Protecting Patients

Pharmacists Requirements under the Drug Supply Chain Security Act

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U.S. Food and Drug Administration Webinar

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Disclaimer

This presentation is intended only to provide a general overview. It is not intended to be comprehensive nor does it constitute legal advice. Please refer to the appropriate guidances, regulations, or law for specific information.

FDA documents or notices summarized in this presentation can be found on our Drug Supply Chain Security Act webpage.
Objectives

• Provide overview and goals of the Drug Supply Chain Security Act (DSCSA).

• Describe dispensers’ current responsibilities under the DSCSA for product tracing, verification, and authorized trading partners.

• Describe dispensers’ future responsibilities under the DSCSA for product tracing and verification, utilizing the product identifier.

• Provide FDA resources for DSCSA law and policy, public meetings, webinars and implementation updates.
Protecting the supply chain ultimately protects patients!
Overview of the DSCSA

Title II: Drug Supply Chain Security Act (DSCSA) adds new sections in the Federal Food, Drug and Cosmetic Act (FD&C Act)

- 581 – Definitions
- 582 – Requirements (product tracing, product identification, verification)
- 583 – Standards for licensure of wholesale distributors
- 584 – Standards for licensure of third-party logistics providers (3PLs)
- 585 – Uniform national policy
Dispenser (Pharmacy)

• A retail pharmacy, hospital pharmacy, or a group of chain pharmacies under common ownership or control, or any other person authorized by law to dispense or administer prescription drugs, and the affiliated warehouses or distribution centers of such entities.

• Excludes:
  – if such entity acts as a wholesale distributor;
  – a person who only dispenses products used with animals.

Refer to definition for “dispenser” in section 581(3) of the FD&C Act.
## DSCSA goals

1. **Implement an interoperable, electronic tracing of products at the package level by 2023 that will:**

| Facilitate electronic exchange of transaction information for each sale of prescription drugs | Use product identifiers to verify product at the package level | Enable prompt response to suspect and illegitimate products when found | Improve efficiency of recalls |

2. **Establish national standards for licensure for wholesale distributors and third-party logistics providers.**
The DSCSA Path

- 3PL and WDD reporting to FDA 2014-2015
- Product tracing, Verification and Authorized trading partners 2015
- Product identification (serialization) 2017-2018
- Product verification (down to package level) 2019+
- Licensure standards for 3PLs and WDDs 2023
- Electronic, interoperable system (product tracing down to package level) 2023
Trading partners under DSCSA

- Manufacturers
- Repackagers
- Wholesale Distributors (WDDs)
- Dispensers (Pharmacies)
- Third-party logistics providers (3PLs)
Products

• What’s covered:
  – Prescription drug in finished dosage form for administration to a patient without further manufacturing (such as capsules, tablets, lyophilized products before reconstitution)

• What’s not covered:
  – Blood or blood components intended for transfusion
  – Radioactive drugs or biologics
  – Imaging drugs
  – Certain IV products
  – Medical gas
  – Homeopathic drugs
  – Lawfully compounded drugs

Refer to the definition for “product” in section 581(13) of the FD&C Act for specific information regarding exceptions.
Transactions

- Involve transfers of product where a *change of ownership* occurs
- Excludes:
  - Intracompany distributions
  - Distribution among hospitals under common control
  - Public health emergencies
  - Dispensed pursuant to a prescription
  - Product sample distribution
  - Blood and blood components for transfusion
  - Minimal quantities by a licensed pharmacy to a licensed practitioner
  - Certain activities by charitable organizations
  - Distributions pursuant to a merger or sale
  - Certain combination products
  - Certain medical kits
  - Certain IV products
  - Medical gas distribution
  - Approved animal drugs

Refer to the definition for “transaction” in section 581(24) of the FD&C Act for specific information regarding exclusions.
Authorized trading partners

Verification

Product tracing

DSCSA

Product identification (serialization)
## Trading partners must be *authorized*

<table>
<thead>
<tr>
<th>Manufacturers and Repackagers</th>
<th>WDDs and 3PLs</th>
<th>Dispensers (Pharmacies)</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Have valid registration with FDA</td>
<td>• Have valid State or Federal license and compliance with reporting requirements</td>
<td>• Have valid State license</td>
</tr>
<tr>
<td>• Check FDA’s drug establishment current registration site database (DECRS)</td>
<td>• Check FDA’s WDD/3PL database</td>
<td>• Check respective state authorities</td>
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</tbody>
</table>
Wholesale Distributor and Third-Party Logistics Providers Reporting

About this Database

Please search using at least one criterion below.

