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+ PHARMACY

Drug Supply Chain Security Act (DSCSA)
Essential Steps to Complying with the Regulations

October 6, 2020

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Things you should know

1. I'm not a pharmacist
2. We are not regulatory experts
3. HRG does not manufacturer or distribute pharmaceuticals
4. HRG does not own or manage pharmacies

But …

1. I've personally been in the industry for nearly 29 years
2. I work for one of the most respected independent pharmacy partner organizations – in its 40th year!
3. I'm very passionate about the success of community pharmacists

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Discussion topics

- Basic DSCSA Requirements
- Steps to Compliance
- Quarantine Procedures
- Wrap-up & Action Steps
- Questions / Discussion

AGENDA

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Basic DSCSA Requirements

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DSCSA objective

What is the objective of DSCSA?

Implement an interoperable, electronic tracing of products at the package level by 2023:

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

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Basic terminology

Who is a Dispenser?

- Dispensers are pharmacies. However, to make sure we're all on the same page (and that you know if the law applies to you), here's how the DSCSA defines "dispenser":
  - A retail pharmacy, hospital pharmacy, a group of chain pharmacies under common ownership and control that do not act as a wholesale distributor, or any other person authorized by law to dispense or administer prescription drugs, and affiliated warehouses or distribution centers of such 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.

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Basic terminology

What drugs are covered?

- Products: Prescription drug in finished dosage form for administration to a patient without further
- Excluded products:
  - ✓ OTC
  - ✓ Medical Devices
  - ✓ API
  - ✓ Medical gases
  - ✓ Homeopathic drugs
  - ✓ Compounded drugs

  - ✓ Drugs indicated for animal use
  - ✓ Blood and blood components for transfusion
  - ✓ Radioactive drugs and radioactive biologics
  - ✓ Imaging drugs
  - ✓ Intravenous products

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DSCSA basic elements

The law requires **ALL** drugs be traced as they move through the supply chain, and pharmacies must:

- Only accept prescription drugs accompanied by three pieces of documentation – transaction information, transaction history, and transaction statement (T3).
- Store product tracing documentation received for a minimum of six years.
- Generate and provide all product tracing documentation with the transaction if you sell a prescription drug to a trading partner.

Note: 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.

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Key milestone dates

July 2015

- For **every** transaction, they're required to exchange "product tracing information" that includes three things – referred to as T3

Nov 2016 – Nov 2019

1. Confirm trading partners are licensed or registered
2. Receive, store, and provide product tracing documentation
3. Investigate and properly handle suspect and illegitimate drugs

Nov 2020

- Buy and sell only products encoded with product identifiers (PIs)
- Verify every product at the package level, including the SNI

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Elements of DSCSA Compliance

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	Review your current status

For most of you, you likely already have processes, procedures, and equipment in place to fulfill your part of the Drug Supply Chain Security Act (DSCSA).

If so, this should be review and confirmation.

If not, this serves as a reminder that DSCSA **IS** a law requiring your compliance.

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Step One	Verify trading partners

Pharmacies must verify that all trading partners have a valid license and are registered per federal and state law.

Protocols should be established for routine verification for <u>all </u>trading partners. To verify licensure, search the WDD/3PL database at www.FDA.gov or your state licensing agency (link below).

https://www.fda.gov/drugs/drug-supply-chain-integrity/verify-wholesale-drug-distributor-licenses

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Step Two   Report suspicious products

Pharmacies are required to identify and report suspicious products that may be illegitimate. Procedures are required to:

- Identify suspect product currently in inventory and among new products
- Inform trading partners about suspect product
- Quarantine suspect product from regular inventory
- Remove illegitimate product from the supply chain
- Notify the FDA and all trading partners within 24 hours after determining that a product is illegitimate

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Step Three   Capture and retain T3 data

1. **Transaction information**
   Includes the name of the product, strength and dosage form, NDC, container size, number of containers, transaction date, shipment date, name and address of the seller and buyer, and lot number, if applicable.

2. **Transaction history**
   This is a paper or electronic statement that includes the transaction information for each prior transaction of the product back to the manufacturer.

3. **Transaction statement**
   This is a paper or electronic attestation transferring ownership of the product.

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Step Four — Only accept products with unique identifier

A product identifier is a standardized graphic that includes:

- Standardized numerical identifier
  (the NDC and a unique alphanumeric serial number)
- Lot number
- Expiration date

This info must be in both human- and machine-readable formats. The machine-readable format must include two-dimensional data matrix barcode for packages and a linear or two-dimensional data matrix barcode for homogenous cases.

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Only accept products with unique identifier

What is a 2D bar code?

Two-dimensional (**2D**) barcodes look like squares or rectangles that contain many small, individual dots.

