninsured prescriptions.
 - ▶ A rebate model would create a huge cost barrier with hopes that we will be awarded the rebate later and would create a barrier to our ability in serving our mission.
 - ▶ With a 15% expected rate of denied claims, how much will this effect our reduced fee program stability?
 - ▶ Including 2026 and 2027 IRA drugs:
 - ▶ Our upfront inventory spend increase is expected to be \$7,409,398.74, at 38,002%.
 - ▶ Average increase in inventory costs pending rebate payments will cause a 45-day cash on hand impact of \$905,496.03



Clinic Administered Drugs



- ▶ In 2025, our health center administered 10,660 patient medication transactions through clinic encounters.
- ▶ Many patients are billed at a PPS rate which does not allow us to collect payment for many of these medication costs.
- ▶ 340B allows us to purchase these clinic drugs at a substantially lower cost.
- ▶ Many of these drugs are in multi-dose packages and are not entirely dispensed due to wastage or expiration. This would negate a rebate.
- ▶ Our farmworker program serves all of PA and most of their medications are dispensed from the clinic, and not from a pharmacy. In 2025, we dispensed nearly 1,600 prescriptions from our farmworker clinics.
 - ▶ We could not sustain the full retail cost to stock these medications and certainly would not dispense full packages within 45 days.



Clinic Administered Drugs – Medical claims

- ▶ Uploading rebate reports for medical claims require additional work and would create additional workload burdens even when full packages were dispensed.
- ▶ Creating these reports would easily take at least 5-10 times longer than uploading pharmacy claims.
 - ▶ With combined use of paper logs and EMR reporting, our IT department would need to build report to pull the necessary data.
- ▶ Our cost to stock these drugs for our farmworker program would increase by 7,000%.
- ▶ A rebate model would remove our ability to provide affordable medications to these patients.



HIV/PrEP

- ▶ Keystone Health Center has an Infectious Diseases clinic in which our HIV program resides. We serve nearly 200 HIV positive patients.
- ▶ The cost of HIV drugs are very costly and a rebate model on these drugs alone would create cash flow problems.
 - ▶ These cash flow problems would cause risk for these patients since we would not be able to carry the cost of stocking these drugs.
- ▶ In 2025, our health center purchased 843 HIV/PrEP drugs, and 451 of those were for Biktarvy.



Staffing

- ▶ With a rebate model, the increased workload could easily require our health center an additional 2.0 FTE to remain compliant.
- ▶ Without a rebate model, we are already spending a minimum of 10 hours weekly managing ESP, Beacon and Truzo.
- ▶ With additional rebate requirements, the addition of medical claims and more medications added each year, this number will grow significantly.
- ▶ With an up-front discount, we can easily identify 340B claims. If the 340B price is removed from the wholesaler, 340B claims will not be identified until after a rebate reconciliation process is completed.
- ▶ In a HRSA audit, providing claims data that were not reconciled through the rebate platform are not truly 340B claims. Only rebate reconciled claims can show true 340B eligibility. With an expected 15% of manufacturer denied claims, post rebate reconciliation is the only adequate process to track 340B claims.



Wholesaler Accounts/Invoices

- ▶ A 10-day rebate payment timeline would significantly increase the cash outlay required to support both entity-owned and contract pharmacies, even if the rebate was requested immediately after purchase and received in 10 days.
 - ▶ This would create measurable cash flow risk for our health center and could impact our ability to meet other obligations such as payroll and other suppliers.
 - ▶ Payment timing would have a direct effect on cash flow.
 - ▶ Our financial impact on cost of goods with just the 2025-2026 IRA drugs was calculated at \$8,310,978.74.
- ▶ Wholesaler payment terms vary by vendor, with invoices generally due within 10-30 days of invoice date. One wholesaler provides a prompt payment discount for payments made within 5 days.
 - ▶ We would forgo prompt payment incentives or discounts if payment timing must be extended to accommodate the delay in rebate receipt.
- ▶ Late fees are assessed if payments are not made within the agreed-upon timeframe.
- ▶ With a rebate model, we would need to renegotiate credit terms or expand credit line to align payment obligations with the timing of rebate receipts.

How is NACHC Helping?

