



Rx Office Hours: **IMPORTANT**

To ensure a high-quality audio experience for all, please:

- Dial in using your phone (NOT your computer.)
- Enter your personal Attendee ID (located in the left-hand box, below the access code) when dialing in.

If you have already clicked on “Call Using Computer”, please log off this site completely and re-enter, this time clicking only on “I will call in.”

While you're waiting – you can download the documents NOW from NACHC's 340B webpage (search “NACHC 340B” & click on May webinar)



Pharmacy/340B Office Hours

May 17, 2018

Focus Topic: Contract Pharmacy 101

This activity is supported by the Health Resources and Services Administration (HRSA) of the U.S. Department of Health and Human Services (HHS) under a cooperative agreement. This information or content and conclusions are those of the author and should not be construed as the official position or policy of, nor should any endorsements be inferred by HRSA, HHS or the U.S. Government.



What are “Office Hours”?

- **A forum to share info and ask questions about technical and operational issues with other health centers & PCAs.**
 - Will not focus on policy developments.
 - Lots of “experts” on the line
- **Format:**
 - Brief operational updates**
 - Brief presentation on topic of broad interest (“focus topic”)**
 - Open Q&A**
 - Topics and questions can be submitted in advance to cmeiman@nachc.org.*
- **Held monthly (except March & August) on the third Thursday at 2:00 ET**



Asking & Answering Questions

- Please post your questions in the Chat Box, and “Send to Everyone.”
- Please respond to each other’s questions in the Chat Box.
- During the Q&A:
 - We’ll first answer questions we received in advance, and then those in the Chat Box.
 - To ask a question over the phone, click the “raise your hand” icon.



Documents available for immediate download

- The following documents are available to download immediately:
 - These slides
 - The chapter from the updated NACHC Manual about contract pharmacies
- To access them:
 - Search for “NACHC 340B”
 - Scroll about halfway down the page, and look under “Office Hours” then “May 2018”



OPERATIONAL UPDATES

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

The Mega-Guidance is NOT Back from the Dead



- Last week, an official government report stated that the 340B mega-guidance was slated to be finalized later in 2018.
- The next day, HRSA announced that this was an error.
 - There are NO official plans to finalize the mega-guidance that was released in draft in 2015.



Another Delay for Reg on Penny Pricing/ Manufacturer Fines

- In its final weeks, the Obama Administration finalized a regulation making “penny pricing” official, and allowing HRSA to fine manufacturers who “knowingly and intentionally” overcharge 340B providers.
- Trump Administration has officially delayed the reg’s effective date for the fifth time, now until July 2019.

Extended Site Registration thru May 25

- HRSA gives FQHCs longer windows to register new service sites on their database.
 - All other providers can only register during first 2 weeks of each quarter
 - ***This quarter, FQHCs have until May 25 to register for July 1 eligibility.***
- Extended window:
 - does not apply to contract pharmacies.
 - is not announced on HRSA website; must call Apexus.



A very important note re: Extended Registration Windows

***Please use extended registration windows only
when absolutely necessary.***

- Whenever possible, please register sites during the normal two-week window at the start of each quarter.
- It is very labor-intensive for HRSA to register sites outside this window – and their bandwidth is very limited.



“Robbery Drills” – No Known Requirements

- Last month, a question was raised about whether FQHCs (and/or other pharmacies) are required to conduct “robbery drills.”
- Mike Glomb (FTLF lawyer) looked into this, and found no Federal mandate to have a plan in place or to conduct robbery drills.
 - He found lots of info re: how to respond to an actual robbery, e.g., don’t be a hero, try to remember details. “I suppose that as an operational matter one could develop a policy for staff on how to deal with an attempted robbery and practice that, but again, I did not see anything *requiring* either.”
- Mike found no state-level requirements either, but stated “something have slipped my search criteria.”

Need equipment to set up a small in-house pharmacy?

- A health center in New England recently closed its 250-foot in-house pharmacy, and is happy to sell its supplies to another FQHC at a very reasonable price plus freight.
- Available items include:
 - really nice shelving to accommodate storage of medications including counters, sinks etc.,
 - two POS cash registers appropriate for QS1 software.
- For more info, contact Colleen at cmeiman@nachc.org

A special 340B University targeting FQHCs

- **Thursday August 23 in Orlando, FL**
 - In same hotel, and day before start of, NACHC CHI
- Geared specifically for health centers
 - Addresses issues specific to us
 - Skips issues that don't impact us
- Is FREE, but registration is requested
- For more info, google "Apexus 340B University"





Looking Ahead – Next Month’s Office Hours

Thursday June 21, 2:00 – 3:00 Eastern

Same web link

Focus Topic:

“Choosing your 340B partners wisely”

Tips for ensuring that outside groups who seek to partner with you on 340B:

- Understand how 340B operates in the 330 world
- Share your (or HRSA’s) views on compliance
- Have your, and your patients’, best interests at heart.



