340B PROGRAM EVOLUTION, ISSUES & CHALLENGES

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Disclaimer

This presentation is for informative discussion purposes only regarding the regulations and guidance pertaining to 340B Covered Entity Audits and the general impact of such regulations on the industry as a whole.
340B PROGRAM EVOLUTION, ISSUES & CHALLENGES

I. 340B Program
   Past, Present, and Future

II. 340B – DSH Hospital

III. 340B- Contracted Pharmacy

IV. Pharmaceutical Manufacturer Perspective
    Areas of Concern to the Manufacturer

V. Important Legislative Issues & Resources
HOW WOULD YOU RATE YOUR COMPANY’S STAFF UNDERSTANDING OF THE 340B PROGRAM?

A. Limited exposure
B. Good working exposure
C. Strong working exposure
D. Excellent working exposure
The 340B Program was established in 1992 and expanded under the ACA, the program provides outpatient drugs to government-funded hospitals, health systems and clinics serving low-income patients.

It is a “voluntary” program to assist safety net providers. If the manufacturer participates in Medicaid and Medicare Part B then they are required to participate in the 340B program when they sign the PPA.

Last year, the 340B drug purchases were approximately $7 Billion.

Controversial nature of the program.

Why is this needed with the Affordable Care Act?
340B TRENDS

► 2014 $7.0 billion purchased

► 2019 $19.00 billion projected

► 1 out of 3 drugs will be specialty drugs

► Community Oncology Alliance (COA) survey trends
340B BACKGROUND

• **Covered Entities:** Facilities or Programs spending federal money with or with significant uninsured populations, including:

  - Federally-qualified health centers
    - Family Planning Clinics
    - AIDS Drug Assistance Programs (ADAPs)
    - Black Lung Clinics
    - Hemophilia Treatment Centers
    - Urban Indian Organizations
    - Tuberculosis/STD Clinics
  - Disproportionate Share Hospital (DSH) Outpatient Programs
    - Children’s Hospitals
    - Free Standing Cancer Hospitals
    - Critical Access Hospitals
    - Rural Referral Centers
    - Sole Community Hospitals
340B COVERED ENTITY – DSH

- Be designated as a not-for-profit hospital
- Be classified as a children’s hospital, cancer hospital, sole community hospital, rural referral center, critical access hospital or a Medicare Disproportionate Share Hospital
- Serve a large proportion of uninsured and low-income patients
- Undergo random audits by the federal government and pharmaceutical manufacturers
- Re-certify annually as an eligible 340B provider
- Maintain auditable inventories for 340B and non-340B prescription drugs
March 2010: HRSA announced that it would allow all 340B covered entities to establish a contract pharmacy arrangement with an unlimited number of pharmacies.

WALGREENS accounts for 44% (April 2014) of all active contract pharmacy arrangements as recorded in OPA’s database.
DISTRIBUTION OF A COVERED 340B OUTPATIENT PHARMACY

- **Manufacturer**
- **HRSA**
- **Covered entity (CE)**
- **Contractual relationship**
- **Pharmacy**

**340B product shipped to pharmacy**

**CE purchases product at 340B price**

**Patient receives 340B product**

**PPA**
340B CONTRACT PHARMACY

The Prescription Process:

- Hospital replenishes retail 340B stock
- Rx Claim
  - Reimbursement ($100 transfer)
  - ACH transfer reimbursement
  - Minus pharmacy fee ($85 transfer)
- Hospital payment ($80 transfer)
- Patient
- Pharmacy
- Payor
- Third-party software vendor

Claim submitted to payor
340B CONTRACT PHARMACY - MEDICAID

- Patient
- Contract pharmacy
- Health Plan
- State Medicaid Claims Administrator
- Manufacturer
- Switch operator
- Third-party administrator
- Covered entity hospital
- Real-time adjudication
KEY CHALLENGES FACING MANUFACTURERS

► 340B membership eligibility
► GPO prohibition
► Duplicate payments
► Noncompliance
WHERE ARE YOUR COMPANY’S CURRENT ISSUES LOCATED REGARDING 340B?

A. Data management
B. Membership maintenance
C. Medicaid
D. Other
E. No issues
HOW IS YOUR ORGANIZATION MANAGING THE 340B PROCESSES TODAY?

A. Managing internally with staff resources

B. Managing internally, but now considering leveraging an external partner

C. Currently working with a external partner
WHERE ARE YOUR COMPANY’S CURRENT ISSUES LOCATED REGARDING 340B?

A. Data management
B. Membership maintenance
C. Medicaid
D. Other
E. No issues
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