



DSCSA Updates and Readiness Check: Requirements for Dispensers and other Trading Partners

**U.S. Food and Drug Administration
Center for Drug Evaluation and Research**

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Who is a Dispenser ?

DISPENSER.—The term ‘dispenser’—

(A) means 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; and

(B) does not include a person who dispenses only products to be used in animals in accordance with section 512(a)(5).

EXCEPTION: The dispenser requirements for product tracing and verification shall not apply to licensed health care practitioners authorized to prescribe or administer medication under State law or other licensed individuals under the supervision or direction of such practitioners who dispense or administer product in the usual course of professional practice.

Other Trading Partners

- ***Trading partners (manufacturers, wholesale distributors, dispensers, and repackagers) engaged in transactions involving “products”*** [defined under section 581(13)] **are required to exchange specific product tracing information in such transactions.** [sections (b)(1), (c)(1), (d)(1), and (e)(1)]
- **A trading partner may meet the definition of more than one entity depending on the activities in which it engages.** [sections 582(a)(1)]
- **When a trading partner meets the definition of more than one entity, it must comply with all applicable requirements, but is not required to duplicate requirements.** [section 582(a)(1)]

The Drug Supply Chain Security Act (DSCSA) Product Tracing Requirements for Dispensers [section 582(d)(1)(A)]

Beginning July 1, 2015, Dispensers (primarily pharmacies) -

- (i) shall not accept ownership of a product, unless the previous owner prior to, or at the time of, the transaction, provides transaction history, transaction information, and a transaction statement;
- (ii) prior to, or at the time of, each transaction in which the dispenser transfers ownership of a product (but not including dispensing to a patient or returns) shall provide the subsequent owner with transaction history, transaction information, and a transaction statement for the product, except that the requirements of this clause shall not apply to sales by a dispenser to another dispenser to fulfill a specific patient need; and
- (iii) shall capture transaction information (including lot level information, if provided), transaction history, and transaction statements, as necessary to investigate a suspect product, and maintain such information, history, and statements for not less than 6 years after the transaction.

DSCSA Implementation: Product Tracing Requirements for Dispensers – Compliance Policy Guidance for Industry (1)

However, FDA does not intend to take enforcement action against dispensers who, prior to November 1, 2015:

- (1) accept ownership of certain human, finished prescription drugs without receiving the transaction information, transaction history, and a transaction statement (product tracing information) prior to or at the time of a transaction [section 582(d)(1)(A)(i)], or**
- (2) do not capture and maintain the product tracing information [section 582(d)(1)(A)(iii)].**

DSCSA Implementation: Product Tracing Requirements for Dispensers – Compliance Policy Guidance for Industry (2)

- This compliance policy **does not extend** to the requirements under section 582(b)(1), (c)(1), and (e)(1) that other trading partners (manufacturers, wholesale distributors, and repackagers) provide product tracing information to dispensers.
- This compliance policy **does not extend** to transactions in which dispensers must provide the subsequent owner with product tracing information. [section 582(d)(1)(A)(ii)]

Key exception: Not required to provide product tracing information for sales by a dispenser to another dispenser to fulfill a specific patient need

DSCSA Implementation: Product Tracing Requirements for Dispensers – Compliance Policy Guidance for Industry (3)

- This compliance policy **does not extend** to other requirements regarding authorized trading partners and verification related to suspect and illegitimate product (including quarantine, investigation, notification and recordkeeping).
- FDA recommends that dispensers and their trading partners use the time until November 1 to work together to ensure dispensers can properly receive product tracing information. Dispensers should also use this time to ensure they are able to properly capture and maintain product tracing information.



DSCSA Updates and Readiness Check: Requirements for Dispensers and other Trading Partners

Are you ready for the DSCSA? (1)

✓ Become familiar with the law

There are new requirements under the [Drug Supply Chain Security Act \(DSCSA\)](#) for manufacturers, repackagers, wholesale distributors, dispensers, and third-party logistics providers (trading partners). Some requirements began in November 2014 and several key requirements begin at various stages in 2015. The new requirements, development of standards, and the system for product tracing will continue to be phased in over the next nine years. FDA will continue working with trading partners and other stakeholders to effectively implement the new requirements.

✓ Work with your trading partners to ensure they are familiar with the law

It is important that all trading partners understand their responsibilities and work together to help facilitate efficient distribution and availability of drug products in the United States.

FDA's DSCSA webpage:

<http://www.fda.gov/Drugs/DrugSafety/DrugIntegrityandSupplyChainSecurity/DrugSupplyChainSecurityAct/default.htm>

Overview of the DSCSA (1)



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

Overview of the DSCSA (2)

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

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
- Exempt
 - 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 retail pharmacy to a licensed practitioner for office use
 - Charitable organization
 - Distributions pursuant to a merger or sale
 - Certain combination products
 - Certain medical kits
 - Certain IV products
 - Medical gas distribution
 - Approved animal drugs

Are you ready for the DSCSA? (2)

✓ Provide product tracing information (manufacturers, repackagers, wholesale distributors, and dispensers)

Start Date	Trading Partner(s)	Requirement
1/1/2015	<ul style="list-style-type: none"> • Manufacturers • Repackagers • Wholesale distributors 	Lot-level product tracing: provide transaction information, history, and statement
7/1/2015	Dispensers (primarily pharmacies)	Lot-level product tracing: provide transaction information, history, and statement

To assist manufacturers, repackagers, wholesale distributors, and dispensers to comply with the new product tracing requirements, FDA has published a draft guidance for industry, [DSCSA Standards for the Interoperable Exchange of Information for Tracing of Human, Finished Prescription Drugs: How to exchange product tracing information](#) (November 2014).

