Neither Gary Merchant nor Robert Theriault have no actual or potential conflicts of interest in relation to this presentation.

The presentations are educational in nature and not a substitute for legal or regulatory rulings. In all cases, compliance and policy decisions are the responsibility of the Covered Entity.
Audience Demographics

- Currently participating in the 340B program
- Researching participation in the 340B program
- Hospital based 340B program
- Grant based 340B program
Learning Objectives

- Review of 340B Program basics
- Introduction to 340B price determinations, Medicaid billing and other considerations
- Pharmacy options under the 340B Program
- Describe pharmacy resources for 340B entities
- Financial Considerations
- Orphan Drugs – regulatory update
- HRSA Audit
The 340B Program

- In 1992, Section 340B of the Public Health Services Act was enacted

- Response to increase in prices resulting from 1990 OBRA law establishing “Medicaid best price”
  - 340B price excluded from “Medicaid best price”

- Established to help specific safety-net programs reduce their drug expenses
1990 OBRA Medicaid Drug Rebate Program

- Drug manufacturers required rebate agreement to state Medicaid program → “best price”

- No pricing incentive to manufacturers

- Unintended consequences
  - Non-Medicaid patients charged higher rates
  - Savings to Medicaid were off-set by higher costs to other providers
Section 340B, PHS Act

- Provides discounts on outpatient drugs to certain safety-net covered entities
  - Entity chooses to participate

- Manufacturers that participate in Medicaid must also participate in the 340B program
  - Same discount as provided to Medicaid
Intent of 340B Program

Permit covered entities “to stretch scarce Federal resources as far as possible reaching more eligible patients and providing more comprehensive services.”


- Improve financial stability
- Stretch dollars to serve vulnerable patients
340B Drug Definition

- **Covered outpatient** drugs (42 USC 340B(b))
  - Prescription drugs, over-the-counter drugs that are prescribed
  - Excludes vaccines
  - Excludes **inpatient** drugs
    - Can be used in SDS, ED, Infusion and other outpatient areas of the hospital
340B Price Determination

- Brand name drugs: 340B price cannot exceed AMP (as reported to CMS under Medicaid rebate program) minus “rebate percentage”

- The 340B price is actually a “ceiling” price
  - Deeper discounts $$\rightarrow$$ 340B Prime Vendor Program

- Savings of 25-50% of AWP
340B Entity Eligibility

- The eligibility to purchase at the 340B price belongs only to the entities
  - Over 15,000 entities now enrolled
- Over 800 manufacturers participate
- $6 Billion in drug spending
- Multiplier effect: hundreds of vendors and consultants
- More getting into this business
Previous 340 Entity Eligibility
Safety Net Providers

- Consolidated Health Centers
- Federally Qualified Health Center or FQHC look-alike
- Ryan White Care Act grantees
- Black lung clinics
- Hemophilia Centers
- Native Hawaiian health centers
- Urban Indian organizations
- Certified tuberculosis Clinics
- Disproportionate Share Hospitals (>11.75%)
- Certified sexually transmitted disease clinics
Eligible Entities – 2010 ACA

- Hospitals
  - DSH Hospitals – DSH > 11.75%
  - Critical Access Hospitals – No DSH
  - Rural Referral Centers – DSH > 8%
  - Sole Community Hospitals DSH > 8%
  - Free Standing Cancer Hospitals – DSH > 11.75%
  - Children’s Hospitals – DSH > 11.75%

- HRSA Grantees – No DSH, HRSA Grant
  - FQHC, Ryan White, Black Lung, Hemophilia, TB
Eligibility Issues for New Entities

- GPO Exclusion
  - Free-standing Cancer Hospital
  - Children’s Hospitals

- Orphan drug restriction for new hospital categories
  - Discounts restored for children’s hospital
  - HRSA proposal pending
340B Enrollment Procedure

- Eligible entities must enroll
- Forms and enrollment information
  - [http://www.hrsa.gov/opa](http://www.hrsa.gov/opa)
  - Click on “Eligibility and Registration”
- Admission Process
  - Submit completed form to OPA
  - OPA verifies eligibility
  - Participation begins next quarterly database update
340B Entity Database