Summary of Operational Updates

1. The mega-guidance is NOT back from the dead.
2. The penny pricing reg has been delayed again, to July 2019.
3. Whenever possible, please register your sites with HRSA during the regular two-week window at the start of the quarter.
4. NACHC knows of no Federal or state requirements to conduct “robbery drills.”
5. FQHC-focused 340B University: Thurs. 8/23 in Orlando, FL
6. Next Office Hours: “Choosing your 340B Partners Wisely.”



Focus Topic: Contract Pharmacy 101

Presenter:

Kris Klein-Bradham, PharmD, MBA, BCPS, CDE
Apexus 340B Education & Compliance Support Manager



340B Prime Vendor Program

Kris Klein-Bradham, PharmD, MBA, BCPS, CDE
Apexus 340B Education & Compliance Support Manager

Objectives

Review the differences between contract and in-house pharmacy models

Review contract pharmacy inventory model types

Discuss pharmacy compliance issues and self-auditing



Contract Pharmacy Overview



What Is a Contract Pharmacy?

A pharmacy that enters into an agreement with a covered entity to provide services to the covered entity's patients, including dispensing entity-owned 340B drugs.



COVERED ENTITY



CONTRACT PHARMACY



340B VENDOR

In-House versus Contract Pharmacy

In-House, Owned Pharmacy	Contract Pharmacy
Owned by Covered Entity	Owned by Third-party
Registered as a “ship-to” address on 340B OPAIS	Registered as a contract pharmacy
May have either a physical or virtual inventory	More likely to require virtual inventory
Space requirements for inventory	No building/ space requirements

Pharmacy Model Benefits

In-House, Owned Pharmacy	Contract Pharmacy
Generally lower average operating costs than contract pharmacy dispensing fees (after start-up costs are covered)	Fewer staffing resources needed; need pharmacy point person and for monthly reporting and compliance.
Pharmacy staff can contribute as part of patient care team, improving patient outcomes and meeting organizational goals.	Increased access for patients across larger geographic area
Achieve higher capture rates for pharmacy; patients can be very loyal.	Low start-up costs: no need for infrastructure development or licensing.
Able to keep uninsured costs very low.	No building space requirements.
Pharmacy can be community resource; retail business can increase business of pharmacy <i>and clinic</i> .	Use negotiated contracts of pharmacy partner; do not need to negotiate your own.

Contract Pharmacy Inventory



What are the Different Contract Pharmacy Inventory Models?

Physical Inventory Model	Virtual Inventory Model
Segregated physical inventories	Single physical inventory
Higher initial inventory costs	Lower initial inventory costs
Greater physical space requirements	Often use third party administrator
Manual process	Automated process
Intensive staff training required	Complex record keeping

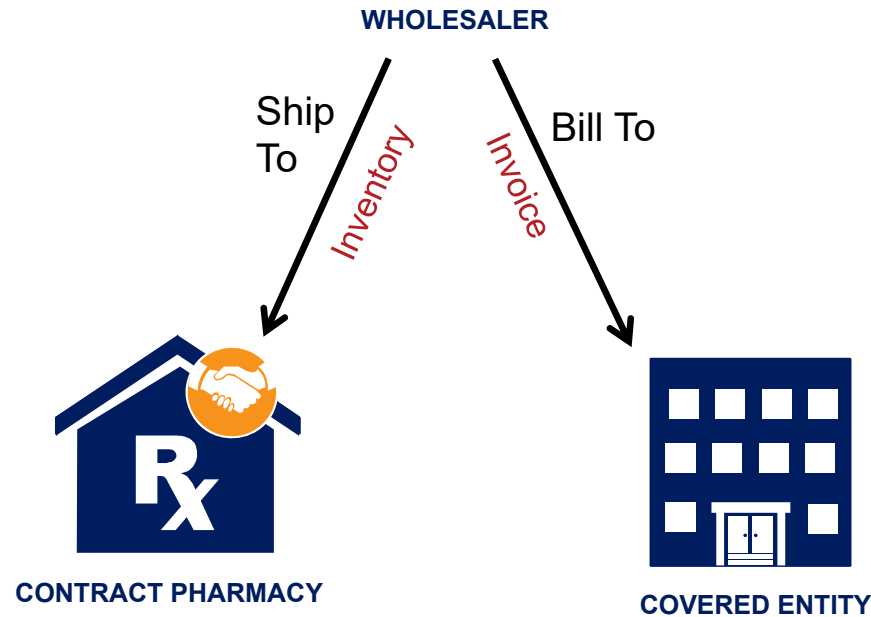
Virtual Replenishment

Virtual replenishment inventory model

1. Product is reordered when eligible product dispensed reaches a package size in the accumulator
2. Inventory is reordered at pre-determined intervals to minimize disruption of workflow
3. Inventory is billed to the entity and shipped to the pharmacy

