cencora

Cencora position on FDA's October DSCSA exemption announcement

December 2, 2024

Dear valued trading partner,

At Cencora, we've been working internally and with our trading partners to be fully compliant with DSCSA requirements by the final deadline for full implementation and stabilization of the DSCSA by November 27, 2024. The Food and Drug Administration (FDA) recently announced an [exemption for eligible trading partners.](#)

Please note the following:

As of November 27, 2024, Cencora will continue to stabilize our processes to capture product identifiers at receiving and picking and validate against the EPCIS data received from suppliers. Based on the FDA exemption announcement, we will not quarantine the physical product until a later date if the trading partner has completed the initial work of setting up data exchange connections and started sending EPCIS files to our DSCSA repository. Suppliers that have not completed any of these steps must have a Waiver, Exemption or Exception from the FDA to continue to ship product. We will continue to require the EDI 856 (ASNs) to be sent for all shipments.

Please see the following key milestone dates:

January 6, 2025

- Cencora will enable all suppliers to receive Automated Exception Notifications (through Lspedia) for the following exceptions:

    - EPCIS file master data failures.
    - EPCIS file failures due to file syntax or EPCIS content issues.
    - Product No Data: EPCIS data is missing at receiving and picking scanning validation.
    - Truck No Data receiving scenarios: pre-receiving data check when EPCIS data is missing for the delivery.

May 5, 2025

- Cencora will begin physically quarantining products received without the required DSCSA EPCIS data. Notifications will continue but will indicate that the product is now quarantined until the issue is resolved.
- By end of May, Cencora will stop relying on the ASN as DSCSA regulatory document (manufacturers will be switching to serialization). **EDI ASNs will remain as a Cencora business requirement for logistical and Supply Chain support purposes.**

- It is critical that all barcode issues are resolved by this time so that the product can be scanned throughout its lifetime in the supply chain. Non-compliant barcodes should be on a WEE.
- Cencora will submit a WEE request to the FDA to cover all NDCs that appear to still not be compliant.

August 25, 2025

- Cencora will require all saleable returns from our customers to be successfully verified against our DSCSA serialization repository. Cencora will not use a Verification Routing Service (VRS) for this purpose.

November 27, 2025

- Enable full Customer Exception processes (overage, underage, etc.).
- Evaluate turning off pseudo commissioning and start quarantining at pick.

Actions items: how you can prepare

- If you are transmitting 100% of the required data, please focus on the exceptions handling processes and ensure that the Cencora team has your updated contact information for various exception scenarios and that you are preparing to triage and resolve these exceptions when they happen in the future.
- If you are NOT currently transmitting 100% aggregated serialized data for all your products and shipments, then it is imperative that you do so immediately. Please ensure that you are in touch with your Cencora EPCIS support contacts to work through any testing needs and expedite your path to full compliance.
- All suppliers should assess their product portfolio and submit a WEE request for any items that may not be 100% compliant **by May 1, 2025**. This includes products with unaggregated inventory, products with barcode issues, products impacted by technical or system issues within your operations that result in missing, incomplete, inaccurate or late serialized TI data.
- If you apply for a WEE or have received approval for a WEE, please communicate that by sending a copy of the WEE or an official letter including applicable information (impacted NDCs & WEE duration) to EPCIS.Support@AmerisourceBergen.com. Note that we are not able to manage WEEs by lot/expiration date, so any WEE must be good for the longest life (expiration date) of the impacted product.

As an industry, it is crucial to use this additional time to ensure that we have near 100% expected TI/TS data received with 100% accuracy and timeliness (before product arrival). In addition, we continue to see barcodes not adhering to global standards or deteriorating over time and not meeting (CFR 201.25(c)(ii) so it is extremely important to resolve these issues quickly and permanently.

All these issues may create disruptions in product supply and inhibit product access to those patients that need it most.

If you have any questions, please contact your Category Manager or your Cencora Manufacturer Operations / Secure Supply Chain contact.

Jan Pallone
President, Strategic Global Sourcing

Matt Sample
SVP, Manufacturing, Quality & Replenishment Operations