Introductions

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Course Objectives

1. Provide an overview of the proposed regulation changes that may impact 340B programs and outline potential next steps covered entities should consider performing.

2. Discuss recent enhancements to the HRSA audit process, including areas of increased focus and best practices to adequately prepare.

3. Present the most frequently identified audit issues, root causes and potential action plans to mitigate the risks moving forward.

340B Program Introduction
340B Basics

The WHAT?
- Created in 1992 under the Public Health Service Act
- Requires drug manufacturers to offer steep discounts
- Applies to “covered outpatient drugs”
- Can result in 25-50% off of outpatient drugs

The WHY?
- The 340B drug discount program allows CEs to stretch scarce federal resources as far as possible, enabling them to reach more eligible patients and provide more comprehensive care.

Eligible Organizations / Covered Entities
340B Basics

The WHO?
• The Office of Pharmacy Affairs (OPA) branch, Health Resources and Services Administration (HRSA) is responsible for Program oversight and ensuring compliance.

The HOW?
• HRSA ensures compliance by performing CE audits
  • Audits began in 2012 and have increased significantly the last two years
  • Audit procedures have been recently enhanced
• Manufacturer Audits
  • Advanced analytics used to identify outliers and/or red flags that may indicate compliance issues
  • CE inquiries (and audits) have increased in recent months
  • Lack of adequate response may result in a full audit; 100% review rate and reported to OIG

340B Policy Update
Reform is Imminent

- Bipartisan support for some level of program reform
- View that the program has grown beyond original intent
- Focus on transparency and reporting
- Tremendous lobbying resources involved

Policy Activity on the Hill

- House Energy & Congress (E&C) 340B Program Review (1/10/2018)
- Senate – HELP (Helping Ensure Low-income Patients have Access to Care and Treatment) Act (1/17/18)
- Senate – Letter from Sen. Orrin Hatch to HHS (1/26/18)
- Senate – Ensuring the Value of the 340B Program Act of 2018 (2/27/18)
- Senate HELP Committee Meeting - Perspectives on the 340B Drug Pricing Program (3/15/18)
E&C 340B Review

Analysis entailed review of the following:
• Data submissions from 19 covered entities
• Information obtained during prior 340B hearings
  • Hearing #1 (July 2017) – HRSA (CAPT Pedley), CMS, OIG
  • Hearing #2 (October 2017) – Select CE representatives
• Interviews with stakeholders from HRSA, CMS, HHS-OIG, GAO, CEs, Manufacturers, Pharmacies, Physicians, Third Party Administrators
• 32 HRSA audit files
• 340B Program growth metrics

E&C Review Conclusions

• Lack of HRSA oversight and authority
• Significant non-compliance per HRSA audit findings
• Rapid growth of 340B program is concerning
• Lack of clarity on program intent
• Absence of transparency on 340B savings and ceiling prices
• Financial incentives for prescribing more and/or more expensive drugs
• Lack of consistency in measurements for charity care and other reported data
• Disproportionate share metric may not be the best measure
E&C Review Recommendations

- Allow HRSA sufficient regulatory authority to improve program integrity
- Enhance CE internal monitoring
  - Require full program independent audits for certain CE types
  - Require independent audits of contract pharmacies at regular intervals for all CEs
- Increase transparency (CEs and Manufacturers)
  - Ceiling prices
  - Track 340B savings
  - Measure charity care provided
- Reassess whether DSH percentage is an appropriate measure for determining hospital eligibility

340B PAUSE Act (H.R. 4710)

- Introduced by Rep. Larry Bucshon (R-IN) and Dem. Scott Peters (D-CA) in December 2017
- Areas of focus include:
  - Two-year moratorium on new DSH parent registrations and new child sites for currently registered DSH entities
  - Extensive data reporting requirements to increase transparency
    - 340B drugs by payor mix
    - Total costs and charity care by site
    - Total 340B drug reimbursement and acquisition costs
  - Names of all third-party vendors providing 340B services
  - HHS reporting of all collected information
340B HELP ACT (S. 2312)

