
Impact of the Drug Supply Chain Security Act on Pharmacy Management: 2015 to 2023

Introduction

On November 27, 2013, the Drug Quality and Security Act (DQSA) was signed into law, and Title II of the DQSA, the [Drug Supply Chain Security Act \(DSCSA\)](#) sets forth new definitions and requirements related to product tracing. The DSCSA outlines critical steps to build an electronic, interoperable system by November 27, 2023, which will identify and trace certain prescription drugs as they are distributed in the United States.

ASHP has compiled this analysis to provide an overview of the DSCSA, outline important dates for participants of the pharmaceutical distribution supply chain, identify suggested actions and considerations for pharmacy leaders, and highlight notable exceptions to the DSCSA requirements.

Beginning in 2015, trading partners (defined as manufacturers, wholesale distributors, repackagers, and dispensers) are required to provide the subsequent purchaser with product tracing information when engaging in transactions involving certain prescription drugs. Trading partners are also required to capture the product tracing information and maintain that data for not less than six years after the transaction occurs.

Purpose of the DSCSA

Implementation of this new electronic, interoperable system, over a 10-year period from the date it was signed into law, will enhance the U.S. Food and Drug Administration's ability to help protect U.S. consumers by improving detection and removal of potentially dangerous products from the pharmaceutical distribution supply chain.

Background

The DSCSA replaces the pedigree requirements of the Prescription Drug Marketing Act (PDMA) and preempts state requirements, and applies to transactions or changes in ownership of product (finished dosage form) performed by authorized trading partners. The FDA guidance documents, [DSCSA Implementation: Product Tracing Requirements – Compliance Policy](#) and [DSCSA Implementation: Identification of Suspect Product and Notification](#), represent the

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Agency’s current thinking on the topic. FDA guidance allows for alternative approaches if the approach satisfies the requirements of the applicable statutes and regulations. Nonetheless, the requirements for the tracing of products through the pharmaceutical distribution supply chain were scheduled to go into effect on January 1, 2015 for manufacturers, wholesale distributors, and repackagers, and on July 1, 2015 for dispensers. This law will be implemented over the course of the next nine years, when “enhanced” traceability will be in force by 2023.

However, since FDA has recognized that some manufacturers, wholesale distributors, and repackagers may need additional time beyond January 1, 2015 to ensure that this new imperative will not result in disruptions in the supply chain, and negatively impact patient access to necessary prescription drugs, FDA does not intend to take action against any trading partner not in compliance with certain aspects of DSCSA prior to May 1, 2015, as described in the December 2014 FDA guidance.

Important DSCSA Milestones for Dispensers

November 27, 2013	DSCSA signed into law
January 1, 2015	Manufacturers and distributors send and receive transaction history/transaction information/transaction statement (TH/TI/TS) ^a (FDA does not intend to enforce until May 1, 2015) Suspect and illegitimate product requirements effective Trading partners must be licensed and authorized
July 1, 2015	Dispensers receive TH/TI/TS, capture information, and maintain documentation for 6 years
November 27, 2015	National standards for TH/TI/TS in paper and electronic format, and waiver, exceptions, exemptions, and grandfathered guidance published by FDA
November 27, 2020	Pharmacy lot-level traceability
November 27, 2023	Unit-level traceability

^aSee [Glossary](#) for definitions of TH/TI/TS.

Responsibilities under the DSCSA for Dispensers

The DSCSA defines a dispenser as: “A retail pharmacy, hospital pharmacy, a group of chain pharmacies under common ownership and control that do not act as a wholesale distributor, or any other person authorized by law to dispense or administer prescription drugs, and the affiliated warehouses or distribution centers of such entities under common ownership and

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control that do not act as a wholesale distributor; and does not include a person who dispenses only products to be used in animals in accordance with section 512(a)(5).”

As of January 1, 2015, all trading partners, including dispensers (i.e. pharmacies), must notify FDA and certain immediate trading partners, when it is determined that a product in its possession or control is a suspect or illegitimate product,¹ not later than 24 hours after making the determination. (See [Important Dates for Dispensers](#).) All trading partners must have systems in place that enable them, upon determining that a product in their possession or control is suspect or upon receiving a request for verification from the FDA, or other appropriate Federal or state official, to quarantine suspect product and promptly conduct an investigation, in coordination with other trading partners, as applicable, to determine whether a product is illegitimate.

As of July 1, 2015, dispensers will be required to comply with the provisions of the DSCSA for the tracing of products through the pharmaceutical distribution supply chain.

