Understanding the Drug Supply Chain Security Act
And how it impacts your pharmacy
Disclosures

- Heather Zenk is an employee of AmerisourceBergen Corporation. 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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Learning Objectives

Following this presentation, attendees should be able to:

- Describe why the DSCSA law was passed.
- Describe the DSCSA legal requirements.
- Explain the role of the dispenser and how it is defined under DSCSA.
- Describe the technical process for receiving and storing the DSCSA required data.
- Explain returns and overages.
Agenda

- Background of the Drug Supply Chain Security Act
- Defining the Drug Quality and Security Act & Drug Supply Chain Security Act
- Dispenser Responsibilities
  - January 1, 2015
  - July 1, 2015

Regulatory details courtesy of the FDA and HDMA
State’s had a patch-work quilt of approaches to tracking Rx products through the supply chain.

Global serialization requirements were beginning to take shape which could potentially impact global commerce.

FDA wanted to preserve “pedigree” and get to a more robust, more transparent track-and-trace system.
What is the Drug Quality and Security Act

- As of January 1, 2015, manufacturers, re-packagers and wholesale drug distribution companies are required to provide any entity or enterprise that receives pharmaceutical products with a single document that includes transaction information, transaction history, and transaction statement. (TI, TH, and TS)
  - Pharmacies must have a process to capture and investigate suspect, illegitimate or counterfeit products.
  - All parties are required to be trading with an Authorized Trading Partner

- As of July 1, 2015, pharmacies and dispensers are required to accept and maintain the TI, TH, TS data.
  - Pharmacies and dispensers are required to obtain and hold the transactional data for a six-year period
Timeline for DSCSA

- **January 1, 2015**: Transactional Information Provided by Manufacturer, Wholesaler and Repackager
- **Manufacturers Serialize**
- **Wholesaler Accept/Sell Serialized Product and Validate Serialize Number on Saleable Returns**
- **State Preemption**
- **May 1, 2015**: FDA Enforcement Discretion Ends
- **July 1, 2015**: Transactional Information Accepted by Dispensers
- **Repackagers Serialize**
- **Federal Licensure Standards for Distributors Raised**
- **Dispensers Accept Serialized Product**
- **Phase II: Complete Traceability**

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What is the TI, TH, TS

<table>
<thead>
<tr>
<th>Transaction Information (TI)</th>
<th>Transaction History (TH):</th>
<th>Transaction Statement (TS):</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Name of the product</td>
<td>• Paper or electronic</td>
<td>• Paper or electronic</td>
</tr>
<tr>
<td>• Strength and dosage</td>
<td>statement</td>
<td>attestation by the entity</td>
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<tr>
<td>form of the product</td>
<td>includes the transaction</td>
<td>transferring ownership</td>
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<tr>
<td>• NDC</td>
<td>information for each</td>
<td>of the product that it:</td>
</tr>
<tr>
<td>• Container size</td>
<td>prior transaction</td>
<td>• Is authorized under the</td>
</tr>
<tr>
<td>• Number of containers</td>
<td>back to the manufacturer</td>
<td>Act</td>
</tr>
<tr>
<td>• Lot number**</td>
<td></td>
<td>• Received the product</td>
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<tr>
<td>• Transaction date**</td>
<td></td>
<td>from an authorized party</td>
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<tr>
<td>• Shipment date</td>
<td></td>
<td>• Received TI &amp; TS from</td>
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<td>• Name &amp; Address of the</td>
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<td>the previous seller</td>
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<td>businesses previous and</td>
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<td>• Did not knowingly ship</td>
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<tr>
<td>subsequent owner</td>
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<td>suspect or illegitimate</td>
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<td></td>
<td></td>
<td>product</td>
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<td>• Systems and processes</td>
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<td></td>
<td></td>
<td>in place to perform</td>
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<td></td>
<td></td>
<td>verification</td>
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<tr>
<td></td>
<td></td>
<td>• Did not knowingly provide</td>
</tr>
<tr>
<td></td>
<td></td>
<td>false transaction</td>
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<td></td>
<td></td>
<td>information and did not</td>
</tr>
<tr>
<td></td>
<td></td>
<td>alter the transaction</td>
</tr>
<tr>
<td></td>
<td></td>
<td>history</td>
</tr>
</tbody>
</table>

** Wholesalers that purchase directly from a manufacturer, an exclusive distributor of the manufacturer, or re-packager that purchased directly from manufacturer -- are exempt from passing the above (** data elements.

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What Products are Exempt

• Blood and blood components intended for transfusion
• Radioactive drugs and radioactive biologics
• Intravenous products
• Medical gas
• Compounded drugs
• Dispensing drugs pursuant to a prescription
• Medical convenience kits and combination products
• Sterile water and products intended for irrigation
Exemptions

• The legal mandate identifies all Rx items as “in scope” unless a manufacturer notifies the trading partner that an Rx item is exempt.

• Additionally, a listing of items determined to be exempt will be made available through customer-facing portals.
What is a Dispenser

• A retail pharmacy, hospital pharmacy, a group of chain pharmacies that do not act as a wholesale distributor, or any other person authorized by law to dispense or administer prescription drugs, and other entities under common ownership and control that do not act as a wholesale distributor.

• Does not include a person who dispenses only products to be used in animals.
What is a Wholesale Distributor

• A person (other than a manufacturer, a manufacturer’s co-licensed partner, a third-party logistics provider, or re-packager) engaged in wholesale distribution as amended by DSCSA.

