Pharmacy Access Office Hours

January 17, 2019

Focus Topic:

Lessons Learned from a HRSA 340B Audit

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We strongly recommend calling in **on your telephone**

Phone: 866-469-3239  
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Your Attendee ID: Listed below the access code in the box under “Select Audio Connection”.

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

You can download these slides & two related handouts from NACHC’s 340B/Rx webpage:  

(or google “NACHC 340B pharmacy” – it should be the first link after the ads)
• Operational Updates
• Focus Topic – Lessons Learned from a HRSA 340B Audit
• General Q&A
• And Comment Box discussions throughout…
OPERATIONAL UPDATES

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The partial government shutdown has no direct impact on health centers or 340B.

- HRSA – which administers the health center and 340B program – and CMS – which administers Medicaid and Medicare – are both fully funded through the end of FY2019 (9/30/19.)

- Audits, funding, etc., are continuing as usual.
Earlier this month, more than 36 pharmaceutical companies increased the list prices of hundreds of prescription drugs by an average of 6.3 percent.

These price hikes are relatively modest compared to previous years, but some drugmakers have not yet revealed their planned price increases.
... & Congress responds

- **Bills** introduced to:
  - allow HHS to negotiate with manufacturers on Medicare Part D costs
  - allow Rx to be imported from Canada
  - get generics to market faster

- **Hearings:**
  - House Oversight Committee on 1/29 to focus on high Rx prices
  - Many more expected.
CA’s new Governor, Gavin Newsom, issued an Executive Order designed to create the largest drug purchasing pool in the US.

While well-intentioned, this raises serious concerns for 340B providers in CA, as it would cause them to lose their 340B savings on most Medicaid drugs.

- CA FQHCs can retain 340B on drugs dispensed under Medicaid managed care. This proposal would transfer all Medi-Cal drugs to FFS*, where it is impossible to retain 340B savings.

The CA PCA and other groups are working hard on the issue.

* There will be more discussion of savings under Medicaid during Q&A.
340B Recertification is Coming!

- Every year, health centers are required to “recertify” their 340B participation.
  - Recertifying entails attesting to the accuracy of your info on OPAIS, and your compliance with all 340B rules.
- The window to recertify this year is January 28 - February 25.
- This is a “can’t miss” activity!
Why is Recertification So important?

- **If you don’t recertify, you’ll lose 340B eligibility for at least 3 months.**

- Recertification involves attesting to your health center’s compliance with all 340B requirements. **You will be held accountable for any non-compliance that may occur.**

- Ideally, it should serve as a triggering event for an annual review of your health center’s entire 340B program, including P&Ps, info on OPAIS, and reporting mechanisms.
For More Info re: Recertification

- Watch your email closely for messages from HRSA.
  - If you’re not getting them, check who is your Authorizing Official on OPAIS.

- HRSA is hosting a webinar on recertification on January 23, 2019 from 1-2pm ET.

- The section of the NACHC 340B Manual re: recertification is posted on the NACHC webpage.
Discriminatory Contracting Keeps Expanding

- Health Centers – and other 340B providers -- are continuing to receive contract addendums from third-party groups offering reimbursement/fee structures that are inconsistent with Congressional intent.

- Increased awareness of this issue outside of the provider community.

States Laws Target PBMs

• Both Arkansas and Kentucky* now have laws and regulations re: PBMs.
  
  • Require transparency about “spread” pricing (the difference between what the PBM is paid and what they pay the pharmacy)

  • PBM can be fined for inappropriate claim denials, and providing inaccurate information to the state.
  
  • Last summer, KY fined CVS Caremark more than $1.5 million and put its PBM license on probation for a year, following 454 violations related to reimbursement claim denials & 38 instances of providing inaccurate information to the state.

• In AR, state insurance commissioner will review PBMs' reimbursement to ensure the rates for pharmacists are fair.

*Other states may have similar laws; these are the only ones I’m currently aware of.
• An on-line platform, limited to members of the health center “family”, to discuss pharmacy and 340B-related issues.
  • Free & open to all health centers -- but as it’s not sponsored by BPHC, won’t go into details now.
  • Do NOT discuss confidential details of reimbursement, etc.
  • Sign up to join at https://www.surveymonkey.com/r/97QQQN3

Many thanks to all our pilot testers!
A Couple Reminders

1. Whenever possible, please register your sites with HRSA during the regular two-week window at the start of the quarter.
   
