

Drug Supply Chain Security Act: Checklist for Dispensers (i.e. pharmacies)

Current Requirements

Authorized Trading Partner Confirmation (effective January 1, 2015)

	<p>Dispensers' trading partner(s) may be only "authorized trading partners"</p> <ul style="list-style-type: none"> - Manufacturers or repackagers must have a valid registration - Wholesale distributor must have a valid licensure under State law or section 583 (National Standards for Prescription Drug Wholesale Distributors) and comply with licensure reporting requirements. Note: FDA's database may help verify wholesale drug distributor licenses - Dispensers must have a valid license under state law
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Transaction Data (effective January 1, 2015; FDA delayed enforcement of some requirements below to March 1, 2016).

For more information: [FDA Draft Guidance DSCSA Standards for the Interoperable Exchange of Information for Tracing of Certain Human, Finished, Prescription Drugs: How to Exchange Product Tracing Information](#)

	<p>Only accept product if the previous owner provides the "3Ts" (Transaction History, Transaction Information, and a Transaction Statement)(effective March 1, 2016)</p> <ul style="list-style-type: none"> - Information can be provided in paper or electronic format (e-mail or Web-based)
	<p>Provide the subsequent owner with the 3Ts. (effective July 1, 2015)</p> <ul style="list-style-type: none"> - 3Ts do not need to be provided when dispensing to a patient - Dispenser transfers to another dispenser for a "specific patient need" are exempt from this requirement. Specific patient need refers to the transfer of a product from one pharmacy to another to fill a prescription for an identified patient. It does not include product transfer to increase or replenish stock in anticipation of a need. Other requirements of the law still apply. - *FDA will not take action against a trading partner who transfer product ownership directly to a first responder without providing product tracing information to the first responder - *Dispensers who transfer products to another dispenser without a specific patient need or satisfying other exemptions or exceptions may need to register as a wholesale distributor
	<p>Trading partners, including pharmacists, capture and maintain the 3Ts for 6 years from date of transaction (effective March 1, 2016).</p> <ul style="list-style-type: none"> - Dispensers relying on third parties (e.g., wholesale distributors and other vendors) for product tracing must maintain a copy of the written agreement

Suspect/ Illegitimate Product Identification and Notification (effective January 1, 2015)

See [FDA Final Guidance Identification of Suspect Product and Notification](#) for more information.

	<p>Upon request from FDA or other official investigating a recall, a dispenser shall, not later than 2 business days, provide (in paper or electronic format) the applicable transaction information, transaction statement, and transaction history the dispenser received from the previous owner</p>
	<p>Have systems in place to quarantine suspect product and promptly conduct an investigation, in coordination with other trading partners, to determine whether a suspect product is illegitimate</p>

**Indicates information is from guidance and not stated in the law*

This checklist was developed as a guide only and is not legal advice. Compliance with the checklist does not guarantee compliance with the DSCSA. For specific language in the DSCSA with regard to pharmacists' requirements (referred to as "dispensers"), visit [FDA's website \(www.fda.gov/Drugs/DrugSafety/DrugIntegrityandSupplyChainSecurity/DrugSupplyChainSecurityAct/ucm376829.htm\)](http://www.fda.gov/Drugs/DrugSafety/DrugIntegrityandSupplyChainSecurity/DrugSupplyChainSecurityAct/ucm376829.htm).

Last updated September 22, 2017.



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.*

7

Source: Food and Drug Administration (Sept. 2015), Drug Supply Chain Security Act, Overview of Product Tracing Requirements, available at:

<https://www.fda.gov/downloads/Drugs/DrugSafety/DrugIntegrityandSupplyChainSecurity/DrugSupplyChainSecurityAct/UCM464907.pdf>, last accessed: September 20, 2017.

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.

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