Drug Supply Chain Security Act

Wholesale Drug Distributor and Third Party Logistics Provider Licensing and Inspection Provisions

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Disclaimer

The content here is intended only to provide a summary and general overview. It is not intended to be comprehensive and does not constitute legal advice.

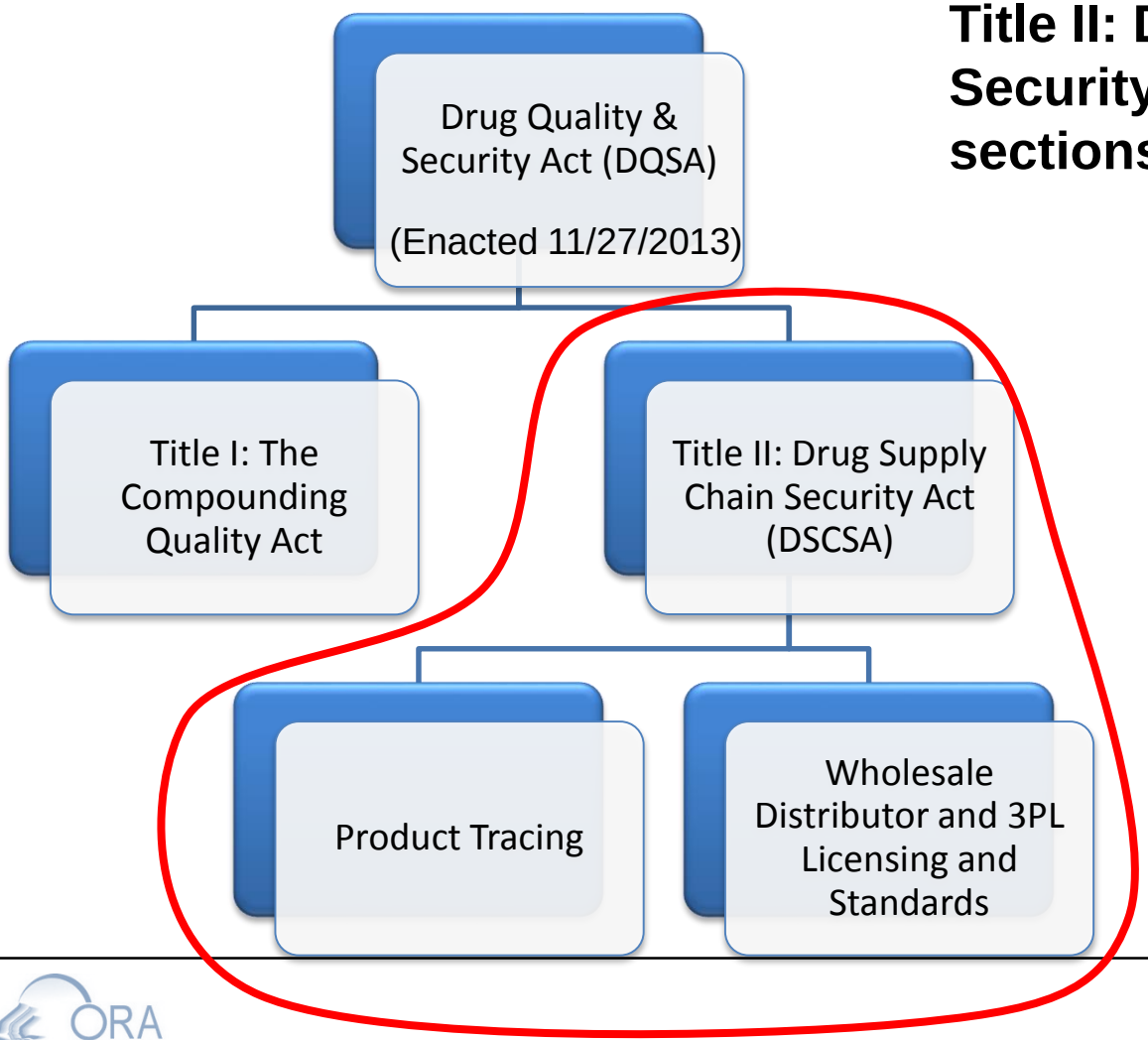
Additional Resources

Updates and links to FDA documents or notices summarized in this presentation can be found on the DSCSA webpage on FDA's website:
http://www.fda.gov/Drugs/DrugSafety/DrugIntegrityandSupplyChainSecurity/DrugSupplyChainSecurityAct/default.htm

