Counterfeit and adulterated prescription drugs in the supply distribution chain pose a significant risk to patient safety. On November 27, 2013, President Obama enacted the Drug Supply Chain Security Act (DSCSA), which amends the Prescription Drug Marketing Act of 1987. The amended Act creates a uniform, national standard for tracing prescription drug products throughout the supply distribution chain with critical staged requirements going into effect soon that will challenge conventional technologies and logistics capabilities.

Specifically, the DSCSA requires by November 27, 2023—10 years after enactment—the establishment of an interoperable, electronic system that traces serialized prescription drug products at the individual unit level throughout all stages of the supply distribution chain. According to the FDA, the product identifier required under this system will permit verification of a product’s legitimacy down to the individual package level; facilitate detection and notification of illegitimate products in the drug supply chain; and enable more efficient recalls of drug products in order to protect consumers.

Express Preemption of State Law

To effectuate this uniform, national standard, the DSCSA expressly preempts any state laws as of November 27, 2013, that establish tracking or tracing requirements, including paper or electronic pedigree systems, to the extent they “are inconsistent with, more stringent than, or in addition to, any requirements applicable” under the DSCSA.

Key Provisions of the DSCSA

The DSCSA establishes specific deadlines for trading partners requirements throughout the ten-year implementation period. (The term “trading partner” includes four entities that accept or transfer direct
ownership of a product—manufacturers, wholesale distributors, dispensers, and repackagers. The requirements under the DSCSA vary by trading partner. If an entity qualifies as more than one category of trading partner, it must comply with all applicable requirements, but need not duplicate requirements.)

A brief summary of key provisions of the DSCSA is included:

Product identification and tracing

- Drug manufacturers and repackagers must put a unique product identifier, such as a bar code, on individual prescription drug packages.

- Manufacturers, wholesaler prescription drug distributors, packagers and certain dispensaries (e.g., pharmacies) in the prescription drug supply chain must provide detailed information about a drug, including who handled it, each time the drug is sold within the United States.

Product verification, detection, and response

- Manufacturers, wholesaler prescription drug distributors, packagers and certain dispensaries (e.g., pharmacies) must establish systems and processes in order to verify product identifiers on the drugs, as well as systems and processes to quarantine, and investigate a drug that has been identified as potentially counterfeit, unapproved, or dangerous. An important aspect of these systems and processes is the ability to notify FDA and others if an illegitimate drug is found within the supply chain.

Product Identifiers

The DSCSA defines “product identifier” as “a standardized graphic that includes, in both human-readable form and on a machine-readable data carrier that conforms to the standards developed by a widely recognized international standards development organization, the standardized numerical identifier, lot number, and expiration date of the product.”

The Act further provides that unless otherwise allowed by the FDA through guidance, the applicable data of a product identifier must be included “in a 2-dimensional data matrix barcode when affixed to, or imprinted upon, a package” and “in a linear or 2-dimensional data matrix barcode when affixed to, or imprinted upon, a homogeneous case.” Additionally, either human or machine readable methods may be used to verify the product identifier.

The FDA has yet to issue guidance on the technology and software to conduct tracking at the package level. However, the FDA is required under the Act to issue a relevant guidance on system attributes necessary to enable secure tracing at the package level, and the current estimated target date to do so is November 27, 2022.³

Download: Labeling and Pedigree Requirements of the Drug Supply Chain Security Act
1. The DSCSA is one of two distinct parts of the Drug Quality and Security Act. The other distinct part is the Compounding Quality Act (CQA)

2. U.S. Food and Drug Administration, *Drug Supply Chain Security Act*

3. Food and Drug Administration, *Drug Supply Chain Security Act (DSCSA) Implementation Plan*