



## **DSCSA and Me #3**

### **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.

While the FDA did announce a stabilization period until November 2024, this time should be used to move forward in DSCSA compliance.

### **Who is considered an authorized trading partner?**

The DSCSA identifies and defines five types of entities in the prescription drug supply chain:

- Manufacturers
- Repackagers
- Dispensers
- Wholesale Distributors
- Third Party Logistics

The FDA requires that only authorized trading partners be a part of the drug supply chain, therefore, all members of the supply chain should confirm that they are only dealing with authorized trading partners.

Manufacturers and repackagers are considered authorized when they have a valid registration with the FDA.

Wholesale distributors and Third Party Logistics providers are considered authorized when they have a valid State or Federal license and are in compliance with all reporting requirements. South Carolina does require State permits for wholesale distributors as well as Third Party Logistics providers.

Dispensers are considered authorized when they have a valid license under State law.

An authorized distributor is a wholesale distributor who contracts with a manufacturer to distribute their products. It is important to remember that you can be an authorized trading partner without being an authorized distributor.

### **How can I confirm that a trading partner is authorized?**

You can verify that a drug establishment (manufacturer and/or repackager) is properly registered by visiting the FDA [website](#).

In addition, the South Carolina Board of Pharmacy requires permitting for wholesale distributors and third-party logistics providers (3PLs) who are doing business in South Carolina. You can find this information on [licensee lookup](#).

### **Won't my wholesale distributor handle DSCSA requirements for me?**

Partnering with your contracted wholesale distributors, who are also authorized trading partners, will be critical for DSCSA implementation. However, there are some things that a wholesale distributor cannot do for you.

The below link outlines what a wholesale distributor can do, and more importantly, what they cannot do for a dispenser in relation to DSCSA requirements.

<https://dscsa.pharmacy/wp-content/uploads/2023/11/How-Can-Your-Wholesale-Distributor-Help-Prepare-for-DSCSA-2023.pdf>

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.*