



Pharmaceutical Policy Experts

AUTOMATION AND THE 340B PROGRAM: THE FORECAST FOR 2015

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Disclosures

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Madeline Wallack is an employee of Rx | X Consulting. The conflict of interest was resolved by peer review of the slide content. She declares no other 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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Presentation Objectives:

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- To explain 340B program requirements and how automation is used to facilitate operations
- To provide examples of common issues that arise from overreliance on automation
- To offer specific suggestions balancing maximized use of automation in 340B, but understanding where manual intervention is needed
- To discuss the forecast for 340B in 2015

340B Program: Overview and Benefits

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

Average savings of 25-50% that may be used to:

- Reduce price of pharmaceuticals for patients
- Expand services offered to patients
- Provide services to more patients

Manufacturers that participate in Medicaid and Medicare Part B must also participate in the 340B Program

340B Program Requirements

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- Participating entities—including certain hospitals, grantees and health clinics—must:
 - ▣ Prevent diversion and use 340B drugs for outpatients where they can demonstrate responsibility for care
 - ▣ Prevent duplicate discounts with the State's Medicaid Drug Rebate Program

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Why do 340B entities use automation?

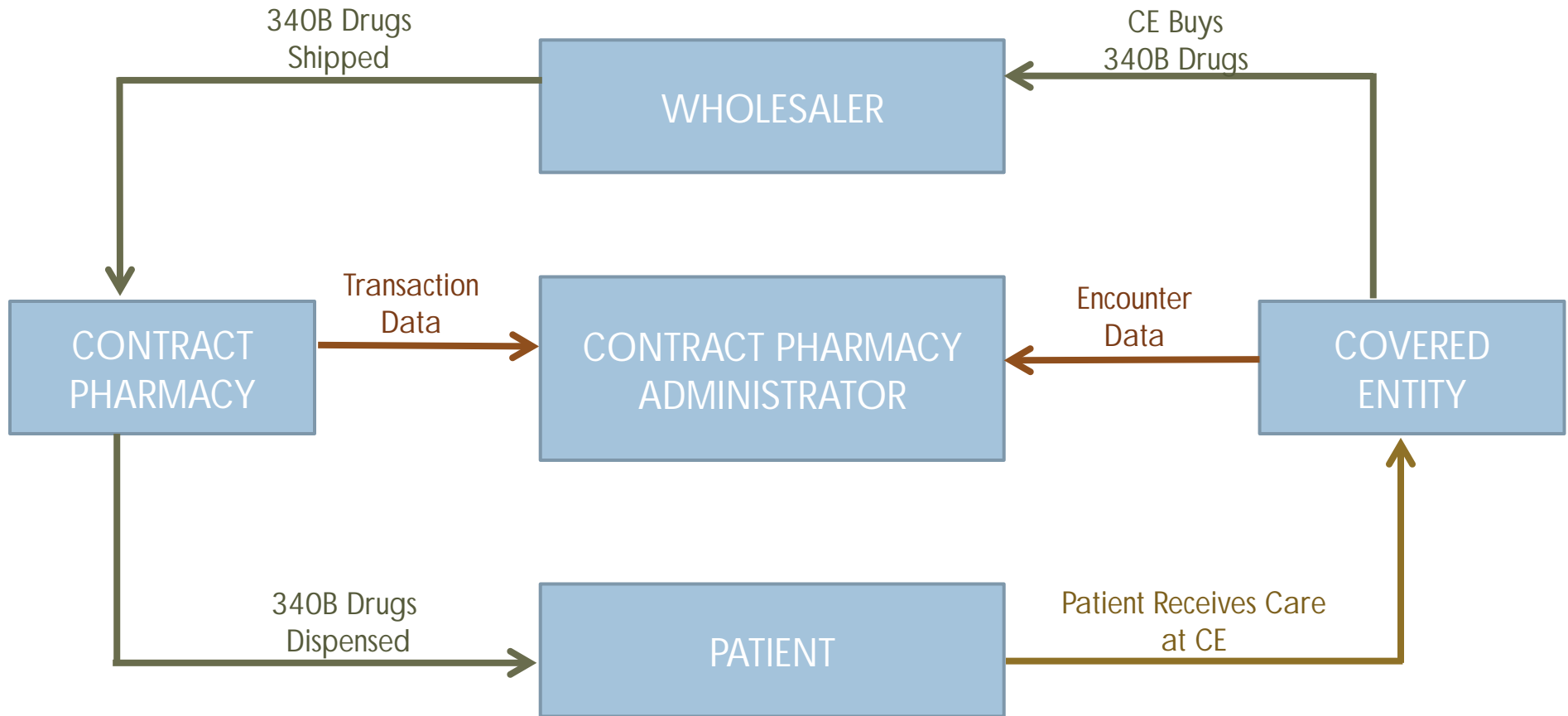
1. To prevent diversion and create an audit trail of 340B dispensed products.

