



Hospital Pharmacy Guide to Compliance

An Overview of Pharmacy Compliance in the Hospital Setting



The “ABCs” of Hospital Pharmacy Compliance

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

Always Be Compliant: DEA. EPA. FDA.



As a hospital management professional with stewardship over a pharmacy, you operate a facility that plays a pivotal role in patient care. It almost goes without saying that, in the hospital setting, pharmacy is a highly regulated function.

Among the many regulations—state and federal—that govern hospital pharmacies, are three critical laws pertaining to the safety and security of patients, hospital staff, and the general public. **These laws govern almost every aspect of a pharmacy’s operations, 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, ensuring that the drugs that are dispensed to patients are legitimate, uncontaminated, and safe.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



Note: Due to their size, the number of drugs they store and dispense, and the large amount of waste produced, hospitals and their associated pharmacies are often at risk for noncompliance in managing controlled substances and pharmaceutical hazardous waste. These areas must be given particular care.^{4,5}



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 hospitals must follow to protect patients from receiving harmful or dangerous drugs.¹

Know your responsibilities under the DSCSA

By law, your hospital is required to do the following:^{1,6}

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 your hospital conducts business.

Store product tracing documentation



For public safety, drugs must be traced as they move through the supply chain. Therefore, for every prescription drug purchased and stocked, a hospital must obtain and store product tracing documentation: *Transaction History*, *Transaction Information*, and *Transaction Statement*—known collectively as “T3.”

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)

Due to their size and the volume of drugs on hand, the risk for controlled substance diversion within a hospital is high. Diversion—when healthcare workers obtain and use drugs outside of appropriate prescription purposes—occurs when drugs are stolen from the inventory of a hospital's pharmacy.²

Because of this, the DEA maintains the responsibility of ensuring that controlled substances are used only for legitimate medical purposes and are handled only by licensed personnel legally authorized to distribute, transport, and dispense them.²

The handling, storage, and distribution of controlled substances in the custody of your hospital's pharmacy is regulated by the DEA via the Controlled Substances Act (CSA) as well as by local and state laws and regulations.²

The CSA provides regulations for controlled substances pertaining to:

The infographic consists of a blue horizontal bar with four white circular icons on a dark blue background. From left to right: a padlock icon labeled 'Security', a document icon labeled 'Inventory & Record-Keeping', a hand holding a pill icon labeled 'Dispensing', and a trash can icon labeled 'Transfer & Disposal'. To the right of this bar is a light green box containing a warning icon (exclamation mark in a triangle) and the text: 'Note: Prescription drug abuse currently affects more than six million Americans, more than the number abusing illicit drugs like cocaine, heroin, hallucinogens, and inhalants—combined.'²

Security & Monitoring: Preventing Controlled Substance Diversion^{7,8}

Physical Safeguards⁷

To prevent diversion, your hospital's 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.

The DEA uses the following factors to evaluate whether controlled substances are adequately secured:

- **Quantity of controlled substances on-hand in your pharmacy's inventory**
- **Number of hospital employees or patients with potential access to the controlled substances**
- **Presence of an effective alarm system**
- **Prior instances of diversion or theft**

Theft or Loss⁸

In the unfortunate event of theft or significant loss of any controlled substance—such as an “in-transit loss” during shipment—your hospital (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)



Inventory & Record-keeping^{2, 8}

By law, your hospital must always maintain complete and accurate inventory records accounting for all controlled substances in your custody. These 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

Dispensing Requirements: Use of Hospital's DEA Registration Number²

A hospital pharmacy may only dispense controlled substances upon receipt of a valid prescription from a licensed medical practitioner who is an employee or agent of the hospital, acting under the hospital's DEA registration.

The prescribing practitioner maintains liability for the legality and safety of the prescription, as does the hospital pharmacist who fills the prescription.

Transfer & Disposal²

Your hospital may hire an outside firm to help with disposal of expired, damaged or unsalable controlled substances in your custody. Your facility is responsible for the the transfer of controlled substances to the outside firm and for maintaining accurate inventory and records pertaining to each transfer.

EPA | The Resource Conservation Recovery Act (RCRA)

Due to the discovery of pharmaceuticals in surface, ground, and drinking water sources, there are rising concerns about the dangers of waste pharmaceuticals in the environment. A paradox of pharmaceutical products is that the chemical properties that make them useful in certain therapeutic contexts are also what make them hazardous in a general sense.^{9,10}

Thus, there is a large responsibility—and an urgent need—for hospitals and other participants in the drug supply chain to properly manage and dispose of the pharmaceutical waste they produce.⁹

Under the Resource Conservation and Recovery Act (RCRA) enforced by the EPA, a hospital 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. Following are the six important steps your hospital must follow in order to maintain compliance with EPA regulations.

