



DSCSA: FDA guidance and next steps

Take action today to ensure compliance by November 27, 2023

September 2023

FDA Guidance -

The Food and Drug Administration (FDA) recently issued [guidance](#) on the Drug Supply Chain Security Act (DSCSA) and has extended enforcement until November 2024. The FDA guidance is clear that the law takes effect on November 27, 2023. We remain committed to our implementation efforts and working with you and our manufacturer partners to meet the enhanced drug distribution security requirements.

The year between compliance and enforcement will be a stabilization period, providing the industry time to build and validate interoperable systems and processes, manage products and data and ensure continuity of the supply chain and product availability to patients.

Take Action TODAY to ensure compliance by November 27, 2023

- **Secure your Global Location Number (GLN)** –The GLN is a unique identifier that each Ship-To location needs **to receive serialized data at the package level**.
 - Customers with 9 or more locations – Please contact your sales representative for instructions on how to forward your GLN information to Cardinal.
 - Customers with fewer than 9 locations – Cardinal Health will provide you with a GLN; no action is required.

To date, we have received GLN submissions from 87 percent of active accounts. We will be unable to do business with customers who have not supplied a GLN for each location that we ship to by November 27, 2023.

- **Choose Your DSCSA Compliance Data Preferences**
Cardinal Health will begin electronically tracking products at the individual package level on November 27, 2023. Customers have two options for receiving DSCSA serialized transaction:
 - **Cardinal Health Web Portal:** If you choose not to use the EPCIS Solution, you will have access to the transaction data via the Cardinal Health Web Portal (Track and Trace Reporting). If you select this option, no action is required.



- **EPCIS Solution:** Cardinal Health and Antares Vision Group/Rfxcel (our solution provider for DSCSA transaction data) continue the onboarding process. If you are a Metro Medical customer and have chosen an EPCIS Solution provider, please contact your sales representative. If you are an SPD customer, then you will need to complete one of the following:

- [GLN data collection](#) form, if you have nine or more locations.
- [Cardinal Health DSCSA EPCIS Solution Provider information \(3rd Party vendor\)](#) form if you have fewer than nine locations.

- **EPCIS Solution Provider Testing – continues for November 27, 2023**

We have partnered with the EPCIS providers listed below to test the connection with Antares Vision Group/Rfxcel:

- Advasur
- Infinitrak
- McKesson
- SureCost
- Axway
- Inmar/RxTransparent
- Rfxcel
- Tracelink
- ConsortiRx
- LSPedia
- RxScan
- Track Trace Rx

In agreement with these EPCIS third-party solution providers we will test a handful of customer accounts across each provider to ensure the file layouts and product aggregations are correct. Unless we and/or Antares Vision Group/Rfxcel have reached out to you, testing is not required. Once testing is complete, we will inform you that your accounts have been onboarded to production.

If you chose an EPCIS third-party solution provider not listed or need a direct connection to your customer system and have not submitted your onboarding information, please complete either of the EPCIS onboarding forms above.

Visit the [DSCSA Resource Center](#) for the latest updates. If you have additional questions, please contact your Cardinal Health representative or email dscsainfo@cardinalhealth.com.

Pharmaceutical Tracing resources

- Follow these [five key steps](#) to prepare for DSCSA.
- Verify your GLN using our [GLN look up tool](#).
- If you find a discrepancy, please send an email to dscsainfo@cardinalhealth.com.
- Read the [FAQs](#) to help answer your DSCSA questions.