



Principles of Controlled Substance Recordkeeping

Presenters



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A veterinarian's take on recordkeeping challenges...



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Objectives

Elements of “good” Recordkeeping

Opioid Recordkeeping

Logbooks

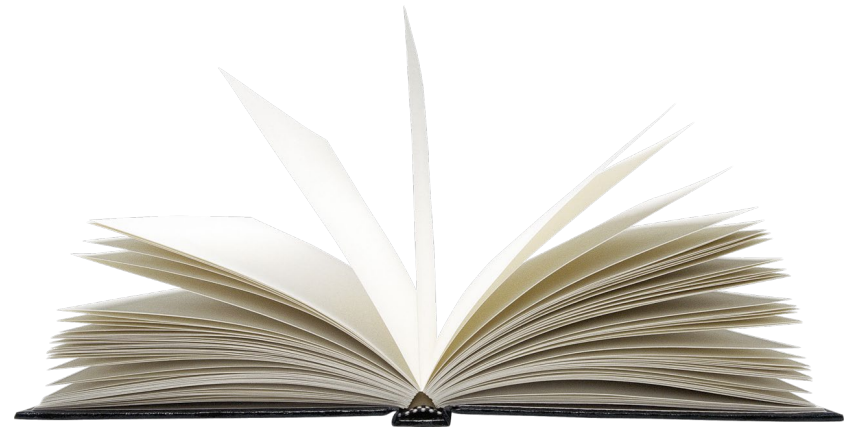
Best Practices



The DEA requires that certain records be maintained to comply with federal regulations. When they are not, the DEA has authority to issue an audit report indicating noncompliance and refer the registrant for disciplinary action, including referral to a U.S. Attorney's Office for fines or criminal prosecution.

Are my records compliant?

Compliant records **tell the story** of the lifecycle of controlled substances from the moment of acquisition to the point of dispensing, administration, waste or disposal.



Elements of “good” recordkeeping

- Start with the order
- Delegate roles and responsibilities
- Witness and document receiving
- Match and attach invoices
- Conduct and balance required inventories
- Implement consistent reconciliation
- Keep a ready and retrievable file
- Document any irregularities
- End with administration, dispensing, waste or disposal



The story begins at the
time of ordering and/or
acquisition.



Serial No: 0123456789012310001
GTIN: 01234567890001
Batch: 09876543210987654321
Exp: 171215

Delegate Roles & Responsibilities

- Streamline recordkeeping by delegating roles and responsibilities to staff in the form of standard operating procedures.
- Utilize checklists to promote an environment of consistency.



Receiving

Always witness and document the receiving process.



- Utilize a witness with an authorized individual anytime controlled substances are received.
- Ensure both the authorized individual and witness review, sign and date the invoice for the order being received.
- As a best practice, unpack controlled substances in a designated area monitored by security cameras and hold the invoice up to the camera to verify what has been received.

Invoices

Make sure to **match and attach** controlled substance invoices to their corresponding orders during the receiving process.





Conduct and balance required inventories

Biennial Controlled Substance Inventory Form

The DEA requires a physical inventory of all controlled substances to be conducted every two years for each registered location. The inventory may be taken on any date within two years of the previous inventory date. The inventory Form must be kept at least for an additional two years at the registered site after completion.

Reference: 21 CFR 1304.04 & 21 CFR 1304.11 Inventory Requirements

Date:		Opening <input type="checkbox"/> Closing <input type="checkbox"/> of Business				
Registrant Name:						
Registrant Address:						
DEA Registration Number:						
Controlled Substance Name	DEA Schedule	Strength and Dosage Form	# of units or volume of each finished form per Container	#of containers in USE	#of containers awaiting disposal	Total
Inventory Performed By:			Signature:			Date:
Witness:			Signature:			Date:



