# DSCSA
# Pharmacy Reference Guide

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Utilize this guide to complete the key steps needed to receive Morris & Dickson products and achieve DSCSA compliance.

**Please contact your Morris & Dickson account representative for additional questions.**

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## What is DSCSA?

The Drug Supply Chain Security Act DSCSA, is Title II of the Drug Quality and Security Act, passed by Congress on November 27, 2013. DSCSA preempts a 50-state patchwork of pedigree requirements to create **one federal traceability framework for prescription medicines**. The DSCSA sets out a 10-year timeline to build an electronic, interoperable system for the exchange of transaction documentation [transaction information (TI), transaction history (TH) and transaction statements (TS)] to enable the tracing of prescription medicines throughout the pharmaceutical supply chain, with the final milestone quickly approaching in November, 2023.[i]

## What is the goal of DSCSA?

- Provide improved efficiency in the ability to help protect consumers from recalled product
- To prevent introduction/ distribution of counterfeit or contaminated drugs into the pharmaceutical supply chain.

## What are the requirements for a pharmacy (dispenser)?

- Only sell products to authorized trading partners with verified licenses.
- Provide proper product tracing documentation within 48 hours of a request from a trading partner, federal agency, or state agency.
- Receive and retain the EPCIS data for a minimum of 6 years
- Notify the FDA if they have an illegitimate product by using FDA Form 3911 and notify other trading partners within 24 hours.
- Verify the authenticity of suspect and illegitimate Rx products.
- Have standard operating procedures in place for DSCSA requirements.

Source: LSPEDIA DSCSA Requirements Checklist

## Key action steps to meet the November 27, 2024 enforcement date for DSCSA readiness

A. **Morris & Dickson Action Steps**
   Prepare pharmacies to receive/share **Electronic Product Code Information Services (EPCIS)** data.
   1. Advanced shipping notice (ASN)/3T reporting will sunset as the required compliance document.

2. This report will continue to be sent from M&D to pharmacies for operational purposes.

3. M&D will also provide interoperable EPCIS data exchange, with our trade partner – LSPedia. DSCSA requires trading partners to exchange interoperable EPCIS data containing transaction information and transaction statement (2Ts).

B. **Dispenser Action Steps**

1. Register with LSPEDIA - Morris & Dickson's third-party provider for EPCIS data exchange. This will give your pharmacy access to all EPCIS data for products you purchases from Morris & Dickson. See Registration Details below.

   **Complete the LSPEDIA Master Data Template** by providing GLN information in the template.

2. **Complete the LSPedia DSCSA Onboarding form** (Master data template will be uploaded here).
   1.

2. Log into the LSPedia portal to view EPCIS data for DSCSA compliance. Pharmacies can also opt to receive EPCIS data via AS2 to their own DSCSA solution provider.

## How M&D pharmacies can obtain/manage Global Location Numbers

1. **Obtain a GLN** if your pharmacy does not already have one. The GLN is required of all pharmacies to participate in interoperable exchange of DSCSA data in the supply chain.
   a. A GLN can be obtained via the GS1 website here.
   b. For health system pharmacies, there is a GLN for the main location (for billing, etc.) and GLNs for each pharmacy location. If unsure about your GLN status, first contact your compliance office.
   c. If you are not sure of the status of your GLN, refer to the M&D portal or ask your Morris & Dickson account representative.
   d. To change your GLN information in the M&D web portal or to verify your GLN information, ask your account representative or go to **Help**, then **Account Information**. Click on the **pencil icon** on the left of the row to edit the GLN.

2. M&D will then provide all GLN numbers to LSPedia for the next steps to connectivity.

## Frequently Asked Questions
**Who is LSPedia?**

[LSPedia](#) is Morris & Dickson's third-party provider for attaining EPCIS data. LSPedia is also a leading provider of turnkey DSCSA compliance and SaaS solutions in the pharmaceutical industry. LSPedia's OneScan solution is designed for dispensers that streamlines the track and trace requirements as part of a dispenser's daily processes.

