CHC Expert Session 3:

Health Center Pharmacy Reimbursement: Threats, Trends, and Compliance

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Statement of Conflicts of Interest

• Matthew Bertsch has no actual or potential conflict of interest in relation to this presentation
Today’s Agenda

Today we're going to have a conversation about the challenges and complexities associated with billing and reimbursement for health center pharmacy services provided through both in-house pharmacies and contract arrangements. Some topics our expert panelists plan to explore include:

- Compliant sliding fee discount programs
- Navigating discriminatory reimbursement practices
- Understanding fees paid to 3rd parties; and
- Avoiding unforeseen legal landmines
Let me introduce our expert panelists:

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CHC Expert Session 3: Health Center Pharmacy
Reimbursement: Threats, Trends, and Compliance

Reimbursement Threats and Legal Pitfalls

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Statement of Conflicts of Interest

- Jason Reddish does not have any conflicts of interest in relation to this presentation
DISCLAIMER

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Jason Reddish is a partner in Feldesman Tucker Leifer Fidell's health care and federal grants practice group. His practice focuses on the drug discount program established under section 340B of the Public Health Service Act (340B program) and other regulatory issues affecting community health centers, AIDS Service Organizations and Ryan White funded clinics, hemophilia treatment centers, safety-net hospitals, and other 340B program stakeholders including pharmacies and vendors.
Today’s Agenda:

- Reimbursement Trends and Threats
  - Private, Medicaid, and Medicare
- 340B Reimbursement Discrimination
- Legal Pitfalls
CE Question:

Which of the following have acted to prevent payers from discriminating against 340B providers:

A. HRSA
B. The Department of Justice
C. State Legislatures
D. Congress
Medicaid

Duplicate Discounts, Fee-for-Service, and Medicaid Managed Care
MCO-BILLED 340B Drugs Not Subject to Duplicate Discount Prohibition

- Congress expanded Medicaid Drug Rebate Program in Affordable Care Act to include MCO-billed drugs in 2010
- Included exception for drugs:
  - Billed to an MCO; and
  - Purchased at 340B pricing
- 340B-purchased drugs billed to an MCO are not subject to the payment of a rebate
- The duplicate discount prohibition only applies to drugs billed to Medicaid FFS (not MCOs) and that are subject to payment of a rebate
Medicaid Reimbursement

- FFS Medicaid reimbursement is settled:
  - In order to “carve in” (use 340B drugs when billing Medicaid), must be listed in HRSA’s Medicaid Exclusion File
  - For 340B drugs dispensed by a pharmacy: enter actual acquisition cost in Usual and Customary field – reimbursement is cost plus the state’s “professional dispensing fee”
  - Contract pharmacies generally may not use 340B when billing FFS Medicaid
- No federal rule applies to whether a covered entity or its contract pharmacy can use 340B drugs when billing MCOs
- Threats to MCO reimbursement include:
  - Mandatory carve-out in contract pharmacies or covered entities (legal?)
  - Directed reimbursement cuts (legal?)
  - Impossible to follow 340B claims tagging procedures
PBMs and PRIVATE PAYERS

- Pharmacy Benefit Managers (PBMs) and private payers are issuing reimbursement contracts that pay 340B providers less than non-340B providers

- Why?
  - They know that you have better margins than most retail providers
  - Drug manufacturers refuse to pay secretly negotiated PBM rebates on 340B drugs – they need to find the money elsewhere

- What Can You Do?
  - Refuse to accept, but that means leaving the network
  - Negotiate, but you might not have the leverage
  - Work with your PCA to push back against discriminatory reimbursement, and look at potential legislative solutions
Other Forms of Discrimination

- Declaring certain drugs handled by FQHCs often to be “specialty drugs” that must pass through specialty pharmacy network
  - Example: Oral HIV drugs, PrEP, HepC treatments
- Offering lower co-pays at “captive” pharmacies
- Prohibiting common services, like mail-order delivery
Relief in Some States

- Minnesota, Montana, Oregon, South Dakota, and West Virginia all passed laws that prohibit reimbursement discrimination against 340B covered entities and contract pharmacies
  - All passed in 2019
- Other states are considering similar legislation
- Other state laws could provide protection
  - Must offer same reimbursement terms
  - Must not discriminate/general terms and conditions
  - No discrimination among provider types
What about Congress?

- Unlikely to see 340B legislation passed that helps or hurts covered entities
- Current Congress has no appetite for 340B
- Any “positive” changes would likely be chained to “negative” changes
Medicare

- Medicare Part D, and Part C prescription drug plans, are essentially treated as private payers with a couple of major exceptions:
  - Federal law states that Part D and Part C drug plans must pay FQHCs no less than what is paid to other entities
    - Currently subject of litigation
    - Similar provision in Medicaid MCO
  - Federal law could pre-empt state law affecting Medicare Part C/D plans
    - Will block anti-discrimination laws?
Patient Inducement Prohibition

- **Blanket cost-sharing waivers** applied to Medicare or Medicaid patients **violate the civil patient inducement prohibition** at Section 1128A(a)(1)(5) of the Social Security Act (SSA)
  - “Any person (including an organization, agency, or other entity…) that…offers to or transfers remuneration to any individual eligible to benefits under [Medicare or Medicaid] that such person knows or should know is likely to influence such individual to order or receive from a particular provider, practitioner, or supplier any item or service for which payment may be made, in whole or in part, under [Medicare or Medicaid].
- Penalty is **civil** - $10,000 per incident (with potential for treble damages and exclusion)
Antikickback Statute

- “Whoever knowingly and willfully solicits or receives any remuneration...directly or indirectly, overtly or covertly, in cash or in kind to any person to induce such person...to purchase...any good, facility, service, or item for which payment may be made in whole or in part under Federal health care programs...” shall be guilty of a felony.

- Giving something of value to a patient that encourages that patient to submit a Medicaid/Medicare claim can constitute an antikickback statute violation.

- But there is good news...
Waiver Test

- However, waiver of coinsurance and deductible amounts not “remuneration” if:
  - The waiver is not offered as part of any advertisement or solicitation
  - The health center/pharmacy does not routinely waive coinsurance or deductible amounts; and
  - The health center/pharmacy waivers after making a good faith determination of financial need or fails to collect the amounts after making reasonable collection efforts

- How to apply?
  - If the patient is <200%, the Waiver Test is likely satisfied because health center made a determination of financial need
  - If the patient is >200%, the Waiver Test is satisfied if health center makes a good faith determination that the patient cannot afford his or her medication
  - Harmonizes “regardless of ability to pay” and patient inducement prohibition
CE Question

Which of the following have acted to prevent payers from discriminating against 340B providers:

A. HRSA
B. The Department of Justice
C. State Legislatures
D. Congress
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340B Contract Pharmacy: Business Analytics = Degrees of Difference

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Hudson Headwaters Health Network
Statement of Conflicts of Interest

- Jim Donnelly has the following conflict of interest in relation to this presentation: Jim also serves as President of Hudson Headwaters 340B, LLC a wholly owned 340B administration and consulting subsidiary of the FQHC.
Today’s Agenda

- Illustrate the evolution of different contract pharmacy models
- Highlight the essential differences in each
- Focus on assessing opportunities wisely
- Talk through tools used to monitor program performance
CE Question

Which of the following is always true?

A. The contract pharmacy model with the lowest dispensing fee produces the greatest benefit for the Entity.

B. The more 340B transactions captured through the contract pharmacy the better the results.

C. Each arrangement is different and should be assessed carefully for a full understanding of feasibility prior to contracting.

D. Contracts presented by the larger stakeholders are non-negotiable.
Hudson Headwaters Health Network

- Not-for-profit system of community health centers
- Service area includes over 5,600 square miles across 6 counties
- 18 health center locations
- Started as a single health center in 1974
- Became a network of health centers in 1980
- Over 80,000 patients seen annually
- Over 360,000 patient encounters
- Over 800 staff members
Hudson Headwaters Health Network

- Federally Qualified Health Center (FQHC), Upstate NY
- 18 Health Center Locations
- 75+ Contract Pharmacy Arrangements
- Self Managed Program through Hudson Headwaters 340B
340B Contract Pharmacy
Building Blocks of the Partnership
Contract Pharmacy Trends

• Mergers, acquisitions, alignment and affiliation
• Evolving fee structures
• Influence on prescribing patterns
• Expanding scope
  • Referral Capture
  • Mail-order
  • Care Management
  • Infusion
Understand ALL fees to effectively evaluate opportunities and measure performance

- Dispensing Fees (Pharmacy) and Processing Fees (Administrator)
  - Flat, Flat + %, % of Margin, % of Retail, Tiered Fees, By Drug Category
- Data Access Fees (Switch Fees)
- DIR Fees
- Batch Processing Fees
- Fees to get Paid by Administrator
- True-ups (repayments) to Manufacturers
- Inventory Replenishment Rates for drugs that did not reach package size (Slow Movers)
- Impact of increased volume and complexity
Understanding the Models:

- Brand and Generic
  - All-In
  - Profitability Filters

- Brand Only
  - Fewer Accepted
  - Focused Benefit

- Reference Price
  - Pharm Kept Whole
  - “All in” vs. “Winners Only”

- Specialty
  - Tiered Approach
  - Limited Formulary
Let’s talk through some examples...
Disclaimer

The following examples have been created for educational purposes only.

The illustrations, charts and graphs presented here are not intended to represent actual/exact program outcomes, nor should they be assumed to suggest or imply a recommended or preferred model.

These examples are presented to facilitate discussion about the factors to be considered in evaluating opportunities and monitoring opportunities and evaluating performance.

