Pharmacy Access Office Hours
July 16, 2020

Focus Topics: 340B Developments & Review of Affordability Options

This session is supported by the Health Resources and Services Administration (HRSA) of the U.S. Department of Health and Human Services (HHS) as part of an award totaling over $6,375,000. The contents are those of the author(s) and do not necessarily represent the official views of, nor an endorsement, by HRSA, HHS, or the U.S. Government. For more information, please visit HRSA.gov.
America’s Voice for Community Health Care

The National Association of Community Health Centers (NACHC) was founded in 1971 to promote efficient, high quality, comprehensive health care that is accessible, culturally and linguistically competent, community directed, and patient centered for all.
WEBINAR LOGISTICS

This is our first time using this new type of WebEx link – so we appreciate your patience.

To ask/answer a question, or share a comments, please use the Chat box on the right hand side of the screen.

You can download these slides from Noddlepod, & from NACHC’s 340B/ Rx webpage:
http://www.nachc.org/focus-areas/policy-matters/340b/

Or go to NACHC.org and search 340B
Agenda

• Operational Updates - Colleen Meiman, NACHC
• Focus Topic: Rx affordability for patients over 200% FPL, Colleen Meiman, Brett Gingrich, PharmD, Cherry Street CHC, Tim Mallett, RPh
• Q&A

Discussions in the comment box throughout the regular presentation
Operational Updates

Colleen Meiman, NACHC
New Project Period, New Web Link(s)

• On July 1, NACHC began a new Project Period as a National Training and Technical Assistance Partner (NTTAP) with BPHC.

• Since BPHC supports Rx Office Hours, the new Project Period brings some new processes.

• Most notably, from now on, there will be a new – and different – web link each month for Office Hours.

• The new monthly link will be available:
  • In BPHC and NACHC emails
  • On the NACHC 340B webpage
  • On Nodlepod
  • Via Outlook invitation

If you’d like to get an Outlook invitation with the new link for each month’s Rx Office Hours, please email Susan Hansen at shansen@nachc.org. Bonus: People who get the Outlook invitation will also get the slides and handouts emailed directly to them!

* Rx Office Hours will no longer meet at https://nachc.webex.com/join/cmeiman
Speaking of BPHC Support

• BPHC provided explicit funding for T&TA related to pharmacy access!

• As Office Hours are supported with Federal funds, we are prohibited from discussing anything related to advocacy in this forum.
Recent 340B Developments

• In the past 3 weeks, there have been important developments in the 340B space, involving:
  
  • Two major drug manufacturers – Eli Lilly and Merck
  
  • The contract pharmacy model
  
  • HRSA’s view of its authority to enforce 340B rules
  
  • Congressional interest in expanding HRSA’s regulatory authority
  
  • Discriminatory contracting
Background: Limits on HRSA’s 340B Enforcement Authority

- Most of the HRSA rules that underlie the 340B program have been issued in the form of sub-regulatory guidance – e.g.:
  - Patient definition; registration and recertification; audit requirements; and contract pharmacies.

- Over the last six years – especially the past year -- a series of legal actions and Administrative decisions have raised questions about HRSA’s authority to enforce rules established via guidance.

- As a result, HRSA currently views itself as having enforcement authority in only five areas of the 340B program. (See box at right.)

Areas where HRSA sees clear enforcement authority for 340B:

1. Preventing duplicate discounts
2. Preventing diversion
3. Setting ceiling prices.
4. Imposing ceiling monetary penalties on manufacturers
5. Establishing a mandatory Alternative Dispute Resolution system
Manufacturer Action #1 – Eli Lilly

- Around July 1, drug manufacturer Eli Lilly announced on the HRSA website that it will no longer allow 340B-priced Cialis to be distributed to contract pharmacies.
  - Their notice suggests that they do not think they are legally required to distribute drugs to contract pharmacies.
  - Lilly states that covered entities without an in-house pharmacy may request an exception to allow distribution to a single contract pharmacy location.
  - Eli Lilly has not publicly said whether they plan to expand this practice to other drugs.
  - This is the first time that a manufacturer has refused to allow a 340B-priced drug to be distributed to a contract pharmacy.
HRSA’s Response to Eli Lilly’s Actions

Quoted in an article from “340B Report”, but not published elsewhere (emphasis added):

