Drug Supply Chain Security Act (DSCSA) – Updates and Actions for Health System Pharmacy

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Drug Supply Chain Security Act – Implementation

Anita Ducca, M.S.

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Drug Supply Chain Security Act

- ***The Drug Supply Chain Security Act*** **(DSCSA) is Title II of *The Drug Quality and Security Act***
- **Signed by the President 11/27/13, effective immediately upon signature; (Public Law 113-54)**
- **Sets out new federal definitions, requirements for all supply chain partners and replaces PDMA and state pedigree requirements**

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Drug Supply Chain Security Act

- **Applies to "transactions" which change ownership of "product" (in finished dosage form) performed by "Authorized Trading Partners"**
- **Phased-in approach, over ten years, then "enhanced" traceability beginning in 2023**

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State Preemption

- **Pedigree - Immediate preemption of all state laws, regulations and requirements for tracing products through the supply chain, including any recordkeeping and pedigree requirements**
- **Licensure - Preemption of certain state activity regarding wholesale distributor and 3PL licensure. States cannot alter the Act's standards, but they may continue to regulate wholesale distributors and 3PLs in certain areas**

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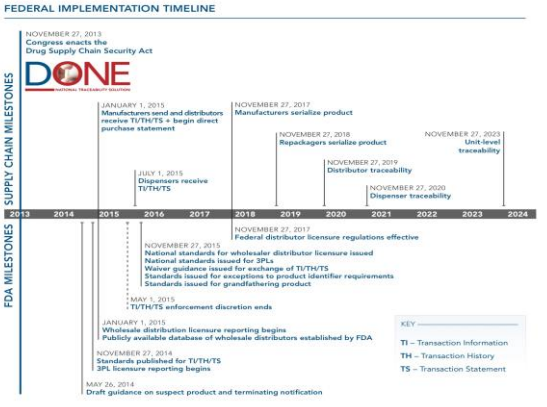

What Do Dispensers Need to Know About Trading Partners?

- How are authorized trading partners defined under the law?
- What are their responsibilities?
- What deadlines pertain to them?
- Recommendations for how dispensers could work with their wholesale distributors.

Wholesale Distributor Definition

- A person (other than a manufacturer, a manufacturer's co-licensed partner, a third-party logistics provider or repackager) engaged in wholesale distribution (as defined in section 503(e)(4), as amended by the Drug Supply Chain Security Act)
- *Wholesale distribution* is, essentially, the distribution of an Rx product to an entity/person other than the patient

Manufacturer Definition

- A person that holds an application approved under section 505 or a license issued under section 351 of the Public Health Service Act for such product, or if such product is not the subject of an approved application or license, the person who manufactured the product
- A co-licensed partner or an affiliate of the manufacturer that obtains the product directly from them

Product Tracing

- Phased approach requiring manufacturers, wholesale distributors, dispensers and repackagers to pass, capture and maintain certain information with respect to each *transaction*
- DSCSA "product tracing" requirements are triggered by transactions which change ownership between trading partners

Product Tracing

- Transaction information (TI) - includes the name of the product; strength and dosage form; NDC; container size; name and address of the seller and the purchaser; and other DSCSA specified information
- Transaction history (TH) - paper or electronic statement that includes the transaction information for each prior transaction back to the manufacturer
- Transaction statement (TS) - paper or electronic attestation by the entity transferring ownership of the product that it is authorized under the Act; received the product from an authorized party; and other DSCSA specified information

Product Tracing

- Each business must (i) provide the TI, TH and TS to the subsequent owner for each transaction, and (ii) capture and maintain for six years the TI, TH and TS for each transaction, whether as the buyer or as the seller
- Began on January 1, 2015 for manufacturers, wholesaler distributors and repackagers
- Begins on July 1, 2015 for dispensers
- Note: Wholesale distributors provide the data to dispensers, ***but***, manufacturers will do so for drop shipped products