- Information from approved application entered into Eligible Entry list ➔ OPA 340B Database website
- Registrations accepted ➔ Eligible date
  - January 1-15 ➔ April 1st
  - April 1-15 ➔ July 1st
  - July 1-15 ➔ October 1st
  - October 1-15 ➔ January 1st
- Not in the database? Manufacturers and wholesalers do not have to sell to you at 340B prices
• Patient receives health care services from health care professional employed/contracted with entity
• Entity has established relationship and maintains record of care
• Patient receives health care consistent with range of services from the covered entity
Program Prohibitions

Diversion to non-eligible patients

- If all three patient requirements are not met, the person is not eligible for 340B drugs
  - Entities are responsible for having procedures to prevent diversion and records to prove it
  - Subject to audit by the manufacturer or the Secretary
- Getting prescription services not enough to make you a patient
Program Prohibitions
Duplicate Discounts

• Protects manufacturers from paying a Medicaid rebate AND giving a 340B discount on the same drug
  • “Double dipping”

• Covered entities must report Medicaid billing status
  • Bill at AAC cost (340B)+ dispensing fee
  • Use a Medicaid carve-out option
  • Shared savings with state
  • Restrictions do not apply for managed care
Inventory Basics

- 340B eligible charges are culled from charge data and are described by charge code, charge description, charge units, location (department), date, and payer

- Convert eligible charge units to purchase units

- Purchase 340B eligible purchase units as needed

- Filter out non-eligible charges/visits as Medicaid, Inpatient, non-eligible locations, orphan drugs, and drug replacement program
Basis of Inventory Management

**Revenue Cycle**
- Patient Demographics
- ICD – 9 Diagnosis code
- Charges
- Payer
- Site of care
- Charge codes
- Visit

**Procurement Cycle**
- Purchases
- Price
- Vendor Account number
- Purchase Date
- Quantity

**NDC**
Approaches to 340B Inventory

1. **Software/Split Billing System**
   - Companies continue to add solutions yearly and vary strategies for payment
   - Companies have agreements with some wholesalers
   - Man hours to perform duties will vary
   - Companies have added features for future 340B changes

1. **Manual System**
   - Utilization of charge data to capture eligible outpatient transactions
   - Patient identifier to show eligible outpatient visit, linked to dispensing of outpatient drug
   - Order replenished when unit of purchase met
   - Make sure NDC purchase matches original NDC dispensed
   - Purchases based on trends

NOTE - From Debra Demers PSSC (HRSA) Presentation on Feb 23, 2011 to NEPC Hospitals
Inventory Problematic Areas

• Charge codes that correspond to multiple National Drug Code (NDC)

• Record of the NDC in charge database does not always match the NDC of the administered drug

• Delays in data (billing) accumulation
Compliance and Program Integrity

• Policy and Procedures
  • Drive compliance and program integrity to align with 340B regulations and program intent

• Compliance Risks (Incorrect or non-working Filters)
  • Duplicate Discounts – Exclude Medicaid (Carve Out)
  • Inpatient Charges
  • Non-Eligible Providers
  • Orphan Drugs ICD-9 Codes
  • Locations or Department not on Medicare Cost Report
  • Visits when Covered Entity is not 340B eligible
Opportunity: Contract Pharmacy

- 340B eligible entity can contract with one or many non-340B outpatient pharmacies
- Entity owns the revenue
- Entity owns medications
- Contract pharmacy dispensing fees
- TPA transaction fees
- Does require active, ongoing monitoring
Contract Pharmacy

- Expands access to Rx Care
- Revenue opportunity from commercial and Part D patients
- Allows providers to capture a larger share of the pharmacy market using 340B
- Many consider outsourcing management to companies specializing in contract pharmacy administration
  - Does NOT require dual physical inventory
Contract Pharmacy (cont.)