   The extended windows should be used only when absolutely necessary.

2. For a Mirena-like IUD at $50 each, contact MDiallo@Medicines360.org

3. FQHCs may use 330 funds to purchase Emergency Contraception, and to dispense it to their patients.
Looking Ahead

• **TODAY:** Q&A will address retaining savings on Medicaid managed care drugs.

• **THURS 2/21, 2:00 – 3:00 ET.** Next Office Hours. Focus topic will be:
  
  “340B Savings: Describing where they come from & where they go”

• **MARCH:** No Pharmacy Office Hours in March, due to P&I.
1. Drug prices keep increasing, and Congress is responding with bills and hearings.

2. Well-intentioned policies could have negative consequences on health center pharmacies and patients.

3. 340B recertification is coming Jan 28 – Feb. 25 – very important!

4. Discriminatory contracting keeps expanding, and states are starting to pass laws to regulate PBMs.

5. Sign up for Noddlepod at

   https://www.surveymonkey.com/r/97QQQN3
Focus Topic:
Lessons Learned from a HRSA 340B Audit
340B Audit October 23rd, 2018 Lessons Learned

Ronnah Alexander CPO

with

Rebecca Cheek, PharmD, BCACP (Cheek Consulting)
Activity Prior to the On-Site Audit

Initial Contact:

- Morning of 09-06-2018 an email arrived from Captain Krista M. Pedley (Director of Office of Pharmacy Affairs at HRSA), that we had been selected for a Bissell Group Audit.
- Later that day we received an email from the Bissell Group explaining the Navigation requests for the next month and the downloads required, and a request to go on-line and select a date for the initial call.
- The first phone conference would be September 19th at 7:30 AM and the requested data must be loaded to them by October 2nd. With the actual audit on October 23rd.
Assembling the Team

- We called a quick 340B Compliance Meeting to discuss how we would proceed.
- There was discussion as to vacations and whether we could navigate around them effectively. Given over one month to prepare, we decided to start immediately and allow all vacations to go as planned.
- Clinic administered medications might be a concern. Issues recently with the transition of books to scanners was in progress but not completed. Our new COO took the lead on that portion of the oversight.
- The auditing time frame was Jan-July 2018. We check 30% of all claims and 100% of all referrals as well as 30% of drugs ordered to dispensing's to end inventory. We did not have this time frame fully completed, so my part-time auditor was pulled to full time for the next few weeks.
Reaching out to Supporting Staff:

- The first contacts were to our TPA’s and our outside yearly auditor.
- We set up conference calls to discuss concerns and what to expect.
- Next all contract pharmacies were notified of the audit and how that might affect them both in the early submissions and the actual day of the audit.
- I also contacted another FQHC in our area that had recently been through an audit for advice and tips.
Requested Data to be Loaded to NIH Secured Site

Data Request List

- Polices and Procedures (there was a detailed description)
- CE Eligibility Documentation (OPAIS Database)
- 340B Universe for the sample period (For all contract pharmacies and clinic administered Medication)
- Provider Panel
- Purchasing Documentation (from every wholesaler)
- Contract Pharmacy Documentation (OPAIS Database)
- Any previous Self-Disclosures during Audit period
- Medicaid Billing Documentation (Actual bills showing how we billed)
Kick-off Conference Call on Sept 19th. 7:30AM

- This was a recorded call between the auditor, a representative at the Bissell Group, our CEO, myself, our CFO and COO.
- There was an agenda as follows: Welcome introduction, discussion of the data requests and navigation of the site, confirmation of the site visit date, discussion of our entity’s drug operations, on-site logistics, closing.
- I was asked if we carved in or out for Ky. Medicaid.
Data Load Issues

- As the data was loaded, the representative at the Bissell Group along with the auditor was reviewing the data.
- If there was a concern, problem, or any other documentation requested, I received correspondence usually within a day or two via email.
- For instance needed more documentation on Medicaid fee for service and MCO actual bills, as well as something from Ky. Medicaid indicating how they check for duplicate discounts.
- After the deadline of October 2nd, we heard nothing until the day prior to the on-site visit.
Agenda sent one day prior to Audit