01

Financial Burden Calculator

02

Administrative Burden Calculator

03

**Guidance to support data
prioritization and instructions**

04

Template Comment Letter

NACHC's 340B RFI Template Letter Themes

Our main message is still: Exempt Community Health Centers from the Rebate Model

Administrative
Complexities

Financial
Challenges

Wholesaler
Implication

Operational
Challenges

Reconciliation
and Rebate
Denials

Patient Impact

Duplicate
Discounts

National
Clearinghouse

Manufacturer
Guardrails and
Accountability

Pulling Data and Using the Template

On behalf of **[INSERT ORG]**, I would like to thank the Health Resources and Services Administration (HRSA) for extending the comment deadline to April 20, 2026. This extension has been vital in enabling our organization to conduct a deep-dive analysis of the operational and financial risks to CHCs posed by the proposed rebate model. The 340B program is the bedrock of their ability to serve the most vulnerable members of our community. However, the proposed shift of responsibility from manufacturers to safety net providers directly serving patients with a rebate model threatens to destabilize CHC pharmacy operations nationwide. Based on national assessments from NACHC, we know that CHCs are facing staggering impacts:

- **Financial Losses:** Nationwide, CHCs report an average loss of **[Insert Your Data / e.g., \$500,000 to \$3 million]** from entity-owned pharmacy operations and **[Insert Your Data**

¹ Weitzman, 2025.

² Volerian A, Carlson B, Wan W, Murugesan M, Asfour N, Bolton J, Chin MH, Sripipatana A, Nocon RS. Utilization, quality, and spending for pediatric Medicaid enrollees with primary care in health centers vs non-health centers. BMC Pediatr. 2024 Feb 8;24(1):100. doi: 10.1186/s12887-024-04547-y. PMID: 38331758; PMCID: PMC10851548. <https://pubmed.ncbi.nlm.nih.gov/38331758/>

³ <https://www.oregon.gov/oha/HPA/dsi-pcpch/Documents/PCPCH-Program-Implementation-Report-Final-Sept-2016.pdf>



[e.g., a 25% reduction in savings] for contract pharmacy arrangements due to the administrative hurdles of manual reconciliation.

- **Projected Cost Increases:** Community health centers anticipate their operational costs will increase significantly. National data shows that a single mid-sized CHC expects to incur over \$3 million in additional costs **annually** to manage the pilot.

NACHC has done the heavy lifting! **But this template letter requires you to collect and input data.**

We have highlighted the areas throughout the letter where you will want to add your own data and information about your health center and patient population.

**Template to be shared shortly!*

Types of Data You Will Want to Start Collecting

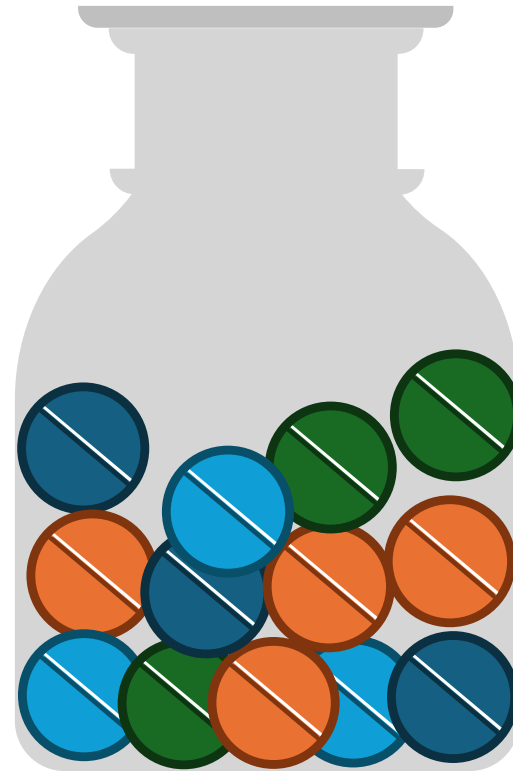
Make sure data does not contain PHI or proprietary information you do not want disclosed



Financial Impact: Utilize the calculator to show the real-time impact of a rebate model on your health center



Generalized Patient Data and Stories: Data about how many patients you serve and the real-life impact contextualizes the response.



State Data and Context: Your PCA can provide information to contextualize the situation in your state.



Operational Changes: From workforce to new systems, share how your health center is planning on implementing a rebate model, and the drastic changes it would require.



