

DSCSA: Prepare for Enhanced Drug Distribution Security Requirements

April 2023

Cardinal Health is committed to the safety and security of the pharmaceutical supply chain and will work with dispensers to prepare for the Drug Supply Chain Security Act (DSCSA) regulations that take effect in November 2023.

The DSCSA, also known as Pharmaceutical Tracing, directly impacts you, our customer, and we will continue to provide updates over the coming months about our readiness and implementation efforts.

For the latest information about DSCSA regulations and the ways Cardinal Health is supporting manufacturers and customers, please visit our <u>Pharmaceutical Tracing website</u>.

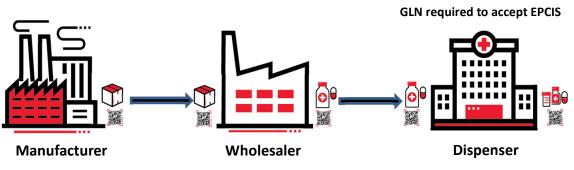
DSCSA Requirements

The DSCSA (Title II of the 2013 Drug Quality and Security Act), establishes a national system for tracing prescription drugs through the supply chain and sets national licensing standards to enhance the U.S. Food and Drug Administration's (FDA) ability to help protect consumers from exposure to drugs that may be counterfeit, stolen, contaminated or otherwise harmful. The DSCSA impacts all trading partners, including manufacturers, dispensers, repackagers and wholesale distributors.

On November 27, 2023, Cardinal Health will begin electronically tracking product at the individual package level using the manufacturer product identifier (2D barcode) that includes lot number and expiration date. Our dispenser customers (pharmacies) will have the option of receiving DSCSA serialized transaction data via EPCIS (Electronic Product Code Information Services) replacing today's transaction information (TI), transaction history (TH) and transaction statements (TS) via ASN 856.

Customers that do not have the system capabilities to accept EPCIS messages, can access the data via Cardinal Health's web portal or online ordering platforms (i.e., Order Express, Weblink and Specialty Online). The FDA recommends that trading partners adopt and implement EPCIS as the global standard to provide and maintain serialized transaction information and transaction statements.





EPCIS visibility between supply chain stakeholders

Global Location Number (GLN) Requirement

Customers will need a GLN for each ship to site to receive DSCSA serialized data in November. The GLN provides businesses the ability to know who is involved in transactions and where things are located throughout the supply chain. By uniquely identifying parties and locations, GLN helps with tracking products, optimizing processes, and providing greater visibility to transactions taking place around the world. GLN does for parties and locations what barcodes do for products.

Cardinal Health cannot send serialized information about product without the standardized GLN for identification, and we cannot complete the EPCIS file for customers' orders without a GLN. Customers who do not obtain a GLN will be out of compliance, and Cardinal Health will be unable to transact with you.

Information about how to obtain a GLNs is available at the <u>GS1 website</u>. Customers will need to provide their 13-digit GLN(s) to Cardinal Health so we can add them to your account information. We will provide details about how to do this soon.

Cardinal Health will continue to provide updates as we move closer to implementation. Visit our <u>Pharmaceutical Tracing</u> <u>website</u> for the latest information, including FAQs. If you have additional questions, please contact your Cardinal Health representative or email <u>dscsainfo@cardinalhealth.com</u>.