Community Health Center Stakeholder Breakout Session
Tuesday, February 11, 2020
4:30 – 5:45 PM
Moderator: Colleen Meiman
Senior Policy Advisor
National Association of Community Health Centers
Where to Find THESE Slides

On Noddlepod
We’ll explain what that is if you don’t know.
OR
On the NACHC 340B website
Google “NACHC 340B”
Panelists:

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Statement of Conflicts of Interest

Colleen Meiman has no actual or potential conflict of interest in relation to this presentation.

Michael Glomb has no actual or potential conflict of interest in relation to this presentation.

Chad Johnson has no actual or potential conflict of interest in relation to this presentation.

Sue Veer Chad Johnson has no actual or potential conflict of interest in relation to this presentation.
Today’s Goals

• Share FQHC-specific resources on 340B
• Provide an overview of recent 340B recent developments, from the FQHC perspective.
• Address the issues raised most frequently in the survey, and direct you to resources with more information.
340B Resources specifically for Health Centers
Resources available to the Health Center 340B RX Community

- NACHC 340B Compliance Manual
- Nodlepod, Nodlepod, Nodlepod
- 340B Office Hours
- 340B Coalition bi-annual conferences with CHC specific programming
- Apexus
  - Apexus Answers
  - Health center specific 340B University at CHI and P&I
- CEO and CFO Institute modules
- Training resources including programs tailored to the needs of states and individual health centers
- 1-1 technical assistance
<table>
<thead>
<tr>
<th>Resource</th>
<th>Best For:</th>
<th>How to Access:</th>
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<tbody>
<tr>
<td>NACHC 340B Manual</td>
<td>Consolidated source of info on wide range of topics</td>
<td>Google “NACHC 340B Manual”</td>
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<tr>
<td>Office Hours – free webinar on third Thursday of the month, 2 PM ET</td>
<td>Operational updates; Q&amp;A. (No advocacy.) Focus is on all pharmacy issues.</td>
<td>See NACHC and BPHC emails; also Colleen’s email signature</td>
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<td>Noddlepod – web-based discussion platform limited to FQHCs</td>
<td>Group discussions; peer input; can discuss advocacy</td>
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<tr>
<td><strong>Technical Assistance</strong> from an operational expert (Tim Mallett) -- under contract with NACHC</td>
<td>Pharmacy operations, 340B, and policy questions</td>
<td><a href="mailto:tmallett@340basics.com">tmallett@340basics.com</a></td>
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<tr>
<td>340B University focused on FQHCs</td>
<td>Free, full-day, in-person overview of 340B, focused on FQHCs. Planned by Apexus, led by FQHCs.</td>
<td>Sun. 3/15/20 in Washington DC; also in August in San Diego (before NACHC CHI)</td>
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<td>Apexus</td>
<td>Technical, operational, and policy questions</td>
<td>888.340.BPVP (2787)</td>
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340B University – JUST for FQHCs

- Sunday March 15, 2020

- Washington DC (same hotel as NACHC P&I)

- Specifically for FQHCs – and taught by FQHCs

- FREE – but pre-registration is required – go to https://www.340bpvp.com/education/340b-university/ or Google "340B University."
Right Here, Right Now

Many of your best resources are right here in this room – your FQHC colleagues.

Q&A/ Networking Breakfast for FQHCs
Tomorrow (Wed) at 7:15 – 8:30
Sapphire Boardroom.
*BYOB* Breakfast from the Exhibit Hall
Recent 340B Developments Impacting FQHCs
Let’s Start on the Hill

- Congressional Oversight:
  - After the whirlwind of 2018, 340B is viewed as “a hornet’s nest made out of hornet’s nests”
  - Intensity may have decreased but the threat remains present

- Focus has shifted to drug pricing with potential for collateral damage: 209 bills match the search criteria of “drug pricing bills” in govtrack

- Lingering questions about 340B:
  - Purpose of the program
  - Regulatory authority
  - Use of savings
  - Medicaid rebates vs 340B discounts
In the Regulatory Arena...

