



## DRUG SUPPLY CHAIN SECURITY ACT (DSCSA) POCKET GUIDE

InfiniTraks' DSCSA Compliance Solution is the leading software that provides trading partner verification, T3 Data Verification & Storage, Suspect Product Wizard, flexible account management, customizable DSCSA SOPs, integration, mobile & 2D scanning, robust search functionality, and access to regulatory experts for comprehensive compliance support.

[WWW.INFINITRAK.US](http://WWW.INFINITRAK.US)

### LEADERS IN DSCSA

InfiniTrak understands the need for an affordable DSCSA compliance solution. It is equally important to partner with experts who understand the law and can provide guidance and support.

InfiniTrak's DSCSA compliance solution is an All-In-One Cloud-based platform designed specifically for dispensers. The innovative technology is easy to use and aggregates all your data into one location.

InfiniTrak provides a complete pharmacy centric DSCSA compliance solution and platform.



### COMPLIANCE MADE EASY



(844) 463-4641  
(567) 277-3660



[info@InfiniTrak.us](mailto:info@InfiniTrak.us)



[InfiniTrak.us](http://InfiniTrak.us)



## OVERVIEW OF FDA REGULATIONS

The Drug Supply Chain Security Act (DSCSA) is a law implemented by the FDA to secure the drug supply chain and improve patient safety. It outlines critical steps to build an electronic, interoperable system to identify and trace certain prescription drugs as they are distributed in the United States. The system is designed to facilitate the exchange of information at the individual package level, showing each stop a drug has been at in the supply chain. This is a complex law that continues to bring significant change to the way most pharmacies track and trace their products. This pocket guide provides guidance on how to be compliant with the law.

## INTEROPERABILITY

The U.S. Pharmaceutical Drug Supply Chain is in the process of moving to a fully interoperable system with full electronic data exchange. This is changing the landscape for all stakeholders, Manufacturers, Suppliers, and Dispensers. The FDA has announced that it will not enforce this law until November 27, 2024. This enforcement delay is referred to as "Stabilization" period. During this time, all stakeholders are expected to move forward with their plans to implement a DSCSA solution.



### OPERATIONS

Dispensers will need to have a system that provides full DSCSA compliance. This includes the ability to conduct product tracing when requested by other stakeholders within the drug supply chain.



### INVENTORY

Dispensers will be required to validate that they have received all pharmaceutical drug products that have been ordered and have procedures in place to quarantine products that require additional investigation.

## UNDERSTANDING DSCSA & HOW IT IMPACTS YOU

### TRANSACTION DATA MANAGEMENT

Holding the data for 6 years is not enough. Are you able to easily search and retrieve your product data? Are you reviewing all transaction data and comparing it to the product received?



You may be asked by auditors to produce documentation within 48 hours. Every product must contain accurate transaction data.

### LICENSE VERIFICATION

Are you verifying that your trading partners have a valid license each time you place an order?



FDA requires supplier license verification for each transaction.

### SUSPECT PRODUCT PROCESS

Do you have a process to identify suspect or illegitimate product? How are you documenting the investigation?



FDA requires suspect products to be quarantined, and if found to be illegitimate you are required to report the product.

### PRODUCT VERIFICATION

Are you looking at each product and verifying it has a unique product identifier?



Beginning Nov. 2020, pharmacies cannot sell product without a unique identifier unless it qualifies as a Grandfathered product.

### POLICIES & PROCEDURES

Do you have written policies and procedures detailing DSCSA and how to handle suspect & illegitimate product?



Pharmacies are required to have a written policy detailing DSCSA compliance.

### INTEROPERABILITY

Is your DSCSA compliance ready to exchange all transaction data electronically?



Interoperability will convert all data to electronic format making it more complex and eliminating the exchange of transaction history.



## COST OF DELAYS

Pharmacies are at risk if delaying the choosing of a DSCSA compliance solution.

- Gaps in current solutions & systems leading to missed deadlines
- Implementation wait times may leave dispensers vulnerable
- Federal and State audits/inspections could result in fines

### ALREADY HAVE A COMPLIANCE SOLUTION?

- Does it meet each requirement of the law?
- Do you have real-time access and support for audits or inspections?
- Are you using the wholesaler portals as your solution to DSCSA?
- Do you have access to experts in DSCSA that can provide guidance?

