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Pharmacy Guide to Compliance

An Overview of Three Federal Laws Central to Pharmacy Compliance

The "ABCs" of Pharmacy Compliance

A. B. C. D. E. F.

Always **B**e **C**ompliant: **D**EA. **E**PA. **F**DA.

As a pharmacy professional, you operate a facility that plays a pivotal role in the nation's drug supply chain: dispensing medications to the public. It almost goes without saying that pharmacy is a highly regulated business.

Among the many regulations—state and federal—that govern the business activities of your pharmacy, are three critical laws pertaining to the safety and security of both the general public and industry professionals. **These laws govern almost every aspect of a pharmacy's business, so compliance is of the utmost importance.**

These laws pertain to: the security of the **drug supply chain**, the regulation and security of **controlled substances**, and the management of **pharmaceutical hazardous waste**—and are enforced by the FDA, DEA, and EPA, respectively.

FDA

Drug Supply Chain Security Act (DSCSA): The DSCSA was enacted to protect the security of the nation's drug supply chain. It ensures that the drugs that are made available to consumers are legitimate, uncontaminated, and safe.1[1]

DEA

Controlled Substance Act (CSA): The CSA sets up regulations for tracking and securing controlled substances to ensure that they don't "fall into the wrong hands," thereby protecting the public by keeping dangerous controlled substances off the streets.[2]

EPA

Resource Conservation and Recovery Act (RCRA): The RCRA provides regulations for tracking, transporting, and safely disposing of pharmaceutical hazardous waste in a way that minimizes negative environmental and human impact.[3]

FDA | The Drug Supply Chain Security Act (DSCSA)

Enacted in 2013 and enforced by the FDA, the Drug Supply Chain Security Act ensures the safety and security of the US drug supply. It provides requirements and processes that pharmacies must follow in order to protect patients from receiving harmful or dangerous drugs.[1]

Know your responsibilities under the DSCSA

By law, your pharmacy is required to do the following:[1]

Confirm licensing and registration

Confirm that the entities you work with are licensed with the FDA. In particular, this applies to all manufacturers, repackagers, wholesale distributors, and third-party logistics providers with whom you conduct business.

Store product tracing documentation

For public safety, drugs must be traced as they move through the supply chain. Therefore, for every prescription drug it receives, a pharmacy must obtain and store product tracing documentation including: transaction information, transaction history, and transaction statement.

Properly respond to suspect and illegitimate drugs

Establish and follow a process to investigate and handle suspect and illegitimate prescription drugs. These include drugs that are or show evidence of being counterfeit, diverted or stolen, intentionally adulterated, or otherwise unsafe for distribution.

DEA | The Controlled Substance Act (CSA)

The handling, storage, and distribution of controlled substances in the custody of your pharmacy is regulated by the DEA and the Controlled Substances Act (CSA). The CSA provides regulations for controlled substances pertaining to:[2]

Transfer & Disposal[2]

Your pharmacy may hire an outside firm to help with inventory, packaging, transfer, or disposal of controlled substances in its custody. Your pharmacy is responsible for every transfer and for accurate inventory and records pertaining to each transfer. For disposal, your pharmacy may use a DEA registered reverse distributor that performs disposal of controlled substances.

Security

Physical Safeguards[4]
To prevent diversion, your pharmacy is responsible for ensuring adequate physical security of the controlled substances in its custody. This typically means storage within a securely locked, heavy-duty cabinet, safe, or vault.

According to the DEA, the following factors are used to evaluate whether controlled substances are adequately secured:

- **Quantity of controlled substances on-hand in your pharmacy's inventory**
- **Number of employees or customers with potential access to the controlled substances**
- **Presence of an effective alarm system**
- **Prior instances of diversion or theft**
- **Location of your pharmacy (high vs low crime area)**

Theft or Loss[2]
In the unfortunate event of theft or significant loss of any controlled substance—such as an "in-transit loss" during shipment—your pharmacy (or the entity with current legal custody of the controlled substances) must do the following within one business day of the discovery of the theft or loss:

1. **Notify DEA and local police**
2. **Complete DEA Form 106** (Report of Theft or Loss of Controlled Substances) to document the specific circumstances of the theft or loss of controlled substances

DEA | The Controlled Substance Act (continued)

Record-Keeping: Required Records[2]

Your pharmacy must maintain complete, accurate, up-to-date records for every controlled substance purchased, received, stored, distributed, dispensed, disposed of, or otherwise passing through your pharmacy.

Among the records required are: **order forms** (DEA Form 222); full and complete **inventory records** of all controlled substances; records of all controlled substances distributed (i.e. sales, returns, and transfers) or dispensed; reports of any **thefts or significant loss** of controlled substances (DEA Form 106); DEA registration certificate; and **prescription records** for all drugs dispensed.

Inventory[2]

By law, your pharmacy must always maintain complete and accurate inventory records accounting for all controlled substances in your custody. Inventory records must be maintained for a minimum of two years, be readily available for inspection by the DEA, and must include the following:

- **Initial inventory:** A physical count of all controlled substances in your pharmacy's possession
- **Biennial inventory:** An inventory taken every two years
- **Newly scheduled controlled substance inventory:** Drugs that are newly scheduled as controlled substances or drugs that are rescheduled to a new category must be inventoried as of the effective date of scheduling or change in scheduling

Prescription[2]

Your pharmacy may only dispense controlled substances upon receipt of a valid prescription from a licensed medical practitioner. This practitioner maintains liability for the legality and safety of the prescription.