A single **2D barcode** can hold a significant amount of information and may remain legible even when printed at a small size or etched onto a product.

NDC 1234-5678-90

Product Name & Contents
000 mg

2D Barcode
GTIN 00312345678906
SN 12345678
EXP JUN 2042
LOT ABC123

GTIN 14
Serial Number
Expiration Date
Lot Number

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Quarantine Best Practices

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Examining quarantine procedures

Pharmacies (dispensers) 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, stolen, diverted, 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.

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Identify ⊘

- Suspected product – reason to believe product is potentially:
  - Counterfeit, diverted, stolen
  - Subject to fraudulent transaction
  - Intentionally adulterated or appears otherwise unfit for distribution
- Illegitimate product – credible evidence that the product is any of the above

Scenarios that warrant attention:

- Purchasing from a new source
- Receiving an unsolicited sales offer from an unknown source
- Purchasing from an unknown Internet source
- Purchasing from a source that is known to have transacted business involving suspected product
- High demand products
- Products that are on the FDA's counterfeit or cargo theft alert

https://www.fda.gov/media/88790/download

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Quarantine

- Have written policies and procedures in place
- Ensure all are on the same page and understand the SOPs
- Clearly define responsibilities in the event of a quarantine situation
- Consistently follow the protocol and adhere to your procedures

http://www.ncpa.co/pdf/sop-track-trace.pdf

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Investigate

- Closely inspect the package and transport package
- Closely examine the label on the package and the unit
- Validate the 3T information you were given
- Ensure you are adhering to your standard operating procedures
- Keep records of investigations for not less than 6 years after conclusion of your investigation

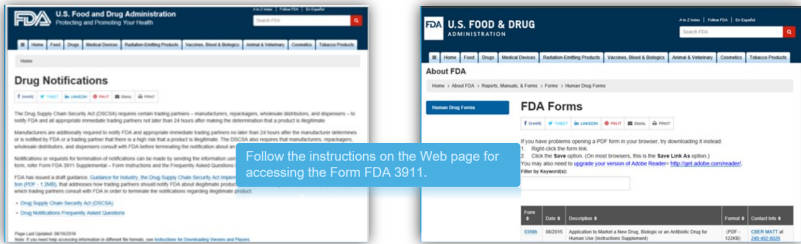**Examples of suspect or illegitimate product:**

- Altered product information
- Missing information on the label
- Looks different than product on shelf
- No "Rx only" symbol
- Bubbling on label
- Foreign language
- Lot numbers or expiration dates do not match outer/inner container
- Missing or wrong package inserts
- Damaged or broken seal
- Open package
- Different product name than FDA version

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Notify

- Upon determination of an illegitimate product one is to notify the FDA **and** all immediate trading partners not later than **24 hours** after making the determination
- Upon request by Federal or State officials, in the event of a recall or for the purpose of investigating a suspect or illegitimate product a dispenser shall provide information not later than **two business days**

Follow the instructions on the Web page for accessing the Form FDA 3911.

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Example SOP

- Investigational product (IP) must be placed in quarantine when it is deemed potentially unfit for use.
    - Reasons for being potentially unfit for use include, but are not limited to:
        - Beyond expiration/retest date
        - Improper storage conditions (i.e., temperature excursion)
        - Visible damage or contamination
        - Product recall
        - Manufacturer/wholesaler request
- Quarantined product will be physically separated from viable inventory, and clearly labeled as "Quarantined."
- Quarantined product will be removed from inventory and designated as such.
- Quarantined product will remain in quarantine pending investigation.

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Moving forward

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Frequently Asked Questions

- Does the law apply to community pharmacy?
- Has the law been postponed due to COVID?
- What is the T3 data and where is it available?
- Are over-the-counter medicines exempt?
- Is it necessary to store lot numbers?
- Isn't the data already stored by my primary wholesaler?
- When a product is recalled, do we need to provide the transaction data?
- If a product is 'borrowed' by another pharmacy must transaction data be provided?
- Do I need to track what drugs are dispensed at the patient level?

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Action steps

- ✓ Review requirements of the law – and ensure you are complying
- ✓ Verify you are only purchasing from Authorized Trading Partners
- ✓ Doublecheck that you are storing – and can access – T3 transaction data
- ✓ Document and test quarantine procedures (everyone on the same page)
- ✓ Familiarize yourself and your team with the 2D barcode matrix (make sure you are only receiving Rx product, unless otherwise exempt, with this identifier as of November 27)
- ✓ Continue to educate yourself on the law and its requirements
- ✓ Seek assistance if you need help:
  - Track and trace partner
  - SOP readiness
  - Pharmacy/workflow redesign
  - Staff education/knowledge training
  - 2D barcode set-up and operation
  - Operational integration

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questions?

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