# Title II – Licensure of Wholesale Distributors and 3PL's:

Where does FDA stand, where do states stand, what about VAWD, and what can you do about it?

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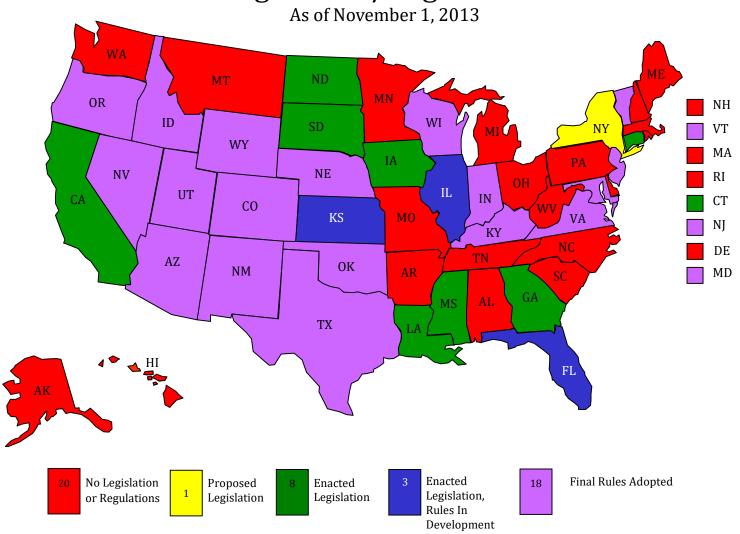
Moderated by Karla L. Palmer, Director, Hyman, Phelps & McNamara, PC and Planning Committee Chair, Drug Quality and Security Act Conference



#### Title II – DSCSA Licensure

- How and why did Title II address licensure?
- How are trading partners defined?
- Impact on manufacturers, wholesalers and 3PLs
- Current status and snapshot of state activity

# 2013 HDMA Map of State Pedigree Legislation/Regulations



#### DSCSA Licensure Overview

- Establishment of uniform national licensing standards for wholesale distributors and 3PLs
- FDA is tasked with issuing regulations to further define those standards. States will continue to license wholesale distributors and 3PLs, but they will be required to do so utilizing the federal standards established.
- DSCSA provides that in the absence of a state licensing program that satisfies the federal requirements, a federal licensing program will be established to license wholesale distributors and 3PLs in those states.

#### Role of the States

- The Act 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 third-party logistics providers 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).
- In other words, states cannot alter the standards established by the Act, but they may continue to regulate wholesale distributors and 3PLs in areas that are not covered by and not directly related to the licensing standards in the Act.

# **Authorized Trading Partners**

- Manufacturers and Repackagers: valid registration with FDA
- Wholesale distributors: valid State or Federal license and compliance with reporting requirements
- Third-party logistic provider: valid State or Federal license and compliance with reporting requirements
- Dispensers: valid State license
- Beginning 1/1/2015 trading partners must be "authorized" to engage in "transactions"

# State Licensing Requirements Current Non-Harmonized Approach

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# State Licensing Requirements General Thoughts

- Different States have different requirements
- No harmonized definitions
- No harmonized requirements
- Must review the law in each state and make sure that you comply with the state regulations

**AND**, if you get it wrong, you may be subject to both civil and criminal penalties

#### Who is a Manufacturer?

#### Some examples of Manufacturer

- "A person except a pharmacy who prepares derives, <u>produces</u>, compounds, <u>packages</u> any <u>drug</u>, <u>medicine</u>, <u>chemical</u> or poison"
  - Alabama, Title 34, Practice of Pharmacy: Act 205, section 34-23-1
- Manufacturer means a person who:
  - "1. Derives, produces, prepares, compounds, mixes, cultivates, grows or **processes any drug or medicine** . . .
    - 3. Produces or makes <u>any devices or appliances</u> that are restricted by federal law to sale by or on the order of a physician."
  - Nevada, State Board of Pharmacy, Chapter 639, Section 639.001

# What are the requirements of the manufacturer to register?

- You must look state by state to determine this.
  - Some states require manufacturers only physically present in that state to register e.g. Hawaii
  - Some states require all manufacturers to register e.g. Alabama
  - Some states exempt manufacturers if they are registered with the FDA and distributing their own products e.g. California
  - Some states offer reciprocity if a wholesale distributor is registered with another state acceptable to that state, e.g. Idaho

#### Who is a Wholesale Distributor?

- Wholesaler means "a person who buys prescription drugs for resale and distribution to persons other than consumers."
  - Maine, 32:117.6 Section 13702-A(34)
- Wholesale Distribution means a person ... operating, either within or outside this state, a manufacturing plant . . .in which prescription drugs. . . Are sold, manufactured.. .or offered for sale at wholesale in this state."
  - Iowa Section 657-17.1(155A)

# What are the requirements of the wholesale distributor to register?

- You must look state by state to determine this.
  - Most states require traditional wholesaler distributors to register; varies by state for registration of 3PL.
  - But where wholesale distributor definition sweeps in manufacturers, it varies state by states and also whether the manufacturer directly or indirectly delivers products into that state.

