Small Dispensers and the 6/12/2024 FDA Announcement Concerning DSCSA

The DSCSA Adventure continues. On June 12, 2024, the FDA released a notice stating that it is issuing exemptions from specific requirements of the Drug Supply Chain Security Act (DSCSA) to small dispensers (pharmacies) to go into effect on 11/27/2024 to ensure patient access. The exemption will last until November 27, 2026, for those small dispensers who qualify. Before getting into who qualifies as a small dispenser and what areas of DSCSA are covered by the exemption, we want to discuss what is not covered by the exemption since the vast majority of the regulations are in effect today and will continue to be in effect. These existing requirements also take up most of the time spent on DSCSA Compliance. Although the exempted requirements simplify and streamline compliance, they require process changes and additional software.

What Do All Pharmacies Still Need to be Compliant With?

The unfortunate news is that most of the regulations are still in effect, and all small dispensers need to follow these existing compliance requirements to ensure the safety and security of the drug supply chain. ***Most of the existing requirements have been in place since 2015 and require Pharmacies to have SOPs, Training, and data storage (or agreements with their ATPs in place) to maintain the required transaction data.***

The four requirements below are handled in various ways. It can be done manually with some pharmacies, usually those with only one or two trading partners. Complying becomes more daunting for pharmacies with two or more trading partners. In many cases, the requirements below are handled by a DSCSA Software Service Provider that, in addition to ensuring compliance with the below requirements, also ensures compliance with the exemptible requirements.

1. **Trading Partners**

   All products ordered by the Pharmacies must be ordered and received from authorized trading partners (wholesalers and manufacturers).

   To be authorized:

   - A Wholesaler must be licensed in the state where the receiving Pharmacy resides
   - A Manufacturer must be registered with the FDA
   - DEA Permit for ATPs you order controlled substances from

   Pharmacies should ensure they receive, maintain, and update these documents as necessary to continue ordering from their ATP and be ready to provide copies of them upon request.

2. **Identifiers**

   All products received must contain a product identifier. This is no big deal; you need to make sure that when you receive the product from your trading partner, it includes the product identifier (NDC (or GTIN), Serial Number, Lot Number, Expiration Date) in a human as well as machine-readable format (2D barcode) on the manufacturer label.

3. **Product Tracing**

   All products covered by DSCSA must be accompanied by the 3Ts (transaction information, transaction statement, and transaction history). The 3Ts must be received before or during product delivery and match the information on the physical product. The 3Ts can be in any format (paper, pdf, email), provided the required contents are all present. At this point, every Pharmacy must maintain and have access to the 3Ts of all DSCSA Covered products for the past six years.

   If the Pharmacy returns products to the ATP they purchased from, the 3Ts do not need to be provided. You will also not need to give the 3Ts if you are "returning" non-salable products to an ATP.

   If the FDA or another regulator requests DSCSA transaction data, the DSCSA regulations give you up to 48 hours to respond.

4. **Verification**

   The Pharmacy must review all products and transaction data coming into the Pharmacy to ensure they are not suspect or illegitimate, including counterfeit, diverted, stolen, resulting from a fraudulent transaction, or unfit for distribution. If you believe a product is suspect, you must work with your ATPs (and manufacturer) to investigate and determine if it is legitimate.

   All suspect products should be investigated, and the Pharmacy must notify the FDA and ATPs within 24 hours if they are illegitimate.

Not All Pharmacies Can Exempt from The 11/27/2024 DSCSA Requirements.

For the purposes of these exemptions,- a dispenser is considered a small dispenser if, as of November 27, 2024, the company that owns the dispenser has 25 or fewer full-time employees (FTEs) licensed as pharmacists or qualified as pharmacy technicians.

The IRS defines a *full-time employee* as, for a calendar month, an employee employed on average at least 30 hours of service per week or 130 hours of service per month. For additional information on identifying full-time employees, see https://www.irs.gov/affordable-care-act/employers/identifying-full-time-employees.

Now the question, what is a qualified Technician? If we look at the PREP Act (we all remember the COVID days), a qualified pharmacy technician meets one of these definitions:

- Pharmacy technicians working in ***states with licensure and/or registration requirements*** must be licensed and/or registered in accordance with state requirements; or
- Pharmacy technicians working in ***states without licensure and/or registration requirements*** must have a Certified Pharmacy Technician (CPhT) certification from either the Pharmacy Technician Certification Board or National Healthcareer Association.

