

DSCSA Pharmacy Reference Guide





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

Please contact your M&D account representative for additional questions.

What is DSCSA?

The Drug Supply Chain Security Act <u>DSCSA</u>, 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.

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.

Definition of dispenser::

- 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}



Morris & Dickson steps to support pharmacies in meeting DSCSA readiness deadline on November 27, 2023.

- 1. Partnership with third party <u>LSPedia</u>
 - LSPedia is a leading provider of turnkey DSCSA compliance and SaaS solutions in the pharmaceutical industry. Trading partners use LSPedia's OneScan solution to make, move, track, verify, ship and receive serialized products. OneScan delivers flexible integrations, high-performance product verification, and state-of-the-art EPCIS data exchange. In addition, LSPedia's Investigator platform is the gold standard for serialization exceptions management.
- 2. 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 <u>LSPedia</u>. DSCSA requires trading partners to exchange interoperable EPCIS data containing transaction information and transaction statement (2Ts).
- 3. Support pharmacies with exchange of EPCIS data
 - Pharmacies must register (following the steps below) and log into the <u>LSPedia</u> <u>portal</u> to view EPCIS data for DSCSA compliance. Pharmacies can also opt to receive EPCIS data via AS2 to their own DSCSA solution provider.
 - 2. **Coming soon!** The M&D web portal will soon provide a user-friendly view to the serialization data. Pharmacies will receive a notification when this function is available to pharmacies.

How M&D pharmacies can register and log into the LSPedia portal

Obtain a GLN (encouraged by Oct 2, 2023), if your pharmacy does not already have one. The GLN is required of all pharmacies in order to participate in interoperable exchange of DSCSA data in the supply chain.

If you are not sure of the status of your GLN, refer to the M&D portal or ask your Morris & Dickson account representative.

- A GLN can be obtained via the GS1 website here.
- 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.



 To change your GLN information in the M&D web portal, 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.

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

What about dropship products?

M&D will forward the dropship EPCIS data file to the pharmacy upon receiving it from the manufacturer.

What about exceptions management?

LSPedia's <u>Investigator</u> tool alerts problems with EPCIS data in real time and helps to fix them. <u>Investigator</u> validates EPCIS data following DSCSA, GS1, and configurable business rules and automatically emails the responsible point of contact (PoC) in real-time.

Additional Pharmacy solution: Cervey Tracker

M&D pharmacies also have the option of subscribing to <u>Cervey Tracker</u>, 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 to learn more.



Additional resources

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
Cervey Tracker serialization solution	Cervey tool that allows pharmacy dispensers to access/exchange EPCIS data with all suppliers
GSI (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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¹ Drug Supply Chain Security Act (DSCSA) Resources for Dispensers. https://dscsa.pharmacy/. Accessed 8/20/23.

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

Drug Supply Chain Security Act (DSCSA) Assessment of Small Dispensers. https://www.fda.gov/drugs/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.