- Requires annual self-audit
- Annual certification
- Other compliance challenges
  - Entity and pharmacy subject to audits
  - Entity and pharmacy must comply with all Federal and State laws
  - Orphan Drug Exclusion
  - Medicaid Exclusion
Office of Pharmacy Affairs (OPA)

- Part of Health Resources and Services Administration
  - www.hrsa.gov/opa
- Administers 340B Program
- Develops innovative pharmacy service models and supports technical assistance
- Serves as Federal resource for pharmacy practice
OPA

- **Mission:** Promotes access to *clinically* and *cost effective* pharmacy services
  - Patient Safety and Clinical Pharmacy Services Collaborative (PSPC)
  - 340B Drug Discount Program

- **Importance of Comprehensive Pharmacy Services**
  - Access to affordable drugs
  - Application of “best practices”
  - Efficient pharmacy management
  - Systems to improve patient outcomes
Program Administration

- Federal Key Parts of the 340B Program
  - Federal Team/HRSA and OPA
  - Pharmacy Services Support Center (PSSC)
  - 340B Prime Vendor Program (Apexus)

- Organizational Key Areas of a 340B Program
  - Compliance, Pharmacy, Patient Billing, IT, Finance, and Legal
Pharmacy Services Support Center (PSSC)

- Helps eligible entities implement and optimize the 340B program
- Provides information resources, policy analysis and education
- Operates:
  - Web site
  - Outreach Program
  - Pharmacy Technical Assistance Program
340B Program Integrity

- Determination of eligibility and maintenance of system
- Recertification
- Quarterly calculations of 340B prices
- Investigations/resolutions
  - Drug diversion
  - Incorrect pricing, duplicate discounts
- Audits by HRSA
- Technical Assistance, webinars, FAQs, guidance
340B Peer-to-Peer Network

- Increase understanding of the issues entities face in implementing and optimizing 340B program
- Connect 340B stakeholders to share operational examples of best practices
- Strengthen training
- Promote the expansion of clinical pharmacy services in underserved communities
- Allow entities to share experiences with HRSA, PSSC, OPA
- Organizations self identify as leading practices
340B Prime Vendor - Apexus

- Required by statute and OPA mission to maximize value of program
- Negotiate sub-ceiling prices
- Provide access to other value-added products and services
- Voluntary, no cost to entities, no need to change current wholesaler
- Education programs as 340B University
340B Prime Vendor (cont.)

• Operates the Call Center and FAQs
• Auditing and overcharge recovery services
• Contracts
  • Over 3500 covered drugs at sub-ceiling pricing
  • Patient assistance program software
  • Apothecary supplies
  • Rx technology and automation
Current Political Context

- Increased scrutiny by Congress and pressure to constrain program growth
- Program facing unprecedented attention
- Several influential lawmakers leading an inquiry into the program
- Various interest groups raising concerns
Restricting Patient Eligibility?

- Concerns about use of program for commercially insured patients
- “...a program that has diverted from its original intent.”
- If eligibility was restricted:
  - Loss in savings that will impact patient care
  - Programs/services would be eliminated
  - Costs would increase for patients/taxpayer
Financial Assessment - Benefit

- Hospital outpatient pharmacy payer mix
- Hospital pharmacy inpatient vs. outpatient mix
- Percent of Orphan Drug Spend in outpatient
  - Opt In or Opt Out on Orphan Drugs
- Medicaid Carve In or Carve Out (GPO Exclusion)
- Type of outpatient clinics that appear on the hospital's most recently *filed* cost report as reimbursable; # of encounters associated with each clinic.
- Status of Providers – number that are employees, and contract
Financial Assessment - Cost

- Start up Costs
  - Manual system ($) vs. Automated system ($$$)
  - IT and HR Resources

- Maintenance Costs
  - HR Resources that have the skills and program knowledge to run a 340B program
  - Split billing software
  - Outside Auditor
Case Studies/Critical Access Hospitals

- **Critical Access Hospital #1**
  - CAH with minimal clinic and outpatient day surgery
  - Annual outpatient drug spending $425,000
  - Insignificant Orphan Drug impact (1 of top 50)
  - Estimated 340B Savings = 50%
  - Estimated Annual Savings $225,000

- **Critical Access Hospital #2**
  - Minimal outpatient surgery and some oncology
  - Annual outpatient drug spending $1.2 Million
  - Significant Orphan Drug impact (14 of top 50)
  - Estimated 340B Savings before Orphan Exclusion = 36%
  - Estimated 340B Savings with Orphan Exclusion = 16%
  - Estimated Annual Savings $200,000

NOTE - From Debra Demers PSSC (HRSA) Presentation on Feb 23, 2011 to NEPC Hospitals
The Orphan Drug Real Impact

- Need to look at total system to determine the real impact.

