

AmerisourceBergen

Meeting 2023 DSCSA Requirements AmerisourceBergen Position – January 2023

Dear Manufacturer Trading Partner,

This year, the United States Pharmaceutical Supply Chain will be implementing the Drug Supply Chain Security Act's (DSCSA) requirements for enhanced product traceability. The following communication provides updated information regarding AmerisourceBergen's (AB) planned processes.

Key milestones

Date	Milestone
January 1, 2023	Supplier/AB technical connections, master data exchange, testing, and system validations deadline.
August 1, 2023	All products shipped to AB must be aggregated and accompanied by complete serialized transaction information (TI) and transaction statement (TS) via EPCIS files.
November 27, 2023	Completion and implementation of product traceability requirements within the entire supply chain.

AmerisourceBergen's position

AmerisourceBergen intends to be fully compliant with the enhanced unit-level tracking requirements by November 2023. In partnership with our manufacturer partners, there are several key milestones that AB must hit to meet the November 2023 deadline to maintain patient access. We have also more clearly defined our operational processes that will go into effect in alignment with implementation.

Our ask of manufacturing partners

AB is asking for our manufacturing partners 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 proactive 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 team to get our template. GTIN 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.

New or updated guidance

Product receipt and DSCSA Transaction Information (TI) and Transaction Statement (TS) –

Suppliers are required to setup their DSCSA TI/TS exchange in accordance with the most recent US GS1 EPC Information Service (EPCIS) implementation guidelines, inclusive of providing the purchase order in the EPCIS file. Suppliers must provide an EPCIS for every shipment prior to the delivery of the physical product. Failure to do so will result in quarantined and/or potential return of the product. Quarantined product will be held for (3) business days while the supplier and AB work to correct/collect the missing DSCSA data. If a solution is not found in (3) business days, the product will be returned, for full credit, at the cost of the supplier.

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National Distribution Center (NDC) deliveries – In the event AB does not receive the complete DSCSA TI/TS EPCIS file before the physical product, AB will not remove the product from the truck until the file is received. Suppliers shall be responsible for any costs associated with holding a delivery at the NDC due to delays in DSCSA compliance data exchange. Suppliers will also be required to have appropriately staffed DSCSA support personnel during the hours of NDC delivery to readily remediate data issues.

Product sale and DSCSA Transaction Information and Transaction Statement – In the event that a product, upon sale to an AB customer, does not have the required DSCSA data, the product will be quarantined for up-to (3) business days while supplier and AB work to correct/collect the missing DSCSA data. If DSCSA data is not provided within (3) business days, the product will be returned, for full credit, at the cost of the supplier.

Damaged products – In the event of GS1 non-compliant/scannable DSCSA barcode, AB shall quarantine and report such barcode issue within thirty (30) days of discovery.

Shipment errors – Supplier is responsible for providing all required DSCSA data in the event of a product overage. Inability to do so within (3) business days will result in the product being returned, for full credit, at the cost of the supplier.

Packaging Changes and Sizes – With the implementation of serialization, AB has seen a significant amount of case size changes over the past few years that have caused challenges. It is our position that suppliers agree to follow GS1 GTIN allocation rules when changing packaging and provide a NEW GTIN when making major case size or quantity changes. Suppliers must notify AB at ProductDataChanges@AmerisourceBergen.com of any packaging changes such as inner-pack or case size/quantity changes. notifications should contain affected NDC, description of change, updated quantities, dimensions, and GTINs (as applicable).

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.

Again, when making case changes, it is imperative that manufacturers check with AB on the impact of the proposed changes as well as notify us of the changes proactively to ensure our systems are updated.

Reminders from previous publication

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 GS1 U.S. 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 DSCSA compliance method but will still 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 was to onboard **all** our manufacturer partners [including repackagers and exclusive distributors] by **January 1, 2023**. If you have not completed this process yet, please contact your AmerisourceBergen representative as quickly as possible. AB does not expect to receive complete serialized TI for all shipments by that date, **but that the technical connections, master data exchange, testing, and system validations are all complete**. AB will

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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. This way, 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 along with the units that make up the remaining outbound volume. 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.

Reference documents

AB 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. AB EPCIS Onboarding requirements – <https://tinyurl.com/ab-Epcis-onboardingGuide>
2. AB Logistics Guide (Case Requirements) – <https://tinyurl.com/AB-Logistics-Guide>
3. GS1 US DSCSA References – <https://www.gs1us.org/industries-and-insights/by-industry/healthcare/standards-in-use/pharmaceutical/dscsa-implementation-guidelines>
4. GS1 US Rx EPCIS Conformance Testing – <https://www.gs1us.org/industries-and-insights/by-industry/healthcare/standards-in-use/pharmaceutical/epcis-conformance-testing>

AmerisourceBergen realizes all our trading partners are at various points on their 2023 journey to comply with the compliance date of November 27, 2023.

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

Thank you,

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