- One day prior to the audit we received an email of the *actual agenda* for the day; with the selection of the pharmacy and clinic that would be visited as part of the daily rounds.
- This gave us the opportunity to have key staff available at those clinics and at that contact pharmacy for questions etc.
- The entire audit would be conducted in one day starting at 7:30 AM. After and introduction, visits to the clinics and pharmacy would occur, then data would be analyze from clinic administered and contract pharmacy dispensing's.
Audit Day October 23rd, 2018

- Present were all key staff along with our outside yearly auditor for support and guidance. (Rebecca Cheek, PharmD Cheek Consulting)
- We were given 60 contract pharmacy claims to pull hard copies on. Phone calls were placed to the contract pharmacies as other members of the team took our auditor by two clinic sites and one contract pharmacy.
- Even though only one clinic and one contract pharmacy was listed on the agenda, another clinic was pulled in at the last minute during the tour.
Clinic Site Visits

Questions were asked such as:

- How do we check the quantities in our log books?
- What is the process and how do we check these totals?
- What do we do when the wrong drug is sent to us?
- What are the processes for getting a drug ordered, put in the system, dispensed and tracked?
Contract Pharmacy Visit

The Topic Questions here were on processes:

- What is the general operation from start to finish?
- How do you know if a referral script is a good referral?
- What happens when you don’t have a drug in stock?
- The pharmacy owner and lead 340B technician were available and on site to accurately address these questions.
Purchasing and Credentialing

- Once our auditor returned from the clinics and pharmacies she met with our purchasing and credentialing lead.
- Copies of invoices were reviewed to make sure that these were a ship to the clinic but bill to the health center set-up.
- The process of Credentialing was explained in detail by our credentialing lead.
Auditing the 60 pulled claims

- Breakdown was only about 15 from clinic administered medication. The remainder from contract pharmacies.
- Clinic administered medication audit went well. Documentation of the visit, administration as well as the diagnosis code was there.
- Contract pharmacy audit more extensive than expected.
- This portion went from around 2-3 PM until 9:00 that evening.
Electronic Medical Record

- Do we have a visit that reflects the prescription?
- Is the medication in the patient documentation?
- If the prescription was a refill, do we have documented in the chart at the visit prior to the refill request that the patient was on that med?
- Do we have diagnosis codes or disease states that reflect the prescribing of each medication?
- If a referral, where is it documented that it was initiated and a closed loop chart note?
- We had to produce a documented escribe in addition to the prescription obtained from the pharmacy.
- If it was a hard copy, did we keep that somewhere on file?
Medicaid Exclusion File

- Our Medicaid Bills reflected the NPI of the parent site. (Providence)
- However on the Medicaid Exclusion File, we had listed all NPI numbers correctly as to the specific number of that clinic site.
- This resulted in a disconnection between the actual bill and the Medicaid Exclusion File.
- Either we Bill each individual clinic site, and keep the Medicaid Exclusion File as is, or we leave the billing alone and assign each clinic the parent site NPI on the Medicaid Exclusion File.
Takeaways and Problems

- We had until close of the next day to download any additional documents either of our choice and the data obtained from our pharmacies and printed from our EMR.
- Pre-Existing referrals Non-Exclusive Provider and pulling a script that came from an outside source on our patient.
- We carve in for Kentucky Medicaid Fee for Service in our clinic sites, but carve out at contract pharmacies. This does not apply to MCO’s and we have let Ky. Medicaid know. This auditor seemed to put these in the same classification which could be an issue.
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General Q&A

Reminder: Qs submitted in advance get priority.
From Amy Baker in OR:

Are other health centers being told by their contract pharmacies that Optum Rx will no longer contract with them if they dispense 340B drugs?
From Corinne in Rhode Island:

“Our state is exploring whether covered entities should be allowed to keep 340B savings, versus the state taking the rebate on Medicaid Managed Care claims. We are preparing to negotiate with the state.

Does anyone have any state specific "models" for sharing 340B savings with the state or any examples of how other states have managed this relationship?”
Other Questions?