



## Drug Supply Chain Security Act (DSCSA)

### Navigating the Regulations

September 8, 2020

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#### discussion topics

- Origin of Drug Quality Security Act (DQSA)
- Basics and terminology
- Preparing to meet the DSCSA requirements
- Questions / Discussion

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## DSCSA Origin & Intent

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## DSCSA Origin

### Historical progression toward drug security

#### Prescription Drug Marketing Act (PDMA) – 1988

- Outdated - didn't address today's counterfeit circumstances, technologies, business conditions (i.e.. interstate distribution)

#### Pedigree laws: California's "e-pedigree"

- Real-time, interoperable tracking system
- Scanners, too much data, super expensive (estimated \$100k per individual pharmacy in the first year)

#### The Drug Quality and Security Act (2013)

- Title I: Compounding
- Title II: The Drug Supply Chain Security Act (DSCSA)

#### DSCSA preempts state pedigree laws

- Understanding the phrase "track-and-trace"

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## DSCSA Origin

### 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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## DSCSA enforcement

### What's the difference between guidance and laws?

- Guidances are **not laws**.
  - There is no requirement to follow them and no penalties if you don't.
  - Guidances issued since the Drug Supply Chain Security Act (DSCSA) was passed are mostly "current thinking" by FDA on how to meet the requirements of the DSCSA.
  - Guidances are non-binding assuming legal requirements are met.
- Noncompliance **will be penalized**
  - Signed by President Obama and was an act of Congress, meaning that noncompliance will be penalized through legal action.
  - The DSCSA states, "...upon conviction of violations of Federal, State, or local drug laws or regulations, may provide for fines, imprisonment, or civil penalties."

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## DSCSA enforcement

### Are there penalties for non-compliance?

- Failure to comply with DSCSA is a “prohibited act”
- Commission of a prohibited act subjects a party to:
  - Injunction of unlawful activity
  - Seizure of goods
  - Civil and criminal fines and penalties (including jail)

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## DSCSA Terminology

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## Basic terminology

**What drugs are covered?**

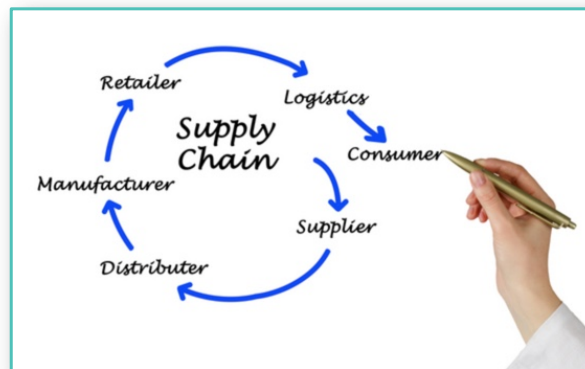
- Products: Prescription drug in finished dosage form for administration to a patient without further
- Excluded products:
  - ✓ OTC
  - ✓ Medical Devices
  - ✓ API
  - ✓ Medical gases
  - ✓ Homeopathic drugs
  - ✓ Compounded drugs
  - ✓ Drugs indicated for animal use
  - ✓ Blood and blood components for transfusion
  - ✓ Radioactive drugs and radioactive biologics
  - ✓ Imaging drugs
  - ✓ Intravenous products

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## Basic terminology

**What is a “transaction?”**

- Any change of ownership from one entity to another (not including dispensing or returns)



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## Basic terminology

### Are some “transactions” excluded?”

- Patient need: Transfer of a product from one pharmacy to another (regardless of whether the two pharmacies are affiliated in any way) to fill a prescription for a **specific** patient
- Office use: Distribution of minimal quantities of products by a licensed retail pharmacy to a licensed practitioner for office use
- Mergers: Distribution of a product pursuant to a sale or merger of a pharmacy or wholesaler
- Combo products: Distribution of combination products (device drug/device/biologic)
- Emergencies: Distribution for emergency medical reasons

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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 the 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

**Who is an authorized trading partner (ATP)?**

- Wholesale distributor: Has a valid license under state law or section 583, in accordance with section 582(a)(6), and complying with the licensure reporting requirements under section 503(e)
- Third-party logistics provider: Having a valid license under state law or section 584(a)(1), in accordance with section 582(a)(7), and complying with the licensure reporting requirements under section 584(b)
- Dispenser: Has a valid license under state law

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**Key DSCSA Milestones**

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## Key milestone dates

**Initial DSCSA Deadline for Dispensers**

The first important deadline for dispensers **was** July 1, 2015

- “T3” information had to be exchanged – and stored – about **every** drug purchased or handled it each time it changed ownership
- (Manufacturers, repackagers, and wholesale distributors had to do this starting January 1, 2015)
- For **every** transaction, they’re required to exchange “product tracing information” that includes three things

**YOU** are responsible for maintaining transaction data for 6 years for any items you receive direct from the manufacturer or from a wholesale distributor (including your primary distributor, as well as secondary, tertiary or others)

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## Key milestone dates

**1. Transaction Information (TI) about a product:**

- Proprietary or established name or names
- Strength and dosage form
- National Drug Code number
- Container size
- Number of containers
- Lot number (certain wholesale distributor transactions were excluded from this requirement)
- Transaction date
- Shipment date (if more than 24 hours after the transaction date)
- Transfer of ownership (the name and addresses of the business/person from whom and to whom ownership is being transferred)

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## Key milestone dates

**2. Transaction History (TH): An electronic statement with the TI for every transaction going back to the manufacturer**

**3. Transaction Statement (TS): An electronic statement confirming entity transferring ownership:**

- Is authorized as required under DSCSA
- Received the product from a person that is authorized as required under DSCSA
- Received TI and a TS from the prior owner of the product, as required under the law
- Did not knowingly ship a suspect or illegitimate product
- Had systems and processes in place to comply with verification requirements under the law
- Did not knowingly provide false TI or alter the transaction history

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## Key milestone dates

### 2016-2019 Milestones

Three key requirements for dispensers between 2016 and 2019:

**1. Confirm trading partners are licensed or registered**

- The FDA has searchable databases to check the registration of manufacturers and repackagers and the licensing of wholesale distributors and third-party logistics providers
- If a dispenser is doing business with another dispenser, it must check licensing through the appropriate state authority

**2. Receive, store, and provide product tracing documentation**

- Accept only prescription drugs with proper T3 information
- Store the T3 information for six years
- Generate and provide all T3 information when they sell a prescription drug to a trading partner

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## Key milestone dates

### 3. Investigate and properly handle suspect and illegitimate drugs

- This includes drugs that may be counterfeit, diverted, stolen, intentionally adulterated, or unfit for distribution.
- Quarantine and investigate suspect drugs to determine if they are fake. If they are determined to be fake, dispensers should work with the manufacturer and take specific action to ensure they do not reach patients/consumers. Pharmacies must also notify the FDA and relevant trading partners (i.e., those they bought the drug from and those they sold it to) about the compromised drug.

## Key milestone dates

### 2020 Milestone

The next phase of implementation concerns authenticating and verifying drugs. Processes must be in place to authenticate and verify **all** medicines purchased before selling them to consumers as of November 27, 2020.

- **Buy and sell only products encoded with product identifiers (PIs)**
  - A PI is a standardized graphic with three elements: the product's standardized numerical identifier (SNI), which comprises the National Drug Code plus a unique alphanumeric serial number); a lot number; and an expiration date. PIs must be in human- and machine-readable formats.
- **Verify every product at the package level, including the SNI**
  - The FDA defines a package as “the smallest unit placed into interstate commerce by the manufacturer or the repackager that is intended by that manufacturer or repackager, as applicable, for individual sale to the pharmacy or other dispenser of the drug product.”



## Assessing your DSCSA readiness

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## Current situation

- Are you complying with DSCSA regulations?
- What concerns and/or obstacles have you encountered?
- Have you considered staffing requirements?
- **ALL** supplier transactions captured and stored in a safe repository – ready for retrieval within 48 hours?
- Is your pharmacy aware of 2D barcodes on packages and ensuring their presence, where required?
- What are the most important functions relative to your DSCSA solution?
- How soon will your pharmacy be ready to transition to an all-encompassing system?



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questions?



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