TUESDAY, MARCH 13:
A REVIEW OF THE 340B DRUG PRICING PROGRAM
WELCOME

Anthony Pudlo, PharmD, MBA, BCACP
Vice President of Professional Affairs
Iowa Pharmacy Association
BRIEF HISTORY OF 340B PROGRAM

• 1990:
  – Medicaid rebate program created

• 1992:
  – Section 340B of the Public Health Service Act (under Section 602 of the Veterans Health Care Act of 1992) was enacted
  – Congress extended rebate program to safety-net providers in similar form at as Medicaid

• October 24, 1996:
  – HRSA defines a patient of a covered entity
BRIEF HISTORY OF 340B PROGRAM

• December 2014:
  – HRSA issues policy notice to help avoid duplicate discounts specific to Medicaid FFS (not Medicaid MCOs)

• April 2016:
  – CMS issues mandates states require MCOs to identify and exclude 340B claims from utilization reports for Medicaid rebate collections

• April 1, 2017:
  – Requirement to states to establish reimbursement polices specific to retail 340B Medicaid FFS drug and to pay based on AAC
BRIEF HISTORY OF 340B PROGRAM

• November 1, 2017:
  – CMS notice on final Outpatient Prospective Payment (OPPS)

• December 2017:
  – Lawsuit filed to challenge rule
  – Bipartisan legislative efforts pursued to reverse or delay the change
  – Late Dec – Lawsuit dismissed on procedural grounds

• January 1, 2018:
  – CMS rules take effect that reduces reimbursement rates from 6% above the sales price to 22.5% less than the sales price
PRESENTERS

Chad Johnson, PharmD, MBA
Manager, 340B Education & Compliance Support
Apexus

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Director, Business & Support Pharmacy Services
University of Iowa Health Care
340B PVP Update
Chad Johnson, PharmD, MBA
340B Education and Compliance Support Manager
Apexus Overview
Prime Vendor Focus

340B Prime Vendor Program

Contracting and Distribution

Education and Training

HRSA - Aligned National Call Center

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Contracting: 340B Prime Vendor

Sub-Ceiling
Negotiate sub-ceiling 340B pricing on brand and generic pharmaceuticals

Sub-WAC
Negotiate sub-WAC pricing on brand and generic pharmaceuticals for entities subject to the GPO Prohibition

Value Added
Vaccines, blood glucose monitoring supplies, point-of-care test kits, pharmacy hardware and software automation

Distribution
Establish wholesale distribution networks that improve access to affordable medications: national, regional, specialty
PVP Purchasing Tools

340Bpvp.com provides participants with several tools:

- Contract optimization & best buy reports, savings reports & other dashboards tools
- Pricing transparency (WAC, PHS, sub-ceiling, AGP, orphan pricing)
- Formulary decision tools (Hepatitis C and biosimilar cost models)
340B University

View 2018 schedule on Apexus.com – Event Calendar
340B University OnDemand

Register at 340Bpvp.com
PVP Education and Compliance Tools

**PVP Tools**

Over 50 tools for entities to learn or to promote 340B compliance
- Template Standard Operating Procedure manuals
- Self-audit tool
- Self-reporting non-compliance

Available for download 340Bpvp.com
Apexus Answers Call Center 888-340-BPVP (2787)
340B Hot Topics and Trends
340B Hot Topics

• Documenting and communicating program savings transparency
• Mergers and acquisitions impacting the 340B space
• Repayment: entity to manufacturer, manufacturer to entity
• Manufacturer good faith inquiries; working with third parties
• Medicaid 340B policy
340B Trend: Program Savings Communication

340B Oversight
Dashboard Best Practices for Covered Entities

PURPOSE: The purpose of this tool is to provide covered entities with a framework for monitoring and communicating 340B oversight based on best practices. Although the 340B statute does not specify how 340B Program savings must be used, the intent of the program is to provide savings to the safety net organizations that participate in the program.

340B University Tools
Use of 340B Savings Tool

PURPOSE: This tool is intended to help all types of 340B covered entities organize and communicate their use of 340B savings. It captures benefits provided to the community based upon total expense for a variety of services. This tool should be used in conjunction with the “Dashboard Best Practices for Covered Entities” tool, which provides guidance on calculating net Program savings, to show corresponding use of savings.
340B Trend: Prioritizing Education and Training

- Increasing demand for dedicated 340B experts to lead 340B programs for organizations
  - 340B coordinator/manager/auditor
  - Contract pharmacy dedicated oversight
- Multi-disciplinary 340B training at covered entities
  - Compliance, finance, billing, c-suite
- Expectations of partner expertise
  - Consultants, vendors, administrators, etc.
## 340B Trend: Program Resources

