

CONTROLLED SUBSTANCES



BASICS

OVERVIEW

- Controlled substances are drugs and chemicals whose manufacture, use, sales and distribution are regulated by the federal government.
- Earliest regulations regarding the use of controlled substances in the United States includes the Harrison Act of 1914 in response to opioid addiction.
- The primary legislation surrounding controlled substances is the Controlled Substances Act (CSA) of 1970.
- The CSA establishes organizational categories for drugs into Schedule I through Schedule V based on abuse and dependence potential and acceptable medical use of the agent. They are often noted on the label as C-I through C-V with “C” denoting the agent as a “Controlled” substance.
- Ordering, storing, and prescribing controlled substances are all highly regulated to prevent drug diversion and ensure they are used in the context of legitimate Veterinary medical practice.
- Due to variation in state regulations, practitioners are encouraged to confer with their local DEA Diversion Office to ensure full compliance and for more information (see **Internet Resources**).

DRUG SCHEDULES

- Schedule I drugs have the greatest abuse and dependence potential and do not have a current acceptable medical use. Schedule I drugs include heroin, hallucinogens (e.g. peyote) and many recreational “Club Drugs” such as ecstasy.
- Schedule II drugs include agents that have a legitimate medicinal use but carry a high risk for abuse or dependence thus requiring limited dispensing quantities in some states and close medical supervision in their use. Such drugs include morphine, fentanyl, oxycodone, meperidine and barbiturates.
- Schedule III, IV and V agents have lesser ability for abuse and dependence. Common drugs in each class include ketamine (Schedule III), diazepam and tramadol (Schedule IV), and diphenoxylate + atropine (Schedule V).
- Access to Schedule V drugs can vary among states. In some cases, a prescription is needed while in other states they are sold over-the-counter (OTC).
- In 2014, hydrocodone combination drugs (e.g. hydrocodone + acetaminophen) were rescheduled from Schedule III to Schedule II in part, due to risk of misuse and abuse.

REGISTERING AND ORDERING CONTROLLED SUBSTANCES

- Veterinarians are required to register and obtain a certificate from the DEA to order and prescribe controlled substances through DEA Form 224. The registration is valid for 3 years and currently costs \$731.
- Ordering of controlled substances is made using DEA Form 222. Order forms are pre-printed with the registrant's name and address and are tracked by the drug distributor and the DEA. Careful review of directions when completing this form is warranted to avoid rejection by the distributor.
- Lost, damaged or accidental destruction of individual Form 222s should be reported to your local DEA Diversion office immediately.

STORING AND INSPECTIONS OF CONTROLLED SUBSTANCES

- Storage of Controlled Substances should be made within a "securely locked cabinet of substantial construction". The risk of crime and theft as well as the physical location and controlled access should be taken into account.
- Discussion of security measures and storage requirements can be made with your local DEA Diversion office.
- DEA Investigators may periodically inspect your facility to ensure intake and dispensing recordkeeping (e.g. Form 222s), security policy and procedures and storage of controlled substances are in compliance.
- They will present credentials and may or may not be accompanied by local law enforcement officers depending on available staff and will present an official Notice of Inspection (DEA Form 82) for the Registrant's signature.
- The Registrant may wish to have an attorney present during the inspection. A warrant can be obtained for refusal of inspection, however.
- Inspections by the DEA are limited to the storage and record keeping of controlled substances and do not involve business documents outside of that scope.

PRESCRIBING CONTROLLED SUBSTANCES

- Variable regulations exist in the writing, dispensing, and refilling of prescriptions for controlled substances based on the Schedule of the drug (see **Internet Resources**). In all cases, prescriptions for controlled substances should be written (or typed/printed) clearly avoiding abbreviations and clearly stating drug name, dose and dosage strength, route, frequency, duration of therapy and quantity to dispense. Spelling out numbers and abbreviations will help avoid confusion and ambiguity.
- Schedule II drugs require a written prescription which includes the prescriber's DEA registration number. Verbal prescriptions are permitted in emergency circumstances. While there are no specified federal limits in

terms of quantities of a drug that can be dispensed, some states may have limits (e.g. 30-day supply).

- Schedule III-V drugs may be prescribed either orally, written or via facsimile and be refilled over the phone or in writing. Refills for Schedule III and Schedule IV drugs can only be made up to five times within six months of the prescription at which point a new prescription is required.

RECORD KEEPING AND DESTRUCTION OF CONTROLLED SUBSTANCES

- Records of Controlled Substances received and dispensed should be meticulously kept (see **Internet Resources**).
- Confirm shipping /receiving of drugs against order forms and report any discrepancies immediately.
- Records of controlled substances should be maintained for at least two years. Records for Schedule I and II drugs should be kept separately from other records.
- A record of all drugs dispensed to the patient should also be kept and should include: date, drug strength and form, amount dispensed and starting/ending quantities in the bottle from which it was dispensed.
- Due to the risk of diversion, special record keeping is required when transferring or destroying Controlled Substances or in the event of theft of a controlled substance.
- New regulations were broadcast in 2014 by the DEA (See **Internet Resources**), but due to periodic changes in regulations, practitioners are encouraged to confer with their local DEA Diversion Office to ensure full compliance with all record keeping requirements.
- In general, controlled substances need to be transferred to another DEA Registrant or disposed of under strict standards to prevent diversion using DEA Form 41.
- Theft of Controlled Substances should be reported immediately to your local DEA office and recorded in DEA Form 106.

PRESCRIPTION DRUG MONITORING PROGRAMS

- Prescription Drug Monitoring Programs (PDMPs) are state-level programs designed to aid practitioners by electronically tracking the prescribing and dispensing patterns of controlled substances to patients (see **Internet Resources**).
- These programs are intended to help identify patients that may be receiving prescriptions for controlled substances from multiple prescribers (“doctor shopping”) allowing for drug diversion.
- Access to the database varies from state to state and is separate from any federal DEA programs on recordkeeping and prescription tracking.

- Because of the relative ease involved in simply changing an animal's name from practitioner to practitioner, it is not clear what impact these laws may have in preventing drug diversion in veterinary medicine.



MISCELLANEOUS

ABBREVIATIONS

- CSA: Controlled Substances Act
- DEA: Drug Enforcement Administration
- OTC: Over-The-Counter
- PDMP: Prescription Drug Monitoring Program

INTERNET RESOURCES

- DEA Homepage with links to programs and regulations: www.deadiversion.usdoj.gov
- Practitioner's Manual Section V: Valid Prescription Requirements
www.deadiversion.usdoj.gov/pubs/manuals/pract/section5.htm
- Practitioner's Manual Section IV: Record Keeping Requirements
www.deadiversion.usdoj.gov/pubs/manuals/pract/section4.htm
- DEA Letter to Registrants 9 Sept 2014:
www.deadiversion.usdoj.gov/drug_disposal/dear_registrant_disposal.pdf
- Prescription Drug Monitoring Programs:
www.deadiversion.usdoj.gov/faq/rx_monitor.htm#6

SUGGESTED READING

Webster LR, Grabois M Current Regulations Related to Opioid Prescribing. PM R. 2015; 7(11 Suppl):S236-47.

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