

KENTUCKY BOARD OF PHARMACY

125 Holmes Street

Frankfort KY 40601

July 31, 2019

9:00 AM

Agenda

I. CALL TO ORDER

II. MINUTES

A. *May 29, 2019

III. ETHICS – Kathryn Gabhart, Executive Director of the Executive Branch Ethics Commission

IV. APPEARANCES

A. *Ashish Parehk – Pharmacy Technician Application

B. *Margaret Sawyers – Pharmacy Technician Application

C. *Alexander Anderson – Permission to sit for exams

D. *Alexander Rababeh – Initial Pharmacist Application

E. *Rich Palombo – Express Scripts

F. *Cubex LLC

1. *201 KAR 3:370 Pharmacy services in long-term care facility(LTCF).

V. INTERAGENCY

VI. BOARD REPORTS

A. Executive Director

1. *eMars – May and June 2019

2. 2019 ASPL Fall Meeting – November 7-10, 2019

3. NABP District III, Chattanooga, TN – August 11-13, 2019

4. MALTAGON, Biloxi, MS – October 27-30, 2019

B. Anthony Gray

1. *Modification of Application for Pharmacist Licensure

2. Medication Error case review panel recommendations

a. *Summary of administrative fines for med error cases

VII. CURRENT/PENDING CASES

A. *Case Update and Fines Report

B. *Pharmacy Technician Summary

C. *Sarah Wallace - Reciprocal

VIII. CORRESPONDENCE

A. *Brett Vickey, 'Farmacy' concern

B. *Chewy Pharmacy, Compounding Equipment Waiver

C. *Genoa Healthcare – Offsite Storage Requests

- D. *St. Matthews Community Pharmacy and Specialty Pharmacy – Offsite Storage Requests
- E. *St. Claire Healthcare – Compounding Waiver
- F. *Meijer – Compounding Equipment Waiver
- G. *Lou Rego – CE Extension Request
- H. *Mark Rueth – CE Extension Request
- I. *Minh-Hai Pelkey – CE Extension Request
- J. *Douglas Mack – CE Extension Request
- K. *David Kazarian – CE Extension Request
- L. *Julie Harting – CE Extension Request
- M. *Peter Van Ess – CE Extension Request

IX. LEGISLATION/REGULATION

- A. *201 KAR 2:310 Compounding for Veterinarian’s Office
 - 1. *Summary of Written Comments
 - 2. *Written Comments
 - 3. *NABP Modeling Act – Compounding Section
- B. *201 KAR 2:095 Pharmacist Interns
- C. 201 KAR 2:175 Emergency 72 hour refills
 - 1. *Current version
 - 2. *HB 64
 - 3. *Proposed amended version due to HB 64
- D. *201 KAR 2:165 Transfer of prescription information.
 - 1. *Written Comments

X. CONTINUING EDUCATION

- A. *CE Programs – 19-39 through 19-42

XI. OLD BUSINESS

- A. *Comments on USP 800
 - 1. *Safe Handling of Hazardous Drugs: ASCO Standards
 - 2. *USP Chapter 800 Hazardous Drugs – Handling in Healthcare Settings, 2017 ACPE Fall Conference
 - 3. USP 795
 - 4. USP 797
 - 5. USP 825

XII. NEW BUSINESS

- A. *Iron Mountain Storage – Offsite Storage Blanket Waiver
- B. *LegitScript

*Information enclosed with this agenda.

1 GENERAL GOVERNMENT CABINET

2 Kentucky Board of Pharmacy

3 (Amendment)

4 201 KAR 2:310. Compounding for a veterinarian's [~~practitioner~~] office or institutional
5 administration for veterinary use.

6 RELATES TO KRS 315.191(1)(a). STATUTORY AUTHORITY:

7 KRS 315.191(1)(a)

8 NECESSITY, FUNCTION, AND CONFORMITY: KRS 315.191(1)(a) requires the board to
9 promulgate administrative regulations to regulate and control all matters relating to
10 pharmacists, pharmacist interns, pharmacy technicians, and pharmacies. This administrative
11 regulation addresses compounding for use by a veterinarian's [~~practitioner~~] office,
12 administration or institutional administration for veterinary use.

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

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

18 Section 3. The pharmacist shall receive a written, verbal, facsimile, or electronic request for a
19 compounded drug from a practitioner, indicating the formulation, strength, and quantity
20 ordered.

