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Alerts

Pharmacies and Prescription Drug Dispensers...Are You Ready for The March 1, 2016 DSCSA Compliance Deadline?

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Health Law Alert

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In order to improve drug security throughout the supply chain, and to facilitate drug recalls and to address drug importation, diversion, and counterfeiting, Congress passed the Drug Supply Chain Security Act (the "DSCSA"). The DSCSA created a national database that allows consumers and regulators to trace each drug ("Product") from the manufacturer down to the prescription drug dispenser. The serialization and traceability requirements of the DSCSA will be phased in over the next ten years; however the Product Tracing, Authorized Trading Partner, and Product Verification requirements are effective March 1, 2016 for all pharmacy manufacturers, wholesale drug distributors, repackagers and pharmacy dispensers. Pharmacy dispensers include hospital pharmacies, retail pharmacies, long-term care pharmacies, and other parties authorized to dispense prescription drugs. Failure to comply with a DSCSA requirement is a "prohibited act" under the Food, Drug, and Cosmetic Act, which may subject a party to: injunction and prohibition of unlawful activity; seizure of goods; and/or civil and criminal fines and penalties (including jail).

Product Tracing

All pharmacy manufacturers, wholesaler drug distributors, repackagers, and dispensers in the drug supply chain must receive and store the following data (and ensure that such data is accessible for at least six (6) years): the Transaction History (TH), Transaction Information (TI), and Transaction Statement (TS) for all drugs received and/or transferred on and after March 1, 2016. Dispensers do not need to provide TH, TI, and TS when dispensing to a patient, returning a product, or selling or transferring a product to a dispenser to fulfill a specific patient need. In all other situations, Dispensers must provide subsequent owners of the drug with TH, TI and TS prior to or at the time of the transaction; and must provide such information to governmental regulators within two days after a request.

*Transaction History (TH):*is a paper or electronic statement that includes the transaction information for each prior transaction of the product back to the manufacturer.

*Transaction Information (TI):*isa paper or electronic statement that includes: (i) Product name; (ii) Product strength and dosage form; (iii) Product National Drug Code; (iv) container size; (v) number of containers; (vi) Product lot number; (vii)

Transaction date; (viii) shipment date; and (ix) name and address of the subsequent owner.

*Transaction Statement (TS):*is a paper or electronic attestation transferring ownership of the product. The statement must attest that the entity transferring ownership in a transaction: (i) is authorized as required under DSCSA; (ii) received the product from a person that is authorized as required under DSCSA; (iii) received transaction information and a transaction statement from the prior owner of the product, as required under the law; (iv) did not knowingly ship a suspect or illegitimate product; (v) had systems and processes in place to comply with verification requirements under the law; (vi) did not knowingly provide false transaction information; and (vii) did not knowingly alter the transaction history.

Product Tracing Compliance Steps for Pharmacies and Other Drug Dispensers: It is essential that all pharmacies review, update, and implement policies and procedures for drug procurement, receiving, and distribution to outside parties. All pharmacies must develop and implement a process to: (i) only accept prescription drugs from an Authorized Trading Partner that provides TH, TI, and TS for each Transaction.; (ii) always provide TH, TI, and TS when the pharmacy sells or loans a product to the subsequent owner; (iii) archive and retrieve TH, TI, and TS upon request; (iv) obtain written agreements with third parties; (v) comply with governmental agency requests for information and investigations; and (vi) train employees on the new requirements and document training dates and activities

Product Verification

As of March 1, 2016, pharmaceutical manufacturers, wholesaler drug distributors, repackagers, and pharmacies must have systems and protocols in place to verify the TH, TI, and TS data received against the Product that was shipped to them; and must have implemented a process to determine whether or not prescription drug products are "suspect" or "illegitimate." Dispensers must have a process to request Product verification from trading partners, and must be able to respond to verification inquiries.

Product Verification Compliance Steps for Pharmacies and Other Drug Dispensers: Pharmacies need to establish systems and processes to be able to comply with the verification requirements, and must develop written policies and procedures to identify suspect and illegitimate products. The policies and procedures should address how the drug dispenser will: (i) identify suspect product currently in inventory and among new products; (ii) quarantine suspect product from regular inventory; (iii) inform trading partners about suspect Product; (iv) conduct an investigation to determine whether or not a suspect product is illegitimate; (v) remove illegitimate products[4] from the supply chain; and (vi) notify the FDA and all trading partners within 24 hours after determining that a product is illegitimate.

Authorized Trading Partners

The DSCSA requires each supply chain participant to only obtain Products from and sell Products to "Authorized Trading Partners." Authorized Trading Partners are Manufacturers, Repackagers, Wholesale Distributors, Third Party Logistics Providers, and Dispensers. A Manufacturer is considered "authorized" if it is registered with the FDA. A Wholesale Distributor is considered "authorized" if it has a valid state license or a federal license if the state does not issue licenses. A Third Party Logistics Provider is considered "authorized" if it has a valid state license or a federal license if the state does not issue licenses. A Dispenser is considered "authorized" if it has a valid state license.

Compliance with the Authorized Trading Partner requirement will involve employee training and education, and implementation of a process to verify and document that each trading partner is authorized. Pharmacies will need to verify that every drug supplier they use is an Authorized Trading Partner and should maintain documentation of such status by obtaining and maintaining copies of licenses/registrations, conducting verifications by checking public databases, and using contractual representations and warranties in agreements.

Authorized Trading Partner Compliance Steps for Pharmacies and Other Drug Dispensers: Pharmacies should (1) compile a list of all of the pharmacy's drug suppliers; (2) verify that all of the pharmacy's trading partners have a valid state or federal license, or have FDA registration; (3) obtain and maintain copies of current licensing/registration for each supplier; (4) develop and implement policies and procedures to verify all new trading partners and regularly audit trading partners to make sure that they maintain authorization.

How We Can Help

Hinshaw & Culbertson LLP attorneys have reviewed and analyzed the DSCSA and have significant experience working with pharmacy manufacturers, wholesale distributors, repackagers, hospital pharmacies, retail pharmacies, long-term care pharmacies, and other dispensers on regulatory compliance matters. If you have questions or need assistance in determining how to make the requisite changes to your policies, procedures, and practices in order to come into compliance with the DSCSA, please call Michael A. Dowell, Noah A. Jussim, or your regular Hinshaw attorney.

This alert has been prepared by Hinshaw & Culbertson LLP to provide information on recent legal developments of interest to our readers. It is not intended to provide legal advice for a specific situation or to create an attorney-client relationship.

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[1] "Product" is defined as prescription drugs in finished dosage form that are for human use. The following drugs are exempted from the definition of "Product:" Blood and blood components intended for transfusion; radioactive drugs and radioactive biologics; Imaging drugs; Intravenous products; Medical gases; Homeopathic drugs; and Compounded drugs.

[2] "Transaction" is defined as "the transfer of Product between persons in whom a change of ownership occurs. Certain transfers are exempt from the definition of transaction including: Dispensing prescription drugs to patients; Intra-company distribution between affiliates; Distribution among hospitals or other health care organizations under common control; Distribution for emergency medical reasons; Distribution of minimal quantities by a licensed retail pharmacy to a licensed practitioner for office use; and Distribution of a Product pursuant to a sale or merger.

[3] Suspect Product means reason to believe that the product is potentially counterfeit, diverted, stolen; the subject of fraudulent transaction; or intentionally adulterated or appears otherwise unfit for distribution such that would result in serious adverse health consequences or death to humans.

[4] Illegitimate Product means credible evidence that the product is potentially counterfeit, diverted, stolen; the subject of fraudulent transaction; or intentionally adulterated or appears otherwise unfit for distribution such that would result in serious adverse health consequences or death to humans.