FDA Compliance Policy Guide

- **On Dec. 24, 2014, FDA Released: "*Product Tracing Requirements — Compliance Policy*" ***

  FDA recognizes that some manufacturers, wholesale distributors, and repackagers may need additional time beyond January 1, 2015, …To minimize possible disruptions in the distribution of prescription drugs… FDA does not *intend* to take action against trading partners who do not, prior to May 1, 2015, provide or capture the product tracing information… (emphasis added)

*http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM427867.pdf

Additional Wholesale Distributor Responsibilities as of 1/1/15

- **Must report to FDA certain state licensure information for each licensed facility**
- **Have systems in place to address suspect and illegitimate products**
- **Only do business with "Authorized Trading Partners"**

2017 Manufacturer Serialization Begins

- **By 11/27/2017, manufacturers* must have affixed or imprinted a unique "*product identifier*" in both human- and machine-readable form to each package and homogenous case**
  - "Product identifier"= the standardized numerical identifier** (SNI), lot number and expiration date
  - Each package must have a 2D barcode; a case may have a 2D barcode or a linear barcode
  - Must meet other requirements, e.g., recordkeeping

*** Note: Repackagers have until 2018 to serialize product**
**** See: http://www.fda.gov/RegulatoryInformation/Guidances/ucm125505.htm#_Toc254967077**

2019 Wholesale Distributors (but Impacts Dispensers)

- **Beginning 11/27/2019, Wholesale Distributors may receive and sell only serialized product (*i.e.,* encoded by the manufacturer with a Product Identifier described earlier)**
- **May accept dispenser returns *"only if [they]…can associate the returned product with the transaction information... associated with that product"*** (emphasis added)
- **Other requirements also effective**

Polling Question

Has your organization communicated with wholesalers to discuss logistics and handling of TH/TI/TS?

A. Yes
B. No
C. Not sure

Recommendations for How Dispensers Could Work With Wholesale Distributors

- **Suggest discussing multiple topics, including**
  - Variability/clarity of DSCSA requirements
  - Handling large volumes of data associated with products
  - Varying dispenser needs and familiarity with the DSCSA
  - Technologies and processes for receiving and maintaining DSCSA required data
  - And much more…

Additional Resources

- **HDMA Website: http://www.healthcaredistribution.org/issues/pharmaceutical-traceability for HDMA Guidelines, Transaction Scenarios, past webinars, etc.**
- **HDMA's Events Website will display dates and location for the 2015 Traceability Seminar (available shortly) http://www.healthcaredistribution.org/events**
- **FDA DSCSA Website: http://www.fda.gov/drugs/drugsafety/drugintegrityandsupplychainsecurity/drugsupplychainsecurityact/ucm382022.htm for timelines, webinars, publications, etc.**

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Track and Trace: What it means for ASHP and its Members

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Objectives

1. Discuss the Drug Quality and Security Act (DQSA)
2. Describe the responsibilities of the wholesale distributor and the dispenser as it relates to the DQSA
3. Understand track and trace impact on 340B contract pharmacies
4. Identify the components included in a *Transaction History* (TH), *Transaction Information* (TI), and a *Transaction Statement* (TS).
5. Innovate methods to transmit, manage, and store TI, TH and TS.
6. Ensure interoperability of track and trace drug information technology.

