Supply Chain and Inventory Management Reference Guide

This guide was developed to help Certified Pharmacy Technicians (CPhTs) prepare for PTCB's Supply Chain and Inventory Management Exam.

The Drug Supply Chain Security Act (DSCSA) - Title II

Access the complete DSCSA.

Products under the DSCSA

In this context, "product" refers to a prescription drug in a finished dosage form intended for administration to a patient without substantial further manufacturing, such as a tablet, capsule, or lyophilized powder prior to reconstitution.

This definition of a product **excludes**:

- blood or blood components for transfusion;
- radioactive drugs or biological products regulated by the Nuclear Regulatory Commission;
- imaging drugs;
- certain intravenous products;
- medical gasses;
- homeopathic drugs marketed in compliance with applicable guidelines; or
- drugs compounded incompliance with specific sections of the act, such as 503A or 503B.

Definitions

- ***Suspect product.*** A product for which there is reason to believe that it may be counterfeit, diverted, stolen, intentionally adulterated to cause serious adverse health consequences, or involved in a fraudulent transaction.
- ***Third-party logistics provider.*** An entity that provides or coordinates warehousing or other logistics services of a product in interstate commerce on behalf of manufacturers, wholesale distributors, pr dispensers, without taking ownership of the product or having responsibility for its sale or disposition.

Transactions under the DSCSA

In general, the term ***transaction*** refers to the transfer of a product between persons in which a change of ownership occurs.

The definition of a transaction **excludes**:

- intracompany distribution;
- distribution of a product among hospitals or other healthcare entities that are under common control;
- distribution of a product for emergency medical reasons, including during a public health emergency;
- dispensing of a product or product samples in accordance with section 503;
- blood or blood components;
- distribution of minimal quantities of a product by a licensed retail pharmacy to a licensed practitioner for office use;
- sale, purchase, or trade of a drug by a charitable organization to a nonprofit affiliate.
- distribution of a product pursuant to the sale or merger of a pharmacy or wholesale distributor;
- dispensing of a product under section 512;
- products transferred to or from facilities licensed by the Nuclear Regulatory Commission;
- distribution of combination products not subject to approval under section 505 or licensure under section 351 of the Public Health Service Act;
- distribution of medical convenience kits assembled for the convenience of the purchaser or user;
- distribution of certain intravenous products for specific purposes, such as an intravenous product intended for the replenishment of fluids or calories;
- distribution of medical gases; and
- distribution or sale of any licensed product under section 351 of the Public Health Service Act that meets the definition of a device.

A ***transaction history*** refers to a comprehensive record, either in paper or electronic format, detailing the transaction information or each prior transaction of a product, tracing back to its manufacturer. Transaction information includes the:

- product's name, strength, and dosage form;
- National Drug Code (NDC) number;
- container size and number of containers;
- lot number;
- transaction date; and
- shipment date (if different from the transaction date by more than 24 hours).

A ***transaction statement*** is a formal declaration, either in paper of electronic format, that the entity transferring ownership in a transaction:

- is authorized;
- received the product from a person that is authorized;

- received transaction information and a transaction statement from the prior owner of the product;
- 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 Drug Establishment Registration

Domestic and foreign establishments that manufacture, repack, or re-label drug products in the United States are required to register with the FDA. Domestic and foreign drug manufacturers, repackers or re-labelers are also required to list all of their commercially marketed drug products. This information helps the FDA maintain a catalog of all drugs in commercial distribution in the United States.

The Drug Establishments Current Registration Site (DECRS) is a searchable publication of currently registered establishments which manufacture, prepare, propagate, compound or process drugs that are distributed in the U.S. or offered for import to the U.S.

The site is updated each business day. Any establishment is automatically removed from the database if its registration is inactivated by FDA due to a compliance case. Registrations that expire, deregister, or are otherwise dropped from submission are also removed from the database.

Establishments must be registered within five days of beginning operations. Additionally, establishments must renew registration annually between October 1 and December 31 of each year.

Establishments that send initial or annual registrations during the October 1 to December 31 period are considered registered until the end of the following calendar year. Any registration submission received outside of this timeframe does not extend the registration expiration date beyond the current calendar year.

- Example 1: A new, updated or annual establishment registration structured product labeling (SPL) is received on October 1, 2020. Registration is current through December 31, 2021.
- Example 2: A new, updated or annual establishment registration SPL is received on September 30, 2020. Registration is current through December 31, 2020. The updated establishment registration must be submitted between October 1, 2020, and December 31, 2020 to remain current through December 31, 2021.

The Code of Federal Regulations (CFR) - Title 21

Access CFR Title 21.

Title 21 applies to any person, partnership, corporation, or business firm in a State engaging in the wholesale distribution of human prescription drugs in interstate commerce. The purpose of Title 21 is to implement the Prescription Drug Marketing Act (PDMA) of 1987 by providing minimum standards, terms, and conditions for the licensing by State licensing authorities of persons who engage in wholesale distributions in interstate commerce of prescription drugs. The primary goal of the PDMA is to ensure the safety and efficacy of prescription drugs and to prevent the introduction of counterfeit or substandard drugs into the market.

Key provisions of the PDMA are as follows.

- The PDMA regulates the distribution of prescription drug samples by requiring manufacturers to provide written requests from licensed prescribers before distributing samples.
- The act imposes regulations on wholesale drug distributors, requiring them to be licensed by the state and to comply with certain record-keeping and storage requirements to prevent diversion or counterfeiting of drugs.
- The PDMA mandates that wholesalers provide documentation, known as a pedigree, for each transaction of prescription drugs, documenting the drug's distribution history from the manufacturer to the point of sale.
- The PDMA establishes guidelines for the proper storage and handling of prescription drugs to maintain their integrity and prevent contamination or adulteration.
- The law restricts the resale of prescription drugs purchased by healthcare facilities, such as hospitals or clinics, to other entities, to prevent the diversion of drugs into secondary markets.
- The PDMA outlines penalties for violations of its provisions, including fines, imprisonment, and suspension or revocation of licenses for wholesalers and distributors found to be in non-compliance.