- Accept ownership of product with applicable transaction information, transaction history, and transaction statements.
 - If your trading partner does not provide the proper transaction documentation, work with your trading partner to promptly get the proper documentation and to minimize disruption in the supply chain.

Provide product tracing information

- 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)*

* See DSCSA Implementation: Product Tracing Requirements for Dispensers – Compliance Policy Guidance for Industry, Issued 6/2015

Definitions: Transaction Information, History, and 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.

Provide product tracing information

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.
- Public docket comments are being reviewed

Are you ready for the DSCSA? (3)

✓ Know how to handle suspect and illegitimate product (manufacturers, repackagers, wholesale distributors, and dispensers)

Start Date	Trading Partner(s)	Requirement
1/1/2015	<ul style="list-style-type: none"> • Manufacturers • Repackagers • Wholesale distributors • Dispensers (primarily pharmacies) 	Establish systems for verification and handling of suspect or illegitimate product.

To assist manufacturers, repackagers, wholesale distributors, and dispensers to comply with the new verification requirements, FDA published the draft guidance for industry, [Drug Supply Chain Security Act Implementation: Identification of Suspect Product and Notification](#) (June 2014). FDA posted a [webinar](#) that reviews how to identify suspect product and the process for notification.

- Establish systems to:
 - Quarantine and investigate *suspect product* to determine if it is illegitimate.
 - Notify FDA and immediate trading partners, if *illegitimate product* is found.

Know how to handle suspect and illegitimate product

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)

Know how to handle suspect and 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

Know how to handle suspect and illegitimate product

Request 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

- 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.

- 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

Are you ready for the DSCSA? (4)

✓ Confirm authorized trading partners (manufacturers, repackagers, wholesale distributors, dispensers, and third-party logistics providers)

Start Date	Trading Partner(s)	Requirement
1/1/2015	<ul style="list-style-type: none"> • Manufacturers • Repackagers • Wholesale distributors • Dispensers • Third-party logistic providers 	Must be authorized, as defined by the FD&C Act

- Check with your trading partner directly to confirm they are authorized, or
 - For manufacturers and repackagers, check [FDA's drug establishment registration database](#) for registration;
 - For wholesale distributors, third-party logistic providers and dispensers, you can check with your respective state authority to confirm licensure.

Note, third-party logistic providers are considered to be licensed under the DSCSA until the effective date of the third-party logistic provider licensing regulations issued by FDA, unless the third-party logistic provider is licensed by a state having a specific third-party logistic provider licensing program.

For more information about DSCSA implementation and new requirements to enhance drug distribution security, please visit [FDA's Drug Supply Chain Security Act web page](#).

Confirm authorized trading partners

Authorized Trading Partners

- **Manufacturers and Repackagers:** valid registration with FDA
- **Wholesale distributors:** 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 logistics providers:** 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:** valid State license

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

Are you ready for the DSCSA? (5)

✓ Report licensure (third-party logistics providers and wholesale distributors)

Start Date	Trading Partner(s)	Requirement
1/1/2015	Wholesale distributors	Report licensure and other information to FDA
11/27/2014	Third-party logistics providers	Report licensure and other information to FDA

To assist third-party logistics providers and wholesale distributors to comply with the new reporting requirements, FDA published a draft guidance, [Drug Supply Chain Security Act Implementation: Annual Reporting by Prescription Drug Wholesale Distributors and Third-Party Logistics Providers](#) (December 2014). The draft guidance outlines the information that should be submitted to FDA, the timing of the submissions, a preferred format for the submissions, and a preferred method for reporting using FDA's [CDER Direct Electronic Submissions Portal](#). FDA posted a [webinar](#) that provides an overview of annual reporting requirements.

For more information about DSCSA implementation and new requirements to enhance drug distribution security, please visit [FDA's Drug Supply Chain Security Act web page](#).

Report licensure (Third-party logistics providers and Wholesale distributors)

- Reporting licensure to FDA
 - 3PL : starting 11/27/2014
 - Wholesale distributors: starting 1/1/2015

- Annual Reporting Webpage:
 - <http://www.fda.gov/Drugs/DrugSafety/DrugIntegrityandSupplyChainSecurity/DrugSupplyChainSecurityAct/ucm423749.htm>
 - FDA's CDER Direct Electronic Submission Portal
 - Guidance explains who, what, when, and how
 - Public docket comments are under review

- **Coordination with State Officials** - to access WD licensure, contact information and significant disciplinary actions

What's next

- Regulations
 - Standards for licensure (WD and 3PLs)
- Guidances (related to section 582)
 - Waivers, Exceptions, Exemptions
 - Grandfathering product
- Public Database for WD licensure information
- Pilot project(s)
- Public meetings or workshops
- Stakeholder calls
- Other...

Enhanced System – 2023

- Establishes package level requirements for the interoperable, electronic tracing of products that shall go into effect 10 years after enactment of this Act, including those relating to:
 - Electronic exchange of transaction information for each sale of certain prescription drugs
 - Verification of product identifiers at the package level
 - Prompt response to suspect and illegitimate products when found
 - Improved efficiency of recalls

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

- National Drug Code
- Serial number

Standardized
numerical
identifier

- Lot Number
- Expiration Date



- Data Carrier – 2D bar code

Product Identification (Serialization)

- Only buy and sell products encoded with product identifiers
 - 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

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