Title			
Drug Supply Chain Security (Track and Trace) - RxScan			
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POLICY

The pharmacist-in-charge is responsible for establishing procedures to comply with the Drug Supply Chain Security Act (DSCSA) requirements for receiving, dispensing, and transferring medication.

STANDARD

21 U.S.C 351

Title II of the Drug Quality and Security Act

21 U.S.C. 360eee-1(d)(1)

DEFINITION

Dispenser – is a community, Long Term Care (LTC), or chain pharmacy under one ownership that is licensed.

Illegitimate Product – a product for which credible evidence shows that the product:

- Is counterfeit, diverted, or stolen;
- Is intentionally adulterated such that the product would result in serious adverse health consequences or death to humans;
- Is the subject of a fraudulent transaction; or
- Appears otherwise unfit for distribution such that the product would be reasonably likely to result in serious adverse health consequences or death to humans.

Drug Supply Chain Security Act (DSCSA) – statute requiring dispensers to develop protocols to identify suspect and illegitimate products.

Manufacturer – a person or company that holds an approved license under Section 505 who manufactures an FDA approved medication.

Standardized Numerical Identifier (SNI) – a set of numbers or characters used to uniquely identify each package or homogenous case that is composed of the National Drug Code that corresponds to the specific product (including the particular package configuration) combined with a unique alphanumeric serial number of up to 20 characters.

Suspect/Illegitimate Products – medications that are counterfeit, diverted, stolen, and intentionally adulterated products that would result in a serious adverse health incident with severe consequences.

Transaction Information (TI) – the proprietary or established name or names of the product:

- Strength and dosage form of product
- National Drug Code number of product
- Container size
- Number of containers

- Lot number of product
- Date of transaction
- Date of shipment, if more than 24 hours after
- Date of transaction
- Business name and address of the person from whom ownership is being transferred, and
- Business name and address of the person to whom ownership is being transferred.

Transaction Statement (TS) – is a statement, in paper or electronic form, that indicates the entity transferring ownership in a transaction

- Is authorized as required under the Drug Supply Chain Security Act;
- Received the product from a person that is authorized as required under the Drug Supply Chain Security Act;
- Received transaction information and a transaction statement from the prior owner of the product, as required under section 582;
- Did not knowingly ship a suspect or illegitimate product;
- Had systems and processes in place to comply with verification requirements under section 582;
- Did not knowingly provide false transaction information; and
- Did not knowingly alter the transaction history.

Trading Partners – The pharmacy's drug wholesalers are considered trading partners. The pharmacy must determine whether the trading partners they do business with (manufacturers, repackagers, wholesale distributors, third-party logistics providers, and pharmacies) are licensed or registered:

- Check the registration of manufacturers and repackagers
- Check the licensing of wholesale distributors and third-party logistics providers
- Check the licensing of pharmacies through the respective state authority.

PROCEDURE

One of the primary requirements of DSCSA is for dispensers (pharmacies) to purchase FDA products from licensed wholesalers to protect the integrity of the drug. Tracking of the drug from source of origin to the patient is documented through a GS1 or 2D data-matrix barcode on the storage container. The 2D barcode contains the manufacturer's product identifier, the National Drug Code (NDC), Lot Number, Expiration Date, and the individual container's serial number.

This closed drug distribution system is to prevent harmful drugs from entering the supply chain, detect harmful drugs if they do enter the supply chain, and enable rapid response when such drugs are found.

The FDA has provided the following:

- Flyer: Protect Your Patients: Know your Responsibilities Under the DSCSA
- A free 45-minute continuing education course for pharmacists to help explain DSCSA requirements.

The pharmacy must accept possession of the drug through a pharmacy software, a specialized DSCSA software (RxScan), or an acceptable manual process which contains the DSCSA required tracking and acceptance or through a stand-alone software, such as www.RxScanPI.com. Upon receipt of the drug from an authorized wholesaler or a licensed pharmacy (transfers), the pharmacy must inspect the transport container and the individual drug containers for any sign of tampering of the drug.

