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 through the 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:

- **Clarified and consolidated supply chain regulations, increasing the efficiency and safety of the supply chain.** Beginning in January 2015, manufacturers and distributors were required to adhere to enhanced product tracing requirements, with pharmaceutical dispensers following later that year. Over the next 10 years, a single system of federal electronic, unit-level traceability requirements will be phased in to apply to the entire supply chain.
- **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 suspicious and illegitimate products in the supply chain.** As required by the law, in June 2014, FDA released draft guidance to help supply chain trading partners more readily identify, quarantine and investigate suspect and illegitimate products. It also seeks to enhance the process for manufacturers, distributors and others to notify the agency of the existence of potentially dangerous products in the supply chain.

BRINGING THE INDUSTRY TOGETHER

The DSCSA implementation process has been one of the most collaborative efforts that pharmaceutical supply chain stakeholders and federal and state regulators have undertaken in recent history. 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 and regulatory agencies — including the FDA and state Boards of Pharmacy — and has served as a forum for members and other professionals to address critical technology and compliance questions.

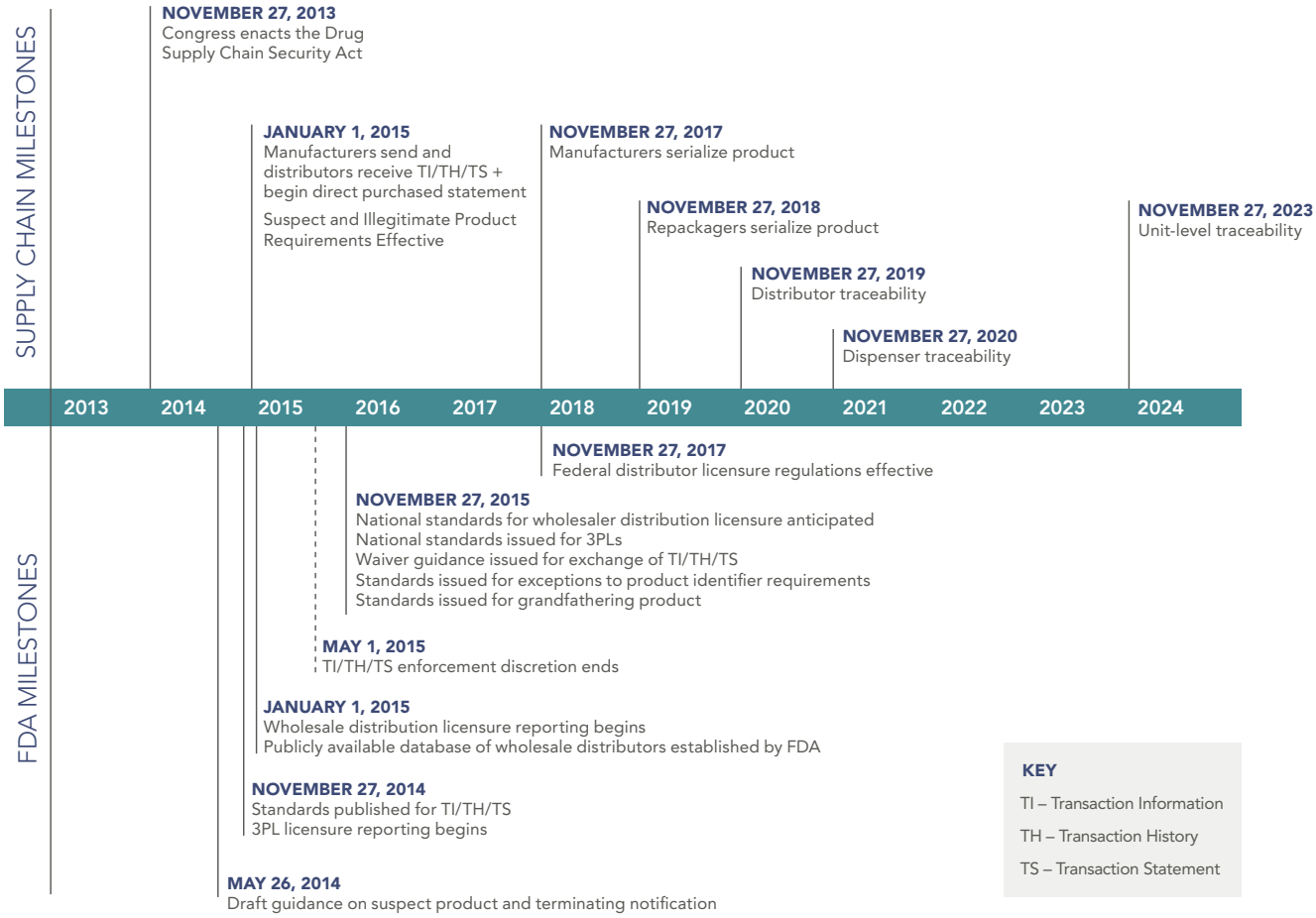
Throughout implementation, HDA has fostered knowledge and collaboration through educational programs, webinars, seminars, and product offerings, as well as a toolkit of supply chain materials touching on a range of topics, including:

- Updated Advance Ship Notice (ASN) EDI guidelines and new ASN exceptions guidelines;
- A series of typical transaction scenarios with related DSCSA data exchange applications;

- A bar code "quick start" guide updated in 2016;
- An updated "Standard Pharmaceutical Product Information" form that includes DSCSA-related elements; and,
- A list of answers to frequently asked questions about how the DSCSA applies to wholesale distribution operations and other law requirements.

Having successfully met past DSCSA implementation milestones, HDA is now coordinating with members and others to conduct pilot studies to understand the technologies and processes required to effectively and efficiently implement future DSCSA requirements. Specifically, to meet a 2019 deadline, HDA worked with EY (formerly Ernst & Young) to complete a pilot study for distributors and manufacturers to examine different methods of verifying product identifiers.

FEDERAL IMPLEMENTATION TIMELINE



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