Traceability: Transforming the Pharmaceutical Supply Chain

THE DRUG SUPPLY CHAIN SECURITY ACT

Leading the effort to make the supply chain safer and more efficient, in 2013 the Healthcare Distribution Alliance (HDA) helped secure a national framework to trace prescription medications, working with Congress and supply chain partners toward enactment of the Drug Supply Chain Security Act (DSCSA). The law preempted a 50-state patchwork of pedigree requirements with one federal traceability solution for prescription medicines.

This groundbreaking law:

- **Implemented traceability requirements, increasing the efficiency and safety of the supply chain.** By 2023, the law calls for unit-level electronic traceability requirements to be phased in across the entire supply chain. A key milestone was achieved early in the DSCSA’s 10-year implementation, when manufacturers, repackagers, wholesale distributors and dispensers began providing, receiving and maintaining product tracing information about a drug each time it is sold in the U.S. market. After accomplishing several additional milestones, on November 27, 2018, all products packaged by manufacturers and repackagers must have a unique, serialized product identifier.

- **Strengthened distributor licensure standards across the United States.** Through the DSCSA, the FDA must issue new federal licensure standards. Once finalized, states have two years to adopt these standards. This approach is intended to create greater uniformity across states and enhance federal authority, while enabling states to maintain their authority to issue licenses and partner with FDA in enforcement efforts.

- **Established new processes for identifying suspect and illegitimate products in the supply chain.** Manufacturers, repackagers, wholesale distributors and dispensers must have systems and processes in place to identify, quarantine and investigate suspect and illegitimate products in the supply chain. The DSCSA also enhances the processes for manufacturers, distributors and others to notify the FDA and trading partners of the existence of dangerous products in the supply chain.

- **Strengthened the pharmaceutical supply chain in other important ways.** The DSCSA requires that all trading partners be authorized and hold valid licenses or registrations. Manufacturers, wholesaler drug distributors, repackagers and many dispensers (primarily pharmacies) must have systems and processes to be able to comply with verification requirements and be able to verify product identifiers in certain circumstances once products are serialized.

The DSCSA implementation process has been one of the most collaborative efforts that pharmaceutical supply chain stakeholders and federal and state regulators have undertaken. Since enactment, supply chain trading partners have been meeting and working toward various milestones on the road to full implementation, including serialization of individual product units, verification of returns and specifications for transacting only in products bearing a unique identifier.

By 2023, the supply chain will be equipped with enhanced drug distribution security measures, systems and processes to be able to promptly respond to appropriate federal or state officials, as well as improved recall procedures and clearer methods to address suspect or illegitimate products, among other capabilities.

BRINGING THE INDUSTRY TOGETHER

Leveraging the deep knowledge and expertise HDA members bring to the pharmaceutical supply chain, HDA has helped form productive partnerships with industry stakeholder groups, customers, state legislators and regulatory agencies — including the FDA and state Boards of Pharmacy — and has served as an industry to address critical technology and DSCSA compliance questions.
Throughout implementation, HDA has fostered knowledge and collaboration through educational programs, webinars, seminars and product offerings, as well as a toolkit of supply chain materials touching on a range of topics, including:

- Updated voluntary industry-wide guidelines for bar coding products under the DSCSA;
- Revised Advance Ship Notice (ASN) EDI guidelines and new ASN exceptions guidelines;
- A series of typical transaction scenarios with related DSCSA data exchange applications;
- An updated “Standard Pharmaceutical Product Information Form” that includes DSCSA-related elements;
- A pilot study exploring methods for saleable returns verification; and,
- A list of answers to frequently asked questions about how the DSCSA applies to wholesale distributors, including the requirements that are applicable when interacting with their trading partners.

SOLVING IMPLEMENTATION CHALLENGES THROUGH TECHNOLOGY

Having successfully navigated past DSCSA implementation milestones, HDA continues its work coordinating with members and other stakeholders to help the industry effectively and efficiently implement the law’s requirements. To meet a critical 2019 deadline for distributor verification of returns, HDA convened industry stakeholders to facilitate discussions of how those companies can develop a Verification Router Service as one means for trading partners to verify serialized product identifiers. Meanwhile, in July 2017 the Alliance launched Origin: HDA’s Product Data Source, a centralized repository service that provides one way for subscribers to securely access and use accurate master data.

For more information on the Drug Supply Chain Security Act, visit HDA’s Traceability Resource Page at HDA.org/Issues/Pharmaceutical-Traceability.