Upcoming Drug Supply Chain Security Act manufacturer requirements

November 23, 2015

Serialization

Beginning **November 27, 2017**, manufacturers must place a unique product identifier on each package and homogeneous case of product.

- **Product identifier**: a standardized graphic that includes, in both human and machine-readable format, the standardized numerical identifier, lot number, and expiration date of the product.
- **Standardized Numerical Identifier (SNI):** a set of numbers or characters used to uniquely identify each package or homogenous case. It is composed of the National Drug Code (NDC) combined with a unique alphanumeric serial number of up to 20 characters.

Product identifiers shall be in a 2D data matrix barcode when on a package and in a linear or 2D barcode when on a homogeneous case.

Manufacturers must maintain the product identifier information for six years after the date of the transaction.

Action item: Begin discussion now on serial number generation, label re-design and planning and budgeting for packaging line enhancements (either internally or with your CMOs)

Verification

Verification means determining whether the product identifier affixed to a package or homogeneous case corresponds to the standardized numerical identifier or lot number and expiration date assigned to the product by the manufacturer.

Beginning **November 27, 2017**, upon receiving a request for verification, manufacturers must respond within **24 hours**. Manufacturers may satisfy these requirements by developing a secure electronic database or utilizing a secure electronic database developed by another entity. The owner of the database must establish processes to respond to requests and may provide for data access to other members of the pharmaceutical supply chain as appropriate.

The development and operation of such a database does not relieve a manufacturer of the requirement to respond to a request for verification submitted by means other than a secure electronic database.

Upon receipt of returned product that a manufacturer intends to further distribute, the manufacturer must verify the product identifier (including the SNI) on each package or each sealed homogeneous case.

Action Item: Decide how you will store product identifier information and how you plan to respond to requests for verification.

Electronic format

Beginning **November 27, 2017**, manufacturers must provide the Transaction Information, Transaction History and Transaction Statement in **electronic format**. Paper will no longer be an acceptable way to provide Transaction Data.

Exception: a manufacturer may continue to provide TI, TH and TS in a paper format to a licensed healthcare practitioner.

Action item: If you are relying on paper to provide Transaction Data for a certain segment of customers or for certain types of transactions such as Drop Shipments, consider how you will transition to electronic format.

Wholesaler returns verification

Beginning **November 27, 2019**, before re-distributing a saleable returned product, a wholesale distributor must verify the product identifier (including the SNI) on each package or each sealed homogeneous case.

The volume of wholesaler returns is significant – averaging two percent of sales overall. At Cardinal Health, within our Pharmaceutical Distribution operations, we process over 30,000 units of saleable returns every business day.

In order to continue the secure and timely distribution of pharmaceutical product between trading partners and to patients, industry will need to identify efficient methods for complying with the 2019 requirements while maintaining operational efficiency.

Action item: HDMA is sponsoring a pilot study with manufacturers and wholesale distributors to examine different methods for verifying product identifiers in preparation for the 2019 requirements. Consider participating in this program to help determine which potential solutions make the most sense from an efficiency standpoint for all stakeholders.