340B Rebate Comment Letters & Manufacturer Restriction Update



Rebate Delays, Denials, & Dilemmas

Delays

- Pre-purchase of 340B stock (physically separate inventory)
- Denials causing a delay with good-faith inquiries (Experience with MFP)
- Operational hurdles (time to upload)

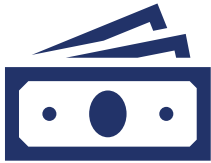
Denials

- Duplicate Discount (Multiple CEs, Medicaid, & MFP)
- Manufacturer Accumulator Logic

Dilemmas

- Unused partial packages
- Expired drugs
- Waste

Comment Letter Highlights



MFP Points

High burden of reconciliation

No timeframe for payment after GFI determination

They have purchase data so no need to provide in claim submission

MDPNP Negotiation & drug removal processes



Patient Access Considerations

Diabetes, Anticoagulants, Behavioral Health drugs

Sliding Fee Scale



Clinic-Administered Drugs

Current records

Needed enhancement to make operational

PPS payment structure & limited Part B



340B Rebate RFI Response Calculator

Data Sources for Calculators

- PVP Historical Purchases report
- PVP price report
- Filed **2025 UDS report**
- Payroll or HR records (wages, fringe, FTE allocations)
- Contracts or invoices from TPAs, consultants, auditors, or legal counsel
- Annual utilization and financial reports from:
 - Contract pharmacies
 - Entity-owned pharmacies
 - Clinic-administered drug tracking systems
- Manufacturer impact or exclusion reports
- Vendor estimates related to rebate-model requirements



K&L GATES

National Association of Community Health Centers

340B Rebate Pilot Comment: Duplicate Discounts

Present by:

Mark Ogunsusi, PharmD, JD
Partner, K&L Gates LLP



NATIONAL ASSOCIATION OF
Community Health Centers®

Mark Ogunsusi, PharmD, JD

FQHC, Pharmacy, and 340B Law

Putting Health Centers First



Mark Ogunsusi is a partner in the Healthcare and FDA practice group at K&L Gates, where he serves as a national leader in drug pricing and pharmacy law. Mark represents federally qualified health centers, retail and specialty pharmacies, group purchasing organizations, and pharmaceutical technology vendors among others.

He is widely recognized for his deep experience with the 340B program, including patient eligibility, virtual inventory management, contract pharmacy design, HRSA audits, manufacturer disputes, and innovative value-based care delivery strategies.

Mark also advises clients on state and federal law governing PBM relationships, drug reimbursement, limited distribution models, and the integration of centralized and specialty pharmacy infrastructure.

Mark's passion for safety net providers stems from his years as a practicing pharmacist serving many rural and underserved communities.

Conflict of Interest Statement

- Mark Ogunsusi represents FQHCs, FQHC-LAs, state primary care associations, clinically integrated networks, pharmacies, hospitals, and other safety-net providers and vendors associated with the 340B program
- Mark Ogunsusi holds minor stock in GSK, Novo Nordisk, Eli Lilly, and Merck
- The materials and discussions contained in this presentation may not be relied upon as legal advice



Medicare (IRA)