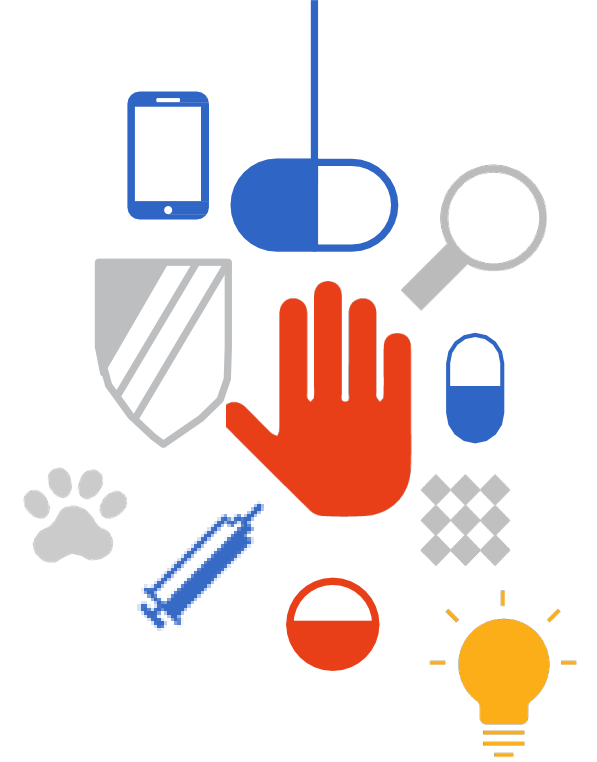
Biennial inventory

The DEA requires that biennial inventory be conducted every two years. As a best practice, consider conducting biennial inventory during your required annual inventory, or every six months.



Reconcile frequently


Implement a system for conducting consistent reconciliations. As a best practice, **reconcile weekly**, at minimum.





Your ready & retrievable file

All required documents and records must be available for inspection by the DEA immediately upon request at the location matching your DEA registration. These records should be maintained in a “readily retrievable” file.



Records



Contents of your readily retrievable file

- Initial inventory
- Biennial inventory
- DEA registration & state licenses/certifications
- Executed and unexecuted DEA Form-222s (or electronic equivalent)
- Power of Attorney forms
- Receipts and/or invoices for schedules III-V controlled substances
- Records of controlled substances distributed (i.e., sales to other registrants, returns to vendors, distributions to reverse distributors)
- Records of controlled substances dispensed
- Reports of Theft or Significant Loss (DEA Form-106), if applicable
- Inventory of Drugs Surrendered for Disposal (DEA Form-41), if applicable
- Records of any transfers of controlled substances
- Authorized Personnel list

Document It!

When in doubt, write it down. Maintain a chronological log documenting any abnormal events that occur with your controlled substances. This will be your “memory” of events if you are ever audited and questioned about your books.

How it ends...

The story of your controlled substance recordkeeping ends at the point of administration, dispensing, wasting and/or disposal.



Schedule I Opioids

- Heroin
- Butyryl Fentanyl
- Clonitazene

Schedule II Opioids

- Codeine
- Fentanyl (Sublimaze, Duragesic)
- Hydrocodone ((Lortab, Norco, or Vicodin)
- Hydromorphone (Dilaudid)
- Meperidine (Demerol)
- Methadone (Dolophine)
- Morphine (MS Contin)
- Opium
- Oxycodone (OxyContin, Percocet)

Schedule III Opioids

- Codeine with aspirin or Tylenol
- Buprenorphine products (Buprenex, Suboxone, Subutex, and Temgesic)

Schedule IV Opioids

- Tramadol
- Butorphanol

Schedule V Opioids

- Cough medicines with Codeine



Schedule II records

Schedule II opioid records must be **kept separate** from schedule III-V controlled substance records.



Ordering

Schedule II's are ordered using a paper **DEA Form-222** or via DEA's Controlled Substance Ordering System ("**CSOS**").



