Drug Supply Chain Security Act
(Title II of the Drug Quality and Security Act)
Implementation Updates

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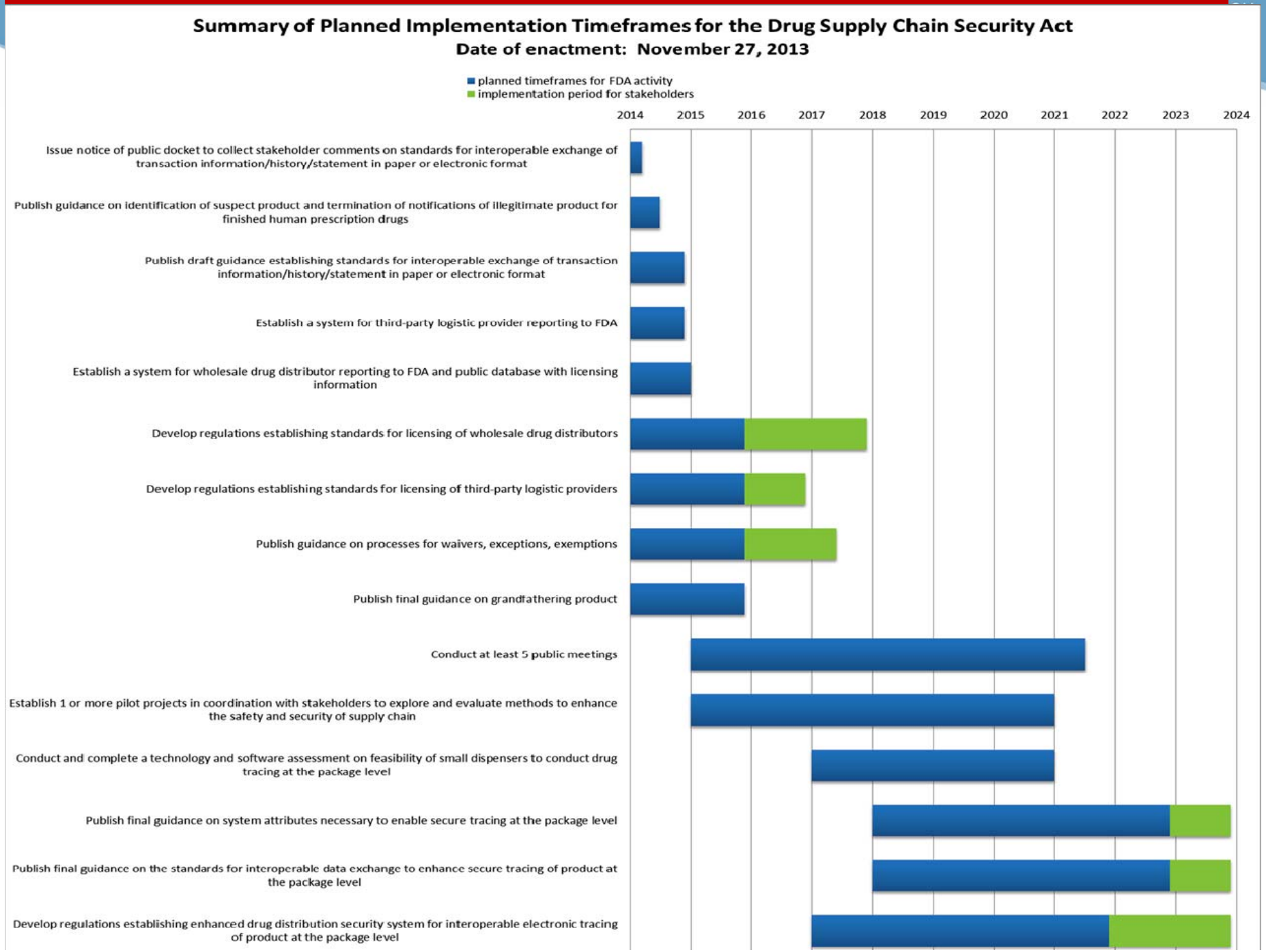
Overview of the DSCSA (enacted 11/27/2013)

- 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

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



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

Product Tracing (1)

- 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*
  - Transaction ***history (TH)***
  - Transaction ***statement (TS)***
- FDA is required to establish standards for the exchange of transaction documentation no later than 11/27/2014.

Product Tracing (2)

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).*

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 1/1/15, 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)

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

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Drug Supply Chain Security Act

Standards for the interoperable exchange of tracing information for finished, human, prescription drugs

Goals of the Workshop

- To obtain input from workshop participants on how trading partners can best comply with the requirements for the interoperable exchange of transaction information, transaction history, and transaction statements under the DSCSA on January 1, 2015 using currently available standards or practices.

- To utilize this input to help FDA establish initial standards for the interoperable exchange of transaction information, transaction history, and transaction statements in paper or electronic format that will be issued in the draft guidance required under Sec. 203 (h) of the DSCSA.

What We Heard

- Flexibility, with structure
- Trading partners, varying degrees of sophistication
- Electronic preferred, paper needed
- Issue guidance ASAP, stakeholders moving forward in the meantime
- Great opportunity for dialogue with all stakeholders at the table
- Clarification (examples – not inclusive)
  - Name of Product
  - NDC
  - Strength
  - Dosage form
  - Container Size
  - Date of transaction
  - Date of shipment

Summary of Supply Chain Options

For transactions between manufacturers or repackagers and wholesale distributors and transactions between wholesale distributors and dispenser –

- EPCIS (Electronic Product Code Information Services)
- EDI (Electronic Data Interchange)/(Advance Ship Notice)
- Web portal
- Package slip

- Invoice
- Email

…are the tools that could be used to meet the requirements

How to submit comments to the docket

- Submit electronic comments to http://www.regulations.gov .
- Submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.
- All comments should be identified with the docket number FDA-2014-N-0337.
- Public workshop docket will close on June 9, 2014.
- Stakeholder input essential and valued!
- Public workshop webpage: *http://www.fda.gov/Drugs/NewsEvents/ucm388993.htm*

THANK YOU!

Comments or questions to:

drugtrackandtrace@fda.hhs.gov