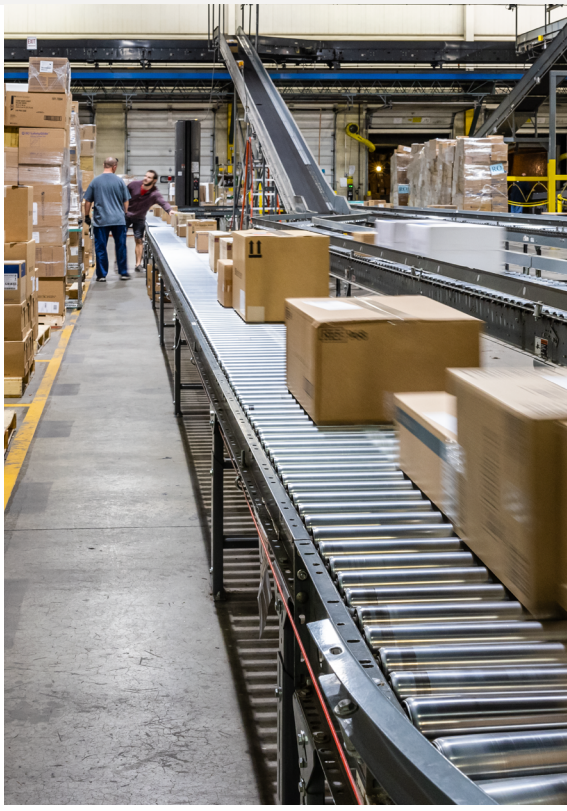
Achieving Full Traceability in the Pharmaceutical Supply Chain:

Mitigating Supply Chain Disruptions Through a Phased Approach to DSCSA Implementation

In 2013, Congress enacted the Drug Supply Chain Security Act (DSCSA), which mandated that all trading partners in the U.S. prescription drug supply chain meet the final requirements of the law no later than November 27, 2023. By that date, manufacturers, wholesale distributors and dispensers must begin interoperably and electronically exchanging data that identifies each prescription drug package purchased and sold. This data exchange will make it possible to trace prescription drugs in the supply chain at the individual package (or unit) level — a very complex capability that does not exist today. Currently, prescription drugs can only be traced at the lot level.

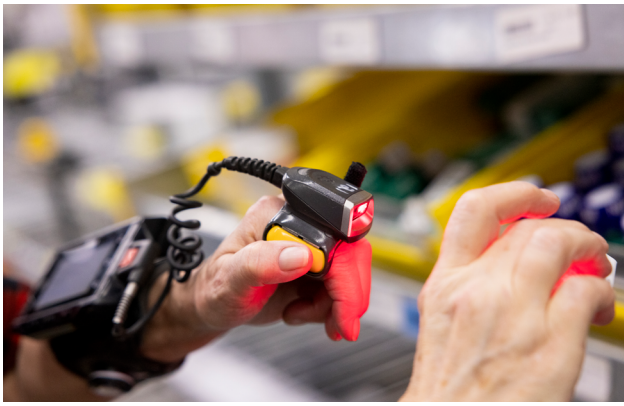


Meeting a Complex Requirement

The package-level data exchange requirement is interdependent among supply chain segments and becomes effective for all trading partners at the same time. Accordingly, the ability of wholesale distributors and dispensers to lawfully purchase and resell medicines depends on a manufacturer's provision of this package-level data in the first instance. Though these 2023 requirements have been known since 2013, given the complexities, many supply chain partners will not be ready by November 27 to send accurate, package-level data to their customers.

This uneven readiness creates serious risks to pharmaceutical supply and patient care. If manufacturers cannot interoperably exchange accurate package-level data, the DSCSA would prohibit wholesale distributors and dispensers from lawfully purchasing and reselling the prescription drugs needed for patient care. Ultimately, this situation could exacerbate existing drug shortages.

Three Phases Toward Full Implementation



HDA and its wholesale distributor members have long supported the DSCSA, collaborating with FDA and industry stakeholders to achieve the law's passage 10 years ago. Since then, HDA's pharmaceutical wholesale distributor members have invested years of work and millions of dollars to reach the DSCSA's final requirements.

However, given the state of supply chain readiness and the DSCSA's single compliance date for all trading partners, HDA recommends that FDA allow for the final requirements to be met in three phases to build capacity and stabilize these complex processes. This stepwise approach would include an FDA grant of enforcement discretion limited to certain DSCSA requirements and trading partners, with full implementation phased in over a two-year period. Trading partners would be able to continue current business practices to ensure medicines can make their way to patients safely and securely, while also continuing the push to package-level tracing and the enhanced supply chain security Congress envisioned.

1 NOVEMBER 27, 2023, TO NOVEMBER 26, 2024

- Manufacturers provide package-level data to wholesale distributors or obtain an exemption from FDA. Manufacturers will also continue the current practice of providing lot-level data with each prescription drug transaction to wholesale distributors.
- Wholesale distributors and dispensers maintain their current DSCSA business processes.

2 NOVEMBER 27, 2024, TO MAY 26, 2025

- Manufacturers must comply with all DSCSA requirements or obtain an exemption from FDA. Manufacturers also continue to provide lot-level data to customers to ensure prescription drugs continue to move in the supply chain to patients.
- Wholesale distributors begin providing package-level data to dispensers with each prescription drug transaction, while also continuing to provide lot-level data.
- Dispensers continue to maintain their current DSCSA business processes.

3 MAY 27, 2025, TO NOVEMBER 26, 2025

- Manufacturers and wholesale distributors must comply with all DSCSA requirements or obtain an exemption from FDA.
- Dispensers work on stabilizing their business processes for receipt of package-level data from wholesale distributors and manufacturers.

HDA's recommended phased approach permits an orderly implementation of the 2023 DSCSA requirements without jeopardizing patient safety or the supply of needed medicines. Full DSCSA implementation will be realized, and the tracing of prescription drug products at the package level will be achieved.

For more information about the distribution industry's approach to pharmaceutical traceability and DSCSA implementation visit: www.hda.org/pharmaceutical-traceability

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