PURCHASER INFORMATION			REGISTRATION INFORMATION		SUPPLIER DEA NUMBER #	
PART 1: TO BE FILLED IN BY PURCHASER Print or type name and title Signature of Requesting Official must be authorized to order for this Date			PART 2: TO BE FILLED IN BY PURCHASER BUSINESS NAME STREET ADDRESS CITY, STATE, ZIP CODE		PART 3: ALTERNATE SUPPLIER IDENTIFICATION (continued in Part 3) ALTERNATE DEA #	
					PART 4: TO BE FILLED IN BY SUPPLIER NATIONAL DRUG CODE NUMBER SHIPPED DATE SHIPPED	
ITEM	NO. OF PACKAGES	PACKAGE SIZE	NAME OF ITEM	NUMBER RECEIVED	DATE (MM/YY)	
1						
2						
3						
4						
5						
6						
7						
8						
9						
10						
11						
12						
13						
14						
15						
16						
17						
18						
19						
20						
← LAST LINE COMPLETED (MUST BE 20 OR LESS)						

DEA Form-222



Return of unused DEA Form 222's

§1305.18



If your registration terminates, is suspended or revoked **you must return** all unused DEA Forms 222's to the nearest DEA office.



Create a 222 log

Track DEA Form-222's in a separate log

Keep blank DEA Form-222's secured at all times

DEA Form-222 Tracking log	Facility Name			
DEA Form-222 Serial Number	Date Stored	Date Used	Date Order Received/ Executed	Date Filed
XXXXXXXXXX	XXXXXXXX	XXXXXXX	XXXXXXX	XXXXXX



Receiving Inventory

When receiving into inventory, schedule II's **must be separated** from schedule III-V controlled substances within storage.



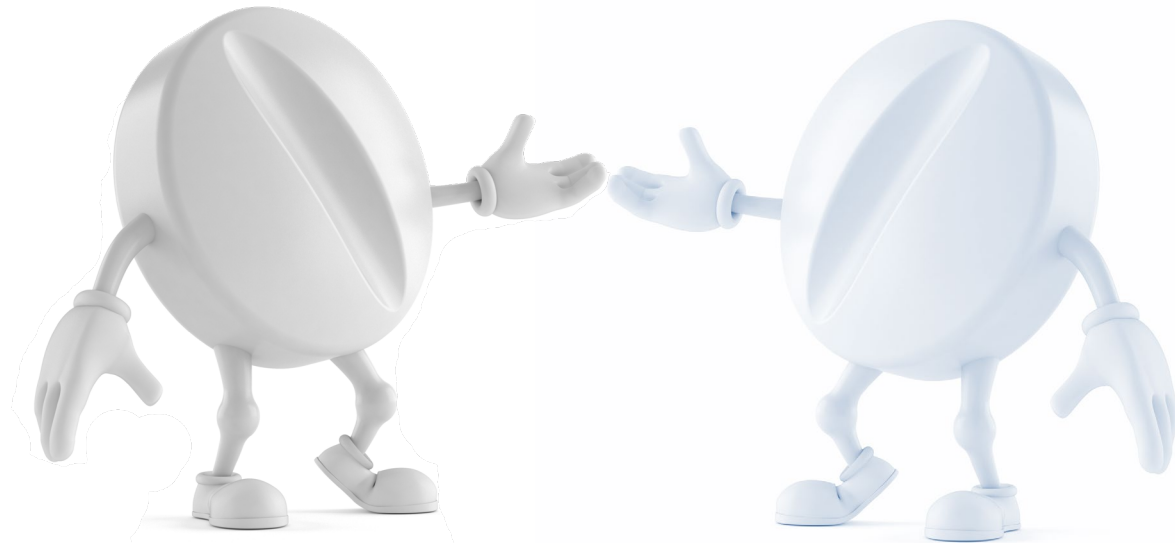
Closing out DEA Form-222

- Your retained copies of DEA Form-222 must be **“closed out”** (filled in completely) once an order is received, including the quantity received and the date received.
- Completed DEA Form-222s must be retained for at least **two years**.



Recording Witnesses

Utilize a witness and make sure to document their presence **via a signature** along with an authorized individual's signature and the date on schedule II invoices.



