



Event: LIVMA
Date: Wednesday June 3, 2020
Time: 8:00pm - 10:30pm

CONTROLLED SUBSTANCE COMPLIANCE “SIMPLIFIED” NOTES

Wish there was an “easy” button for controlled substance compliance? Navigating compliance “dos and don’ts” can be an overwhelming task. While there may not be an “easy” button for compliance, this session is designed to provide attendees with a simplified approach to achieving and maintaining controlled substance compliance.

FEDERAL OVERSIGHT

The DEA is responsible for enforcing the controlled substances laws and regulations of the United States, by operating according to Title 21 of the U.S. Code of Federal Regulations (CFR) and The Controlled Substances Act (CSA).

Mission of the DEA

DEA’s mission is to enforce controlled substances laws and regulations of the United States and bring to the criminal and civil justice system those organizations and principal members of organizations, involved in the growing, manufacture, or distribution of controlled substances appearing in or destined for illicit traffic in the United States; and to recommend and support non-enforcement programs aimed at reducing the availability of illicit controlled substances on the domestic and international markets.

DEA Responsibilities

In carrying out its mission, the DEA's primary responsibilities include:

- Investigation and preparation for prosecution of major violators of controlled substance laws operating at interstate and international levels.
- Management of a national drug intelligence program in cooperation with federal, state, local, and foreign officials to collect, analyze, and disseminate strategic and operational drug intelligence information.
- Seizure and forfeiture of assets to be used for illicit drug trafficking.
- Enforcement of the provisions of the Controlled Substances Act
- Coordination and cooperation with federal, state and local law enforcement officials
- Liaison with the United Nations, Interpol, and other organizations on matters relating to international drug control programs.

Controlled Substances Act (CSA)



The CSA was established in 1970 as a “closed system” to track and account for controlled substances from import and/or manufacturing through wholesale distribution to the ultimate end-user.

Scheduling

Controlled Substances are segregated into DEA Schedules I, II, III, IV or V based upon:

- Abuse potential
- Medical value
- Danger of serious physical effects

Conflicting Laws

If a regulatory conflict arises between DEA regulations and New York State regulations, as a rule of thumb, always adhere to the more stringent set of regulations.

RECORDKEEPING

According to the DEA Office of Diversion, one of the top four reasons a veterinary facility fails a DEA regulatory inspection is for poor recordkeeping. Recordkeeping is the backbone of controlled substance compliance. If your records are not properly maintained, the rest of your compliance program will fall apart.

Poor Recordkeeping Violations

When required records are not maintained, 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. The failure to “make, keep, or furnish” any record required by regulation is punishable by up to one year in prison and a \$100,000 fine. The “negligent” failure to do so is treated as a civil violation, punishable by a fine up to \$15,040 per occurrence.

Required Records

DEA requires that you maintain the following records, either handwritten or electronically:

- Keep a record of all controlled substances received, dispensed, administered and destroyed
- Retain all records for two years from the date of execution.
- Inventory all on-hand stocks of controlled substances on the date that you begin operations.
- At least once every two years, conduct and document a biennial inventory of controlled substance on hand

Your “Readily Retrievable” File:

DEA requires that you maintain a regulatory inspection “ready and retrievable” file that contains all required DEA documentation, i.e. power of attorney (POA) for ordering drugs, state medical licenses, DEA registration certificate, and a copy of the initial and biennial inventories.

Logbooks



Logbooks act as a system for recording inventory. A logbook must be maintained for each drug. Think of your logbook as a checkbook register. You must keep an accurate running balance of your drug inventories as if you were balancing your checkbook. Types of logbooks include:

- Disposition Record
- Authorized Signature Log
- Unopened Container Log
- Opened Container Log
- Biennial Report
- Inventory Audit Form

Biennial Inventory

- DEA requires a physical inventory of all controlled substances to be conducted every two years for each registered location.

Reconciliation v. Inventory

- **Reconciliation:** To check (a financial account) against another for accuracy and to account for changes. The minimum reconciliation standard for veterinary facilities should be weekly for most companion animal facilities.
- **Inventory:** A complete count of items available in-stock that have been tracked and logged.

SECURITY

Drug Diversion is the transfer of any legally prescribed controlled substance from the individual for whom it was prescribed, to another person, for any illicit use other than its original medical purpose.

Drug Storage

DEA registrants are responsible for **secure storage** of controlled substances in their facilities, which means that controlled substances:

- Must be stored in a secured container.
- The storage box must be bolted or otherwise secured to an immovable object.
- The holder of the license should have possession of the keys to the storage box.

Drug Diversion Risks

- Improper disposal protocols
- Inaccurate logging systems
- Lack of proper Power of Attorney (“POA”)
- Out of date video surveillance systems
- Lack of standard operating procedures (“SOP’s”)
- Lack of employment security/background checks
- Inadequate controlled substance storage

Veterinary Doctor-Shopping



- “Doctor shopping” is the practice of visiting multiple physicians to obtain prescriptions for otherwise illegal drugs, or the medical opinion that one wants to hear. It is illegal!

DRUG SHORTAGES:

To combat the opioid epidemic the DEA decreased manufacturing quotas for certain controlled substances. In 2020, DEA proposed to reduce the amount of five opioids manufactured in the U.S., which when combined with Morphine, represents a 53% decrease since 2016:

- Fentanyl: 31% reduction | Hydrocodone: 19% reduction | Hydromorphone: 25% reduction
Oxycodone: 9% reduction | Oxymorphone: 55% reduction

STANDARD OPERATING PROCEDURES (SOP’S):

- Develop SOP’s for every aspect of your controlled substance policy.
- Follow a written protocol to reduce errors & inaccuracies.
- Rotate roles so that the roll of “auditor” is shared amongst staff
- As part of audit protocol, the DEA registrant should regularly review drug logs and audits

BEST PRACTICES:

Recordkeeping

- Success depends on documenting facts, gathering information and maintaining inventory records. Good recordkeeping tells a story that starts when a controlled substance is ordered to the time it leaves your facility via by being dispensed or disposed of.
- Maintain a chronological daily log documenting any abnormal events that occur with your controlled substances.
- We recommend routinely conducting audit reconciliations at the end of each shift.
- We recommend conducting biennial inventory annually at the same time you conduct your yearly inventory.

Employees

Know your employees! This starts with the hiring process. Conduct background checks on new and existing employees and make sure employees complete a screening statement annually.

Education/Training

- Educate and Train your employees on the mechanics of good recordkeeping, drug security, signs of drug diversion and/or individuals that may be abusing or misusing controlled substances.



- Create your SOP's and ensure your employees know them like their "ABC's"

Security

- Enhance overall controlled substance security
- Do not label your controlled substance storage safe/cabinet on the outside

Plan

- Simplifying controlled substance compliance is much easier when you have a plan.
- Noncompliance will inevitably come back to bite you. Have a plan!