• Wholesale distribution is distribution of an Rx product to an entity/person other than the patient.
What is a Manufacturer

• 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, or the person who manufactured the product.

• A co-licensed partner or an affiliate of the manufacturer that obtains the product directly from them.
DIRECT PURCHASE TO DISPENSER

MANUFACTURER

DISTRIBUTOR
(Direct Purchaser)

DISPENSER
( Including Practitioner)

KEY
PRODUCT  DATA  OWNERSHIP

Courtesy of HDMA
MULTIPLE DISTRIBUTORS

MANUFACTURER
(Direct Purchaser)

DISTRIBUTOR X

DISTRIBUTOR Y
(Not Direct Purchaser)

DISPENSER
( Including Practitioner )

KEY
PRODUCT
DATA
OWNERSHIP

Courtesy of HDMA
January 1, 2015 Requirements

• Your trading partners must be “authorized trading partners”.
• Must be able to verify suspect and illegitimate product.
• Must have a “system” in place to quarantine, investigate, notify, on suspect and illegitimate products.
What defines an authorized trading partner

• Authorized trading partner as defined by the FDA
  – Manufacturers/re-packagers must have a valid FDA registration.
  – Wholesalers/3PLs must have a valid State or Federal license.
  – Dispensers must carry a valid State license.
What is Verification

Determining whether the product identifier affixed to, or imprinted upon, a package or homogeneous case corresponds to the standardized numerical identifier and expiration date assigned to the product by the manufacturer or the re-packer.
What is a Suspect Product

• Suspect Product is a product for which there is reason to believe that such product:
  – Is potentially counterfeit, diverted, or stolen.
  – Is potentially intentionally adulterated such that the product would result in serious adverse health consequences or death to humans.
  – Is potentially the subject of a fraudulent transaction.
  – Appears otherwise unfit for distribution such that the product would result in serious adverse health consequences or death to humans.
How Do I Verify a Suspect Product

• If you determine that a product in the possession or control of the dispenser is a suspect product or are responding to a request for verification from the Secretary that a product within the possession or control of a dispenser is a suspect product, a dispenser shall --
  – Quarantine such product within the possession or control of the dispenser from product intended for distribution until such product is cleared or dispositioned.
  – Promptly conduct an investigation in coordination with trading partners to determine whether the product is an illegitimate product.
What Determines an Illegitimate Product

• Illegitimate product – a product for which credible evidence shows that the product:
  – Is counterfeit, diverted, or stolen.
  – Is intentionally adulterated such that the product would result in serious adverse health consequences or death to humans.
  – Is the subject of a fraudulent transaction.
  – Appears otherwise unfit for distribution such that the product would be reasonably likely to result in serious adverse health consequences or death to humans.
How Do I Handle Illegitimate Product

• Upon determining, in coordination with the manufacturer, that a product in the possession or control of a dispenser is an illegitimate product, the dispenser shall:
  – Disposition the illegitimate product within the possession or control of the dispenser;
  – Take reasonable and appropriate steps to assist a trading partner to “disposition” an illegitimate product not in the possession or control of the dispenser; and
  – Retain a sample of the product for further physical examination or laboratory analysis of the product by the manufacturer or Secretary (or other appropriate Federal or State official) upon request, as necessary and appropriate.
Cleared Product / Recordkeeping

- CLEARED PRODUCT: If the dispenser makes the determination that a suspect product is not an illegitimate product, the dispenser shall promptly notify the Secretary, if applicable, of such determination and such product may be further distributed or dispensed.

- RECORDS: A dispenser shall keep records of the investigation of a suspect product for not less than 6 years after the conclusion of the investigation.
July 1, 2015 Requirements

- You can receive and capture TI, TH, TS
  - Note: You may have a third party perform this function, in which third party maintains TI, TH, TS.
- TI, TH, TS must be maintained for 6 years.
- This does not relieve the dispenser of investigation or verification obligations.
- System in place to segregate and investigate suspect product.
- Verification process: quarantine, investigation, disposition, and notification.
How are Wholesalers Providing the Data

- The TI, TH, TS data is available via electronic portals.
- Long-term storage of the data may be commercialized.
- Some accounts are utilizing another method – of transmitting data – namely utilizing ASNs via EDI.
Third Party Maintenance

• You may enter into a written agreement with a third party, including an authorized wholesale distributor, under which the third party confidentially maintains the TI, TH, TS required under the law.

• You must maintain a copy of agreement.

• Third-party agreements shall not relieve you of the obligations to meet the laws requirements.
How are Returns Defined Under DSCSA

• The Returns process is the procedure of returning a product to the immediate authorized trading partner from which the product was purchased or received, or to a returns processor or reverse logistics provider for handling of the product.

• No TI, TH, TS is required with the above process.
Borrowing and loaning of Rx products – what’s different

- DSCSA requires that TI, TH, TS be provided upon a change of ownership between trading partners.
- Therefore, if customers loan product between pharmacies under different ownership, they would be accountable to provide the TI, TH, TS to the entity that is loaned the product.
- If the product being loaned is pursuant to a prescription one does not need to provide the TI, TH, TS.
- However, customers should seek out regulatory guidance as they see fit.
Questions?
Next Steps
Timeline for DSCSA

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2014

2015

2016

2017

2018

2019

2020

2021

2022

2023

Manufacturers Serialize

Wholesaler Accept/Sell Serialized Product and Validate Serialize Number on Saleable Returns

Repaggers Serialize

Dispensers Accept Serialized Product

Phase II: Complete Traceability

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