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Pharmacy Guide: New FDA Enforcement Delays

New FDA delays & exemptions for DSCSA and how they impact your pharmacy.

SUMMARY

The Drug Supply Chain Security Act was introduced in 2013 with the goal of achieving full compliance with the law by November 27, 2023. Due to delays in connectivity and data integrity, the FDA initiated a stabilization period in August 2023. This stabilization period was designed to allow all stakeholders to establish connections and finalize testing.

Although the stabilization period made a significant impact, it was still not enough to allow the industry to fully comply with the Enhanced Drug Distribution Security at the package level. As of July 2024, the FDA has granted **small dispensers – defined as those pharmacies with 25 or fewer full-time pharmacy staff** - an additional two years to comply with the Electronic Drug Distribution System (EDDS) requirements. This extension postpones the compliance deadline to November 27, 2026. The FDA has provided pharmacies and suppliers the option to request a Waiver, Extension, or Exemption (WEE). If granted, this WEE would provide the trading partner with additional time to finish preparing for this phase of the law.

In July 2024, key industry stakeholders, including the Healthcare Distribution Management Association (HDMA) and the National Association of Boards of Pharmacy (NABP) raised concerns that 25% to 50% of drugs in the supply chain possessed full and accurate serialized data. This, combined with an unexpectedly high volume of WEE submissions, prompted the FDA to **implement yet another enforcement delay. The new exemption provides a gradual, phased approach to compliance with EDDS.**

These **exemptions apply solely to the EDDS requirements** outlined in the law. They **do not alter the existing requirements**. Furthermore, the new exemptions include a stipulation. The pharmacy or supplier **must provide documented proof** that they are **actively working** towards **compliance with EDDS** requirements between now and the new cutoff date.

NEW DATES

The new timeline for DSCSA compliance with EDDS requirements:

Small Dispensers (25 or fewer full-time pharmacists & technicians)	11/27/2026
Large Dispensers (26 or more full-time pharmacists & technicians)	11/27/2025
Manufacturers & Repackagers	5/27/2025
Wholesalers & Distributors	8/27/2025

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CURRENT REQUIREMENTS FOR PHARMACIES NOW:

1. Receive & store transaction data for a minimum of six years.
2. Only accept products that are accompanied by complete and accurate transaction data, which can be in digital or paper format.
3. Only purchase from licensed or registered suppliers.
4. Establish a process to identify, quarantine, investigate, and, if necessary, report any suspect and/or illegitimate products.
5. Physically inspect the product to verify that it includes a product identifier, also known as a 2D barcode.
6. Create a Standard Operating Policy and ensure that the pharmacy understands the importance of DSCSA and their part in protecting the US Pharmaceutical Supply Chain and, more importantly, the patients. Ensure the policy details how the pharmacy will meet the requirements of the DSCSA and ensure the staff is training in the process. It is important to note that inspectors may request to see this policy, and they will be verifying the pharmacy's actions align with the SOP.

HERE IS A LIST OF THE REQUIREMENTS THAT ARE DELAYED:

Enhanced Drug Distribution Security (EDDS), also referred to as Interoperability.

1. All transaction data exchanged between entities in the supply chain must be in an electronic format.
2. Transaction information must include the unique product identifier for each prescription drug product covered under the Drug Supply Chain Security Act (DSCSA), down to the lowest saleable unit for every prescription drug product that is covered under DSCSA.
3. Saleable returns must be accompanied by transaction information and a transaction statement. Please NOTE that some suppliers are now requiring customers to provide transaction data for their saleable returns before accepting the product.
4. The pharmacy is required to have a system in place to verify suspect products. This system must include a process for sending a message to the manufacturer to verify the lot and serial number on the product in question is legitimate.
5. With the implementation of EDDS, transaction history will no longer be a required component of the transaction data. Consequently, pharmacies must establish a method to trace the products from the pharmacy back to the manufacturer. The pharmacy may be required to conduct product tracing at the request of an auditor or other industry regulator and must complete this process within 24 hours.