Manufacturers must provide the lower of 340B or MFP

No authority for up-front WAC pricing or post-purchase 340B rebates

Rebate model allows denial of 340B pricing even when it is lower than MFP



Medicaid

Covered entities alone decide whether a drug is billed as 340B

Duplicate discount prevention occurs at claim submission

Rebate model forces billing before 340B status is known

Duplicate Discounts: Medicare & Medicaid

Duplicate Discounts: Commercial Claims

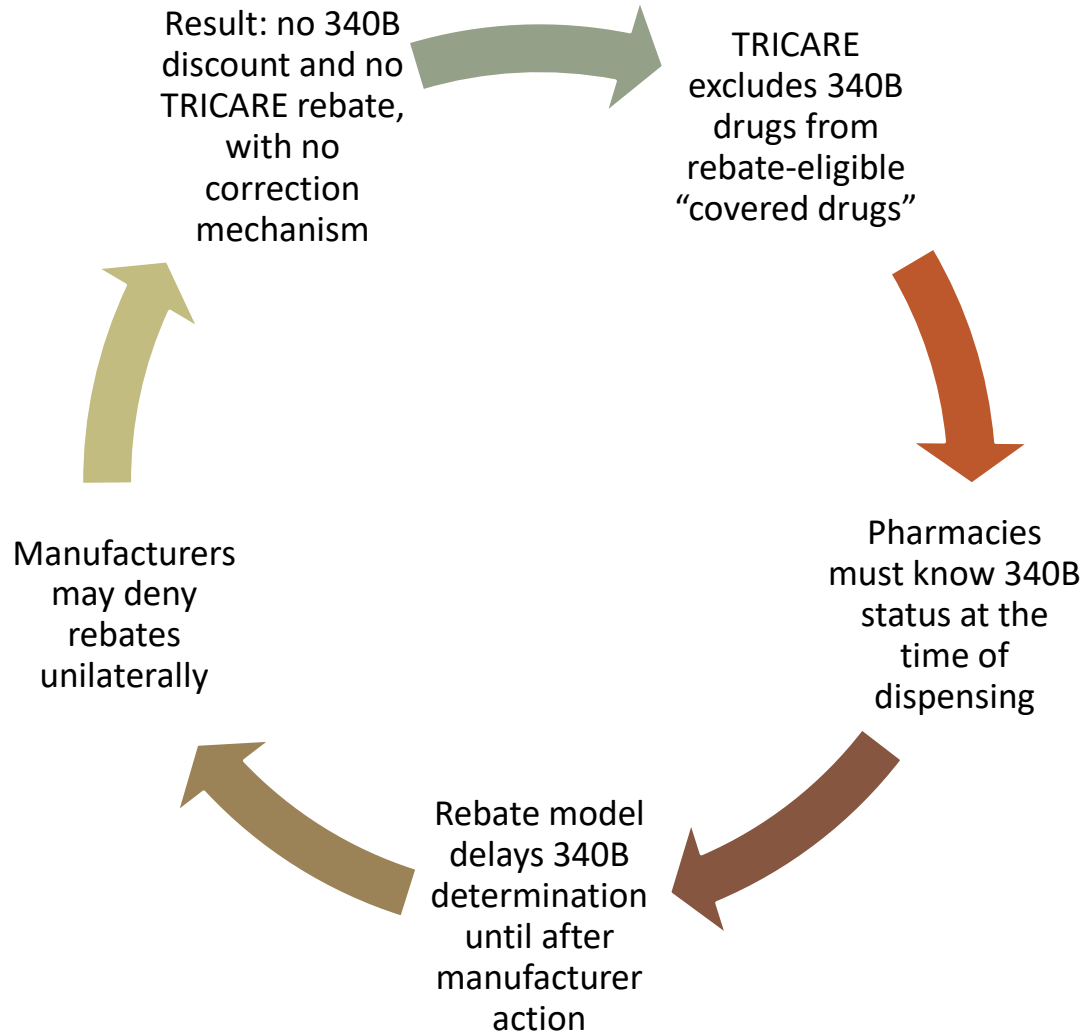
Congress did not prohibit commercial duplicate discounts

HRSA lacks authority to require commercial claims data submission

Conditioning 340B pricing on data transfer exceeds statutory authority

Commercial claims data is valuable proprietary property

Mandatory disclosure enables PBM and manufacturer discrimination



Duplicate Discounts — TRICARE

Contact Mark

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1601 K St NW
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Manufacturer Restriction Updates

A photograph of a modern glass-walled building with the 'Lilly' logo in red cursive script mounted on a dark grey panel above the windows. The sky is clear blue, and a street lamp is visible on the right side of the building.

Lilly

Eli Lilly Announcement

Eli Lilly Announcement

- Effective February 1, 2026, Eli Lilly will require claims level data submission for ALL 340B dispenses, including **entity-owned pharmacies** and **clinic-administered drugs**
- Requires submission of claims dispensed **on or after 2/1/26** within **45 days**
- “Failure to provide timely, complete, and accurate data for all products dispensed at 340B ceiling prices **may result in loss of access** to pricing until such time as the outstanding data is provided.”
- Applies to Labeler Codes: **00777**, 00002, & 66733
- State Exceptions
 - All Covered Entities: Colorado, Maine, Nebraska, North Dakota, Oregon, Rhode Island, South Dakota, Tennessee, Vermont & West Virginia
 - FQHCs & FQHC-LAs: New Mexico



Deadline for Submissions:
Wednesday, March 18



Novo Nordisk Announcement

Novo Nordisk Announcement

- Effective April 1, 2026, Novo Nordisk will require claims level data submission for ALL 340B dispenses from ALL CE types, including **entity-owned pharmacies** and **clinic-administered drugs**
- Requires submission of claims dispensed **on or after 4/1/26** within **45 days**
- “Failure of a grantee CE with an in-house pharmacy to submit complete and accurate claims level data associated with any CP according to the timeline set forth in this notice **will result in suspension** of the distribution of drugs purchased at the 340B price **to all CPs**, and **may result in suspension of access** to 340B pricing by the **CE’s in-house pharmacy locations**, until the required data is submitted.”
- Applies to Labeler Codes: 00169, 71090, & 73070
- **No State Exemptions Documented in Policy**



