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NEW JERSEY STATE BOARD OF PHARMACY

newsletter to promote pharmacy and drug law compliance

DSCSA: Know the Rules!

The Drug Supply Chain Security Act (DSCSA) (Title II of Public Law 113-54) amended the Federal Food, Drug, and Cosmetic Act to establish requirements for product tracing, verification, and product identification for certain drug products that are distributed in the United States.

The following are the major provisions of the DSCSA. These provisions apply to manufacturers, repackagers, wholesale distributors, dispensers (primarily pharmacies), and third-party logistics providers (3PLs) as noted below:

- Product identification: Manufacturers and repackagers will be required to put a unique product identifier on certain prescription drug packages, for example, using a barcode that can be easily read electronically.
- Product tracing: Manufacturers, wholesale drug distributors, repackagers, and many dispensers (primarily pharmacies) in the drug supply chain will be required to provide information about a drug and who handled it each time it is sold in the US market.
- Product verification: Manufacturers, wholesale drug distributors, repackagers, and many dispensers (primarily pharmacies) need to establish systems and processes to be able to verify the product identifier on certain prescription drug packages.
- Detection and response: Manufacturers, wholesale drug distributors, repackagers, and many dispensers (primarily pharmacies) must quarantine and promptly

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investigate a drug that has been identified as suspect, meaning that it may be counterfeit, unapproved, or potentially dangerous.

- Notification: Manufacturers, wholesale drug distributors, repackagers, and many dispensers (primarily pharmacies) must establish systems and processes to notify Food and Drug Administration (FDA) and other stakeholders if an illegitimate drug is found.
- Wholesaler licensing: Wholesale drug distributors must report their licensing status and contact information to FDA. This information will then be made available in a public database.
- 3PL licensing: 3PLs, those who provide storage and logistical operations related to drug distribution, need to obtain a state or federal license.

Advice for Pharmacists and Pharmacy Technicians

The DSCSA defines a dispenser as:

> (A) a retail pharmacy, hospital pharmacy, a group of chain pharmacies under common ownership and control that do not act as a wholesale distributor, or any other person authorized by law to dispense or administer prescription drugs, and the affiliated warehouses or distribution centers of such entities under common ownership and control that do not act as a wholesale distributor; and (B) does not include a person who dispenses only products to be used in animals in accordance with section 512(a)(5).

- Confirm that the entities you do business with are licensed or registered.
    - To help determine whether trading partners who you do business with (manufacturers, repackagers, wholesale distributors, 3PLs, and pharmacies) are licensed or registered:
        - check the registration of manufacturers and repackagers;
        - check the licensing of wholesale distributors and 3PLs; and/or
        - 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 – the transaction information (TI), the transaction history, and the transaction statement (TS). 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 they are counterfeit, diverted, stolen, intentionally adulterated, or unfit for distribution, including steps to quarantine and investigate suspect prescription drugs to determine if they are illegitimate.
        - Pharmacies should work with the manufacturer and take specific steps to ensure that patients do not receive the illegitimate drugs.
        - Pharmacies must also notify FDA and the trading partners of the source of the drug purchased and sold.

New Responsibilities for 2023

FDA has delayed enforcement of certain DSCSA requirements until November 27, 2024. By November 2023, pharmacists should ensure that their organization has policies and procedures in place that allow for unit-level traceability under the DSCSA, including:

- ensuring that all required TI and TS are exchanged between trading partners via a secure, interoperable, electronic system;
- checking for inclusion of a package identifier to identify the prescription pharmaceutical product at the package level;
- verifying the product identifier on a package or sealed case by the trading partners via a secure, interoperable, electronic system;
- ensuring that trading partners can provide TI and TS via a secure, interoperable, electronic system when requested by authorized agents;
- ensuring that secure, interoperable, electronic systems allow for the prompt production of TI for each transaction going back to the manufacturer; and
- addressing saleable returns by ensuring that secure, interoperable, electronic systems are in place and the TI and TS are returned with the product.

