Drug Supply Chain Security Act
(Title II of the Drug Quality and Security Act)
Federal – State Collaboration

Connie Jung, RPh, PhD
Eleni Anagnostiadis, RPh
U.S. Food and Drug Administration

NABP 110th Annual Meeting
May 17, 2014

Financial Disclosure

- We declare that neither we nor any immediate family member have a current affiliation or financial arrangement with any potential sponsor and/or organization(s) that may have a direct interest in the subject matter of the above stated continuing pharmacy education program.

Objectives

- Overview of the Drug Supply Chain Security Act (Title II of the Drug Quality and Security Act),
- FDA's implementation plan of the law
- Product Tracing Requirements
- Wholesale Drug Distributor and Third-Party Logistics Provider Provisions
- Role of State Boards

Self-Assessment Questions (1)

What stakeholders are impacted by the new Drug Supply Chain Security Act?

a. Manufacturers
b. Wholesale drug distributors
c. Third-party logistics providers
d. Dispensers
e. All of the above

Self-Assessment Questions (2)

The state boards of pharmacy are not impacted by the new Drug Supply Chain Security Act?

a. True
b. False

Self-Assessment Questions (3)

Beginning _____,wholesale drug distributors shall report annually to FDA information including licensing status, contact information, and disciplinary actions.

a. November 27, 2014
b. January 1, 2015
c. January 1, 2016
d. January 1, 2017

DSCSA

The Drug Supply Chain Security Act

What is it?

Overview of the DSCSA (enacted 11/27/2013)

- Product tracing
- Product verification
  - Quarantine and investigation (steps for detection and response)
  - Notification
  - Recordkeeping
- Product identification
- Wholesaler standards for licensure
- Third-party logistics provider standards for licensure
- Enhanced system – 10 years
- Penalties
- National uniform policy

Stakeholders Involved

- Dispenser
- Manufacturer
- Repackager
- Third-party logistics provider
- Wholesale distributor
- FDA
- State officials
- International regulatory counterparts
- Others

Definitions

- Dispenser
- Distribute
- Illegitimate product
- Manufacturer
- Package
- Product
- Product identifier
- Quarantine
- Repackager
- Return
- Standardized numerical identifier
- Suspect product
- Trading partner
- Transaction
- Transaction history
- Transaction information
- Transaction statement
- Wholesale Distributor
- Among others...

Definitions: Scope

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
- Exempt
  - Intercompany 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
  - Charitable organizations
  - Distributions pursuant to a merger or sale
  - Certain combination products
  - Certain medical kits
  - Certain IV products
  - Medical gas distribution
  - Approved animal drugs

Product Tracing

- Beginning 1/1/2015, manufacturers, wholesaler drug distributors, repackagers, and many dispensers (primarily pharmacies beginning 7/1/2015) in the drug supply chain will provide information about a drug and who handled it each time it is sold in the U.S. market.
- This transaction documentation consists of:
  - Transaction ***information (TI)*** *which include lot number of product (except for certain wholesale drug distributor transactions; see slide 29)*
  - Transaction ***history (TH)***
  - Transaction ***statement (TS)***
- FDA is required to establish standards for the exchange of transaction documentation no later than 11/27/2014.

Definitions: Transaction Information, History, and 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.

Authorized Trading Partners

- Manufacturers and Repackagers: valid registration with FDA
- Wholesale distributors: 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 logistic provider: 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: valid State license

Beginning 1/1/2015 - trading partners must be “authorized”

Product Verification

No later than 1/1/2015, manufacturers, wholesaler drug distributors, repackagers, and many dispensers (primarily pharmacies) shall establish systems and processes to be able to comply with the verification requirements.