- **HRSA:**
  - Audit activity “reboot”
  - Increased oversight of contract pharmacy arrangements
  - Clarity re: sliding fee discounts
  - Clarity that contract pharmacies go in Column 2

- **CMS**
  - Purpose and philosophy – strengthen and serve state Medicaid programs
  - CMS Bulletin: Best Practices for Avoiding 340B Duplicate Discounts in Medicaid
Have You Recertified???

• Every year, health centers must to “recertify” their 340B participation.
  • Recertifying entails attesting to the accuracy of your info on OPAIS, and your compliance with all 340B rules.

• The deadline for 2020 recertification is February 24.

• Health centers that miss the deadline are kicked out of 340B for at least three months!

See Chapter 6 of the Manual
Growing challenges with reimbursement...

Some challenges are impacting pharmacies everywhere:
- DIR fees
- Growing power or PBMs
- Specialty drugs

And some are specific to FQHCs – namely, shrinking 340B savings caused by discriminatory reimbursement and disparate treatment.

These financial concerns were cited as the biggest challenge to health center pharmacy programs.
A Short Look at Your Biggest Questions
Thank you to everyone who completed our survey!!!

Your input was enormously helpful in planning this session, and future educational activities.

- Biggest challenge = 76 responses
- Need for clarity = 66 responses
- Questions = 50 responses
Here are the most common areas where you have expressed challenges, questions, and concerns:

- Discriminatory contracting – i.e. disparate treatment of 340B covered entities
- Eligibility across the continuum of care – i.e. prescriptions written outside of the health center
- Establishing charges – i.e. sliding fee and cash pricing > 200 FPL
- Clinic Administered Drugs and Devices – i.e. tracking and auditing, inventory management, impact on billing
- Contract Pharmacy Oversight
- Audits – i.e. HRSA and self audits (Integrity Plan)
- C-Suite – i.e. getting their attention and Bringing Pharmacy Into the Fold
- HRSA/BPHC expectations – i.e. Form 5A, sliding fee, etc.
Resources for Engaging Your C-Suite

- Chapter 2 of the NACHC 340B Manual is “The Minimum the C-Suite Needs to Understand and Do re: 340B”

- 340B University at NACHC P&I – Sun March 15, 2020 in DC

- 340B Overview Session at NACHC P&I

- Education on why 340B is so much more important and complex than it used to be.
What a difference a decade makes!

Over the past ten years, the 340B program has expanded dramatically in size, complexity, potential, and risk.
Since February 2010

1. The ACA extended Medicaid rebates to managed care drugs. *(Previously, Medicaid rebates were only on FFS drugs.)*

2. The ACA made more types of providers eligible for 340B.

3. HRSA permitted providers to have multiple contract pharmacies

4. More -- and more expensive -- drugs entered the market.

5. The role of Rx in primary care has expanded significantly.
So in February 2020...

- 340B is now a much larger, more important, and more visible program than it was 10 years ago.

- No other government program is simultaneously so:
  - High benefit to patients
  - Complex and constantly evolving
  - Precarious

Every C-Suite member should ask:
“How important is 340B to our patients and organization?”
and then
“Does our focus on compliance and operations reflect this importance?”
Discriminatory Contracting

Resources:

• NACHC toolkit for state legislation – email kfriedman@nachc.org
  • Contains draft bill language, talking points, etc.

• Your health center’s one-pager describing the importance of 340B savings to your patients and operations!

• Chapter 3 of the NACHC 340B Manual
Lots of Variations on the Theme...

“Discriminatory contracting” refers to circumstances when a pharmacy is reimbursed less and/or subject to unique terms solely because it participates in 340B. Examples:

- Reduced reimbursement
- Exclusion from networks
- Higher fees and/or portion of savings retained
- Excluding drugs as “specialty drugs” that must be filled through a specialty pharmacy network
- Lower co-pays at “captive” pharmacies
- Prohibiting common services like mail-order
- Additional/increased performance requirements
Public VS. Private Payers

In Medicaid:
- CMS
  - Requires states to take the 340B savings under FFS, encourages them to do so under managed care
- State Medicaid agencies
  - A growing number are taking the savings under Medicaid managed care organizations (MCOs)

Privately-Insured Patients:
- Third-party insurers
- Pharmacy Benefits Managers (PBMs)
- TPAs*
- Contract Pharmacies*
- Groups that offer to help manage our 340B programs*

* In all of these cases, it is appropriate for the group to charge a fee for their 340B-related services; however, concerns arise when the fee exceeds the fair market value of the service provided.
What can we do about it?