Prescriptions must be signed and dated on the date issued and must include: the full name and address of both the **patient** and the **practitioner**; the **practitioner's DEA number**; along with the **drug information**—name, strength, dosage form, quantity prescribed, directions for use, and number of authorized refills.

Ordering[2]

To order a schedule II controlled substance, an official DEA 222 order form must be used. This form is also required for each distribution, purchase, or transfer of a schedule II controlled substance.

Schedule III-V controlled substances do not require DEA Form 222 for ordering, but detailed receipts (invoices, or packing slips) must be kept that record the date of receipt of each substance and provide confirmation of order accuracy.

Dispensing Requirements[2]

When dispensing prescriptions for controlled substances, your pharmacy must include a label on the package with: **filling date** for the prescription, **pharmacy** name/address, prescription **serial number**, the names of the **patient** and prescribing **practitioner**, directions for use—as well as any cautionary statements as required by law under the FDA.

Schedule II drugs may only be dispensed upon receipt of a written prescription from the practitioner, whereas schedule III-V drugs may be dispensed with a written, faxed, electronic, or oral prescription from a practitioner.

EPA | The Resource Conservation Recovery Act (RCRA)

Due to the discovery of pharmaceuticals in surface, ground, and drinking water sources around the country, there are rising concerns about the dangers of waste pharmaceuticals in the environment. As a result, there is a large responsibility—and an urgent need—for pharmacies and other participants in the drug supply chain to properly manage and dispose of pharmaceutical waste.[5]

Under the Resource Conservation and Recovery Act (RCRA), enforced by the EPA, a pharmacy is considered a generator of hazardous waste, and maintains responsibility for identifying, safely handling, and coordinating disposal of hazardous waste products in its custody.[3]

Steps for Compliance with Hazardous Waste Regulations

Through the RCRA, the EPA regulates hazardous waste from "cradle to grave" i.e. from the time the waste is created, all the way through transport, treatment, storage, and disposal.[5]

Following are the six important steps your pharmacy must follow in order to maintain compliance with EPA regulations:[3]

1 Identify

Identify each item of hazardous waste generated by your hospital. Generally speaking, pharmacies may stock anywhere from 2000 to 4000 drugs in their inventory:

- About 5% (~200) of these drugs are subject to the hazardous waste regulations of the RCRA
- About 10% of these drugs should be regarded and managed as hazardous waste as part of standard best practices

2 Count

EPA regulations under the RCRA vary significantly depending on the amount of waste your pharmacy generates:

Calculate the total weight of all hazardous waste that falls under the regulations of the RCRA. From this, determine which of the following three generator categories applies to your pharmacy:

Very Small Quantity Generators (VSQGs)	Small Quantity Generator (SQG)	Large Quantity Generator (LQG)
Generates one of the following per month: • 100 kilograms or less of hazardous waste • 1 kilogram or less of acutely hazardous waste • < 100 kilograms of acute spill residue or soil	Generates between 100 to 1000 kilograms of hazardous waste per month	*Generates one of the following per month:* • 1000 kilograms (~2200 lbs) or more of hazardous waste • > 1 kilogram of acutely hazardous waste • > 100 kilograms of acute spill residue or soil

3 Notify

Large and Small Quantity Generators must notify the EPA or the applicable state agency of their production of hazardous waste. In some states, Very Small Quantity Generators are required to notify as well.

4 Manage

Manage the hazardous waste your pharmacy generates in accordance with the regulations for your generator category. For example, depending on your category, there are limits to the amount of waste your facility is permitted to "accumulate" onsite without a permit—and the amount of time you can store this waste at your facility.

5 Transport

All of the hazardous waste your pharmacy generates must be tracked from your pharmacy's location to the waste management facility that will ultimately dispose of it. Therefore, a manifest is required whenever your pharmacy transports hazardous waste off site.

6 Recycle, Treat, Dispose

Small and Large Quantity Generators are permitted to recycle hazardous waste onsite without a permit as long as they comply with regulations regarding the accumulation of onsite waste. Generally speaking, treatment and disposal of hazardous waste must be handled by an appropriate EPA-licensed Treatment, Storage, and Disposal Facility (TSDF).

EPA | The Resource Conservation Recovery Act (continued)

Is your pharmacy a Conditionally Exempt Small Quantity Generator (CESQG)?

If your pharmacy generates less than 100 kg (220 lbs) of hazardous waste per month, then you qualify as a Conditionally Exempt Small Quantity Generator (CESQG). Your facility is exempt from the full hazardous waste regulations that must be followed by facilities generating larger quantities of waste. To maintain your exemption, you simply need to meet three specific waste management requirements:[6]

1. Identify

Follow the EPA-mandated process for identifying all of the hazardous waste you generate.

2. Restrict

Do not store more than 1000 kg (2200 lbs) of hazardous waste onsite at your facility at any time.

3. Recycle / Treat / Dispose

Arrange delivery of your hazardous waste to an appropriate licensed Treatment, Storage, and Disposal Facility (TSDF). If you treat or dispose of waste onsite, your facility must be licensed as a TSDF.

References

1. Drug Supply Chain Security Act Poster
2. Pharmacist's Manual: An Informational Outline of the Controlled Substances Act
3. Steps in Complying with Regulations for Hazardous Waste
4. Controlled Substances Security Manual: Security Requirements For Practitioners
5. Managing Pharmaceutical Waste: A 10-Step Blueprint for Healthcare Facilities in the United States
6. Overview of Requirements for Conditionally Exempt Small Quantity Generators

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