340B Drug Pricing Program- Preventing Diversion

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Disclosures

- Jane McLaughlin-Middlekauff, PharmD, BCACP, Bill Pong, PharmD, Nicole Crase, RPh, PharmD, John Iilic, PharmD, MBA, Cathie Jamieson, MA, BS Pharm, RPh, and Catherine Amey declare(s) no conflicts of interest, real or apparent, and no financial interests in any company, product, or service mentioned in this program, including grants, employment, gifts, stock holdings, and honoraria.

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Target Audience: Pharmacists

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Activity Type: Knowledge-based

Learning Objectives

- Describe statutory requirement to prevent diversion of 340B drugs
- Describe a systematic approach used by covered entities to determine the 340B eligibility of a drug order
- Describe a process to test eligibility determination systems at the covered entity and contract pharmacy as an approach to self-audit and program oversight

- Incorporate patient definition eligibility criteria into split billing software and test compliance of eligible and ineligible transactions
- Discuss processes that Peer Mentors from the 340B Peer-to-Peer Program use to test internal controls as an approach to self-audit
- Describe methods to mitigate risk by accurately and adequately managing physical and virtual inventory data
What is Considered Diversion?

A. A drug is provided to an individual who is a patient of that covered entity
B. A drug is dispensed in or from a location that is not listed on the entity’s Medicare cost report or registered on its 340B database
C. A drug is properly accumulated in the 340B split-billing software
D. A drug dispensed as part of an episode of care which is supported by a medical record maintained by the covered entity

Which of the Following is Not Required to Ensure the Accuracy of the 340B Eligibility Determination Filters?

A. Each 340B eligibility determination filter needs to be addressed
B. Locations are identified as eligible vs ineligible
C. All inpatients codes do not need to be excluded
D. Ensure the eligible provider list is updated regularly
E. Understand state Medicaid requirements

Which One is Not a Common Inventory Vulnerability or Risk?

A. NDC crosswalk mapped incorrectly
B. Debits from the accumulator not match with order or shipment
C. Excessive or undocumented manual manipulations to the accumulator
D. Reconciling purchases with dispensations and/or administrations

340B Review of Diversion

American Pharmacist Association
Annual Meeting
March 5, 2016

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Office of Pharmacy Affairs (OPA)
Healthcare Systems Bureau
Health Resources and Services Administration
U.S. Department of Health and Human Services

Program Integrity

Areas of Focus

- Eligibility
  - Group Purchasing Organization (GPO)
  - Auditable records
- Duplicate Discount
- Diversion

Diversion

- 340B drug is provided to an individual who is not a patient of that entity
- Statutory requirement for prevention of diversion
  - Section 340B(a)(5)(B) of the PHSA prohibits diversion
- Patient definition guidelines
  - 3 elements of patient definition
Patient Definition Requirements

1. Covered entity has a relationship with the individual and maintains records of the individual’s health care

2. Individual receives health care services from a health care professional
   - Employed by entity; or
   - Under contractual or other arrangements (e.g., referral for consultation) with entity

3. Patient must receive a health care service or range of services from the covered entity which is consistent with the scope of services for which grant funding has been provided to the entity (applies to grantees – not hospitals)

Patient Definition Requirements

Program Integrity

Guiding Principles:
- Maximize oversight reach
- Manage compliance risk

Strategy
- Initial certification
- Annual recertification
- Program audits
- Site Visits

Resources
- Systems
- Staff

Improvements in Program Integrity

- Processes and protocols
- Desk audits
- Training and Education
- Site visit questionnaire
- Program integrity analysts
- Manufacturer audits

Things to Know About Audits

- Responsibility for 340B Program compliance
  - Plan for oversight
  - Policies and procedures compliant with 340B Program requirements
- Final Report
  - Agreement
  - Disagreement
  - Corrective Action Plan (CAP)
### Types of Audits

**Risk-Based**
- # of contract pharmacies
- Complexity of program
- # of outpatient facilities
- Volume of purchases

**Target-Based**
- Reported Allegations
- Reported Violations
- Follow ups on CAPs

### HRSA Audits by the Numbers
**as of February 2016**

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<td>Number of finalized reports</td>
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### HRSA Audit Steps

**Pre-Audit**
- Engagement letter
- Scheduling
- Data request

**Onsite Audit**
- Opening meeting
- Staff interviews
- Data sample review

**Post-Audit**
- Preliminary Findings
- Notice and Hearing
- Corrective Action Plan (CAP)
- Final Report
- Attestation
Example HRSA Audit Findings

- Covered entity provides 340B drugs to an ineligible individual
- Individual receives 340B drugs from ineligible location
- Drug is improperly accumulated

Steps to a Compliant 340B Program

- Registration
- Procurement & inventory
- Reports & documentation
- Audits

Diversion

- Ineligible Site
- Ineligible Patient
- Ineligible Provider
- No Referral
- No Record of Care
- No Maintenance of Health Care Records
- No Responsibility for the Care of the Individual
- Care Provided which Resulted in the Prescription was not Within the Scope of What (Grantees)

Diversion

- Ineligible Site
- Ineligible Patient
- No Record of Care
- No Maintenance of Health Care Records
- No Responsibility for the Care of the Individual
- Care Provided which Resulted in the Prescription was not Within the Scope of What (Grantees)

Does your covered entity have policies and procedures in place to identify eligible providers?

