



AAVSB
AMERICAN ASSOCIATION OF
VETERINARY STATE BOARDS

MODEL REGULATIONS – APPROPRIATE USE OF OPIOIDS AND OTHER CONTROLLED SUBSTANCES

As recommended by the AAVSB Regulatory Policy Task Force in August 2019

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Introduction

These Model Regulations are meant to support the statutory language that can be found in the AAVSB Practice Act Model (PAM). Each model regulation from the AAVSB is presented separately for ease of use for the AAVSB Member Boards to utilize as a model in developing regulations or rules specific to targeted topics. The AAVSB Regulatory Policy Task Force will continue to develop Model Regulations to address pressing issues in the regulation of Veterinary Medicine.

Revisions

Created 2019

Structure and Format

The AAVSB Model Regulations have been structured to allow Member Boards to develop new regulations or rules within their jurisdiction to address the specific language that can be found in the jurisdiction's existing statute or bylaws. It has been formatted to include the model language with corresponding commentary. To provide the rationale and thought processes behind the Model Regulations, readers are encouraged to read the commentary as well as the Regulation to receive a complete perspective. Commentary follows each section if appropriate.

Appropriate Use of Opioids and Other Controlled Substances

Model Regulation.

Veterinarians are allowed to prescribe, administer, and dispense controlled substances in keeping with the requirements of the laws of this Jurisdiction, and the statutes and regulations governing the practice of Veterinary Medicine. A Veterinarian-Client-Patient Relationship (VCPR) as set forth in the Act, must first exist before drugs may be prescribed by a Veterinarian.

Commentary

Article I, Section 105 (b). Practice of Veterinary Medicine in the AAVSB Practice Act Model (PAM) indicates that any individual practices Veterinary Medicine when performing any one or more of the following on an Animal:

- (b) Prescribes, dispenses or administers a drug, medicine, anesthetic, biologic, appliance, apparatus, application or treatment.

Opioids and other controlled substances (i.e. benzodiazepines, tranquilizers, and barbiturates) can be very useful for pain management and the control of other conditions in Animals, but they have a high potential for misuse, addiction and overdose death in humans; therefore, these controlled substances are closely regulated by Jurisdictions and the federal government. The magnitude of the veterinary community's role in the opioid epidemic is unclear. However, Veterinarians prescribe, dispense, administer, and stock many of the same opioid drugs that have the potential to be diverted and abused by humans. Therefore, the veterinary community needs to be part of the effort to address this national crisis.

Veterinarians are required to be compliant with all applicable Jurisdictional and federal veterinary and pharmacy laws and regulations related to controlled substances. One of the methods Jurisdictions have chosen to address the crisis is the implementation of prescription monitoring programs. Multiple Jurisdictions already require Veterinarians to participate in these programs. However, this document does not address whether Veterinarians should be required to participate in these programs. Regulatory boards should seek to provide commentary to ensure that special circumstances pertaining to veterinary medicine are taken into consideration. In light of the opioid crisis, many veterinarians are considering dispensing fewer controlled substance and writing prescriptions to be filled at a commercial pharmacy.

Section 1. Definitions.

Opioids means all pure opioids and partial agonist and antagonist opioids (including tramadol).

Controlled substances mean all Schedule II through V drugs as set forth in the U.S. Controlled Substances Act of the Drug Enforcement Act and the Canadian Controlled Drugs and Substances Act.

DEA is the United States Drug Enforcement Administration.

Section 2. Prescribing of Controlled Substances for Acute Pain and Chronic Conditions

- (a) Veterinarians must have a valid DEA license or meet requirements of the provincial licensing body, establish a Veterinarian-Client-Patient Relationship (VCPR) and comply with all DEA, federal, and Jurisdictional laws and statutes in order to provide opioids and other controlled substances for their Patients.
- (b) The Veterinarian shall perform a history and physical examination appropriate to the complaint and conduct an assessment of the Patient's history as part of the initial evaluation.
- (c) Before initiating treatment, nonpharmacologic and non-opioid treatment shall be given consideration prior to treatment with an opioid or other controlled substance.
- (d) If an opioid or other controlled substance is necessary for treatment of acute pain, the Veterinarian shall prescribe it in the lowest effective dose appropriate to the size and species of the animal for the least amount of time. The initial dose shall not exceed a XX-day supply.
- (e) For prescribing an opioid or other controlled substance for management of pain after the initial XX-day prescription, the Patient shall be seen and re-evaluated for the continued need for an opioid or a controlled substance.
- (f) A Veterinarian may prescribe an opioid or other controlled substance containing an opioid for management of chronic pain, terminal illnesses, or certain chronic conditions, such as chronic heart failure, chronic bronchitis, osteoarthritis, collapsing trachea, or related conditions.
- (g) For the prescribing of an opioid or other controlled substance for terminal illnesses or certain chronic conditions, it is not required to see and reevaluate the patient for prescribing beyond XX days. For any prescribing of an opioid or other controlled substance beyond XX days, the Veterinarian shall develop a treatment plan for the patient, which shall include measures to be used to determine progress in treatment, further diagnostic evaluations or modalities that might be necessary, and the extent to which the pain or condition is associated with physical impairment.
- (h) The medical record for prescribing controlled substances shall include signs or presentation of the pain or condition, a presumptive diagnosis for the origin of the pain or condition, an examination appropriate to the complaint, a treatment plan, and the medication prescribed to include the date, type, dosage, and quantity prescribed.
- (i) For continued prescribing of a controlled substance, the patient shall be seen and reevaluated at least every XX months, and the justification for such prescribing documented in the Patient record.

