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Drug Supply Chain Security Act (DSCSA) 2023 - Are you Ready?

Hilda Gurley, JD, RPh
Attorney/Pharmacist/Compliance Strategist
Pharmacy Compliance Strategies, LLC

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Learning Objectives

- Describe the history of DSCSA regulation in the United States.
- Examine the current requirements of DSCSA and their purpose as they apply to your pharmacy.
- Discuss the requirements that go into effect in November, 2023 and how they apply to your pharmacy.

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Disclosures

My spouse/partner or I do not have any relevant commercial interests with any organization or institution whose products or services are being discussed in this learning activity.

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Drug Supply Chain Security Act (DSCSA)

- Introduction to DSCSA and History
- Dispenser Requirements
  - Authorized Trading Partners
  - Product identifier
  - Product Tracing Requirements
  - Waivers
  - Exceptions
  - Exemptions
  - Verification/Investigation
    - Cleared Product
    - Product Not Cleared
    - Notification
- Enhanced Drug Distribution Security
- Product Identifiers/Investigation of Suspect Product
- Sunset

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Drug Quality and Security Act (DQSA)

- **Drug Quality and Security Act (DQSA) - Enacted November 27, 2013**
  - Title I of DQSA – Compounding Quality Act
    - followed 2012 New England Compounding Center fungal meningitis outbreak
    - national registration system for outsourcing facilities
    - compounding guidelines for health systems and pharmacies that are not outsourcing facilities
  - Title II of DQSA - the Drug Supply Chain Security Act (DSCSA)
    - Mandates a ten-year, step-by-step process for building an electronic, interoperable system for identifying and tracing prescription drugs as they move through the United States supply chain

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Drug Supply Chain Security Act (DSCSA)

- **Title II of DQSA - the Drug Supply Chain Security Act (DSCSA)**
  - Requires that FDA establish national licensure standards for wholesale distributors and third-party logistics providers
    - Annual reporting of licensure and other information to FDA
  - Requires identification and tracing of drugs through the supply chain
    - Makes it easier to detect and remove potentially dangerous drugs from the supply chain
    - Protects patients from counterfeit, stolen, contaminated, or otherwise harmful drugs

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DSCSA History

- History of delays in enforcement due to industry concerns
  - As expressed by FDA
    - "concern with industry-wide readiness"
    - "challenges with implementation"
    - "capabilities and readiness"
- "some dispensers – primarily smaller, independent pharmacies and health systems … unable to comply"
    - "additional time to work with trading partners"

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DSCSA History

- Additional enforcement discretion with respect to
  - a dispenser who transfers ownership of a product directly to a first responder without providing product tracing information, if certain conditions are met
  - a trading partner who conducts business with a first responder that is not "authorized" as a dispenser
  - a first responder who does not comply with certain provisions of DSCSA
- Historic of DSCSA reflects the enormity of the undertaking and the challenges and driving technology

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DSCSA Requirements

- Requirements apply to authorized participants in the "legitimate" supply chain
  - Manufacturer
    - Wholesale distributor
      - Repackager
        - **Dispenser (e.g., pharmacies)**

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Authorized Trading Partners

Purpose: to restrict access to the prescription drug distribution system

Dispensers can only trade with:

- Manufacturers or repackagers who are validly registered
- Wholesale distributors and third-party logistics providers who are licensed by the State (or federal government) and comply with licensure reporting requirements
- Dispensers who have a valid state license

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Authorized Trading Partners

- If in doubt as to trading partner status, check or make inquiries.
  - Wholesale Distributor and Third-Party Logistics Providers Reporting https://www.accessdata.fda.gov/scripts/cder/wdd3plreporting/index.cfm https://www.accessdata.fda.gov/cder/wdd_3pl_facilities_report.txt
  - Drug Establishments Current Registration Site (manufacturers, compounders, processors) https://www.fda.gov/drugs/drug-approvals-and-databases/drug-establishments-current-registration-site
  - State Board of Pharmacy License Lookup Pages

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Product Identifier

Purpose: to facilitate the tracing of product through the distribution chain, make sure the product is legitimate

Dispenser may not engage in transactions unless product is encoded with a product identifier (unless grandfathered per grandfathering policy or otherwise exempted)

