PDSA
Pharmaceutical Distribution Security Alliance

Drug Supply Chain Security Act of 2013 (DSCSA) Requirements

The Drug Supply Chain Security Act (DSCSA) established national uniform requirements for manufacturers, repackagers, wholesale distributors, dispensers, and third-party logistics providers to achieve interoperable electronic tracing of certain prescription drugs at the package level in the United States. All DSCSA requirements are effective beginning November 27, 2023.

Up until November 27, 2023, shared data must include the **Transaction information (TI).** TI consists of the proprietary name of the product, the strength and dose form of the product, the National Drug Code (NDC) number of the product, the container size, the number of containers, the lot number of the product, the date of the transaction, the data of the shipment, the business name and address of the seller, and the business name and address of the buyer.

DSCSA 2023 Requirements:

The DSCSA requirements for 2023 are comprised of three specific, but highly interrelated statutory components that go into effect on November 27, 2023:

- **Interoperable Exchange.** Trading partners must exchange required TI in the GS1 US EPCIS standard format and transaction statements (TS) in a secure, electronic, interoperable manner, and the TI must include the product identifier at the package level.
- **Interoperable Verification.** Trading partners must be able to verify the product identifier on a package or sealed homogenous case in a secure, electronic, interoperable manner.
- **Interoperable Tracing.** Trading partners must maintain secure, electronic, interoperable systems and processes to provide TI and TS in response to a request for it and to promptly facilitate gathering the information necessary to produce the TI for each transaction going back to the manufacturer.

Penalties for Non-compliance (21 USC §§ 333(b(1) & (3))

- Failure to comply with DSCSA requirements may be penalized by up to 10 years in prison, a fine up to $250,000, or both.
- Failure to report according to the DSCSA requirements may be penalized by a fine of up to $100,000.

Authorized Trading Partner Status

- Manufacturers and repackagers in the United States must have a current Drug Establishment registration with FDA to be “authorized” under the DSCSA.
- Wholesale distributors, 3PLs, and dispensers must have a current federal or state license to be considered “authorized” under the DSCSA.

Manufacturers

- Must use a secure, interoperable, and electronic system for the exchange of Transaction Information (TI) data, supply customers with TI for each transaction, provide the TI to a federal or state official upon request, and maintain TI for each transaction for at least six years.
- Affix or imprint on each package and homogenous case a product identifier (PI) that includes in a human-readable and machine-readable format the standardized numerical identifier, lot number, and expiration date of the product.
- Have in place systems and processes to enable verification, quarantine, and investigation of suspect and illegitimate product, and notify FDA and all immediate trading partners if a product is determined to be illegitimate.

Repackagers

- Must use a secure, interoperable, and electronic system for the exchange of TI data, only accept products with TI and PI, provide TI to its customers, provide the TI to a federal or state official upon request, and maintain TI for each transaction for at least six years.
- Have in place systems and processes to enable verification, quarantine, and investigation of suspect and illegitimate product, and notify FDA and all immediate trading partners if a product is determined to be illegitimate.

Wholesale Distributors/Third Party Logistics Providers (3PLs)

- Must use a secure, interoperable, and electronic system for the exchange of TI data, only accept products with TI and PI, provide TI to its customers, provide the TI to a federal or state official upon request, and maintain TI for each transaction for at least six years.
- Have in place systems and processes to enable verification, quarantine, and investigation of suspect and illegitimate product, and notify FDA and all immediate trading partners if a product is determined to be illegitimate.
- A wholesale distributor will be exempt from the TI requirements if it does not physically handle or store the product and the manufacturer, repackager, or other wholesale distributor provides the product and accompanying transaction information to the dispenser.

Dispensers

- Must use a secure, interoperable, and electronic system for the exchange of TI data, only accept products with TI and PI, provide the TI to a federal or state official upon request, and maintain TI for each transaction for at least six years.
- Have in place systems and processes to enable verification, quarantine, and investigation of suspect and illegitimate product, and notify FDA and all immediate trading partners if a product is determined to be illegitimate.

Additional Resources

- FDA Guidance Documents & Policies: https://www.fda.gov/drugs/drug-supply-chain-security-act-dscsa/drug-supply-chain-security-act-law-and-policies
- PDSA Q&A on DSCSA: https://pdsaonline.org/wp-content/uploads/2022/10/PDSA-DSCSA-2023-QA-Document.pdf
- GS1 US DSCSA Implementation Guideline: https://www.gs1us.org/content/dam/gs1us/documents/industries-insights/by-industry/healthcare/guideline-toolkit/Applying-the-GS1-Lightweight-Messaging-Standard-for-DSCSA-Verification-of-Product-Identifiers.pdf
- PDG Blueprint for 2023 Interoperability: https://dscsagovernance.org/blueprint/