#### Harmonization

- Without harmonization, difficult to determine who is a manufacturer, who is a wholesale distributor and whether you need to register
- Costly for manufacturers and wholesale distributors to keep up with changing state regulations.

## Wholesale Distributor and 3PL Perspectives

- While slightly less "different" for wholesalers under the current state (vs. under PDMA), variation and challenges continue at the state level, in conflict with the intent of DSCSA;
- Experience with states varies lack of understanding / awareness often compounds the problem, different processes (e.g., legislative vs. regulatory), as well as differences in state culture/interpretation with respect to uniformity and preemption;
- States act independently of one another, causing issues when dealing with in-state or non-resident entity movement of product across state lines.
- VAWD continues to be a state requirement in some cases, or a de facto requirement in many.

#### DSCSA Wholesaler Definitions

- WHOLESALE DISTRIBUTOR.—The term 'wholesale distributor' means a person (other than a manufacturer, a manufacturer's co-licensed partner, a third-party logistics provider, or repackager) engaged in wholesale distribution (as defined in section 503(e)(4), as amended by the Drug Supply Chain Security Act).
- WHOLESALE DISTRIBUTION.—The term 'wholesale distributor' means a person (other than a manufacturer, a manufacturer's co-licensed partner, a third-party logistics provider, or repackager) engaged in wholesale distribution (as defined in section 503(e)(4), as amended by the Drug Supply Chain Security Act).

### DSCSA Wholesaler Licensing

- No later than 11/27/2015, FDA is required to develop new federal standards for licensing of wholesale drug distributors and a federal system for wholesale drug distributor licensing for use when a state system does not meet federal standards.
- Beginning 1/1/2015, wholesale drug distributors shall report their licensing status and contact information to FDA. This information will then be made available in a public database.
- Coordination with appropriate State officials

#### Standards for Wholesale Distributors

- Storage and handling of prescription drugs, including facility requirements
- Establishment and maintenance of distribution records
- Surety bond for issuance or renewal of a WD license
- Background checks and fingerprinting of facility managers or designated representatives
- Qualifications for key personnel
- Mandatory inspection of the facility following initial application for licensure (by Federal or State licensing authority or an approved third-party inspection service)
- Persons prohibited from receiving or maintaining a WD license

#### DSCSA 3PL Definition

THIRD-PARTY LOGISTICS PROVIDER.—The term 'third party logistics provider' means an 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.

### DSCSA 3PL Requirements

- THIRD-PARTY LOGISTICS PROVIDERS.—Notwithstanding paragraphs (1) through (4), each entity that meets the definition of a third-party logistics provider under section 581(22) shall obtain a license as a third-party logistics provider as described in section 584(a) and is **not required to obtain a license as a wholesale distributor if the entity never assumes an ownership interest in the product it handles**.".
- THIRD-PARTY LOGISTICS PROVIDER LICENSES.—Until the effective date of the third-party logistics provider licensing regulations under section 584, a third-party logistics provider **shall be considered 'licensed**' under section 581(9)(B) **unless** the Secretary has made a finding that the third-party logistics provider does not utilize good handling and distribution practices and publishes notice thereof.

### DSCSA 3PL Licensing

- No later than 11/27/2015, FDA is required to develop new federal standards for licensing of 3PLs and a federal system for 3PL licensing for use when a state system does not meet federal standards.
- The licensing regulations go into effect 1 year after regulations are finalized. At that time, 3PLs are required to obtain a state or federal license.
- Beginning 11/27/2014, 3PLs shall report their licensing status and contact information to FDA.

# DSCSA 3PL Licensing Standards

- "(A) establish a process by which a third-party accreditation program approved by the Secretary shall, upon request by a third-party logistics provider, issue a license to each third-party logistics provider that meets the requirements set forth in this section;
- "(B) establish a process by which the Secretary shall issue a license to each third-party logistics provider that meets the requirements set forth in this section if the Secretary is not able to approve a third-party accreditation program because no such program meets the Secretary's requirements necessary for approval of such a third-party accreditation program;
- "(C) require that the entity complies with storage practices, as determined by the Secretary for such facility, including—
- '(i) maintaining access to warehouse space of suitable size to facilitate safe operations, including a suitable area to quarantine suspect product;
- "(ii) maintaining adequate security; and
- "(iii) having written policies and procedures to—
- "(I) address receipt, security, storage, inventory, shipment, and distribution of a product;

# DSCSA 3PL licensing standards (cont'd.)

- "(II) identify, record, and report confirmed losses or thefts in the United States;
- "(III) correct errors and inaccuracies in inventories;
- "(IV) provide support for manufacturer recalls; "(V) prepare for, protect against, and address any reasonably foreseeable crisis that affects security or operation at the facility, such as a strike, fire, or flood;
- "(VI) ensure that any expired product is segregated from other products and returned to the manufacturer or repackager or destroyed;
- "(VII) maintain the capability to trace the receipt and outbound distribution of a product, and supplies and records of inventory; and
- "(VIII) quarantine or destroy a suspect product if directed to do so by the respective manufacturer, wholesale distributor, dispenser, or an authorized government agency;

