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.

The FDA has announced it does not intend to act on the enforcement of DSCSA until November 27, 2024. While the DSCSA law still goes into effect this November, this creates 1-year stabilization period that allows manufacturers, distributors, dispensers, and all trading partners within the pharmaceutical supply chain additional time to refine systems and processes necessary to maintain compliance under DSCSA. The FDA has stated that it is critical that everyone must continue to show progress during this discretionary enforcement. You can review the full guidance from the FDA here.

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 without any slowdown and use the stabilization period to ensure our data and processes are mature for November 2024. We will remain actively engaged with industry partners and the FDA to navigate the implementation of DSCSA and its enforcement.

We highly recommend that you continue the momentum to be aware of and prepared for DSCSA despite the stabilization period. This additional timeframe offers an extended opportunity for education, understanding, and preparation including data testing and onboarding. 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
  - **July 1**: Transactional information accepted by dispensers; federal licensure standards for distribution raised
- **2016**: March 1; FDA enforcement discretion ends
- **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
- **2024**: Phase 2: Complete traceability