Regulatory Update:

The US Drug Supply Chain Security Act (DSCSA)

December 2017

Regulatory Agency	U.S. Department of Health and Human Services (HHS), Food and Drug Administration (US FDA)
Regulation Name or System Name	The Drug Supply Chain Security Act (DSCSA), which is Title II of the Drug Quality and Security Act (DQSA), and which amended the Food, Drug and Cosmetics Act (FD&C) of the U.S. Code of Federal Regulations (CFR)
Compliance Dates	January 1, 2015: All members of the supply chain must be licensed and must investigate suspect product May 1, 2015: Manufacturers, wholesale distributors and repackagers must being passing, receiving and storing transaction information on every change of ownership; March 1, 2016: Dispensers must begin passing, receiving and storing transaction information on every change of ownership; November 27, 2017: Manufacturers must begin applying a new "product identifier", composed of a Datamatrix barcode with NDC, serial number, lot and expiry on all drug packages, and either a Datamatrix or linear barcode with NDC, serial number, lot and expiry on all homogeneous cases. Manufacturers must begin providing their transaction data in electronic form only (except to individual practitioners), and they must begin offering a drug verification service. ***In a draft compliance policy statement, the FDA announced that this requirement will not be enforced for one year, thereby making the new serialization deadline November 27, 2018.*** November 27, 2018: Repackagers must begin applying the same "product identifier" to all drug packages and cases as above; November 27, 2019: Wholesale distributors may only buy and sell drugs that have been marked by the manufacturer or repackager with the new "product identifier", they must follow more stringent returns requirements, and they must begin verifying suspect product using the serial number.

	Because of the draft compliance policy issued by the FDA, the FDA will not enforce this date, except for drugs that were serialized and introduced into the supply chain before November 27, 2017 or after November 26, 2018. Drugs introduced to the supply chain by the manufacturer (the date they were packaged) between those dates will not require serialization at the wholesaler. Wholesalers must retain documentation that shows when the drugs were packaged by the manufacturer. According to the FDA's draft guidance on Grandfathering, this can be as simple as relying on the truthfulness of the Transaction Statement received from the manufacturer. November 27, 2020: Dispensers may only buy and sell drugs that have been marked by the manufacturer or repackager with the new "product identifier", and they must begin verifying 10% of all suspect product using the serial number. Like the wholesalers, the FDA will not enforce this date except for the same conditions spelled about above; November 27, 2023: All members of the supply chain must begin following new requirements known as Enhanced Drug Distribution Security (EDDS). Many of the characteristics and requirements of the EDDS will be defined by the FDA between 2018 and 2021
Applies to	Drug manufacturers, repackagers, wholesale distributors, and dispensers. "Dispensers" include any company that is authorized to dispense or administer prescription drugs to patients. Third-party logistics providers also have new requirements.

Unit-level Packaging ("units of sale"):

Barcode Symbology	2-dimentional data matrix
Barcode Contents	The machine-readable portion of the "product identifier" consisting of: ○ Standardized numerical identifier (SNI) (made up of the 10-digit NDC and serial number up to 20 characters); ○ Lot number; ○ Expiration date of the product
Serial Number Randomization	None
Serial Number Reuse	Not specified
Human Readable Expiry Date Format	Not specified
Barcode Data Encoding	The barcode must be "*…a standardized graphic…on a machine-readable data carrier that conforms to the standards developed by a widely recognized international standards development organization…"*
Product Code notes	○ According to FDA's SNI guidance from 2010, SNI's can be generated using GS1 standards, or ICCBBA standards for certain biological products. When using GS1 standards, the NDC may be encoded within a GS1 GTIN structure for the purpose of generating the barcode. ○ The DSCSA "Product Identifier" includes the human readable contents, which must reflect the data contents of the barcode. ○ See guidance from the Healthcare Distribution Alliance for properly marking product and cases with the DSCSA product identifier
Free Samples must be marked?	No
Stickering after manufacturing allowed?	Yes, as long as the product is still owned by the original manufacturer

Homogeneous Cases

Barcode Symbology	Linear or 2-dimensional data matrix barcode
Barcode Contents	Same as unit-level packaging (see above)

Logistics Units

Logistics Units Must be Serialized?	No

Data Capture

Unit-to-Case Aggregation Capture?	Prior to November 27, 2023, no. After that date, aggregation may be necessary. The FDA will make the final decision before about 2021. However, wholesale distributors have strongly requested this data from their suppliers in 2018.

Data Exchange

Send Unit Data to Government Repository?	No
Send Unit Data to Third-Party Repository?	No
Send Unit Data to Trading Partner?	Transaction data must be "provided", which must include the unit-level data, except the serial number. Some exceptions apply to wholesale distributors who buy directly from the drug manufacturer, repackager or exclusive distributor of the manufacturer. After November 27, 2023 the serial number must be added to the Transaction Information provided to the buyer.
Send Aggregation Data to Government Repository?	No
Send Aggregation Data to Third-Party Repository?	No
Send Aggregation Data to Trading Partner?	Prior to November 27, 2023, no. After that date, aggregation may be necessary. The FDA will make the final decision before about 2021

Authentication

Who Offers Data Repository for Authentication?	N/A
Manufacturers Must Register Shipments in Repository?	N/A
Downstream Trading Partners Must Authenticate on Receipt?	No
Downstream Trading Partners Must Authenticate on Shipment?	No

Government Reporting

Manufacturer Activity Reported?	No
Downstream Trading Partner Activity Reported?	No

Challenges

- U.S. wholesale distributors have mandated the use of electronic means to transmit the transaction data to them by manufacturers, as of January 1, 2015;
- U.S. wholesale distributors have mandated the use of Electronic Data Interchange (EDI) Advance Ship Notices (ASNs) for passing the required transaction data to them by manufacturers, as of January 1, 2015 and through November 27, 2023;
- U.S. wholesale distributors have requested aggregation data (or just the list of serial numbers included in their shipment) in GS1 EPCIS event format from manufacturers as part of their shipments in early 2018 as one way to help them with their 2019 saleable returns requirements. The HDA is developing a Verification Router Service (VRS) that may be usable for solving the saleable returns requirements without the need for a list of serial numbers with each shipment.
- The FDA must work with stakeholders and the public between 2017 and 2023 to debate exactly how the EDDS will work after November 27, 2023, particularly with regard to data exchange and access. At some point prior to that date, the FDA must publish final rules with the EDDS regulatory requirements. This will require all companies to change their DSCSA solutions to meet those new requirements. In the summer of 2017 the FDA announced a pilot program and a series of three public meetings aimed at collecting ideas for the operation of the supply chain in 2023. The last meeting will occur on February 28, 2018.
- The FDA has still not published three guidance documents that were due on November 27, 2015. One of these documents are important for some companies to help them develop a compliance strategy for the November 27, 2017 (not enforced until November 27, 2018) serialization requirement. These include guidance on on waivers, exemptions and exceptions.
- The FDA published draft guidance on "Grandfathering" on November 27, 2017 (exactly two years late). The guidance established the date of "packaging" as the date when a drug "enters the supply chain". This means that drug manufacturers may sell non-serialized drugs after the enforcement deadline of November 27, 2018 as long as those drugs were packaged/labeled prior to that date.

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