201 KAR 2:311. Compounding drugs for veterinary use.

RELATES TO: KRS 315.191(1)(a), 321.441
STATUTORY AUTHORITY: KRS 315.191(1)(a)
NECESSITY, FUNCTION, AND CONFORMITY: KRS 315.191(1)(a) authorizes the board to promulgate administrative regulations necessary to regulate and control all matters relating to pharmacists, pharmacist interns, pharmacy technicians, and pharmacies. This administrative regulation establishes requirements for compounding for veterinary use.

Section 1. The pharmacist shall receive a written, verbal, facsimile, or electronic request for a compounded drug from a practitioner, indicating the formulation, strength, and quantity ordered.

Section 2. A compounded drug containing a controlled substance shall only be compounded for patient specific dispensation from the pharmacy to the ultimate user.

Section 3. (1) A pharmacist, pharmacist intern, or pharmacy technician may prepare a non-controlled compounded drug to be dispensed for veterinary use or administration that is either institutional or ambulatory, and which does not designate a specific patient for the purpose of direct administration to patients for:
(a) Emergency treatment;
(b) Situations when a time delay would negatively affect a patient outcome; or
(c) Diagnostic purposes.
(2) The compounded drug shall have a beyond use date.
(3) The veterinary institution or ambulatory unit shall maintain only an emergency stock supply.
(4) A veterinarian or licensed veterinary technician, as defined in KRS 321.441, may administer a compounded drug for veterinary use.

Section 4. Label Requirements. Except as provided for in Section 5, a label shall be generated for the compounded drug and shall include:
(1) The name of the requesting veterinarian;
(2) The designated name and strength of the compounded drug;
(3) The quantity dispensed;
(4) If for a specific patient and the patient is a food producing animal, the withdrawal time;
(5) A lot or batch number of the compounded drug;
(6) The beyond use date for the compounded drug;
(7) The date the compounded drug is dispensed;
(8) The pharmacy's name, address, and telephone number;
(9) Any special storage requirements;
(10) A notation stating "For veterinary use"; and
(11) Any auxiliary label required for the compounded drug.

Section 5. (1) A non-controlled substance compounded drug shall be dispensed by a veterinarian for emergency take home use when in his or her professional judgment, failure to provide the drug would result in potential harm to the patient.
(2) If dispensed from the veterinary institution or ambulatory unit, a compounded drug prescription for a veterinary patient shall be for up to a 14-day supply in accordance with the veterinarian prescription and dispensation labeling requirements as established in 201 KAR

16:600.

Section 6. The prescription for the compounded drug shall be kept pursuant to 201 KAR 2:170. (46 Ky.R. 3063; 47 Ky.R. 941; eff. 11-19-2020)