

The Drug Supply Chain Security Act

The [Drug Supply Chain Security Act \(DSCSA\)](#), enacted in 2013, fundamentally changed the way pharmaceutical products and their associated data move in tandem through the supply chain, while increasing safety and security for patients.

The Healthcare Distribution Alliance (HDA) and the distribution industry have [led](#) on federal traceability issues for approximately two decades. 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.

On the DSCSA's final implementation deadline of November 27, 2023, supply chain trading partners will be 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).

Final Implementation: Each Supply Chain Partner Has a Role To Play

The supply chain is at a critical inflection point, and industry readiness is not where it should be. HDA and the HDA Research Foundation have identified [inconsistent implementation](#) as supply chain partners prepare for November 2023.

[DSCSA implementation](#) is a highly integrated process, and the distributor community depends on receiving complete and accurate serialized data from manufacturers to facilitate compliance. Each stakeholder has an important interdependent role to play:



Manufacturers should communicate with distributors their plans for sending DSCSA-required data and start connecting their systems now.



Dispensers should understand what is expected of them under the law and start making plans for compliance (working with their distributors, manufacturers or technology providers as appropriate).



Likewise, FDA should pursue narrow exemptions for underprepared manufacturers, while providing flexibility for trading partners to work through data exceptions. Doing so will help avoid significant supply chain disruptions and product shortages and support the safe and efficient flow of critical medicines after the final implementation date.

As we approach the DSCSA's final deadline on November 27, 2023, HDA and our members continue to work with supply chain partners to address critical technology and compliance questions and engage with FDA. By working together, we can effectively implement this groundbreaking law to ensure a more resilient supply chain and increase safety and security for patients.

For more information about the distribution industry's approach to pharmaceutical traceability and DSCSA implementation visit: www.hda.org/pharmaceutical-traceability