Today's Agenda

- Overview of the DSCSA
- Definitions
- Current WD and 3PL licensing and inspection landscape
- WD and 3PL licensing and inspection under the DSCSA
- Implementation Issues and Challenges
- Available resources

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 wholesale distributors
- 584 – Standards for licensure of third party logistics providers
- 585 – Uniform national policy

Definitions

- Wholesale Distributor (WD) – a person (other than a manufacturer…) engaged in wholesale distribution as defined in section 503(e)(4)
  - Wholesale drug distribution – distribution of a prescription drug to a person other than the consumer or patient (many exceptions)
- Third-party logistics provider (3PL) - entities that provide or coordinate warehousing, or other logistics services on behalf of a manufacturer, distributor…but do “not take ownership of the product, nor have responsibility to direct the sale or disposition…”

Definitions

- Authorized Trading Partners
  - Manufacturers and Repackagers: valid FDA registration under section 510 of the FD&C Act
  - WD: valid State or Federal license and compliance with reporting requirements; considered authorized before FDA licensing regulations are effective if they possess a valid State license
  - 3PL: valid State or Federal license and compliance with reporting requirements; "…considered 'licensed'…" and authorized before FDA licensing regulations are effective, unless FDA has made a "finding" and publishes notice thereof
  - Dispensers: valid State license

Beginning January 2015, unlawful to conduct transactions with trading partners that are not authorized

WD/3PL Licensing Historical View

- WD- licensed through State licensing programs that meet minimum requirements established by FDA in 1990 (21 CFR Part 205)
  - All States have some kind of WD licensing program
  - Inspections conducted by states
    - 24 States recognize, 3 require inspections conducted through the NABP Verified-Accredited Wholesale Distributors (VAWD) program

WD/3PL Licensing Historical View

- 3PL – not addressed in PDMA, not explicitly covered by FDA minimum requirements
  - Currently ~3 States specifically and separately license 3PLs
  - Most license 3PLs as WDs
  - Under the DSCSA they can no longer be licensed as WDs

WD Licensing - DSCSA

- No person may engage in wholesale distribution of a prescription drug in any State unless such person is licensed
  - By the State from which the drug is distributed; or
  - By the Secretary (FDA) if the State from which the drug is distributed has not established a licensure requirement; and
  - The State into which the drug is distributed if required by that State.
- All licenses must follow uniform national standards
- All WDs must be licensed according to the national standards 2 years after publication of final regulations

WD Uniform National Standards

- Apply to all State and Federal WD licenses and must cover:
  - Storage and handling of prescription drugs
  - Facility requirements
  - Establishment and maintenance of records related to distributions of prescription drugs
  - Establishment and implementation of qualifications of key personnel
  - Furnishing of a bond or equivalent means of security
    - Surety bond of $100,000 or equivalent acceptable to the State
    - Can accept $25,000 bond if WD annual gross receipts ≤ $10 million

WD National Standards (cont.)

- Mandatory background checks, fingerprinting of certain personnel
- Requirements to prohibit a person from receiving or maintaining a WD license if they have
  - Been convicted of certain felonies related to drug counterfeiting, adulteration or misbranding; or
  - Engaged in a pattern of violating requirements for WD licensure that presents a threat of serious adverse health consequences or death to humans.

WD National Standards (cont.)

