AmerisourceBergen

DSCSA Manufacturer FAQs

Updated April 18, 2023

Last year, AmerisourceBergen communicated that our manufacturing trading partners should had established a serial number data connection by January 2023. By August of 2023, all shipments should contain 100% of the serial number product data in GS1 US Healthcare EPCIS V1.2 message format.

What are the possible consequences for manufacturers that miss the deadlines?

The deadlines were established to assure AB can comply with the 2023 regulation and utilize our resources effectively. AB requires ample time to connect all manufacturers and provide feedback to manufacturers on non-compliant labels, data issues and other technical challenges. This activity will reduce the risk of technical issues preventing products from not flowing through the supply chain to provide critical medicines to patients.

The Pharmaceutical US Supply Chain is the first country to use EPCIS and inoperable data exchange for every shipment transaction between trading partners in the supply chain. This process is complicated and is highly technical so there is time required for issue remediation before November 2023.

For manufacturers, that have not completed the data exchange onboarding process to send data by August 2023, a manufacturing risk assessment will be conducted by AB. Based on the risk assessment, AB will start investigating alternative manufacturers where possible. AB will comply with all FDA DSCSA regulations, so if a manufacturer is not compliant, AB will require a manufacturer to obtain a DSCSA WEE (Waiver, Exception and Exemption), from the FDA, to move the product.

Has AB provided feedback to manufacturers on their product labeling barcodes that cannot be scanned?

There are three situations in which AB has reported a barcode issue to a manufacturer:

1) The barcode is not encoded correctly per GS1 specifications
2) The barcode isn't meeting GS1 standards recommendations
3) The barcode itself has faded or degraded in quality

DSCSA defines that the DSCSA Product Identifier means: *"a standardized graphic that includes, in both human-readable form and on a machine-readable data carrier that conforms to the standards developed by a widely recognized international standards development organization, the standardized numerical identifier, lot number, and expiration date of the product."*

What happens to those products after November 2023?

GS1 is an international standards organization that the industry has chosen to implement DSCSA. If a manufacturer isn't following GS1 standard (issue #1 and #2 above), then they must request a DSCSA WEE from the FDA for the shelf life of the impacted products. This is the only way that AB will be able to move the non-complaint product after November 2023.

If the barcode is degrading or fading over time, then the product isn't compliant to 21 CFR 201.25(c)(ii): *"Remain intact under normal conditions of use"*.

We recommend that the manufacturer work with the FDA on how to address the non-compliance. This may include requesting an exception / waiver from the FDA to enable AB to continue to transact this product; otherwise, AB will treat these products as damaged and request immediate credit.

What will AB do about product in their inventory that was received before November 2023, but does not have serial number data?

Since these products were received prior to the November 27, 2023 compliance date, AB will still sell through this inventory if we can link the product lot number to a lot number received in the lot-level DSCSA data.

What will AB do if non-aggregated product and/or serial number data is not provided AFTER November 27, 2023?

Currently there is no DSCSA provision or FDA DSCSA guidance regarding "grandfathered" products with regards to aggregation. The law requires that manufacturers provide transaction information, including the serial numbers after November 2023. The manufacturer, unless they open every case and scan every sellable unit those products can't move in the supply chain after November 27, 2023.

The AB receiving processes will ensure that we do not accept non-aggregated product. The product will be quarantine for disposition.

Manufacturers that are unable to send complete transaction information, with serial numbers, must request a DSCSA WEE (Waiver, Exception, and Exemption) from the FDA for the shelf life of the impacted products. This is the only way that AB will be able to move the non-complaint product after November 2023.

Is there a recommended manufacturing timeline to apply for a WEE (Waiver, Exception or Exemption) and communicate to AB for one or more products?

If a manufacturer knows they are going to have a challenge with any element of the DSCSA, including barcode issues, AB recommends that they do not wait until October to request a WEE. We anticipate that several manufacturers may have challenges and that the FDA may struggle to manage all the requests. Manufacturers should apply for a WEE as early as possible. AB will need the WEE 72 hours prior to shipment for our files.

What are AB's requirements for manufacturers without DSCSA data after November 2023?

AB will continue to require the sending EDI 855 and EDI 856 transactions. AB will use EDI to identify a serialized issue prior to the arrival of the product to our locations, so AB can resolve the Serial number data transmission issue before the product arrives at the distribution center. However, if the product arrives without DSCSA data one of two scenarios will occur:

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1) National Distribution Center shipments – There is no physical space to quarantine products. AB will request that the driver hold the product while we attempt to get the DSCSA data. Depending on the tolerance of the driver to wait, AB may need to reject the entire shipment due to missing data.

2) Forward Distribution Center shipments – AB will receive and quarantine the product for up-to 3 days. AB will work with the manufacturer to resolve the issue.

How will DSCSA impact future formulary decisions?

AB fully intends to use DSCSA as a method to evaluate the cost to serve of a specific manufacturer. Manufacturers that have minimal data issues, have optimal case sizes, serialize inner packs and are adhering to industry barcode best practices and standards will be ranked higher in our manufacturer scorecards. Incremental costs and operational efficiencies linked to sub-optimal manufacturer or product compliance will be considered with high regard when evaluating primary formulary awards.