



# DEA Compliance Checklist for Controlled Substance Disposal

**Ensure compliance with DEA, 21 CFR, and industry best practices**

**Audience:** Compounding Pharmacies, Retail Pharmacies, Hospitals, Pharmaceutical Manufacturers **Covers:** DEA Forms 222 & 41, recordkeeping, storage, destruction, and audit readiness **Last Updated:** May 2025 — in line with 21 CFR Part 1304 and DEA audit protocols



# DEA Compliance Requirements

## 1. Registration & Licensing

- DEA registration is current and valid for all controlled substance schedules handled
- Controlled substances are handled only by authorized, trained personnel
- Reverse distributor used is DEA-registered and listed on the DEA registrant database

## 2. Secure Storage of Controlled Substances

- Controlled substances are stored in a locked, tamper-proof cabinet or vault per 21 CFR §1301.72
- Access is limited to authorized staff only
- All containers are clearly labeled with NDC or internal identifier
- Expired, damaged, or returned drugs are segregated and secured until disposal

## 3. Inventory & Logging

- Initial inventory completed at the start of controlled substance handling
- Biennial inventory records maintained per 21 CFR §1304.11
- Real-time perpetual inventory system used (preferred)
- Logs include:
  - Drug name, strength, dosage form
  - Quantity received, dispensed, wasted
  - Dates and personnel initials/signatures
- Inventory records are retained for at least 2 years



## 4. Disposal Readiness

- Reverse distributor is scheduled regularly (or as needed)
- Chain-of-custody tracking is maintained from storage to destruction
- Controlled substances marked for disposal are counted and verified before handoff
- Witnessed destruction SOP is in place for on-site disposal (if applicable)



## 5. DEA Form 222 (Schedule I & II Transfers)

- Completed when transferring CII drugs to a reverse distributor
- Form includes:
  - Correct registrant info
  - Drug names, quantities, NDC
  - Dates of shipment and receipt
- Form is signed and filed properly
- Triplicate forms (paper) or CSOS (electronic) records are retained for 2+ years



## 6. DEA Form 41 (Destruction Documentation)

- Required for documenting destruction of Schedule I–V substances
- Form includes:
  - Name and quantity of drugs destroyed
  - Method of destruction
  - Names and signatures of two authorized witnesses
- Submitted to DEA (or retained per state rules)
- Certificates of Destruction (COD) from reverse distributors are also retained

## 7. Reverse Distributor Coordination

- Vendor is DEA-registered
- Pickup schedules align with waste volume and compliance needs
- DEA Form 222 is completed before transfer of Schedule II
- Chain-of-custody is confirmed upon pickup
- Destruction dates and CODs are confirmed within 30 days



## 9. Staff Training

Annual training conducted for:

- Controlled substance handling
- DEA form procedures
- Reverse distributor process

SOPs are available in print or digital

Staff signatures collected on training logs

## 8. Documentation & Record Retention

- All records (invoices, DEA forms, destruction logs) retained for **2+ years**
- Electronic systems are audit-ready and backed up
- Staff is trained on documentation access and audit procedures
- Random internal audits are scheduled to verify compliance



## 10. DEA Audit Preparedness

A designated compliance officer is assigned

Most recent Forms 222, 41, and CODs are easily retrievable

Disposal log matches DEA inventory reports

DEA contact info and local compliance resources are readily available

Internal audits occur at least annually