**How can a pharmacy get EPCIS data for all products, not just M&D purchases?**
Morris & Dickson recommends that pharmacy customers consider subscribing to an DSCSA solution provider. Many providers already integrate with many of the pharmacy management systems.

Two solutions to consider include:

[Cervey Tracker](#), a web-based tool for pharmacy dispensers of all sizes that tracks product in accordance with DSCSA guidelines. Available at a market competitive rate, this tool allows your pharmacy to receive EPCIS data from M&D as well as all of your other suppliers. Contact Cervey at [tracker@cervey.com](mailto:tracker@cervey.com) to learn more.

[LSPedia's OneScan solution](#) is designed for dispensers that streamlines the track and trace requirements as part of a dispenser's daily processes. See link in resources section of this document or contact LSPEDIA at [trace@LSPedia.com](mailto:trace@LSPedia.com).

**How should a dispenser manage exceptions?**
LSPedia's [Investigator](#) tool alerts problems with EPCIS data in real time and helps to fix them. [Investigator](#) validates EPCIS data following DSCSA, GS1, and configurable business rules and automatically emails the responsible point of contact (PoC) in real-time.

## Key Terms

**Definition of dispenser[ii]:**

- A retail pharmacy;

- A hospital pharmacy;

- A group of chain pharmacies under common ownership and control that do not act as a wholesale distributor; or

- Any other person authorized by law to dispense or administer prescription drugs and the affiliated warehouses or distribution centers of such entities under common ownership and control that do not act as a wholesale distributor

**Definition of small dispenser:** having 25 or fewer full-time employees.[iii]

**EPCIS:** Electronic Product Code Information Services is the GS1 Standard for creating and sharing visibility event data, both within and across enterprises. An event is the data record that

describes the individual steps in the supply chain process – commissioning, packing, shipping, receiving, etc.

**GLN:** The **Global Location Number (GLN)** is a 13-digit numerical identifier standardized by GS1 (a non-profit for improved business communication).[iv]

**Stabilization Period:** This policy was issued by the [Food & Drug Administration](#) (Administration, 2024) on August 30, 2023 that: it "does not intend to take action to enforce" these 2023 requirements until November 27, 2024." … The additional time is for "systems to stabilize and be fully interoperable for accurate, secure, and timely electronic data exchange."

**Additional resources**

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| [Morris & Dickson web portal](#) | Access this portal for product information and ordering, resources |
| [LSPEDIA](#) | Third-party DSCSA compliance vendor for Morris & Dickson. Once registered, M&D pharmacies can access EPCIS data via the LSPEDIA web portal |
| [LSPEDIA Dispenser Checklist](#) | Key action steps for pharmacies to follow in order to prepare for DSCSA compliance |
| [LSPEDIA Onboarding Form](#) | M&D pharmacy customers must complete this form in order to receive M&D EPCIS data |
| [LSPEDIA ONESCAN Form](#) | (Optional) If your pharmacy chooses to use LSPEDIA for all EPCIS data access, begin this process by completing this form. |
| [Cervey Tracker serialization solution](#) | Cervey tool that allows pharmacy dispensers to access/exchange EPCIS data with all suppliers |
| [GS1](#) (gs1us.org) | Access to acquire a Global Location Number |
| [dscsa.pharmacy](#) | Joint resource center developed by: APhA, ASHP, HDA, NABP, NCPA, PDG and PDSA |
| [FDA-DSCSA](#) | FDA resource website |

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[i] Drug Supply Chain Security Act (DSCSA) Resources for Dispensers. https://dscsa.pharmacy/. Accessed 8/20/23.

[ii] Drug Supply Chain Security Act (DSCSA) Resources for Dispensers. https://dscsa.pharmacy/. Accessed 8/20/23.

[iii] Drug Supply Chain Security Act (DSCSA) Assessment of Small Dispensers. https://www.fda.gov/drugs/drug-supply-chain-security-act-dscsa/drug-supply-chain-security-act-dscsa-assessment-small-dispensers. Accessed 8/20/23.

[iv] Global Location Number. https://www.definitivehc.com/resources/glossary/global-location-number. Accessed 8/20/23.