Assessing Compliance to the Drug Supply Chain Security Act (DSCSA)

Scope and Disclaimer:

This document is intended to provide a starting point to assess compliance to the federal requirements of the Drug Supply Chain Security Act (DSCSA). This document is **not** intended to provide a comprehensive or exhaustive list of all applicable requirements under DSCSA. It is the ultimate responsibility of licensees of the commission, and where necessary with the guidance of their own legal counsel, to ensure continued compliance to the applicable DSCSA requirements.

Introduction:

Q: What is DSCSA?

A: The Drug Supply Chain Security Act (DSCSA) is federal legislation which, among other things, grants the FDA authority to establish regulations aimed at securing the U.S. drug supply chain to protect patients from receiving drug products that are counterfeit, diverted, stolen, obtained from fraudulent transactions, intentionally adulterated, which may lead to patient harm. DSCSA is a new section of law added under Title II of the Federal Food Drug and Cosmetics Act (FD&C Act).

The primary goals of DSCSA are to:

1. Implement an interoperable system to allow for the electronic tracing of drug products at the package level across trading partners, and when necessary, allow for verification of products in the drug supply chain.
2. Establish national standards for licensure for all entities involved in the drug supply chain.

Q: Who does DSCSA apply to?

A: DSCSA applies to all "trading partners" involved with the drug supply chain. Trading partners include manufacturers, repackagers, wholesale distributors, and dispensers (pharmacies and HCEs) where there is a transfer of ownership of drug product. See Sec. 581. Definitions of the FD&C Act.

Q: Do all drug products fall under the requirements of DSCSA?

A: DSCSA applies to prescription drug "products" in finished dosage form for administration to a patient without further manufacturing (such as capsules, tablets, and lyophilized products before reconstitution).

Certain products **not subject** to the requirements of DSCSA are:

- blood or blood components intended for transfusion;
- radioactive drugs or radioactive biological products;
- imaging drugs;
- certain intravenous products;
- any medical gas
- homeopathic drugs marketed in accordance with applicable guidance under the FD&C Act
- drugs compounded in compliance with sections 503A or 503B of the FD&C Act (21 U.S.C. 353a or 353b)

Please see Section 581(13) of the FD&C Act for additional information regarding excluded products.

Q: Do licensees of the Pharmacy Quality Assurance Commission need to comply with the provisions of DSCSA?

A: **Yes**, RCW 18.64.026(1) requires all facilities licensed by the pharmacy commission to comply with all applicable state and federal laws.

Section 1: Authorized Trading Partners

All transactions of drug products covered under DSCSA, where a change of ownership occurs, **must** be made between authorized trading partners. Depending on the type of business entity, to become an "authorized trading partner", a pharmaceutical facility must obtain registration from the FDA and/or obtain a state license from the pharmacy commission. The following table outlines the current requirements to be an "authorized trading partner".

Authorized Trading Partners					
Trading Partner	**Manufacturers & Repackagers**	**Wholesale Distributors & 3PLs**	**Dispensers**		
			All Pharmacies	**Health Care Entities (HCE)**	**Drug Other Controlled Substances Registrants***
Steps to become "authorized"	Obtains a registration with the FDA in accordance with section 510 of the FD&C. Obtains a state manufacturer license if located in WA**	Obtains a state wholesaler license (for WA wholesalers) or a non-resident wholesaler license.	Obtains a WA state pharmacy license (for WA resident pharmacies) or a non-resident pharmacy license.	Obtains a PQAC health care entity license.	Obtains PQAC license or registration.
Links to verify a trading partner is authorized	Drug Establishments Current Registration Site (FDA DECRS)	Check Licensure of Wholesale Drug Distributors and Third-Party Logistics Providers | FDA	WA DOH Facility Search	WA DOH Facility Search	WA DOH Facility Search

*Provisions of DSCSA apply when there is dispensing of drug products to patients (i.e., opioid treatment programs).
**WA state law requires those who engage in the manufacturer of drugs to also obtain a state manufacturers license.

Please refer to the FDA's Guidance Document titled "Identifying Trading Partners under the Drug Supply Chain Security Act" for further information pertaining to authorized trading partners.