Does your covered entity have policies and procedures in place to address the eligibility of the sites where 340B drugs are used?
Referral for Consultation Process

Is your covered entity’s referral for consultation process outlined in its policies and procedures?

Consultation Notes

Written in standard business format
- Name of both providers
- Addresses of the providers’ practices
- Date
- Signature (either e-signature or manual)

Basic patient identifiers
- Reason for consult
- Outcome of the referral visit

340B Eligibility Determination Filters

Does your covered entity’s written policies and procedures identify each inventory method used for each of your areas that utilize 340B drugs and are those areas independently monitored to ensure accountability for all 340B drugs?

Inventory Methods

Virtual replenishment inventory
- Replenishes regular non-340B stock already dispensed with 340B purchased drugs
- 340B accumulations and replenishment for exact NDC-11 match
- Neutral inventory
- All 340B accumulations are eligible and tracked

Physical inventory
- Pre-purchased 340B stock in advance of dispensation or administration
- Re-orders 340B stock as needed
- NDC-11 match not required when re-ordering
- Can identify 340B drugs from non-340B drugs in stock
- All 340B drugs are accounted for and tracked

Data Vulnerabilities

Virtual Inventory
- Inventory Management
  - Data vulnerabilities
  - Neutral inventory
  - Dimension data vulnerabilities

Physical Inventory
- Inventory Management
  - Data vulnerabilities
  - Neutral inventory
  - Inventory Management
  - Data vulnerabilities

Data Vulnerabilities in a Virtual System

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Data Vulnerabilities in a Physical Inventory System

Data Vulnerabilities in a Virtual System

340B Eligibility Determination Filters

Diversion Vulnerabilities in a Physical Inventory System

340B Eligibility Determination Filters

Key points

1) Each 340B eligibility determination filter needs to be addressed
2) Locations are identified as eligible vs ineligible
3) All inpatients codes need to be excluded appropriately
4) Ensure the eligible provider list is updated regularly
5) These filters should be reviewed and updated routinely
**Patient Eligibility Data Vulnerabilities**

Are the 340B eligibility determination filters correctly identifying 340B eligible patients?

- Is the patient an outpatient at the time the drug was used?
- Are all of the eligible and registered areas included?
- Are all the ineligible areas excluded?
- Are all the eligible providers included?
- Are all the ineligible providers excluded?
- Are Medicaid beneficiaries being carved-out (if applicable)?

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**Questions**

- How does Loyola ensure that its 340B patient definition matches the 340B eligibility determination processes with their 340B software vendor?
  - How are all eligible locations and providers included?
  - How are all ineligible locations and providers excluded?
  - How frequently is this tested?
  - How is it documented?

- What is your process for updating the eligible provider list?
  - How frequently is it done?
  - How is it documented?

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**Questions**

- How does Five Rivers ensure that its 340B patient definition matches the 340B eligibility determination processes?
  - How are all eligible locations and providers included?
  - How are all ineligible locations and providers excluded?
  - How frequently is this tested?
  - How is it documented?

- What is your process for updating the eligible provider list?
  - How frequently is it done?
  - How is it documented?

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**Data Vulnerabilities in a Virtual System**

**Accumulation**

- **Negative Accumulation**
  - Returns
  - Discovered error

- **Positive Accumulation**
  - Neutral inventory
  - Usage in both patient types

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Accumulation Data Vulnerabilities
Are the correct administrations/dispenses being sent to the split billing software?
Is the split-billing software accumulating appropriately?
Test the pharmacy operating system, hospital billing system, and the split-billing software
• Correct NDC
• Correct Quantity
• Correct Location
• Correct Payor
Required data includes: CDM to NDC crosswalk; Quantity accumulated; payor identification (if carving-out)

Questions for Loyola University Health System
How does Loyola ensure that the NDC crosswalk is mapped accurately so that the correct administration/dispenses are being sent to the split billing software and that medications are being accumulated appropriately?
  • What is the frequency in which this is done?
  • What documentation is maintained to demonstrate that the mapping is accurate?

