THE DRUG SUPPLY CHAIN SECURITY ACT (DSCSA)
CHANGES BECOME EFFECTIVE NOVEMBER 27, 2023

For those DTA members manufacturing and distributing prescription drugs or involved in that supply chain, a reminder that the DSCSA will take full effect on November 27, 2023. Passed by Congress in 2013, and rolled out in stages thereafter, the DSCSA requires all trading partners in the drug supply chain to ensure that prescription drugs are identified, serialized, and traceable through every stage of manufacture and distribution. The goal of the DSCSA is to create a serialized pharmaceutical supply chain where every drug and drug ingredient can be traced from start-to-end, to keep harmful or counterfeit drugs from being introduced into the drug supply chain, and to allow for easy initiations of recalls or agency investigations.

Who must comply with DSCSA? The law is broadly written to capture within its scope the entire prescription drug supply chain, as it includes all FDA-approved drugs intended for human use and which require a prescription from a practitioner licensed to administer such drugs. Whether you are a manufacturer, wholesaler, repackager, distributor, dispenser or other stakeholder that encounters prescription drugs, then you must comply.

Why is November 27, 2023, an important deadline? While companies involved in the prescription drug supply chain have had ten years to meet the requirements of the DSCSA, November 27, 2023, marks the date when the FDA will require full compliance, to be enforced by civil penalties and fines. Companies will not be able to operate within the drug supply chain unless they meet the following requirements:

1. You must participate in a secure, interoperable electronic exchange. This means that each party in a drug supply chain transaction must be able to exchange and verify at the unit package level the product identifier information. In other words, one company states it is shipping X units, and one company verifies receiving X units, allowing for tracking from beginning to end of the drug supply chain.
2. The ability to trace in this secure electronic exchange will be pegged to the serialization of product identifiers ("PI") assigned at the package or unit level for each package or unit in the transaction. The PI includes several data elements, including the National Drug Code, lot number, expiration date and serial number.
3. The exchange of transaction information and transaction statements in the interoperable electronic exchange must include the ability to trace back upstream in the supply chain in the event of an FDA or governmental recall or investigation.

Where can I learn more about the DSCA requirements and exemptions? The FDA website provides more information and resources to help members with their unique requirements.

DTA members with questions about implementing sufficient systems to address the DSCSA and its upcoming deadline should consider the assistance of a pharmaceutical industry consultant. The following names are ones researched and identified by the DTA and believed to be able to provide off-the-shelf and/or specialized DSCSA packages. They are provided in no particular order, and DTA is not recommending or endorsing any of them; this list is provided as member assistance.

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