

Ensuring  
Integrity in use  
of 340B pricing:  
Responsibility,  
Compliance,  
Accountability

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## **The 340B Federal Drug Discount Program: Responsibility, Accountability, and Compliance**

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**Activity Type: Knowledge-based**

**Following this presentation, attendees should be able to:**

1. List the major 340B compliance components.
2. Describe the key personnel responsible for compliance with the 340B program and their roles.
3. Describe the process for addressing 304B policy and for maintenance of integrity of 340B program participation.
4. Outline areas where technology could assist in compliance with the 340B program.



## **Disclosures**

Fern Paul-Aviles declares no conflicts of interest or financial interest in any product or service mentioned in this program, including grants, employment, gifts, stock holdings, and honoraria.

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# Goals

- List the major 340B compliance components
- Review the key personnel responsible for compliance with the 340B program and their roles
- Describe the process for addressing 304B policy and for maintenance of integrity of 340B program participation
- Outline areas where technology could assist in compliance with the 340B program

# Top three 340B watchwords

- Responsibility
- Compliance
- Accountability

# 340B program history

- Intent was to stretch scarce health care resources, *not* to save patients money
- Only outpatient care areas are eligible
  - Outpatient clinics & pharmacies
  - ED & Obs, One-Day Surgery, Endoscopy
- General Acctg Off report recommendations
  - Audits
  - Finalize new, more specific guidance on the definition of a 340B patient – July 18, 2012

# Major compliance areas

- Patient definition:
  - Patient must be cared for in a hospital outpatient area AND
  - The physician caring for the patient must be employed or contracted by the hospital; AND
  - The hospital must “own” the pt’s medical record
  - Meds must be for a condition the HC is treating
- Duplicate discounts
  - Since the mfr has given the covered entity a discount up-front, it is the covered entity’s responsibility to ensure that Medicaid does not ask for a rebate on the back end
- GPO exclusion
  - Drugs bought for use in 340B-eligible areas cannot be purchased using GPO-negotiated pricing

# Major Compliance Areas

## ○ Patient definition

- Locations of hospital outpatient areas:
  - Must be on reimbursable lines of hospital's Medicare cost report, lines 50-118 of 2011 version
  - Create lists of eligible clinics if screening manually
- Patient registration (eligibility)
  - Need a time-stamp the actual time of admission to an inpatient area (or discharge then re-admit)
  - Differentiate between patient indicator and service date patient type when pulling reports
- Utility of eligible patient file - HC