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NOTE - From Debra Demers PSSC (HRSA) Presentation on Feb 23, 2011 to NEPC Hospitals
### 340B Cost Report Impact

**Critical Access Hospitals**

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<tr>
<th>Hospital</th>
<th>340B Gross Savings</th>
<th>Cost Report Impact</th>
<th>340B Net Savings</th>
<th>Net Savings as % of Gross Savings</th>
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Orphan Drug Update

- August 2013 HRSA releases a Statutory Regulation with an effective date October 1, 2013
- PhRMA files lawsuit in October 2013
- May 23, 2014 Court rules HRSA does not have statutory authority to issue the Orphan Drug Regulation
- July 21, 2014 HRSA issues a non-binding Interpretive Rule on Orphan Drugs (basically same as the Statutory Regulation)
- HRSA has stated the statute, not the rule per se, is binding on manufacturers and covered entities by establishing binding norms
- October 2014, Manufacturers file lawsuit challenging HRSA authority to issue a ‘Guidance Rule or Regulation’
- Currently there is much confusion in the market
Resources

- HRSA Office of Pharmacy Affairs
  - www.hrsa.gov/opa

- Pharmacy Services Support Center
  - 1-800-628-6297
  - Email pssc@aphanet.org
  - Pssc.aphanet.org

- Prime Vendor Program (Apexus)
  - 1-800-340-2787
  - Email 340B_primevendor@340bpvp.com
  - www.340bpvp.com
Thank You

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Please note: This presentation is educational in nature and not a substitute for legal or regulatory rulings. In all cases, compliance and policy decisions are the responsibility of the Covered Entity.
Lessons from the New London Hospital Audit

Data Collection

More Data Collection

Audit

Exit Interview
New London Hospital Audit

- Data Collection
  - First Priority Items
    - List of Claims
    - List of all Drugs
    - List all Child sites, include screen print of OPA site
    - List all Contract Pharmacies, include screen print
    - List all Providers
    - Medicare Cost Report Worksheets
New London Hospital Audit

Data Collection continued

- Second Priority Items
  - All Policies & Procedures
  - Report of Most Recent Physical Inventory
  - 340B Drug Formulary
  - Schedule of 340B Purchases
  - Description of 340B Drug Ordering Software
  - Description of Split-Billing System
  - Description of Medical Record System
  - Bio/Timeline of New London History
New London Hospital Audit

- Data Collection **continued**
  - Other – may request while on-site
    - Demonstration of Processes
    - Interview with Buyer
    - Interview with Inventory
    - Interview with Medical Billing
New London Hospital Audit

- More Data
  - Prescription
  - Process Clarifications
  - Reports
  - NEPC Relationship
New London Hospital Audit

- Audit (3 days)
  - Line By Line Review of Claims
  - Visited All Child Sites and 1 Contract Pharmacy
New London Hospital Audit

- Audit Results & Recommendations
  - Claim Review had no discrepancies
  - Change Medicaid System Review Process
  - Document Practice for In-House Physicians
  - Conduct Risk Assessment on All Sites
  - Have Finance Review on Vendor Inventory (hospital)
  - Remove Inactive Medical Staff Licenses
  - Remove Children Who are Not Active and Participating in 340B

Overall Favorable
Lessons from the New London Hospital Audit

- Be Prepared
  - Policies, Procedures & Standard Work
Does your Covered Entity have a 340B Multi-disciplinary Team?

Discussion/Questions
Thank you!!

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