
THE DRUG QUALITY AND SECURITY ACT: WHOLESALE DISTRIBUTORS

Starting January 1, 2015, wholesale distributors must receive from the pharmaceutical drug manufacturers and provide to their customers transaction information, transaction history, and a transaction statement for all pharmaceutical drugs covered under the Drug Quality and Safety Act. The FDA is required to publish final guidance on the standards for interoperable data exchange to enhance secure tracing of products at the package level by November 27, 2022.

TRANSACTION INFORMATION AND TRANSACTION HISTORY

The transaction information being required by the FDA is the following:

- Proprietary or established name or names of the product
- Strength and dosage form of the product
- National Drug Code number of the product
- Container size
- Number of containers
- Lot number of the product
- Date of the transaction
- Date of the shipment, if more than 24 hours after the date of the transaction
- Business name and address of the person from whom and to whom ownership is being transferred²¹

Currently the wholesale distributors provide the majority of this information on pharmaceutical drugs to their pharmacy customers. For instance, according to Walmart, McKesson provides transaction information to Walmart on its invoices. What will be new is the placement of lot information and the National Drug Code number on the invoice. Walmart currently gets this information on the product itself directly from the pharmaceutical drug manufacturer.