Section 2: Labeling Requirements of Drug Products Distributed Under DSCSA

Authorized trading partners may conduct transactions of drug products that meet the following labeling requirements of DSCSA.

- Manufacturers and repackagers must affix or imprint a product identifier on each package and homogenous case of product intended to be introduced in a transaction in commerce.

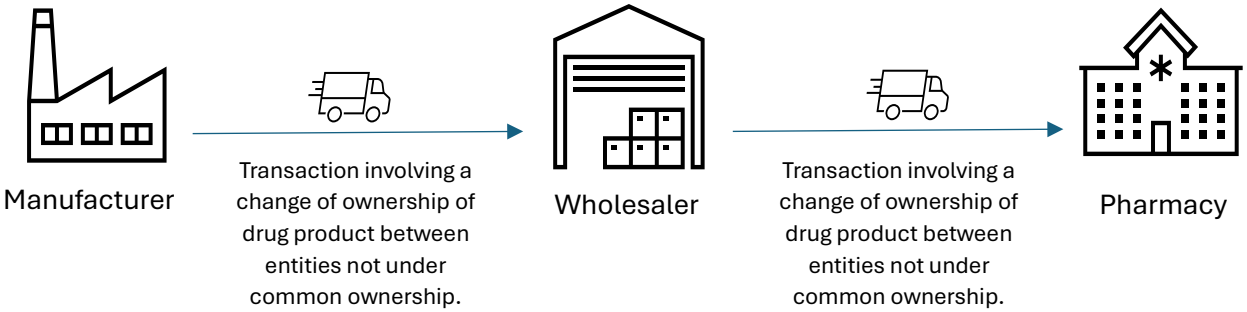
- The human-readable portion of the product identifier must include:
  - National Drug Code (NDC)
  - The standardized numerical identifier (serial number)
  - The lot number
  - The expiration date of the product

- The product identifier must be in both human-readable form and on a machine-readable data carrier that conforms to the standards outlined in the FDA guidance document titled "Product Identifiers Under the Drug Supply Chain Security Act – Questions and Answers".

Section 3: Covered Transactions and Product Tracing Information

DSCSA defines transactions as a "transfer of product between persons in which a change of ownership occurs" Sec. 581 (24). Some examples of transactions covered under DSCSA are illustrated below.

Transactions Subject to DSCSA Requirements:



Transactions Not Subject to DSCSA Requirements:

Intracompany transactions between division, subsidiary, parent or affiliated, or related company under the common ownership and control of a corporate entity would not be subject to the requirements of DSCSA.

Some other exemptions include:

- The distribution of a product among hospitals or other health care entities that are under common ownership.
- Dispensing of drug products pursuant to a valid prescription.
- For a full list of exempt transactions, please see Sec 581 (24)(B) Transaction Exemptions.

Required Transaction Information

For each covered transaction, drug product tracing information must be provided that includes the following elements:

- Transaction Information [1]
- Transaction Statement [1]

Product tracing information must be stored in a secure electronic manner that permits the interoperable exchange of product tracing information to facilitate product tracing and verification. Product tracing information must be stored for at least **6 years**.

Please refer to the FDA's Guidance "DSCSA Standards for the Interoperable Exchange of Information for Tracing of Certain Human, Finished, Prescription Drugs" for specific guidance on standards to achieve interoperable product tracing requirements.

Exemptions to Product Tracing Requirements:

FDA has the authority to grant waivers, exceptions and exemptions from **certain requirements** in DSCSA. More information on the process to obtain an exemption can be found here: The Drug Supply Chain Security Act (DSCSA) Waivers, Exceptions, and Exemptions | FDA

More recently, the FDA granted exemptions to "connected trading partners" and "small dispensers". Information related to these exemptions can be found here: Waivers and Exemptions Beyond the Stabilization Period | FDA. Please note, that these exemptions apply to specific requirements of DSCSA granted, the entity has made documented efforts to complete data connections with their immediate trading partners, but still face challenges exchanging data.