Facility Name: Facility Name

Facility Type: All

Facility Address (State): Select location

Facility License (State): Select license state

Search Reset

Database Last Updated: Monday, May 7, 2018
## Guidance: Identifying trading partners

<table>
<thead>
<tr>
<th><strong>Manufacturers</strong></th>
<th>Manufacturing establishments, application holders, co-licensed partners, affiliates</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Repackagers</strong></td>
<td>Does not include a pharmacy solely engaged in packaging/labeling for an identified patient after receipt of a valid Rx</td>
</tr>
<tr>
<td><strong>WDDs</strong></td>
<td>Differences in the definition of wholesale distribution in PDMA and DSCSA, some entities are now 3PLs</td>
</tr>
</tbody>
</table>
| **3PLs**          | • “Other logistic services”  
                   | • Not brokers, solution providers, common carriers, etc. |
| **Dispensers**    | No product tracing requirements if product is dispensed to a patient or if it is a dispenser to dispenser sale to fulfill a specific patient need |
# How to handle product tracing documentation

| Receive | Only accept prescription drugs with product tracing information:  
1) Transaction Information (TI)  
2) Transaction History (TH)  
3) Transaction Statement (TS) |
|---------|------------------------------------------------------------------|
| Provide | --Generate and provide product tracing information with each transaction if you sell a prescription drug to another trading partner.  
--You do not need to provide product tracing information when you dispense a prescription drug to a patient or you sell to a pharmacy for dispensing to a specific patient. |
| Respond | Respond to a request for information within 2 business days, in the event of a recall or to investigate a suspect or illegitimate product. |
| Store   | Store product tracing information you receive in paper or electronic format for at least 6 years. |
| Return  | Return product to the trading partner that you bought the drug from |
Guidances: Standards for product tracing

Standards for the Interoperable Exchange of Information...How to Exchange Product Tracing Information

- Can use or build on current systems and processes to comply with requirements
- Paper- or electronic-based
- Examples of methods that could be used include, but are not limited to:
  - Invoices, packing slips and electronic data interchange standards (ex. Advance Ship Notice and Electronic Product Code Information Services)
- Email or web-based platforms are acceptable, as long as the information that is captured, maintained, and provided is in compliance with the law

Standardization of Data and Documentation Practices for Product Tracing

- Recommends how to standardize the data contained in product tracing information (TI, TH, TS)
- Describes data elements that should be including in product tracing information, including situations where it is permitted by law for certain data to be omitted
  - Dispenser to dispenser sales to fulfill a specific patient need
  - Drop shipments to a dispenser
  - Grandfathered product
- Use of third-party agreements
Investigate and properly handle suspect and illegitimate products

Suspect Product: *reason to believe* that product potentially is:

- counterfeit, diverted, stolen
- subject of fraudulent transaction
- intentionally adulterated or appears otherwise unfit for distribution such that would result in serious adverse health consequences or death to humans

Illegitimate Product: *credible evidence* shows that the product is:

- counterfeit, diverted, stolen
- subject of fraudulent transaction
- intentionally adulterated or appears otherwise unfit for distribution such that would result in serious adverse health consequences or death to humans

www.fda.gov
Identifying suspect product: Examples of what to look for...

- Altered product info
- Missing info on label
- Looks different than product on shelf
- No “Rx only” symbol
- Bubbling on the label
- Foreign language
- Lot numbers or expiration dates do not match the outer/inner container
- Missing or wrong package inserts
- Damaged, broken seal, open package
- Different product name than FDA approved version
Verification requirements

- **Quarantine and Investigate**: Suspect prescription drugs to determine if illegitimate

- **Investigation**: --Must include validating applicable transaction information and transaction history
  --Starting 2020: Verify lot number and product identifier

- **Notify**: If the product is illegitimate, notify FDA and trading partners that you bought the drug from and sold it to, within 24 hours

- **Respond**: If the product is illegitimate, work with manufacturer to take steps to prevent it from reaching patients

- **Store**: Store records of investigation of suspect product and the disposition of illegitimate product for at least 6 years
Identification of Suspect Product and Notification

Guidances: Verification

Guidances: Verification

Identifies scenarios that increase risk of suspect product entering the supply chain:
• recommendations on how to identify and make determination of suspect product
• sets forth process to notify FDA and consult with FDA to termination notifications about illegitimate product

Definitions of Suspect Product and Illegitimate Product for Verification Requirements

Clarifies FDA interpretations of terms within the definitions:
• counterfeit, diverted, subject of fraudulent transaction, unfit for distribution
• aids in determining when to report an illegitimate product to FDA
Notify FDA if you have illegitimate product

<table>
<thead>
<tr>
<th>DEPARTMENT OF HEALTH AND HUMAN SERVICES</th>
<th>Form Approved: OMB No. 0910-0600</th>
</tr>
</thead>
<tbody>
<tr>
<td>Drug Notification</td>
<td>Expiration Date: December 31, 2018</td>
</tr>
</tbody>
</table>

Refer to instruction sheet (Form FDA 3911 Supplement) for more information.

1. Type of Report (Select one): □ Initial Notification □ Follow-Up Notification □ Request for Termination

2. Incident Number (Provide this number, assigned by FDA, if you selected Follow-up Notification or Request for Termination above; see instructions.)

