

DSCSA and Me

This begins our 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 the background.

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.

Why are we hearing about DSCSA now?

When the DSCSA was enacted in November of 2013, it set out a 10-year timeline to build an electronic, interoperable system for the exchange of transaction documentation [transaction information (TI), transaction history (TH) and transaction statements (TS)], currently known as T3, to enable the tracing of prescription medicines throughout the pharmaceutical supply chain. This means that the law goes into effect in November of 2023.

However, the FDA did release guidance in August of this year regarding a stabilization period for DSCSA because they determined that many stakeholders were not prepared to be fully compliant. Therefore, the stabilization period was put into place to ensure continued movement of medications through the supply chain while trading partners finalize the implementation of their DSCSA-compliant systems. It is important to note that the stabilization period is **NOT** a delay in the enactment of the law and should be used to implement and troubleshoot systems and processes.

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.