

Understanding Drug Supply Chain Security Act (DSCSA)

Preparing for the future of the supply chain

The Drug Supply Chain Security Act (DSCSA) is a federal law that outlines the requirements that manufacturers, repackagers, wholesale distributors, dispensers/providers, and third-party logistics providers (trading partners) must follow to enhance unit level tracing of prescription drugs throughout the supply chain to protect patients from receiving harmful drugs, such as counterfeit or other illegitimate drugs.

Although the DSCSA law went into effect last November, the FDA announced it will not enforce the law until November 27, 2024, creating a 1-year stabilization period for trading partners to refine their systems and processes to maintain compliance. During this discretionary enforcement period, it is critical that all involved parties continue to show progress towards compliance. The FDA has confirmed and communicated that no additional extensions will be granted. However, Waiver, Exception, and Exemption (WEE) requests are available to mitigate some of these risks as the official stabilization period ends.

Our operational teams have been diligently working for years and will maintain our commitment and focus to be fully prepared for DSCSA by this November. In an effort to prioritize patient access as the DSCSA stabilization period comes to an end, Cencora has submitted a Waiver, Exception, or Exemption (WEE) application for certain products. This application does not indicate that Cencora is not ready or prepared for full DSCSA compliance; rather, this WEE covers any National Drug Codes (NDCs) for which Cencora is not receiving full serialized data from the manufacturer to ensure patient access for those products. We remain actively engaged with industry partners and the FDA to navigate DSCSA implementation and enforcement.

As a dispenser, it is important to continue the momentum towards DSCSA readiness despite the stabilization period. This additional timeframe has offered an extended opportunity for education, understanding, and preparation, including data testing and onboarding. In addition to the stabilization period, the FDA is granting exemptions from certain DSCSA requirements to small dispensers until November 27, 2026. A small dispenser is defined as a company with 25 or fewer full-time employees licensed as pharmacists or qualified as pharmacy technicians as of November 27, 2024. If you qualify for the small dispenser exemption or have submitted a Waiver, Exception, or Exemption (WEE) application, the new returns process will still apply this November, meaning dispensers must track serial numbers for every return to remain compliant. Our team is here to assist and support you throughout this process.

Evolving the prescription drug supply chain timeline

- 2014** • State preemption
- 2015** • **January 1**
Transactional information provided by manufacturer, wholesaler and repacker
- May 1**
FDA enforcement discretion ends
- July 1**
Transactional information accepted by dispensers federal licensure standards for distribution raised
- 2016** • **March 1**
FDA enforcement discretion ends for pharmacies and dispensers
- 2017** • Manufacturers serialize
- 2018** • Repackagers serialize
- 2019** • Wholesalers accept/sell serialized products and validate serialized number on salable returns
- 2020** • Dispensers accept serialized product
- 2021**
- 2022**
- 2023** • **November 27**
DSCSA law goes into effect with 1-year stabilization period
- June 12**
FDA grants exemptions until 11/27/2026 to small dispensers with 25 or less full-time employees licensed as pharmacy technicians. 1-year stabilization period
- 2024** • **Phase 2**
Complete traceability