Definitions

Suspect Product - reason to believe that the product is potentially:

- Counterfeit, diverted, stolen
- Subject of fraudulent transaction
- Intentionally adulterated or appears otherwise unfit for distribution such that would result in serious adverse health consequences or death to humans

Illegitimate Product - credible evidence that the product actually is any of the above

Product Identification (Serialization)

- No later than 4 years (11/27/2017), manufacturers, followed by repackagers (11/27/2018) shall place a unique product identifier on certain prescription drug packages
  - 2D bar code
- Product identifier
  - National Drug Code
  - Serial number
  - Lot number
  - Expiration date

- After 6 years (11/27/2019), wholesalers, followed by dispensers (11/27/2020), will only trade products with product identifiers.
- Verification requirements change once product is serialized. (starting in 2017 for M, 2018 for R, 2019 for WD and 2020 for D)

Wholesaler Licensing and Standards

- 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

Third-Party Logistics Provider (3PL) Licensing and Standards

- 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 by federal law to obtain a state or federal license.
- Beginning 11/27/2014, 3PLs shall report their licensing status and contact information to FDA.

Enhanced System – 10 years

- Establishes package level requirements for the interoperable, electronic tracing of products that shall go into effect 10 years after enactment of this Act, including those relating to:
  - Electronic exchange of transaction information for each sale of certain prescription drugs
  - Verification of product identifiers at the package level
  - Prompt response to suspect and illegitimate products when found
  - Improved efficiency of recalls

Uniform National Standards - Preemption

- Product tracing and other requirements:
  - No state or local government may establish or continue in effect requirements for tracing products through the distribution system which are inconsistent with, more stringent than, or in addition to, any requirements applicable under 503(e) (as amended by such Act) or the subchapter, or which are inconsistent with any waiver, exception, exemption, or restrictions under sections 581 or 582.