“Contract pharmacies are a mode for dispensing 340B drugs and serve a vital function in covered entities’ ability to serve underserved and vulnerable populations. Manufacturers that refuse to honor contract pharmacy orders would have the effect of significantly limiting access to 340B discounted drugs for many underserved and vulnerable populations who may reside in geographically isolated areas and rely on a contract pharmacy as a critical point of access for obtaining their prescriptions. **HRSA strongly encourages all manufacturers to sell 340B priced drugs to covered entities through contract pharmacy arrangements.**”

“The 2010 guidance is still in effect. However, guidance is not legally enforceable.** Regarding the 340B Program’s guidance documents, HRSA’s current authority to enforce certain 340B policies contained in guidance is limited unless there is a clear violation of the 340B statute. Without comprehensive regulatory authority, HRSA is unable to develop enforceable policy that ensures clarity in program requirements across all the interdependent aspects of the 340B Program.”
Manufacturer Action #2 – Merck

• In early July, Merck sent a letter to all 340B providers requesting that they submit data on all Merck pharmaceuticals purchased at 340B prices and dispensed by contract pharmacies.

• Data should be submitted every two weeks.

• While the first paragraph references the prohibition on duplicate discounts under Medicaid, Merck later states that they do not want to pay “duplicate discounts” on drugs covered by Medicare Part D and private drugs.
Merck letter, continued

- Merck has no authority to require 340B providers to submit this information.

- Merck states that failure to participate may lead them to take steps that are “less collaborative, and substantially more burdensome”.

- Some contend that Merck’s request:
  - Goes far beyond the “good faith effort” that 340B providers are required to make to ensure compliance.
  - Would give Merck a significant competitive advantage
  - Would expand discriminatory contracting.

- Merck states that its deadline for responding is August 14.
Discriminatory Contracting

- Refers to when a third party (e.g., PBM, contract pharmacy, insurer) pays a health center less for a drug simply because it was purchased under 340B.
  - Result is to transfer the benefit of the 340B savings from the health center to the third-party.

- CVS-Caremark recently released a pair of “payer sheets” indicating that pharmacies may not bill more than their Actual Acquisition Cost (plus a pdf) for drugs purchased under 340B and dispensed to many Medicaid managed care patients, effective July 1.
  - The scope and impact of the payer sheets are unclear; we are still seeking information.
A Couple Reminders

• Rxs prescribed during telehealth visits can be filled with 340B drugs – as long as the usual requirements are met:
  • Prescriber must be employed by or under contract with the health center
  • Medical Records of telehealth visit
  • Service provided must be within the scope of health center’s grant

• HRSA is willing to enroll new sites – and even some contract pharmacies – into 340B very quickly, in response to COVID-19, immediate enrollment.
A few more reminders

• Questions about the Walgreens process for dealing with excess 340B inventory?
  • Was discussed during last month’s Office Hours
  • Extensive discussion on Noddlepod.

• To sign up for the Noddlepod site for Pharmacy, contact Tim at tmallett@340Basics.org.

• 340B audits are still being done remotely. See last month’s Office Hours for one health center’s experience.
340B Coalition Summer Conference has gone virtual!
July 20-29, 2020

About the event:
• 5 day event spread across 2-weeks
• Includes the pre-conference workshops
• Virtual exhibit hall and networking opportunities
• 4 CHC specific sessions
  • Breakout session
  • Expert Session 1: Evolving Practice Models
  • Expert Session 2: Role and Adaptation in a Pandemic
  • Expert Session 3: Clinic Administered Drugs
• Opportunity for “chat room” sessions with panelists following sessions

Why this Coalition Conference is a “must”:
• Never has the need to network with our peers been greater
• Cost reduced by 30% and no travel expenses
• Full CEU credit
• Many sessions are offered “on-demand”
• We can’t afford to loose the momentum gained over the last 10 years
• We have the opportunity to set the standard for future events

https://www.340bsummerconference.org/
Please do the 1-minute evaluation

https://www.surveymonkey.com/r/WMH2SBB

(Your past responses helped us demonstrate to BPHC that these sessions are a valuable use of their funding!)
Focus Topic: Review of Options for Helping Patients with Affordability

Tim Mallett, 340Basics/ NACHC Consultant
Do we need different rules for Rx discounts for patients above and below 200% FPL?

• Short answer: YES.

• Reasons involve:
  • Staying in compliance with BPHC rules
  • Maximizing reimbursement from private insurers
    • avoiding setting your U&C rates too low.

