

Secure Supply Chain

Secure Supply Chain: What you need to know before November 2023

What is The Drug Supply Chain Security Act (DSCSA)

- The DSCSA, which is Title II of the 2013 Drug Quality and Security Act (DQSA), outlines steps to achieve interoperable, electronic tracing of products at the package level to identify and trace certain prescription drugs as they are distributed in the United States.
- This will enhance FDA's ability to help protect consumers from exposure to drugs that may be counterfeit, stolen, contaminated, or otherwise harmful. These requirements will also improve detection and removal of potentially dangerous drugs from the drug supply chain to protect U.S. consumers.

What is AmerisourceBergen doing?

- Effective November 27, 2023, AmerisourceBergen (AB) will include product identification through the standardized numerical identifier (SNI) in the transaction information (TI) and exchange the information electronically as outlined by the Drug Security Supply Chain Act (DSCSA)
- As part of DSCSA, AB is establishing systems and processes to verify the product identifier on products it distributes to its human health customers. This will allow AB to expeditiously notify impacted customers in scenarios, such as a recall and when specific drugs are deemed dangerous by the FDA or pharmaceutical manufacturers.

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What does this mean for AmerisourceBergen Customers?

- AB customers across all human health segments must verify the product they've received from AB by the standardized numerical identifier (SNI).
- With DSCSA, enhanced unit level tracing will be available for all transactions, via receipt of an EPCIS data feed or through reporting access to ABC Order.
- Additional changes occurring as part of DSCSA include:
 - Saleable returns must be matched to the serialized data in AB systems.
 - More expansive DSCSA report for up to 2 years of transactions, now including serial number for each individual product.
 - Manufacturers will need processes to respond to customers' "request for information", or "trace request."
 - Customers must maintain processes to verify potential illegitimate products in support of this requirement.
- AB is gathering requirements to support providing enhanced DSCSA reporting in ABC order and developing a returns solution to support the returns process that is mandated by DSCSA.
- If customers do not comply with the requirements, legally, they will no longer be able to return product to AB.

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