- Introduced by Rep. Dr. Bill Cassidy (R-LA) on January 16, 2018
- Areas of focus include:
  - Two-year moratorium on new DSH parent registrations and new child sites for currently registered DSH entities
  - Would impact all CEs registered after 12/31/17 (PAUSE would be as of the effective date of the bill)
  - Grants Health and Human Services (HHS) regulatory authority
  - Additional child site eligibility requirements
  - New contract requirements with state/local governments
  - Consistent 340B claims level modifier requirements
  - Extensive data reporting requirements to increase transparency
  - 340B annual revenue
  - Utilization of 340B within Medicaid, Medicare Part B programs
  - Charity care details
  - Names of all third-party vendors providing 340B services

Ensuring the Value of the 340B Program Act of 2018 (S. 2453)

- Introduced by Sen. Chuck Grassley (R-IA) on February 27, 2018
- Areas of focus include:
  - Provide the Secretary with information on the hospital’s aggregate acquisition costs for 340B drugs and the total revenues received by the hospital for such drugs, disaggregated by insurance status
What else could be coming?

While we await additional legislation, below are a few others items we’ve heard are under consideration:

• Transparency and reporting
• Consistent eligible patient definition
• Limit to number of registered contract pharmacies
• Clarity around certain questionable areas:
  • Infusion eligibility
  • MCO treatment

Outpatient Prospective Payment System (OPPS) Final Rule

• Basis for Change
  • CMS utilized past GAO, MEDPAC and OIG audits as support for the Final Rule
  • Concern that current Medicare payments far exceed the overhead and acquisition costs for 340B drugs

• Timing
  • Final Rule posted to Federal Register on 11/13/17
  • Effective date of 1/1/2018
OPPS Final Rule – Payment Reduction

**340B Hospitals**
Medicare Part B/Separately Payable Drugs
Reimbursement Reduced From ASP +6% to ASP -22.5%.
This is expected to result in $1.6B in cuts.

- Impact by 340B Entity
  - DSH, urban SCH, and RRC subject to payment reduction
  - Inapplicable to non-excepted off-campus PBDs subject to Section 603 and CAH (not paid under OPPS)
  - Rural SCH, PED, PPS-exempt Cancer Hospitals also excluded from the reduction at this time
- Redistribution of Funds
  - Budget neutral - $1.6B will be distributed across ALL OPPS hospitals

OPPS Final Rule – CMS Tracking

Required Claims Level Modifiers for CMS to Identify 340B-Acquired Drugs

- **DSH, Urban SCH, RRC**
  - JG modifier for separately payable drugs (status indicator K)
  - TB modifier for pass-through drugs (status indicator G)
- **Rural SCH**
  - TB modifier for separately payable and pass-through drugs (status indicator K and G)
- **CAH**
  - Exempt; TB modifier optional when acquired at the 340B price (status indicator K and G)
- **Non-excepted off-campus PBDs subject to Section 603**
  - TB modifier on separately payable and pass-through drugs (status indicator K and G)

*Note: No modifier needed if the drug is not purchased at 340B-pricing*
OPPS Final Rule – Next steps?

Lawsuit filed
• Against CMS on November 13 (American Hospital Assoc, Assoc of American Med Colleges and America’s Essential Hospitals)
• Case on appeal; hearing date set for May 4

H.R. 4392 Introduced
• Rep. David McKinley (R-WV)
• Would re-instate ASP+6% reimbursement formula
• 190 co-sponsors

Unclear if H.R. 4392 will ever pass

HRSA Audit Enhancements
2018 HRSA Audit Expectations

HRSA is now utilizing The Bizzell Group to conduct all audit fieldwork. Important details include:

- Audit approach similar to prior years
- Pre-audit research and analytics are now leveraged
- Further depth to audit procedures
- Enhanced auditor training, which has led to a more consistent approach
- Higher sophistication with many auditors having Pharmacy and 340B backgrounds

HRSA Oversight

HRSA Audits

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HRSA Audit Process

**Audit Notification**
- CE receives engagement letter informing them of the audit, including scope, data request and onsite requirements.
- CE must set an introductory phone call to discuss program structure and specifics.
- Data request due two weeks from initial notification.
- Onsite visit is typically 4-5 weeks from initial notification.
  - Accelerated timeline compared to prior HRSA audits
HRSA Audit Process

