RESOURCES

DSCSA 2023: 3 Key Requirements for Pharmacies and Health Systems



Key takeaways for DSCSA 2023 compliance

- Dispensers (pharmacies and health systems) will be responsible for meeting enhanced **FDA DSCSA** verification and traceability requirements by November 2023 through electronic, interoperable data exchange.
- Serialized Transaction Information (TI) that includes serial numbers, lot numbers and expiration dates will supplant the advance shipping notice (ASN) and will require purpose-built solutions that can support EPCIS event data at the individual unit level.
- Unlike other markets that have a centralized government track-and-trace system, meeting DSCSA traceability and verification requirements will depend on implementing a secure data exchange network to connect with both direct and indirect trading partners.

“DSCSA 2023” requirements add a new level of complexity for dispensers

The final phase of the 10-year rollout of the **Drug Supply Chain Security Act (DSCSA)** charges the pharmaceutical industry with the implementation of an “enhanced system” for the interoperable, electronic tracing of drugs by November 27, 2023. According to the FDA[(1)], the enhanced system will:

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- Enable secure tracing of products at the package level
- Use product identifiers to verify products at the package level
- Enable prompt response to suspect and illegitimate products
- Improve the efficiency of recalls

How will this be accomplished? The FDA is emphasizing interoperability as the key to achieving a safer, more secure drug supply. Over the course of the next 24 months, retail pharmacies and health systems need to assess, plan, design, and implement new processes for meeting 3 key **DSCSA 2023 compliance** interoperability requirements:

Interoperable Data Exchange

All-electronic, interoperable data exchange is the core of the FDA's Enhanced Drug Distribution Security (EDDS) initiative. Trading partners must be able to exchange required Transaction Information (TI) and Transaction Statements (TS) in a secure, electronic, interoperable manner. In addition, the TI requirements have been expanded to include the complete serialized product identifier at the package level, which includes the package serial number and product expiration date as well as the lot number and National Drug Code (NDC). As a result, the electronic TI supplants the advanced shipping notice (ASN) that is currently used as the "document" for providing transaction information and the Transaction History (TH)—required for traceability since 2015—will be eliminated. In effect, today's T3 will become a digital T2.

Interoperable Verification

Under DSCSA, all trading partners—including dispensers—must have the ability to verify a suspect or illegitimate product identifier upon request from a trading partner, federal agency, or state agency or to submit a request for verification from a trading partner. Because verification is required at the serialized package level, rather than at the lot level, health systems and pharmacies will need to implement highly scalable solutions that can capture and store large volumes of

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serialized product data as well as processes for matching, retrieving, and exchanging the product information being requested—and for issuing a notification to trading partners within the mandated 24-hour response time if the product is determined to be illegitimate.

Interoperable Tracing

Since 2015, health systems and pharmacies have been prohibited from accepting ownership of a product unless the previous owner can provide a complete T3: Transaction Information, Transaction Statement, and Transaction History. Beginning on November 27, 2023, that information will be only available electronically, and the Transaction History will be retired. In addition to having a solution in place to receive the product information electronically, dispensers will also be required to provide the Transaction Information and Transaction Statement—electronically—when transferring ownership of a product unless an exception applies. Dispensers are also required to capture and maintain all Transaction Information and Transaction Statements for not less than 6 years.

Achieving interoperability: Preparing for EPCIS data exchange

The key to industry-wide interoperability is finding a common language for exchanging product data. The **Electronic Product Code Information Services (EPCIS)** standard breaks down supply chain business processes into individual "events"—such as commissioning, packing, shipping, or receiving—and provides a standard format for communicating essential business information about each step to trading partners.

A global supply chain standard established by GS1, EPCIS has been recognized by the Healthcare Distribution Alliance (HDA) as the "only internationally recognized standard that will meet DSCSA requirements"[(2)] for interoperable, electronic tracing of pharmaceutical products at the package level. HDA recommends that their trading partners—which include health systems and retail pharmacies—begin to make capital and staffing investments in implementing an EPCIS-capable solution

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as early as possible, noting that the Covid-19 pandemic has placed a premium on solution providers with EPCIS expertise.

Getting up to speed on DSCSA? Download "DSCSA 2023 for Health Systems and Pharmacies: 50 Essential Terms"

Are you ready for “all-digital” DSCSA traceability requirements?

In June, 2021, The U.S. Food and Drug Administration (FDA) released 4 guidance documents that articulate the agency’s vision for “secure, electronic, interoperable unit-level tracing, verification, and reporting.” One month later, the Partnership for DSCSA Governance, and the industry consortium, released Chapter 1 of its *Foundational Blueprint for 2023 Interoperability*. Taken together, these documents are the “starting gun” in the race to DSCSA 2023. For dispensers, the complexity of item-level traceability requires early planning and budgeting to ensure a smooth transition and to minimize any disruption to pharmacy operations.

Contact us to learn how TraceLink can help you meet your DSCSA 2023 compliance requirements.

(1) "Enhanced Drug Distribution Security in 2023 Under the DSCSA", FDA, October 5, 2021

(2) “Getting Ready for EPCIS”, Healthcare Distribution Alliance, September 29, 2020

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Learn more about TraceLink's solutions for DSCSA 2023 compliance

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