AmerisourceBergen

# DSCSA – Industry Focus on Meeting 2023 Requirements

## AmerisourceBergen Position – June 2021

Dear Manufacturer Trading Partner,

The United States Pharmaceutical Supply Chain is now two and a half years away from having to implement the Drug Supply Chain Security Act's (DSCSA) requirements for enhanced product traceability. While we have made strides in the last few years, the final implementation in 2023 will be the most complex and challenging.

**What You Need to Know:**

AmerisourceBergen (AB) intends to be fully compliant with the enhanced unit level tracking requirements by November 2023. At this time, AB does not believe the Food and Drug Administration (FDA) will provide any *additional* enforcement discretion. In partnership with our manufacturer partners, there are several key milestones that AB must hit to meet the November 2023 deadline while not disrupting patient access -- below is our expectations to be completed July 1, 2023.

**Transaction Information (TI) Exchange** – DSCSA requires the use of a widely recognized international standard to accomplish interoperability in 2023. The GS1 EPC Information Service (EPCIS) standard R1.2 is the only recognized standard, coupled with the GS1US Guideline version 1.2, that meets the industry's needs to exchange serialized transaction information. AB intends to only utilize GS1 EPCIS R1.2 to be compliant for 2023 and will sunset EDI 856 ASN as a compliance method and only require an ASN for supply chain receiving purposes.

**Technical Onboarding** – To ensure that there is sufficient time to work out technical and data exchange issues, our goal is to onboard **all** our manufacturer [including repackagers and exclusive distributors] by **January 1, 2023**. AB does not expect to be receiving complete serialized TI for all shipments, but that the technical connections, master data exchange, testing, and system validations are all complete. AB will continue to phase in all products after technical onboarding is complete. To expedite onboarding, it is recommended that each manufacturer utilizes the GS1 service for conformance testing prior to sending EPCIS data to a trading partner.

**Product Aggregation** – DSCSA does not explicitly require product aggregation, however the industry has aligned on the need to aggregate product, so inference can be utilized to ensure effective, movement of serialized product through the supply chain and prevent delays of medicines to the patient. Without using inference, trading partners would need to open ***every*** non-aggregated case and scan every saleable unit within the case to generate the required Transaction Information. For context, AB receives around 110,000 homogenous cases of product a day while only shipping out 5,500 cases a day. Without the use of inference to receive and confirm TI from the manufacturer, our supply chain could grind to a halt.

To ensure products in our inventory are aggregated, by November 27, 2023, AB requires all products shipped to us must be aggregated and contain complete serialized TI by **August 1, 2023.** This will allow four months of non-aggregated product to move out of the commercial supply chain.

**Packaging Changes and Sizes** – With the implementation of serialization, AB has seen significant amount of case size changes over the past few years that have caused challenges. When proposing larger case sizes (see AB Logistics Guide for dimensions), it is important to keep a few key items in mind:

1) Larger shipper size burden dispenser's storage capabilities and acceptance of the product
2) Larger shipper size may not fit our automation and conveyer systems.
3) Larger cases often result in velocity issues and additional product handling in our distribution centers, creating additional potential for damages and increased operational costs.
4) Case ***or*** Inner-pack unit of measure (UoM) changes, that are not coordinated well with trading partners, **WILL** result in errors during receiving, dispenser ordering and shipping.

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**When making case changes, it is imperative that manufacturers check with AmerisourceBergen on the impact of the proposed changes as well as notify us of the changes pro-actively to ensure our systems are updated.**

**What You Need to Do:**

AmerisourceBergen has published all of our reference documents on our manufacturer operations webpage that can be found here:
https://www.amerisourcebergen.com/manufacturer-solutions/manufacturer-operations-and-replenishment

Specifically, there are several DSCSA references that we encourage all trading partners to review:

1) AmerisourceBergen EPCIS Onboarding requirements – https://tinyurl.com/AB-Epcis-Onboarding
2) AmerisourceBergen Logistics Guide (Case Requirements) – https://tinyurl.com/AB-Logistics-Guide
3) GS1 US DSCSA References – https://www.gs1us.org/industries/healthcare/standards-in-use/pharmaceutical
4) GS1 US Rx EPCIS Conformance Testing – https://www.gs1us.org/industries/healthcare/standards-in-use/pharmaceutical/epcis-conformance-testing

**Finally, AB is asking for our manufacturing customers to please provide the following information to our Secure Supply Chain team (securesupplychain@amerisourcebergen.com):**

1) If your company is not currently live with EPCIS, AB asks that you provide your company's timeline and contact information to get on our onboarding schedule.
2) If your company is looking to make case changes, please be pro-active in notifying our team so we can review the operational impact and assist in planning to phase in any appropriate changes.
3) Please provide your company's updated product Global Trade Item Numbers (GTINs) and Global Location Numbers (GLNs) if you have not done this task in the last year. Please reach out to our serialization team to get our template. GTINs information is required prior to beginning any onboarding activity.
4) Contact us if you have questions around our expectations or concerns on ABs 2023 milestones.

AmerisourceBergen realizes all our trading partners are at various points on their 2023 journey to comply withe the compliance date of November 27, 2023. While some of our milestones may appear aggressive, AB firmly believes that the FDA will not give additional enforcement discretion, and these dates represent the realistic deadlines that AB, our manufacturer partners, and customers must meet to ensure we are all successful.

While enhancing the security of the supply chain is the ultimate end goal, AB and the industry must also ensure the final implementation of this ten year effort does not impact patients' ability to receive critical, lifesaving, medicines.

Thank you,

Matt Sample
VP, Manufacturer Operations

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Sr. Director, Manufacturer Operations

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