The Drug Supply Chain Security Act: An Overview for Health-System Pharmacy Staff

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Disclosure

- The opinions expressed herein are my own, and not necessarily those of my employer or of VSHP

- This presentation abides by the non-commercialism guidelines provided on the CE requirements page
Learning Objectives

The purposes of this activity are to:

• Describe key information from the Drug Supply Chain Security Act

• Review what health-system pharmacy staff need to know about the legislation and important compliance dates
1) Are health-system pharmacies currently responsible for compliance with the DSCSA?
   Yes

2) On July 1, 2015, will departments that further distribute be responsible for transmitting or recording TI/TH/TS for all products?
   No

3) How long will one have to retrieve information should the FDA request it?
   2 business days
“The care of human life and happiness, and not their destruction, is the first and only object of good government.”

-Thomas Jefferson

Tragedy Due to Drug Supply Chain Mismanagement

- 2008 Tainted Heparin from Chinese Factory
- 2009 Levemir Cargo Theft
- 2010 Eli Lilly Warehouse Heist
- 2012 Counterfeit Avastin Penetrates US Supply Chain

WSJ accessed 3/14/15: http://www.wsj.com/articles/SB10001424052748704688604575125522684707974
Where Do Good Drugs Go Bad?

- Manufacturer
- Repackager
- Wholesaler
- Wholesaler
- Other Source of Drugs (e.g., institutional pharmacies, closed door pharmacies, foreign market)
- Hospital (Dispenser)

• Signed November 27, 2013 by President Barrack Obama

• Title I: The Compounding Quality Act
  o Contains important provisions related to oversight of compounding of human drugs

• Title II: Drug Supply Chain Security Act
  o Outlines critical steps to build an electronic and interoperable system to identify and trace prescription drugs throughout the supply chain
  o Electronic
  o Interoperable

A Short Bit of History…

Florida Pedigree (S.B. 2312)

- Paper Based
- Lot Pedigree
- Did not involve Manufacturer

California Pedigree (S.B. 1307)

- Item Level Serialization
- Unique identifier exchanged via electronic pedigree in supply chain
- Responsibility shared across supply chain

Hate The Player, Not The Game

- Manufacturer
- Repackager
- Wholesale Distributor
- Third-Party Logistics Provider
- Dispenser

Would The Real Dispenser Please Stand Up?

• Dispenser – Any company or individual that is authorized to dispense or administer prescription drugs to a patient.

• Examples of entities with dispense status under the DSCSA:
  
  o Chain or Independent Pharmacy  
  o Health-Systems  
  o Retail Clinics (Patient First, etc.)  
  o Dispensing Oncology Clinics  
  o Dentists or physicians if dispensing
Describing “Traceability”

Transaction Information (TI)
• Data about products and trading partners

Transaction History (TH)
• TI for each previous change in ownership

Transaction Statement (TS)
• Multiple statements related to the veracity of the history of the product and data provided
• Single, paper or electronic form

How DSCSA Traceability Works

<table>
<thead>
<tr>
<th>CA Law</th>
<th>DSCSA</th>
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<tbody>
<tr>
<td>Manufacturer</td>
<td></td>
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<tr>
<td>Wholesaler</td>
<td></td>
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<tr>
<td>Hospital</td>
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Requirements for Dispensers

- **January 1, 2015**
  - Have systems in place to trace, investigate, quarantine, and alert officials to potential illegitimate products
  - Use only authorized trading partners
  - Further distribution to other pharmacies requires transmitting TI/TH/TS

- **July 1, 2015**
  - Do not accept any product without TI/TH/TS
  - Must maintain this information for six years
  - Respond to requests from officials within 2 business days

Key Exemptions

The following products are **not** subject to the tracing requirements in the bill:

- Compounded Drugs (Title 1 of DQSA)
- Imaging Drugs
- Medical Gasses
- IV Fluids
- Irrigation products and sterile water
- OTC Drugs
- Radioactive drug products (NRC)

Tracking Requirement Exceptions

The following tracking exceptions are defined within the bill:

