Pharmacy Access Office Hours

February 21, 2019

Focus Topic:
DIR Fees

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

Phone: 866-469-3239  
Access Code: 632 274 023 #

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 & related handouts on Noddlepod, & from NACHC’s 340B/ Rx webpage:

(or google “NACHC 340B pharmacy” – it should be the first link after the ads)
• Operational Updates
• Focus Topic – DIR Fees
• Q&A – Staffing levels for pharmacy and compliance

• And Comment Box discussions throughout…
OPERATIONAL UPDATES

Colleen Meiman
Senior Policy Advisor
National Association of Community Health Centers
cmeiman@nachc.org
Have You Recertified?!?

• Every year, health centers are required to “recertify” their 340B participation.
  • Failure to recertify = loss of 340B eligibility for at least 3 months.

• The deadline is 11:59 PM next Monday February 25.

• This is a “can’t miss” activity!
Info on Medicaid & 340B

Gavin Magaha, Apexus
Reduced Price Vaccines

• While vaccines aren’t included under 340B, FQHCs can purchase vaccines at reduced rates through Apexus (the 340B PVP).
  • There is no minimum order quantity or upfront costs.

• You can either order direct from the manufacturer or through your distributor.

• Some of the manufacturers require a bit of paperwork upfront.

• For more details, contact Apexus at 888.340.BPVP or apexusanswers@340Bpvp.com
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 by emailing cmeiman@nachc.org or cdevoe@nachc.org

Are You on “Noddlepod”?

It’s actually noDDlepod, not nOOdlepod – but I still thought the image might help.
• 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.

• Some recent developments.
• Starting 4/1/19, 340B providers should be able to verify that they are not being overcharged for 340B drugs.*

  • Info will be available in a new section of the Office of Pharmacy Affairs Info System (OPAIS.)

* Remember that the 340B CEILING price is not always the same as the 340B PURCHASE price, since the PURCHASE price may contain “sub-ceiling” discounts & distributor fees.
Miscellaneous

• Recordings of most Rx Office Hours sessions are now available on the NACHC Pharmacy website.
  • A couple months are missing due to Colleen’s IT learning curve....

• GAO now conducting a study of methods to avoid duplicate discounts.

• Contact cmeiman@nachc.org if you’ve had issues with Medicaid reimbursement for Lantus.
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

• **MARCH**: No Pharmacy Office Hours in March, due to P&I.

• **APRIL**: Focus topic will be Clinic-Administered Drugs. (Becky Cheek)

• **MAY**: Clinical Pharmacy 101 (Matt Bertsch)

• **JUNE**: TPAs? (Jim Donnelly) or Recent Trends in Audit Findings (Matt Atkins)
1. Recertification deadline is next Monday, 2/25!

2. Apexus has state-specific info on Medicaid & 340B on their website; also offers discounts on vaccines.

3. Sign up for Noddlepod by emailing cmeiman@nachc.org or Cdevoe@nachc.org.

4. Discriminatory contracting continues to be a challenge.

5. No Office Hours in March; we’ll resume in April with a focus on Clinic-Administered Drugs.
Please do the 1-minute evaluation

https://www.surveymonkey.com/r/XFHLNWC
Focus Topic: DIR Fees

Speaker: Kala Shankle  
Director, Regulatory Affairs and Policy  
National Community Pharmacists Association (NCPA)
An Overview of Pharmacy DIR Fees

Presented to the National Association of Community Health Centers

February 21, 2019
The strength of our numbers
NCPA represents the interests of America's community pharmacists, including the owners of 22,000 independent community pharmacies. Together they represent an $76 billion health care marketplace and employ 250,000 people.
What differentiates our members

As *community-based healthcare professionals* and entrepreneurs, independent pharmacists are *uniquely positioned to customize solutions* to healthcare challenges affecting *local communities and employers.*
• I declare that neither I nor any immediate family member have a current affiliation or financial arrangement with any potential sponsor and/or organization(s) that may have a direct interest in the subject matter of this presentation.
Objectives

• Understand the historical federal legislative and regulatory framework around DIR fees, and more specifically pharmacy DIR fees

• Assess the impact of pharmacy DIR fees on plan sponsors, the government, and consumers

• Identify the various types DIR fees and the terminology for pharmacy DIR fees

• Recognize how legislators and regulators are addressing or may address pharmacy DIR fees and other retroactive fees
Origins of DIR

- Part D Regulations and Rules
  - Plan’s bid process and CMS reporting
  - The PBM’s role, rebates, and the pharmacy’s negotiated price
  - The beneficiary’s benefit phases (deductible, donut hole, catastrophic)
- Other Retroactive Fees
  - Medicaid
  - Commercial
For purposes of this part, negotiated prices shall take into account negotiated price concessions, such as discounts, direct or indirect subsidies, rebates, and direct or indirect remunerations, for covered part D drugs, and include any dispensing fees for such drugs."


DIR includes discounts, chargebacks, rebates, cash discounts, free goods contingent on a purchase agreement, up-front payments, coupons, goods in kind, free or reduced-price services, grants, legal judgment amounts, settlement amounts from lawsuits or other legal action, and other price concessions or similar benefits. DIR also includes price concessions from and additional contingent payments to network pharmacies that cannot reasonably be determined at the point-of-sale.

