



U.S. Food and Drug Administration
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U.S. Traceability: the Drug Supply Chain Security Act

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DSCSA

The Drug Supply Chain Security Act

What is it?



Elements of the New Law

- 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



New Definitions

- Distribute
- Illegitimate product
- Package
- Product
- Product identifier
- Quarantine
- Return
- Standardized numerical identifier
- Suspect product
- Trading partner
- Transaction
- Transaction history
- Transaction information
- Transaction statement
- 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 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

- Beginning 1/1/15, manufacturers, wholesaler drug distributors, repackagers, and many dispensers (primarily pharmacies beginning 7/1/15) 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
- FDA is required to establish standards for the exchange of transaction documentation that consists of:
 - Transaction ***information (TI)***
 - Transaction ***history (TH)***
 - Transaction ***statement (TS)***



Transaction Information, History, & Statement

Transaction Information (TI):

- Proprietary or established name or names of the product;
- strength and dosage form of the product;
- NDC 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;
- 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.



Definitions: suspect and illegitimate product

- Suspect Product - reason to believe that product 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 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
 - Notify trading partners and FDA of illegitimate product
 - Respond to notifications of illegitimate product
 - Recordkeeping

Product identification (serialization)

- No later than four years (11/27/17), manufacturers, followed by repackagers (11/27/18) 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 six years (11/27/19), wholesalers, followed by dispensers (11/27/20), will trade only products with product identifiers
- Product verification – using the product identifier





Wholesaler licensing and standards

- No later than 11/27/15, 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 11/27/15, 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 11/27/14, 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 ten 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



DSCSA

The Drug Supply Chain Security Act

FDA's implementation plan



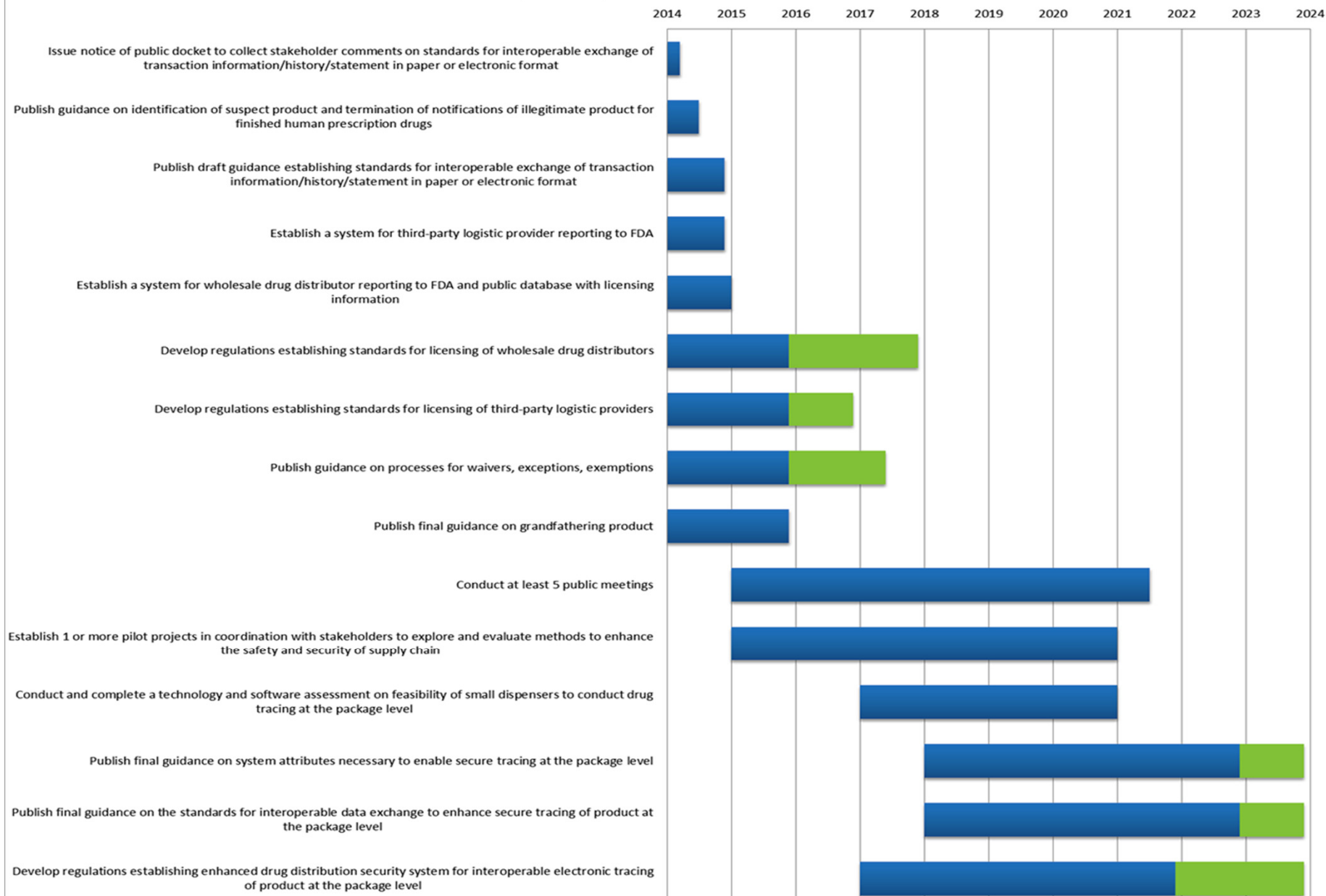
Implementation

- 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 Center/Office(s) involved in the implementation
 - Center for Drug Evaluation and Research (CDER) - LEAD
 - Center for Biologic 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 External Affairs