What Dispensers Need to Do Now to Prepare for Compliance with the DSCSA

- Review the regulations with legal counsel and ensure that appropriate health-system staff members, including pharmacy directors and technicians, information technology staff, and vendors, are familiar with the regulations and the implementation schedule.
- Establish policy and procedures that mitigate scenarios that might permit suspect product entering the pharmaceutical distribution supply chain. (See FDA Guidance for Industry in [Other Resources](#).)
- Establish policy and procedures on ways that can expeditiously identify suspect product and determine whether the product is illegitimate. (See FDA Guidance for Industry in [Other Resources](#).)
- Establish policy and procedures for verification and handling of suspect or illegitimate product, including quarantine procedures and reporting timeframes and requirements. See DSCSA regulation and FDA guidance to the industry for DSCSA.
- Consult with wholesalers to determine how they can support these new and evolving requirements.
- Confer with all other non-wholesaler suppliers regarding their awareness of and readiness for implementation, including their intended processes for providing TH/TI/TS.
- Budget for implementing and sustaining a plan to create, receive, store, and retrieve the TH/TI/TS information, whether in electronic or paper format.

¹Suspect or illegitimate product is defined in section 581(21) of the Food, Drug and Cosmetic Act as a product for which there is reason to believe it (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.

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- Explore if a third-party provider will be necessary to provide a storage and retrieval solution for the TH/TI/TS.
- Ensure necessary agreements are in place if a third party provider (e.g. wholesaler) is storing TH/TI/TS which ensure dispenser's documents meet their organization's requirements for data integrity and security.
- Determine how trading partners and wholesalers that may have plans to store pharmacy's TH/TI/TS on its server or platform plan to transfer information to dispenser in the event that business relationships change.
- Test compliance, usability, and storage of data for retrieval purposes, as all information must be maintained for six years.
- Evaluate your health system's supply chain to hospital-owned facilities and hospital partners to determine when "business as normal" for drug distribution is within compliance as it relates to the definitions of dispensers and wholesalers. (See "Exceptions to the DSCSA Tracing Requirements.")

Exceptions to the DSCSA Tracing Requirements

- Intracompany distribution of any product between members of an affiliate or within a manufacturer.
- Distribution of product between hospitals or healthcare entities under common control.
- Distribution of product for emergency medical reasons, which includes a public health emergency, and excludes a drug shortage unless caused by such a public health emergency.
- Distribution of minimal quantities by a licensed retail pharmacy or licensed practitioner for office use.
- Distribution of intravenous product intended for fluid and electrolyte replenishment (e.g., sodium, chloride, potassium) or calories (e.g., dextrose and amino acids).
- Distribution of intravenous product used to maintain equilibrium of water and minerals in body (e.g., dialysis solution).
- Product intended for irrigation or sterile water.
- Distribution of medical gas.
- Drugs compounded in compliance with section 503A or 503B.

Unresolved Issue: 340B Drug Pricing Program

Hospitals that use contract pharmacies to serve patients through the federal 340B Drug Pricing Program will face compliance issues unless FDA resolves an unintended consequence of the regulations. Currently, wholesalers' systems are set up to send 340B drugs directly to the contract pharmacies, but the corresponding tracing information goes to the hospital that oversees the contract pharmacy. ASHP is working with a group of pharmacy organizations to address this issue with FDA. The group met with FDA in fall of 2014 and is creating a document asking that 340B contract pharmacies be exempt.

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ASHP Monitoring of DSCSA Implementation

ASHP has been actively engaged in monitoring and commenting on the DSCSA. Examples of past and ongoing effort are listed below.

- Comment Letter to FDA of April 21, 2014 on the Public Docket on its Standards for the Interoperable Exchange of Information for Tracing of Human, Finished, Prescription Drugs in Paper or Electronic Format
- DSCSA Implementation for Healthcare Distribution Management Association (HDMA) Association Partners Webinar, November 5, 2014
- [Rollout of Federal Track and Trace Requirements Begins Soon](#), AJHP, December 1, 2014
- ASHP Connect Discussion – Ongoing Dialogue with ASHP Membership
- [DSCSA Webinar in Collaboration with HDMA, March 24, 2015](#)

Summary

The DSCSA will help protect U.S. consumers by improving detection and removal of potentially dangerous products from the pharmaceutical distribution supply chain. The industry will need to implement the requirements set forth in the law and utilize the FDA guidance documents to develop systems that are compliant. Dispensers will need to proactively assess their role in the pharmaceutical distribution supply chain, including communication with trading partners and continuous attention to the DSCSA timelines and future FDA guidance documents.

