

# 2014

## HDMA DISTRIBUTION MANAGEMENT CONFERENCE AND TECHNOLOGY EXPO

Co-hosted with IFPW (International Federation of Pharmaceutical Wholesalers)  
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- **Title II of The Drug Quality and Security Act (H.R. 3204):  
Traceability and Licensing  
Overview**
- **Brian Waldman, Arent Fox LLP**

## 2014 HDMA Distribution Management Conference and Technology Expo

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# Title II of The Drug Quality and Security Act (H.R. 3204): A Traceability and Licensing Overview

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# **Drug Quality & Security Act (H.R. 3204)**

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- **Signed into law on November 27, 2013**
- **Title I – Compounding Quality Act**
- **Title II – Drug Supply Chain Security Act**
  - Focus of this presentation will be Title II
  - Federal traceability system for prescription drugs that preempts State pedigree requirements
  - Phased-in implementation over the next 10 years; ultimately unit-level traceability
  - Also raises licensure standards for Rx drug wholesale distributors nationally and establishes separate licensure for 3PLs

# Overview: Drug Supply Chain Security Act

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- **Traceability provisions**
  - Immediate preemption of State activity
  - Manufacturer deadlines
  - Repackager deadlines
  - Wholesale distributor deadlines
  - Dispenser deadlines
  - Unit-level traceability at 10-year mark
- **Wholesale distributor licensing provisions**
  - National standards
  - Preemption of inconsistent State requirements

# New Definitions of Supply Chain Members

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## ➤ **Manufacturer:**

- Application holder
- Co-licensed partner of application holder
- Affiliate of application holder or co-licensed partner

## ➤ **Repackager**

## ➤ **Wholesale distributor**

## ➤ **Dispenser**

## ➤ **3PL**

# General Traceability Timeline

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## ➤ Phase 1

- Preemption of State activity
- Pre-serialization “pedigree” requirements
- Serialization by manufacturers (“product identifier”) and lot level product tracing
- “Verification” of suspect and illegitimate product and saleable returns

## ➤ Phase 2

- Unit level traceability
- Transaction History (“pedigree”) sunsets
- New FDA authority and responsibilities

# Preemption of State “Pedigree” Laws

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- The Act preempts all State laws, regulations, and requirements for tracing products through the pharmaceutical supply chain (paper or electronic), including any recordkeeping requirements.
- Preemption takes place “upon the date of enactment,” which is Nov. 27, 2013.
- Federal pedigree requirements under existing PDMA regulations continue until January 1, 2015 when phased-in implementation of the Act’s traceability provisions begins.

# Phase 1a: Pre-Serialization

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## ➤ Effective Jan. 1, 2015:

- Manufacturers must provide to subsequent product owners a single document (electronic or paper) that includes Transaction Information (TI), Transaction History (TH) and Transaction Statement (TS).
- Wholesale distributors and repackagers must receive TI/TH/TS and provide it to subsequent purchasers of the product.
- Manufacturers, wholesale distributors, and repackagers must capture and maintain for 6 years the TI/TH/TS for each transaction, whether as the buyer or the seller.

## ➤ Dispensers must be able to receive TI/TH/TS information by July 1, 2015.



# “Verification” Pre-Serialization

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- By January 1, 2015, manufacturers, wholesale distributors, and repackagers also must have in place systems and processes for investigating and quarantining suspect or illegitimate products, including the validation of any applicable TI/TH.
  - If a suspect product is determined to not be illegitimate, HHS Secretary must be notified promptly.
  - If a product is determined to be illegitimate, HHS Secretary and all trading partners must be notified within 24 hours.
- Records of investigation and disposition of product must be kept for at least 6 years after the investigation/disposition concludes.
- Dispensers must have these verification systems in place by July 1, 2015.

# Suspect & Illegitimate Product Definitions

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- **“Suspect product” = product for which there is reason to believe that such product:**
  - a) is potentially counterfeit, diverted, or stolen;
  - b) is potentially intentionally adulterated such that the product would result in serious adverse health consequences or death to humans;
  - c) is potentially the subject of a fraudulent transaction; or
  - d) appears otherwise unfit for distribution such that the product would result in serious adverse health consequences or death to humans.
  