Summary of Planned Implementation Timeframes for the Drug Supply Chain Security Act

Date of enactment: November 27, 2013

■ planned timeframes for FDA activity
 ■ implementation period for stakeholders



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



Deliverables - Guidances

- Identification of suspect product and termination of notifications of illegitimate product – 5/27/2014
- Establishing initial standards for interoperable exchange of transaction information/history/statement (TI/TH/TS) in paper or electronic form -- 11/27/2014
- Process for waivers, exceptions, exemptions – 11/27/2015
- Grandfathering product – 11/27/2015
- System attributes necessary to enable secure tracing at the package level – 11/27/2022
- Establishing standards for interoperable data exchange to enhance secure tracing at the package level – 11/27/2022



Deliverables - Regulations

- Establishing standards for licensing of wholesale drug distributors – 11/27/2015
- Establishing standards for licensing of third-party logistic providers – 11/27/2015
- Establishing enhanced drug distribution security system for interoperable electronic tracing of product at the package level – 11/27/2021



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Next steps....



Standards for interoperable exchange of information in paper or electronic format

- FDA Docket established 2/20/2014 to accept comments
- Questions seeking information about current practices, research, and ideas for:
 - interoperable exchange of transaction information/history/statement (TI/TH/TS)
 - providing, receiving, and terminating notifications
 - requests for verification, and
 - responding to requests from FDA or other Federal/State officials
- Questions related to the feasibility of establishing standardized documentation to convey TI/TH/TS
- Docket **closes April 21, 2014**



Standards for interoperable exchange of information in paper or electronic format

- Type of information currently exchanged:
 - What types of information about transactions do you exchange?
 - What practices, processes, or systems, either paper-based or electronic, do supply chain stakeholders use to exchange this information?
 - Are the practices, processes, or systems based on a standard?
 - Are they interoperable with other systems that supply chain stakeholders may be using?



Standards for interoperable exchange of information in paper or electronic format

- Exchange of information about prior transactions:
 - What practices, processes or systems, either paper-based or electronic, do supply chain stakeholders use to exchange information related to prior transactions?
 - Are the practices, processes, or systems based on a standard?
 - Are they interoperable with other systems that supply chain stakeholders may be using?
 - Do the practices, processes, or systems that supply chain stakeholders use to exchange transaction information or transaction histories include or have the ability to include lot level data?
 - If you are currently using paper means to exchange transaction information or history, when do you plan to move to an electronic format?



Standards for interoperable exchange of information in paper or electronic format

- TI/TH exchange
 - Are there challenges to adopting and using a system, in paper or electronic format, for the interoperable exchange of transaction information or history?
 - How can these challenges be addressed?
- TS exchange
 - Are there practices, processes, or systems that supply chain stakeholders can use now to exchange the information in the transaction statement required by the DSCSA?
 - Are there challenges to providing the transaction statement to supply chain stakeholders in either paper or electronic form? How can these challenges be addressed?



Standards for interoperable exchange of information in paper or electronic format

- Model systems/technologies
 - Are there standards or current practices that you would recommend for FDA to consider as a model for providing any or all of the transaction information, transaction history, or transaction statement to other supply chain stakeholders?
 - Are there other technologies, systems or solutions available now that would enable the interoperable exchange of transaction information, transaction history, or transaction statements?



Standards for interoperable exchange of information in paper or electronic format

- Providing/receiving/terminating notifications
 - Are there current practices, processes or systems that could be used to exchange information between supply chain stakeholders and FDA with respect to providing, receiving, and terminating a notification that an illegitimate product is found in distribution?
 - Are these practices, processes or systems effective? If not, please provide recommendations to improve these practices, processes or systems.



Standards for interoperable exchange of information in paper or electronic format

- Verification requests
 - Are there current practices, processes or systems that could be used to exchange information between supply chain stakeholders or with FDA to respond to requests to verify the lot number, expiration date, and other indices of identity assigned to a product by the manufacturer or repackager (i.e., requests for verification of suspect product)?
 - Are these practices, processes or systems effective? If not, please provide recommendations to improve these practices, processes or systems.



Standards for interoperable exchange of information in paper or electronic format

- Information requests from officials
 - Are there current practices, processes or systems that could be used for providing information in response to requests from FDA or other appropriate Federal or State officials in the event of a recall or for the purpose of investigating a suspect or illegitimate product?
 - Are these practices, processes or systems effective? If not, please provide recommendations to improve these practices, processes or systems.



Standards for interoperable exchange of information in paper or electronic format

- What else should FDA consider?
 - Are there other considerations related to standards for the interoperable exchange of information for tracing of human, finished, prescription drugs that have not been addressed by the previous questions?
 - Please provide any additional information that you think could be helpful for the Agency to consider as it implements these provisions of the DSCSA.



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-0200
- **Stakeholder input essential and valued**
(Early submissions appreciated)



THANK YOU!!!

**Comments or questions to:
drugtrackandtrace@fda.hhs.gov**