- 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

DSCSA

The Drug Supply Chain Security Act

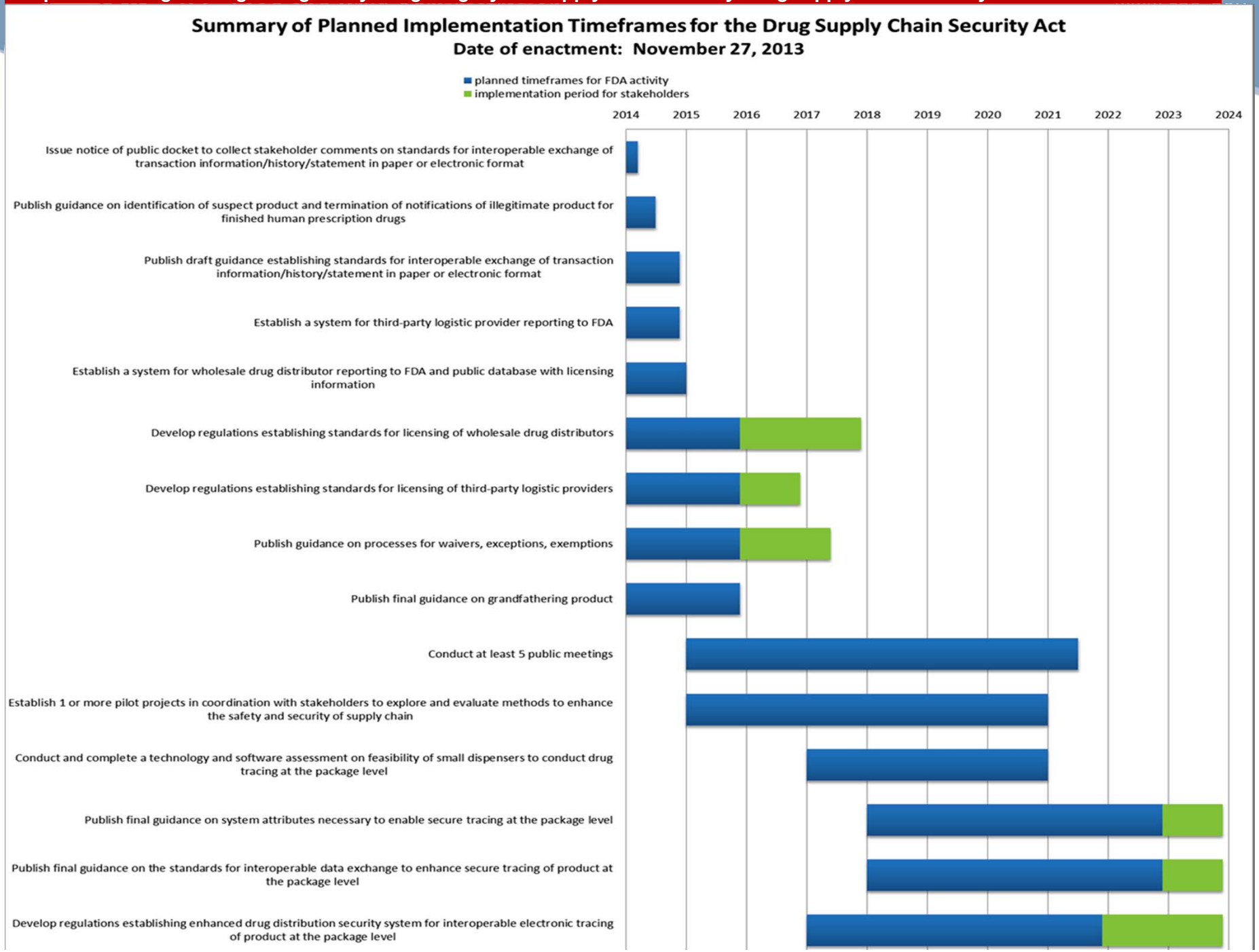
FDA's implementation plan

DSCSA Implementation Plan

- The law requires FDA to develop standards, guidances, regulations, pilot programs, and licensing programs and hold public meetings and other efforts to support efficient and effective implementation of the law.

- FDA Offices involved in the implementation
  - Center for Drug Evaluation and Research (CDER) - LEAD
  - Center for Biologics Evaluation and Research (CBER)
  - Office of Regulatory Affairs (ORA)
  - Office of the Commissioner (OC)
    - Office of Chief Counsel
    - Office of Policy/Office of Planning
    - Office of External Affairs

http://www.fda.gov/Drugs/DrugSafety/DrugIntegrityandSupplyChainSecurity/DrugSupplyChainSecurityAct/ucm382022.htm



http://www.fda.gov/Drugs/DrugSafety/DrugIntegrityandSupplyChainSecurity/DrugSupplyChainSecurityAct/ucm382022.htm

The following table highlights certain deliverables described in the law. Estimated target dates are based on applicable statutory deadlines and may be listed as "TBD" (to be determined) when dependent on completion of other deliverables or activities. As FDA works with stakeholders to implement the provisions of the law, additional deliverables may be identified. FDA's Center for Drug Evaluation and Research is the lead for the Drug Supply Chain Security Act Implementation and other agency components are actively engaged.

Section of DSCSA	Deliverable Type	Deliverable Description	Estimated Target Date
202	FR Notice	Issue notice of public docket to collect stakeholder comments on standards for interoperable exchange of transaction information/history/statement in paper or electronic format	2/20/2014
202	Guidance	Publish draft guidance establishing standards for interoperable exchange of transaction information/history/statement in paper or electronic format	11/27/2014
202	Guidance	Publish guidance on processes for waivers, exceptions, exemptions	11/27/2015
202	Guidance	Publish final guidance on grandfathering product	11/27/2015
203	Assessment	Conduct and complete a technology and software assessment on feasibility of small dispensers to conduct drug tracing at the package level	TBD
203	Guidance	Publish guidance on identification of suspect product and termination of notifications of illegitimate product for finished human prescription drugs	5/27/2014
203	Public Meeting	Conduct at least 5 public meetings	TBD
203	Pilot Project	Establish 1 or more pilot projects in coordination with stakeholders to explore and evaluate methods to enhance the safety and security of supply chain	TBD
203	Guidance	Publish final guidance on system attributes necessary to enable secure tracing at the package level	11/27/2022
203	Guidance	Publish final guidance on standards for interoperable data exchange to enhance secure tracing of product at the package level	11/27/2022
203	Regulation	Develop regulations establishing enhanced drug distribution security system for interoperable electronic tracing of product at the package level	11/27/2021
204	Database	Establish a system for wholesale drug distributor reporting to FDA and public database with licensing information	1/1/2015
204	Regulation	Develop regulations establishing standards for licensing of wholesale drug distributors	11/27/2015
205	Database	Establish a system for third-party logistic provider reporting to FDA	11/27/2014
205	Regulation	Develop regulations establishing standards for licensing of third-party logistic providers	11/27/2015

