

GENERAL GOVERNMENT CABINET
Kentucky Board of Veterinary Examiners
(New Administrative Regulation)

201 KAR 16:300. 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.

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 official 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 drug; 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, not to exceed the limitations set forth in Section 6(2) of this administrative regulation.

(2) A veterinarian shall not prescribe for or dispense to a client a veterinary prescription drug or a drug for extra-label use without first personally examining the patient unless a veterinary-client-patient relationship already exists between the prescribing veterinarian, client and patient, and the veterinarian determines that the client has sufficient knowledge to administer the drug properly.

(3) A veterinarian shall not 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.

(4) A veterinarian shall not prescribe a drug to a client for extra-label use on a patient unless all of the following apply:

(a) The 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;

(b) 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;

(c) The veterinarian recommends procedures to ensure that the identity of the patient(s) receiving the drug can be readily ascertained in the future; and

(d) 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.

(5) A veterinarian shall not transmit a prescription electronically unless the client approves the transmission and the prescription is transmitted to a pharmacist or veterinarian designated by the client.

(6) A veterinarian shall not refuse to write an otherwise appropriate prescription for a patient solely because the prescription may be filled at an establishment other than the veterinarian's own clinic or pharmacy.

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 at least 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 may refuse to write a prescription for controlled substances 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 federal legend drugs and veterinary prescription drugs are maintained, logged, administered, prescribed, dispensed, and destroyed in compliance with 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 discuss it with the animal's owner (or the owner's 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 licensed veterinary technician or a veterinary assistant may assist in the delivery of a veterinary drug, legend drug, or veterinary prescription drug only while he or she is under the direct supervision of the veterinarian who is his or her employer.

(3) If the dispensing veterinarian does have a veterinarian-client-patient relationship, a licensed veterinary technician or veterinary assistant may assist in the delivery of a veterinary drug, legend drug, or veterinary prescription drug while he or she is under the indirect supervision of the veterinarian who is his or her employer.

(4) If a licensed veterinary technician or veterinary assistant acts under the provisions of this section, it shall be the responsibility of the licensed veterinarian to ensure that the require-

ments of this administrative regulation are met.

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

- (1) Inspect the premises on which the person possesses, prescribes, dispenses, labels or administers veterinary drugs;
- (2) Inspect relevant records, equipment, materials, containers, or facilities;
- (3) Collect samples of veterinary drugs found on the premises; and
- (4) Conduct any other investigative activities necessary to open a case and issue a determination and, if necessary, hold hearings and enact discipline on the individual.

STEVEN J. WILLS, DVM, Chair

APPROVED BY AGENCY: June 14, 2019

FILED WITH LRC: June 19, 2019 at 3 p.m.

PUBLIC HEARING AND PUBLIC COMMENT PERIOD: A public hearing on this administrative regulation shall be held on August 27, 2019 at 1:00 p.m., at the Kentucky Department of Agriculture, 111 Corporate Drive, Frankfort, Kentucky 40601. Individuals interested in being heard at this hearing shall notify this agency in writing by five workdays prior to the hearing, of their intent to attend. If no notification of intent to attend the hearing was received by that date, the hearing may be cancelled. A transcript of the public hearing will not be made unless a written request for a transcript is made prior to the end of the hearing. If you do not wish to be heard at the public hearing, you may submit written comments on the proposed administrative regulation. Written comments shall be accepted through August 31, 2019. Send written notification of intent to be heard at the public hearing or written comments on the proposed administrative regulation to the contact person.

CONTACT PERSON: Clint Quarles, Staff Attorney, Kentucky Department of Agriculture, 107 Corporate Drive, Frankfort Kentucky 40601, phone (502) 330-6360, fax (502) 564-2133, email clint.quarles@ky.gov.

REGULATORY IMPACT ANALYSIS AND TIERING STATEMENT

Contact Person: Clint Quarles

- (1) Provide a brief summary of:
 - (a) What this administrative regulation does: This regulation establishes the requirements for persons with a veterinary license for prescription and dispensation of drugs for animal use.
 - (b) The necessity of this administrative regulation: This regulation is necessary to establish the KBVE board requirements for prescription and dispensation of drugs for animal use.
 - (c) How this administrative regulation conforms to the content of the authorizing statutes: KRS 321.235 and 321.240 each require the board to create requirements for prescription and dispensation of drugs for animal use. This filing fulfills that requirement.
 - (d) How this administrative regulation currently assists or will assist in the effective administration of the statutes: This administrative regulation will assist in effective administration by clearly expressing what requirements are created by the KBVE board for prescription and dispensation of drugs for animal use.
- (2) If this is an amendment to an existing administrative regulation, provide a brief summary of:
 - (a) How the amendment will change this existing administrative regulation: This is a new administrative regulation.

(b) The necessity of the amendment to this administrative regulation: This is a new administrative regulation.

(c) How the amendment conforms to the content of the authorizing statutes: This is a new administrative regulation.

(d) How the amendment will assist in the effective administration of the statutes: This is a new administrative regulation.

(3) List the type and number of individuals, businesses, organizations, or state and local governments affected by this administrative regulation: 2392 veterinary licenses

(4) Provide an analysis of how the entities identified in question (3) will be impacted by either the implementation of this administrative regulation, if new, or by the change, if it is an amendment, including:

(a) List the actions that each of the regulated entities identified in question (3) will have to take to comply with this administrative regulation or amendment: Applicants will be required to submit application materials as outlined in this filing.

(b) In complying with this administrative regulation or amendment, how much will it cost each of the entities identified in question (3): No costs are associated with compliance, as this is a prerequisite for application.

(c) As a result of compliance, what benefits will accrue to the entities identified in question (3): Administrative ease of clear communication of the approved requirements.

(5) Provide an estimate of how much it will cost the administrative body to implement this administrative regulation:

(a) Initially: No costs are anticipated.

(b) On a continuing basis: No costs are anticipated.

(6) What is the source of the funding to be used for the implementation and enforcement of this administrative regulation: This administrative regulation does not establish fees. Fees for the KBVE come from license and certification fees.

(7) Provide an assessment of whether an increase in fees or funding will be necessary to implement this administrative regulation, if new, or by the change if it is an amendment: No fees are necessary at this time.

(8) State whether or not this administrative regulation established any fees or directly or indirectly increased any fees: No fees are established.

(9) TIERING: Is tiering applied? No. All regulated entities have the same requirements.

FISCAL NOTE ON STATE OR LOCAL GOVERNMENT

(1) What units, parts, or divisions of state or local government (including cities, counties, fire departments, or school districts) will be impacted by this administrative regulation? The KBVE

(2) Identify each state or federal statute or federal regulation that requires or authorizes the action taken by the administrative regulation. KRS 321.235, KRS 321.240

(3) Estimate the effect of this administrative regulation on the expenditures and revenues of a state or local government agency (including cities, counties, fire departments, or school districts) for the first full year the administrative regulation is to be in effect.

(a) How much revenue will this administrative regulation generate for the state or local government (including cities, counties, fire departments, or school districts) for the first year? No revenue will be generated from this filing.

(b) How much revenue will this administrative regulation generate for the state or local government (including cities, counties, fire departments, or school districts) for subsequent years? No revenue will be generated.

(c) How much will it cost to administer this program for the first year? Staff time for record

keeping.

(d) How much will it cost to administer this program for subsequent years? Staff time will be required for record keeping. Costs will be very minimal.

Note: If specific dollar estimates cannot be determined, provide a brief narrative to explain the fiscal impact of the administrative regulation.

Revenues (+/-): None

Expenditures (+/-): None or negligible.

Other Explanation: