



Drug Supply Chain Security Act **(Title II of the Drug Quality and Security Act)** **Overview of Wholesale Distributor and** **Third-Party Logistics Requirements and** **Standards for Licensure**

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

Definitions- WD and 3PL

WHOLESALE DISTRIBUTOR (WD) — a person (other than a manufacturer...) engaged in wholesale distribution (as defined in section 503(e)(4))

- **Wholesale Distribution** is defined as the distribution of a drug... to a person other than a consumer or patient, or receipt of a drug... by a person other than the consumer or patient
- **Contains a number of exceptions** for example : intracompany distribution, transfers to and from third-party logistics providers and common carriers, distribution of certain drugs in medical convenience kits, IV fluid replenishment and dialysis drugs, medical gases, etc.

THIRD-PARTY LOGISTICS PROVIDER (3PL) — entity that provides or coordinates warehousing, or other logistics services of a product in interstate commerce on behalf of a manufacturer, wholesale distributor, or dispenser of a product, but does not take ownership of the product, nor have responsibility to direct the sale or disposition of the product.

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 logistics provider** 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”

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

- Reporting licensure to FDA
 - 3PL : started 11/27/2014
 - Wholesale distributors: started 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

- **Public Database:** FDA is required to establish a database of authorized wholesale distributors and make it available to the public on FDA's website.

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

Wholesale distributor licensing and standards

- FDA shall develop regulations establishing standards for licensing for Wholesale Distributors (WD).
- WD standards for licensure go into effect 2 years after regulation are finalized.
- The federal system for wholesale drug distributor licensing shall be used when the state from which the drug is distributed has not established a licensure requirement.

Third-party logistics provider (3PL) licensing and standards

- No state shall regulate 3PLs as wholesale distributors.
- FDA shall develop regulations establishing standards for licensing for 3PLs.
- 3PL standards for licensure go into effect 1 year after regulations are finalized.
- The federal system for 3PL licensing shall be used when the state from which the drug is distributed has not established a licensure requirement.

Uniform national policy

Section 585(b)

- Wholesale distribution and 3PL standards:
 - Prohibits any state or local government from establishing or continuing any standards, requirements, or regulations with respect to the licensing of wholesale prescription drug distributors or 3PLs that are inconsistent with, less stringent, directly related to, or covered by standards and requirements applicable under section 503(e) (as amended by such Act) or section 584 (for 3PLs).
 - No state shall regulate 3PLs as wholesale distributors

The effect of Section 585...

- Q&A Guidance for Industry; published on 10/8/2014
<http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM417564.pdf>
- To assist industry and State and local governments in understanding the effects of section 585 of the FD&C Act
 - Immediate effects of the law
 - Clarifies effect on State product tracing and standards and requirements for wholesale distributor and third-party logistics provider licensing
- Public docket comments are under review

State licensing fees

- Wholesale distributors – The DSCSA does not prohibit States from collecting fees from wholesale distributors in connection with State licensing.
- 3PLs – For a program established by a State, the State can collect fees from a 3PL for issuing a license. If a State does not establish a program, the State is prohibited from collecting fees from 3PLs.

Key points for State authorities

NOW...

- 3PLs and WDs are separate entities defined under the law *[defined under FD&C Act section 581(22) and (29)]*
- Cannot regulate 3PLs as WDs *[section 585(b)(2)]*
- All entities that meet the definition of a wholesale distributor are required to be licensed.
- All entities that meet the definition of a 3PL are required to be licensed.

IN ADDITION, AFTER FINAL REGULATIONS PUBLISH...

- State and federal licensing programs are to be based on the new standards.
- All entities that meet the definition of a 3PL or WD are required to obtain a state or federal license, based on the new standards :
 - no later than 1 year after FDA regulations are finalized (for 3PLs)
 - no later than 2 years after the FDA regulation are finalized (for WDs)

What does the DSCSA mean for state licensure?

- Each State will have to analyze its own laws to determine the impact of the DSCSA
- States may continue to license wholesale distributors
- States may continue to license 3PLs
- State licensure programs cannot be *inconsistent with, less stringent than, directly related to, or covered by* the federal standards



DSCSA

The Drug Supply Chain Security Act

Role of State Regulatory Authorities

DSCSA items for State Board's to consider (1)

- Familiarize yourself with the DSCSA
- Obtain a good understanding of how the DSCSA will impact your future role of licensing WDs and 3PLs
- Identify if your state plans to continue to license WDs once the new federal regulations take effect
 - WDs will need to comply with the new federal requirements effective 2 years after federal regulations are finalized.
 - Will your board update your statutes and/or regulations to meet the new federal standards for licensure?

DSCSA items for State Board's to Consider (2)

- Identify if your state plans to create new licensure requirements for 3PLs
 - 3PLs will need to comply with the new federal requirements effective 1 year after federal regulations are finalized.
 - Will your board create a new 3PL licensure program?
 - Will your board update your statutes and/or regulations to meet the new federal standards for licensure?

Resources

FDA DSCSA web page:

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

- Overview
- Implementation Plan
- Links to FDA webinar(s)
- 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