

FDA Reiterates November 2023 Deadline for DSCSA-Compliant Systems with 12-Month Stabilization Period

tracelink[®]
NETWORK FOR GREATER GOOD

FDA guides industry not to slow or delay projects and use 12-month period to stabilize systems

What's happening?

On August 25, 2023, the U.S. Food and Drug Administration (FDA) released a [“Guidance for Industry”](#) document related to the Enhanced Drug Distribution Security (EDDS) provisions of the U.S. Drug Supply Chain Security Act (DSCSA) that goes into effect on November 27, 2023. The FDA has heard from stakeholders across the drug supply chain that trading partners need more time to stabilize systems that are regulated under the EDDS provisions.

To ensure that products continue to move smoothly through the supply chain, the FDA has announced a 12-month stabilization period that extends through November 27, 2024, to give trading partners the time they need to finalize the implementation of DSCSA-compliant processes and systems. The FDA's new guidance applies to all EDDS requirements for all trading partners, but the FDA reiterated that this is not a delay in the law and trading partners need to use this time to stabilize systems and processes.

Key Takeaways

- The FDA is urging trade partners to view the extra 12 months as a “stabilization period” to finish implementation, troubleshoot problems, and otherwise prepare their systems for accurate, secure, electronic data exchange.

- The FDA reiterates that this guidance should not be used as a justification for trade partners to postpone implementation efforts. The law has not been delayed and the FDA can still penalize companies that violate it.
- The FDA announcement eliminates any ambiguity related to the deadline. The 12-month stabilization period applies to all segments: pharmaceutical manufacturers, wholesale distributors, and dispensers.
- While the FDA has issued new guidance, one of the largest wholesale distributors has publicly stated that it expects all manufacturers to be sending EPCIS transactions by October 2023 so they can test EPCIS transactions with dispensers by April 2024.

What actions are needed?

Pharmaceutical Manufacturers

In a Healthcare Distribution Alliance (HDA) [letter](#) to the FDA, the organization justified the request for an extension based on the need to work through inventory that does not have item-level compliance data. Based on the updated guidance from the FDA and recommendations from the HDA, TraceLink recommends that manufacturers*:

- Put a plan in place immediately to achieve full compliance by March 31, 2024 at the latest. Many wholesalers expect manufacturers to be live much earlier than this, as they need to replenish their inventories with EDDS-compliant inventory.
- Continue to send electronic lot-level transactions during the transition period.
- Enable warehouse and distribution processes to capture and manage aggregation in preparation to ship.
- Deploy a VRS solution to support enhanced verification and address suspect and illegitimate products discovered in the supply chain.
- Accelerate DSCSA EPCIS data exchange with any dispensers they ship to directly, either through normal business channels or drop shipments. Support dispenser readiness activities as they await EPCIS data from wholesalers.
- Anticipate a high number of compliance exceptions and determine systems and processes for collaborating, troubleshooting, and resolving these exceptions.

Wholesale Distributors

Wholesale distributors have the most complex set of requirements as they are dependent on both suppliers and customers to achieve compliance. While the November 27, 2024 deadline puts wholesale distributors on a more rational path to compliance, it still requires immediate attention. Based on the updated guidance from the FDA and recommendations from the HDA, TraceLink recommends that wholesale distributors*:

- Put a plan in place immediately to begin exchanging EPCIS data with manufacturers by March 31, 2024 and with dispensers by May 27, 2024. Earlier is better.
- Continue to send lot-level compliance data to dispensers while testing the interoperable exchange of EPCIS data.
- Ensure warehouse processes are serialization-aware, including receiving, aggregation, de-aggregation, sampling, shipping, etc.
- Deploy a VRS solution to support enhanced verification for suspect and/or illegitimate product investigations and saleable returns.
- Anticipate a high number of compliance exceptions and determine systems and processes for collaborating, troubleshooting, and resolving these exceptions.

Dispensers

While the HDA noted that dispensers are dependent on both the manufacturers and wholesale distributors achieving compliance and that dispensers should be given a full two years to stabilize their systems, the FDA guidance stated that **all trading partners** should have projects in place for DSCSA-compliant systems by November 27, 2023—with a 12-month stabilization period until November 27, 2024. Based on the updated guidance from the FDA and recommendations from the HDA, TraceLink recommends that dispensers*:

- Communicate their supplier requirements and timelines to both wholesalers and manufacturers they receive shipments from.
- Determine whether they function as a wholesaler under the definitions of DSCSA. If they do, determine their approach for creating and exchanging DSCSA EPCIS documentation.
- Put a plan in place to start receiving DSCSA EPCIS transactions from manufacturers for direct shipments and drop shipments by May 27, 2024. Earlier is better so it does not disrupt trading partners' integration work.
- Deploy a VRS solution to support enhanced verification for suspect and/or illegitimate product investigations.
- Anticipate a high number of compliance exceptions and determine systems and processes for collaborating, troubleshooting, and resolving these exceptions.

HDA* Recommended Timeline Shortened to the FDA Stabilization Period

Now to 3/31/2024 (HDA Phase 1)**	4/1/2024 to 5/26/2024 (HDA Phase 1)**	5/27/2024 to 8/26/2024 (HDA Phase 2)**	4/1/2024 to 5/26/2024 (HDA Phase 3)**
<p>Manufacturers sending lot-level data and testing EPCIS event files with customers</p> <p>Wholesale distributors receive/send lot-level data and testing EPCIS event files with suppliers</p> <p>Dispensers continue/initiate compliance systems project</p>	<p>Manufacturers sending lot-level transactions and stabilizing EPCIS systems</p> <p>Wholesale distributors receiving EPCIS and lot-level data from suppliers and stabilizing systems</p> <p>Dispensers receiving lot-level data and completing systems to receive serialized data</p>	<p>Manufacturers live with all EDDS requirements and sending lot-level data</p> <p>Wholesale distributors live with all EDDS requirements with suppliers and testing EPCIS with dispensers</p> <p>Dispensers receiving lot-level data and stabilizing systems to receive serialized data</p>	<p>Manufacturers are fully compliant with capability to handle exceptions and verifications</p> <p>Wholesale distributors complete testing and onboarding dispensers</p> <p>Dispensers stabilize processes and systems to receive EPCIS data</p> <p><i>All trading partners go live on 11/27/2024</i></p>

**TraceLink has adjusted the original HDA phases to reflect the shorter FDA discretion period and industry input from large wholesale distributors, which need an accelerated timeline to accommodate the thousands of suppliers they must onboard.

How can TraceLink help?

Customers that are not already working with TraceLink on DSCSA compliance should immediately contact their account executive for advice on how to initiate an engagement to become compliant. For many customers, this can be done in a few days or weeks.

TraceLink customers should ensure their projects include:

- DSCSA EPCIS data exchange (Product Track)
- Verification for suspect product investigations (Product Information Manager - Verification)
- Exchanging GTIN-related master data (Product Information Manager - Master Data Sharing)
- Managing serialization and aggregation in the warehouse (Smart Inventory Tracker)
- Troubleshooting and resolving exceptions with trade partners (Serialized Product Intelligence and Supply Chain Work Management for Compliance Exceptions)

If you are not currently a customer, the turnkey TraceLink DSCSA Compliance solutions are the fastest and lowest-cost path to compliance. [Contact TraceLink](#) today to get started.