CELEBRATING 140 YEARS!
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HILTON ST. LOUIS AT THE BALLPARK
340B in Community Pharmacy
Today

George L. Oestreich, PharmD, MPA
Principal, Clinical Pharmacist
G.L.O. and Associates
Disclosure and Conflict of Interest

I, George L. Oestreich, have a financial relationship with an entity that provides services.

G.L.O. and Associates provides consulting services in many areas of Medicaid, population based analytics and 340B discount drug services.
Pharmacist Objectives

At the conclusion of this program, the pharmacist will be able to:

1. Define a 340B eligible patient.
2. Explain MDRP in context of 340B.
3. Discuss HRSA Audits for 340B use.
At the conclusion of this program, the technician will be able to:

1. Define a 340B eligible patient.
2. Explain the Medicaid Drug Rebate Program.
3. Discuss the technician's role in a HRSA Audit.
340B Eligible Entities

- **Health Centers**
  - Federally Qualified Health Centers
  - Federally Qualified Health Center Look-Alikes
  - Native Hawaiian Health Centers
  - Tribal / Urban Indian Health Centers

- **Hospitals**
  - Children’s Hospitals
  - Critical Access Hospitals
  - Disproportionate Share Hospitals
  - Free Standing Cancer Hospitals
  - Rural Referral Centers
  - Sole Community Hospitals

- **Specialized Clinics**
  - Black Lung Clinics
  - Comprehensive Hemophilia Diagnostic Treatment Centers
  - Title X Family Planning Clinics
  - Sexually Transmitted Disease Clinics
  - Tuberculosis Clinics

- **Ryan White HIV/AIDS Program Grantees**
  - Ryan White HIV/AIDS Program Grantees

340B Eligible Patients Definition

- EHR Documentation
- Prescriber / Location
- Provider Scope of Practice
Why Pharmacy Managers and Staff need to Focus on 340B

• The potential for revenue is significant

• The risk associated with errors and omissions is significant

• The range and distribution of risk areas is significant

• The cost of errors can be huge
340B Pricing Is Complex

- Quarterly Pricing
  - 340B prices change quarterly
  - Manufacturers upload to authorized wholesalers 15-30 days prior to beginning of a quarter
  - 340B pricing lags behind market by 2 quarters

<table>
<thead>
<tr>
<th></th>
<th>Q1</th>
<th>Q2</th>
<th>Q3</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Sales transactions occur</td>
<td>Q1 AMP and BP calculated, submitted to CMS; 340B ceiling price calculated, submitted to wholesalers</td>
<td>340B ceiling price becomes effective (based on Q1 transactions)</td>
</tr>
</tbody>
</table>
Medicaid Net Cost Example: Drug With $100 WAC

Non-340B

340B

Medicaid rebate

$61

$51

10% Delta
HRSA Policy Around Duplicate Discounting Medicaid Drug Rebate Program (MDRP)

- **40B Statute**: [Note: developed in the context of FFS]
  “[a] covered entity shall not request payment under [Medicaid] . . . with respect to a drug that is subject to an agreement under [the 340B Program] if the drug is subject to the payment of a rebate under [the Medicaid drug rebate statute].” 42 U.S.C. § 256b(a)(5).

- **Medicaid Exclusion File** to prevent duplicate discounts; one provider number or NPI must have the same carve-in or carve-out decision

- **Contract Pharmacy Guidance**: No 340B drugs for Medicaid patients in contract pharmacy, absent an agreement between entity, Medicaid, and contract pharmacy; HRSA notification required

- **Medicaid Guidance**: Consult state billing requirements (no HRSA AAC mandate for 340B entities)
Contract Pharmacy Services

• Entity may contract with one to many pharmacies per site
• Entity purchases and owns medications
• “Ship to, bill to” virtual inventory arrangement
• Detailed receiving/dispensing records
• Diversion prevention tracking system
Covered Entity Oversight

• The contract pharmacy shall assure the covered entity that the contract pharmacy will establish the necessary information for the covered entity to meet its ongoing responsibility of ensuring:
  • maintaining accurate records of 340B discount drug use
  • the restriction for the utilization preventing diversion
    • Prescriber records
    • patient access records
  • the independent audits to validate adherence to those restrictions
  • prevention of collection of duplicate federal rebate discounts
Contract Pharmacies

