Drug Supply Chain Security Act (DSCSA) Dispenser Frequently Asked Questions

Q. What is the Drug Supply Chain Security Act (DSCSA)?
A. DSCSA is a federal law enacted in 2013 that addresses the distribution of most prescription drugs from the manufacturer to the dispenser (ie, the pharmacy). The law is intended to protect the public from potentially counterfeit, stolen, or contaminated drugs. By November 2023, the law requires the identification and traceability of prescription drugs down to the package level.

Q. What drugs are not covered under the DSCSA?
A. DSCSA does not apply to over the counter drugs and animal drugs. Additionally, several types of drugs are exempted from the definition of transaction and do not have the same traceability requirements. Those exempted drugs include active pharmaceutical ingredients (API), imaging drugs, certain intravenous fluids, medical gases, radioactive drugs and compounded drugs from outsourcing facilities.

Q. What is a pharmacy (dispenser) required to do under the DSCSA?
A. Currently, a pharmacy is required to:

1. Confirm that your trading partners are appropriately licensed or registered
2. Receive and maintain product tracing documentation*
3. Identify, investigate, and report suspect and illegitimate products

*As of November 27, 2023, the product tracing will change from provided transaction documentation to an interoperable electronic exchange.

Q. How does a pharmacy confirm that a trading partner is appropriately licensed or registered?
A. Pharmacists can verify that manufacturers and repackagers are registered with the FDA on their website.

Wholesale distributors and third party logistics providers (3PL) servicing Kentucky pharmacies must be licensed with the Board of Pharmacy. That license can be verified on the board's website. Keep in mind that the Board's website lists the names of entities' parent companies, which may differ from the names that companies "do business as."

Q. May a pharmacy only purchase products from a wholesale distributor with a Drug Distributor Accreditation (DDA), formerly VAWD accreditation?
A. No, Kentucky does not require wholesale distributors to obtain Drug Distributor Accreditation.

Q. What is the interoperable electronic exchange? How does the pharmacy access that information?
A. Beginning November 27, 2023, dispensers are required to use secure, interoperable, electronic approaches to track and trace purchased products. Dispensers will work with their trading partners to select an interoperable electronic system. Pharmacies must be able to use this system to exchange transaction information for receipt and returns, to verify products at the package level, and provide transaction information for a product in the event of an investigation into suspect or illegitimate products.

FDA has issued draft guidance on the standards for the interoperable exchange. Organizations such as NABP are working on developing an exchange.

Q. How long does product tracing documentation need to be kept?
A. Six years.

Q. What is a suspect product? What is an illegitimate product?
A. The term "suspect product" means a product for which there is reason to believe that such product: (A) is potentially counterfeit, diverted, or stolen; (B) is potentially intentionally adulterated; (C) is potentially the subject of a fraudulent transaction; or (D) appears otherwise unfit for distribution.

The term "illegitimate product" means a product for which credible evidence shows that the product meets one or more of the above standards.

Examples of products that would be considered "suspect" and should be investigated include:

- Products that are abnormal in appearance. This may include smudged or misspelled labels, unusual coloration or shape of the package, missing security features, or dosage forms that are different in color, shape, or imprint from the normal product.
- Products that arrive with missing or incomplete information, such as incomplete shipping information or missing package inserts, lot numbers, expiration dates, or National Drug Codes.

FDA has issued guidance to help identify suspect product.

Q. What does a pharmacy do if they determine a product is suspect or illegitimate?
A. If a pharmacy determines a product is suspect, they must quarantine and investigate the suspect prescription drug to determine if the drugs are illegitimate. If the product is discovered to be illegitimate after investigation, the pharmacy must then report this to the wholesaler, manufacturer, and FDA.

Q. May a pharmacy sell prescription drugs to another pharmacy?
A. Yes, the DSCSA allows a pharmacy to sell to another pharmacy, without being licensed as a wholesale distributor, to address a specific patient need. The seller does not have to supply transaction history, transaction information, and a transaction statement if the sale is fulfilling a specific patient need. Both pharmacies will still have to document the sale.

Specific patient need "refers to the transfer of a product from one pharmacy to another to fill a prescription for an identified patient. Such term does not include the transfer of a product from one pharmacy to another for the purpose of increasing or replenishing stock in anticipation of a potential need."

Q. May pharmacies transfer product between pharmacies that are under common ownership or amongst a health care system?
A. Yes, intracompany distribution of product and distribution among hospitals or other health care entities that are under common control are exempted from the definition of a transaction.

The transaction history, transaction information and a transaction statement are not required. The pharmacies will still have to document the transfer.

Q. May a pharmacy sell prescription drugs to a practitioner for office use?
A. Yes, the DSCSA exempts distribution of minimal quantities of product from a pharmacy to a practitioner from the definition of transaction. Kentucky limits that distribution in a twelve (12) month period to less than five percent (5%) of the total number of units dispensed by the pharmacy during the immediate twelve (12) month period.

The pharmacy does not have to supply the practitioner with a transaction history, transaction information, and a transaction statement. The pharmacy will still have to document the sale.

Q. According to DSCSA, what records must a pharmacy maintain if it purchases or merges with another pharmacy?
A. The purchasing pharmacy must maintain the transaction history, transaction information and transaction statement for the products acquired by the closing pharmacy.

Q. Where can a pharmacist go to find more information related to DSCSA?
A. FDA has a variety of resources including published guidance documents and frequently asked questions.
NABP also has a resource page on DSCSA specifically for dispensers.