Voided DEA Form-222s



If a DEA Form-222 is returned by the distributor, or filled out incorrectly, **“VOID”** should be written on the DEA Form-222.



All three copies of voided or unusable DEA Form-222s must be retained for two years according to federal law (five years per Illinois requirements).

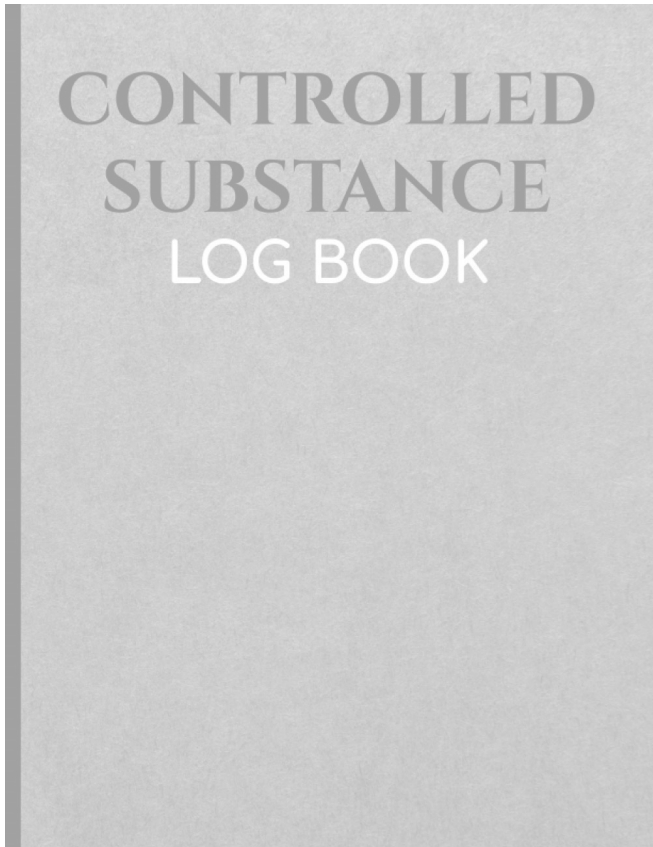
Waste/disposal records

- Schedule II controlled substances being sent to a reverse distributor for disposal must be **transferred using a DEA Form-222. The reverse distributor will then complete DEA Form-41.**
- DEA Form-41 must be kept by the DEA registrant for a period of 2 years per 21 U.S.C. 827.
- Record two signatures on waste documentation and maintain copies of records for the transfer and disposal at least 2 years .





Prioritize logging



Train staff on the mechanics of “good logging” to ensure inventories are properly maintained. With proper training, your employees will be able to maintain consistent recordkeeping for controlled substance transactions in your practice.

Reconciling v. Inventory



Reconciliation: To check (a financial account) against another for accuracy and to account for changes.

Inventory: A complete count and list of items available in-stock that have been tracked and logged.

Balance your inventory like a checkbook.

Think of your logbook as a checkbook register. When it comes to controlled substances oversight, keep a running balance of your inventory as if you were balancing a checkbook.

Pay attention to decimal points

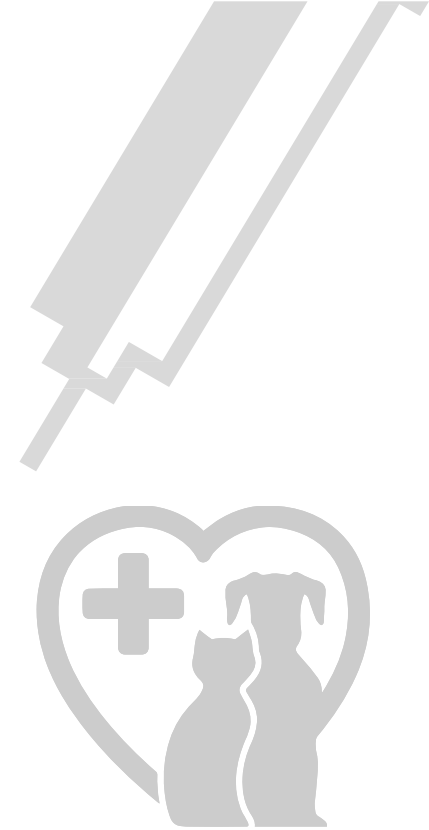
Over time, going from .010 to .0010 can compound into significant discrepancies.