• The contract between the covered entity and the contract pharmacy should cover the total relationship
  • What drugs will be covered (may have a stop loss feature)?
  • How the reimbursement will be determined (all drug classes the same?)
  • Who will be covered and the benefit (how is eligibility shared)?
• The reporting is a critical part of the relationship
  • What information is recorded and shared
  • Frequency of reporting
  • Support during an audit (internal or HRSA focused)
  • How is the drug replenishment to occur, how often, how are partial containers resolved, what happens if an NDC changes
Audits

• Both parties understand that they are subject to audits
  • the covered entities initiated (internal or external by contract)
  • participating manufacturers (HRSA approved)
  • HRSA initiated and performed
• The audits may cover
  • records that directly pertain to the entities compliance with the resale (prescriber, records, location and patient)
  • transfer provisions of 340B drugs to external partners
  • prohibitions of duplicate discounts
• Upon request the covered entity will provide a copy of the contract with the pharmacy services agreement to the office of pharmacy affairs (OPA, HRSA).
HRSA Audit: Next Steps

1. HRSA Notice and Hearing; entity has 30 days to disagree with report

2. 60 days to submit corrective action plan*;

3. Audit Summary, public letter and corrective action, once approved, posted on HRSA website

4. Results support education of covered entities

*If no corrective action plan within 60 days of final report, entity terminated
Example HRSA Audit Findings

<table>
<thead>
<tr>
<th>Diversion</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>340B drugs dispensed at ineligible sites</strong></td>
</tr>
<tr>
<td>Not spot checking inventory to check for diversions and correcting them (variance)</td>
</tr>
<tr>
<td><strong>340B drugs dispensed at ineligible site or by an ineligible provider</strong></td>
</tr>
<tr>
<td><strong>340B drugs dispensed to non-patient at contract pharmacy</strong></td>
</tr>
</tbody>
</table>
## Example HRSA Audit Findings

### Duplicate Discount

<table>
<thead>
<tr>
<th>Billing Medicaid contrary to HRSA Medicaid Exclusion File listing</th>
<th>340B drugs used for Medicaid patients at contract pharmacy, with no arrangement to prevent duplicate discounts</th>
<th>Medicaid claims incorrectly coded when provided to the state</th>
<th>Incorrect Medicaid or NPI in HRSA Medicaid Exclusion File</th>
<th>Outpatient sites incorrectly listed on HRSA Medicaid Exclusion File</th>
</tr>
</thead>
</table>

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**Medicaid**

**340B**

**Duplicates**

**Incorrect**

**Medicaid**

**Exclusion**

**File**

**Medicaid**

**Claims**

**Incorrectly**

**codes**

when provided to the state.

**Medicaid**

**Exclusion**

**File**

**Incorrect**

**Medicaid** or NPI in HRSA Medicaid Exclusion File.

**Outpatient** sites incorrectly listed on HRSA Medicaid Exclusion File.
## Example HRSA Audit Findings

### Eligibility, Auditable Records

| Incorrect Authorizing Official | Primary location and contact information incorrect | Closed child sites remained registered; incorrect name listed for a child site | Incorrect address for facility, incorrect ship-to address, pharmacy listed as entity with 340B ID | No written contract in place for contract pharmacies |
Covered Entity Self-Disclosure of Non-Compliance

- Covered Entity
  - Identifies Issue(s)
  - Corrects Issue(s)
  - Self-Discloses issue and proposed corrective action plan (CAP) to OPA
  - Self Discloses to manufacturer – works in good faith to implement CAP
- Manufacturer
  - Identifies impact to manufacturer’s products
  - Works with covered entity to resolve issue
Corrective Action Plans

- Covered entity must:
  - Prospectively correct issue
    - Conduct root cause analysis of underlying issue
    - Implement Plan to correct issue moving forward
  - Retrospectively correct issue
    - Identify products (and units) affected
    - Determine inappropriate discounts
  - Repayment challenges
    - Refund vs. Offset
  - Work with manufacturers to determine best course
HRSA Audits of Manufacturers