Actual factors to be considered and results will vary based on circumstances and expectations specific to each health center.
Understanding the Reference Price Model*
*As compared to traditional pricing models

**Total Amount Collected**
- Dispensing Fee
- Additional Fee
- 340B Purchase Price
- Margin to Entity

**Total Amount Collected**
- Pharmacy Keeps Margin
- NADAC FEES
- 340B Purchase Price
- Negative Margin Transactions (All In)
- Margin to Entity
Monitoring Tools

- Cumulative Inventory Reports
- Aging Reports
- Slow Mover/True Up Reports
- Invoice Detail Reports
- Positive Inventory Reports
- Error/Omitted Transaction Reports
- Trend Tracking
- Dashboards
Financial Overview Dashboard

Estimated Benefit by Pharmacy Chain

- Demo Independent Chain: 26.02%
- Demo Grocery Chain: 20.23%
- Demo Independent Single: 26.81%
- Demo Big Box Stores: 26.92%

Benefit Trends

- Current Benefit: 0.52%
- Net Reconcile Count: 1.19%
- Average Benefit Per Dispense: -0.28%

Benefit vs. Fees

Benefit vs. Dispenses vs. Avg. Benefit Per Dispense

Total Benefit:

- Total Benefit
- Avg. Benefit Per Dispense
- Dispenses

CE Question

Which of the following is always true?

A. The contract pharmacy model with the lowest dispensing fee produces the greatest benefit for the Entity.

B. The more 340B transactions captured through the contract pharmacy the better the results.

C. Each arrangement is different and should be assessed carefully for a full understanding of feasibility prior to contracting.

D. Contracts presented by the larger stakeholders are non-negotiable.
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Ensuring Compliance with Section 330 Sliding Fee Requirements and Expectations

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Statement of Conflicts of Interest

- Cristie Pellegrini has no actual or potential conflict of interest in relation to this presentation
Today’s Agenda

Today we're going to have a conversation about ensuring your pharmacy SFS discount program is in line with Section 330 Grant requirements. Considerations:

- Establishing your nominal fee, number of tiers, and U&C
- Ensuring U&C is consistent with locally prevailing rates
- Managing your own PBM
- How to work with an external PBM
CE Question

Which of the following **must** be included in your Sliding Fee Scale Cost determination?

- Service (Dispensing) Costs
- Drug Costs
- Markup Costs
- All of the Above
Background on SFS requirements

- 340B is not prescriptive in how CEs charge patients for Drugs
- BUT! Section 330 of Public Health Service Act is
- Full discounts are given to patients below 100% FPL (or nominal charge, which must be lower than first pay class fee)
- Must be 3 pay classes between 100-200% FPL
- SFS requirements apply to the service part of the costs of providing a drug (dispense costs) not the cost of the drug itself
More on SFS

- Start your scale (<100% FPL) with the nominal fee, and go up in small increments for each scale
- Consider a 30 day-supply as well as 31-90 day-supply charges (e.g. $5 for 30 day, $10 for 31-90 day)
- Consider different charges for formulary and non-formulary drugs (e.g. $5 for formulary, $10 for non-formulary)
- Consider a monthly cap per individual (track via PBM)
- KISS – Keep It Simple, Steven!
- Multiple tiers, days supply, and formulary/non-formulary gets complicated quickly
- How to manage it?
But First, A Word on U & C

- Calculate your in-house pharmacy U&C based on local prevailing rates
- Use AWP - % plus your **Undiscounted** Service Fee
- e.g. Brand: AWP – 15% + $10 dispense fee
- Maintain a “generic price list” of medications to remain consistent with local rates
- Use pharmacy software and/or PBM to maintain the generic price list
- CUC has a managed care pharmacist to monitor price changes, DURs, formulary opportunities, etc
Utilizing a PBM for SFS at the Network

- PBMs can be used to offer your SFS program at your contract/network pharmacies as well as your in-house pharmacies.
- CUC utilizes its entire pharmacy program to manage different aspects of its own PBM, including our in-house pharmacies, for cost saving measures.
- Our P&T committee manages our formulary.
- Our Clinical Pharmacists manage complicated patients and review prior authorizations (non-formulary drug requests).
- Our PAP team procures manufacturer-provided medications for expensive non-formulary medications.
- Our PBM techs answer phones to provide customer support.
- CUC partners with a 340B TPA and PBM, to manage the claims adjudication and work with our teams.
Utilizing an External PBM

• The degree to which you utilize the external PBM’s services is up to the CE and its specific needs
• At a minimum, you will need adjudication services
• The larger the CE, the more economy of scale you receive by having your own team members (pharmacists, techs) manage some aspects of the PBM and SFS coverage (formulary, prior auths, customer service)
• Make sure your PBM is willing to work with you to establish and maintain your SFS tiers and formulary. The coverage matrix can get complex!
• PBM should be willing to program new price tiers and special programs per your specifications
**Final Notes**

- It is possible to provide SFS coverage at pharmacies that are not 340B contract pharmacies, by paying them network rates.
- **IMPERATIVE** to work closely with Eligibility team when utilizing a PBM at your contract/network and in-house pharmacies to ensure patient access.
- Work with 340B compliance team to ensure adherence with 340B program requirements.
CE Question

Which of the following **must** be included in your Sliding Fee Scale Cost determination?

- Service (Dispensing) Costs
- Drug Costs
- Markup Costs
- All of the Above
Additional Questions?

"We combined all your medications into ONE convenient dose."
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