NOTE: *The DSCSA statute does not specifically state a software system "Must" be used; however, the pharmacy must possess the capability to scan the barcode, print the DSCSA TI and TS information, or have established a manual process.*

- If the drug containers indicate a possible tampering or alteration, the drug is immediately quarantined and the DSCSA Quarantined document is initiated and kept with the suspect drug. The manufacturer, wholesaler, or pharmacy that shipped the drug must be contacted as well as the FDA. The FDA will provide instructions on handling, transporting, and disposal. The DSCSA Quarantined form is completed and kept within the pharmacy for six (6) years.
- If there is no sign of possible tampering or alteration, the drug when using a software solution, is scanned and "accepted" by the pharmacy and placed into stock.

The pharmacy **WILL NOT** accept ownership of any product, without the TI data having been received. The TI and the TS must match the physical product's Product Identifier information. Errors must be resolved within three (3) business days. The product cannot be placed into the active stock until the error is resolved.

Pharmacy Computer Software

Some pharmacy prescription software systems have included the Track and Trace acceptance requirements when the drug is scanned into the pharmacy dispensing software if the software is compliant with the DSCSA standards.

RxScan's software can work in conjunction with a pharmacy software system or independent of it.

Serialization

Dispensers may not accept DSCSA products that are not serialized with a product identifier on each smallest saleable package and homogenous case that meets the FDA Standard Numerical Identifier (SNI) requirement. Dispensers may accept non-serialized products manufactured before Nov. 27, 2018, provided there is documentation of such "grandfathered" status. Dispensers must still verify the lot number of suspect product and validate any applicable transaction history and transaction information in their possession.

Electronic Product Tracing

When suppliers, including dispensers, provide a medication to other dispensers, they must provide the TI and TS in an electronic format. Paper packing lists or paper invoices can't be accepted by trading partners as of Nov. 27, 2017. Shipments received by trading partners without electronic product tracing or proper TI or TS information will be returned to the supplier.

Interoperable Electronic Tracing

Dispensers may not accept DSCSA products that aren't serialized or properly aggregated starting Nov. 27, 2023. To meet this requirement, manufacturers need to aggregate unit packages to case packages, case packages to pallet, and provide the aggregated shipment data to downstream trading partners.

Completing the DSCSA requirements

The final step for completing all the DSCSA requirements, is successfully accepting each stock bottle and placing the bottle in the active inventory. The pharmacy is not required to track the stock bottle's medication to the patient. If the pharmacy is using an automatic dispensing system, only the NDC, quantity, and expiration date is entered into the dispensing system's software.

The only exception is when a drug is transferred from one pharmacy to another.

Pharmacy-to-Pharmacy Drug Transfers

The same TI and TS transaction information must be sent to the receiving pharmacy as described above.

Effective November 27, 2023, pharmacies can only accept, transfer, or sell pharmaceutical products that have a DSCSA-compliant product identifier.

Receiving a Pharmacy-to-Pharmacy Transfer

The pharmacy must receive the TI and TS information into their system to accomplish the recordkeeping.

Counterfeit, Suspect, or Illegitimate Drugs

If a counterfeit, suspect, or illegitimate (illicit) drug is found, the pharmacist-in-charge will notify the wholesaler and the FDA within 24 hours of the receipt. In addition, the pharmacist will:

- Investigate and handle suspect and illegitimate prescription drugs, which includes drugs that may be or have evidence that they are counterfeit, diverted, stolen, intentionally adulterated, or unfit for distribution, including steps to:
  - Quarantine and investigate suspect prescription drugs to determine if they are illegitimate; and
  - If they are illegitimate, pharmacies should work with the manufacturer and take specific steps to ensure patients do not receive the illegitimate drugs
  - Notify the trading partners they bought the drug from and sold the drug to.

See the FDA's Drug Supply Chain Security Act Implementation: Identification of Suspect Product and Notification Guidance for Industry for information on:

- The identification of a suspect product and recommendations on how to identify a suspect product
- The concept of high risk of illegitimacy; and
- The processes for notifying the FDA of an illegitimate product or product with high risk of illegitimacy and for requesting termination of a notification which includes using Form FDA 3911.

Note: Detailed procedures are found in the Counterfeit, Suspect or Illegitimate Drugs Policy and Procedure.