Bill To – Ship To Overview

HRSA requires the covered entity to maintain ownership of the 340B medication



Contract Negotiations: Fee Structure Considerations

Flat dispensing fee

e.g., \$25 per prescription

Percentage-based dispensing fee

e.g., 13% of each prescription

Stop-loss

Stops transaction from going through the program when:
 $\text{Dispensing Fee} + \text{Admin Fee} + \text{Drug Cost} > \$ \text{ collected}$
on prescription

Fees on reversals

Do charges per transaction apply to reversed transactions?

Lowest fee logic

Computer algorithms evaluate which price model would cost the patient the least

Contract Pharmacy Compliance



Supporting Compliance

All compliance requirements of the 340B Program apply to contract pharmacy arrangements

- Patient definition/diversion prevention

- Duplicate discount prevention

- Appropriate inventory management

Data from entity and contract pharmacy are used to help ensure that these requirements are met

Compliance Data Elements

Diversion Prevention

- Patient information
- Provider information
- Date and location of service
- Diagnosis codes
- Written and fill dates of prescription
- EMR prescription orders (e-prescribe, fax, printed, etc.)

Duplicate Discount Prevention

- BIN/PCN
- Payer information

Inventory Management

- Quantity dispensed
- NDC

Strategies: Prescription Self-Audits

Audit a random sample of prescriptions

Number/percentage of prescription volume and frequency of audits determined by entity and documented in policies and procedures

Patient meets all eligibility requirements

Eligible provider, eligible service in CE's medical record

Consistent with scope for grantees


Claim was not billed to Medicaid (unless other arrangement between CE and state and approved by HRSA)

Resolving non-compliance


Incorrect claims are addressed

Entity self-reports to HRSA as deemed necessary in policies and procedures

Sample of Monthly Audit



Date	PT First	PT Last	Medicaid	Pharmacy	Provider	Active	Eligible Location	RX #	Pass
5/28/16	xxx	xxx	no	xxxx	Buchsbaum	yes	yes	120269	yes
5/2/16	xxx	xxx	no	xxxx	Bowen	yes	yes	1176509	yes
5/18/16	xx	xxx	no	xxxx	Sornberger	yes	yes	1201566	yes
5/1/16	xxx	xxx	no	xxxx	Lockhart	yes	yes	1204278	yes
5/26/16	xxx	xxx	no	xxxx	Elliot	yes	yes	1182940	yes
5/24/16	xxx	xxx	N/A	xxxx	Reversed	N/A	yes	1201143	N/A
5/16/16	xxx	xxx	no	xxxx	Patten	yes	yes	1206596	yes



Process: Inventory Self-Audits

1. Product accumulated matches product dispensed, product reordered, and product received
2. Inventory reports are compared to invoices and dispensing records to detect diversion
3. Entity self-reports to HRSA as deemed necessary in policies and procedures
4. Verify that reversals are accurately reflected in data feeds and are handled appropriately within the pharmacy

Is a Contract Pharmacy Right for My Organization?

SWOT Analysis of a Contract Pharmacy

Strengths

Lower startup costs

Enhanced geographic access

Follows existing prescription flow

Opportunities

Health care partner collaboration

Expanded prescription data access

Rapid entry into retail pharmacy space

Weaknesses

Potential barriers to access of CE providers/records

Limited staff investment in program

Financial reliance on external group

Threats

Compliance

Partner integrity and program participation

Potential increased risk of HRSA audit



Q&A



THIRD PARTY INSURERS & 340B....

Derek Pihl, PharmD
Salina Family Healthcare Pharmacy
Kansas



Please submit Qs & Suggested Focus Topics in Advance

- Pharmacy/ 340B Office Hours will continue on the third Thursday of each month (except March & August) at 2:00 ET
 - Use the same link as today.
 - Specific date and focus topic will be announced in NACHC Washington Update and BPHC Digest
- Future focus topics:
 - June 21 – Choosing your 340B Partners Wisely
 - July 19 - ??? – ***What would YOU like to know more about???***
Send ideas to Colleen at cmeiman@nachc.org