2023 Update to DSCSA for Pharmacy

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Learning Objectives

- Describe the Goal of the Drug Supply Chain Security Act and how it will protect patients and the US supply chain.
- Review the current four aspects (Authorized Trading Partners, Product Identifiers, Product Tracing, and Verification) of the Drug Supply Chain Security Act.
- Discuss the upcoming 11/27/2023 Enhanced Drug Distribution Security requirements.
- Describe the process of identifying suspect products and situations Pharmacies should be aware of to reduce the risk of suspect products.

Terms

- Trading Partners
- Transaction Information (TI)
- Transaction History (TH)
- Transaction Statement (TS)
- Standardized Numerical Identifier
- Product Identifier
- Suspect product
- Illegitimate Product
- EPCIS
- GLN

The Drug Supply Chain Security Act Overview

WHAT IS DSCSA?

- Designed to prevent illegitimate medication from entering the Supply Chain
- Provides key guidelines for all levels within the Drug Supply Chain, including the Manufacturer, Wholesaler, and Dispensers

WHY WAS IT CREATED?

- Federal law signed in 2013 to replace state-level regulations to reverse upward trend of U.S. counterfeit rate projections
- Compliance implemented in stages beginning in 2014 and ending November 27, 2023

WHAT DOES THIS MEAN FOR Pharmacy?

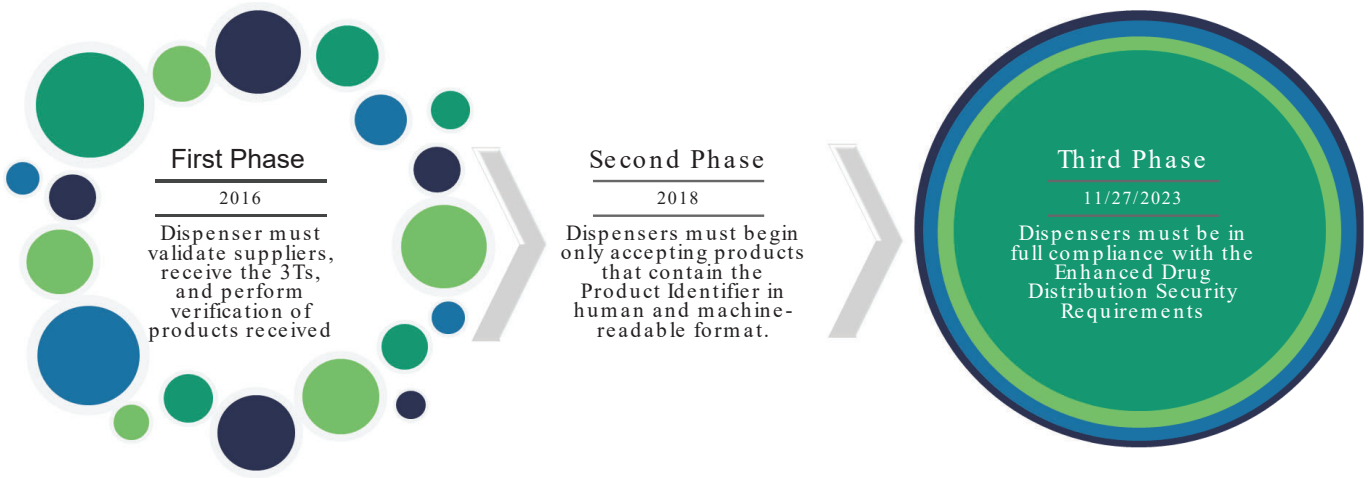
- Pharmacy's Role:
  - **Check and Validate** all Suppliers and Products coming into the Pharmacy
  - **Receive, Review (against physical product), and Maintain** transaction data from your wholesalers and direct order manufactures

Who does this effect?

Manufacturers → Wholesalers → Pharmacies

The DSCSA Requirements do not filter down to Patient Prescriptions, so you do not need to link any required DSCSA Information to a specific patient prescription.

DSCSA Implementation Rollout Phases



Not All Rx Products Apply!

DSCSA requirements apply only to Rx Pharmaceutical In a final dosage from the manufacturer.

EXCLUSIONS INCLUDE

RX Products

Blood products

Imaging drugs

IV Fluids

Other Healthcare Products

OTC, HBA, Nutritional Supplements, Blood monitoring devices or other products under the FDA CBER jurisdiction as a medical device

Recent Guidance from the FDA

- **Drug Product Tracing: The Effect of Section 585 of the FD&C Act** – (2/22)
  – Reiterated that no State may preempt the DSCSA
- **Verification Systems Under the DSCSA for Certain Prescription Drugs** – (3/22)
  – Covers the verification process to be in place when suspect products are identified
- **DSCSA Standards for the Interoperable Exchange of Information for Tracing of Certain Human, Finished, Prescription Drugs Guidance for Industry** – (7/22)
  – Strong recommendation for the use of the EPCIS Standard
- **Identifying Trading Partners Under the Drug Supply Chain Security Act** – (7/22)
  – Reiterated that selling to other Pharmacies might constitute the Pharmacy being a Wholesaler
- **Exemption and Exclusion From Certain Requirements of the Drug Supply Chain Security Act for the Distribution of FDA-Approved Naloxone Products During the Opioid Public Health Emergency Guidance for Industry** – (9/22)
  – Naloxone for dispensing as part of a harm reduction program is exempt from the DSCSA requirements
- **Definitions of Suspect Product and Illegitimate Product for Verification Obligations Under the Drug Supply Chain Security Act Guidance for Industry** – (3/23)
  – Provided final guidance on suspect and illegitimate products

Recent Guidance from the FDA (and the effect on Pharmacy)

- **Identifying Trading Partners Under the Drug Supply Chain Security Act** – (7/22)
  - Reiterated that selling to other Pharmacies might constitute the Pharmacy being a Wholesaler (with all of the DSCSA Wholesaler requirements needing to be met).
- **Exemption and Exclusion From Certain Requirements of the Drug Supply Chain Security Act for the Distribution of FDA-Approved Naloxone Products During the Opioid Public Health Emergency Guidance for Industry** – (9/22)
  - Naloxone for dispensing as part of a harm reduction program is exempt from the DSCSA requirements for as long as the Opioid PHE is in effect'
- **Definitions of Suspect Product and Illegitimate Product for Verification Obligations Under the Drug Supply Chain Security Act Guidance for Industry** – (3/23)
  - Provided final guidance on suspect and illegitimate products

Drug Supply Chain Security Act Law and Policies (**https://www.fda.gov/drugs/drug-supply-chain-security-act-dscsa/drug-supply-chain-security-act-law-and-policies**)

A Few Questions

1. ***How many of you have copies and verified your wholesaler state licenses and DEA Permits (if ordering controlled substances)?***

2. ***How many of you are verifying that the Transaction data (3Ts) (paper or, more likely, a pdf somewhere on your wholesaler website) matches the physical product?***

3. ***How many of you know how to retrieve your transaction data (3Ts)?***

What do I need to be doing now?

80% of the DSCSA is already in place.

Authorized Trading Partnered

- Authorized Trading Partners are:
  - Manufacturers and repackagers registered with the FDA
  - Wholesalers licensed by the State
  - Dispensers (typically a Pharmacy) licensed by the State
  - Third-party logistics (3PL) Providers licensed by the State
- If you cannot verify their license or registration, you cannot conduct business with them
- Request and maintain updated copies of their FDA, DEA, and State Licenses and registrations
- The FDA is also currently drafting national standards for Drug Wholesalers and 3PLs

Product Identifier

- All products received must have the Product Identifier on the label in a human and machine-readable 2d barcode.
  - Serial Number
  - NDC (or GTIN with embedded NDC)
  - Lot Number
  - Expiration Date

- Exception
  - Products manufactured before 11/27/2017
  - Products repackaged before 11/27/2018

Product Tracing

- 3Ts (TI, TS, and TH)
  - Receipt of the 3Ts for each product before or at the time of delivery (Products should be quarantined until the 3Ts are received)
  - Missing or incorrect data must be amended with the ATP
  - Maintain copies of the 3Ts for six years
  - Written Agreements with vendors if they maintain the 3Ts on your behalf
- Returns
  - Salable Returns may be made to the ATP the pharmacy purchased from without the pharmacy providing the 3Ts
  - Non-salable Returns may be made to the ATP from whom the product was purchased or to a returns processor without the pharmacy providing the 3Ts

Product Tracing (continued)

- Respond to FDA, Federal, and State requests for information within 48 hours
- May sell product to other Pharmacies:
  - To fill specific patient's prescription (no 3Ts required)
  - The share common share ownership (no 3Ts required)
  - Merger or acquisition of a Pharmacy (3Ts must be provided to the new owners)
  - If one of the above does not apply, the DSCSA will most likely consider you a wholesaler
  - All State and DEA Rules must be followed
- Minimal Quantities (5% of Total Sales) sold to Prescriber Officers

Verification

- Identify, Quarantine, and Investigate Suspect Products
- Work with trading partners and manufacturers during the investigation
- Illegitimate products
  - Notify FDA within 24 hours (FDA FORM 3911)
  - Notify relevant trading partners
  - Retain the product until you receive instructions from the FDA or Manufacturer
- Products determined to be good may be released from quarantine and dispensed
- Maintain all documentation related to the investigation for six years

What do I need to be doing on and after 11/27/2023?

Enhanced Drug Distribution Security (EDDS)

- The 3Ts become 2Ts (TI and TS)
- The TI must include the product identifier (Serial, NDC, Lot, and Expiration)
- The 2Ts must be ***received in an electronic, secure, and interoperable format (FDA is pushing EPCIS)*** before or at the time of delivery for all products
- Pharmacies will need to obtain a GLN for EPCIS
- Verifications for suspect products must be down to the product identifier
- Respond to FDA, Federal, and State requests for information within 24 hours with the electronic 2Ts
- Salable returns may be made to the ATP it was purchased from only if the original TI and TS can be identified

Enhanced Drug Distribution Security (EDDS) - TI

Pre-November 2023

Transaction Information:

- Proprietary or established name or names of the product
- Strength and dosage form of the product
- National Drug Code number of the product
- Container size
- Number of containers
- Lot number of the product ← In Some Cases.
- Date of the transaction
- Date of the shipment, if more than 24 hours after the date of the transaction
- Business name and address of the person from whom and to whom ownership is being transferred

Paper or Electronic

November 2023+

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- Serial number
- Expiration date

Electronic Only

Enhanced Drug Distribution Security (EDDS) - GS1, EPCIS, GLN

Who is GS1?

- GS1 is a standard organization that creates standards to be used in several industries
- These standards range from barcode structures to file formats
- Regulate the standards for EPCIS and GLN

What is EPCIS?

- Electronic Product Code Information System
- Created by GS1
- The file format provides businesses with key information related to the movement of products within a supply chain
- Selected by the FDA in July of 2022 as the Standards

What is the GLN/sGLN?

- Global Location Number / Serialized Global Location Number
- Provides location information that is used to identify a unique location, including a Pharmacy or even a shelf in the Pharmacy
- Required to be used in the EPCIS by all ATPs in the supply chain
- The creation of the GLN through GS1 can be tricky since the address information must be correct down to the 9-digit zip code and even suite # as it is officially known to the post office

Who is inspecting the DISPENSERS for Compliance? What are the Dispensers' risks?

PRESENT DAY

The DSCSA Four

- Authorized Trading Partners
- Product Identifiers
- Product Tracing
- Verification

EFFECTIVE 11/28/2023

The DSCSA Five

- Authorized Trading Partners
- Product Identifiers
- Product Tracing
- Verification
- Electronic Drug Distribution Security

Suspect and Illegitimate Products

What are suspect and illegitimate products?

SUSPECT PRODUCT—The term "suspect product" means a product for which there is reason to believe that such product:

(A) is potentially counterfeit, diverted, or stolen;
(B) is potentially intentionally adulterated such that the product would result in serious adverse health consequences or death to humans;
(C) is potentially the subject of a fraudulent transaction; or
(D) appears otherwise unfit for distribution such that the product would result in serious adverse health consequences or human death.

ILLEGITIMATE PRODUCT—The term "illegitimate product" means a product for which credible evidence shows that the product:

(A) is counterfeit, diverted, or stolen;
(B) is intentionally adulterated such that the product would result in serious adverse health consequences or death to humans;
(C) is the subject of a fraudulent transaction; or
(D) appears otherwise unfit for distribution such that the product would reasonably likely result in serious adverse health consequences or human death.

Identifying Suspect Products

Specific Scenarios That Could Significantly Increase the Risk of a Suspect Product Entering the Pharmaceutical Distribution Supply Chain

- *Trading Partners and Product Sourcing*
  - Purchasing from a new trading partner
  - Receiving unsolicited sales offer from unknown sources (internet, email, fax, telephone, and in-person sales calls)
  - Purchasing from a source that has engaged in questionable business practices
- *Supply, Demand, History, and Value of the Product*
  - High Demand Product
  - High sales volume products
  - Offered at prices too good to be true
  - Known highly counterfeited or diverted (HIV, antipsychotic or cancer drugs)
  - Products currently in shortage
  - Products that are currently or recently part of a drug quality alert from a trading partner or FDA

Identifying Suspect Products (cont)

Specific Scenarios That Could Significantly Increase the Risk of a Suspect Product Entering the Pharmaceutical Distribution Supply Chain

- *Appearance of the Product*
  - Appearance of package or container used for transport
  - Packaging with unusual or excessive adhesive
  - Packaging contains foreign identification feature in place of NDC
  - Package missing information (i.e., lot or expiration)
  - Missing security or anti-counterfeiting technologies that are usually present on the specific packaging
  - Medication does not match what was expected (i.e., color, shape, markings)

Identifying Suspect Products (cont)

Recommendations on How Trading Partners Might Identify Suspect Product and Determine Whether the Product Is a Suspect Product as Soon as Practicable

- Be alert for deals "too good to be true"
- Closely examine the label on the package, and the label on the individual retail unit, if applicable, for:
  - Any missing information, such as the lot number or other lot identification, NDC, or drug strength.
  - Any altered product information (i.e., hard to read, smudged print, or misspelled words.
  - Bubbling on the surface of a label.
  - Lack of an "Rx only" symbol (when appropriate).
  - Foreign language with little or no English provided.
  - Foreign language that is used to describe the lot number.
  - A product name that differs from the name on the FDA-approved drug label or labeling.
  - A product transported in a case or tote when not expected under the circumstances.
  - Mismatch of information between outer containers and product container

Packing this all up

Current Requirements:

- Began to ensure you ATP were licensed and authorized entities
- Receive and Maintain the 3Ts
- Have a process to validate the products vs. the 3Ts (verify NDC Match)
- Have a process for the investigation of suspect products (and reporting illegitimate)
- Have a process for responding to information requests (48hrs)
- Have a process to return saleable products only to the ATP you purchased from
- Have a process to ensure received products have a product identifier (NDC, SN, Lot, Expiry)

On November 27, 2023:

- The 3Ts become 2Ts and must be received in a secure, electronic, and interoperable format
- Receive the Transaction Information with the complete product identifier
- Develop a process to validate the products vs. the 2Ts (verify product identifiers match)
- Develop a process for responding to information requests (24hrs)
- Develop a process to return saleable products only to the ATP you purchased from (they will begin verifying that the product identifier matches a product they sold you)

Questions

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