

DSCSA dispenser impact checklist

DSCSA impacts all “dispensers” which is any provider in a health system, hospital, community or specialty pharmacy, or independent community practice dispensing or administering pharmaceuticals that require enhanced unit level tracking per DSCSA definition.

✓ Ability to access and receive serialized data one of two ways:

1. Through the DSCSA report in ABC Order.
2. Through a third-party Electronic Product Code Information Services (EPCIS) vendor solution. If you plan to use this option, you will need to choose a third-party EPCIS pharmacy partner vendor and complete integration onboarding. *EDI does not go away but is no longer DSCSA compliant.

✓ Evaluate your option to apply for a DSCSA Waiver, Exception, and Exemption (WEE) with your legal council

Your legal advisors may also want to evaluate your option to apply for a DSCSA Waiver, Exception, and Exemption (WEE) if you are unable to meet the enhanced drug distribution security requirements of section 582 of the FD&C Act, you have concerns about access disruption, or as a risk mitigation strategy. This will help keep your entity compliant in the event that you experience any data failures at the product level at any point or are awaiting completion of EPCIS integrations. To learn more about waivers, exceptions, and exemptions [click here](#)

To submit a WEE, visit the [FDA NextGen portal](#)

✓ Understand the updated returns and claims process

As part of DSCSA compliance, you are now required to match serialized product data—including GTIN (Global Trade Item Number) and Serial Number—against an invoice for shipments dated August 27 or later, when submitting returns and claims requests. Additionally, all claims must include GTIN and serial number details for the associated products. ABC Order will allow you to type in the SNI number, search by product and invoice, or use a 2D scanner to quickly scan. We recommend obtaining a 2D barcode scanner, but it is not required. If you qualify for the small dispenser exemption or have submitted a Waiver, Exception, or Exemption (WEE) application, the updated returns and claims process still applies. *These process updates do not change our returns or claims policies. The returns and claims policy you use today will continue to apply.

There may be an increase in returns and claims processing time to account for additional steps and matching serialized data to returned products. Providing accurate and complete serialized product data, matched to the appropriate invoice and product you send back, can help reduce processing time.

✓ A Global Location Number (GLN) is essential for identifying ship-to locations and covered entities in the supply chain, in compliance with FDA tracing requirements.

They also provide critical data in the serialized data files for transactions and reporting. We need your GLN on file in order to ship products and accept returns or claims. You can use the same GLN across distributors. If you need assistance finding your GLN, obtaining a GLN, or any GLN account related questions, reach out to the GS1 customer service team.

✓ Establish processes and procedures (SOPs)

Have SOPs in place for buying product from an authorized trading partner and how to investigate and properly handle suspect and illegitimate drugs. If you qualify for the small dispenser exemption or have submitted a Waiver, Exception, or Exemption (WEE) application, you have additional time for SOPs to be in place.