References

1. *https://www.fda.gov/drugs/drug-supply-chain-security-act-dscsa/what-do-i-need-know-about-supply-chain-security-requirements-under-drug-supply-chain-security-act*

2. *https://www.govinfo.gov/content/pkg/PLAW-113publ54/pdf/PLAW-113publ54.pdf*
3. *https://www.fda.gov/drugs/drug-supply-chain-security-act-dscsa/drug-supply-chain-security-act-law-and-policies*
4. *https://www.ashp.org/-/media/assets/pharmacy-practice/resource-centers/drug-supply-chain/docs/ASHP-Drug-Supply-Chain-and-Security-Act-Requirements.pdf*
5. *https://www.fda.gov/drugs/drug-supply-chain-security-act-dscsa/pharmacists-utilize-dscsa-requirements-protect-your-patients*

Closed for Business

There are rules regarding temporarily closing and permanently closing a pharmacy. New Jersey Administrative Code (N.J.A.C.) 13:39-4.12 Business hours; unauthorized closing explains the regulations regarding an expected or unauthorized closing of a pharmacy:

> (a) All pharmacies shall be kept open for the transaction of business at least 40 hours per week and at least five days per week.
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> (b) If any permanent changes are made in the opening or closing hours of a pharmacy, the Board office shall be notified in writing of these changes **within 30 days.**
>
> (c) A notice shall be conspicuously displayed on the exterior of any pharmacy indicating any temporary changes in the opening or closing hours of the pharmacy, or indicating a temporary closing of the pharmacy whenever such changes occur.
>
> (d) Any temporary closing of a pharmacy for **more than 48 hours shall be reported to and approved by the Board.** Notification to the Board shall include contingency plans for accessing patient records. Any temporary closing of more than 48 hours without prior Board approval shall result in the pharmacy being **deemed a discontinued pharmacy** requiring compliance with the requirements of N.J.A.C. 13:39-4.10 and 4.11. (emphasis added)

Now that your pharmacy is discontinued, what should you do? See 13:39-4.10 Discontinued pharmacies for details:

> (a) Whenever a pharmacy is to be discontinued and closed for any reason, including suspension or retirement of the permit holder, sale or insolvency, the permit holder shall immediately send written notification of the anticipated closing to the State Board of Pharmacy, the Office of Drug Control and the Drug Enforcement Administration **at least 15 days prior** to the anticipated closing date. Whenever a pharmacy is to be discontinued and closed as a result of an unanticipated occurrence, such as the death of the permit holder, the permit holder's representative shall send written notification to the Board, the Office of Drug Control and the Drug Enforcement Administration, as soon as possible prior to the actual closing date. All medications,

including prescription legend and controlled drugs, should be transferred to the holder of a current pharmacy permit; a wholesaler; a reverse distributor; and/or a manufacturer. All medications not properly transferred shall remain on the pharmacy premises with all licenses and registrations in effect until such medications are disposed of in the manner prescribed by the Board, the Office of Drug Control and/or the Drug Enforcement Administration.

(b) Within 30 days of closing a pharmacy pursuant to (a) above, the permit holder or his or her representative shall remove all drug signs from both the inside and outside of the discontinued pharmacy and shall notify the Board in writing of the location of the **previous five years of prescription and patient profile records** . . . The permit holder or his or her representative shall return the permit to the Board for cancellation **within 30 days of the closing.** (emphasis added)

Please note, prescription records and other information may be requested by the New Jersey State Board of Pharmacy.

After a pharmacy is discontinued or closes, what should happen to the pharmacy records? See N.J.A.C. 13:39-4.11 Availability of records upon termination of business or change of ownership for complete details:

(a) When a pharmacy ceases operation as the result of a suspension, retirement, or death of the owner, sale, or other cause including insolvency, the permit holder, or the one responsible for supervising the disposition of the practice, shall make every effort to notify patrons that they have the right to obtain copies of currently valid prescriptions and/or copies of their patient profile and the location of the prescriptions and patient profile for a one-year period following notice, using all of the following methods:

1. Notification in writing to the Board;

2. Publication, once weekly for two successive weeks in a newspaper whose circulation encompasses the geographic area in which the pharmacy is located, of a notice advising patrons that they have the right to obtain copies of their prescriptions and/or patient profile, and the location of the prescriptions and patient profile for a one-year period following publication;

3. A sign placed in the pharmacy location informing the patrons that they have the right to obtain copies of their prescriptions and/or patient profile, and the location of the prescriptions and patient profile; and

4. For a permitted pharmacy that uses social media that is specific to individually identified locations, the pharmacy shall post notice on all social media platforms used by the pharmacy informing patrons of the pharmacy closure, that they have a

right to obtain copies of their prescriptions and/or patient profile, and the location of the prescriptions and patient profile. The pharmacy shall also discontinue and remove all commercial advertising from social media sites.

(b) Upon a sale of assets or a change in ownership . . . both the new and former pharmacy permit holders shall ensure that there is access to patient prescription and profile records **within 24 hours** of the transfer of business assets, and that all telephone calls to the former pharmacy shall be forwarded to the new pharmacy. (emphasis added)

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