Hub loss

Remember to account for hub loss!

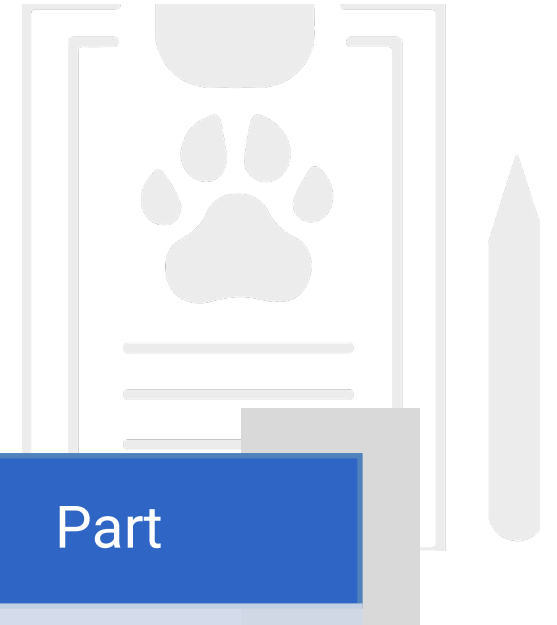
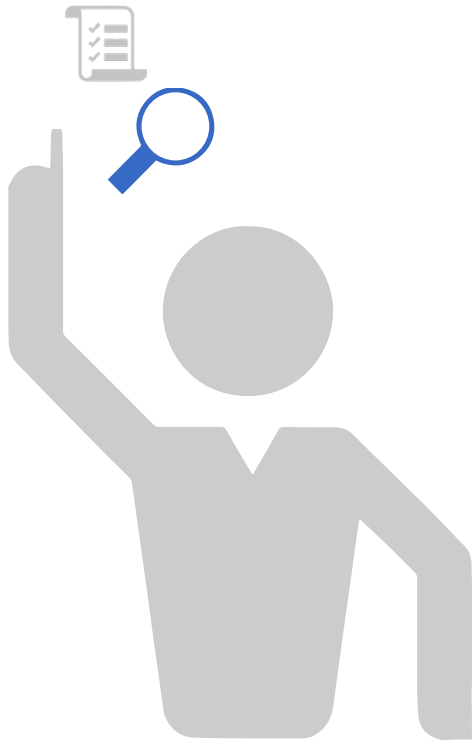
- There is an allowance made for loss due to withdrawal from a bottle.
- “Hub loss” is loss due to withdraw and is normally between 0.1 and 0.2 mils for withdraw. An example would be if 12 withdrawals were made from bottle a total of up to 2.4 mil





Avoiding recordkeeping pitfalls.

Implement SOP's



Follow

Follow a written protocol to reduces errors & inaccuracies.

Rotate

Rotate roles so that the roll of “auditor” is shared amongst staff

Part

As part of audit protocol, the DEA registrant should regularly review controlled drug logs and audits

Witnesses

While the DEA does not require a witness during receiving or transfers, it is **highly recommended** that you have a witness present for verification purposes.



Always implement a witness when **inventorying** controlled substances and conducting inventory (initial and biennial).



Additional Tips



- Allocate recordkeeping duties to staff
- Match and attach invoices
- Conduct required inventories
- Perform consistent reconciliations (at least weekly)
- Keep track of decimals
- Don't forget to account for hub loss
- Create a ready and retrievable file

We provide a variety of solutions, guidance, education and support to the veterinary and healthcare industries — covering all aspects of DEA regulatory compliance — managed by subject matter experts and former DEA Agents and Diversion Investigators to assess risk, generate a proactive compliance environment and remediate issues that arise. .

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