- Distribution between hospitals or entities under common control
- Distribution for public health emergency, NOT including drug shortages
- Distribution of all exempt products
- Intracompany distribution
  - Affiliate members
  - Within a manufacturer

## Thoughts for a Departmental Approach

<table>
<thead>
<tr>
<th>Topic</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Regulatory Compliance</strong></td>
<td>How will you respond to a request for information?</td>
</tr>
<tr>
<td><strong>What are you tracking?</strong></td>
<td>Specify your exclusions!</td>
</tr>
<tr>
<td><strong>Plan for Loan/Borrow</strong></td>
<td>Only those external to your dispenser health-system</td>
</tr>
<tr>
<td><strong>Drop-ship purchasing</strong></td>
<td>How will you obtain TI/TH/TS?</td>
</tr>
<tr>
<td><strong>Record Retention and Access</strong></td>
<td>How will you store and retrieve information?</td>
</tr>
<tr>
<td><strong>Non-Pharmacy Inventory</strong></td>
<td>What if it has an NDC and isn’t excluded?</td>
</tr>
</tbody>
</table>
| **Plan your Procedure and Know Your Workflow** | • Quarantine Process  
• Notification  
• Product Returns                                                      |
| **Staff Training**                         | Who owns the process?                                                       |

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Timeline for Dispensers

January 1, 2015
• Quarantine suspect drug products
• Investigate suspect drug product

November, 2020
• Reject deliveries without barcoded:
  • NDC  • Serial Number
  • Lot Number  • Expiration Date

July 1, 2015
• Reject deliveries unless transaction information and history provided
• Archive new data for 6 years
• Respond to FDA and other agencies
• Retrieve documentation within 2 business days

November, 2023
• Trace items back to manufacturer
• Verify product at package level
• Respond to FDA and other agencies at package level

Your Checklist For Compliance

• Review regulations with legal counsel and stakeholders
  ✓ Ensure current licensure as a manufacturer, wholesaler, or repackager
  ✓ Confirm ability to transfer TI/TH/TS in a single paper or electronic message
  ✓ Consult with wholesaler and drop ship suppliers on meeting requirements
  ✓ Budget for implementing and sustaining a plan

• Write a standard operating procedure or make a plan to:
  ✓ Receive and store TI/TH/TS for six years
  ✓ Retrieve information or respond to inquiries within six years
  ✓ Investigate potential problems and quarantine product with timeframes
  ✓ Contact 3PL, contract if necessary

Post-Lecture Questions

1) Are health-system pharmacies currently responsible for compliance with the DSCSA?
   
   Yes

2) How long will pharmacy departments need to keep records of TI/TH/TS?
   
   Six years

3) On July 1, 2015, will departments that distribute for shortages or loan/borrow be responsible for transmitting or recording TI/TH/TS?
   
   Yes
Thank you!
The 340B Program in Transition: Current Challenges, Opportunities and a Glimpse of the Future

April 17, 2015

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McKesson Pharmaceutical
Disclosure

- Comments, assessments and estimates in presentation represent the opinion of the author and do not reflect McKesson policy or practice unless so identified. Comments are intended to be conservative and are based on public information. Comments, assessments and estimates do not constitute recommendations and are not suitable for independent use without internal legal, regulatory, compliance and other business review and validation.

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Agenda

• Current 340B Environment
  o 340B Basics
  o Practice and business imperatives
• Regulatory and Compliance
  o Interpretation of current guidance
  o Role of HRSA, Apexus
  o New Guidance
• Audits
  o What’s going on?
  o How should I prepare?
• The “Business of 340B”
  o Software Vendors
  o Orphan Drugs?
  o Policies & Procedures
  o Tips, Tricks and Traps
  o Contract Pharmacy?
340B Basics
What is the 340B Program

- Federal program created in 1992
- Benefits providers serving the indigent
- Discounted pharmaceuticals
- Outpatient drugs only
- Compliance & administration
- Creates an opportunity for “covered entities” to contract with retail pharmacies to improve access
340B Program Purpose

• “...to enable [covered entities] to stretch scarce Federal resources as far as possible, reaching more eligible patients and providing more comprehensive services.”