See CMS, Final Medicare Part D DIR Reporting Requirements for 2016 (June 23, 2017).
How DIR Fees Work

1. **Day 1**: RPh dispenses the medication to the patient.
2. **Day 14**: RPh receives a Wholesaler Invoice for the drug and Pay $90.
3. **Day 90**: RPh receives a DIR Fee Deduction Notice for the medication already dispensed and Return $15.
4. **Final Accounting**: Pharmacy Balance Sheet shows Bought Drug $90, Reimbursed $95, DIR Fee (-$15), Net Reimbursement: $80, Net Loss: (-$10).
How DIR Fees Impact the Patient

How Retroactive Pharmacy DIR* Fees Hurt Medicare Patients & Taxpayers
*Direct and Indirect Remuneration

1. **At the Pharmacy Counter**
   - Medicare-enrolled seniors pay pharmacies a copay for medications,
   - while the full price of the drug is credited against the patient's coverage limit.

2. **Weeks or Months Later**
   - The PBM administering Medicare's prescription benefit decides to take back a portion of the pharmacy's reimbursement for the actual costs of the patient's medication.

3. **The Result**
   - The original higher price - not the adjusted price - is still counted against the patient, pushing her more quickly into Medicare's "donut hole" coverage gap, in which she becomes responsible for a much greater portion of her prescription costs.

4. **Eventually**
   - As the patient's health care expenses mount, she'll be pushed out of the donut hole...
   - ...and into Medicare's catastrophic coverage phase, in which taxpayers are now on the hook for 100% of her health care expenses.

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NCPA
National Community Pharmacists Association
The Impact on the Patient Continued...

- IHS Markit found over the next 10 years, passing rebates to the point of sale for diabetes medications “could reduce total medical spending by approximately $20 billion”

- Many prescriptions for brand medicines are subject to patient cost-sharing, including specialty medications on specialty drug tiers with 20% cost-sharing

- Even patients with flat copays would benefit because rebates at point of sale would stave off their quick progression through the coverage phases of the Part D benefit

Types of DIR

- Manufacturer Rebates
- Pharmacy Price Concessions
- Explosion of DIR Fees in Recent Years
Types of Pharmacy DIR Fees

• Preferred Pharmacy Fee
• Effective or Contracted Rates
• Performance Metrics
  • Payment mechanism to pharmacies for the fulfillment of various quality measures
  • Alternately, a fee assessed to pharmacies for non-compliance with quality measures
Ways DIR Fees are Assessed

• Pharmacy level vs. PSAO or network level
• Percentage of ingredient costs vs. a flat fee per prescription
• DIR fee estimator tools or calculators
What’s Next?

• Executive
  • November 2017 Proposed Rule: CMS sought comments on requiring sponsors to include at least a minimum percentage of manufacturer rebates and all pharmacy price concessions received for a covered Part D drug in the drug's negotiated price at the point-of-sale
  • April 2018 Final Rule: CMS asserted its authority to make changes to DIR
  • Blueprint/HHS’ Request for Information: Agency requested comment on what CMS should do to restrict or reduce the use of rebates
What’s Next Continued...

- Pending Federal Legislation
  - H.R. 1034, *Phair Pricing Act*
What’s Next Continued...

• State Legislation
  • States have banned retroactive fees:
    • MO: SB 826 (2018)
    • SC: HB 5038 (2018)
    • NY: SB 7507 (2018)
    • UT: SB 208 (2018)
    • AR: SB 2 (2018)
    • NC: HB 466 (2017)
    • GA: SB 103 (2017)
    • ND: SB 2258 (2017)
    • NM: HB 122 (2017)
What’s Next Continued...

- Modernizing Part D and Medicare Advantage to Lower Drug Prices and Reduce Out-of-Pocket Expenses, CMS 4180-P
  - All pharmacy price concessions, excluding positive contingent amounts, would be assessed at the point of sale
  - Patient savings
- Move to establish pharmacy level quality metrics
Questions?

• Kala Shankle, Director of Policy and Regulatory Affairs
• Kala.shankle@ncpanet.org
Please do the 1-minute evaluation

https://www.surveymonkey.com/r/XFHLNWC
General Q&A

Reminder: Qs submitted in advance get priority.
Are there recommended standards for staffing levels (e.g., pharmacists, techs) in an FQHC pharmacy?

Responder: Tim Mallett, 340Basics
What is an appropriate level of compliance staffing for a 340B Program?

- As an example, consider an FQHC that:
  - serves over 25,000 patients a year
  - 10+ primary care clinics, as well as several satellite sites.
  - 1 contract pharmacy and multiple dispensaries.
  - Foresees opening 2-4 additional care sites in the next year.
  - Has 1 FTE compliance staff that is responsible for 340B along with all other health center compliance matters.

Responders: Matt Atkins, 340B ACE and CIA, Draffin-Tucker
Gail Kuwahara. Rx Coordinator, Open Door CHC, CA
Please do the 1-minute evaluation

https://www.surveymonkey.com/r/97V69ZX
Other Questions?