

The Drug Supply Chain Security Act

The Healthcare Distribution Alliance (HDA) helped secure passage of the [Drug Supply Chain Security Act \(DSCSA\)](#) in 2013. Since then, HDA has worked closely with members to engage with FDA on regulation, support industry with educational content and developed resources that helped supply chain stakeholders navigate implementation.

HDA and the distribution industry are [leaders](#) on federal traceability issues. DSCSA implementation is a clear example of how the distribution sector's collaborative spirit and logistics expertise benefit the entire healthcare sector.

What Is the DSCSA?

The DSCSA establishes a uniform, interoperable framework for tracing pharmaceutical products throughout the supply chain. The systems and processes implemented across the supply chain over the past decade enhance the Food and Drug Administration's (FDA) ability to protect U.S. consumers by improving identification and removal of potentially dangerous products from the pharmaceutical distribution supply chain.

The groundbreaking law:



Replaced a 50-state patchwork of pedigree requirements (the "product ownership" information associated with a drug as it moves through the supply chain) with one federal solution.



Strengthened distributor licensure standards uniformly across the United States.



Established new processes for identifying and investigating suspect and illegitimate products in the supply chain.

The final enhanced requirements of the DSCSA are now in effect. This means that trading partners are required to provide and receive serialized transaction data along with serialized product upon a change of ownership (for example, a manufacturer to distributor or a distributor to a pharmacy).

Some companies may be operating under time-limited exemptions granted by FDA for certain requirements. These exemptions apply only where a company has submitted a request to FDA and FDA has granted that request. Companies operating under such exemptions are required to notify their trading partners.

Finally, FDA is currently working to establish national licensure standards for wholesale distributors and third-party logistics providers and requires these entities to report licensure and other information to FDA annually. Those licensure standards are expected to be finalized in the next couple of years.