Drug Supply Chain Security Act
(Title II of the Drug Quality and Security Act)
Overview of Product Tracing Requirements

September 2015

Disclaimer

The content here is intended only to provide a summary and general overview. It is not intended to be comprehensive nor does it constitute legal advice.

Additional Resources

Updates and links to FDA documents or notices summarized in this presentation can be found on the DSCSA webpage on FDA's website.

Overview of the DSCSA

Title II: Drug Supply Chain Security Act (DSCSA) adds new sections in the Federal FD&C Act

- 581 – Definitions
- 582 – Requirements (product tracing, product identification, verification)
- 583 – Standards for licensure of WDs
- 584 – Standards for licensure of 3PLs
- 585 – Uniform national policy

DSCSA Major Provisions

- Product tracing (*by 2015 lot-level, by 2023 package-level*)
- Product verification
  - Quarantine and investigation (steps for detection and response)
  - Notification, recordkeeping
- Product identification (*applied to product beginning 2017*)
- Wholesale distributor and Third-party logistics provider standards for licensure
- Enhanced system (*electronic, interoperable system to trace products at the package-level by 2023*)
- Penalties
- National uniform policy

Stakeholders Involved

- Dispenser
- Manufacturer
- Repackager
- Third-party logistics provider
- Wholesale distributor
- FDA
- State officials
- International regulatory counterparts
- Others

Definitions (Section 581 of the FD&C Act)

- Dispenser
- Distribute
- Illegitimate product
- Manufacturer
- Package
- Product
- Product identifier
- Quarantine
- Repackager
- Return
- Standardized numerical identifier
- Suspect product
- Trading partner
- Transaction
- Transaction history
- Transaction information
- Transaction statement
- Wholesale Distributor
- Among others...

Scope of the law*

Product

- What's covered:
  - Prescription drug in finished dosage form for administration to a patient without further manufacturing (such as capsules, tablets, lyophilized products before reconstitution)
- What's not covered:
  - Blood or blood components intended for transfusion
  - Radioactive drugs or biologics
  - Imaging drugs
  - Certain IV products
  - Medical gas
  - Homeopathic drugs
  - Lawfully compounded drugs

Transaction

- Transfer of product where a change of ownership occurs
- Exemptions
  - Intracompany distributions
  - Distribution among hospitals under common control
  - Public health emergencies
  - Dispensed pursuant to a prescription
  - Product sample distribution
  - Blood and blood components for transfusion
  - Minimal quantities by a licensed pharmacy to a licensed practitioner
  - Certain activities by charitable organizations
  - Distributions pursuant to a merger or sale
  - Certain combination products
  - Certain medical kits
  - Certain IV products
  - Medical gas distribution
  - Approved animal drugs

**Refer to definitions in Section 581(13) for product and 581(24) for transaction for specific information regarding exclusions or exemptions.*

Product tracing

- Beginning 7/1/2015, dispensers in the drug supply chain must exchange information about a drug and who handled it each time it is sold in the U.S. market.

- Manufacturers, repackagers and wholesale distributors – began 1/1/2015

- For each transaction, “product tracing information” should be exchanged. Product tracing information consists of:
  - Transaction *information (TI)* *(which include lot number of product (except for certain wholesale drug distributor transactions))*
  - Transaction *history (TH)*
  - Transaction *statement (TS)*

Definitions: Transaction Information, Transaction History, and Transaction Statement

Transaction Information (TI):

- 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;
- Date of the transaction;
- Date of the shipment, if more than 24 hours after the date of the transaction; and
- Business name and address of the person from whom and to whom ownership is being transferred.

Transaction History (TH): A statement in paper or electronic form, including the transaction information for each prior transaction going back to the manufacturer of the product.

Transaction Statement (TS): A statement, in paper or electronic form, that the entity transferring ownership in a transaction—

- Is authorized as required under DSCSA;
- Received the product from a person that is authorized as required under DSCSA;
- Received transaction information and a transaction statement 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 transaction information; and
- Did not knowingly alter the transaction history.

FDA established standards

Draft Guidance: DSCSA Standards for the Interoperable Exchange of Information…How to Exchange Product Tracing information

- Can use or build on current systems and processes to comply with the product tracing requirements
- Can use current paper-based or electronic-based methods as long as the selected method(s) allow product tracing information to be exchanged in a manner that complies with the applicable requirements.
- Examples of methods that could be used include, but are not limited to:
  - paper or electronic versions of invoices;
  - paper versions of packing slips;
  - Electronic Data Interchange (EDI) standards, such as the Advance Ship Notice (ASN),
  - EPCIS (Electronic Product Code Information Services)
- Email or web-based platforms are acceptable for transmitting or providing access to the product tracing information, as long as the information that is captured, maintained, and provided is in compliance with the law.