National:
- Statutory fix (very long shot)
- Educate policymakers about trends & impacts
- Monitor for threats & opportunities
- Partnerships

State level:
- Medicaid – educate policymakers about funding leaving the state*
- Anti-discrimination legislation**
- Partnerships

Operational:
- Open-door RX
- PSAO
- Demonstrate what services would be lost
- Ideas?

* See next slides. **Email kfriedman@nachc.org for the state legislation toolkit.
Why the majority of “state savings” on Medicaid 340B drugs accrue to the Federal government

- Medicaid costs are split between the Federal government and the states.
  - *The exact split varies, based on the state, the service, and the patient.*

- The Feds pay at least 50% - & as much as 90% - of total Medicaid costs.

- So 50 to 90% of Medicaid savings accrue to the Feds, rather than states.
Assume: Ms. Jones, a Medicaid managed care patient, gets a Rx at a FQHC. The drug’s regular price is $40. The 340B discount and the Medicaid rebate are both $10. So the net price under both 340B and Medicaid is $30.

**OPTION ONE:**
- The FQHC buys the drug under 340B ($30)
- Medicaid reimburses the FQHC the regular price ($40)
- **The FQHC retains $10 in savings.**

**OPTION TWO**
- The FQHC buys the drug under 340B ($30)
- Medicaid reimburses the FQHC the 340B price ($30)
- **“The state saves $10.”**

**OPTION THREE**
- The FQHC buys the drug at regular price ($40)
- Medicaid reimburses the FQHC the regular price ($40)
- The state applies for the rebate ($10)
- **“The state saves $10.”**

But that’s not the end of the story!
When “the state gets the $10 savings”, only a fraction of those dollars stay in the state. For example:

Ms. Jones is a “traditional” Medicaid enrollee in a state like AK, CA, or VA, where the Feds pay 50% of costs for traditional enrollees:

Of her state’s $10 in Rx savings, $5 goes back to the Feds – so the state retains $5 in net savings.

Ms. Jones is a “traditional” Medicaid enrollee in a state like WV or MS, where the Feds pay around 75% of costs for traditional enrollees:

Of her state’s $10 in Rx savings, $7.50 goes back to the Feds – so the state retains $2.50 in net savings.

Ms. Jones is a Medicaid expansion enrollee, so the Feds pay 90% of her costs:

Of her state’s $10 in Rx savings, $9 goes back to the Feds – so the state retains $1 in net savings.

When the FQHC gets the $10 savings, the full $10 stays in the state and is invested in activities that expand access for underserved populations.
• Technically, when a state keeps the drug savings, it doesn’t “send back” the Feds’ share in the form of a check or refund.

• Rather, the State reduces how much it bills the Feds.
  • So the Feds access the savings by paying less upfront, rather than getting money back.

• Assume Ms. Smith is a Medicaid expansion enrollee, so the Feds pay 90% of her costs. For her $40 drug with a $10 discount:

  If the FQHC keeps the savings:
  - The State pays $40 for the drug
  - The Feds reimburse the State $36 (90% of $40).
  - The State’s net cost is $4 -- and $10 stays in the community.

  If the State keeps the savings:
  - The State pays $30 for the drug
  - The Feds reimburse the State $27 (90% of $30.)
  - The State’s net cost is $3 -- and no funds are left in the community.

So, when a State pays $10 less for Ms. Smith’s drug, it receives $9 less in Federal reimbursement.
Some of the states where the battle has been (or is being) waged...
Prescriptions written by non-FQHC providers
Also known as “eligibility across the continuum of care.”