Audit Fieldwork
• Typically onsite 1-3 days
• Procedures normally include:
  • Confirming CE has a 340B policy/procedures and ongoing monitoring program
  • Confirming CE information within the OPA database is accurate
  • Onsite testing of a sample of 340B dispenses to validate:
    - Eligible patient
    - Eligible provider
    - Eligible location
    - Absence of duplicate discounts

Audit Reporting
• HRSA confirmation of findings and draft report issuance (can take months for this to be completed)
• CE should closely review the report and respectfully challenge if there is disagreement with any findings (within 30 days of receiving the draft report)
• Corrective action plan submission for each finding (within 60 days of preliminary report)
  • Corrective actions must be reviewed and agreed with HRSA, which can take months
  • Often includes manufacturer repayment plans
  • Must identify and make all “affected” manufacturers whole
HRSA Audit Process

HRSA Audit Findings
- Published online (https://www.hrsa.gov/opa/program-integrity/index.html)
- Most common issues identified during 2017 audits surround:
  - Diversion
  - Incorrect database records
    - Child site registration (or lack thereof)
    - Inaccurate CE or contract pharmacy information
  - Duplicate Discounts
    - Dispensing
    - Billing

HRSA Audits – Current Hot Topics

- GPO Prohibition – Single violation can result in removal from the program and extensive repayments
- Program oversight (especially contract pharmacies)
- Contract with State/Local Govt
- Time period of non-compliance
- Split-billing access/documentation requests

Be aware of all communications with the auditors. We’ve seen information disclosed during conversations turn into significant audit issues.
HRSA Audit Prep Best Practices

- Conduct routine internal reviews
- Conduct independent audits under attorney/client privilege
- Consistently engage your split-billing and contract pharmacy vendors
- Routinely update your physician lists and other eligibility tools (not doing this can be fatal)
- Engage sufficient resources to properly manage the program
- Perform due diligence before submitting data
- Define an audit team and practice

Manufacturer Inquiries/Audits

- HRSA Audits are most common, but Manufacturers also have the right to audit CE’s
  - Failure to adequately respond can lead to an audit
  - 100% of claims will be reviewed during defined audit period
  - Degree of compliance dictates the amount of leverage
  - HRSA and OIG receives a copy of the final audit report
  - Kalderos inquiries
Manufacturer Inquiry/Audit Best Practices

- Seek the assistance of counsel right away
- Demand written request and any underlying data from the manufacturer
- Study the request and consider what could be prompting the inquiry
- Carefully study your data to determine leverage
- Use legal arguments to narrow the scope of the exercise
- Establish agreed upon terms of review before providing data
- Execute a non-disclosure agreement w/ government carve-out

Only then should you exchange data

Audit Issues Summary
CHAN Audit Summary

- Information in this section is based on actual audit issues:
  - Over 110 covered entity audits performed
  - Over 450 audit issues identified

Audits Under Privilege

ACP Vs Non-ACP

Note – Issues identified in ACP audits are not included in this presentation.
340B Risk Areas – Issues Identified

Program Management
Diversion
Lost Opportunity
Purchasing/NDC Match
Duplicate Discounts
GPO Exclusion
Other

Program Management Issues – Further Details

Lack of Monitoring
Inadequate Policy
Contract Issues
Technology/Configuration
Inadequate Record Retention
Inaccurate OPA Database
Split-Billing System Errors
Other
Program Management – Root Causes

• Areas with the most room for improvement:
  • Program ownership
  • Pharmacy-only focus
  • No compliance/legal presence
  • Program education
    • Initial and ongoing
    • In advance of registering
  • Splitter education
    • Configuration options
    • Qualification process
    • Reporting offerings
  • Push the vendors

