

Drug Supply Chain Security Act

August 27 – DSCSA enhanced security requirements go into effect for wholesale distributors

Dear valued partner,

Cencora is pleased to announce our readiness to support DSCSA Enhanced Security Requirements for serialization and is announcing that this will go into full effect for your account with Cencora on August 27, 2025. We appreciate being in a position of support with the FDA over the last several years as they have exercised enforcement discretion to allow the industry and other partners to prepare and transform our companies in preparation for this massive change to our supply chain. After 12 long years, Cencora is proud and ready to continue partnering with you to achieve this historic milestone.

Additionally, Cencora appreciates the effort that many manufacturer partners and distribution clients have invested over the last 10+ years, to establish live interoperable connections to exchange the required enhanced DSCSA data prior to May 27, 2025, deadline. We also appreciate those partners who have invested time, team members, and unmeasurable effort to establish accurate processes to mitigate exceptions and keep lifesaving medications moving throughout the supply chain.

August 27 is a major pivot for our supply chain and every prescription medication must be accompanied by its corresponding serialization data as required by DSCSA to continue to move through the supply chain from one authorized trading partner to the next. Without that data, the product does not move, and the supply chain is interrupted. To that end, we have integrated serialization and other DSCSA components into our current operations and established dedicated support teams to enable constant exception support. Like many of you, we have done everything within our control to keep the product moving to serve patients and our communities.

What's going to happen on August 27, 2025?

Expectations for inbound deliveries to Cencora

We expect that the serialization data (EPCIS) arrives complete and prior to the delivery of the actual product. We expect the file to have the latest correct master data and syntax so that the file processes correctly.

If Cencora does NOT receive the correct data prior to shipment, or if the file processing fails due to a syntax error, or the EPCIS file fails due to master data changes (i.e., GTIN changes) that were not communicated, then:

1. If delivering to the Cencora National Distribution Center (NDC), all trucks will be held, and **product will NOT be unloaded into our warehouse**
 - o Cencora does not have space to quarantine a large volume of products. We will notify the manufacturer immediately after determining whether the purchase order(s) are missing the required data. We expect the manufacturer to respond to exceptions during their delivery windows. If we are unable to resolve an exception in a reasonable time, the delivery may need to be returned to the manufacturer.

2. If delivering directly to our forward distribution centers (FDCs), we will quarantine the product until the exceptions can be resolved. We will keep the product in quarantine as long as capacity permits but fully expect the exceptions to be **resolved within 3 business days** or we reserve the right to return the product at the manufacturers expense.
3. We will be integrating DSCSA and serialization into our Overages, Shortages, or Damages Process (OSD). We will have this process updated at our NDC. For direct shipments to our FDCs, we will be phasing it in the coming months.
4. To maintain product availability, we have been monitoring data quality and timeliness since May 27, 2025.

Expectation to resolve barcode issues

Currently, there are approximately 100 barcodes we have identified with issues that prevent us from scanning and successfully capturing DSCSA data. These issues include **incorrect GS1 encoding**, persistent **quality issues with the physical barcode (fading, poor printing, etc.)**, and/or **lot/expiry mismatches** between the EPCIS and the encoded barcode data.

We expect manufacturers, when notified of these issues, to request their own Waiver, Exception, Exemption request (WEER). If we have not received a WEE for these products, we will add these products to our own WEER, until the issues are resolved and the erroneous lots have expired. In the future, we expect these issues to be identified as mislabeled product and should be treated as a recall.

Outbound shipments

Given that we are still working through inventory received before the requirement to send enhanced serialized data was enforced, we will continue to ship product that does not have serialized data until we exhaust this inventory. To handle this transition, we will be taking the following approach and actions:

1. For shipment of single saleable units, we will check that we have a lot-level ASN for the product and generate a pseudo commissioning event so we can create an outbound DSCSA file for our customers. We will monitor this over 6 months and turn off “pseudo commissioning” when we are at a point where we have exhausted all remaining transitional inventory. Based off current inventory, we anticipate this process lasting at least 6 months. For products in this category, we will not be notifying manufacturers of data issues specific to those products.
2. For shipment of cases, where we do not have DSCSA serialized data, we are in the process of estimating how much inventory we have in our warehouse. If we identify problems that require FDA notification post August 27, we will work with manufacturer partners and the FDA to resolve them in a compliant manner.

Expectations for customer returns

1. For invoices **prior to August 27, 2025** – we will permit our customers to **return product utilizing our pre-enhanced DSCSA process**. We will not require them to match a serial number to an invoice, we will accept returns for products without matching a serial number to an invoice, and we will verify that the lot the customer is returning was shipped to Cencora via the lot level DSCSA requirements.

2. For invoices **on or after August 27, 2025** – customers will be required to generate a return goods authorization (RA) by **selecting an invoice and serial number combination**. Products returned to Cencora that were not sold to that customer initially will be rejected and denied returns credit.

We realize this implementation represents significant change. These actions are the crucial next steps to achieving compliance with the wholesale distributors DSCSA requirements that will be enforced on August 27, 2025.

We are grateful for our year-long partnership with our manufacturers. It is and has truly been an industry changing regulation and one that has impacted and transformed our organizations. **Thank you for your part in helping us achieve this milestone!**

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