



Inventory & Logging for Controlled Substances: Your First Line of Defense in DEA Compliance

Maintaining accurate inventory records for controlled substances is one of the most critical aspects of DEA compliance. Whether you're a pharmacy, hospital, compounding facility, or pharmaceutical manufacturer, your ability to track every unit of a Schedule I–V drug is essential for regulatory success and operational integrity.

This process must be consistent, well-documented, and accessible for both internal audits and DEA inspections.



Key Requirements for Controlled Substance Inventory Management

Initial Inventory

When first engaging in the handling of controlled substances (i.e., after receiving DEA registration or adding a new schedule), your facility is required to complete a full initial inventory of all controlled substances on hand.

This includes:

- Drug name (trade and generic, if applicable)
- Strength (e.g., 10 mg)
- Dosage form (e.g., tablet, solution, injectable)
- Total quantity per container and total containers
- Date of inventory
- Signature of the responsible DEA registrant or designated compliance officer

Note: If no controlled substances are on hand at the time of registration, a zero inventory must still be recorded and filed.

Biennial Inventory (Required by Law)

According to 21 CFR §1304.11, all DEA registrants must conduct a complete and documented inventory at least once every two years.

- The biennial inventory must reflect the controlled substances on hand at the open or close of business on the inventory date.
- It must be dated and signed, and must separately list each drug by schedule.
- Some states (e.g., California, New York) may require annual inventory—always check local law in addition to federal requirements.

Perpetual Inventory (Best Practice)

Although not required by federal law, a perpetual inventory system is considered best practice, especially for high-volume or high-risk environments such as:

- Hospital central pharmacies
- Compounding facilities
- Long-term care pharmacies
- 503A and 503B outsourcing facilities
- Manufacturers and distributors

A real-time perpetual inventory system helps you:

- Identify variances early (e.g., diversion, spoilage, or wastage)
- Simplify DEA and internal audits
- Improve ordering accuracy and stock control
- Document every controlled substance movement

Logging Requirements

Every inventory or transaction log should clearly document the following fields for each controlled substance:

- Drug name (e.g., Hydrocodone, Midazolam)
- Strength and dosage form (e.g., 2 mg/mL injection, 5 mg tablet)
- NDC or SKU, if available
- Quantity received (with DEA Form 222 or purchase documentation)
- Quantity dispensed, returned, wasted, or transferred
- Date of each transaction or inventory event
- Initials or full signature of the staff member recording the entry
- Running total of on-hand inventory (for perpetual systems)

For Schedule II substances, separate logs are required from Schedule III–V records under most compliance protocols.

Record Retention and Access

Minimum retention period: All inventory and transaction records must be kept for at least 2 years from the date of creation.

Accessibility: Records must be readily retrievable during a DEA inspection—this means clearly labeled, organized, and stored in a central compliance location or system.

Electronic systems must be backed up and secured. Consider an audit log to track any edits or deletions.

Hybrid systems (digital + paper) should clearly indicate where originals are stored and how to produce them on demand.

Tips for Audit Success

- Reconcile inventory monthly to match physical counts and log entries
- Flag variances over 1% for immediate review and incident documentation
- Assign a designated compliance manager to review logs weekly
- Use a consistent inventory template or software system
- Keep DEA Form 222s and Form 41s cross-referenced with inventory changes

Summary: Why Inventory Integrity Matters

Inventory errors are one of the top three reasons DEA registrants receive warning letters or face civil penalties. Even a minor inconsistency—such as failing to update a count after a destruction or transfer—can trigger an audit or investigation.

By maintaining detailed, timely, and verified records, you:

- Demonstrate due diligence
- Protect your license
- Reduce liability
- Ensure safe, compliant handling of controlled substances

Need help setting up or auditing your inventory tracking system? Easy Rx Cycle offers DEA-compliant inventory tools, reverse distributor coordination, and SOP development tailored for your facility type.

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