Drug Quality and Security Act

Signed into law by President Obama on November 27, 2013

Adds new section 582(h)(2) to the Food Drug and Cosmetic Act (FD&C)

Purpose: to aid trading partners in identifying a suspect product and report illegitimate products

Drug Quality and Security Act

- ***Suspect product* is defined in section 581(21) of FD&C Act as a product that is believed to be:**
  1) Counterfeit, diverted, or stolen;
  2) Intentionally adulterated;
  3) Subject of a fraudulent transaction;
  4) Otherwise unfit for distribution;
- **Such that, the product would result in serious adverse health consequences or death to humans.**

Drug Quality and Security Act

- ***Trading Partners*** **include:**
  - Manufacturers
  - Repackagers
  - Wholesale Distributors
  - Dispensers

Requirements for Wholesalers

As of January 1st, 2015

Shall not accept ownership of product from manufacturer *without prior:*

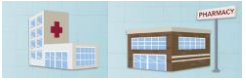
- **Transaction History** ;
- **Transaction Information** ; and,
- **Transaction Statements**; in a single paper or electronic form

Requirements for ***Dispensers***

Must have systems available to track, quarantine, investigate, retain samples, clear, notify others, and dispose of suspect or illegitimate products

Keep records of the drug investigation for at least 6 years from the conclusion of the investigation

Trade only with authorized trading partners



Polling Question

Each business must provide the TI, TH, and TS to the subsequent owner for each transaction, and capture and maintain for:

A. Five years if managed by wholesaler
B. Six years by buyers and sellers
C. Still being decided by FDA

Requirements for ***Dispensers***

Shall not accept ownership of product from wholesale distributor *without prior:*

- **Transaction History**;
- **Transaction Information**; and,
- **Transaction Statements**; in a single paper or electronic form

Requirements for ***Dispensers***

Must provide subsequent owner *with:*

- **Transaction History**;
- **Transaction Information**; and,
- **Transaction Statements**; unless the transaction is otherwise exempt or the sale is from dispenser to dispenser to fill a specific patient need.

Requirements for *Dispensers*

Must retain records of inbound and outbound TI, TH and TS, for **no less than 6 years** after the transaction.

Must respond to requests for TI, TH, and TS in the case of a recall or investigation of suspect or illegitimate product from the Secretary (or other appropriate Federal or State official) **within 2 business days** after the receipt of the request via paper or electronic form.

HOW WILL TRACK AND TRACE REGULATIONS AFFECT 340B CONTRACT PHARMACIES?

Exemption for 340B Ship to/Bill to Contract Pharmacy Arrangements

- **Request that the FDA:**
  1) Exempt Wholesale Distributors from sending the TI/TH/TS to the 340B Covered Entity Purchasing the Drug Product; and,
  2) Instead, require Wholesale Distributors to send *both* the TI/TH/TS and the Drug Products Solely to the Contract Pharmacy ; and,

Transaction Information (TI)

- Product Name
- Strength and Dosage Form
- NDC
- Container Size and Number
- Lot Number
- Transaction Date
- Shipment Date
- Name and Address of Previous and Subsequent Owner

Transaction History (TH)

Paper or electronic statement of transaction information for each transaction since manufacturing

Transaction Statement (TS)

Paper of electronic attestation by entity transferring ownership that states the product:

- Is authorized under the act
- Is being received from an authorized party
- Includes TI and TS from the previous owner
- Is not known to be suspect or illegitimate
- Is not known to have an altered transaction history or any false transaction information

Interoperability of Technology

- ✓ **Need a standardized and universal system across manufacturers, for wholesale distributors to capture unique parameter of product transaction**
- ✓ **If any parameter of the barcode scanned does not match, the software must alert recipient to suspect product illegitimacy**
- ✓ **Software must be able to scan inbound and outbound products and flag received products not intended for shipment, or products scanned multiple times in different places.**

Recommendations

Contact Wholesale Distributer

- How are they maintaining product tracking information?
- Is software available to allow access to track and trace product data?

Third Party Maintenance

- Establish and maintain a copy of a written third party agreement
- Third party to confidentially maintain the TI/TH/TS required under law

Stay Tuned…

- ASHP Webinar
- FDA response to request to issue exemption for 340B program
- Best Practices

Updates and Actions for Health System Pharmacy

Raymond Lake, R.Ph. M.S.