(House Report, No. 102-384, Part II, Pg. 12, 102nd Congress, Second Session)
340B Challenges

- Increased scrutiny by Congress
  - Focus on program oversight and constraining program growth
  - Questions about limiting the program to uninsured patients or exempting certain categories of drug products
  - Focus on use of program proceeds

- Pharmaceutical industry, PBMs, and oncologists have raised concerns about whether the 340B program is working appropriately

- Questions raised about whether patients are benefiting and whether hospitals are undermining care
Requirements for Dispensers

- **OPA Guidance**
  - Multiple Contract Pharmacy

- **ACA Passage**
  - New Entities, Integrity Provisions, GAO Study

- **ACA/Litigation**
  - Orphan Drugs

- **SSI Calculations**
  - MCO Changes

- **Medicaid (MCO)**
  - Retail, Contract, OP Infusion

- **GAO Report**
  - Audits, Recertification

- **Politics**
  - Grassley, Hatch, Cassidy, Pitts
  - PhRMA/ Biotech

- **GPO Exclusion**
  - Strict Guidance

- **“Coming Soon”**
  - “Mega Guidance”, Patient Definition
340B Covered Entity Requirements

- Must meet the entity-specific requirements set out in the statute and interpretive regulations
- Hospitals: government owned or controlled, or
- If non-government, non-profit and have an agreement with a government entity
- Meet uninsured/Medicare/Medicaid DSH threshold
- Must apply for participation
- Must be listed on the HRSA website
- May not *double-dip* with Medicaid (some “carve out” Medicaid purchases)
- Mixed use settings must *segregate inventory*
- May not *divert* product to non-patients
- DSH may not use GPO-purchased drugs for outpatients
340B Market Components

- **Hospitals & Clinics**
  - Covered Entities
    - DSH
    - Children’s
    - Critical Access
    - Sole Community
    - Rural Referral
    - Cancer
    - Clinics
  - Distributed
    - Cardinal
    - ABC
    - McKesson
    - Regionals

- **Software & Service**
  - Software
    - Inventory Management
    - Networks
    - Payment allocation
  - 340B Vendors
    - Macro Helix
    - Sentry
    - Walgreens (WAG Only)
    - CaptureRx
    - SunRx
    - Wellpartner
    - Consultants

- **Pharmacies**
  - Retail Pharmacy
    - Small Chains
    - Walgreens, CVS, Rite Aid
    - Independent
  - Specialty & Others
    - Diplomat
    - WAG Specialty
    - CVS /Caremark
    - PBMs?
340B Covered Outpatient Drugs

Vaccines
- Inpatient drugs
- Drug not directly reimbursed
- FDA doesn’t require NDC

Outpatient Prescription Drugs
- Over-the-counter drugs (with a prescription)
- Clinic administered drugs
- Biologics
- Insulin
340b Split Billing

**Receiving**
- 340B and Medicaid items arrive in daily order
- McKesson DC ships with daily order
- Pooled dispensing data imported to 340B Manager under the same DEA number
- Data tracked and accumulated at item level

**340B/Medicaid Reporting**
- Dispensing Report
- Purchase Order Report
- Savings Report
- Accumulated Dispensing Report

**Dispensing**
Prescription dispensed to 340B eligible or Medicaid patient

**Tracking**
Item-level data captured in pharmacy information system

**Ordering**
Buyer creates usual daily order
- 340B Order
- Non-340B Order
- Medicaid Order

**Data tracked and accumulated at item level**
In Congress & Washington DC

• MedPAC Hearing
• Energy and Commerce Committee Hearing
• Mega-Guidance from HRSA
• New GAO Report
• New OIG Reports

Fall 2014 Agenda for HHS Rules
April 2015:
• Civil monetary penalties for drug manufacturers that intentionally overcharge covered entities
• Define standards and methodology for calculation of 340B ceiling prices

September 2015:
• Creation of a mandatory and binding 340B administrative dispute resolution process
HRSA Mega-Guidance

- From SNHPA:
  o Expected to be released in June 2015 with 60-day comment period
  o HRSA does not expect to finalize prior to FY 2016

- Topics:
  o Patient definition
  o Hospital eligibility
  o Contract pharmacy
  o Covered outpatient drug definition
  o Annual covered entity recertification
  o Audit
  o Medicaid duplicate discount
  o Manufacturer limited distribution plans
  o Procedures for manufacturers to repay entities
Audits

- September 2011 GAO report recommended selective audits of entities
- HRSA began entity audits in January 2012
- HRSA uses a risk-based determination for audit
  - volume of purchases,
  - complexity of program administration, and
  - use of contract pharmacies
- HRSA also conducts “targeted” audits based on allegations of 340B violations
  - 51 audits in FY 2012,
  - 94 in FY 2013, and
  - 99 audits in FY 2014
  - Up to 200 audits for FY 2015
Audit Findings Trends

• Types:
  o Inaccurate database record,
  o Diversion,
  o Duplicate discount,
  o Eligibility,
  o GPO Prohibition
  o Contract Pharmacy oversight

• Repayment obligation for:
  o Diversion
  o Duplicate discount (if state collected rebates)
  o GPO exclusion

• Eligibility finding reportedly can lead to removal of hospital and/or its contract pharmacies from 340B program (none removed so far)
  o GPO Prohibition = removal from program
  o Contract Pharmacies; No independent audits or oversight leads to potential penalty of having all the hospital’s contract pharmacies being removed from the program

• Appeals
  o Most findings are not appealed
  o Of those that are appealed, more than half succeed on one or more findings
  o Successful appeals coincide with incorrect findings or misinformation or lack of data subsequently provided by the hospital
HRSA Audit Preparedness

• Form a 340B Program Oversight Committee today.
  o Active engagement of Leadership, Finance and Compliance
  o Include:
    ▪ Administration
    ▪ Legal
    ▪ Compliance
    ▪ Pharmacy leadership & staff
    ▪ Finance/Medicare Cost Report Office
    ▪ Information Technology

• Identification of point person for communication with HRSA

• Reach out to similar facilities recently audited

• Build your audit plan
  o Mock Audits
## HRSA Data Request

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<tr>
<th>Name</th>
<th>Date modified</th>
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</thead>
<tbody>
<tr>
<td>1. 340B Drug Orders</td>
<td>2/19/2014 9:58 PM</td>
</tr>
<tr>
<td>3. Listing of VUMC Entities</td>
<td>1/23/2014 3:48 PM</td>
</tr>
<tr>
<td>4. Pharmacy Settings</td>
<td>1/23/2014 2:55 PM</td>
</tr>
<tr>
<td>5. Documentation to verify 340B</td>
<td>1/23/2014 2:57 PM</td>
</tr>
<tr>
<td>7. Providers</td>
<td>1/23/2014 3:08 PM</td>
</tr>
<tr>
<td>8. Current Inventory Listing</td>
<td>1/23/2014 3:09 PM</td>
</tr>
<tr>
<td>9. 340B Purchase Orders (Included in #10)</td>
<td>1/14/2014 2:43 PM</td>
</tr>
<tr>
<td>10. All Purchase Accounts (340B,GPO,WAC)</td>
<td>2/24/2014 4:02 PM</td>
</tr>
<tr>
<td>11. Contract Pharmacy List</td>
<td>2/22/2014 8:36 PM</td>
</tr>
<tr>
<td>14. Medicare Provider enrollment NPI Medic</td>
<td>1/31/2014 11:40 AM</td>
</tr>
<tr>
<td>15. Org Charts</td>
<td>2/24/2014 4:26 PM</td>
</tr>
<tr>
<td>17. Software utilization</td>
<td>1/23/2014 3:22 PM</td>
</tr>
</tbody>
</table>