DSCSA

The Drug Supply Chain Security Act

Product Tracing

Product Tracing

- Beginning 1/1/15, manufacturers, wholesaler drug distributors, repackagers, and many dispensers (beginning 7/1/15) must provide TI, TH, TS to the subsequent owner for each transaction (which change of ownership occurs)
  Note: Dispensers do not need to provide this information to patients pursuant to a prescription.
- Transaction documentation consists of:
  - Transaction ***information (TI)***
  - Transaction ***history (TH)***
  - Transaction ***statement (TS)***
- TI includes lot number of product
  (except for certain wholesale drug distributor transactions, see slide 29)

Product Tracing

Accepting ownership

Beginning 1/1/15, wholesaler drug distributors, repackagers, and many dispensers (beginning 7/1/15) **cannot accept ownership** of a product, unless the previous owner, prior to, or at the time of, the transaction provides TI, TH, and TS for the product

Record keeping (capturing and maintaining information)

- Manufacturers and repackagers shall capture TI (including lot level information), TH, TS for each transaction and maintain such information, history and statement for not less than 6 years (record keeping requirement).
- Wholesaler distributors shall capture TI (including lot-level information as described in the law) , TH, TS and maintain for not less than 6 years.
- *Dispensers shall capture TI (including lot-level information, if provided), TH, TS as necessary to investigate suspect product for at least 6 years (record keeping requirement).*

Product Tracing

Manufacturer Specific

Manufacturers -

- Shall provide to subsequent owner TI, TH, and TS, prior to, or at the time of each transaction (transfer of product with change of ownership) of a product, in a single document (paper or electronic).
- Beginning 11/27/17, shall provide TI, TH, TS in electronic format.
  Exception: may continue to use paper format to licensed health care practitioners authorized to prescribe medication under State law or other licensed individual under the supervision or direction of such a practitioner who dispenses product in the usual course or professional practice.

Product Tracing

Wholesale Distributor Specific (1)

- If a WD **purchased directly** from the manufacturer (M), the exclusive distributor (ED), or repackager (R) that purchased directly from M –
  - "direct purchase statement" becomes the transaction statement for this WD
  - TH and TI are not required to include lot number of product, initial transaction date, or the initial shipment date from the manufacturer as defined in section 582(26)
  - TI, TH, and TS provided to a dispenser shall be in a single document in paper or electronic format
  - TI/TH,TS shall be provided to subsequent WDs, but can be in any combination of self-generated paper, electronic data, or manufacturer-provided information on the product package.

Product Tracing

Wholesale Distributor Specific (2)

- If the WD **did not purchase a product directly** from the M, ED, or an R that purchased directly from the M, then prior to or at the time of transaction or subsequent transaction, the WD shall provide to the subsequent purchaser a TI, TH, and TS in paper or electronic format that complies with the initial standards guidance FDA publishes.

- For this WD, the TH will begin with the WD that purchased directly from M, ED, or an R that purchased directly from the M, and this WD will inform subsequent purchasers that it received a direct purchase statement from the WD that purchased directly from M, ED, or an R that purchased directly from the M.

- Shall maintain the confidentiality of the transaction information, history and statement in a way that prohibits disclosure to any person, with a few exceptions (for example, when sharing with State or Federal officials).

Product Tracing

Dispenser Specific

Dispensers (Pharmacies) -

- May enter into a written agreement with a third party, who confidentially maintains the TI, TH, TS on behalf of the dispenser (could be an authorized wholesale distributor).
- Shall maintain a copy of the written agreement.
- Are not relieved of obligations of the dispenser.