- Manufacturer perspective
  - Calculation of 340B Ceiling price
    - Average manufacturer's price (AMP) – unit rebate amount (URA)
  - Sub-ceiling pricing
  - Nominal pricing
  - Transmission of 340B Ceiling price to distributors
  - Resolution of inquiries regarding appropriate prices
340B Audits

- HRSA Audit results for 2017 through September 2018

<table>
<thead>
<tr>
<th>Type</th>
<th>FQHCs</th>
<th>Hospitals</th>
<th>Health Depts</th>
<th>Ped Hospitals</th>
</tr>
</thead>
<tbody>
<tr>
<td>Audits/Findings</td>
<td>30/20</td>
<td>140/97</td>
<td>2/1</td>
<td>5/3</td>
</tr>
</tbody>
</table>
Types of Audit Findings
(Most to Least)

• Improper execution of database
• Duplicate discount (linked to MEF)
• Ineligible patient
• Incorrect documentation of contract pharmacy
• Improper documentation of use and replenishment
Frequency of Consequences (Most to Least)

- Corrective Action Plan
- Repayment to manufacturers
- Loss of access to 340B
- (virtually all were the first two bullets with less than 10 resulting in loss of access)
Information Provided to CEs

1. Verify your HRSA 340B Database listing is accurate
2. Contact your state Medicaid agency to ensure you understand state requirements and they approve of your 340B usage plan through your pharmacy
3. If you plan to use a contract pharmacy be sure you have concurrence from the state and HRSA and you have an arrangement to prevent duplicate discounts (MO Healthnet does not allow contract pharmacies)
4. Perform a self or assisted internal audit periodically to insure ongoing policy adherence and DD prevention
Takeaways

• HRSA and manufacturers may both audit entities
• There are lessons to be learned from prior audits
• There are specific choices that place an entity at a higher risk of being audited
• Internal audits (self or contract) are valuable to assure quality and integrity of the program
Current MO FQHC Pricing

- Maximum pricing if 340B is carved in:
  - WAC -25% (for all FQHCs and hospitals)
- Clinic and carve out continues to receive:
  - 92% of billed charges
  - Plus enhanced fee of $4.82
  - Plus generic incentive (if applies) $5.00
- If the clinic is 340B "carve-in", the AAC is expected to be billed on the cost report.
- The state indicates the surrogate pricing is a temporary solution until the agency can receive or calculate the accurate 340B price
MO Healthnet (MHD) Proposed Pharmacy Reimbursement Rule

• Comment period closed October 4, 2018

• Reimbursement Methodology Effective December 16, 2018
  • National Average Drug Acquisition Cost (NADAC) or
  • Missouri Maximum Allowed Cost (MAC); if no NADAC; if no NADAC or MAC or
  • Wholesale Acquisition Cost (WAC); or
  • The usual and customary (U and C); if no NADAC, MAC or WAC
Reimbursement (current) for covered drugs for 340B providers:

- WAC minus 25% (forty-nine) percent; or
- The U and C if it is lower
HRSA or Apexus Updates

- Implementing the pending rule to require manufacturers to appropriately calculate 340B prices
- Several bills pending before the House Energy and Commerce Committee that would revamp areas of 340B section
Manufacturer: 340B Calculation

• 340B Price based on quarterly Medicaid metrics which are based on commercial contracting practices

**AMP: Average Manufacturer Price**

- For most drugs, it’s the weighted average price (net of discounts) to retail community pharmacies

**BP: Best Price**

- Lowest price to US customers, certain federal pricing, such as 340B, excluded

**URA: Unit Rebate Amount**

- **Brand:** Greater of [(AMP * 23.1%) or (AMP – BP)] plus inflation penalty
- **Generic/OTC:** 13% of AMP
Manufacturer: 340B Calculation

• 340B Ceiling Price

WAC minus AMP equals URA equals 340B Unit Price times Units per Package equals 340B Ceiling Price

- General accounting software and process
- Pharmacy point-of-sale system
- Budget entries and process
• **Assessment Question #1**

All patients are eligible for the 340B drug discount program?
• **Assessment Answer #1**

No, to be eligible for the 340B drug discount program the patient must meet the eligibility requirements.
• **Assessment Question #2**

