

PROTECT YOUR PATIENTS

Know your responsibilities under the Drug Supply Chain Security Act

The Drug Supply Chain Security Act (DSCSA) includes requirements that pharmacies must follow to protect patients from receiving harmful drugs, such as counterfeit or other illegitimate drugs.

The DSCSA was enacted in 2013 to further secure our nation's drug supply. It creates a tighter, closed prescription drug distribution system to **prevent** harmful drugs from entering the supply chain, **detect** harmful drugs if they do enter the supply chain, and enable rapid **response** when such drugs are found.

By law, pharmacies are required to:



Confirm the entities you do business with are licensed or registered

To help determine whether trading partners who you do business with (manufacturing, repackagers, wholesale distributors, third-party logistics providers, and pharmacies) are licensed or registered:



Check the registration of manufacturers and repackagers. See FDA's drug establishments current registration site database to confirm registration. You can find this database by searching for DECERS at www.fda.gov.



Check the licensing of wholesale distributors and third-party logistics providers. See FDA's wholesale drug distributor and third-party logistics providers reporting database. You can find this by searching for WDD/3PL database at www.fda.gov.

Check the licensing of pharmacies through the respective state authority.



Receive, store, and provide product tracing documentation

The law requires drugs to be traced as they move through the supply chain, and pharmacies must:

- Only accept prescription drugs that are accompanied by three pieces of product tracing documentation – transaction information, transaction history, and transaction statement. If the trading partner you purchased the drugs from does not provide all this documentation, work with them to promptly get it.
- Store the product tracing documentation you receive in paper or electronic format for six years.
- Generate and provide all product tracing documentation with the transaction if you sell a prescription drug to a trading partner. You do not need to provide this information when you dispense a prescription drug to a patient or if you sell to a pharmacy for dispensing to a specific patient.



Investigate and properly handle suspect and illegitimate drugs

Pharmacies must have a process to investigate and handle suspect and illegitimate prescription drugs, which includes drugs that may be or have evidence that it is counterfeit, diverted, stolen, intentionally adulterated, or unfit for distribution, including steps to:

- Quarantine and investigate suspect prescription drugs to determine if they are illegitimate; and
- If they are illegitimate, pharmacies should work with the manufacturer and take specific steps to ensure patients do not receive the illegitimate drugs. Pharmacies must also notify FDA and the trading partners they bought the drug from and sold the drug to. You can find more information by searching "drug notifications" at www.FDA.gov.

This information is only a summary of the DSCSA pharmacy requirements and is not a comprehensive list. Go to www.fda.gov to learn more about DSCSA, including the law and FDA's policies. You'll easily find information by searching "DSCSA."

Email us at drugtrackandtrace@fda.hhs.gov for more information.