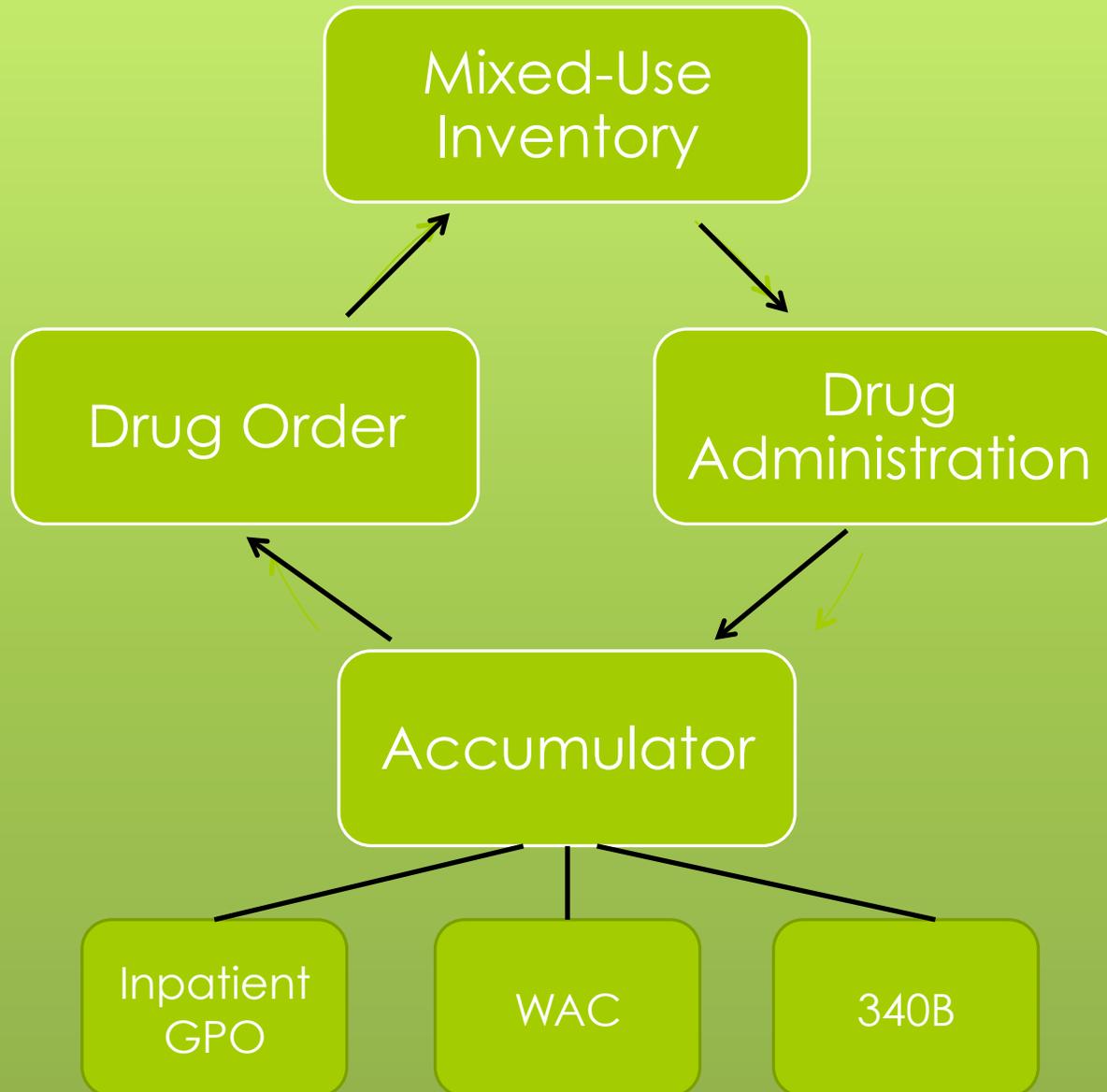
# Major compliance areas

- Duplicate discounts
  - Avoidance of duplicate discounts
    - Easy in retail pharmacies
    - Hard to avoid when there is more than one type of billing at a given covered entity (e.g. retail pharmacies and hospital mixed-use setting)
    - Harder to avoid in hospital mixed-use settings
  - States' handling of duplicate discount provision
    - States differ on use of OPA's Medicaid Exclusion file
    - Some states require billing at actual acquisition cost –
    - Some states require UD modifiers on claims to signify to Medicaid that drugs were purchased at 340B prices

# Major compliance areas

- GPO exclusion
  - Difficult to avoid with split-billing methodology
  - Hospital pharmacies have existing GPO accounts before enrolling in 340B

# Compliant 340B In Mixed-Use Areas



# Required involved parties

- Hospital-wide committee
  - C-Suite (CEO, COO, CFO, etc.)
    - Savings projections are difficult
    - Evaluate savings vs. investment
  - Corporate Compliance or Internal Audit
  - Director of Hospital Reimbursement/Finance
  - Patient registration/Access
  - Information Services
    - Utilization reports pulled for eligible areas
    - Spreadsheet with hospital outpatient areas
  - Wholesaler
    - Correct account set-up
  - Pharmacy chargemaster - mapping from charge item to NDC #
  - Pharmacy Buyer - override wholesaler generic programs

# Where can technology help?

- Split-billing
  - Extraction of utilization data (patient definition)
    - Maximization – identifying all eligible patients
    - Compliance – identifying only eligible patients
  - Savings reports
  - Alerts
    - No data in utilization file
    - No product in wholesaler system
    - No product in hospital computer system (virtual inventory)
    - No invoices uploaded
    - Negative accumulation for specific NDC
  - Wide discrepancy between dispenses and purchases
- Contract pharmacies
  - Enrollment files vs eligibility testing through registration system
  - Creation of invoices

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# Self-assessment questions

- Which of these is the only determinant of whether an area of the hospital is 340B-eligible?
  - Billing is done via facility billing (CMS 1500/837p submission)
  - Because your Finance person wants to believe it is so
  - It is on the reimbursable lines of the hospital's cost report
  - Because the patients who are served there are indigent and the practice agreed to care for them
- Which of the following key stakeholders are responsible for compliance with the 340B programs?
  - The 340B entity
  - The vendor of split-billing software
  - The wholesaler
  - The contract pharmacy
  - All of the above
- Which program of the Office of Pharmacy Affairs is intended to prove the value of clinical pharmacist activities?
  - PSPC (Patient Safety and Clinical Pharmacy Collaborative)
  - 340B program
  - Annual recertification

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