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Important Dates for Dispensers

Starting January 1, 2015, a dispenser:

- Shall have the systems available to trace, quarantine, investigate, retain samples, clear, notify others about findings, and dispose of suspect or illegitimate products.^a Records of the drug investigation must be kept for at **least 6 years** from the conclusion of the investigation.
- May only trade with authorized trading partners.^b

Starting July 1, 2015, dispensers will be required to:

- Accept ownership of product only if the prior owner provides the transaction history, transaction information, and a transaction statement (TH/TI/TS), which can be in paper or electronic format. (See the [Glossary](#) for definition of TH/TI/TS.)
- Provide the subsequent owner with the TH/TI/TS unless the transaction is otherwise exempt or the sale is from dispenser to dispenser to fill a specific patient need.
- Retain records of TH/TI/TS for **no less than 6 years** after the transaction.
- Respond to requests for TH/TI/TS in correlation with a recall or investigation of suspect or illegitimate product from the Secretary of Health and Human Services or other appropriate Federal or State official **within 2 business days**. (Until November 2016, such requests will only be made if the recall involves a seriously adverse health consequence or human death and will be limited to the 6 months preceding the request or other relevant date, and the dispenser will be granted additional time for requests of the lot number level that the dispenser received in paper format.)

Starting July 1, 2015, dispensers may:

- Have a written agreement with a third-party provider, including an authorized wholesale distributor, to confidentially maintain the required TH/TI/TS. The dispenser will be required to maintain a copy of the written agreement.
- Resell returned product to the trading partner where the dispenser obtained the product without providing the tracing information.
- Return^c a nonsaleable product to the manufacturer, repackager, or wholesale distributor where the product was purchased; a returns processor; or a person acting on behalf of such a person without providing the tracing information.

By November 27, 2015, FDA will:

- Publish guidance on processes for waivers for the exchange of TH/TI/TS.
- Issue standards for exceptions to product identifier requirements.
- Issue standards surrounding grandfathered product.
- Issue national standards for wholesaler distributor licensure.
- Issue national standards for third party logistics providers.

^aA trading partner who determines that a product in its possession or control is an illegitimate product must notify FDA and certain immediate trading partners under section 582 of the FD&C Act as added by the DSCSA. See Guidance for Industry, Drug Supply Chain Security Act Implementation: Identification of Suspect Product and Notification for details on identifying and reporting suspect product listed in the Other Resources section of this document.

^bAuthorized trading partners are defined by the Food, Drug and Cosmetic Act. To verify authorization for manufacturers and repackagers, refer to FDA's drug establishment registration database for registration. To verify authorization for third-party logistic providers and dispensers, check with the respective state authority to confirm licensure.

^cThe term "return" means 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.

Glossary

TRANSACTION HISTORY (TH)—The term “transaction history” means a statement, in paper or electronic form, including the transaction information for each prior transaction going back to the manufacturer of the product.

TRANSACTION INFORMATION (TI)—The term “transaction information” means the:

- (A) proprietary or established name or names of the product;
- (B) strength and dosage form of the product;
- (C) National Drug Code number of the product;
- (D) container size;
- (E) number of containers;
- (F) lot number of the product;
- (G) date of the transaction;
- (H) date of the shipment, if more than 24 hours after the date of the transaction;
- (I) business name and address of the person from whom ownership is being transferred; and
- (J) business name and address of the person to whom ownership is being transferred.

TRANSACTION STATEMENT (TS)—The “transaction statement” is a statement, in paper or electronic form, that the entity transferring ownership in a transaction:

- (A) is authorized as required under the Drug Supply Chain Security Act;
- (B) received the product from a person that is authorized as required under the Drug Supply Chain Security Act;
- (C) received transaction information and a transaction statement from the prior owner of the product, as required under section 582;
- (D) did not knowingly ship a suspect or illegitimate product;
- (E) had systems and processes in place to comply with verification requirements under section 582;
- (F) did not knowingly provide false transaction information; and
- (G) did not knowingly alter the transaction history.

Other Resources

FDA Drug Security and Quality Act of 2013, Title II, Drug Supply Chain Security Act:

<http://www.fda.gov/drugs/drugsafety/drugintegrityandsupplychainsecurity/drugsupplychainsecurityact/ucm376829.htm>

FDA Drug Supply Chain Security Act Implementation Plan:

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

FDA Guidance for Industry: DSCSA Implementation: Identification of Suspect Product and Notification:

<http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM400470.pdf>

FDA Guidance for Industry: DSCSA Implementation: Product Tracing Requirements – Compliance Policy

<http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM427867.pdf>

FDA Website: Are you ready for the Drug Supply Chain Security Act?

<http://www.fda.gov/Drugs/DrugSafety/DrugIntegrityandSupplyChainSecurity/DrugSupplyChainSecurityAct/ucm427033.htm>

FDA Website: Know Your Source: Protecting Patients from Unsafe Drugs

<http://www.fda.gov/Drugs/ResourcesForYou/HealthProfessionals/ucm389121.htm>

FDA Center for Drug Evaluation and Research, Small Business and Industry Assistance (CDER SBIA) Webinar on The Drug Supply Chain Security Act (Title II of the Drug Quality and Security Act): Overview & Implementation - March 12, 2014

<http://www.fda.gov/Drugs/DevelopmentApprovalProcess/SmallBusinessAssistance/ucm388150.htm>

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