

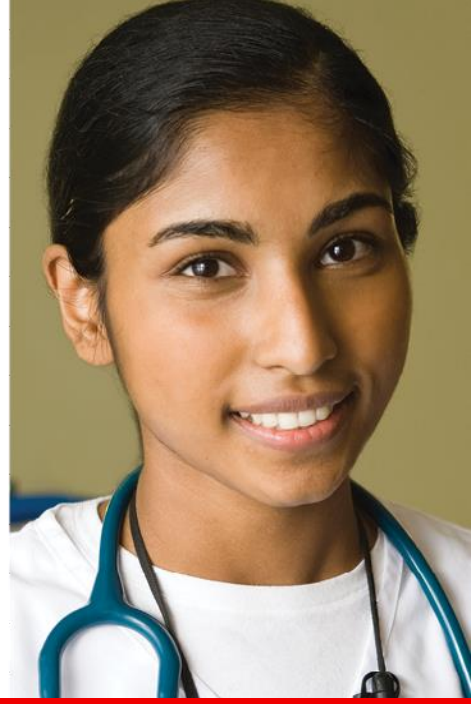

Cardinal Health Perspectives on DSCSA

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Today's Topics

- Verification and 2019 returns
- Aggregation and Inference
- Grandfathering
- Data standards and the use of identifiers
- Master Data Complexities
- Communications and expectations for trading partners

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Verification and 2019 returns

- Beginning November 2019, before re-distributing a saleable returned product, a wholesale distributor must verify the product identifier on each package or each sealed homogeneous case.
- The volume of wholesaler returns is significant – averaging 2% of sales overall.
  - At Cardinal Health, within our Pharmaceutical Distribution operations, we process over 30,000 units of saleable returns every business day.
- Industry will need to identify efficient methods for complying with the 2019 requirements while maintaining operational efficiency.

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Verification and 2019 returns

- HDMA sponsored pilot study with manufacturers and wholesale distributors to examine different methods for verifying product identifiers in preparation for 2019 requirements.
  - Manufacturers send product identifiers for product they ship to wholesale distributor and WD verifies internally
  - Wholesale Distributor scans all outbound units and cases to capture product identifiers and verifies internally
  - Central repository - Manufacturers send product identifiers to database, WD contacts central database to verify
  - Verification discovery service - Manufacturers have their own database - router link to appropriate place to verify
- As we wait for pilot recommendations, we anticipate that we will likely need to facilitate multiple solutions

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Aggregation and Inference

- While the DSCSA does not specifically require aggregation at this time, it does indicate that the FDA will issue guidance allowing for the use of inference and aggregation as necessary, based on the results of pilot activity and industry input.
- Cardinal Health believes that aggregation will be necessary to *efficiently* provide serial numbers as part of Transaction Information.

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Aggregation and Inference

- We support aggregation to upper level packaging.
  - Unit to Case
  - Unit to Inner-pack/Bundle
  - Inner-pack/Bundle to Case
  - Case to Pallet
- Should the results of the HDMA Pilot indicate that the option of manufacturers sending aggregated serialized data to wholesalers would best facilitate the returns verification process, we would like to receive this data by January 2019.

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Grandfathering

- Still awaiting final guidance from FDA on grandfathering product.
  - specifying whether and under what circumstances product that is not labeled with a product identifier and that is *in the pharmaceutical distribution supply chain* as of November 2017 would be exempt
- We are prepared to accept non serialized product in November 2017 that meets criteria for grandfathering outlined by the FDA

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Data standards – Product Identifiers

- It is our desire to align tightly with GS1 standards and HDMA industry guidelines for barcodes and serialization in order to minimize or eliminate any special requirements that manufacturers will need to follow for Cardinal Health.
- At the package level, our expectation is that manufacturers will use a GS1 2D data matrix barcode as the machine readable product identifier.
  - GTIN (Global Trade Item Number)
    - Use 14 digit GTIN which contains the encoded 10 digit NDC.
  - Serial Number - variable length - up to 20 characters
  - Lot Number - variable length - up to 20 characters
  - Expiration Date - fixed length - 6 digits - YYMMDD

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Data Exchange

- We expect serialized data exchange via the GS1 EPCIS format in 2023
- If serialization data is sent prior to 2023, send in EPCIS format
  - Pilot programs
  - Facilitate wholesaler returns verification
  - 3PL services
- Manufacturers may continue to send TI TH TS via EDI ASN 856 up until 2023.
- Serialized ASN will likely not be supported.

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Master Data Complexities

- Product and Location Identifiers are integral to EPCIS master data exchange
  - GTINs (Global Trade Item Numbers)
  - GLNs (Global Location Numbers)
- Barriers to adoption
  - Lack of understanding of the use of GTINs and GLNs
  - Costs for NDC Labeler codes & GS1 Company Prefix
- Allocation of GTINs required for each product at every packaging level
- If your organization is not currently using GTINs and GLNs, start to prepare

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Master Data Complexities

- EPCIS 1.1 is explicit in passing Master Data for Lot and Serialized Item level.
  - Variations in passing Master Data elements is an ongoing debate subject to industry preference and FDA acceptance.

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Expectations for trading partners

- Trading Partner Technical Guide will provide Cardinal Health expectations for meeting DSCSA requirements via EPCIS including:
  - Scenarios we expect trading partners to be in between now and 2023.
  - Overview of our pilot and expectations we have of our manufacturer trading partners.
  - Pointers to key industry standards and guidance.
  - Details for barcoding and supporting data elements.
  - Cardinal Health specific requirements for EPCIS and Master Data.
- We expect to have the Guide available by the beginning of April.

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Interested in Pilot Activities?

- Cardinal Health welcomes the opportunity to work with manufacturers to learn the costs and benefits of utilizing serialized product information.
- Pilot scenarios we anticipate include but are not limited to:
  - EPCIS file transmissions
    - DSCSA-compliant Lot-level
    - DSCSA-compliant Serialized
    - Serial numbers only, with or without aggregation
  - Various methods for exchanging Master Data
  - Serial number verification
- Send requests to drugtracing@cardinalhealth.com

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Q&A

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Thank you!

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