Stakeholder Breakout Session

Community Health Center Breakout Session

Facilitator: Colleen Meiman, Senior Policy Advisor
National Association of Community Health Centers
These Slides Can Be Downloaded...

- From Noddlepod – They were posted this morning.

- From the NACHC 340B website:
  - Or google “NACHC 340B policy”
Should You be in this Room?

- Everyone in this room should be either:
  - From a health center, PCA or HCCN, or
  - Have permission from Colleen Meiman or Sue Veer to be in the room.

- If you are not one of the above, we are happy to help you find the room you should be in. Thank you.
To Everyone Who Belongs in this Room
Statement of Conflicts of Interest

None of the following individuals have any actual or potential conflict of interest in relation to this presentation:

- Colleen Meiman, NACHC
- Michaela Keller, NACHC
- Bethany Hamilton, NACHC
- Tim Mallett, 340Basics and NACHC consultant for pharmacy TA
- Mike Glomb, Feldesman-Tucker
- Jason Reddish, Feldesman-Tucker
- Sue Veer, Carolina Health Centers
- Matt Atkins, Draffin-Tucker
- Kris Klein-Bradham, Apexus
What are important “take-aways” from this session?

A. The importance of compliance cannot be overstated.

B. Be cautious when unfamiliar groups reach out re: 340B.

C. NACHC is developing more T&TA resources around pharmacy and 340B.

D. There is considerable confusion about whether BPHC sliding fee rules apply at contract pharmacies.

E. All of the above.
Today’s Agenda

• Operational Updates

• Policy and Advocacy Updates
Conference Sessions Aimed Specifically at FQHCs

• Two breakouts sessions have been designed specifically for FQHCs:
  • 4:00 PM Tuesday – Billing and Reimbursement for FQHC Pharmacies
  • 8:30 AM Wednesday – Specific Strategies for Enhancing the Value of your 340B Program

• This session is the only one limited to members of the “health center family.”
Operational Updates
Compliance!

- The importance of compliance can not be overstated.
- Extremely complex; requires staying up-to-date with ever-changing rules.
- Consider how important 340B is to your FQHC and your patients.

Does your focus on 340B compliance reflect this degree of importance?
Caution Needed

• If unfamiliar groups reach contact you with questions or opportunities around 340B – be cautious!

• Several groups are actively seeking info or action from health centers that would:
  • Give them a competitive advantage;
  • Bolster their own political agenda re: 340B; and/or
  • Engage FQHCs in activities that are inconsistent with program requirements or intent.

• The number of such group has skyrocketed in recent months.
If an unfamiliar group contacts you...

- Ask who is funding them and what their goals are.
- Ask your health center colleagues if they know the group
  - Noodlepod is a good way to do this.
- Be particularly suspicious if they are offering to increase your patients or 340B revenue
- If in doubt, please do not respond.
Manufacturers: Increased admissions of overcharges

- The number of manufacturers that are publicly acknowledging that they have overcharged for 340B drugs has more than doubled this year.

- Some suspect this is due to HRSA’s new authority to fine manufacturers for “knowingly and intentionally” overcharging for 340B drugs.

- FQHCs may start seeing checks from manufacturers for overpayments.
  - NACHC will monitor HRSA website announcing overpayments.
Manufacturers: Timelines for Lookbacks & FQHC Repayments

• Some manufacturers are claiming that:
  • There is no limit on how far back they can look for examples of diversion/ duplicate discount.
    • Kalderos – a research firm working on behalf of manufacturers – is looking back five years.
      • *If you are contacted by Kalderos, we recommend that you respond promptly.*

• If a FQHC offers to repay several times and the manufacturer does not respond, the manufacturer can still demand the repayment months or years later.
BPHC, OSVs, and SFS

• In 2015, BPHC added questions about 340B to the official OSV protocol.
  • They involved demonstrating appropriate P&Ps, contracts, etc.

• Earlier this year, BPHC officially removed the 340B questions from the OSV protocol.
  • Likely due to concerns about variation and limited 340B expertise among auditors.
• However, some auditors are now placing conditions on FQHCs for not offering SFS discounts at contract pharmacies.
  
  • *In short, BPHC requires SFS to be applied to dispensing fee, but not ingredient cost – but many contract pharmacies are unwilling to implement a SFS.*

• **We will discuss SFS and related issues in Tuesday session.**

• NACHC, Feldesman-Tucker, and others are working on this issue.
  
  • If you have received a finding around this, please talk to Colleen.
Are You Overpaying for Vaccines or IUDs?

• Neither vaccines nor IUDs are subject to mandatory discounts 340B.

• BUT… as a 340B provider, you are eligible for discounts on vaccines, and $50 IUDs (similar to Mirena.)

For info on discounted vaccines, contact Apexus at 888.340.BPVP or apexusanswers@340Bpvp.com

For info on $50 IUDs, contact mdiallo@medicines360.org or go www.medicines360.org
Discriminatory Contracting

Leaky Hose

Refers to the many ways that third parties subvert Congressional intent by finding ways to access FQHCS’ 340B savings for themselves.