21 (a) Section 4. Label Requirements. A label shall be generated for the compounded drug and

- 1 (b) shall include:
- 2 (1) The name of the practitioner;
- 3 (2) The designated name and strength of the compounded drug;
- 4 (3) The quantity dispensed;
- 5 (4) 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 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 Only-
- 11 Do Not Dispense [~~to Patient~~];
- 12 (10) Any auxiliary label required for the compounded drug.

13 Section 5. The compounded drug shall be administered in the veterinarian's [~~practitioner~~]

14 office or institution and shall not be dispensed [~~to the patient~~].

15 (11) Section 6. The prescription for the compounded drug shall be kept pursuant to 201

16 KAR 2:170.

Larry A. Hadley, R.Ph.
Executive Director
Kentucky Board of Pharmacy

Date

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

201 KAR 2:310 Compounding for a practitioner's office or institutional administration

Contact person: Larry Hadley

Contact Phone No.: 502-564-7910

Contact email: larry.hadley@ky.gov

(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? (Explain why tiering was or was not used) 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

Regulation No. 201 KAR 2:310 Compounding for a practitioner's office or institutional administration.

Contact Person: Larry Hadley

Contact Phone No.: 502-564-7910

Contact email: larry.hadley@ky.gov

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:

201 KAR 2:310 Written Comments - Bullets

1. Compounding pharmacies may not be open for the client to pick up prescription.
2. Veterinarians need to retain the ability to dispense compounded medications.
3. Not all horse facilities are convenient to the location of the compounding pharmacies.
4. Compounds are often compounded at the time the order is placed rather than being available in pharmacy stock resulting in delay of being available.
5. Most prescriptions are necessary for immediate implementation for the health and well-being of the patient.
6. Availability to clients to have on site or pick up if no immediate need.
7. Many medications have become unavailable through veterinary distributors because of back order and discontinuance of production.
8. Some veterinary practice locations extend beyond the doors of a fixed clinic, e.g. mobile clinic.
9. Time is critical for the patients.
10. The unique nature of veterinary medicine requires not only access to compounded medication, but immediate access to compounded medications.
11. Other states have passed regulations allowing pharmacies to compound medications for veterinary office use administration and dispensing without restrictions on quantities sold or dispensed.
12. Access to required medications is a vital component to veterinarians.
13. Compound pharmacies offers us the ability to find drugs in specific strengths, vehicles (liquid vs chewable tablets, topical cream) to facilitate client/owner administration.
14. Many therapies only exist in compounded form due to not being commercially available.
15. Veterinarians need medication at the time of diagnosis.
16. While we appreciate the tremendous pressure placed on the Board of Pharmacy to address controlled substance diversion and opioid abuse, we believe that complete prohibition of compounded controlled substances for veterinary office use is inconsistent with the Board's mission to protect the public.

201 KAR 2:310 Written Comments Summary

1. Compounding pharmacies may not be open for the client to pick up prescription.
2. Veterinarians need to retain the ability to dispense compounded medications.
3. Not all horse facilities are convenient to the location of the compounding pharmacies.
4. Compounds are often compounded at the time the order is placed rather than being available in pharmacy stock. Therefore, there is a lag time between the prescription being placed and being available.
5. Most prescriptions are necessary for immediate implementation for the health and well being of the patient, i.e. antibiotics, pain medications and the lag time between prescription and driving to the pharmacy to pick up the prescription is inappropriate.
6. We are required by law to offer prescriptions directly to the client instead of dispensing from stock so the opportunity is already there for the client to pick up or have the compounds shipped if there is no immediate pressing need.
7. Many medications have become unavailable through veterinary distributors because of back order and discontinuance of production.

Example: Aminopentamide was commonly available for years under the name Centrine. Centrine was a wonder drug for small animal diarrhea and vomiting because it was safe and effective. After going off the market, several compounding pharmacies began to make Aminopentamide tiny tabs. We keep it on hand at our clinic for dosing in house and dispensing. This eliminates the 3-4 day wait time for a mail-in prescription.

Example: Metronidazole is commonly used to treat small intestinal disease, liver disease, and some parasite diseases. The small dose available on the market is 250 mg tablet. This is fine for a 50 lb dog but a 4 lb puppy or kitten would be overdosed using this size, resulting in neurological problems and seizures. Before compounding we had to cut a 250 mg tablet into 8-10 pieces to administer to tiny pets. We now have compounded Metronidazole tiny tabs which are 50mg tablets which can be scored for efficient and accurate dosing. It needs to be kept on hand and dispense to clients on an outpatient basis in order to treat the condition immediately and not have to wait up to a week to get the medication in the mail.

