CAPITAL DRUG
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# DSCSA Frequently Asked Questions

**Updated September 6, 2023**

### Q: What is the Drug Supply Chain Security Act (DSCSA)?

The Drug Supply Chain Security Act was enacted in 2013 to protect our supply chain against counterfeit and illegitimate drugs. DSCSA requires Authorized Trading Partners to have an electronic, interoperable system to trace prescription pharmaceutical products at the package level. The law was created to prevent, detect, and respond to suspect and illegitimate products.

### Q: How do the recently released FDA guidance documents impact the implementation of the DSCSA regulations and what are current dispenser requirements?

On November 27, 2023, the DSCSA regulation goes into full effect; however, the FDA will not enforce the electronic interoperable system requirements or verification of saleable returns until November 27, 2024.

Dispenser requirements have not changed. Dispensers must only purchase from an Authorized Training Partner (ATP). They must have processes to identify product, receive and maintain product tracing data, and verify product is legitimate. They must have procedures to identify, quarantine, and investigate suspect product.

### Q: What is an Authorized Trading Partner and how can I verify that my supplier is an ATP?

Under DSCSA, only Authorized Trading Partners (ATP) can sell or buy prescription pharmaceuticals from other Authorized Trading Partners.

Authorized trading partners must meet criteria as defined by the FDA such as:

1. Manufacturers and Repackagers
    - Must have a valid registration with the FDA
    - Accept and transfer direct product ownership
2. Wholesale distributors
    - Must have a valid state license and comply with reporting requirements to the FDA
    - Accept and transfer direct product ownership
3. Dispensers
    - Must have a valid state license
    - Accept and transfer direct product ownership
4. Third Party Logistics Partners (3PLs)
    - Must have a valid state license and comply with reporting requirements to the FDA
    - Take possession of product but not ownership

There are multiple compliance solutions that can help you monitor and maintain your Authorized Trading Partners. Without a compliance solution, you can still validate licenses by using websites such as State Boards of Pharmacy, the FDA, and NABP.

### Q: What is a Product Identifier?

A product identifier must be on every saleable unit label and include:

1. Serial number
2. NDC
3. Lot number
4. Expiration date

This information can be found in the format of a 2D bar code and human readable label.

### Q: What is on a current traceability statement? When will these requirements change?

A current traceability statement, or T3, has been required since 2015 and contains transaction history, transaction information, and the transaction statement. This information can be provided in paper format or with an advanced ship notice (ASN). Since the FDA has provided delayed enforcement, ASNs and T3 documents will be acceptable compliance documents until November 27, 2023.

After that time, the transaction history will no longer be required and Authorized Trading Partners must exchange data electronically including product serial numbers with each transaction.

### Q: What is an ASN?

Advance Ship Notice is an electronic data interchange (EDI) message sent from the shipper to the receiver prior to the departure of the shipment from the shipper's facility. The message includes complete information about the shipment and its contents. Information contained within the ASN includes a description of the medication being shipped such as NDC, lot number and expiration date.

### Q: What is EPCIS and how does it relate to traceability statements?

EPCIS or Electronic Product Code Information Services will be the standard for tracing medications electronically. The data includes product identifiers (serial numbers, name, strength, container size, GLN information) that will follow the medications and track the ownership and physical location of the medication throughout the supply chain.

Electronic Drug Distribution Security (EDDS) will be enforced beginning November 27, 2024 and will require data be exchanged in a secure, electronic, and interoperable format. The FDA recommends using the EPCIS format to achieve this requirement.

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**Q: What is a global location number (GLN) and why is a dispenser required to have one**?

A Global Location Number is assigned to a pharmacy based on the United States postal address. The GLN is necessary to exchange EPCIS data and is used to identify ownership and location of products.

**Q: How does a pharmacy obtain a GLN?**

A GLN is assigned by GS1. At this time, most dispensers have been assigned a GLN as part of a managed GLN program where pharmacies were assigned a GLN by their primary wholesaler. Check with your primary wholesaler to verify if you were assigned a GLN. If you do not have a GLN, go to GS1us.org store to purchase a GLN for $30. GS1 Store - GLN

Review GS1 US - How to Identify your Location for DSCSA Requirements for more information.

**Q: How can I look up a GLN?**

A GLN can be looked up for a specific customer by going to GEPIR.gs1.org then search by party name (or by current GLN if you are trying to verify your GLN). If the dispenser has a common name, you can expand the search function to include a specific address by clicking on show option fields. Search by Party Name | GEPIR (gs1.org)

**Q: What is interoperability tracing?**

Tracing data must follow the medications throughout the supply chain. Starting with medications shipping between ATPs from the manufacturers to wholesaler to a dispenser. The ability to track the medications upstream and downstream is the interoperability required to meet the DSCSA regulations.

**Q: Third Party Solution Providers: what are they?**

Third party DSCSA solution providers are companies that will help dispensers manage the DSCSA compliance regulations by monitoring traceability documents. There are a variety of these companies contacting dispensers to sell their solution (scanners, software systems, repositories, etc.).