Covered entities can only contract with one contract pharmacy?
• Assessment Answer #2
No, covered entities can contract with as many contract pharmacies as they choose to.
• **Assessment Question #3**

As long as your pharmacy’s NPI is correct on the HRSA database you should be good to go?
• **Assessment Answer #3**

No, all of your pharmacy’s information must be correct on the HRSA database including your Medicaid provider number (in Missouri it starts with 60 and is 9 digits long).
• **Assessment Question #4**

Only HRSA can audit covered entities?
• **Assessment Answer #4**

No, HRSA and the manufacturers can audit covered entities.
The following slides provide additional detail on several items that may be helpful and useful.
Provisions of the Contract Pharmacy’s Contract (Detail)

- The covered entity owns the covered drugs and arranges to be billed directly for such drugs
- The pharmacy will compare all shipments received to the orders and inform the covered entity of discrepancies the earliest possible time
- The covered entity will make timely payments for drugs delivered to the pharmacy
- The covered entity will verify the contract pharmacies customer customary business records and a tracking system shall exist that will ensure drugs purchased under 340 B are not diverted to individuals that are not part of the covered entity
- Records may include prescription files velocity records ordering in receipt
- These records will be maintained for time frames prescribed by state etc. and federal regulations
- Prior to the contract pharmacy providing services the covered entity will have an opportunity to inspect the pharmacy and the tracking system to be used by the pharmacy and samples of dispensing records and the ability to compare six months after dispensing records to the 340 B purchasing records for routine reconciliation
- The pharmacy will dispense covered drugs only upon receiving a prescription for an eligible patient of the covered entity and it being signed by the healthcare provider affiliated with the entity or receipt of a prescription order by phone or fax or electronic transmission with the same qualifications

Resources

Celebrating Yesterday, Advancing Tomorrow.
MPA's 140th Anniversary 1879-2019
Pharmacy Responsibilities

- The pharmacy will dispense covered drugs only upon receiving a prescription for an eligible patient of the covered entity and it being signed by the healthcare provider affiliated with the entity or receipt of a prescription order by phone or fax our electronic transmission with the same qualifications.

- The covered entity will furnish the list to the pharmacy of all such qualified healthcare prescribers and update the list of prescribers regularly if errors are discovered regarding coverage of the covered entities patients or those providers affiliated with the covered entity the contract pharmacy will pay the covered entity the amount of the discount in question so that it may be reimbursed to the manufacture.

- Essential covered entity contract compliance elements - the covered entity will purchase a drug and maintain title to the drug and assume responsibility for its price pursuant to the grant and applicable law.
Audits, What to Expect

• Unlike pre-2012 340B audits, 340B auditors are taking a much deeper dive into 340B compliance protocol. They want to see that the 340B covered entity has monitored and maintained their program as federally mandated.

• What you need to be ready for a HRSA audit:
  • Independent audits, in addition to internal audit procedures
  • Audit data requests which are extremely comprehensive and serve to test the reconciliation process consistent with 340B regulations and, a clear 340B audit trail must exist
  • A thorough review of policies and procedures will be conducted. Your written procedures are used as a blueprint for auditors as they seek to understand discrepancy documentation, “grey area” opinion reports such as 340B patient definition and monitoring roles, testing and internal audit reviews throughout the year should be available.

• A comprehensive approach and compliance program must be in place or the consequences could be serious
Apexus Actively Facilitates State Medicaid Collaborations

- Apexus has dedicated staff and a consultant to support best practice in 340B drug use for Medicaid
- Apexus is releasing an overview of state activities in 340B reimbursement and will provide updates
- A companion document is also available that provides detailed descriptions of Medicaid issues impacting 340B use
- A state Medicaid database is under development
- The Apexus goal: a win-win shared savings model supporting the use of 340B drugs
Speaker Contact Information

Prepared by:

George L. Oestreich, Pharm.D., MPA
Email: george@gloetal.com

G.L.O. & Associates
A Division of Comprehensive Pharmaceutical Services, Inc.
3432 W. Truman Blvd., Suite 201
Jefferson City, MO 65109

(t) 573.632.2412
(f) 573.632.2411
(c) 573.230.7075