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Home
Resources
Resource Center

Ensuring DSCSA Compliance: A Guide for Hospitals



The Drug Supply Chain Security Act (DSCSA) is a federal law in the United States that aims to enhance the security and traceability of pharmaceutical products throughout the supply chain. For hospitals, compliance with DSCSA is crucial to ensure patient safety, prevent counterfeit drugs, and maintain transparency.

What is DSCSA compliance?

The DSCSA provides a framework for tracing prescription drugs as they are distributed across the United States. Key components of the DSCSA include:

- **Product Tracing:** Requires trading partners to provide detailed information regarding every product transaction, ensuring traceability from manufacturer to dispenser. This includes exchanging serialized T2 information as part of an EPCIS transaction.
- **Product Verification:** Mandates the ability to verify the legitimacy of the product identifier as part of a suspect product investigation or salable return.
- **Detection and Response:** Establishes systems and processes to identify and handle suspect and illegitimate products.
- **Notification:** Requires notification of the FDA and other stakeholders about illegitimate products.

DSCSA Guidance: Compliance Requirements for Hospitals

- **DSCSA Serialization:** Hospitals must ensure that all prescription drugs are serialized according to DSCSA guidelines. This involves updating systems and processes to handle serialized products.
- **Verification:** Hospitals should verify the authenticity of received drug products using authorized systems.
- **Maintaining Transaction Documentation:** Hospitals must maintain records of transaction information, transaction history, and transaction statements (commonly referred to as T3 information) for a minimum of six years. Additionally, at the end of the stabilization period, T3 will transition into a **serialized T2**.
- **Suspect Product Investigations:** Hospitals need to establish protocols for identifying, investigating, and reporting suspect or illegitimate products to the FDA and trading partners.
- **Utilizing Compliance Software:** Implementing specialized compliance software can streamline the management of DSCSA requirements. These systems can automate record-keeping, facilitate verification processes, and ensure timely reporting.

Challenges Faced by Hospitals in DSCSA Compliance:

- **Complexity:** Implementing serialization and maintaining accurate records can be complex and resource-intensive.
- **Workflow:** Introduces an additional “check” and potential scan of the product during intake, which adds more work to hospital pharmacy staff.
- **Integration:** Hospitals need to integrate their systems with other supply chain partners (manufacturers, wholesalers, etc.).
- **Training:** Staff must be trained on DSCSA requirements and compliance procedures.
- **Data Management:** Maintaining and managing large volumes of transaction

data over six years requires robust data management solutions.

- **Coordination with Trading Partners:** Effective communication and coordination with manufacturers, wholesalers, and other trading partners are critical to ensure seamless compliance.

Penalties for Non-Compliance:

- **Patient Safety:** Patients could be put at risk if counterfeit or adulterated product is dispensed.
- **Monetary Fines:** The FDA can impose substantial fines on hospitals for failing to comply with DSCSA requirements.
- **Legal Action:** Persistent non-compliance can lead to legal actions, including lawsuits and injunctions.
- **Reputation Damage:** Non-compliance can harm a hospital's reputation, leading to a loss of trust among patients and partners.

DSCSA Exemptions and Special Cases:

Certain products and scenarios are exempt from DSCSA requirements. These include:

- **Blood and Blood Components:** Blood and blood components intended for transfusion are exempt from DSCSA regulations.
- **Medical Convenience Kits:** Kits that include drugs and are intended for the convenience of the patient or healthcare provider may be exempt under specific conditions.
- **Certain Intravenous Products:** Products that are for fluid replacement, irrigation, or nutritional support may also be exempt.

Role of DSCSA Compliance Software:

- **Track and Trace Solutions:** Hospitals can use specialized software to track drug movements, verify authenticity, and maintain compliance records.

- **Automated Reporting:** Compliance software streamlines reporting processes, reducing manual effort.
- **Auditing and Monitoring:** Regular audits using software help hospitals identify gaps and ensure ongoing compliance.

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