8. The dilemma this restrictive language presents in veterinary medicine reduces, in some practice types, the benefit that could be gained in dispensing compounded medication by a larger group of veterinary practitioners. Some veterinary practice locations extend beyond the doors of a fixed clinic, due to the ambulatory practice many rural veterinary practitioners continue to maintain in service to owners of large animals unable to be transported to a fixed location. The logistics of acute therapy in many of these animal patients would be interrupted if needed medication was not available.

201 KAR 2:310 Written Comments Summary

Example: As ambulatory practitioners, we utilize vehicles equipped to handle regular daily calls, stocked with diagnostic equipment, drugs and supplies, as well as emergency equipment that might be needed. A routine day consists of leaving the home or office before daylight and spending most of the day attending to numerous clients (trainers) having training horses under their oversight and management. This process is a continuum most often times only returning to the office for resupply once a day or restocking the vehicles at the end of the day. Treating these animals can be from an individual daily requirement, i.e. antibiotic injections, to medications that are oral or topical and can be managed by the trainer/custodian, followed up on by the attending DVM. Not having these drugs/compounds would compromise the care and welfare of our patients.

9. Many of the patients in veterinary practice suffer from exercise induced myopathy. The ability to use dantrolene liquid (only available compounded) makes a large number of horses able to compete. Time is of critical essence for the patients.

10. Unlike human medical doctors, veterinarians' offices often serve as emergency rooms, hospitals, and pharmacy for animal patients. Veterinarians must, in many instances, travel to their animal patients for on-site treatment. For example, veterinarians treating horses at a barn or animals in a zoo must do so on-site as such animals cannot travel to a veterinary office for treatment. As a result, the unique nature of veterinary medicine requires not only access to compounded medication, but immediate access to compounded medications. Without access to compounded medications for office use, animal patients would not receive the medical treatment they often desperately need.

Example: In states that do not allow office use of compounded medications, 78% report that this has had a negative impact on their ability to practice medicine. Not allowing veterinarians to dispense compounded medications from office use stock to pet owners threatens uninterrupted treatment and can present risk to human health.

11. The states of Florida and Illinois have passed regulations allowing pharmacies to compound medications for veterinary office use administration and dispensing without restrictions on quantities sold or dispensed. California and Ohio passed similar legislation, although with some limits on the days of supply of dispensed medication. Most recently, the State Boards of Pharmacy in Missouri, Georgia and Mississippi have amended their regulations to allow for veterinarians to both stock and dispense medications compounded for office use. Legislation containing similar language awaits the Governor's signature in Minnesota.

12. While we appreciate the tremendous pressure placed on the Board of Pharmacy to address controlled substance diversion and opioid abuse, we believe that complete prohibition of compounded controlled substances for veterinary office use is inconsistent with the Board's mission to protect the public. Access to required medications is a vital component of public safety. If a pharmacy has fulfilled the requirements to distribute compounded preparations under the Federal Controlled Substances Act, the Kentucky Board of Pharmacy should not deny veterinarians access to those medications.

201 KAR 2:310 Written Comments Summary

13. Compound pharmacies offers us the ability to find drugs in specific strengths, vehicles (liquid vs chewable tablets, topical cream) to facilitate client/owner administration. In many cases, compounded drugs offer an owner a cost effective method of purchasing drugs. It offers us the ability to even find certain drugs.

Example: Itraconazole: DMSO ophthalmic ointment. This compound is used in certain equine eye cases. We have to be able to dispense it to an owner to use at home. There is no way that it can be feasibly used only in the office. The only way to purchase it is through a compounding pharmacy. It cannot even be purchased at any of our veterinary drug distributors.

14. Many therapies only exist in compounded form due to manufacturers discontinuing production due to lack of profit, long-term back orders or just doesn't exist in the form or concentrations we need for our huge range of patients. Human medicine only uses 1-2 sizes or forms of a medicine while in veterinary medicine, we may need 5 or more.

15. Medications like tacrolimus ophthalmic solution must be compounded as it cannot be purchased in an ophthalmic solution. If I order this medication and have the pharmacy mail it to the client, at best, there is a 2-day wait. These animals need this medication at the time of diagnosis.

16. Felids sometime need antibiotics like doxycycline for respiratory infections. Common medical knowledge tells us using a capsulated form of doxycycline would almost guarantee a medical malpractice suite. Since this medication is not produced in a flavored solution that cats prefer, compounding is mandatory. These animals need medication two days ago ... not tomorrow.



