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Law Helps Ensure Safety of the Supply Chain

Pharmacy Health-System Managers Should Understand the Key Components of the Drug Quality and Security Act

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THE DRUG QUALITY and Security Act was signed into law on November 27, 2013, and included the Title 2 Drug Supply Chain and Security Act (DSCSA).¹

This legislation was introduced to enact a federal prescription drug safety standard to decrease contamination, counterfeiting, diversion, and otherwise harmful illicit activities. It also improves the detection and elimination of potentially unsafe drugs from the drug supply chain to protect US consumers.

DSCSA required that several key initiatives be implemented and maintained to ensure supply chain safety. These have included building an interoperable system for the handling of suspected counterfeit products and product serialization, tracing, and verification. Components of this regulation have been phased in over time, and manufacturers and suppliers have spent unspecified funds relabeling, retooling, and working on the supply chain with the ultimate goal of unit-level traceability by November 27, 2023.²⁻⁴

DSCSA was broad in scope, encompassing prescription drugs in finished form for administration (capsules, tablets, and lyophilized powder for reconstitution). It does not cover, or exempts, several items that are difficult to monitor, including blood or blood components for transfusion; compounded, homeopathic, and imaging drugs; intravenous and OTC products; medical gases; and radioactive biologics and drugs.

Critical components of DSCSA that pharmacists need to know and continuously monitor include the following:

- **Product tracing.** Supply chain participants have been required to

electronically share product transaction history with the next member of the chain (interoperable data) until the member is providing the medication to the final user.² This part often has included significant documentation if the pharmacies are transferring medication between 2 locations. This can now be done electronically. Also, DSCSA required that the transaction, history, information, and statement be provided upon a change of ownership between trading partners.¹ Therefore, if pharmacies loan products between pharmacies under different ownership, they would be accountable to provide the statements to the entity where the product is loaned and maintain records for 6 years. Exceptions include distribution among hospitals under common control, intracompany distributions, and public health emergencies dispensed under a prescription.¹

- **Serialization.** For serialization, a unique serial number is added to each saleable unit of each prescription product, which has been linked to the information about the product's batch number, expiration date, and origin. This process allows end-to-end tracing and gives businesses the ability to manage and track many transactions and large data sets between trading partners. The key for pharmacies is that these systems are interoperable.⁴
- **Suspect product.** This is a product for which there is reason to think that it appears unfit for distribution because it could result in serious adverse health consequences or death or it is poten-



tially counterfeit, diverted, stolen, or the subject of a fraudulent transaction. In case of any of these events, the pharmacy will need policies and procedures in place and a segregated area to store the product until a resolution is found.⁴

- **Transaction history.** This is a statement in electronic or paper form, including the information for each prior transaction going back to the product manufacturer.
- **Transaction information.** This includes the names and addresses of the businesses from which and to which ownership was transferred, dosage form, established or proprietary name of a product, lot size, National Drug Code container size, number of containers, product strength, and shipment and transaction dates.
- **Transaction statement.** This is a document or electronic statement showing that the entity transferring ownership in a transaction did not deliberately provide false transaction information, knowingly alter the transaction history, or intentionally ship an illegitimate or suspect product; had processes and systems in place to comply with verification requirements under the law; received the product from an individual authorized as required under DSCSA; and received transaction information and a statement from the prior owner of the product, as mandatory under the law.
- **Verification.** In the event of a suspect product inquiry, supply chain companies must be able to produce relevant transaction documentation within 24 hours (dispensars have 48


hours). Businesses need a storage and retrieval system that quickly supports these queries. The verification process requires a system be put into place to allow for the quarantine and investigation of suspect products and a mechanism to notify the FDA and trading partners if an illegitimate product is found.⁵

Conclusion

DSCSA was enacted and phased in over the past several years with the intent to help secure the pharmaceutical supply chain. Pharmacy health-system managers should continue to work with FDA-approved partners to analyze their data requirements, operations, and technology and to understand their responsibilities around tracking and tracing. ■

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