| <p>1 Identify^{3,9}</p> | <p>Identify each item of hazardous waste generated by your hospital. Generally speaking, hospital pharmacies tend to stock anywhere from 2000 to 4000 drugs in their inventory:</p> <ul style="list-style-type: none"> • 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 according to standard best practices | | | | | | | | |
|--|---|--|--|--|--------------------------------|--------------------------------|--|---|--|
| <p>2 Count³</p> | <p><i>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 facility:</i></p> <table border="1" data-bbox="381 1092 1529 1348"> <thead> <tr> <th data-bbox="381 1092 816 1144">Very Small Quantity Generators (VSQGs)</th> <th data-bbox="816 1092 1151 1144">Small Quantity Generator (SQG)</th> <th data-bbox="1151 1092 1529 1144">Large Quantity Generator (LQG)</th> </tr> </thead> <tbody> <tr> <td data-bbox="381 1144 816 1348"> <p><i>Generates one of the following per month:</i></p> <ul style="list-style-type: none"> • 100 kilograms or less of hazardous waste • 1 kilogram or less of acutely hazardous waste • < 100 kilograms of acute spill residue or soil </td> <td data-bbox="816 1144 1151 1348"> <p>Generates between 100 to 1000 kilograms of hazardous waste per month</p> </td> <td data-bbox="1151 1144 1529 1348"> <p><i>Generates one of the following per month:</i></p> <ul style="list-style-type: none"> • 1000 kilograms (~2200 lbs) or more of hazardous waste • > 1 kilogram of acutely hazardous waste • > 100 kilograms of acute spill residue or soil </td> </tr> </tbody> </table> <p>Note: <i>Incorrectly determining the generator category is a common EPA violation found in hospitals¹¹</i></p> | | | Very Small Quantity Generators (VSQGs) | Small Quantity Generator (SQG) | Large Quantity Generator (LQG) | <p><i>Generates one of the following per month:</i></p> <ul style="list-style-type: none"> • 100 kilograms or less of hazardous waste • 1 kilogram or less of acutely hazardous waste • < 100 kilograms of acute spill residue or soil | <p>Generates between 100 to 1000 kilograms of hazardous waste per month</p> | <p><i>Generates one of the following per month:</i></p> <ul style="list-style-type: none"> • 1000 kilograms (~2200 lbs) or more of hazardous waste • > 1 kilogram of acutely hazardous waste • > 100 kilograms of acute spill residue or soil |
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| <p>3 Notify³</p> | <p>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.</p> | | | | | | | | |
| <p>4 Manage³</p> | <p>Manage the hazardous waste your hospital 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.</p> | | | | | | | | |
| <p>5 Transport³</p> | <p>All of the hazardous waste your hospital generates must be tracked from your hospital’s location to the waste management facility that will ultimately dispose of it. Therefore, a manifest is required each time hazardous waste is transported off site.</p> | | | | | | | | |
| <p>6 Recycle, Treat, Dispose³</p> | <p>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).</p> | | | | | | | | |

Did You Know?

Common hazardous waste violations found in hospitals^{5,12}

1. **Labeling:** Improper or inadequate labeling of pharmaceutical hazardous waste substances
2. **Few inspections:** Few or no weekly inspections of hazardous waste storage areas
3. **Open containers:** Open containers of hazardous waste
4. **Improper disposal:** Improper disposal of chemotherapy agents or other hazardous waste (throwing hazardous waste down the drain)
5. **Improper identification:** Improper or inadequate hazardous waste identification
6. **Inadequate manifests:** Inadequate or no hazardous waste manifests to accompany and track hazardous waste in transit to a disposal facility
7. **Inadequate training:** Inadequate or no training of hospital and pharmacy staff in hazardous waste management
8. **Use of outdated underground storage tanks:** Failing to close or upgrade tanks installed before December 1998

References

1. [Drug Supply Chain Security Act Poster](#)
2. [Practitioner's Manual: An Informational Outline of the Controlled Substances Act](#)
3. [Steps in Complying with Regulations for Hazardous Waste](#)
4. [Five Risk Areas Lurking within Your Pharmacy](#)
5. [Pollution Prevention and Compliance Assistance Information for the Healthcare Industry: 15 Most Common Hazardous Waste Violations and Problems Found at Hospitals](#)
6. [Protecting patient safety and the Drug Supply Chain Security Act \(DSCSA\)](#)
7. [Controlled Substances Security Manual: Security Requirements For Practitioners](#)
8. [Pharmacist's Manual: An Informational Outline of the Controlled Substances Act](#)
9. [Managing Pharmaceutical Waste: A 10-Step Blueprint for Healthcare Facilities in the United States](#)
10. [Pollution Prevention and Compliance Assistance Information for the Healthcare Industry: Pharmaceuticals - Hazardous Waste](#)
11. [Pollution Prevention and Compliance Assistance Information for the Healthcare Industry: Generator Status](#)
12. [Tank Closure](#)



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