- **“Illegitimate product” = product for which credible evidence shows that the product:**
  - a) is counterfeit, diverted, or stolen;
  - b) is intentionally adulterated such that the product would result in serious adverse health consequences or death to humans;
  - c) is the subject of a fraudulent transaction; or
  - d) appears otherwise unfit for distribution such that the product would result in serious adverse health consequences or death to humans.

# FDA Obligation regarding Suspect Products

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- **180 days post-enactment (May 26, 2014), FDA must provide guidance to aid trading partners in the identification of suspect product.**
- **The guidance also should set forth a process to terminate notifications regarding illegitimate product.**

# “Authorized Trading Partners”

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- **All trading partners (manufacturers, repackagers, wholesale distributors, 3PLs, and dispensers) must be properly registered or licensed.**
  - Registration with FDA for drug manufacturing or repackaging facilities
  - State (or Federal, once that becomes effective) licensure for wholesalers or 3PLs
  - State licensure for dispensers
- **Manufacturers, repackagers, wholesale distributors, and dispensers may only do business with “authorized trading partners” (i.e., those that are properly registered or licensed) as of January 1, 2015.**

# Transaction Information/History/Statement

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- **Transaction Information (TI) includes:**
  - the proprietary or established name of the product;
  - strength and dosage form of the product;
  - NDC number of the product;
  - container size and number of containers;
  - lot number of the product;
  - date of the transaction and date of the shipment (only if >24 hours after the transaction);
  - the business name and address of the person *from whom* ownership is being transferred; and
  - the business name and address *to whom* ownership is being transferred.
  
- **A “transaction” is always a change in ownership between trading partners (never a change in possession as under some current state laws).**

# Transaction Information/History/Statement

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- **Transaction History (TH) = paper or electronic statement that includes the transaction information for each prior transaction going back to the manufacturer**
  
- **Transaction Statement (TS) = paper or electronic attestation by the entity transferring ownership of the product that it:**
  - is “authorized” under the Act;
  - received the product from an authorized party;
  - received TI/TS 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.

# FDA Obligation regarding TI/TH/TS

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- **FDA must publish draft standards for the exchange of TI/TH/TS in paper or electronic format no later than 1 year after enactment (Nov. 27, 2014). Public input and a 60-day comment period are required.**
- **Is time between Nov. 27, 2014 and Jan. 1, 2015 (when trading partners are required to begin providing/receiving TI/TH/TS) sufficient? FDA should be encouraged to issue draft standards sooner than the November 2014 deadline.**

