



RESOURCES

Home
Resources
Resource Center

Understanding the Drug Supply Chain Security Act (DSCSA)



The Drug Supply Chain Security Act (DSCSA) is to ensure the safety and security of the pharmaceutical supply chain in the United States. Its primary goal is to protect consumers from counterfeit, contaminated, or harmful drugs by establishing a robust system for tracking and tracing prescription medications. The DSCSA establishes national licensure standards for wholesale distributors and third-party logistics providers and requires these entities to report licensure and other information to the **U.S. Food and Drug Administration (FDA)**.

What is DSCSA?

The DSCSA, which stands for Drug Supply Chain Security Act, sets forth stringent requirements for the identification, tracing, and verification of prescription drugs. The DSCSA meaning is significant as it mandates that every entity involved in the pharmaceutical supply chain, from manufacturers to pharmacies, must adhere to these standards to ensure that only legitimate and safe products reach consumers.

Key Provisions of the Drug Supply Chain Security Act

The **Drug Supply Chain Security Act** includes several essential provisions designed to protect the integrity of the pharmaceutical supply chain:

- **Product Identification:** All prescription drugs must be labeled with a unique

product identifier that includes a Global Trade Identification Number (GTIN), a serial number, lot number, and expiration date. This helps in tracking individual packages throughout the supply chain. This information is encoded in a 2D data matrix barcode and also available in human-readable form.

- **Tracing:** Detailed transaction records must be maintained by all entities in the supply chain, including Transaction Information (TI), Transaction History (TH), and Transaction Statements (TS). Industry has aligned on exchanging this information using the EPCIS standard.
- **Verification:** It requires the verification of drugs at various points in the supply chain to ensure that the product identifier matches the same combination of GTIN, serial number, lot number and expiration date, when it was placed into commerce. Verification use cases include suspect and illegitimate product investigations as well as before a returned product is resold to another entity.
- **Serialization :** By 2017 (enforcement discretion to 2018), manufacturers were required to serialize their products. Subsequent deadlines were set for wholesalers, repackagers, and dispensers to only ship and receive serialized products.

Importance of DSCSA

The significance of the DSCSA in the pharmaceutical industry cannot be overstated. Here's why the DSCSA is crucial:

- **Protects Patients:** The DSCSA plays a vital role in safeguarding public health by ensuring that only safe and legitimate medications reach patients.
- **Enhances Transparency:** The act creates a transparent supply chain where each entity is accountable for their role, reducing the risk of counterfeit or adulterated drugs entering the legitimate supply chain.
- **Improves Efficiency:** The DSCSA streamlines recall processes and enhances the industry's ability to respond to safety concerns promptly.
- **Strengthens Trust:** By ensuring the integrity of the pharmaceutical supply

chain, the DSCSA builds trust among consumers, healthcare providers, and industry stakeholders.

Learn more about DSCSA and FDA Guidance

Understanding the DSCSA and its importance is essential for anyone involved in the pharmaceutical industry. The Drug Supply Chain Security Act (DSCSA) represents a significant step toward securing the drug supply chain, enhancing transparency, and protecting public health. By adhering to the DSCSA's stringent requirements, the pharmaceutical industry can ensure that patients receive safe and effective medications, thereby reinforcing trust in the healthcare system.

Staying informed about the latest **FDA DSCSA** guidance and compliance requirements is essential for maintaining adherence to this vital legislation. For those seeking to navigate the complexities of DSCSA compliance, TraceLink offers expert guidance and solutions. TraceLink's services are designed to help organizations achieve and maintain compliance with DSCSA regulations, ensuring the security and integrity of the pharmaceutical supply chain.

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