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Small Dispenser & Healthcare Facility

DSCSA Compliance Checklist

DSCSA Regulatory requirements are currently **active and enforceable** for all authorized trading partners across the pharmaceutical supply chain. As of August 6, 2026, the FDA has extended the requirements for Enhanced Drug Distribution Security requirements for Small Dispensers, including Healthcare Facilities, until November 27, 2027. All other sections are enforceable.

> If a small business dispenser relies on the exemptions outlined below, we recommend communicating such reliance to its trading partners as needed to further facilitate distribution of product without difficulty or delay. The exemptions described below do not apply to other requirements in section 582 of the FD&C Act.

FDA Letter Issued August 6, 2026

DSCSA Compliance Imperatives

Standard Operating Procedures (SOPs)

All Trading Partners must have documented SOPs in place outlining the facility's policies and procedures and **addressing each section of the DSCSA regulatory requirements**. Procedures should be followed exactly as written and should have documentation supporting the adherence to the policies.

Authorized Trading Partner Verification & Audits

Trading Partners are required to limit the purchase or sale of pharmaceuticals to only those facilities which have been independently verified as an authorized trading partner. Supplier and customer onboarding procedures should be thorough and with a clear process as outlined in the facility SOPs. This includes ongoing and regular audits of trading partners' standing to ensure licenses are current and valid.

Product Inspection, Investigations & Audits

Trading Partners are required to inspect each item which is received in their possession to ensure the integrity of each item and must have policies and procedures in place for reporting suspect or illegitimate products. Procedures must be outlined in the facility SOPs, including procedures for the quarantine of product and disposition of expired products.

Product Transaction Tracing and Record Storage

Trading Partners are required to obtain a product transaction record tracing back to the manufacturer for each product it receives into inventory. Facilities must verify each transaction history component for every product and have SOPs in place outlining the procedures for obtaining and storing product records and a plan of action if product is received without documentation.

Fusion Support Solutions provides customizable solutions to help achieve DSCSA Compliance adherence. The list above should not be considered legal advice or an exhaustive list of DSCSA Compliance requirements. Contact Us to learn more about our services and solutions today!

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