# Wholesale Distributor Traceability Obligations

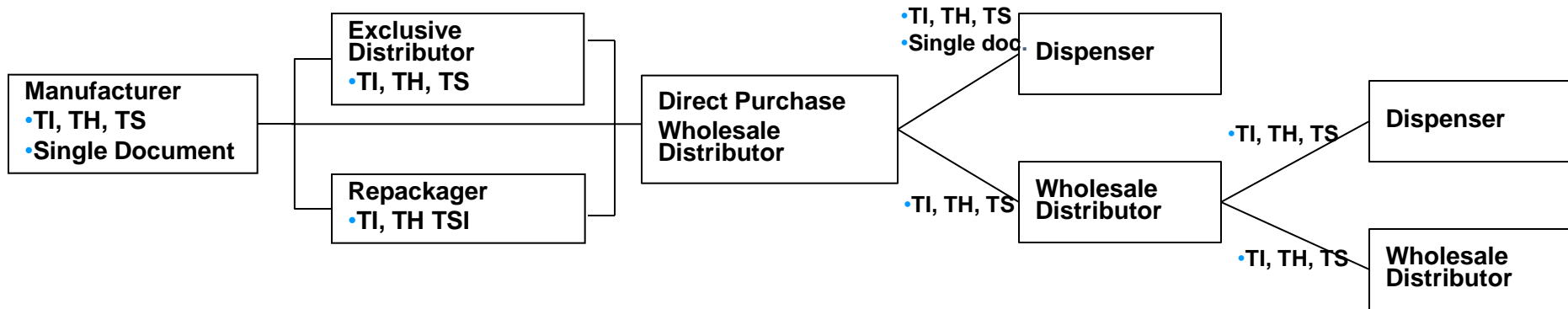
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- **When providing TI/TH/TS to subsequent purchasers of the product, a wholesale distributor has 2 options:**
  - For direct purchases made from a manufacturer, an exclusive distributor, or a repackager that purchased directly from a manufacturer, the wholesaler shall provide a “direct purchase statement.” In a direct purchase, the TI/TH does not need to include lot number, initial transaction date, or initial shipment date from the manufacturer.
  - For all other, non-direct purchases, the wholesaler shall provide the full TI/TH/TS, but TH starts with direct purchase wholesaler.
- **If the product is sold by a direct purchase wholesaler to a dispenser, the information must be provided on a single document in electronic or paper format.**
- **If the product is sold to another wholesaler, the information may be any combination of self-generated paper, electronic data, or manufacturer-provided information on the product package.**



# Traceability Requirements

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# Returns Pre-Serialization

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- **“Return” defined as providing product to the authorized immediate trading partner from which such product was purchased or received, or to a returns processor or reverse logistics provider for handling of such product.**
- **Wholesale distributors may accept returns from dispensers or repackagers under the terms and conditions of any agreement between the parties, and may redistribute saleable units without providing TH.**
  - Dispensers should return saleable products to the entity from which the products were purchased or received.
- **For subsequent transactions, the TH will begin with the accepting wholesale distributor.**

# Phase 1b: Serialization

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- **Four years after enactment (Nov. 2017), manufacturers must provide TI/TH/TS in electronic format.**
- **Not later than 4 years after enactment, manufacturers must have affixed or imprinted a product identifier in both human- and machine-readable form to each package and homogenous case of Rx drug product.**
  - “Product identifier” consists of standardized numerical identifier (SNI), lot number, and expiration date. SNI is the NDC number + a unique alphanumeric serial number up to 20 characters.
  - Each package must have a 2D barcode; a case may have a 2D barcode or a linear barcode.
- **Product identifier information must be maintained for a product for at least 6 years after the date of transaction.**

# Serialization: FDA Obligations

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- **Two years post-enactment (Nov. 2015):**
  - Guidance for grandfathering of products that are not serialized and are present in the supply chain when Product Identifier requirements become effective
  - Guidance on waivers from information exchange for supply chain members, which FDA may grant upon a determination that the requirement would cause undue economic hardship or for emergency medical reasons (e.g., public health emergency declaration)
  - Guidance on Product Identifier exceptions, such as if a product is packaged in a container that is too small or unable to accommodate the required information

# More Post-Serialization Manufacturer Req'ts

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- Also at 4 years after enactment, manufacturers must have systems and processes in place to respond to verification requests from authorized wholesale distributors, repackagers, or dispensers.
- Verification of the product must be at the package level, including the SNI, and notification of the person making the request must be done within 24 hours. If the product identifier does not correspond, the manufacturer must treat the product as suspect and conduct an investigation.
  - “Verification” means determining whether the Product Identifier affixed to, or imprinted upon, a package or homogenous case corresponds to the SNI or lot number and expiration date assigned to the product by the manufacturer.

# More Post-Serialization Manufacturer Req'ts

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## ➤ Also at 4 years post enactment:

- Manufacturers must retain a sample of illegitimate product at the request of the Secretary.
- Manufacturers must verify saleable returned products at the package level before further distributing such products (i.e., by verifying the Product Identifier for each sealed homogenous case or, if not in a case, on each package).