- Product identifier includes product's standardized numerical identifier, lot number, and expiration date
  - standardized numerical identifier uniquely identifies each package or homogenous case
  - NDC plus unique alphanumeric serial number, up to 20 characters
- Human-readable or machine-readable

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Tracing Requirements

Purpose: to facilitate the tracing of product through the pharmaceutical distribution supply chain

Dispensers may only accept ownership of drugs for which the previous owner provides:

- Transaction information
- Transaction history
- Transaction statement

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Tracing Requirements

- **Transaction information**
  - Product name, strength, dosage form, NDC and lot number
  - Container size, number of containers
  - Transaction date, shipment date (if more than 24 hours after transaction date)
  - Seller/Transferor and buyer/transferee business name and address

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Tracing Requirements

- **Transaction history**
  - paper or electronic record (initially)
  - transaction information for each prior transaction (back to product manufacturer)
- **Transaction statement**
  - Statement in paper or electronic form (initially) that the transferor
    - is "authorized" (registered or licensed)
    - received the product, transaction information and a transaction statement from an authorized party
    - did not knowingly ship a suspect or illegitimate product, provide false transaction information or alter the transaction history
    - **had systems and processes in place to comply with DSCSA verification requirements**

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Tracing Requirements

Dispensers who transfer ownership of a product must provide the subsequent owner with transaction history, transaction information and transaction statement .

- Does not apply to:
  - sale by one dispenser to another for a specific patient need
    - meaning - to fill a prescription for an identified patient
    - NOT transferring product to stock in anticipation of a potential need
  - dispensing to a patient
  - returning product

Dispensers must capture all three documents as necessary to investigate a suspect product.

- Maintain for not less than 6 years after the transaction.

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Tracing Requirements

Notable "Transaction" Exemptions

- Intra-company distributions between affiliates
  - power to control or common control
- Distribution among hospitals or other health care entities under common control
- Distribution for emergency medical reasons
  - e.g., distribution of FDA-approved naloxone products to harm reduction programs and to harm reduction suppliers during the opioid public health emergency
  - NOT drug shortage unless caused by a public health emergency

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Tracing Requirements

Notable "Transaction" Exemptions (cont'd)

- Dispensing pursuant to prescription
- Distribution of samples by manufacturer or distributor
- Distribution of blood or blood components for transfusion
- Distribution of minimal quantities by retail pharmacy to practitioner for office use
- Transfers by charitable organization to nonprofit affiliate

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Tracing Requirements

Notable "Transaction" Exemptions (cont'd)

- Distribution pursuant to sale or merger of pharmacy(ies)
  - Any required records must be transferred to the new owner
- Products transferred to or from a Nuclear Regulatory Commission-licensed facility
- Distribution of IV products
  - For replenishment of fluids and electrolytes or calories
  - To maintain the equilibrium of water and minerals (e.g., dialysis solutions)
- Distribution of products for irrigation, or sterile water
- Distribution of a medical gas

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Tracing Requirements

Acceptable to have a third party (such as an authorized wholesale distributor) confidentially maintain the transaction information, transaction history, and transaction statements on dispenser's behalf. However,

- Dispenser must maintain a copy of the written agreement
- Dispenser is not relieved of its obligations
- Contract carefully

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Tracing Requirements

Requests for information

- FDA or State official may request transaction information, transaction statement, and transaction history
  - in the event of a recall
  - to investigate a suspect or illegitimate product
- Dispenser must respond electronically or on paper within 2 business days or as requested

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Waivers

A waiver from any of these requirements may be requested of FDA

Criteria:

- requirement would result in an undue economic hardship or
- emergency medical reasons, including a public health emergency declaration

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Exceptions From Product Identifier Requirements

An exception from the product identifier requirements may be determined by FDA, or requested, if a product's package:

- is too small or
- otherwise cannot accommodate a label large enough for the required information

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Exemptions

FDA may exempt other products or transactions from these requirements

Example - DSCSA Exemptions for Covered COVID-19 Products – May 11, 2023

- In order to:
  - transition after the end of the COVID-19 Public Health Emergency and
  - avoid supply chain disruptions that could impact COVID-19 response and recovery
- Dispensers are exempted from the following requirements for covered COVID-19 products introduced into commerce before November 27, 2024:
  - Product tracing requirements and product identifier requirements
  - Requirement to verify a portion of suspect products at the package level
  - Requirement to validate transaction history and transaction information to investigate a suspect product when responding to an illegitimate product notification

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Verification/Investigation

Purpose: to identify and remove from commerce drugs that are counterfeit, diverted, stolen, adulterated or unsafe

You SHOULD HAVE systems AND PROCESSES in place to comply with quarantine and investigation requirements for suspect and illegitimate products.

Per FDA draft guidance, March, 2022, a "system" is "a coordinated body of processes and procedures that forms an organizational scheme."*

If you have nothing written, GET SOMETHING!

*Verification Systems Under the Drug Supply Chain Security Act for Certain Prescription Drugs

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Verification/Investigation

Suspect product

A product that there is reason to believe

- is potentially counterfeit, diverted, or stolen
- is potentially intentionally adulterated such that it would result in serious adverse health consequences or death to humans;
- is potentially the subject of a fraudulent transaction; or
- appears otherwise unfit for distribution such that the product would result in serious adverse health consequences or death to humans.

There is FDA guidance to help you determine whether a product is suspect (below).

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Verification/Investigation

Illegitimate product

A product that credible evidence shows

- 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; or
- appears otherwise unfit for distribution such that the product would be reasonably likely to result in serious adverse health consequences or death to humans.

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Verification/Investigation

Suspect Product

- If you determine that a product in your possession or control is a suspect product

or

- If you receive a request for verification from FDA that has determined that a product in your possession or control is a suspect product,

as a dispenser, you must:

- quarantine the product; and
- conduct an investigation with assistance of trading partners as needed to determine whether the product is an illegitimate product.

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Verification/Investigation

Suspect Product

- The investigation should include:
  - Beginning November , 2020 - verifying whether the lot number of the suspect product corresponds with the lot number for the product;
  - Beginning November, 2020 - verifying that the product identifier of at least the greater of 3 packages or 10 percent of the suspect product (all packages if fewer than 3) corresponds with the product identifier for the product;
  - HOWEVER, October, 2020 Compliance Policy/Guidance
    - FDA delayed, until November 27, 2023, enforcement against dispensers who do not verify the product identifiers of suspect product

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Verification/Investigation

Suspect Product

- The investigation should also include:
  - validating any applicable transaction history and transaction information in your possession; and
  - otherwise investigating to determine whether the product is an illegitimate product.

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Cleared Product

Suspect product

- If you determine that the suspect product IS NOT illegitimate, promptly notify HHS, if applicable.
- The product may be distributed or dispensed.
- Records of the investigation must be kept for at least 6 years after conclusion of the investigation.

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Product Not Cleared

Illegitimate product

- If you determine, in coordination with the manufacturer, that a product in your possession or control IS an illegitimate product, you must
  - remove the product from the supply chain (e.g., by disposal or returning for disposal)
  - assist a trading partner in removing the product from the supply chain
  - retain a sample of the product for further physical examination or laboratory analysis by the manufacturer or appropriate Federal or State official upon its request, as necessary and appropriate
  - notify FDA, and all immediate trading partners you have reason to believe may have received the illegitimate product, not later than 24 hours after your determination.

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Notification

Illegitimate product

- If you receive notification from FDA or a trading partner that a product has been determined to be illegitimate, you must
  - identify all of the illegitimate product in your possession or control
  - treat it like a suspect product (quarantine, investigation, etc.).
- You must have in place a system to enable you to terminate notifications, in consultation with FDA.
  - If you determine, in consultation with the FDA, that a notification is no longer necessary, you must
    - promptly notify your immediate trading partners that the notification has been terminated.
- Document everything well!
- Record-retention - records of the disposition of an illegitimate product - 6 years

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FDA Guidance – Suspect Products, Notification

US Food and Drug Administration, Drug Supply Chain Security Act Implementation: Identification of Suspect Product and Notification Guidance for Industry, June 2021

- guidance for identifying a suspect product
- specific scenarios where increased vigilance would be warranted to address the risk of a suspect product entering the supply chain, e.g.,
  - supplier is new to you
  - unsolicited offer from an unknown source
  - price is too good to be true
  - package has odd or too much adhesive residue
- process for notifying FDA of an illegitimate product
  - accessing Form FDA 3911 online
- guidance for terminating notifications
  - Form FDA 3911

Q&A - https://www.fda.gov/drugs/drug-supply-chain-security-act-dscsa/notify-fda-illegitimate-products

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Enhanced Drug Distribution Security

- Interoperable, Electronic, Package Level Product Tracing
  - Effective November 27, 2023
    - You must be prepared (process, technology) to exchange transaction information and transaction statements (not transaction history) in a manner that is
      - secure
      - interoperable
      - electronic - paper no longer acceptable
    - Transaction information must include standard numerical product identifier of product at package level (not lot level)
    - You must have systems and processes in place for prompt response to federal or state official's request for transaction information and transaction statement
      - Due to recall or for investigating a suspect or illegitimate product
    - You must be able to verify product at the package level, including the standardized numerical identifier

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Enhanced Drug Distribution Security

- (With transaction history no longer required:)
- You must have systems and processes necessary to facilitate prompt gathering of information necessary to produce transaction information for each transaction going back to the manufacturer, as applicable
  - per Federal or State official 's request, for product recall or investigating a suspect or illegitimate product; or
  - per request of an authorized trading partner to investigate a suspect product or assist Federal or State official with a request
  - must be secure to protect confidential commercial information and trade secrets
- Standards to be established by guidance

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Enhanced Drug Distribution Security

FDA Draft Guidance, July, 2022*

"FDA recommends that trading partners use the **Electronic Product Code Information Services (EPCIS)** standard to provide and maintain the data associated with transaction information and transaction statements…

allows trading partners to capture and share information about products as they are transacted through the supply chain …

help ensure compliance with the DSCSA requirements …

compatible with a range of different technological approaches…

considerable agreement among stakeholders that EPCIS is a suitable standard to adopt for the enhanced drug distribution security requirements."

*DSCSA Standards for the Interoperable Exchange of Information for Tracing of Certain Human, Finished, Prescription Drugs

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Enhanced Drug Distribution Security

- A dispenser can contract with a third party (e.g., wholesale distributor) to confidentially maintain required information and statements.
  - Dispenser must maintain a copy of the written agreement
  - Still responsible for compliance with dispenser requirements

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Enhanced Drug Distribution Security

- There appear to be a number of products available to facilitate compliance, promising:
  - EPCIS data compatibility
  - Unit level traceability
  - Tracking of tracing documentation
  - Checking of authorized trading partner licensure/registration
  - Form 3911 preparation
  - Verification of saleable returns

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Enhanced Drug Distribution Security

- But there are also concerns,
  - e.g., Healthcare Distribution Alliance, *HDA Foundation Serialization Survey Shows Slow Progress, Industry Concerns Leading Up to 2023 DSCSA Compliance Deadline,* October, 2022
    - Particularly, lack of manufacturer communication
- FDA to provide alternative methods of compliance with enhanced drug distribution security, including
  - establishing timelines for small businesses (including small business dispensers with 25 or fewer full-time employees) to comply
    - to avoid undue economic hardship for small businesses
  - establishing a process for dispensers to request a waiver from enhanced drug distribution security to avoid undue economic hardship, including a process for the biennial review and renewal of the waiver process

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Investigation of suspect product

- Beginning November 27, 2023 (enforcement delayed since November, 2020)
  - Dispensers must include in investigation of suspect products, or illegitimate products that are the subject of a notification from FDA or a trading partner:
    - verifying that the product identifier, including the standardized numerical identifier, of at least the greater of 3 packages or 10 percent of the suspect product (all packages if fewer than 3) corresponds with the product identifier for the product.
      - "Package" - smallest unit of product distributed for sale to the dispenser.
  - Dispenser can request that manufacturer or repackager verify whether the product identifier is the correct one for the product.
  - The manufacturer or repackager must tell the dispenser if it has reason to believe the product is an illegitimate product.

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Sunset

As of November 27, 2023, the following provisions of DSCSA are no longer in effect:

- transaction history requirement
- saleable returns made without transaction information and transaction statement
  - must now be included with the return

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Question and Answer

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Thank You!

Hilda Gurley, JD, RPh
Pharmacy Compliance Strategies, LLC
hgurley@pharmacycompliancestrategies.com

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