

Drug Supply Chain Security Act: Requirements, Questions, and Consequences

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DSCSA: Basic Requirements

- Transfer of transaction history, transaction information, and transaction statement
- Product identifiers
- Business only with authorized trading partners
- Returns
- Suspect and illegitimate product quarantine, investigation, and notifications

DSCSA: Applicability

- Application-Manufacturers, repackagers, distributors, dispensers
- Exemptions (by example)
 - Over-the-counter products
 - Intracompany distributions
 - Emergency medical situations
 - Samples
 - Minimal quantities by a licensed retail pharmacy to practitioner for in-office use
 - Pharmacy/wholesale distributor mergers/acquisitions
 - Certain combination products not subject to 505 approval or licensure
- Questions Raised
 - Who is covered?-Contract manufactures?

DSCSA: Transaction Documents

- Must be provided to and received from trading partners
 - Transaction History
 - Transaction Information
 - Transaction Statement—statement that the entity transferring ownership is authorized; received the product from a person that is authorized; received transaction information and a transaction statement from the prior owner; did not knowingly ship a suspect or illegitimate product; had systems and processes in place to comply with verification requirements; did not knowingly provide false transaction information; and did not knowingly alter the transaction history
- Questions Raised
 - What does it mean to act knowingly?—actual knowledge, imputed knowledge?
 - What are the consequences of a false certification?
 - FDA prohibited act to fail to comply with Section 582
 - Other potential liability-e.g., False Claims Act

DSCSA: Product Identifier

- Standardized graphic that includes, in both human-readable form and on a machine-readable internationally recognized data carrier, the standardized numerical identifier, lot number, and expiration date of the product
- Must be affixed to each package and homogenous case
- May not engage in transactions concerning a specific product unless product is encoded with a product identifier
- Questions Raised
 - How to develop technology that will keep up with technological advancements during the product shelf life and that will stay ahead of potential illegitimate streams of commerce?

DSCSA: Authorized Trading Partners

- Must verify that trading partners are authorized trading partners
 - Manufacturers/repackagers must be registered with FDA
 - Wholesale distributors/3PLs must have a valid state or federal issued license and must comply with reporting requirements
 - Dispensers must have valid state license
- Questions Raised
 - What diligence efforts are trading partners required to undertake?
 - Contractual representations
 - Copies of registrations/licensure and required reports
 - Verification on public databases
 - Certified verification by the registration/licensing authority
 - How often must authorization be verified?

DSCSA: Suspect/Illegitimate Products

- Quarantine
- Conduct investigation in coordination with trading partners
- FDA notification of cleared suspect products
- Disposition of illegitimate products
- FDA and trading partner illegitimate product notification
- Request to FDA to terminate an illegitimate product notification
- Questions Raised
 - What steps need to be taken to detect suspect/illegitimate products?
 - What steps must be taken to investigate a suspect/illegitimate product?
 - How much evidence indicates illegitimacy?
 - If a product is an illegitimate product, who is primarily responsible for the disposition/what kind of assistance must be provided to trading partners?
 - How is illegitimate product that is not in the hands of a trading partner dispositioned?
 - How are patients/doctors notified of any potential risks?
 - What are the consequences of there being a high risk of illegitimacy?

DSCSA: Returns

- Manufacturer-Must verify product identifier before further distributing a returned product
- Wholesale Distributors-May accept returned product from dispenser or repackager only if can associate the product with the transaction information and statement; must verify product identifier before further distributing a returned product
- Repackagers-Must verify product identifier before further distributing a returned product

DSCSA: FDA Guidance

From FDA Website:

<http://www.fda.gov/Drugs/DrugSafety/DrugIntegrityandSupplyChainSecurity/DrugSupplyChainSecurityAct/ucm424963.htm>

Date Published	Type	Title	Additional Information
10/28/2015	Final Guidance	DSCSA Implementation: Product Tracing Requirements for Dispensers – Compliance Policy Guidance for Industry (Revised)	Notice of Availability
12/31/2014	Guidance	DSCSA Implementation: Product Tracing Requirements — Compliance Policy Guidance for Industry	Notice of Availability
12/09/2014	Draft Guidance	Drug Supply Chain Security Act Implementation—Annual Reporting by Prescription Drug Wholesale Distributors and Third-Party Logistics Providers	Notice of Availability
11/28/2014	Draft Guidance	DSCSA Standards for the Interoperable Exchange of Information for Tracing of Certain Human, Finished, Prescription Drugs: How to Exchange Product Tracing Information	Notice of Availability Public Workshop
10/08/2014	Draft Guidance	The Effect of Section 585 of the FD&C Act on Drug Product Tracing and Wholesale Drug Distributor and Third-Party Logistics Provider Licensing Standards and Requirements: Questions and Answers	Notice of Availability
06/11/2014	Draft Guidance	Drug Supply Chain Security Act Implementation: Identification of Suspect Product and Notification	Notice of Availability Webinar

Trading Partner Timeframe

(based upon Nov. 27, 2013 enactment)

	Manufacturers	Distributors	Dispensers	Repackagers
Transaction Docs	May 1, 2015	May 1, 2015	Jul. 1, 2015 (Mar. 1, 2016 for receipt)	May 1, 2015
Electronic Transaction Docs	Nov. 27, 2017	See Interoperable Tracing	See Interoperable Tracing	See Interoperable Tracing
Product Identifier	Nov. 27, 2017	Nov. 27, 2019	Nov. 27, 2020	Nov. 27, 2018
Authorized Trading Partner	Jan. 1, 2015	Jan. 1, 2015	Jan. 1, 2015	Jan. 1, 2015
Suspect/Illegitimate Product	Jan 1, 2015 (package level verification Nov. 27, 2017)	Jan. 1, 2015 (package level verification Nov. 27, 2019)	Jan. 1, 2015 (lot/package level verification Nov. 27, 2020)	Jan. 1, 2015 (package level verification Nov. 27, 2018)
Requests for Verification	Nov. 27, 2017	NA	NA	Nov. 27, 2018
Returned Product	Nov. 27, 2017	Enhanced requirements Nov. 27, 2019	NA	Nov. 27, 2018
Interoperable Electronic Tracing at Package Level	Nov. 27, 2023	Nov. 27, 2023	Nov. 27, 2023	Nov. 27, 2023

DSCSA: Potential Broad Impact

- New contractual provisions
- New commercial relationships for outsourced functions
- Consequences of false certifications
- New systems/policies and procedures
- Cost shifting
- Allocation of responsibility for remedial actions