Data Vulnerabilities in a Virtual System

340B GPO WAC
Eligible outpatient
Inpatient
Lost charges

Covered outpatient drug
Bundled drug
Wasted drug

Bundled drug
Non-drug/Special

Off-site location
Undocumented administration/dispensation

Ordering Data Vulnerabilities
Are orders correctly decremented from accumulations?
Are the purchased drugs mapped to the correct NDC-11?
Are any returns of purchased drugs captured correctly?
Are manual orders adjusted and documented?
Test the wholesaler ordering, manufacturer direct ordering, split billing software
Required data elements include: Purchase orders; Invoices; Quantity: NDC

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Questions for Loyola University Health System

How does Loyola ensure that the medications ordered are properly debited from the accumulator?

How are return of purchased drugs captured?

Are manual orders adjusted and documented?

Physical Inventory Data Vulnerabilities

Can all 340B stock on hand be accounted for?
Can all 340B drugs be identified from non-340B drugs?
Is the perpetual inventory system working correctly? (if applicable)

Testing the manual or perpetual inventory system
- Purchases reconciled with dispensation
- Periodic physical count reconciled with stock on hand
- Adjustments made as necessary
- Return to stock items accurately processed
- Expired medications accurately debited

Required data elements: NDC, quantity, identifier for 340B stock (if applicable)

Ordering (Clinic)

PO (Requisition Form)

Pharmacy

Wholesaler

Mixed-Use Pharmacy

340B

WAC

Question for Five Rivers Health Centers

How do Five Rivers Health Centers track and account for their 340B drugs?

Is there a perpetual inventory and/or an inventory system?

How is the accuracy of the data input verified?

Are debits occurring correctly from the inventory system?
CJ3  frpelqh#wzr#volghv#
Fdwklh#Mdplhvrq/#525925349
Ordering Data Vulnerabilities
Are orders correctly placed on correct account?

Testing the inventory system
- Interfacing with wholesaler ordering
- Manual, paper system transmitted to wholesaler
- For non-340B ordering when Medicaid carve-out
- For covered drugs related to scope of practice / providing scope

Required data elements: 340B account (s); WAC account; Quantity

Questions for Five Rivers Health Centers and Loyola
How do your health centers order test the ordering system to ensure that orders are placed on the correct account?

Diversion Vulnerabilities in a Virtual Inventory System

Shipment

Diversion Vulnerabilities in a Physical Inventory

Receiving (Clinic)
Shipment Data Vulnerabilities

Are the drugs and quantities received the same as what was ordered, including NDC?

Test the wholesaler ordering, manufacturer direct ordering, split billing software
- For accurate capture of 340B drugs received
- NDC and quantities updated in perpetual or manual log inventory system

Required data elements include: purchase orders, invoice, quantity, NDC

Questions for Loyola University Health System

How does Loyola verify that the drugs and quantities received the same as what was ordered, including NDC?

Are any adjustments made to the inventory system? If so, are these adjustments documented?

Questions for Five Rivers

How does Five Rivers verify that the drugs and quantities received the same as what was ordered?

Are any adjustments made to the inventory system? If so, are these adjustments documented?

Contract Pharmacies

- Self-audit using virtual inventory process.
- Ensure the 340B eligibility determination filters are working appropriately
- Reconcile purchases with accumulator and dispensations


Contract Pharmacies

How do you self-monitor the activities of your contract pharmacies to ensure that 340B medications are tracked and accounted for?

Covered Entities Must Ensure Against 340B Diversion

Inadequate inventory management can result in an entity’s inability to account for all 340B drugs purchased and lead to diversion
Patient Definition Case Study

• Patient visits covered entity
• Covered entity sends patient to private practice
• Private practice writes prescription
• Can covered entity’s in-house pharmacy deem prescription from private practice 340B-eligible?

Patient Definition Case Study

• Patient visits the Emergency Department
• Patient is admitted by the Hospital
• Should the covered entity administer 340B drugs to patient?

Take Home Messages

• Be prepared
• Covered entity’s responsibilities for oversight
• Eligibility includes maintaining auditable records showing compliance
• Methods to prevent diversion and duplicate discounts

Resources

• Office of Pharmacy Affairs
• About 340B Program Audits of Covered Entities
• Policy Releases
• Office of Pharmacy Affairs Frequently Asked Questions
• 340B Peer-to-Peer Webinars
• 340B University with slides, notes and other tools

Contact Information

Office of Pharmacy Affairs (OPA)
Main Office Phone Line: 301-443-4353
Web: www.hrsa.gov/opa

Prime Vendor Program (PVP)
Phone: 1-888-340-2787
ApexusAnswers@340bpvp.com
Web: www.340bpvp.com

Questions?
Covered Entities Must Ensure Against 340B Diversion

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