# DSCSA 3PL licensing standards (cont'd.)

- "(D) provide for periodic inspection by the licensing
- authority, as determined by the Secretary, of such facility
- warehouse space to ensure compliance with this section;
- "(E) prohibit a facility from having as a manager or
- designated representative anyone convicted of any felony
- violation of subsection (i) or (k) of section 301 or any
- violation of section 1365 of title 18, United States Code
- relating to product tampering;
- "(F) provide for mandatory background checks of a
- facility manager or a designated representative of such
- manager;

#### Practical effects for 3PL Licensure

- Some states repealed 3PL licensure category or are no longer licensing 3PLs;
- Some states are "waiting" for federal rules and direction from FDA;
- Some states are creating a new 3PL category, but using wholesaler standards, or some "hybrid" variety.

# State DQSA Activity in 2017

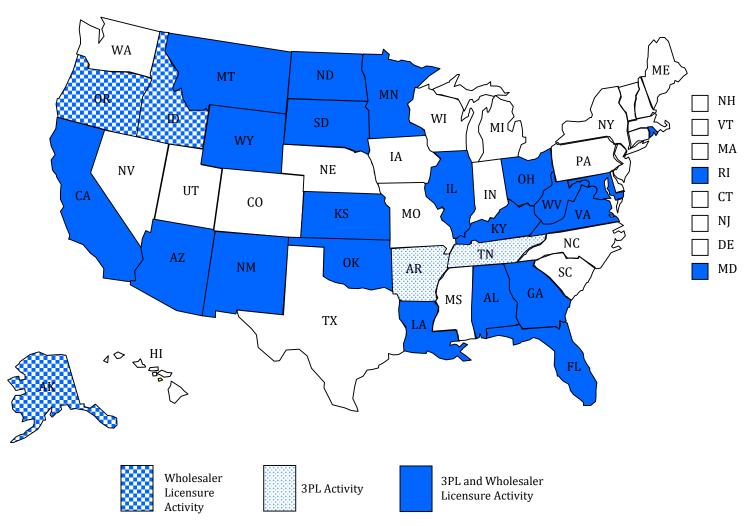
- AK: BoP accepted most HDA suggested language; changes relate to the licensing and inspection of
  certain facilities located outside the state; relates to drug supply chain security; creates a position
  of executive administrator for the Board of Pharmacy. Legislation will be considered in 2018.
- AL: Amends to rename board drug inspectors as drug investigators; clarifies the status of a pharmacist as a health care provider; lists the qualifications a laboratory must satisfy for the board to use its product analysis data; increases the maximum fee for certain new pharmacy.
- AZ: HDA worked with BoP on amended language. Provides requirements for permits related to pharmaceuticals; provides for a third-party logistics provider permit.
- **FL:** HDA continues to coordinate with DBPR to clarify traceability/transaction documentation requirements regarding licensed facilities.
- **KS:** Pharmacy Act amendments relating to a repackager, wholesale distributor and a third-party logistics provider; relates to automated packaging systems and biological products. HDA comments and suggestions were largely accepted.
- KY: HDA staff worked closely with the KY BoP to amend DSCSA definitions throughout proposed regulation.
- MN: Revises and adds definitions, changes licensing requirements for businesses regulated by the Board of Pharmacy

## State DQSA Activity in 2017 (cont.)

- MT: HDA worked with staff to ensure language complied with DSCSA; narrower scope of "applicant", fingerprints required only upon change of applicant.
- **NM:** HDA joined BoP workgroup to provide comments during drafting of regs. All of HDA's comments were accepted and enacted in June, 2017.
- **OH:** Specifies minimum standards for wholesalers. The rule is being amended to specify required information on an application as well as specifying the individuals (certain employees) who are subject to a background check.
- **SD:** HDA worked with the BoP to update definitions and remove pedigree language; HDA comments were largely accepted, language revises certain provisions regarding wholesale drug distributors, to provide for licensure and regulation of outsourcing facilities for certain drugs, and to establish a fee for licensure of outsourcing facilities. Continue to work with Board on exemption language in rulemaking.
- **WI:** Current rule project in progress, objective to come into compliance with DSCSA.
- WY: Pulled proposed rule after HDA suggestions, will revisit (this Fall 2017?).

#### HDA DSCSA State Activity Map

November 6, 2017



# Conclusions and Closing Thoughts

- Post-DSCSA, licensure is no more consistent at the state level than before, and in some cases, it is more varied.
- What can trading partners or advocacy organizations do to mitigate the state-by-state variation?
- What happens to VAWD requirements?
- Will the DSCSA goal of uniformity ever be achieved?

# Questions?