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- Virtually manage 340B, WAC & GPO inventory
 - Physical stock is “neutral”; credits for 340B purchases accumulate and drugs are replenished retrospectively
 - Inpatient and outpatient dispensing are separated
- Virtually manage 340B inventory dispensed through contract pharmacy arrangements.
- Track all points of prescription origination, outside prescribers, and potential for referrals

2. To manage 340B Contract Pharmacy points of access

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3. To prevent duplicate discounts

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- HRSA Medicaid Exclusion File: “Will you bill Medicaid for drug purchased at 340B drug price?”
 - ▣ Carve-In: List Medicaid provider numbers and NPI
 - Pass through 340B price
 - ▣ Carve-Out: Do not list Medicaid provider numbers/NPI
 - Bill according to hospital standards

340B requirements complicate reliance on automation

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- Current technology relies on perfect inputs
 - ▣ Provider Lists often overstate eligibility
- Configurations required for 340B compliance can be incongruent with other systems
 - ▣ HRSA requires inventory replenishment at 11-digit; Chargemaster often not unique
- The potential for hidden issues requires manual intervention

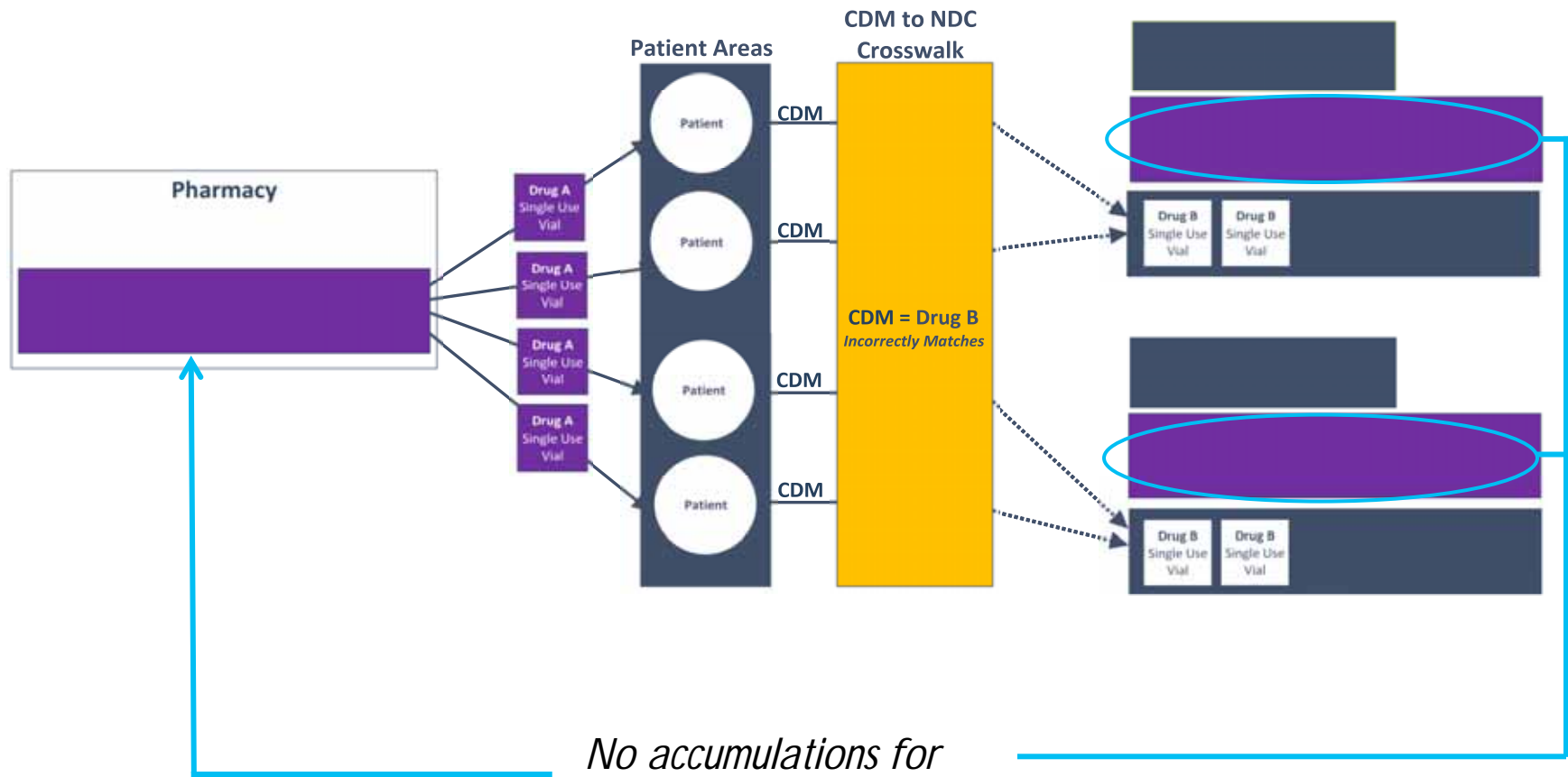
Common Pitfalls: 340B Inventory Management

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- ❑ You neglect your CDM to NDC cross-walk and overaccumulate, underaccumulate, don't accumulate 340B purchases and default orders to WAC
- ❑ You do not accumulate 340B purchases on the correct unit of measure
- ❑ Your direct purchases do not accumulate
- ❑ You do not have procedures for return to stock

The Neglected Crosswalk...

