

GENERAL GOVERNMENT CABINET
Kentucky Board of Pharmacy
(Amendment)

201 KAR 2:310. Compounding for a veterinarian's~~[practitioner]~~ office or institutional administration 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 use by a veterinarian's~~[practitioner]~~ office, administration or institutional administration for veterinary use.

Section 1. A pharmacist, pharmacist intern, or pharmacy technician may prepare a compounded drug for a veterinarian's~~[practitioner]~~ office administration or institutional administration for veterinary use.

Section 2. A compounded drug that contains a controlled substance shall not be compounded for office or institutional administration for veterinary use.

Section 3. 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. A label shall be generated for the compounded drug and shall include:

- (1) The name of the practitioner;
- (2) The designated name and strength of the compounded drug;
- (3) The quantity dispensed;
- (4) A lot or batch number of the compounded drug;
- (5) The beyond use date for the compounded drug;
- (6) The date the compounded is dispensed;
- (7) The pharmacy's name, address, and telephone number;
- (8) Any special storage requirements;
- (9) A notation stating "For Office or Institutional administration for veterinary use Only-Do Not Dispense~~[to Patient]~~";
- (10) Any auxiliary label required for the compounded drug.

Section 5. The compounded drug shall be administered in the veterinarian's~~[practitioner]~~ office or institution and shall not be dispensed~~[to the patient]~~.

Section 6. The prescription for the compounded drug shall be kept pursuant to 201 KAR 2:170.

LARRY A. HADLEY, R.Ph., Executive Director

APPROVED BY AGENCY: May 14, 2019

FILED WITH LRC: May 15, 2019 at 10 a.m.

PUBLIC HEARING AND PUBLIC COMMENT PERIOD: A public hearing on this administrative regulation shall be held on June 21, 2019, at 9:00 a.m. Eastern Time at the Kentucky Board of Pharmacy, 125 Holmes Street, Suite 300, State Office Building Annex, 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 is received by that date, the hearing may be canceled. This hearing is open to the public. Any person who wishes to be heard will be given an opportunity to comment on the proposed administrative regulation. A transcript of the public hearing will not be made unless a written request for a transcript is made. 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 June 30, 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: Larry Hadley, Executive Director, Kentucky Board of Pharmacy, 125 Holmes Street, Suite 300, State Office Building Annex, Frankfort, Kentucky 40601, phone (502) 564-7910, fax (502) 696-3806, email Larry.Hadley@ky.gov.

REGULATORY IMPACT ANALYSIS AND TIERING STATEMENT

Contact person: Larry Hadley

(1) Provide a brief summary of:

(a) What this administrative regulation does: This administrative regulation addresses compounding for use by a veterinarian's office administration or institutional administration for veterinary use.

(b) The necessity of this administrative regulation: 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 use by a veterinarian's office administration or institutional administration for veterinary use.

(c) How this administrative regulation conforms to the content of the authorizing statutes: This administrative regulation addresses compounding for use by a veterinarian's office administration or institutional administration for veterinary use.

(d) How this administrative regulation currently assists or will assist in the effective administration of the statutes: Retitle this regulation to Compounding for a veterinarian's office or institutional administration for veterinary use. Update language to restrict this practice to veterinary 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: Retitle this regulation; Retitle this regulation to Compounding for a veterinarian's office or institutional administration for veterinary use. Update language to restrict this practice to veterinary use.

(b) The necessity of the amendment to this administrative regulation: The criteria needed to be updated.

(c) How the amendment conforms to the content of the authorizing statutes: KRS 315.191 authorizes the board to promulgate administrative regulations pertaining to pharmacists and pharmacies.

(d) How the amendment will assist in the effective administration of the statutes: The amendment will further promote, preserve, and protect public health through effective regulation of pharmacists and pharmacies by updated language to restrict this practice to veterinary

use.

(3) List the type and number of individuals, businesses, organizations, or state and local governments affected by this administrative regulation: The board anticipates pharmacies and pharmacists will be affected minimally by this regulation amendment.

(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: Pharmacies and pharmacists will have to familiarize themselves with amended language. The board will help to educate pharmacists and pharmacies in these changes.

(b) In complying with this administrative regulation or amendment, how much will it cost each of the entities identified in question (3): There are no expected costs for the identities to comply with the amendment.

(c) As a result of compliance, what benefits will accrue to the entities identified in question (3): This amendment will clarify previous statutory language. .

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

(a) Initially: No costs will be incurred.

(b) On a continuing basis: No costs will be incurred.

(6) What is the source of the funding to be used for the implementation and enforcement of this administrative regulation: Board revenues from pre-existing fees provide the funding to enforce the regulation.

(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 increase in fees or funding will be required because of this new regulation.

(8) State whether or not this administrative regulation establishes any fees or directly or indirectly increases any fees: This administrative regulation does not establish fees or directly or indirectly increase any fees.

(9) TIERING: Is tiering applied? Tiering is not applied because the regulation is applicable to all pharmacists and sponsors that desire approval for continuing education credit.

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 Kentucky Board of Pharmacy will be impacted by this administrative regulation.

2. Identify each state or federal statute or federal regulation that requires or authorizes the action taken by the administrative regulation. KRS 315.191(1)(a).

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? This administrative regulation will not generate revenue for the board in the first year.

(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? This administrative regulation will not generate revenue for the board in subsequent years.

(c) How much will it cost to administer this program for the first year? No costs are required to administer this program for the first year.

(d) How much will it cost to administer this program for subsequent years? No costs are required to administer this program for subsequent years.

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

Revenues (+/-): 0

Expenditures (+/-): 0

Other Explanation: