DSCSA
The Time is Now!

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How fast is the earth moving?
A history of my journey

Training

Preparing
- Understanding the law
- Setting goals and timelines
- Networking
- Writing SOPs
- Defining systems, processes, hardware and software requirements
- Defining the internal team

Finding a Service Provider
- RFP process
- Reporting and support needs

Tracking and encouraging participation from upstream trading partners
Why DSCSA?

- **Traceability**
- **Focused on transfer of ownership**
- **Counterfeit and suspect products**
- **Recalls**
- **Unified Federal vs. State Regulations**

**Benefits**
- Recalls - lot number tracking
- Expiration dates tracking and visibility
- 2D bar codes and EPCIS provide more product data
FDA Established Timeline

The goal for the Drug Supply Chain Security Act

- Interoperable electronic unit-level traceability (serialization) of every regulated drug in the United States
- Key dates of the DSCSA timeline include the following:
  - **November 27, 2013**: DSCSA enacted
  - **November 27, 2014**: Third-party logistics providers (3PLs) must report licensure information to FDA annually
  - **November 27, 2015**: Manufacturers must print lot numbers on packaging
  - **November 27, 2017**: Manufacturers must serialize and verify products
  - **November 27, 2018**: Re-packagers must serialize products
  - **September 23, 2019**: FDA delays enforcement of saleable returns requirement for wholesalers
  - **November 27, 2019**: Wholesalers/distributors can only receive and distribute serialized products
  - **August 25, 2023**: FDA announces extended stabilization period, postponing enforcement for one year
  - **November 27, 2024**: Full interoperable electronic unit-level traceability for all stakeholders
Drug Supply Chain Security Act
Dispenser Requirements

2015 - 2017
- Purchase products from licensed trade partners
- Receive & retain lot traceability (TI, TH, TS) from suppliers
- Provide TI, TH, TS if selling or loaning product
- MAH must send TI, TH, TS in electronic form only (2017)

2020
- Only transact in serialized product (i.e., receive & ship)
- Verify product identifier, including serial and lot number, for suspect product investigation

2023
- Receive and Store serialized TI and TS in an electronic database
- Transaction History (TH) is no longer required
- Fully electronic, interoperable, system
- Unit level traceability
- EPCIS replacing ASN

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Drug Supply Chain Security Act
Manufacturers and Distributor Requirements

2015
• Federal licensure standards for Wholesalers
• Transaction Information, History & Statement (T3) for each shipment provided by Manufacturers and Wholesalers

2017 - 2018
• Manufacturers serialized product with 2D barcode
  - GTIN
  - Serial Number
  - Lot Number
  - Expiration Date

2019 - 2020
• Wholesaler can only accept and sell serialized product
• Wholesalers verify product identifier for salable returns
• MAH responds to product identifier verification

2023
• Exchange serialized Transaction Information and Statement
• Product identifier verification for suspect product investigation
• “Product Tracing”
• Authorized Trade Partner credentialing
EXEMPTIONS UNDER DSCSA

- Intracompany distributions
- Distribution of product samples
- Distribution of over-the-counter drugs
- Medical convenience kits
- Anesthetics, Anti-coagulants, Vasopressor, IV solutions, Sympathomimetics
- Approved animal drugs
- Medical gas distribution
- Blood and blood components for transfusion
Implementation Time

**Upstream**
- Suppliers
- Wholesalers

**Downstream**
- Dispensers

**Finding resources**
- HDA
- NACDS
- PDG
- FDA
What do you need for your Pharmacy in November ’24?

- Have a system to receive and transmit transaction information as product changes ownership.
- 24-hour time limit for notification to trading partners of illegitimate product.
- GLNs-unique identifiers that define the parties in the change of ownership (Transaction).
  - Purchased from GS1.
  - Assigned by location.
Considerations unique to your business

• Number of direct suppliers vs. wholesale only model
• Store vs. warehouse receiving
• Training and SOPs
• Data flow
  • Receive and set up EPCIS internally vs. using a third-party provider
• Service provider selection and management
• Who will enforce and audit?
  • State boards
  • FDA
Caution

“If a wholesale distributor, dispenser, or re-packager purchases product and identifies a potential clerical error or other discrepancy in the product tracing information it received, that trading partner should resolve the error or discrepancy within 10 business days.”

Carefully inspect when receiving
- Broken seals
- Altered tape or wrap

Handle clerical errors
- Trading partners should work together to resolve
- No further distribution of the product
- Document

“If either trading partner determines the product is suspect or illegitimate, the trading partners must follow applicable verification requirements, including quarantine, investigation, and proper disposition.”
DELAYS and Surprises

- Enforcement discretion
- Stabilization period now until 11/27/24
- Lack of an “interoperable system”
- 2D bar code reader shortages
- Cloud server connections
- Aggregation issues at manufacturers
- Each vs. Case invoicing issues
- What to do with EDI
- 10 days to clear a suspect product
- Space for the 2D bar code on the bottle
What do you do?

KEEP MOVING FORWARD!
THE WORLD WILL KEEP TURNING

SOPS

TRAINING

ENCOURAGE SUPPLIERS AND WHOLESALERS WHO ARE UPSTREAM