

# Drug Supply Chain Security Act



## 1 What is DSCSA?

The Drug Supply Chain Security Act (DSCSA) is a law implemented by the FDA to secure the drug supply chain and improve patient safety. It outlines critical steps to build an electronic, interoperable system to identify and trace certain prescription drugs as they are distributed in the United States. The system is designed to facilitate the exchange of information at the individual package level, showing each stop a drug has been at in the supply chain. This is a complex law that continues to bring significant change to the way most pharmacies track and trace their products.

The U.S. Pharmaceutical Drug Supply Chain is in the process of moving to a fully interoperable system with full electronic data exchange. This is changing the landscape for all stakeholders, Manufacturers, Suppliers, and Dispensers. The FDA has announced that it will not enforce this law until November 27, 2024. This enforcement delay is referred to as “Stabilization” period. During this time, all stakeholders are expected to move forward with their plans to implement a DSCSA solution.

Dispensers will need to have a system that provides full DSCSA compliance. This includes the ability to conduct product tracing when requested by other stakeholders within the drug supply chain. Dispensers will also be required to validate that they have received all pharmaceutical drug products that have been ordered and have procedures in place to quarantine products that require additional investigation.

## 2 What are the DSCSA Requirements for Pharmacy Dispensers?

### 1. Transaction Management –

- Receive and store transaction data for a minimum of six years.
- Be sure the pharmacy can quickly retrieve the data if requested.
- Only except prescription drugs if they are accompanied by complete and accurate product tracing documentation.

### 2. License Verification –

- The pharmacy should engage in business only with licensed or registered suppliers.

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## 2 What are the DSCSA Requirements for Pharmacy Dispensers? (continued)

3. Suspect Product Process –
  - The pharmacy must have a method to identify, quarantine, investigate, and if necessary, report suspect and/or illegitimate product.
4. Product Identifier –
  - Physically inspect the product to ensure it has a product identifier, also known as a 2D barcode.
5. Policies & Procedures –
  - Make sure the pharmacy understands the importance of DSCSA and their part in protecting the US Pharmaceutical Supply Chain and more importantly, the patients.
  - Have a policy detailing how the pharmacy will meet the requirements of the DSCSA and ensure the staff is fully trained in the process.
6. Interoperability – Also known as Enhanced Drug Distribution Security (EDDS)
  - All transaction data traveling between entities in the supply chain must be exchanged in an electronic format.
  - Transaction information must include the unique product identifier down to the lowest saleable unit for every prescription drug product that is covered under DSCSA
  - Saleable returns must be accompanied by transaction information and transaction statement.
7. Product Verification & Product Tracing
  - The pharmacy is required to have a system in place to verify suspect product in which a message is sent to the manufacturer to verify the lot and serial number on the product in question is legit.
  - With EDDS, transaction history will no longer be part of the required transaction data therefore the pharmacy must have a method to trace the product from the pharmacy all the way back to the manufacturer.
  - The pharmacy may be required to perform product tracing at the request of an auditor or other industry regulator and must do so within 24 hours.

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## 3 How does DSCSA impact the pharmacy?

The biggest impact on the pharmacy is the day-to-day handling of prescription drugs, primarily the receiving process. Pharmacies need to determine the best procedures for receiving products while minimizing the impact on business workflow, all while maintaining DSCSA compliance. This means:

- Checking every product for a unique product identifier
- Checking that transaction data is provided for every product received & confirming the data matches the product – NDC, description, GTIN, lot, expiration, & serial number
- Inspecting product to identify any suspect product and promptly quarantine the product for further investigation.

## 4 Don't dispensers have two more years before they need to worry about DSCSA?

As the stabilization period ends, the industry has realized that not all stakeholders are fully DSCSA compliant and will be by November 27, 2024. HDMA, NABP, and others stressed the need to allow the dispensers to have additional time to comply with DSCSA regulations. The FDA has granted a two-year extension to small dispensers. They define small dispensers as any pharmacy dispenser with 25 or fewer full-time pharmacists and pharmacy technicians by November 27, 2024. The important thing to note about this extension is that it only delays enforcement of the EDDS phase of DSCSA. This means all the other requirements are in effect and enforceable. For example:

- Pharmacies are still required to receive transaction data for every prescription drug product, store that data for six years, and be able to retrieve it. However, the transaction data does not have to be electronic until November 27, 2026.
- The transaction data must have lot level information, but it is not required to have serialized data for every product.
- Pharmacies must be able to identify and investigate suspect products, but they are not required to perform a product verification or product tracing.



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## Don't dispensers have two more years before they need to worry about DSCSA? (continued)

- The pharmacy may be asked by an industry regulator, or even a potential supplier, to provide a policy and procedures manual, as well as be able to show progress towards full compliance with EDDS.

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## Why does the pharmacy need a solution provider, can't they do DSCSA on their own?

DSCSA can be achieved without the expense of a solution provider, but in the end, it will cost the pharmacy more in expenses. The pharmacy will need to consider the following questions:

- Who will oversee DSCSA compliance?
- How will the pharmacy electronically receive the transaction data and most importantly, interpret the transaction data to allow the staff to reconcile the data and the products.
- What electronic system will be used to store the data and how will it be quickly retrieved?
- Who will be responsible for manually completing a product tracing or product verification, including contacting the manufacturer and each stakeholder who had possession of the product.
- If the pharmacy chooses to use a wholesaler portal to retrieve & store the transaction data, do they have access to a portal for every supplier they purchase from? Who will be responsible for logging into each of these portals and searching for the data every time a purchase arrives or needs to be received?

Once the pharmacy answers these basic questions, look at the cost before moving onto other requirements. Can the pharmacy employ staff whose only job is DSCSA compliance?



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## Why worry about compliance now, can't the pharmacy wait until we get closer to November 27, 2026?

The FDA and industry regulators are looking for progress. The one-year stabilization period and the two-year small dispenser extension are not excuses to stop moving towards compliance. They are simply a way to keep the industry moving towards compliance without hindering the flow of prescription products, which would cause patients to go without lifesaving medication. The Boards of Pharmacy, PBMs, DEA, and other regulatory bodies are still looking for the dispensers to have a plan in place and to be taking steps to put that plan into action. Furthermore, prior to the stabilization period, the industry saw a mass stampede in August of dispensers looking for DSCSA compliance and expecting it to be as simple as flipping a switch. They found out that is not the case. Implementing a DSCSA solution takes time – time to establish connections with all the pharmacy's suppliers, time to train staff, and time to create procedures. Connecting with the suppliers alone is time consuming with some suppliers having a 30-60 day wait list before they can begin working on the connection which then can take up to 7 days to complete.



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