• This means **you should not have a standard charge for a drug that applies to all your patients, regardless of income.**

To be clear: **All** CHC patients that meet the patient definition may receive 340B purchased meds – but **not all** patients should automatically get a discounted price.

For more info on this topic, see the May and June 2020 Office Hours.
Rx Affordability for Patients Below 200% FPL

During May’s Office Hours we discussed that:

• Health centers are generally expected to make Rx affordable for patients below 200% FPL

• However, BPHC’s detailed SFS rules:
  • Do NOT apply to the ingredient cost of a drug
  • DO apply to the professional dispensing fee (pdf) that a patient is charged for getting the drug – but only if the FQHC charges an explicit pdf
    • Most FQHCs do not charge an explicit pdf. For these FQHCs, the BPHC SFS rules do not apply to drug charges.
    • OSV auditors look at the mandatory Schedule of Fees to see if a pdf is listed.
      • If nothing for pharmacy – they are to move on
(Re)Introducing a New Acronym

- Since:
  - BPHC’s SFS rules do not apply to pharmaceutical charges at FQHCs that do not charge an explicit professional dispensing fee
    - BUT
  - FQHCs are still expected (under both 330 and 340B) to seek to make drugs affordable for patients below 200%
  - FQHCs should still have a system for discounting drug charges for patients below 200%.

- The avoid the connotations that come with the term “Sliding Fee Scale”, I created a new acronym for describing a system of drug discounts for persons below 200% FPL:

**EPPAP = Eligible Patient Prescription Assistance Program**
Affordability for Patients Above 200% FPL

During June Office Hours, we discussed that neither 330 grant funds nor Program Income should be used to discount the cost of drugs for patients over 200% FPL. This is because:

- In practice, BPHC does not allow Program Income (PI) to be used for any discounts for persons above 200% FPL, even for services. 
  - They view the statutory limit of 200% as applying to all 330-related funding.

- It can be argued that even 330 grant funds should never be used to discount the ingredient cost of a drug (regardless of patient income).
  - Is because it’s a supply, not a service.
So how can we help patients above 200% facing high drug costs?

- Patient Assistance Programs (PAPs)
  - Can be run out of the pharmacy or other department
  - Some manufacturer allow up to 400% FPL
  - Keep PAP medications separate from pharmacy stock
    - In a separate room
- Choose to accept discount cards
  - Even at a financial loss
- Set up a $4 program for some generics
  - U&C for those medications are now $4
- Use less expensive insulin products
- My least favorite option
  - Suggest patient use another pharmacy that offers lower discounts that you choose to offer
What about patients with insurance but high copays?

• Once again, the rules differ based on whether or not a patient is above or below 200%?

• All PBMs have a clause in the base contract which states
  • You may not waive or discount copays

• Exception: For Medicare patients: 42 CFR 1001.952(k)(2) and (3).
  • May waive or reduce co-pay
  • May not advertise
  • Is not routine
  • Done in good faith

• Not a bad thing
  • Levels the playing field

• Hurts us when we want to assist underinsured patients

• Reducing the copay to the SFS/EPPAP amount “feels” like the right thing to do
Pitfalls of arbitrarily discounting co-pays

- PBM could disenroll you from all plans that they process
  - We have no “safe harbor” here.

- SFDS requirements for insured patients do not necessarily apply to pharmacy from compliance manual ???
  - Health Center patients eligible for SFSD and who have 3rd party coverage should be charged no more for any and all out-of-pocket costs (co-pays, deductibles non-covered services) than what they would have paid under the applicable SFDS payment level subject to legal/contractual restrictions

- Our pharmacy PBM contracts place restrictions on waiving or discounting co-pays

- Patient’s insurance never knows if they are compliant with medications

- Hurts pharmacy star ratings.
So....what can I do for these patients?

• Throw caution to the wind
  • Bill insurance and just charge the patient the SFS/EPPAP price
  • “They'll never find it” !! (the PBMs)

• Contract with an independent PBM for secondary billing
  the insurance co-pay down to the SFS/EPPAP cost
  • CHC pays the PBM for the service

• Do an “in-house” secondary billing to a Co-pay Assistance Fund or Foundation (more on this next)
  • Show money going from that account back to pharmacy to make them whole
Please do the 1-minute evaluation

https://www.surveymonkey.com/r/WMH2SBB

(Your past responses helped us demonstrate to BPHC that these sessions are a valuable use of their funding!)