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CardinalHealth

February 22, 2017

Dear Valued Manufacturer Partner,

We are less than a year away from the next key milestones under the Drug Supply Chain Security Act (DSCSA)[1] and Cardinal Health is committed to working with you to comply with the requirements of the law. As we prepare for unit level serialization and enhanced verification, Cardinal Health would like to share the expectations for how serialized products and data will be exchanged, to ensure that you plan appropriately.

DSCSA Requirements effective November 27, 2017

Manufacturers must place a unique product identifier on each package and homogeneous case.

- Cardinal Health expects that GS1 standards and HDA industry guidelines for barcodes and serialization are followed. See page two of this letter "Product Identifiers/Barcodes" for details.
- We anticipate that the U.S. Food and Drug Administration (FDA) will issue final guidance regarding grandfathering - specifying under what circumstances product that is not labeled with a product identifier and that is in the pharmaceutical distribution supply chain would be exempt. Cardinal Health trusts that manufacturers will properly implement any guidance provided by the FDA and we plan to accept non serialized product after November 27, 2017 that meets the criteria identified.

Manufacturers must provide the Transaction Information, Transaction History and Transaction Statement in electronic format. Cardinal Health has required lot-based DSCSA transaction data electronically via EDI ASNs since January 2015. Some manufacturers have continued to provide paper packing lists in lieu of electronic information. This will no longer be acceptable beginning November 27, 2017. Product received without electronic TI, TH, TS information will be returned back to the manufacturer. This includes any corrected TI TH TS due to exception processing.

DSCSA Requirements effective November 27, 2019

Wholesale Distributors must trade only in serialized product. Effective November 27, 2019, Cardinal Health will **not** accept DSCSA products that are not serialized.

Saleable Returns Verification - Before re-distributing a saleable returned product, a wholesale distributor must verify the product identifier on each package or each sealed homogeneous case. Based on the recommended options set forth by the HDA Saleable Returns Pilots, Cardinal Health plans to support the following options:

1. Manufacturers send aggregated serialized data with each shipment so product identifiers can be verified internally.

[1] The full text of the law, including requirements for manufacturers of pharmaceutical products, can be found on the FDA website.

- This scenario requires aggregation and serialized data exchange via EPCIS. If you choose this option, we ask that you start to send us data by January 2019 so we are prepared to begin self-verification in November 2019. As it can take up to 90 days to successfully complete testing, we encourage you to begin the process well in advance of the target date.

2. Verification Router Service (VRS)
    - In this scenario, manufacturers maintain their own database of serial numbers and subscribe to a third-party routing service that brokers all requests for verification and corresponding manufacturer responses.
    - While development of this solution is in the very early stages and challenges related to governance, funding and establishment will need to be worked out, an industry task force composed of manufacturers, distributors and service providers has been formed to develop the requirements for this system. Cardinal Health is participating in this work group and will keep you updated on its progress.

Please note that there is no single, industry wide solution for compliance with the 2019 saleable returns requirements. Regardless of which option a company chooses, manual processing will be required in some instances. We will be reaching out to you over the next several months to understand which solution you intend to implement for saleable returns verification.

Product Identifiers/Barcodes

At the package level, our expectation is that manufacturers will use a GS1 2D data matrix barcode, containing the NDC (in the form of a GTIN - Global Trade Item Number), serial number, lot number and expiration date. For case level requirements and information on bar code placement and size, please refer to the *Cardinal Health Manufacturer Reference Manual* and follow the guidance in the HDA Quickstart Guide.

Cardinal Health is encouraging our manufacturer partners to test barcodes with us prior to products being distributed into the supply chain. Please contact us at barcodes@cardinalhealth.com to provide sample labels and barcodes for testing and feedback.

Trading Partner Technical Guide and Pilot Activity

Cardinal Health has published a Trading Partner Technical Guide which provides our requirements for barcodes, master data and EPCIS serialized data exchange. The guide is posted on our Pharmaceutical Tracing Website. We welcome the opportunity to work with manufacturers to test the exchange of serialized product information. If you are interested in piloting with Cardinal Health, please send requests to drugtracing@cardinalhealth.com.

The safety and security of our nation's pharmaceutical supply is one of our top priorities. We take this responsibility seriously, as a safe and reliable drug supply is central to our customers' business and critical to the health and well-being of patients. As a valued manufacturer partner, we recognize the efforts you are making to implement a traceability solution and we look forward to working together to establish an industry-wide, standards-based approach to comply with the DSCSA.

Please send any questions or requests for additional information to drugtracing@cardinalhealth.com

Sincerely,

Dianne Pfahl
Vice President
Global Sourcing