

DRUG & PHARMACY ALERT

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FDA Delays Enforcement of Product Tracing Rules for Pharmacies

In a last minute reprieve, the FDA published a Compliance Policy Guidance on June 30, 2015, that delays enforcement of the product tracing requirements applicable to dispensers until **November 1, 2015**. The requirements were originally slated to go into effect on July 1, 2015. Pursuant to the Drug Supply Chain Security Act (DSCSA), most pharmacies in the U.S. were required to have compliance mechanisms in place by July 1 to receive Transaction History, Transaction Statement, and Transaction Information (collectively known as “3T information”) regarding the prescription drugs they purchase from suppliers.

The Compliance Policy appears to concede that many dispensers have been unable to put in place electronic systems and procedures sufficient to capture and maintain all of the required 3T information by the original July 1 deadline. In practice, this means that the FDA does not intend, prior to November 1, 2015, to take action against dispensers that:

- Accept ownership of a covered drug product without receiving the 3T information; or
- Do not capture and maintain the 3T information provided by the dispenser’s trading partner.

The delay in enforcement of the 3T product tracing requirements, however, does not affect other aspects of the DSCSA. For example, the Compliance Policy does not affect the requirement that manufacturers, wholesale distributors, and other “trading partners” covered under the law supply product tracing information to pharmacies and other dispensers. Further, the enforcement delay does not relieve dispensers of the requirement of confirming that all trading partners are authorized, or relieve dispensers of the requirement to provide subsequent owners with 3T information.

The enforcement delay put in place by the Compliance Policy gives pharmacies and other dispensers an additional 4 months of breathing room to put in place proper mechanisms and systems to comply with the 3T requirements. Pharmacies should use the latitude granted by the FDA’s enforcement delay to continue to work toward compliance with the DSCSA’s new product tracing requirements.

For further information or assistance in putting in place a compliance program designed to meet the requirements of the DSCSA, please contact any of the following lawyers at Roetzel & Andress:

Brian E. Dickerson
Practice Group Manager
White Collar Litigation & Corporate
Compliance
202.570.0248 | bdickerson@ralaw.com

Anthony J. Calamunci
419.254.5247 | acalamunci@ralaw.com

Nicole Hughes Waid
202.906.9572 | nwaid@ralaw.com