DRUG SUPPLY CHAIN SECURITY ACT (DSCSA) GUIDANCE FOR PHARMACIES

Q. What is the Drug Supply Chain Security Act (DSCSA)?

A. The Drug Supply Chain Security Act (DSCSA) is a federal law found at Title II of the Drug Quality and Security Act (DQSA). DSCSA's purpose is to develop and enhance drug distribution security. DSCSA sets forth requirements for trading partners (i.e., manufacturers, wholesale distributors, repackagers, dispensers, and third-party logistics providers) regarding the tracing of prescription pharmaceutical products during distribution throughout the United States. Interoperable, electronic tracing systems required by DSCSA will allow the Food and Drug Administration (FDA) to protect U.S. consumers by readily identifying compromised prescription pharmaceutical products (counterfeit, stolen, contaminated, dangerous, or harmful) and removing them from the pharmaceutical drug supply chain.

A broader description of DSCSA's purpose and operation is found here: https://www.fda.gov/drugs/drug-supply-chain-integrity/drug-supply-chain-security-act-dscsa

Q. Are pharmacies "dispensers" under DSCSA?

A. Yes. DSCSA defines dispensers as:

1. A retail pharmacy
2. A hospital pharmacy
3. A group of chain pharmacies under common ownership and control that do not act as a wholesale distributor
4. Any other person authorized by law to dispense or administer prescription drugs, and the affiliated warehouses or distribution centers of such entities under common ownership and control that do not act as a wholesale distributor

Q. What are a dispenser's responsibilities under DSCSA?

A. Dispensers have four key responsibilities under DSCSA:

1. Know your prescription drug suppliers (sources) and confirm that they are authorized trading partners.
2. Know where your product tracing and transaction data is being stored and how to access it.
3. Know what suspect product is, how to identify it, how to investigate it, and what to do if it is deemed illegitimate.

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4. Develop, update, and adhere to robust prescription drug purchasing policies and procedures.

Q. Where can I find guidance to DSCSA compliance?

A. Key resources include:

The National Association of Boards of Pharmacy (NABP) Dispenser's Guide to DSCSA Compliance. The NABP Dispenser's Guide was developed specifically for pharmacies and contains comprehensive – and practical – guidance on compliance with DSCSA's four key responsibilities:
https://www.ncbop.org/downloads/DSCSADispenserGuide_FINAL090324.pdf

FDA Continuing Education DSCSA Course for Pharmacists:

https://collaboration.fda.gov/p8uo9k0lkn2/

FDA Guidance On Identifying Trading Partners:

https://www.fda.gov/regulatory-information/search-fda-guidance-documents/identifying-trading-partners-under-drug-supply-chain-security-act

FDA Guidance On Product Tracing Requirements:

https://www.fda.gov/drugs/drug-supply-chain-security-act-dscsa/drug-supply-chain-security-act-product-tracing-requirements-frequently-asked-questions

FDA Guidance On Identifying Suspect and Illegitimate Products:

https://www.fda.gov/media/88790/download

https://www.fda.gov/regulatory-information/search-fda-guidance-documents/definitions-suspect-product-and-illegitimate-product-verification-obligations-under-drug-supply

Q. Where can I find on-line resources for verifying the licensure status of a manufacturer, wholesaler, third-party logistics provider, or pharmacy?

A. Online resources include:

North Carolina Department of Agriculture License Verification of Manufacturers, Wholesale Distributors, and Third-Party Logistics Providers:

https://apps.ncagr.gov/AgRSysPortalV2/licensesearch

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FDA Compilation of Links to State Board of Pharmacy Licensing Databases:

https://www.fda.gov/drugs/besaferx-your-source-online-pharmacy-information/locate-state-licensed-online-pharmacy

Q. Which North Carolina agencies have a role to play in DSCSA compliance?

A. The FDA of course enforces compliance with DSCSA requirements. Two North Carolina agencies have DSCSA compliance responsibilities as well:

North Carolina Department of Agriculture's Consumer Services Food and Drug Protection Division's Drug Program plays the primary role in that it regulates the wholesale distribution of prescription drugs throughout the state.

North Carolina Board of Pharmacy plays a secondary role in that NCBOP permits the pharmacies (dispensers) in the state.

Q. What is the North Carolina Department of Agriculture and Consumer Services Food and Drug Protection Division's Drug Program

A. The North Carolina Department of Agriculture and Consumer Services Food and Drug Protection Division's Drug Program (https://www.ncagr.gov/divisions/food-drug/drug-program) licenses the manufacturers, repackagers, wholesale distributors, and the third-party logistics providers (3PLs) who distribute drugs within the state of North Carolina.

The Drug Program is administered by Jeremy Evans, PharmD jeremy.evans@ncagr.gov

Q. What is the regulatory scope of the North Carolina Department of Agriculture and Consumer Services Food and Drug Protection Division's Drug Program?

A. The Drug Program registers, licenses, and inspects firms engaged in the wholesale distribution of prescription drugs and ensures that all prescription drugs and medical gases are stored and handled in a safe manner and are safely distributed within North Carolina.

Regulated firms include Prescription Drug Manufacturers, Virtual Manufacturers, Re-packagers, Sterile 503B Outsourcing Facilities, Wholesale Distributors, Reverse Distributors, Pseudoephedrine Distributors, Third Party Logistic Providers, Medical Gas Manufacturers, and Medical Gas Distributors.

In addition to its licensing and inspection responsibilities, the Drug Program may take enforcement actions, including: action on observations noted from inspections;

investigating consumer complaints for prescription drug products; initiating and completing all compliance and recall actions, on-site actions, embargoing of products as necessary, and actively partnering with other agencies and law enforcement to address and prevent drug diversion within North Carolina.

Q. What role does the North Carolina Board of Pharmacy play in DSCSA compliance?

A. The Board plays a secondary DSCSA enforcement role.

For example, if FDA or the North Carolina Department of Agriculture identified potential suspect or illegitimate drug distribution that tracked down to individual pharmacies, Board staff would get involved in the investigation. The investigation would include determining what the pharmacy was (or was not) doing in terms of DSCSA compliance.

If Board staff discovered potential suspect or illegitimate drug product in a pharmacy via a complaint or inspection, Board staff will investigate. The investigation would include determining what the pharmacy was (or was not) doing in terms of DSCSA compliance.