- Mandatory physical inspection of any facility to be used in wholesale distribution within a reasonable time frame from the initial application, to be conducted by:
  - The licensing authority (State or FDA) issuing the license
  - The State licensing authority in which the facility is located, or
  - "A third-party accreditation or inspection service approved by the Secretary or State licensing such wholesale distributor"

- Annual reporting to FDA of license information (State, name, address, contact information) for each facility
  - Certain "significant disciplinary actions" must also be reported

3PL Licensing - DSCSA

- No 3PL may conduct activities in any State unless each facility of the 3PL is licensed by
  - The State from which the 3PL distributes drug, or
  - FDA, if that State has not established a licensure requirement, and
  - The State into which the 3PL distributes drug, if that State requires it - unless the 3PL has an FDA-issued license.
- As of January 1, 2015, no 3PL can be licensed as a WD
- 3PL is “deemed” licensed until the effective date of the 3PL licensing regulations (§582(a)(7))
  - Unless FDA makes a “finding” and publishes a notice thereof
- All licenses must follow national standards
- All 3PLs must be licensed according to national standards 1 year after publication of final regulations

3PL Uniform National Standards

- FDA is required to issue regulations regarding the standards for licensing of 3PLs, including revocation and reissuance. These standards must cover:
  - Establishing a third-party accreditation program and process that is available upon request of a 3PL to issue licenses to 3PLs that meet the standards;
  - Establishing a process for FDA to issue 3PL licenses where no third party accreditation program is approved;
  - "Storage practices" including
    - Adequate warehouse size and space, with adequate security
    - Written policies and procedures to address receipt, storage, and distribution of product; thefts, errors, losses of product; support for manufacturer recalls; preparing for emergencies; handling of suspect, expired and other products.

3PL National Standards (cont.)

- Mandatory background checks of certain personnel
- Requirements to prohibit persons convicted of certain felonies from being a facility manager or designated representative
- Requirement that 3PL provide the licensing authority, upon request, a list of all manufacturers, wholesale distributors and dispensers for whom the 3PL provides services
- Requirement for periodic inspection by the licensing authority, as determined by FDA, of “such facility warehouse space” to ensure compliance with the standards
- Annual reporting to FDA of license information (State, name and address of each facility, all trade names)

Accreditation Programs

- WD – law says the required "mandatory physical inspection of any facility … within a reasonable time frame from the initial application…" can be conducted "by a third-party accreditation or inspection service approved by [FDA] or the State…" licensing authority.

- 3PL – law requires FDA to establish a process to have "third-party accreditation program[s] approved by [FDA]…" available to be involved in the 3PL licensing process.

WD/3PL Annual Reporting

- To be considered "authorized" WD and 3PL have to report certain license information to FDA
  - 3PL - required since 11/27/2014
  - Wholesale distributors – required since 1/1/2015
    - Also required to report certain disciplinary information
- *"Annual Reporting by Prescription Drug Wholesale Distributors and Third-Party Logistics Providers"* (draft Guidance for Industry, December 2014)

- Annual Reporting Database webpage:

http://www.fda.gov/Drugs/DrugSafety/DrugIntegrityandSupplyChainSecurity/DrugSupplyChainSecurityAct/ucm423749.htm

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

Costs and Licensing Fees

- FDA – can collect a “reasonable fee” to cover costs to establish and administer the licensing program and to conduct inspections, subject to certain appropriations limitations.
  - Shall adjust fees annually as needed
  - Applies to both the WD and 3PL licensing programs

- States – can collect fees “in connection with” licensing WDs and 3PLs
  - Statute points out a State that does not have a 3PL licensing program cannot collect a licensing fee.

Uniform National Policy (Section 585)

- WD and 3PL standards:
  - No State or local government may establish or continue 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) (for WDs) or section 584 (for 3PLs).
  - No State shall regulate 3PLs as wholesale distributors

"Effect of Section 585…" Draft Guidance (10/2014)

- WD Licensing:
  - "each State will have to analyze its own laws…" but because current State laws are based on Federal standards, … "it is likely those State laws would not fall below the minimum standards established by federal law and would not need to be changed."
  - And once DSCSA licensing regulations go into effect, …"States will be preempted from…licensing in any way that falls below the minimum standards established by those Federal regulations."

