

DSCSA Implementation Period

Actions Required

The August 25, 2023, FDA release of Final Guidance titled, "Enhanced Drug Distribution Security Requirements Under Section 582(g)(1) of the Federal Food, Drug, and Cosmetic Act," addressing FDA's implementation of certain electronic interoperability provisions of the Drug Supply Chain Security Act (DSCSA), which were due to become effective on November 27, 2023, has been misinterpreted by many as a delay of DSCSA requirements.

Speaking at the August HDA Traceability Seminar in Washington, D.C., Dr. Connie Jung and Dr. Leigh Verbois made clear that all pharmaceutical trading partners need to push forward with progress on DSCSA implementation. The time between November 27, 2023, and the same date in 2024 is a stabilization period: "additional time to implement, troubleshoot, and mature systems and processes while supporting the continued availability of products to patients."

In short, FDA expects all trading partners to make full use of the time remaining in 2023 and 2024 for DSCSA compliance. This stabilization period does not push back the deadline; it grants the time needed to complete implementations that are (or should be) already underway and make sure they work well.

Importantly, State Boards of Pharmacy can still enforce DSCSA requirements, and may undertake audits to ensure that businesses have systems in place as of November 27, 2023.

The presentation made clear that enforcement is ongoing:

- ✓ This is a "stabilization period," not enforcement discretion.
- ✓ All current DSCSA requirements continue as a condition of FDA's non-enforcement.
- ✓ Stopping or slowing efforts to get into compliance with 582(g)(1) puts a trading partner at risk of FDA enforcement.

What should pharmacies have in place today?

Below are some of the items you should have in place. Refer to the FDA website for complete requirements and details. APhA, ASCP, and NCPA have guidance documents on their websites for members. DSCSA solution partners, such as [InfiniTrak](#), will guide you through the compliance process:

- Pharmacies must have written standard operating procedures to ensure compliance with DSCSA and staff training records for the procedure.
- Pharmacies must confirm they are buying from licensed Authorized Trading Partners (ATPs).
- Pharmacies must have a way to verify that a manufacturer made an item with a specific NDC number, lot number, expiration date, and serial number.
- Pharmacies must make sure that the label on each individual saleable package received displays a DSCSA-compliant product identifier including the NDC, lot number, expiration date, and serial number.
- Pharmacies must be able to tell an investigator who they received an item from, and any other dispenser who they sold or loaned product to.
- Pharmacies must respond to information requests from an authorized trading partner, the Food and Drug Administration, or any other appropriate federal or state official within two business days.
- Pharmacies must receive product tracing data, and store that information for at least 6 years, for applicable pharmacy purchases.
- Pharmacies must store information about any suspect or illegitimate product investigations for 6 years from the date of the investigation's conclusion.

- Pharmacies must identify, quarantine, and investigate suspect product to determine if it is illegitimate.
- Pharmacies, when notified that they received suspect or illegitimate product, must respond to the notification and conduct any additional investigation, response, or notification needed.
- Pharmacies must notify the FDA and other trading partners within 24 hours if they have illegitimate product, and quarantine that product.

Resources:

The [Drug Supply Chain Security Act \(DSCSA\)](#) will enhance FDA's ability to help protect consumers from exposure to drugs that may be counterfeit, stolen, contaminated, or otherwise harmful. These requirements will also improve detection and removal of potentially dangerous drugs from the drug supply chain to protect U.S. consumers.

- [DSCSA guidance and policies](#)
- [What do I need to know about supply chain security requirements under the Drug Supply Chain Security Act \(DSCSA\)?](#)
- [Notify FDA of illegitimate product](#)
- [Verify a wholesale drug distributor license](#)
- [Check FDA's wholesale drug distributor and third-party logistics provider annual reporting database](#)

<https://dscsa.pharmacy/resources/>

<https://www.fda.gov/drugs/drug-supply-chain-security-act-dscsa/pharmacists-utilize-dscsa-requirements-protect-your-patients>

https://www.thefdalawblog.com/2023/08/trading-partners-may-exhale-fda-releases-guidance-exercising-a-year-long-period-of-enforcement-discretion-related-to-dscsa-enforcement-of-certain-provisions/?utm_source=rss&utm_medium=rss&utm_campaign=trading-partners-may-exhale-fda-releases-guidance-exercising-a-year-long-period-of-enforcement-discretion-related-to-dscsa-enforcement-of-certain-provisions