### Resources Benchmarking Survey

<table>
<thead>
<tr>
<th>Outpatient drug expenses</th>
<th>Average number of FTEs (dedicated and shared)</th>
<th>% with an oversight council</th>
<th>% completing monthly audits</th>
<th>% said had enough resources</th>
<th>% said confident could pass an audit</th>
</tr>
</thead>
<tbody>
<tr>
<td>&lt;$1M (n=34)</td>
<td>1.18</td>
<td>35%</td>
<td>41%</td>
<td>62%</td>
<td>53%</td>
</tr>
<tr>
<td>$1M-$10M (n=15)</td>
<td>1.78</td>
<td>47%</td>
<td>40%</td>
<td>40%</td>
<td>73%</td>
</tr>
<tr>
<td>$10M-$50M (n=9)</td>
<td>3.26</td>
<td>78%</td>
<td>78%</td>
<td>56%</td>
<td>100%</td>
</tr>
<tr>
<td>&gt;$50M (n=5)</td>
<td>4.75</td>
<td>80%</td>
<td>80%</td>
<td>60%</td>
<td>80%</td>
</tr>
</tbody>
</table>
Covered Outpatient Drug Rule

- CMS State Plan Amendment (SPA) requirements for States
- States must reimburse 340B entities and contract pharmacies (FFS) based upon actual acquisition cost (AAC) plus a professional dispensing fee
- SPAs due by June 30, 2017
- Call Center inquiries on Medicaid: 45% increase
Iowa Medicaid 340B Billing Policy (FFS/MCO)

• Outlined in Medicaid Information Letter #1638-MC, March 21, 2016
  – SPA approved June 28, 2017

<table>
<thead>
<tr>
<th>Setting</th>
<th>Medicaid Options</th>
<th>Uses HRSA MEF?</th>
<th>Carve-in 340B Cost Required</th>
<th>Carve-in 340B Modifier</th>
</tr>
</thead>
<tbody>
<tr>
<td>Physician Administered Drugs</td>
<td>Carve-in or Carve-out</td>
<td>Yes</td>
<td>AAC (invoice)</td>
<td>&quot;UD&quot; modifier on UB04 or CMS 1500 claim forms</td>
</tr>
<tr>
<td>Entity-Owned Retail Pharmacy</td>
<td>Carve-in or Carve-out</td>
<td>Yes</td>
<td>AAC (invoice)</td>
<td>Basis of Cost Determination Field or Compound Ingredient Basis CDF &quot;08&quot; in field 423-DN AND Submission Clarification Code &quot;20&quot; in field 420-DK Dispense Fee: $10.02</td>
</tr>
<tr>
<td>340B Contract Pharmacy</td>
<td>Carve-out</td>
<td>N/A</td>
<td>N/A</td>
<td>N/A</td>
</tr>
</tbody>
</table>
CE Resources

• HRSA website
  – hrsa.gov/opa
• HRSA 340B FAQ’s
  – 340bpvp.com/faqs
• Apexus Answers
  – Call: 888-340-2787
  – Email: ApexusAnswers@apexus.com
  – Chat
• Iowa Medicaid 340B Billing
  – Letter 1638-MC
  – IMEProviderServices@dhs.state.ia.us
  – 800-338-7909
340B Update

- Increase in activity for past 5 years
- Program goal: stretch scarce federal resources to eligible patients and provide more comprehensive services
- Medicaid: to carve in or carve out?
  - Carve in: reimbursed at cost of drug at 340B cost + dispensing fee on retail side
  - Carve out: reimbursed at Medicaid rate; however, must purchase drug at higher WAC cost
  - Determine how many carve in versus carve out
  - Do others charge a dispensing fee for clinic administered medications?
340B Update

• Medicare Payment Reductions
  – Cost to organization: payment reduction, programing for billing, monitoring
  – Estimated payment reduction?
  – Avalere Health research
    • Increase in other Medicare Part B payments which will offset the decrease in Part B pass through payments
  – Current law suit: pending court date
  – Important to monitor billing to determine true impact

• Other insurance companies
  – Wellmark request for modifiers on claims effective April 1, 2018
340B Update

• PAUSE Act
  – Introduced to house on December 21st

• House Energy and Commerce Committee Review of 340B Drug Pricing Program
  – Introduced January 10th

• HELP Act
  – Introduced January 16th

• Ensuring Value of the 340B Program Act
  – Introduced March 1st
  – Senator Grassley
340B Update

• Increase scrutiny
• Consistent theme of transparency into program
• Revisit program goal
• What will be the future?
• What can be done now?
STAY ENGAGED. STAY INFORMED.

JOIN US WEDNESDAY, MARCH 21 AT 2 PM
340B COMPLIANCE & AUDIT PREP

Questions? Contact David Schaaf at dschaaf@iarx.org or 515-270-0713
STAY ENGAGED. STAY INFORMED.

JOIN US TUESDAY, APRIL 10

CHANGES TO THE IOWA PMP

Questions? Contact David Schaaf at dschaaf@iarx.org or 515-270-0713