3. Date of Initial Notification (mm/dd/yyyy)

4. Date Company Determined Product Was Illegitimate (mm/dd/yyyy)

5. Classification of Notification (Select from list)

6. Name of Product as It Appears on Label

7. Primary Ingredient(s) (if known)

8. Drug Use (Select from list)

9. Drug Description (Select from list)

10. Strength of Drug

11. Dosage Form (Select from list)

12. Quantity of Drug (Number and Unit)

13. NDC Number (if applicable)

14. Serial Number (if applicable)

15. Lot Number(s)

16. Expiration Date(s)

17. For Notification: Description of Event/Issue

18. For Request for Termination of Notification: Description of why notification is no longer necessary

19. If you have submitted information to FDA through an alternative mechanism, check all that apply.
   □ BPDOR □ MedWatch 3500 □ None
   □ FAR □ MedWatch 3500DA □ Other (Specify):

FORM FDA 3911 (12/15) Page 1 of 2

www.fda.gov

Notify FDA within 24 hours using Form FDA 3911

Notify other trading partners within 24 hours

Request notification termination using Form FDA 3911
Product identifier - Serialization

November 2018: Manufacturers/Repackagers

- Place product identifiers on prescription drug packages
  --- Determine smallest individual saleable unit
  --- Human and machine readable format

November 2020: Dispensers

- Can only buy/sell product that is serialized

What is the Product Identifier?

- National Drug Code (NDC)
- Serial Number
- Lot Number
- Expiration Date

Barcode: 2D data matrix
## Packages Without Product Identifiers

**Excluded Products**

Not all prescription drugs are required to have a product identifier and are excluded.

**Grandfathered**

Some products will be in the supply chain before the product identifier requirement took effect.

**Waiver or Exempt**

Some products were granted a waiver or exemption from the product identifier requirement.

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If you are unsure whether a product should have a product identifier, verify with the manufacturer or repackager.
Protect your patients

Prevent harmful drugs from entering the supply chain.

Detect harmful drugs if they enter the supply chain.

Respond rapidly when harmful drugs are found.

www.fda.gov
The DSCSA Path

Product tracing, Verification and Authorized trading partners 2015

3PL and WDD reporting to FDA 2014-2015

Product identification (serialization) 2017-2018

Product verification (down to package level) 2019+

Electronic, interoperable system (product tracing down to package level) 2023

Licensure standards for 3PLs and WDDs
Resources

• DSCSA webpage

• DSCSA regulatory documents (i.e., regulations, guidances, federal register notices, pilot programs)
PROTECT YOUR PATIENTS

Know your responsibilities under the Drug Supply Chain Security Act

The Drug Supply Chain Security Act (DSCSA) includes requirements that pharmacies must follow to protect patients from receiving harmful drugs, such as counterfeit or other illegitimate drugs.

The DSCSA was enacted in 2013 to further secure our nation’s drug supply. It creates a tighter, closed prescription drug distribution system to prevent harmful drugs from entering the supply chain, detect harmful drugs if they do enter the supply chain, and enable rapid response when such drugs are found.

By law, pharmacies are required to:

Confirm the entities you do business with are licensed or registered
To help determine whether trading partners who you do business with (manufacturing, repackers, wholesale distributors, third-party logistics providers, and pharmacies) are licensed or registered:

- Check the registration of manufacturers and repackers. See FDA’s drug establishments current registration site database to confirm registration. You can find this database by searching for DECRS at www.fda.gov.

- Check the licensing of wholesale distributors and third-party logistics providers. See FDA’s wholesale-drug distributor and third-party logistics providers reporting database. You can find this by searching for WDD/3PL database at www.fda.gov.

- Check the licensing of pharmacies through the respective state authority.

Receive, store, and provide product tracing documentation
The law requires drugs to be traced as they move through the supply chain, and pharmacies must:

- Only accept prescription drugs that are accompanied by three pieces of product tracing documentation – transaction information, transaction history, and transaction statement. If the trading partner you purchased the drugs from does not provide all this documentation, work with them to promptly get it.

- Store the product tracing documentation you receive in paper or electronic format for six years.

- Generate and provide all product tracing documentation with the transaction if you sell a prescription drug to a trading partner. You do not need to provide this information when you dispense a prescription drug to a patient or if you sell to a pharmacy for dispensing to a specific patient.

Investigate and properly handle suspect and illegitimate drugs
Pharmacies must have a process to investigate and handle suspect and illegitimate prescription drugs, which includes drugs that may be or have evidence that it is counterfeit, diverted, stolen, intentionally adulterated, or unfit for distribution, including steps to:

- Quarantine and investigate suspect prescription drugs to determine if they are illegitimate; and

- If they are illegitimate, pharmacies should work with the manufacturer and take specific steps to ensure patients do not receive the illegitimate drugs. Pharmacies must also notify FDA and the trading partners they bought the drug from and sold the drug to.

You can find more information by searching “drug notifications” at www.fda.gov.

This information is only a summary of the DSCSA pharmacy requirements and is not a comprehensive list. Go to www.fda.gov to learn more about DSCSA, including the law and FDA’s policies. You’ll easily find information by searching “DSCSA”
Key takeaway messages

- Confirm that the entities that you do business with are registered or licensed
- Receive, store, and provide product tracing documentation
- Investigate and properly handle suspect and illegitimate drugs

Be vigilant and diligent!!
QUESTIONS?

Thank You!