We need more clarity here to see if this is what the FDA is planning.

If I Choose to be Exempt, What Am I Exempt From?

This exemption does not apply to the current DSCSA requirements described above; it only covers the sections of the law that were to be enforceable on 11/27/2024, specifically the Enhanced Drug Distribution Security (EDDS) and part of the Verification section.

Enhanced Drug Distribution Security

The main area you are exempting from is Enhanced Drug Distribution Security (EDDS), which became enforceable on 11/27/2024. The EDDS Requirements are:

- Receiving the Transaction Data in a secure, electronic, and interoperable format
- Ensuring the product identifier is included in the transaction Information
- Using the Product identifier when conducting verification activities between ATPs
- Responding to the FDA within 24 hours of a request for information
- Utilizing systems to be able to gather information to produce the transaction information promptly

Verification (down to the Product Identifier)

The last exemption area covers part of the verification section of the regulations, which requires you to use the product identifier when investigating suspect products. While the product identifier on the package will still be used during investigations, you may not be able to connect the physical product to the transaction information since the product identifier may not be contained within the transaction information.

Notification

If you choose to accept the exemption, the FDA recommends communicating this decision to your trading partners as needed to further facilitate the distribution of products without difficulty or delay.

What if I do not qualify for the exemption?

If you do not qualify for the small dispenser exemptions and cannot meet the EDDS requirements of section DSCSA by 11/27/2024, you may request a waiver or exemption from those requirements. Although requests can be submitted anytime, the FDA recommends that trading partners submit a waiver or an exemption request by 8/1/2024. The FDA expects continued compliance with the DSCSA requirements until the FDA has approved or denied the request.

What should I be using this time for?

The FDA was clear: You should use this time to implement, troubleshoot, and mature systems and processes to fully implement the Drug Supply Chain Security Act (DSCSA) Enhanced Drug Distribution Security requirements. Additionally, they strongly urge small dispensers to continue their efforts to implement necessary measures to satisfy these Enhanced Drug Distribution Security requirements. So, this exemption should not be a reason to delay your compliance. Pharmacies must continue utilizing and updating their SOPs and receiving, reviewing, and maintaining all their transaction data from their ATPs

or contracting with a DSCSA Software Service Provider to simplify the data handling requirements of existing DSCSA Requirements and the EDDS.

Who will be enforcing DSCSA Compliance?

The short answer: compliance is required by federal and state law. However, the PBMs (doing what PBMs do) and other entities also require DSCSA compliance (or contain wording requiring compliance with all federal and state laws in their contracts). PRS member Pharmacies have notified us of requests over the past eight years or so for DSCSA-related SOPs and documents covering the four existing requirements as well as copies or proof of ATP licensure from:

- FDA
- State Boards of Pharmacy
- PBMs
- Accreditation Organizations

Conclusion

While the exemption, effective from November 27, 2024, to November 27, 2026, offers some relief by temporarily removing specific requirements, it is important to recognize that most DSCSA regulations remain in full effect. Small Dispenser Pharmacies must continue to adhere to existing standards to maintain the integrity and safety of the drug supply chain, including managing trading partner documentation, product identifiers, transaction data, and verification processes. The exempted requirements aim to provide small dispensers the time and flexibility to adopt and refine systems and processes necessary for future compliance. However, small dispensers must use this period proactively to ensure full compliance with Enhanced Drug Distribution Security requirements by the exemption's end.

The PRS DRUGSUPPLY*Track™* and Advasur 360™ have been combined to create DSCSA 360™ to ensure your Pharmacy has the tools to be compliant today and into the future. If you have any questions about DSCSA, please do not hesitate to call us at 1-800-338-3688.

DSCSA service and solution leaders Advasur and PRS stand ready to serve dispenser pharmacies for full compliance with current and future DSCSA requirements with minimal disruption to business workflow operations and patient care.

Links

Exemptions from certain requirements under section 582 of the FD&C Act for small dispensers (Notice)

Waivers and Exemptions Beyond the Stabilization Period (website)