Product Verification

- No later than 1/1/15, manufacturers, wholesaler drug distributors, repackagers, and many dispensers (primarily pharmacies) shall establish systems and processes to be able to comply with the verification requirements
  - Must be able to respond to verification requests from Secretary about suspect product
  - Quarantine and investigate suspect product to determine if illegitimate product (includes validating applicable TI and TH)
  - Notify trading partners and FDA of illegitimate product (within 24 hours of determination)
  - Respond to notifications of illegitimate product
  - Recordkeeping
- Verification requirements change once product is serialized.

  (starting in 2017 for M, 2018 for R, 2019 for WD and 2020 for D)

Request for Information

When responding to **requests for information** from FDA or other appropriate Federal or State official in the event of a recall or for the purpose of investigating a suspect or illegitimate product,

- **Manufacturers, Wholesale Distributors, Repackager:**

  Shall provide applicable TI, TH, and TS, not later than 1 business day, not to exceed 48 hours after receiving request

- **Dispensers:**

  Shall provide applicable TI, TH, TS not later than 2 business days (or another reasonable time as determined by FDA) after receiving request; shall not include lot, initial transaction date or initial shipment date unless such information was provided; may respond in paper or electronic format; certain limitations to information requests apply until November 27, 2017.

DSCSA

The Drug Supply Chain Security Act

Wholesale Drug Distributor and Third-Party Logistics Provider Provisions

Definitions

WHOLESALE DISTRIBUTOR — 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 — 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.

Wholesaler licensing and standards

- FDA shall develop regulations establishing standards for licensing for Wholesale Distributors (WD) by 11/27/2015.
- WD standards for licensure go into effect 2 years (11/27/2017) 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 Third-Party Logistic Providers by 11/27/2015.
- 3PL standards for licensure go into effect 1 year (11/27/2016) after regulations are finalized.
- At that time, 3PLs are required by federal law to obtain a state or federal license
- The federal system for 3PL licensing shall be used when the state from which the drug is distributed has not established a licensure requirement.

Wholesaler and 3PL Reporting to FDA

Who	When	Frequency	What
3PL	11/27/2014	annually	Licensing status and contact information
WD*	1/1/2015	annually	Licensing status, contact information, significant disciplinary actions

*FDA is required to establish a database of authorized wholesale distributors which will include licensing status and contact information and be available to the public on FDA's website.

Wholesaler Reporting to FDA

FDA Public Database - established no later than 1/1/2015

Coordination – FDA shall establish a format and procedure for appropriate State officials to access the information in the database in a prompt and secure manner.

- State and license #
- Facility information, including all trade names
- Significant disciplinary actions such as revocation or suspension of license

State Licensing Fees

- WDDs – The DSCSA does not prohibit States from collecting fees from wholesale distributors in connection with State licensing.

- 3PLs – For program establish by a State, the State can collect fees from a 3PL for issuing a license. If a State does not established program, the State is prohibited from collecting fees from 3PL.

DSCSA

The Drug Supply Chain Security Act

Role of State Regulatory Authorities

Action Items for your Board 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?

Action Items for your Board to Consider (2)

- Identify if your state plans to create a new licensure program 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?
  - Would you recognize a national 3rd party accreditation program to fulfill that role?

Interactive Dialogue/Open Mic

Welcome the boards to stand up and share:

- Preliminary thoughts or tentative plan of action related to the WD and 3PL licensing moving forward
- Comments you would like to share with FDA related to WD and 3PL licensing, product tracing or other elements of the DSCSA

Self-Assessment Questions (1)

What stakeholders are impacted by the new Drug Supply Chain Security Act?

a. Manufacturers
b. Wholesale drug distributors
c. Third-party logistics providers
d. Dispensers
e. All of the above

Self-Assessment Questions (2)

The state boards of pharmacy are not impacted by the new Drug Supply Chain Security Act?

a. True
b. False

Self-Assessment Questions (3)

Beginning _____,wholesale drug distributors shall report annually to FDA information including licensing status, contact information, and disciplinary actions.

a. November 27, 2014
b. January 1, 2015
c. January 1, 2016
d. January 1, 2017

THANK YOU!

Comments or questions to:

drugtrackandtrace@fda.hhs.gov