



DSCSA and Me

This is the second in the educational series from the South Carolina Board of Pharmacy focusing on the Drug Supply Chain Security Act and how it impacts you. The purpose of this series is to:

- Provide background on DSCSA
- Educate on federal requirements
- Provide information on how DSCSA impacts the individual licensees
- Discuss the stabilization period

Today, we will focus on dispensers under the DSCSA.

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

The Drug Supply Chain Security Act (DSCSA), which was first enacted in 2013, outlines requirements for manufacturers, repackagers, wholesale distributors, dispensers, and third-party logistics providers (trading partners), regarding the tracing of legend pharmaceutical products throughout the entire supply chain. These required interoperable, electronic tracing systems will assist in protecting consumers by readily identifying compromised prescription pharmaceutical products, including those that may be counterfeit, stolen, contaminated, dangerous, or harmful, and removing them from the pharmaceutical supply chain.

Who does the DSCSA consider a dispenser?

According to DSCSA, the following are considered dispensers and subject to the requirements of the Act:

- A retail pharmacy, hospital pharmacy, or a group of chain pharmacies under common ownership or control, or
- Any other person authorized by law to dispense or administer prescription drugs, and
- Affiliated warehouses or distribution centers of such entities.
- Excludes:
 - if such entity acts as a wholesale distributor
 - a person who only dispenses products used in animals

What is a dispenser required to do under DSCSA *currently*?

Currently, under DSCSA, a pharmacy is required to:

- Confirm that your trading partners are appropriately licensed or registered
- Receive and maintain product tracing documentation
- Identify, investigate, and report suspect and illegitimate product

What changes in November of 2023?

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](#) platform in order to meet the DSCSA interoperability requirements.

Interoperable Exchange. Trading partners must exchange required transaction information (TI) and transaction statements (TS) in a secure, electronic, interoperable manner, and the TI must include the product identifier at the package level. Transaction information shall include the product identifier at the package level for each package included in the transaction. [Section 582(g)(1)(B) of the FD&C Act]

Interoperable Verification. Trading partners must be able to verify the product identifier on a package or sealed homogenous case in a secure, electronic, interoperable manner.

Interoperable Tracing. Trading partners must maintain secure, electronic, interoperable systems and processes to provide TI and TS in response to a request for it and to promptly facilitate gathering the information necessary to produce the TI for each transaction going back to the manufacturer.

For additional DSCSA information, please visit:

[For Pharmacists – Partnership for Safe Medicines](#)

[Resources - DispenserEDU DispenserEDU \(dscsa.pharmacy\)](#)

Disclaimer: The information provided by the SCBOP is not all encompassing and is meant to provide high-level education, not legal advice.