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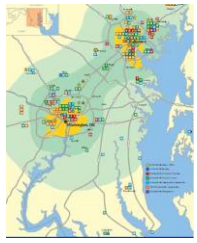
MedStar Health - Overview

MedStar Health

- **10 hospital IDN – MD/DC**
  - Net Operating Revenue $4.6B
  - 3,314 licensed beds
  - >4M orders per year
  - >10M doses administered per year
  - 30,000 associates, 6000 affiliated physicians
- **7 outpatient pharmacies**
- **Elkridge, MD site - Centralized IV Admixture Center (CIVAC)/home infusion pharmacy/ Centralized ADM fulfillment (MedAC)**



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Key Milestones for Dispensers

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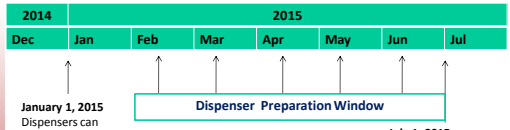

January 1, 2015
Dispensers can receive traceability data from trading partners

July 1, 2015
Dispensers receive TH, TI, TS.
FDA can request information from Dispensers

Also on January 1, 2015:
Manufacturers send, and distributors send and receive TH/TI/TS
Wholesale distributors report state licensure info. to FDA
Suspect and illegitimate product requirements in effect
Trading partners must be authorized/licensed

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Informational Needs

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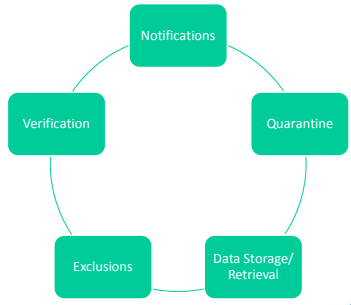

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Identification of Suspect Product or Verification

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1. Product Sourcing
2. Supply, Demand, History, and Value
3. Appearance of the Product
4. Strategies to ID Suspect Product
   a. Pricing
   b. Packaging
   c. Labeling

http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM400470.pdf

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Notifications

MedStar Health

1. **Notifications from FDA**
2. **Notification to FDA**
   a. beginning on January 1, 2015, trading partners must, as applicable, make notifications related to illegitimate product determinations.
   b. Use of FDA Form 3911
3. **Terminating Notification**
   a. Beginning January 1, 2015, trading partners must have in place systems to enable them to terminate notifications, in consultation with FDA, when appropriate
   b. Use of FDA Form 3911

See: http://www.accessdata.fda.gov/scripts/cder/email/drugnotification.cfm

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Polling Question

Has your organization started evaluating trading partners' plans to ensure compliance with the DSCSA?

A. Yes, all trading partners have been contacted
B. Yes, some trading partners have been contacted
C. No
D. Not Sure

Gaps to Consider

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Dispenser Preparatory Tasks

MedStar Health

Prior to July 1, 2015

- Develop Compliance P & P
- Work with internal Information Services to plan for storage/retrievability of TH, TI, TS
- Talk to your Wholesaler(s) - contract
- Talk to your Direct Vendors - contract
- Meet with 3PLs, contract if necessary
- Budget Prep
- Educate staff

Activity to Date

MedStar Health

- **HDMA Dispenser Panelist 11/14**
- **Discussions with peers – MNS**
- **3PL Demo Overview of Services**
- **3PL Demo**
- **Wholesaler discussions**
- **Direct Vendor discussions**
- **Listening to other vendor/consultant offerings**
- **P & P Draft**

Dispenser Policy & Procedure

MedStar Health

- **Regulatory compliance - KEY**
- **NDC item purchases outside of pharmacy (e.g.. Materials Mgmt, Lab, other)**
- **Loan/borrow situations external to system**
- **Data storage and retrieval requirements**
- **Quarantine process**
- **Verification systems**
- **Notification systems**
- **Specify exclusions**
- **Product returns to vendors**
- **Direct Purchasing – acquisition of TH, TI, TS**
- **Recordkeeping**

QUESTIONS