Diversion Issues – Further Details

<table>
<thead>
<tr>
<th>Issue</th>
<th>Count</th>
</tr>
</thead>
<tbody>
<tr>
<td>Patient Status Errors</td>
<td></td>
</tr>
<tr>
<td>Provider List Inaccuracies</td>
<td></td>
</tr>
<tr>
<td>Ineligible Locations</td>
<td></td>
</tr>
<tr>
<td>No Patient Encounter</td>
<td></td>
</tr>
<tr>
<td>Drug Exclusion Errors</td>
<td></td>
</tr>
<tr>
<td>NDC Match Issues</td>
<td></td>
</tr>
<tr>
<td>Manual Adjustment Errors</td>
<td></td>
</tr>
<tr>
<td>Splitter Errors</td>
<td></td>
</tr>
<tr>
<td>Duplicate Dispenses</td>
<td></td>
</tr>
<tr>
<td>Other</td>
<td></td>
</tr>
</tbody>
</table>
Lost Opportunity – Further Details

• Majority of missed opportunities relate to:

  Software Configuration

Corrective Action Plans
CHAN Audit Process

The following slides relate to action plans implemented based on CHAN audits, not HRSA audits. However, you’ll see many could be leveraged (or at least assist) when developing HRSA corrective account plans.

Program Monitoring and Oversight

<table>
<thead>
<tr>
<th>Compliance Risk</th>
<th>Example Action Plan</th>
</tr>
</thead>
<tbody>
<tr>
<td>Program Integrity (Oversight/Monitoring)</td>
<td>Management will develop a 340B steering committee that includes a representative from each department with responsibility for maintaining 340B compliance. The committee will meet on a monthly basis, with meeting minutes compiled and sent to the group within two business days of the meeting taking place. Committee details will be recorded in the policy document.</td>
</tr>
<tr>
<td>Program Management (Auditing)</td>
<td>Management will develop a monthly audit process for each contract pharmacy arrangement and a quarterly audit process for the mixed-use setting that includes selecting a sample of 340B dispenses and validating each meets all attributes of eligibility. The internal audit process will be recorded in the policy document.</td>
</tr>
<tr>
<td>Program Management (Policy)</td>
<td>Management will update the 340B policy to include all items included in the Apexus example policy and will review the policy at least every two years.</td>
</tr>
</tbody>
</table>
### Diversion

<table>
<thead>
<tr>
<th>Compliance Risk</th>
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<tr>
<td>Diversion (Provider Issues)</td>
<td>Management will work with the physician credentialing and IT departments to create an initial eligible provider listing that agrees to the definition as stated in the 340B policy. This list will be updated monthly to account for new and terminated physicians and will be sent to each contract pharmacy. This provider maintenance process will be recorded in the policy document.</td>
</tr>
<tr>
<td>Diversion (Eligible Encounter, Drug)</td>
<td>Management will work with the IT department to review the current data extract file that is being uploaded into the splitter software and verify that it accurately excludes those departments and locations that do not currently qualify for the program, as stated in the OPA database. In addition, management should review the logic that is excluding certain drugs from the program to confirm that the logic is accurate given the program setup. Any modifications to the extract logic should be updated as necessary within the policy document.</td>
</tr>
</tbody>
</table>

### Purchasing

<table>
<thead>
<tr>
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<th>Example Action Plan</th>
</tr>
</thead>
<tbody>
<tr>
<td>Purchasing (NDC-to-NDC Match)</td>
<td>The pharmacy management department will review purchasing procedures and determine if there is a way to automate all aspects of the process in order to eliminate the ability to manually adjust the bucket in which the drug is to be purchased, as provided by the splitter. Any changes will be recorded within the policy document.</td>
</tr>
<tr>
<td>Purchasing (Accumulation)</td>
<td>The pharmacy management department will review the conversion factors currently included in the splitter software and compare them to their internal factors by NDC. Any discrepancies will be communicated to the splitter software. If discrepancies are identified, management will determine the impact on prior accumulation and 340B purchases. Management will implement a process to review periodically all changed conversion factors so that the covered entity and splitter agree.</td>
</tr>
</tbody>
</table>
Additional 340B Information

HRSA Guidance
http://www.hrsa.gov/opa/index.html

OPAIS CE Database

HRSA Audit Results
http://www.hrsa.gov/opa/programintegrity/auditresults/results.html

Apexus Tools and Sample Documents
https://www.apexus.com/solutions/education/340b-tools

Apexus 340B University

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