Section 4: Suspect and Illegitimate Products

The term "suspect product" means a drug product for which there is reason to believe may be counterfeit, diverted, stolen, obtain from fraudulent transactions, intentionally adulterated, and may lead to patient harm (Section 581(21) of the FD&C Act). In contrast, an "illegitimate product" means a product for which credible evidence shows that the product may be counterfeit, diverted, stolen, obtain from fraudulent transactions, intentionally adulterated, and may lead to patient harm (Section 581(8) of the FD&C Act).

[1] Transaction information and transaction statement are defined in sections 581(26) and (27) of the FD&C Act, respectively.

Please refer to the FDA's guidance document "Definitions of Suspect Product and Illegitimate Product for Verification Obligations Under the Drug Supply Chain Security Act" for additional guidance on identifying suspect and illegitimate products in the U.S. pharmaceutical distribution supply chain.

Authorized trading partners must take the following key steps when a product is believed to be suspect.

Key Steps	**Authorized Trading Partner**		
	Manufacturer	**Wholesaler**	**Dispenser**
Step 1: Quarantine	Immediately quarantine the **suspect** drug product		
Step 2: Investigate	Promptly investigate, in coordination with trading partners as applicable, to determine whether the product is an illegitimate product. See FDA Guidance document: "Definitions of Suspect Product and Illegitimate Product for Verification Obligations Under the Drug Supply Chain Security Act."		
Step 3: Determination	If the manufacturer makes the determination that a suspect product is not an illegitimate product, the manufacturer shall promptly notify the FDA, if applicable, of such determination and such product may be further distributed. If upon determining that a product in the possession or control of a manufacturer is an illegitimate product, the manufacturer shall, take the additional steps below (Steps 4 through 5)	If the wholesale distributor determines that a suspect product is not an illegitimate product, the wholesale distributor shall promptly notify the FDA, if applicable, of such determination and such product may be further distributed. If upon determining, in coordination with the manufacturer, that a product in the possession or control of a wholesale distributor is an illegitimate product, the wholesale distributor shall, take the additional steps below. (Steps 4 through 5)	If the dispenser makes the determination that a suspect product is not an illegitimate product, the dispenser shall promptly notify the FDA, if applicable, of such determination and such product may be further distributed or dispensed. If upon determining, in coordination with the manufacturer, that a product in the possession or control of a dispenser is an illegitimate product, the dispenser shall take the additional steps below. (Steps 4 through 5)
Step 4: Sampling and Disposition	Continue quarantining such product until its disposition. Retain a sample of the product for further physical examination or laboratory analysis by the manufacturer or by Federal or State officials.		
Step 5: Notification	The manufacturer shall notify the FDA and all immediate trading partners that the manufacturer has reason to believe may have received an illegitimate product of such	The wholesaler shall notify the FDA and all immediate trading partners that the wholesaler has reason to believe may have received an illegitimate	The dispenser shall notify the FDA and all immediate trading partners that the dispenser has reason to believe may have received such illegitimate product of such determination

	determination not later than **24 hours** after making such determination. Take reasonable and appropriate steps to assist a trading partner to disposition an illegitimate product not in the possession or control of the manufacturer.	product of such determination not later than **24 hours** after making such determination. Take reasonable and appropriate steps to assist a trading partner to disposition an illegitimate product not in the possession or control of the wholesale distributor.	not later than **24 hours** after making such determination.
Records Retention	A manufacturer shall keep records of the investigation of suspect and illegitimate products for not less than **6 years** after the conclusion of the investigation.	A wholesale distributor shall keep records of the investigation of suspect and illegitimate products for not less than **6 years** after the conclusion of the investigation.	A dispenser shall keep records of the disposition of an illegitimate product for not less than **6 years** after the conclusion of the disposition.

Section 5: Record Retention Requirements

In contrast to the pharmacy commission record retention requirements (WAC 246-945-020), DSCSA requires certain records to be retained for not less than **6 years**. These records include:

- Records related to transactions of drug products. This includes transaction information (including lot level information), transaction history, and transaction statement for each transaction and maintain such information, history, and statement for not less than 6 years after the date of the transaction.
- Records of the investigation of a suspect product for not less than 6 years after the conclusion of the investigation.
- Records related to the disposition of an illegitimate product for not less than 6 years after the conclusion of the disposition.
- Manufacturers shall maintain the product identifier information for such product for not less than 6 years after the date of the transaction.