

201 KAR 16:110. Prescription and dispensation of drugs for animal use.

RELATES TO: KRS 321.181(5)(b)

STATUTORY AUTHORITY: KRS 321.235(3), 321.240(5)

NECESSITY, FUNCTION, AND CONFORMITY: KRS 321.181(5)(b) provides that the practice of veterinary medicine includes the prescribing, administering, or dispensing of drugs and medications for veterinary purposes. KRS 321.235(3) and 321.240(5) authorize the board to promulgate administrative regulations to carry out and enforce the provisions of KRS Chapter 321. This administrative regulation establishes a procedure for the prescription and dispensation of drugs by licensed veterinarians for use in animals and livestock.

Section 1. Definitions. (1)"Legend drug" means veterinary prescription drug.

(2) "Prescription" means an order from a veterinarian to a pharmacist or another veterinarian authorizing the dispensing of a veterinary prescription drug to a client for use on or in a patient;

(3) "Veterinary drug" means:

(a) A drug for animal use recognized in the official United States Pharmacopoeia or National Formulary of the United States;

(b) A drug intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in animals;

(c) A drug, other than feed, medicated feed, or a growth promoting implant intended to affect the structure or function of the body of an animal; or

(d) A drug intended for use as a component of a drug in paragraph (a), (b), or (c).

(4) "Veterinary prescription drug" means:

(a) A drug that is not safe for animal use without a veterinarian using or ordering the use of the product, and that is required by federal law to bear the following statement: "Caution: federal law restricts this drug to use by or on the order of a licensed veterinarian";

(b) A drug that is required by state law to be dispensed only on order or prescription of a licensed veterinarian;

(c) The extra-label use of an over-the-counter animal drug or human drugs; and

(d) A medicament compounded by mixing two (2) or more legally-obtained over-the-counter or prescription drugs.

Section 2. Prescribing and Dispensing. (1) A veterinary prescription shall include all of the following:

(a) The name and address of the veterinarian and, if the prescription is a written order, the signature of the veterinarian;

(b) The name and address of the client;

(c) The species and identity of the patient for which the prescription is issued;

(d) The name, strength, and quantity of the drug prescribed;

(e) The date on which the prescription is issued;

(f) The directions for administering the drug;

(g) If the patient is a food producing animal, the withdrawal time for the veterinary drug;

(h) If the prescription authorizes extra-label use, the manner in which the client may use the drug;

(i) Any cautionary statements required by law; and

(j) Number of refills allowed.

(2) A veterinarian shall not:

(a) Prescribe for or dispense to a client a veterinary prescription drug or a drug for extra-

label use without personally examining the patient unless a veterinary-client-patient relationship exists between the prescribing veterinarian, client and patient, and the veterinarian determines that the client has sufficient knowledge to administer the drug properly;

(b) Prescribe or dispense a veterinary prescription drug to a client unless the veterinarian indicates in the appropriate records described in Section 4 of this administrative regulation, within seventy-two (72) hours after the prescription is issued or the drug is dispensed, that the prescription has been issued or that the drug has been dispensed;

(c) Prescribe a drug to a client for extra-label use on a patient unless all of the following apply:

1. A veterinary-client-patient relationship exists between the veterinarian, client and patient and the veterinarian has made a careful medical diagnosis of the condition of the patient within the context of that veterinarian-client-patient relationship;

2. The veterinarian determines that there is no drug that is marketed specifically to treat the patient's diagnosed condition, or determines that all of the drugs that are marketed for that purpose are clinically ineffective;

3. The veterinarian recommends procedures for the client to follow to ensure that the identity of the patient shall be maintained; and

4. If the patient is a food producing animal, the veterinarian prescribes a sufficient time period for drug withdrawal before the food from the patient may be marketed; or

(d) Transmit a prescription electronically unless the client approves the transmission and the prescription is transmitted to a pharmacist or veterinarian designated by the client.

Section 3. Labeling. (1) A veterinarian shall not dispense a drug that has been prepared, mixed, formulated or packaged by the veterinarian unless the veterinarian affixes to the container in which the drug is dispensed a label containing all of the information specified in Section 2(1) of this administrative regulation, except the address of the client.