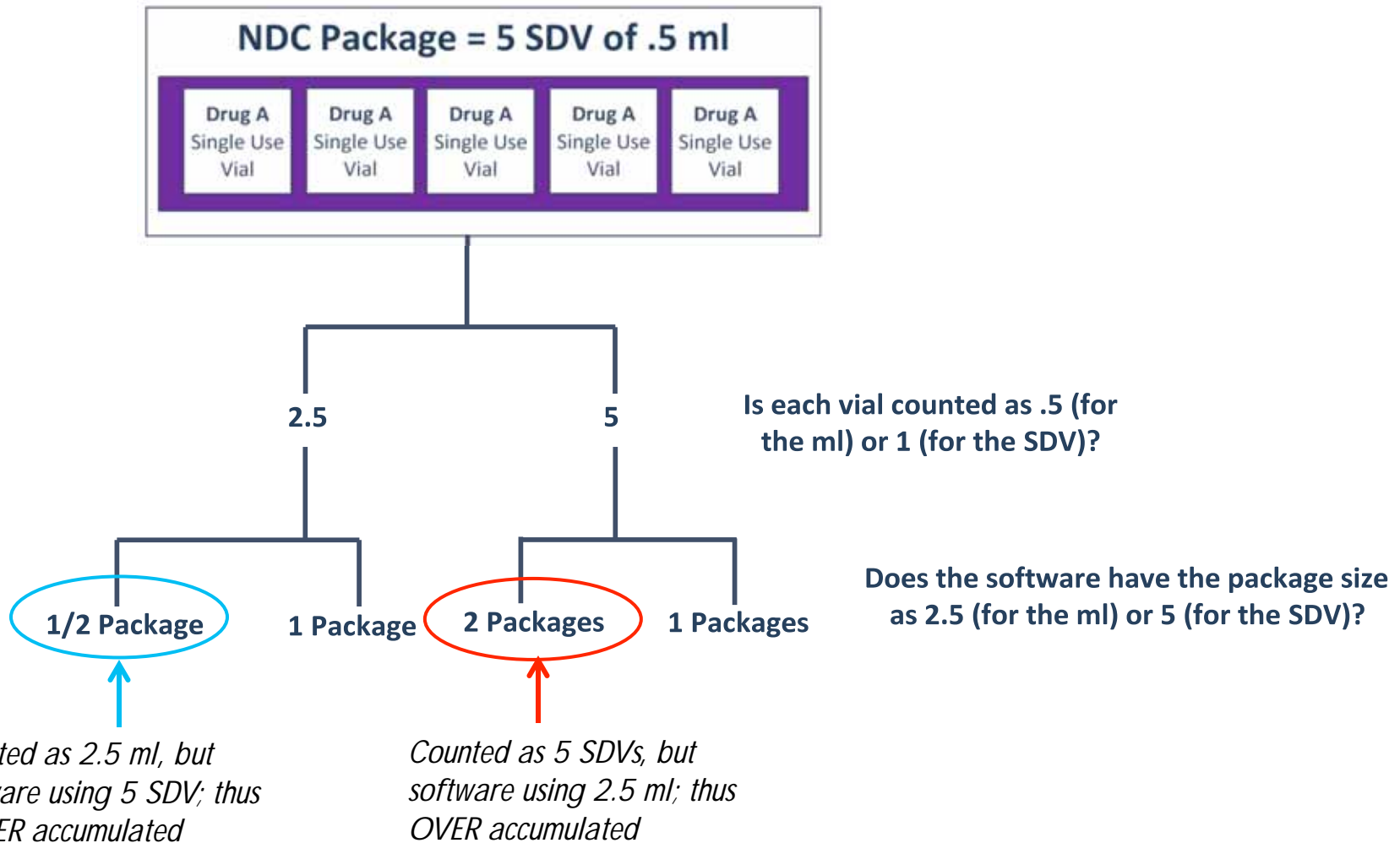
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No accumulations for orders; Defaults to WAC

The Incorrect Unit of Measure...

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Inventory Controls Best Practices

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- Monitor NDCs purchased against data housed in CDM
 - ▣ Regularly review the crosswalk
 - ▣ Manage purchases to maximize use of 340B accumulations
- Scrutinize issues with Unit of Measure
 - ▣ Issues can lead to both over and under accumulations
- Review procurement practices across clinics/ departments (including off-site)
- Integrate manual purchasing processes from secondary wholesalers and manufacturers

Challenges with Preventing Duplicate Discounts

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- State requirements vary and aren't always clear
- Physician administered Drugs
 - ▣ "UD modifier" required in many States
 - ▣ Changing "cost" to the 340B price can create issues
- Retail
 - ▣ NCPDP Code 20
 - ▣ Contract pharmacy must "carve-out" Medicaid
- Medicaid Managed Care Requirements still unclear.

340B in 2015

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- Additional guidance from HRSA on patient definition and the prevention of duplicate discounts
- Continued Congressional interest
- Proposed regulations
 - ▣ Calculation of 340B ceiling prices and manufacturer civil monetary penalties
 - ▣ Dispute resolution
- Covered entities' continued investment in compliance
- More HRSA and manufacturer audits



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