# Wholesale Distributors Post-Serialization

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- **Beginning 6 years after enactment (Nov. 2019):**
  - Wholesale distributors may receive and sell only serialized product (i.e., encoded by the manufacturer with a Product Identifier).
  - Distributors must receive and maintain TI/TH/TS electronically.
  - Distributors must retain a sample of illegitimate product at the request of the Secretary.
  - Distributors may accept returns only if associated with the original TI/TS for the returned product and must verify the Product Identifier before further distribution.

# Dispensers Post-Serialization

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- **Beginning 7 years after enactment (Nov. 2020):**
  - Dispensers may receive and sell only serialized product.
  - Dispensers must retain a sample of illegitimate product at the request of the Secretary.
  - Dispensers must verify lot number for suspect product and also verify Product Identifiers for 3 packages or 10% of suspect product.



## Phase 2: Unit-Level Traceability

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- 10 years after enactment (Nov. 2023), TH requirements sunset.
- All supply chain members must have in place interoperable electronic systems for unit-level product tracing.
- FDA must conduct a series of assessments, public meetings, and at least 1 pilot program during the interim period to develop the precise requirements for, and ensure the technological feasibility of, Phase 2.

## Phase 2: FDA Obligations

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- Establish 1 or more pilot projects to evaluate methods to enhance safety and security of the supply chain.
- Issue guidance on unit-level traceability, including inference, enhanced verification activities, aggregation, etc. no later than 18 months after conducting a public meeting on system attributes necessary to enable tracing at the package level.
- Hold at least 5 public meetings regarding how to enhance supply chain safety and security, the first no earlier than 1 year post-enactment.

## Phase 2: FDA Obligations (cont'd)

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- **No later than 18 months after issuing final guidance on suspect and illegitimate product and unit-level tracing, FDA must conduct an assessment of small dispenser capabilities (technology and software), to be completed no later than 8.5 years after enactment.**
- **Necessary and appropriate updates to previously issued guidance should be done no less than 18 months after convening a public meeting on interoperable standards.**

# Licensure for Wholesale Distributors

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- **Title II also requires FDA to develop Federal licensing standards for wholesale distributors through notice-and-comment rulemaking.**
  - Standards must be finalized no later than 2 years after enactment (Nov. 2015), with their effective date to be 2 years after publication in the Federal Register (Nov. 2017, assuming FDA does not complete rulemaking process before Nov. 2015).
  
- **Effective January 1, 2015, wholesale distributors must be licensed by the State from which the drug is distributed (or, if the State does not have a licensing program, by FDA) and the State into which the drug is distributed, if required.**

# Licensure for Wholesale Distributors

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- Also as of January 1, 2015, FDA must have in place a publicly available database of authorized wholesale distributors by name, contact information, and each State in which such WD is licensed to engage in wholesale distribution.
- Wholesale distributors must begin reporting annually to FDA (beginning Jan. 1, 2015) the following information in order to populate the agency's database:
  - Each State in which the wholesale distributor is licensed
  - Name, address, and contact information for facility
  - Any significant disciplinary actions (e.g., revocation or suspension of a license)

# Federal Licensing Standards

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- **The Act requires the standards to address:**
  - 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

## Preemption of State WD Licensure Req't's

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- The Act preempts State and local “standards, requirements, or regulations with respect to wholesale prescription drug distributor... licensure that are inconsistent with, less stringent than, directly related to, or covered by” the Federal standards issued by FDA.
- Federal standards not required to be promulgated until Nov. 2015, and made effective 2 years later. Therefore, it appears that preemption does not take place until the Federal standards are in effect in order to displace State requirements (i.e., Nov. 2017, if not sooner).

## Preemption of State WD Licensure Reqt's

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- Preemption provision effectively requires States either to incorporate Federal standards by reference or to develop consistent licensure requirements.
  - Language of preemption provision creates a floor for States (“less stringent than”), and most likely a ceiling for State licensing requirements.
  - Further, States may impose requirements unrelated to WD licensing and the subjects covered by the Federal standards; e.g., controlled substance storage and distribution; manufacturer licensing.
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# Session Wrap-up

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