

Drug Supply Chain Security Act Cencora's position on the end of DSCSA Exemption period

Dear valued trading partner,

At Cencora, we've been working diligently 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, 2025. The Food and Drug Administration (FDA) recently announced an [exemption for eligible trading partners](#) utilizing a phased approach as outlined below.

Date	Milestone
May 27, 2025	Exemption ends for Manufacturers and Repackagers.
August 27, 2025	Exemption ends for Wholesale Distributors.
November 27, 2025	Exemption ends for Dispensers. <i>(*small dispensers have until Nov 27, 2026)</i>

Please note the following:

Cencora continues to stabilize our processes to capture product identifiers at receiving and picking and validate against the EPCIS data received from suppliers. In the event Cencora does not receive the complete DSCSA TI/TS EPCIS file before the physical product, there is a potential that the shipment will not be removed from the truck until the file is received as we are enabling full DSCSA activities throughout our network. Suppliers shall be responsible for any costs associated with holding a delivery at the National Distribution Center (NDC) due to delays in sending accurate DSCSA compliance data. Suppliers will also be required to

have appropriately staffed DSCSA support personnel during the hours of NDC delivery to readily remediate data issues.

Based on the FDA exemption announcement, we will attempt to not quarantine physical product however we are aiming to begin fully ramping up our network activities beginning August 1, 2025 which could lead to product being quarantined. Given the volume of product that flows through our National Distribution Center (NDC), this will be the final location that will be activated for full quarantine activities. Those Suppliers that have signed up for the Early Adopter program are running under the auspices of the DSCSA and will have product held when an exception is uncovered. Suppliers that have not completed any of the DSCSA EDDS requirements must have a Waiver, Exemption, or Exception (WEE) from the FDA to continue to ship product. We will continue to require EDI 856 (ASNs) for all shipments.

Please see the following key milestone dates:

May 26, 2025

- Cencora will enable all suppliers to receive Automated Exception Notifications (through Lspedia).
- Cencora will gradually begin to physically quarantine products received without the required DSCSA EPCIS data. Notifications will continue and will indicate that the product triggered an exception and should be treated as high priority and worked on until the issue is resolved.
- 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 are still not in compliance.

August 1, 2025

- Cencora to begin activating quarantine procedures throughout its Distribution Center network, beginning with our Forward DCs (FDC) and ending with the NDC.

August 25, 2025

- Cencora will physically quarantine any 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.
- 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.
- Products received with non-compliant barcodes will be returned to suppliers unless an FDA-approved WEE is provided.
- Full outbound serialized TI/TS data available to our customers.

November 27, 2025

- Enable full Customer Exception processes (overage, shortage, 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 23, 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 or receive 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.

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For additional questions or concerns, please email
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