Resources:
• Will be addressed in the various operational sessions here and at Coalition Summer Conference.
• Chapter 7 of the NACHC 340B Manual.
• December 2018 Office Hours.
• Auditors, and Apexus.
340 Shades of Gray (& Counting...)

- **Question:** Can a prescription written by a non-FQHC doctor for a FQHC patient be filled by a health center using 340B inventory?
- **Answer:** It depends.
  - In some circumstances, the answer is clearly “yes”.
  - In others, it is clearly “no.”
  - But there is much gray area in between the two – and it’s getting grayer....
340B purchased drugs may only be dispensed to fill prescriptions for those patients who meet the HRSA definition, AND that **emanate** from a health center medical site that is registered on the OPAIS, or a service that is **in the health center’s Scope of Project as reflected on Form 5C in the EHB.**

**emanate** verb

emanate | \
emanated, emanating

Definition of emanate

intransitive verb

: to come out from a source

// a sweet scent emanating from the blossoms
Supporting and Demonstrating Compliance

- **Infrastructure**
  - Pharmacy Oversight Committee
  - Comprehensive policy/procedure
  - Staff training

- **Point of Dispensing**
  - Eligibility screens
  - RX access to identify individual referrals from eligible health center sites

- **Closing the Loop**
  - 30/45 day audit protocol
  - Care management follow-up
  - Corrective action
Sliding Fee, Charges, etc.

Resources:
- Covered during the Wednesday 11:00 AM CHC Expert Session.
- Chapter 4 of the Manual.
- The December 2019 Office Hours discussed
  - how BPHC’s SFS rules apply to pharmacy, and
  - a model for implementing SFS in contract pharmacies
- The February 2019 Office Hours discuss DIR fees.
HRSA Rules re: Charges

- The 340B program has no explicit requirements re: how much patients should be charged for 340B Rx.

- BPHC's sliding fee rules:
  - Do apply to the service cost (aka pdf) – if any -- associated with a drug
  - Do not apply to the ingredient cost of the drug.

So... if you charge patients an explicit pdf on dispensed drugs:
- This pdf is subject to the SFS rules
- The pdf should be listed on your official schedule of charges.
Goals: Affordability and Viability

- Beyond these rules, health centers have flexibility to set their Rx charges – provided that these charges do not pose a financial barrier for patients.

- While 330 funds and program income can not be used to slide the pdf for persons above 200% FPL, there are no explicit rules for the ingredient cost.

Setting charges for pharmaceuticals requires a delicate balance between affordability for the patient and financial viability of the program for the health center.
Clinic-Administered Drugs

Resources:

- April 2019 and Sept. 2019 Office Hours feature discussions of on-the-ground strategies for purchasing, tracking, and auditing, by Becky Cheek and Sabrina Allen.
- Will be addressed in the first session tomorrow AM.
- There will be a full 90-minute session on this topic at this year’s 340B Summer Conference in DC.
Optimal Utilization System-wide

- Prescriptions dispensed from pharmacy
- Clinic administered drugs and devices

Systematic tracking from purchase to patient at the unit/NDC level

Compliance requirement
Clinic-Administered Drugs

- Currently a “hot topic” for HRSA auditors.
- Not using 340B for clinic-administered drugs is “leaving money on the table.”
- But adequate tracking can be complex and cumbersome.
  - Must track from purchase to patient at the NDC level.
- There are ways to achieve 340B savings on clinic-administered drugs, while also ensuring compliance.
Audits & Compliance

Resources:

- Discussed in **Chapters 13 & 14** of the Manual. The Manual also contains several self-audit tools.

- The **January 2029 and June 2019 Office Hours** discussed
  - Lessons learned from a 340B audit (thank you Becky Cheek)
  - Recent trends in audit findings (thank you, Matt Atkins)
Still have questions?

Join us for tomorrow’s Q&A/Networking Breakfast for FQHCs
7:15 – 8:30
Sapphire Boardroom

BYOBBreakfast from the Exhibit Hall
Additional Questions?

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