- (j) Prior to prescribing or dispensing an opioid or other controlled substance, the Veterinarian shall document a discussion with the Client about the known risks and benefits of drugs, the responsibility for the security of the drug and proper disposal of any unused drug.

Commentary

Section 2. Prescribing of Controlled Substances for Acute Pain and Chronic Conditions.

Regulations should cite the specific sections of the Jurisdiction's drug control act or section(s) of the Veterinary Medicine Act related to prescribing or dispensing controlled substances.

Section 2 (d) – The AAVSB recommends that the Jurisdiction limit the initial dose of an opioid or other controlled substance that is dispensed or prescribed to a maximum 14-day supply. Following the initial 14-day supply, the AAVSB recommends that Jurisdictions require that the Patient be seen and re-evaluated for the continued need of the opioid or other controlled substance.

Section 2 (g) – For terminal illnesses or chronic conditions, the AAVSB believes that the Veterinarian should not be required to see and re-evaluate the Patient after the specified time for the initial dose. However, the regulations should specify that the Veterinarian develop a specified treatment plan with measures to determine progress and further evaluations to assess the need for continued prescribing of the opioid or other controlled substance.

Section 2 (i) – The AAVSB recommends that for the continued prescribing of opioids or other controlled substances that the Patient should be seen and re-evaluated at least every six months and justification for continued use of the opioid or other controlled substance be documented in the medical record.

Section 3. Labels of Dispensed Opioids and Other Controlled Substances

- (a) For labeling of dispensed opioid and other controlled substance prescriptions, labels must be compliant with federal and provincial laws and should contain at a minimum:
- (1) the name and address of the Facility
 - (2) first and last name of the Client
 - (3) the name or identification of the Patient
 - (4) species of the Patient
 - (5) date dispensed
 - (6) directions for use
 - (7) the name, strength and quantity of the drug
 - (8) the expiration date
 - (9) number of refills, if applicable
 - (10) the name of the prescribing Veterinarian
- (b) The label must be affixed to container.

Commentary

Section 3. Labels of Dispensed Opioids and Other Controlled Substances.

In addition to the prescription label requirements outlined in this section, the Jurisdiction may require that the individual filling the prescription initial the label. The Jurisdiction may also want to require that the client initial the label once it has been filled.

Boards are encouraged to check the pharmacy requirements in their Jurisdiction to avoid conflicting regulations.

Section 4. Prescription Orders for Commercial Pharmacies.

Prescription orders for commercial pharmacies must be compliant with the requirements of the Jurisdiction.

Commentary

Section 4. Prescription Orders for Commercial Pharmacies.

The AAVSB encourages The Veterinary Medical Board to work with the pharmacy board on rules for accepting and recording prescriptions from a Veterinarian. As Veterinarians are not granted an NPI number, the AAVSB suggests that rules be established to identify the Veterinarian on a prescription record by their Jurisdiction of license and license number.

Section 5. Recordkeeping

Inventories and records, including original invoices, of Schedule II drugs shall be maintained separately from all other records, and the establishment shall maintain a continuous inventory of all Schedule II drugs received, administered, or dispensed, with reconciliation at least monthly. Reconciliation requires an explanation noted on the inventory for any difference between the actual physical count and the theoretical count indicated by the distribution record. A continuous inventory shall accurately indicate the physical count of each Schedule II drug in the general and working stocks at the time of performing the inventory.

Commentary

Section 5. Recordkeeping.

Maintaining inventories and records is federally required for all Schedule II drugs. The AAVSB also recommends that Jurisdictions consider drafting rules that require regular inventories and record keeping for Schedule III-V drugs.

Section 6. Reporting Requirements.

[Placeholder for future regulations on reporting to a Prescription Drug Monitoring Program]

Commentary

Section 6. Reporting Requirements.

If there are no requirements in the Jurisdiction to report to a Prescription Drug Monitoring Program, Jurisdictions are encouraged to draft regulations that require the Veterinarian to retain records described in Section 5 to be available for inspection by Jurisdiction and federal authorities.

The AAVSB Regulatory Policy Task Force is seeking information from the AAVSB Member Boards on effective measures for Veterinarian use of the Jurisdiction's PMP program. As requirements for Veterinary Medicine differ from human medicine, reporting requirements may conflict with existing regulations, such as:

- Veterinarians are not addressed under HIPAA regulations and may be in conflict with privacy requirements for the Client if asked to query the PMP.
- Veterinarians are not required to keep electronic medical records and may have difficulty reporting to the PMP given the nature of rural and mobile practices.
- Drugs reported for Patient use listing the Client may be confused with physician reports for drugs that have been prescribed directly to the Client.

Section 7. Reporting Discrepancies

Whenever a theft or any unusual loss of Schedules II through V drugs is discovered, such theft or loss shall be immediately reported to the Board of Veterinary Medicine and the DEA and any other required entities. The report to the Board of Veterinary Medicine shall be in writing and sent electronically or by regular mail. The report to the DEA shall be in accordance with 21 CFR 1301.76(b). If the exact kind and quantity of the drug loss cannot be determined, a complete inventory must be immediately taken of all Schedules II through V drugs.

Commentary

Section 7. Reporting Discrepancies.

DEA reporting requirements can be found here:

https://www.deadiversion.usdoj.gov/21cfr/cfr/1301/1301_76.htm

Section 8. Security

The DEA registrant under which the drugs were purchased is responsible for the effective security of the drug stock. Opioids and other controlled substances must be stored in a securely locked cabinet of substantial construction as per DEA requirements.

In order to minimize the opportunities for theft or diversion of controlled substances, Licensees have an obligation not only to provide effective physical security, but also to initiate additional procedures to reduce access by unauthorized persons as well as to provide alarm system where necessary

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