Hands in the Cookie Jar
Discriminatory Contracting

• What happened with CVS?
  • In February, they cancelled their plans to reduce reimbursement for all drugs dispensed by a pharmacy that used any 340B drugs.
  • But the lower reimbursements rolled out last summer/fall are still in effect.

• There are ways to push back – we will discuss those in the policy & advocacy section.
Feel like you’re drinking from a fire hose?

Fortunately, there are lots of resources to help FQHCs navigate the 340B world.
# Some Current Resources

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<thead>
<tr>
<th>Resource</th>
<th>Most Helpful For</th>
<th>To Access</th>
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<tbody>
<tr>
<td>NACHC 340B Manual</td>
<td>Consolidated source of info on full range of topics</td>
<td>Google “NACHC 340B Manual”</td>
</tr>
<tr>
<td>Office Hours</td>
<td>Operational updates; Q&amp;A. (No advocacy.)</td>
<td>See NACHC and BPHC emails; also Colleen’s email signature</td>
</tr>
<tr>
<td>Noddlepod</td>
<td>Group discussions; peer input; advocacy</td>
<td>Email Colleen or give her your business card</td>
</tr>
<tr>
<td>Kris at Apexus</td>
<td>Technical, operational, and policy questions</td>
<td><a href="mailto:kristina.klein-bradham@apexus.com">kristina.klein-bradham@apexus.com</a></td>
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Resources under Development

• Two-hour webinars for CEOs and CFOs (separately) on their roles and responsibilities re: 340B– starting this fall*

• Full-day in-person trainings offered around the US starting early 2020 on:
  • Compliance 201
  • In-House pharmacy

• Adding a “340B University for FQHCs” in conjunction with the 2020 P&I. (A similar session is already held in conjunction with the CHI.)

• Two Rx-related session at FOM-IT 2019. Hopefully more in 2020.
Policy and Advocacy Updates
Within health policy, drug pricing is currently the “hot” issue.

- Addressing price inflation is proving harder than many had hoped.
  - Drugs prices increased 10.5% in the last 6 months.

- Since late June, the future of the ACA is back in question.
In the midst of many, many other changes in the healthcare system, the impact on health centers’ 340B programs would include:

- No impact on FQHC eligibility for 340B.
- Minimum 340B discounts (not the inflationary penalties) would drop from 23.1% to 15% for brand and from 13% to 11% for generics.
- Penny pricing would remain.
- State Medicaid programs would lose Medicaid rebates for managed care drugs. (But with time they could still access FQHCs’ 340B savings.)
- HRSA would lose ability to fine manufacturers who overcharge for 340B drugs.
- Potential loss of ceiling price database and some program integrity initiatives.
## Status of Administration Drug Pricing Initiatives

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<thead>
<tr>
<th>Initiative</th>
<th>Status</th>
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<tr>
<td>Eliminating PBM rebates in Medicare and Medicaid Managed Care</td>
<td>Not publishing a Final Rule</td>
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<tr>
<td>Changes to DIR fees</td>
<td>Changes not included in Final Rule</td>
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<tr>
<td>Limiting Medicare coverage for drugs in “protected classes”</td>
<td>Changes not included in Final Rule</td>
</tr>
<tr>
<td>Requiring TV ads to show Rx list prices</td>
<td>Blocked by courts</td>
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<tr>
<td>Excluding rebates from “medical loss ratio” calculations</td>
<td>In effect</td>
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Drug Pricing Ideas Under Consideration

Administration:
• Linking Medicare Part B reimbursement to prices in other countries
• Allowing states to import drugs from other countries.

Congressional action
• Senate Finance Committee working on a package
• Discussing inflationary rebates (similar to Medicaid and 340B)
NACHC’s 340B Strategic Advisory Group

• To help guide and support our activities around 340B, NACHC recently formed a 340B Strategic Advisory Group.

  • Consists of 14 individuals from across the country with extensive expertise in 340B and representing different states.

  • Include pharmacists, CEOs, and PCAs, as well as the current and a former Board Chair.

  • Will serve as a “strike force” when support is needed around messaging, advocacy, etc.

To date, the SAG has:

  • Encouraged NACHC to expand its focus and trainings around 340B compliance.

  • Reviewed and advised on strategies to address discriminatory contracting.

  • Developed a document around effective messaging.
Addressing Discriminatory Contracting

• There is no silver bullet.

• Actions to push back can be grouped as follows:
  • Private/ Commercial – working directly with the groups engaging in the discriminatory contracting
  • State
  • Federal

• All approaches require being able to effectively “tell your 340B story.” We will discuss this in Wednesday’s session.
Federal Updates

Michaela Keller, NACHC
State Updates

Bethany Hamilton, NACHC
CE Question

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Additional Questions?

Colleen Meiman
Senior Policy Advisor
National Association of Community Health Centers
301-906-5958
cmeiman@nachc.org