



CardinalHealth

Cardinal Health
7000 Cardinal Place
Dublin, Ohio 43017

cardinalhealth.com

April 22, 2016

Dear Valued Manufacturer Partner,

The next key milestones under the Drug Supply Chain Security Act (DSCSA) are fast approaching and Cardinal Health is committed to working with you to comply with the requirements of the law.

DSCSA expectations for manufacturers

As we prepare for unit level traceability and enhanced drug distribution security, Cardinal Health would like to share our expectations for how serialized data will be exchanged, so you can plan appropriately. We believe that an industry-wide, standards-based approach is necessary to maximize efficiency and insure interoperability.

As a reminder, key upcoming dates include:

November 27, 2017 - Manufacturers must place a unique product identifier on each package and homogeneous case of product. Manufacturers must provide Transaction Information, Transaction History and Transaction Statement in electronic format. Manufacturers must respond to requests for verification within 24 hours.

November 27, 2018 - Repackagers must place a unique product identifier on each package and homogeneous case of product.

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 full text of the DSCSA, including complete requirements for manufacturers, can be found on the [FDA website](#).

Serialized data exchange

The secure interoperable exchange of serialized data among pharmaceutical supply chain partners will require standardized form and format.

Cardinal Health expects DSCSA serialized data will be exchanged using the EPCIS format following GS1 standards

Manufacturers may continue to send *lot-based* DSCSA transaction data via EDI ASN 856 up until November 2023. The current process is working for regulatory purposes and there is no need to change it. EPCIS transmissions of serialized data can run in parallel.

Serialized ASNs will not be supported. EDI was not specifically developed for track and trace purposes or serialized data exchange. Serialized ASN files have the potential for reaching such a large size that they would negatively impact all EDI channel throughput.

The timing of when serialized shipment data will be required is pending the outcome of the HDMA 2019 Saleable Returns Verification pilots. If the results indicate that option of manufacturers sending aggregated serialized data to wholesalers would best facilitate the returns verification

process, Cardinal Health will require this data by January 2019. This will allow us to build up a repository of serial numbers so we are prepared to begin self-verification in November 2019.

Aggregation

Aggregation is necessary to efficiently provide serial numbers as part of Transaction Information and to easily move product through the supply chain. Cardinal Health expects that manufacturers will aggregate individual units up to the case level.

We also support aggregation of product to upper packaging levels.

- Unit to Inner-pack/Bundle
- Inner-pack/Bundle to Case
- Case to Pallet

Product identifiers

It is our objective to align tightly with GS1 standards and HDMA industry guidelines for barcodes and serialization so that efficiencies are maximized for everyone.

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 [“HDMA Guidelines for Bar coding in the Pharmaceutical Supply Chain.”](#)

Master Data

Product and Location Identifiers, including GTINs (Global Trade Item Numbers) and GLNs (Global Location Numbers) are integral to EPCIS master data exchange and data integrity. If your organization is not currently using GTINs and GLNs, please prepare to do so. Remember that a separate GTIN is required for each product at every packaging level.

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, cardinalhealth.com/trace. 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.

As a valued manufacturer partner, we recognize you are making significant investments as you implement a traceability solution. We trust that you see the value of adopting an industry-wide, standards-based approach to comply with the DSCSA track and trace legislation in the most efficient manner possible.

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

Sincerely,



Dianne Pfahl
Vice President
Manufacturer and Industry Relations