*Courtesy of Brent Brumagin, Vanderbilt University Medical Center*
Ongoing Audit Preparation

• Annual mock HRSA/Manufacturer audit
  o Policies and Procedures
  o New/updated regulations
  o Billing Medicaid
  o GPO exclusion
  o HRSA website information

• Monthly Review
  o Drugs & Purchasing
  o Patient Data flow and screening results
  o Locations

• Ongoing Assessments
  o Pharmacy systems
  o Split billing systems
  o Billing systems
  o Workflow audits
  o Interview staff
  o Monitor spend trends – not just WAC
1. Improve 340B Program Accountability
   - Interdisciplinary team is essential
   - Acquisitions and divestitures
   - Chargemaster updates
   - Medicaid status changes

2. Choose the right software
   - Ask the right questions
     - How do you define a drug? Your wholesaler? Your pharmacy IS?
     - Prepare your drug dictionary / formulary / chargemaster for 340B
   - How will you accumulate doses for 340B replenishment?
     - This decision has financial and compliance ramifications.

3. Optimize Medicaid
   - Contact State Medicaid regularly
   - Review bulletins & Notifications
   - Carve In/Carve Out?
   - How many Medicaid provider numbers do you have?

4. Consider Owned Retail Pharmacies
   - Does the Pharmacy have a unique Medicaid provider number?
   - Apexus Generics portfolio is critical
   - Can you find your PBM contracts?
4. Improve Contract Pharmacy Process
   - No Audit = No Contract Pharmacies
   - Software logic, no matter how intricate is perfect
   - Acquire resources for audits
   - Use business resources to tie revenue, fees, accruals, purchases and reversals
   - Dramatic restatements of results can harm your program and your reputation

5. What is your net 340B Program Savings?
   - Compare to WAC or GPO?
   - Include all purchases
   - WAC Spend or WAC Premium?
   - You can give back through WAC and even have a net loss
   - WAC purchasing stems from:
     - Incomplete charge capture
     - Incomplete chargemaster/crosswalk
     - Incorrect conversion factors
     - Shortages and inconsistent purchasing

6. Other Considerations
   - Understand how your split billing and contract pharmacy software works
   - Determine your organization's interpretation of covered outpatient drugs
   - If ACA designated hospital, understand the orphan drug prohibition
   - Know what it takes to compliantly manage a contract pharmacy program
   - Investigate pricing models and fee schedules for contract pharmacy
   - Know the challenges with compliance with the patient definition
Where Did Contract Pharmacy Come From

- Federal Register, Volume 75, No. 43 – Friday, March 5, 2010 Notice
  - Multiple contract pharmacies allowed
  - Contract requirement, suggested provisions
  - Essential compliance elements
  - Compliance expectations
Operationalizing 340B Contract Pharmacy

- A two part test on prescriptions using the pharmacy’s prescription claims and hospital encounter data:
  1. Did the customer in the pharmacy receive a health service from the 340B covered entity?
  2. Was the health service proximal to the prescription filled?
     - (i.e. a hospital chest pain patient filling a blood pressure medication would be deemed qualified whereas the same patient filling a prescription for a skin rash would not because the prescription isn’t proximal to the service provided by the 340B hospital)

- 340B inventory is ordered based on the pharmacy’s supply chain preferences:
  - Integration with the pharmacy’s inventory system
  - Ordering
  - Order splitting and/or user prompted orders

- Revenue pass through and dispensing fees are calculated, tracked, and facilitated under the contract terms
Contract Pharmacy: How Does It Work?
The Prescription Process

Pharmacy Processes and Dispenses 340B Prescription

$15

Reimbursement

Rx Claim

Third-Party Software Vendor

$100

Claim Data to Vendor

$60

ACH Transfer Reimbursement, Retain Pharmacy Fee

Hospital Replenishes Retail 340B Stock

$20

$80

Hospital Payment, Retain Vendor Fee

$85

$5
Questions?

Thank you!

Pharmacotherapy: A Pathophysiologic Approach 6th Ed (Past Tense)