

FDA announces extended enforcement discretion for dispensers; DSCSA still in effect

On October 29, 2015, the U.S. Food and Drug Administration (FDA) issued a guidance announcing that it is extending the previously issued Enforcement Discretion Policy **from November 1, 2015 to March 1, 2016** because dispensers have expressed that they need additional time. **The FDA has announced that it does not intend to take action against dispensers, who, prior to March 1, 2016 either accept ownership of product without receiving the transaction data or do not capture and maintain the transaction data.**

As a reminder, on June 30, 2015, the FDA issued guidance regarding the product tracing requirements under the Drug Supply Chain Security Act (DSCSA) that affect all dispensers of prescription drugs. Under the DSCSA, dispensers of prescription drugs may only accept ownership of DSCSA-eligible products if the prior owner provides transaction information, transaction history and a transaction statement, collectively referred to as transaction data, beginning July 1.

Requirements effective July 1

The FDA's enforcement discretion is limited and does not extend to other DSCSA requirements. As of July 1, 2015, dispensers must still

- Have processes in place to verify suspect and illegitimate product
- Transact only with authorized or licensed trading partners
- Provide subsequent owners with transaction data including transaction history when further distributing product. If dispensers sell or loan product to other non-affiliated dispensers, this enforcement discretion does not apply to those transactions.

In addition, this enforcement discretion does not extend to manufacturers, wholesale distributors and repackagers who must still provide product tracing information to dispensers.

Cardinal Health transaction data is available online

Cardinal Health has been providing transaction data since January 1, 2015 through Order Express and Specialty Online. Customers who do not use these systems may go to cardinalhealth.com/trace and click on the "Access Transaction Data" link and follow instructions to request access to the reporting system. Customers may also visit the "Customers" section of the site to view a [user guide](#) and [video](#) that explain how to access and read transaction data.

Cardinal Health will also maintain transaction data electronically for six years at no cost to customers.

For more information about the DSCSA please visit cardinalhealth.com/trace or submit any questions to drugtracing@cardinalhealth.com.