Keeping Control of Controlled Substances: A Review of Regulatory Requirements

Laws pertaining to controlled substances can be confusing and thus, the CVMA receives more inquiries about this subject than any other. This article is intended to assist veterinary practices in understanding and complying with controlled substance regulations. The Federal Drug Enforcement Administration (DEA) enforces regulations pertaining to all aspects of controlled substance management. These include manufacturing, wholesale distribution, transport, prescription, dispensation, and disposal, among others. The DEA requires a closed system throughout these phases, which means that all controlled substances are transferred between DEA registrants, handled in accordance with the law, and can be accounted for at all times. As practitioner registrants with the DEA, veterinarians must know and follow the laws set forth to ensure that for their part, they are maintaining a closed system.

Record Keeping Requirements

Dispensation Log: Section 1304.22(c) of the Code of Federal Regulations Title 21 requires that practitioners who administer or dispense controlled substances must record the following information: the name of the substance; the number of units or volume dispensed, including the name and address of the person to whom it was dispensed; the date of dispensing; and the name or initials of the individual who dispensed or administered the substance on behalf of the dispenser. The law does not specify that dispensation records must be maintained in paper format. Whether they are maintained in paper or electronic format, they must be current and readily producible for inspection. All Schedule II controlled substance dispensation information should be separate and distinct from other schedules. Schedules III–V may be grouped together. Effective separation of Schedule II records can be achieved through the use of a separate binder or distinct tabulated sections within one binder (i.e. binder divider tabs). Controlled substance records must be maintained for a minimum of two years [21CFR, 1304.04(a).] A sample dispensation log can be found on the California Veterinary Medical Board website (www.vmb.ca.gov) under the Licensee tab in the Hospital Inspection Information section.

Biennial Inventory Log: Title 21 of the California Code of Regulations, Sections 1304.11(b)(c) and (e)(1)(iii) outline the requirements for maintaining controlled substance inventory information. The law requires that no longer than every two years, practitioner registrants must obtain and record the following information regarding controlled substances in their possession: the name of the substance; each finished form of the substance (e.g., 10-milligram tablet or 10-milligram concentration per fluid ounce or milliliter); the number of units or volume of each substance in its commercial container (e.g., 100-tablet bottle or 3-milliliter vial) and; the number of commercial containers of each drug (e.g. four 100-tablet bottles or six 3-milliliter vials). A separate biennial inventory must be taken for controlled substances located at each location for the registrant. Unlike dispensation logs, biennial inventory logs must be maintained in “written, typewritten, or printed form at the registered location.” This implies that electronic records are not permissible. A sample biennial inventory log can be found on the California Veterinary

Medical Board website (www.vmb.ca.gov) under the Licensee tab in the Hospital Inspection Information section.

Storage Requirements
Title 21 of the Code of Federal Regulations, Section 1301.75(a) describes the physical security controls that are required of practitioners who obtain controlled substances. Specifically, the regulations state that all controlled substances "shall be stored in a securely locked, substantially constructed cabinet." This means that the cabinet cannot be easily accessed by forced entry and cannot be easily removed from the premises. Section III of the DEA Practitioner's Manual offers more information regarding security controls for controlled substances. The manual can be accessed in the Resources section of the DEA website (www.deadiversion.usdoj.gov).

Access Requirements
Federal law prohibits registrants from allowing individuals to access controlled substances if they have been convicted of a felony offense relating to controlled substances (21CFR, Section 1301.76(a). Both licensed veterinarians and registered veterinary technicians have fingerprints on file with the Department of Justice and thus are monitored by the Veterinary Medical Board (VMB) for felony offenses. For all other practice staff (veterinary assistants), Section 4836.1(b) of the California Business and Professions code states that,

> *A veterinary assistant may obtain or administer a controlled substance pursuant to the order, control, and full professional responsibility of a licensed veterinarian, only if he or she meets both of the following conditions:*
>
> *(1) Is designated by a licensed veterinarian to obtain or administer controlled substances.*
>
> *(2) Holds a valid veterinary assistant controlled substance permit issued pursuant to Section 4836.2.*

The Veterinary Assistant Controlled Substance Permit (VACSP) may be applied for online at the Veterinary Medical Board website: www.vmb.ca.gov

Transfer Requirements
The DEA does not prohibit the transfer of controlled substances between practitioners, provided that both hold valid DEA registrations. All Schedule II controlled substance transfer must be documented by a DEA Form 222 for all Schedule II controlled substances, while Schedule III-Vs can be documented with an invoice. An invoice should include the names, contact information and DEA registration numbers of the shipper and the receiver, the name, strength, quantity, form and schedule of the controlled substance(s) being transferred, and the date that the transfer is taking place.

Disposal Requirements

A practitioner may dispose of out-of-date, damaged, or otherwise unusable or unwanted controlled substances, including samples, by transferring them to a registrant who is authorized to receive such materials. These registrants are referred to as reverse distributors. The practitioner should contact his or her local DEA field office for a list of authorized reverse distributors. The DEA has diversion field offices in a number of California cities. To find your regional office, visit the DEA website (deadiversion.usdoj.gov) and click on the About Us tab, then select Contact Us and look for the Diversion Field Offices link. Schedule II controlled substances should be transferred via the DEA Form 222, while Schedule III–V compounds may be transferred via invoice. Reverse distributors generally provide specified documentation as part of their service. The practitioner should maintain records documenting the transfer and disposal of controlled substances for a period of two years. While awaiting reverse distribution, controlled substances should be stored in a closed box inside the locked controlled substance cabinet. The box should say, “Discarded – For Reverse Distribution” clearly on all sides to avoid accidental use.

More Information

The DEA Practitioner’s Manual offers more information regarding practitioner requirements for registration, security, recordkeeping, disposal and transfer of controlled substances. The manual can be accessed in the Resources section of the DEA website (www.deadiversion.usdoj.gov). Additionally, all DEA controlled substance schedules can be accessed at deadiversion.usdoj.gov/schedules/index.html. The CVMA has more resources to assist with DEA compliance, located in the Government section of cvma.net.