Deadline for Submissions:
Saturday, May 16

Required Data Elements

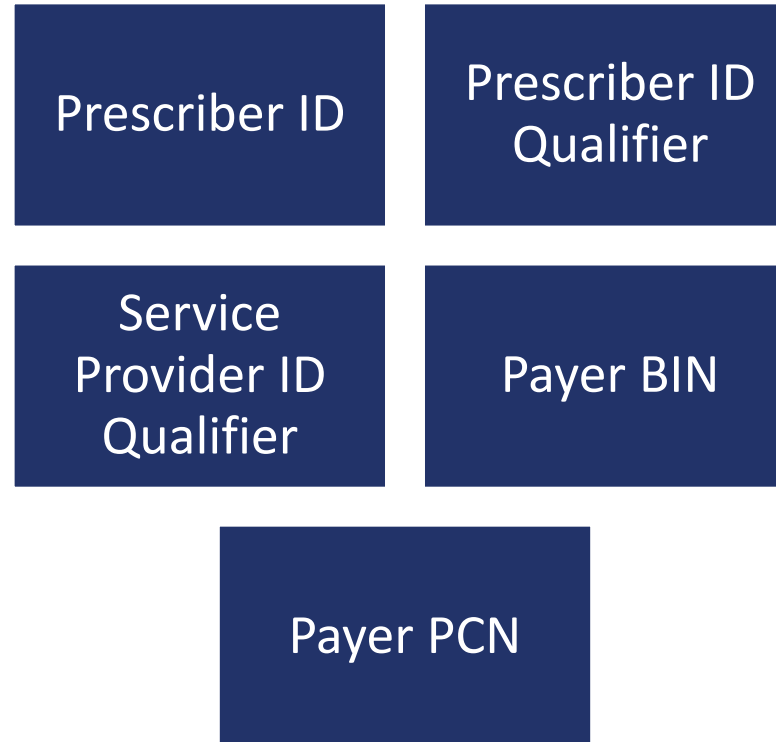
PHARMACY CLAIMS

340B ID	Date of Service	Date Prescribed
NDC-11	Quantity	Rx Number
	Service Provider ID (Generally NPI)	

MEDICAL CLAIMS

340B ID	Claim Number	Claim Line Number
Date of Service	Health Plan Name	Health Plan ID
NDC-11	Quantity	Service Provider ID (NPI)

Additional Pharmacy Data Elements Required by Other Manufacturers



Lessons Learned with Lilly Submissions

- From our experience, all FQHC Entity-Owned Pharmacy uploads have been under labeler code 00002 (None yet for 00777 and 66733)
- Make sure to filter out non-340B claims & limit to restricted manufacturers (**340B ESP will accept non-restricted claims**)
- ESP has mapped in-house NPIs to 340B IDs & you may receive submission errors – re-upload to correct
- If a TPA is submitting on your behalf, they should be submitting with the correct associated site's 340B ID, not the necessarily the main CE ID

Questions?

Felicity@fqhc340b.com
Logan@fqhc340b.com
Chelsea@fqhc340b.com



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**

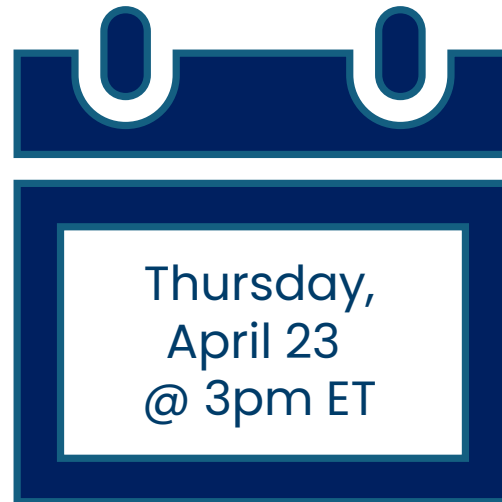
Questions?



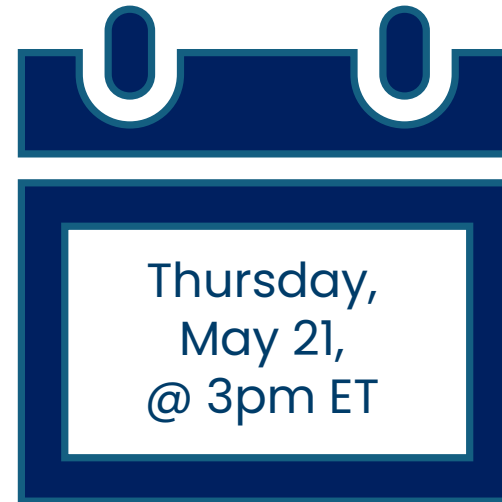
Upcoming 340B Office Hours

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: TBD



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"**

Thank You For Joining
March's 340B Office
Hours

Questions?

Email:
regulatoryaffairs@nachc.org