FDA Deliverables

- Regulations to implement 583 and 584
  - Covering the national standards
- Revise current Part 203 to make changes consistent with the DSCSA
- Establish the WD and 3PL reporting system and coordinate access for appropriate State officials
- Establish a user fee process and schedule
- Establish a new licensing capability
- Establish a new inspection and enforcement program
- Establish a third-party accreditation program and process

DSCSA Implementation Challenges

- WD/3PL licensing – changing established system
- DSCSA drafting anomalies
  - Multiple interacting definitions with multiple exemptions
  - WD distribution of “prescription drugs” is licensed
  - 3PL handling of “product” is licensed
  - 3PL provisions call for licensing and inspection of “facilities”
    - Some business models do not feature facilities
  - 3PL “other logistics services” not defined
- Establishing parallel “third-party accreditation” programs
- Multiple unknowns

Unknowns for FDA

- How many States will be ready to license and inspect WDs and 3PLs by the effective dates?
  - How many potential licensees? How many will FDA be licensing and inspecting?
- How many accredited organizations will be available to be involved in licensing and inspections?
- How complex will the inspections be?

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 should continue to license wholesale distributors
- States with a 3PL licensure program may continue to license them – since January 1, 2015, no 3PL could be licensed as WD
- Once FDA final regulations publish:
  - State licensure programs cannot be *inconsistent with, less stringent than, directly related to, or covered by* the federal standards

Unknowns for States

- What will the FDA regulations say?
- Will we have to change our current program?
- Similar questions to those facing FDA
  - How many new licenses, new inspections
  - How many accreditation programs will be available

Resources

- DSCSA Homepage: http://www.fda.gov/Drugs/DrugSafety/DrugIntegrityandSupplyChainSecurity/DrugSupplyChainSecurityAct/default.htm
- All DSCSA Guidance Documents: http://www.fda.gov/Drugs/DrugSafety/DrugIntegrityandSupplyChainSecurity/DrugSupplyChainSecurityAct/ucm424963.htm
- "WD/3PL reporting page: http://www.fda.gov/Drugs/DrugSafety/DrugIntegrityandSupplyChainSecurity/DrugSupplyChainSecurityAct/ucm423749.htm

Drug Supply Chain Security Act

Resources for You

- Main page: Drug Supply Chain Security Act (DSCSA)
- FDA's guidance on uniform national policy (Section 585 of the FDCA) (PDF - 155KB)
- Wholesale Distributor and Third -Party Logistics Providers Reporting

The DSCSA: Resources for State Officials

The Drug Supply Chain Security Act (DSCSA), which was signed into law on November 27, 2013, outlines new requirements to develop and enhance drug supply chain security by 2023. This includes product tracing requirements that went into effect in 2015 for manufacturers, repackagers, wholesale distributors and dispensers (primarily pharmacies). In addition to establishing national licensure standards for wholesale distributors (WD) and third-party logistics providers (3PL), the DSCSA requires WDs and 3PLs to report licensure and other information to FDA annually. The DSCSA also requires FDA to make certain information available to the public.

This webpage will be updated as new information becomes available. Note that 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

To learn more about DSCSA product tracing and licensure requirements, please review our presentations:

- Overview of Product Tracing and Other Requirements (PDF - 189KB)
- Overview of WD and 3PL Requirements and Standards for Licensure (PDF - 338KB)

A copy of the Drug Supply Chain Security Act (Public Law 113-54) can be found here. States may be particularly interested in the topics that are addressed in the sections below:

- Definitions - Section 202
- Enhanced drug distribution security (product tracing, product identification, verification)– Section 203
- National standards for prescription drug wholesale distributors – Section 204
- National standards for third-party logistics providers -Section 205
- Uniform national policy – Section 205
- Penalties – Section 206

Questions?

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Submit questions about wholesale distributor/3PL requirements to:

wdd3plrequirements@fda.hhs.gov

Submit questions about DSCSA/product tracing to:

drugtrackandtrace@fda.hhs.gov