Authorized trading partners are:

- Manufacturers and repackagers with valid registration with FDA
- Wholesale distributors with valid State or Federal license and compliance with reporting requirements; considered authorized before federal licensing regulations effective if possesses valid license under State law
- Third-party logistic providers with valid State or Federal license and compliance with reporting requirements; considered authorized before federal licensing regulations effective, unless FDA makes certain findings and gives notice
- Dispensers with valid State license

Beginning 1/1/2015 - trading partners must be “authorized”

Verification

- No later than 1/1/2015, manufacturers, wholesaler drug distributors, repackagers, and many dispensers (primarily pharmacies) shall establish systems and processes to be able to comply with the verification requirements
  - Must be able to respond to verification requests from Secretary about suspect product
  - Quarantine and investigate suspect product to determine if illegitimate product (includes validating applicable TI and TH)
  - Notify trading partners and FDA of illegitimate product (within 24 hours of determination)
  - Respond to notifications of illegitimate product
  - Recordkeeping
- Verification requirements change once product is serialized. (starting in 2017 for manufacturers, 2018 for repackagers, 2019 for wholesale distributors and 2020 for dispensers)

Definitions: Suspect and illegitimate product

- Suspect Product - reason to believe that product potentially:
  - counterfeit, diverted, stolen
  - subject of fraudulent transaction
  - intentionally adulterated or appears otherwise unfit for distribution such that would result in serious adverse health consequences or death to humans
- Illegitimate Product - credible evidence that the product actually is any of the above

How to handle suspect or illegitimate product

Draft Guidance: Identification of Suspect Product and Notification

- Describes scenarios that increase risk of suspect product for entering supply chain
- Recommendations on how to identify and make determination of suspect product
- Sets forth process to notify FDA and consult with FDA to termination notifications about illegitimate product

  http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM400470.pdf

  - Proposes draft form FDA 3911: Drug Notification
  - Public docket comments are under review

Requests for information

When responding to requests for information from FDA or other appropriate Federal or State official in the event of a recall or for the purpose of investigating a suspect or illegitimate product

- Manufacturers, Wholesale Distributors, Repackagers:

  Shall provide applicable TI, TH, and TS, not later than 1 business day, not to exceed 48 hours after receiving request

- Dispensers:

  Shall provide applicable TI, TH, TS not later than 2 business days (or another reasonable time as determined by FDA) after receiving request; shall not include lot, initial transaction date or initial shipment date unless such information was provided; may respond in paper or electronic format; certain limitations to information requests apply until November 27, 2017.

Product identification (Serialization)

- Put a unique product identifier on certain prescription drug packages
  - Manufacturers (No later than 11/27/2017)
  - Repackagers (No later than 11/27/2018)

- Product identifier consists of
  - National Drug Code
  - Serial number
  - Lot Number
  - Expiration Date

Standardized numerical identifier

- Data Carrier – 2D bar code

After products are serialized

- Only buy and sell products encoded with product identifiers *(unless grandfathered under section 582(a)(5))*
  - Repackagers (beginning 11/27/2018)
  - Wholesale distributor (beginning 11/27/2019)
  - Dispensers (beginning 11/27/2020)
- Verification product at the package level, including the standardized numerical identifier *(NDC and serial number)*
  **see respective sections of 582 for specific verification requirements*
  - Manufacturers: starting 11/27/2017
  - Repackagers: starting 11/27/2018
  - Wholesale distributors: starting 11/27/2019
  - Dispensers: starting 11/27/2020
- Enhanced product tracing by 2023 at the package-level

DSCSA pilot project(s)

- FDA shall establish 1 or more pilot projects
- Coordinate with manufacturers, repackagers, wholesale distributors and dispensers
- Explore and evaluate methods to enhance the safety and security of the pharmaceutical distribution supply chain
- Design: utilization of product identifiers for product tracing and verification, improve technical capabilities needed to utilize product identifiers, identify system attributes that are necessary, other

Resources

- **FDA DSCSA web page:**
  http://www.fda.gov/Drugs/DrugSafety/DrugIntegrityandSupplyChainSecurity/DrugSupplyChainSecurityAct/default.htm

  - Overview
  - Implementation Plan
  - Links to FDA webinars
  - Regulatory Documents (Guidances, FR notices…)

- **Questions about the DSCSA can be sent to:**
  drugtrackandtrace@fda.hhs.gov

- **Questions about Wholesale Distributor or 3PL requirements can be sent to:**
  wdd3plrequirements@fda.hhs.gov