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FDA DELAYS ENFORCEMENT OF DISPENSERS' DRUG PRODUCT TRACING OBLIGATIONS UNTIL NOVEMBER 1, 2015

EXECUTIVE SUMMARY

On June 30, 2015, the Food and Drug Administration ("FDA") issued draft guidance delaying the enforcement of key track and trace requirements of the Drug Supply Chain Security Act ("DSCSA") for Dispensers[1] until November 1, 2015 ("Guidance"). Specifically, the FDA indicated that it does not intend to take action against Dispensers that accept ownership of Product (defined below) without receiving the product tracing information. It is important to note that this enforcement delay does not affect obligations of manufacturers, distributors and repackagers to provide product tracing information to dispensers. As such, this enforcement delay only minimally affects the ability to trace drugs, if necessary.

A copy of the Guidance is available here. Originally, enforcement of these requirements was to begin on July 1, 2015. In delaying the enforcement of these requirements for Dispensers, the FDA cited industry concerns regarding Dispensers' ability to electronically exchange, capture and maintain product tracing information. In part, this delay may have been the result of concerns raised by Dispensers that partner with distributors that do not have centralized electronic data repositories and by 340B Drug Discount Program participating covered entities and their partner contract pharmacies.

BACKGROUND AND DISPENSER REQUIREMENTS

The DSCSA was signed into law on November 1, 2013 and introduced a federal program designed to enhance the security of certain prescription drugs ("Product"). Generally, the DSCSA requires that entities involved in the supply chain distribution channel of Product exchange certain Product information with each other unless an exception applies. By restricting the distribution chain to such authorized trading partners and requiring trading partners to exchange certain information with each other, the DSCSA seeks to accomplish its goal of making the Product distribution chain safer.

The track and trace provisions of the DSCSA only apply to instances in which a transaction occurs. While the DSCSA broadly defines "transaction" as a transfer of Product between persons when a change of ownership occurs, it also sets forth 18 exemptions to this definition. Some of the most relevant exceptions for Dispensers include the following:

1. The intracompany distribution of any Product between members of an affiliate (as defined by the DSCSA) or within a manufacturer;
2. The distribution of a Product among hospitals or other health care entities that are under common control;
3. The dispensing of a Product pursuant to a prescription; and
4. The distribution of minimal quantities of a Product by a licensed retail pharmacy to a licensed practitioner for office use.

Beginning on November 1, 2015, a Dispenser may not accept ownership of Product unless the previous trading partner supplied the Dispenser with the transaction history, transaction information and transaction statement (collectively, "Transaction Documents") for such Product. Further, Dispensers will be responsible for communicating these Transaction Documents, including lot level information if provided, to any subsequent trading partner of the Product unless an exception applies. The FDA's stated hope is that this additional time will allow Dispensers and their authorized trading partners to better design electronic systems to capture and maintain the Transaction Documents.

PRACTICAL TAKEAWAY

While the Guidance ensures that Dispensers will not be subject to enforcement action by the FDA until November 1, 2015, Dispensers should continue their efforts to develop processes to ensure compliance with the DSCSA including, but not limited to, the DSCSA's track and trace requirements. As part of this process, Dispensers and their trading partners should consider analyzing the types of Product transfer activities in which they are involved to determine if such activity is subject to the track and trace requirements. For example, 340B Program contract pharmacy replenishment arrangements will require additional attention to ensure compliance with DSCSA requirements.

Please note that the Guidance does not extend the requirements for Dispensers to only engage in transactions of Product with "authorized trading partners" nor does it change a Dispenser's responsibility related to the verification of suspect and illegitimate Product.

If you have any questions or would like additional information about this topic, please contact:

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[1] Under the DSCSA, a Dispenser includes a pharmacy that does not act as a wholesale distributor or any other person authorized by law to dispense or administer prescription drugs (subject to certain exceptions).