(2) A veterinarian shall not dispense a veterinary prescription drug that has been prepackaged by its manufacturer for dispensing unless the veterinarian affixes to the container in which the drug is dispensed a label containing all of the information specified in Section 2(1) of this administrative regulation, except the address of the client.

(3) A veterinarian may dispense a veterinary over the counter drug without affixing any information to the container in which the drug is dispensed if a label that has been affixed to the container by its manufacturer provides adequate information for its use.

Section 4. Prescription Records. (1) A veterinarian shall maintain complete records of each veterinary prescription drug that the veterinarian receives, prescribes, dispenses or administers, and of each prescription issued by the veterinarian that authorizes extra-label use.

(2) Records of each veterinary prescription drug shall include the name of each veterinary prescription drug that is received, the name and address of the person from whom the drug is received and the date and quantity received, the name and address of the person to whom the drug is dispensed and the date and quantity dispensed and, if the veterinarian prescribes or administers the drug, the information specified in Section 2(1) of this administrative regulation.

(3) Records of each prescription authorizing extra-label use shall include the information specified in Section 2(1) of this administrative regulation.

(4) A veterinarian shall maintain records of each veterinary prescription drug for not less than five (5) years after the date on which the veterinarian prescribes, dispenses or administers the drug or extra-label use.

Section 5. (1) A veterinarian shall not be required to write a prescription for controlled sub-

stances or a prescription for any medication that, in the veterinarian's medical judgment, is not appropriate for the patient's medical care.

(2) A veterinarian may refuse to write a prescription if it is not directly requested by a client with whom there is, in the veterinarian's opinion, a current and existing veterinarian-patient-client relationship.

(3) A prescription shall be construed to include any manner of authorization for filling a prescription, including verbal or electronic communication.

(4) The veterinarian may delegate to an office employee the authority to communicate a refill of a legend drug to the pharmacy on behalf of the veterinarian pursuant to written protocol established prior to the delegation of that authority.

Section 6. (1) A veterinarian shall ensure that all federal legend drugs and veterinary prescription drugs are maintained, administered, prescribed, dispensed, and destroyed in compliance with all state and federal laws.

(2) A veterinarian shall not prescribe or dispense a quantity of drug that is greater than that the amount required for six (6) months of treatment for an animal, herd, or flock.

(3) To prescribe, sell, distribute, or dispense any drug requiring a prescription for use in the context of an animal, herd, or flock, a veterinarian shall first do all of the following:

(a) Perform an appropriate history and physical examination;

(b) Make a diagnosis based upon the history, physical examination, and pertinent diagnostic and laboratory tests;

(c) Formulate a therapeutic plan, and discussed it with the animal's owner, agent, or guardian, along with the basis for it and the risks and benefits of various treatments options, a part of which might be a prescription drug; and

(d) Ensure availability of the veterinarian or the veterinarian's staff for appropriate follow-up care.

Section 7. (1) A veterinarian may dispense a prescription drug only if the prescribing veterinarian has established a veterinarian-client-patient relationship.

(2) If the dispensing veterinarian does not have a veterinarian-client-patient relationship, a veterinary assistant may assist in the delivery of a veterinary drug, legend drug, or veterinary prescription drug only under the direct supervision of the licensed veterinarian by whom the assistant is employed.

(3) If the dispensing veterinarian does have a veterinarian-client-patient relationship, a veterinary assistant may assist in the delivery of a veterinary drug, legend drug, or veterinary prescription drug under the indirect supervision of the veterinarian by whom the assistant is employed.

(4) If a veterinary assistant acts under the provisions of this section, it shall be the responsibility of the licensed veterinarian to ensure that the requirements of this administrative regulation are met.

Section 8. Enforcement. Except as provided in subsection 2 of this section, if the board has reason to believe that a person is violating or has violated this administrative regulation, the examining board may:

(1) Inspect the premises on which the person possesses, prescribes, dispenses, labels or administers veterinary drugs;

(2) Inspect pertinent records, equipment, materials, containers or facilities that are relevant to determining whether the person is violating or has violated this administrative regulation; and

(3) Collect relevant samples of veterinary drugs found on the premises. (35 Ky.R. 1902; eff. 10-31-2008.)