KENTUCKY BOARD OF PHARMACY

via teleconfence

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Special Called Board Meeting
September 8, 2020
10:00 a.m.

Agenda

I. Call to Order

II. 201 KAR 2:311, Compounding for veterinary use.

III. Adjournment

BOARDS AND COMMISSIONS

Kentucky Board of Pharmacy

(Amended after Comments)

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

RELATES TO KRS 315.191(1)(a).

STATUTORY AUTHORITY: KRS 315.191(1)(a)

NECESSITY, FUNCTION, AND CONFORMITY: KRS 315.191(1)(a) requires the board to promulgate administrative regulations to regulate and control all matters relating to pharmacists, pharmacist interns, pharmacy technicians, and pharmacies. This administrative regulation addresses 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.** **[~~A pharmacist, pharmacist intern, or pharmacy technician may prepare a compounded drug to be dispensed for a veterinarian's administration with beyond use dates as assigned in accordance.~~]**

Section 2. A compounded drug **containing** **[~~that contains~~]** a controlled substance shall only be compounded for patient specific dispensation **[~~directly~~]** from 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 (institutional or ambulatory) and which does not designate a specific patient for the purpose of direct administration to patients for emergency treatment, situations when a time delay would negatively affect a patient outcome, or 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) shall be able to administer a compounded drug for veterinary use. **[~~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 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 [**~~practitioner~~];

(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[**~~**(5)**~~**]**) The beyond use date for the compounded drug;

(**7**[~~(6)~~]) The date the compounded **drug** is dispensed;

(**8**[~~(7)~~]) The pharmacy's name, address, and telephone number;

(**9**[~~(8)~~]) Any special storage requirements;

(**10**[~~(9)~~]) A notation stating "For **[~~Office or Institutional administration for~~]** veterinary use";

(**11**[~~(10)~~]) Any auxiliary label required for the compounded drug.

Section 5. (1) A non-controlled substance **[~~(11) The~~]** compounded drug shall be **[~~administered or~~]** dispensed by **a[~~the~~]** veterinarian **[~~or veterinarian technician~~]** 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) When 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 found in 201 KAR 16:600. **[~~for up to a 14 day supply in accordance with veterinarian labeling requirements.~~]**

Section **6**[~~5~~]. The prescription for the compounded drug shall be kept pursuant to 201 KAR 2:170.