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Labeling and Pedigree Requirements of the Drug Supply Chain Security Act

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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.[1] 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.[2]

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.

[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*

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]

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

Guidance Issued by the FDA

To date the FDA has issued the following guidance. (Note, FDA guidance is not binding or exhaustive, but offers the FDA's current thinking on a given topic.)

- *Requirements for Transactions with First Responders Under Section 582 of the Federal Food, Drug, and Cosmetic Act—Compliance Policy Guidance for Industry*, published February 29, 2016, Guidance.
- *DSCSA Implementation: Product Tracing Requirements for Dispensers – Compliance Policy Guidance for Industry (Revised)*, published October 28, 2015, Final Guidance.
- *DSCSA Implementation: Product Tracing Requirements – Compliance Policy Guidance for Industry*, published December 31, 2014, Guidance.
- *Drug Supply Chain Security Act Implementation – Annual Reporting by Prescription Drug Wholesale Distributors and Third-Party Logistics Providers*, published December 9, 2014, Draft Guidance.
- *DSCSA Standards for the Interoperable Exchange of Information for Tracing of Certain Human, Finished, Prescription Drugs: How to Exchange Product Tracing Information*, published November 28, 2014, Draft Guidance.
- *The Effect of Section 585 of the FD&C Act on Drug Product Tracing and Wholesale Drug Distributor and Third-Party Logistics Provider Licensing Standards and Requirements: Questions and Answers*, published October 8, 2014, Draft Guidance.
- *Drug Supply Chain Security Act Implementation: Identification of Suspect Product and Notification*, published June 11, 2014, Draft Guidance.

Under the Act, the FDA is also required to hold public meetings to address, among other things "the systems and processes needed to utilize the product identifiers to enhance tracing of product at the package level, including allowing for verification, aggregation, and inference, as necessary" and "[t]he technical capabilities and legal authorities, if any, needed to establish an interoperable, electronic system that provides for tracing of product at the package level." Finally, the FDA is also required to establish at least one pilot project.

Take Away

The Drug Supply Chain Security Act of 2013 establishes specific requirements to create and implement a national electronic, interoperable system by November 27, 2023. This system will eventually enable tracking certain prescription drugs to the individual package throughout the supply distribution chain. This system will also enable the detection and removal of dangerous drugs—such as counterfeit or contaminated drugs—from the distribution chain, in order to promote the ultimate goal of protecting consumers.

Upcoming Deadlines

July 1, 2015

- Dispensers must establish systems for verifications and handling of suspect or illegitimate product, which includes protocols to quarantine and investigate suspect product to determine if it is illegitimate. The trading partners may satisfy this requirement by utilizing a secure electronic data base developed or operated by another entity.

- Dispensers must provide subsequent owner with transaction history, information, and statement for each product. However, this requirement does not apply when dispensing a product to a patient or to returns.
- Upon an appropriate request—such as a recall or investigating a suspect of illegitimate product—a dispenser must supply the transaction information, history, and statement for a product within 48 hours of the request.
- Dispenser may enter into a written agreement with a third party (including an authorized wholesale distributor) under which a third party confidentially maintains transaction information, etc.

July 1, 2015 (compliance extended to March 1, 2016)

- Dispensers shall not accept ownership of a product unless the previous owner provides the transaction history, transaction information, and transaction statement.
- Dispensers must capture transaction information including lot level information if provided, transaction history and statements, and maintain such information for six years after transaction date.

November 27, 2015

- The FDA must establish a process by which an authorized trading partner may request a waiver, exception, or exemption. Such exemptions include grandfathering certain products already in the supply distribution chain.

November 27, 2017

- Manufacturers must affix or imprint a unique product identifier to each package and homogenous case of a product to be introduced in a transaction to commerce. An exception to this requirement is where a product is required to have a standardized numerical identifier.
- Manufacturers must maintain product identifier information for six years after transaction date.
- Manufacturers must provide transaction information, history, and statement in electronic format.
- Manufacturers must respond to trading partner's request for product identifier information within 24 hours and notify if the product corresponds to a product identifier affixed or imprinted by the manufacturer.
- Manufacturer must verify the product identifier of any returned product that it intends to further distribute.

November 27, 2018

- Repackagers must affix or imprint a product identifier to each package and homogenous case of product intended to be introduced in a transaction in commerce.
- Repackagers may engage in a transaction only if a product is encoded with a product identifier (unless product is exempt).
- Repackagers must maintain product identifier information for each product for six years from transaction date; and shall maintain records for six years to allow repackagers to associate its own product identifier with product identifier assigned by original manufacturer of the product.
- Repackagers must respond to a trading partner's request for product identifier information within 24 hours and notify if the product corresponds to a product identifier affixed or imprinted by the repackager.

November 27, 2019

- Wholesaler distributors must engage only in transactions in which each product has a product identifier unless the product is otherwise exempt.
- Wholesaler distributors must verify the product identifier of any returned product that the wholesale distributor intends to further distribute.
- Wholesale distributors may disclose the transaction information, including lot level information, transaction history, or transaction statement of a product to the subsequent purchaser of the product, pursuant to a written agreement between such wholesale distributor and such subsequent purchaser.
- Wholesale distributors must respond to a trading partner's request for product identifier information within 24 hours and notify if the product corresponds to a product identifier affixed or imprinted by the manufacturer.

November 27, 2020

- Dispensers must engage only in transactions in which each product has a product identifier (unless product is exempt)

November 27, 2023 (Ten years after enactment of the DSCSA)

- The FDA must establish and implement a national, interoperable, electronic tracing of product at the package level, permitting exchange of transaction information and transaction statements in a secure, interoperable, electronic manner.

If you have any questions about the content of this alert, please contact the Pillsbury attorney with whom you regularly work, or the authors below.

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