Pres. Craig Martin/Executive Director Larry Hadley

Kentucky Board of Pharmacy

State Office Building Annex, Suite 300

125 Holmes Street

Frankfort, KY 40601

larry.hadley@ky.gov

June 21, 2019

We would like to thank the Board for the opportunity to comment on the upcoming proposed rule amendments. We represent several Federally Registered Outsourcing Facilities that currently do business in your state and would like to preserve safety of compounded products for animal use.

Comments Regarding Proposed Amendments to 201 KAR 2:310 Compounding for a Practitioner's Office or Institutional Administration

We would like the Kentucky Board of Pharmacy to consider the role of 503B outsourcing facilities when drafting or amending regulations that address office-use compounding. Veterinary compounded products are available from outsourcing facilities. These compounded products are produced under the same stringent quality standard as traditional drug manufacturers, CGMP (current good manufacturing practices). Veterinarians should be required to purchase office-use products from outsourcing facilities. Meeting CGMP quality standards for office-use is critical for human and veterinary use as indicated by several State Boards of Pharmacy that do not allow veterinary dispensing of United States Pharmacopeia (USP) compounded drugs at all, but allow unlimited dispensing of outsourcing drugs pursuant to a prescription. Along these same lines, Connecticut has recently mandated that veterinarians procure ALL of their office-use compounded products from a licensed and registered outsourcing facility. CGMP is the quality standard that Congress and the Food and Drug Administration (FDA) demand for human office-use compounds and there is no credible reason Kentucky should not demand as much for its companion animals.

Federal Law and FDA Allow Veterinary Compounding by Outsourcing Facilities

FDA acknowledges that compounding animal drugs from bulk substances is appropriate under certain circumstances¹. In addition, FDA has acknowledged on several occasions that veterinary compounding takes place in outsourcing facilities. Nowhere in the federal regulations is it stated that outsourcing facilities may not compound animal drugs. FDA both acknowledges and allows animal compounding by outsourcing facilities.

Availability of Veterinary Compounds from Outsourcing Facilities

Human sterile drug products and other human compounded products are used for veterinary use to a very large extent. FDA maintains a list of the products outsourcing facilities have produced over previous six-month periods. This list is available to the public and to healthcare practitioners, including

¹ <https://www.fda.gov/AnimalVeterinary/NewsEvents/CVMUpdates/ucm580525.htm>

veterinarians, is searchable and sortable, and contains active ingredients, package sizes and descriptions, as well as other information. This list is reflective of the products already available, sterile and non-sterile, for veterinary use. If State Boards begin to require veterinarians to obtain CGMP products for office-use, as Connecticut has, the number of available CGMP veterinary products will increase at an even more rapid pace. At least one member of our 503B group estimates that its outsourcing facility can already fulfill 75% of its nationwide veterinarian office-use orders, and this estimate increases to 90% if the veterinarians determines a minor dosage adjustment is acceptable. Keep in mind, this estimate is only for one outsourcing facility, there are approximately 74 other outsourcing facilities registered with FDA. In addition, FDA is working diligently to provide outsourcing facilities the ability to provide small batches of product to practitioners. This allows for an even greater availability of veterinary products. Further evidence of the availability of veterinary products is provided by FDA regulations allowing for outsourcing facilities with a controlled substance manufacturing license to compound controlled substances for office use.

CGMP vs. USP

CGMP is the standard that Congress demands for widespread human office use compounding. There is no reason this standard should not be met for office use products provided for Kentucky's companion animals. FDA has stated that by registering as an outsourcing facility, the facility is agreeing to produce all of its compounded drugs (this would include compounded animal drugs) under CGMP quality standards. CGMP requires several testing procedures that USP does not require at all, such as finished product testing for potency and endotoxins. Several procedures, including viable monitoring, are required to be performed much more often under CGMP than USP. CGMP also requires a much higher level of documentation ensuring that the ingredient information and equipment information used to compound each batch are recoverable. CGMP also demands stability testing which provides oftentimes for longer expiration dates than Beyond Use Dates, assigned under USP. Several traditional compounding pharmacies go above and beyond USP, which is admirable, but CGMP quality standards are required, rather than being left as a choice for individual pharmacies to adopt.

Conclusion

Kentucky should require that veterinarians obtain their office-use stock from Kentucky licensed and FDA registered outsourcing facilities. Products for veterinary health are widely available as evidenced by FDA's spreadsheet listing thousands of compounded products as well as FDA's more recent efforts to enable outsourcing facilities to produce small batch sizes. These products are manufactured under the same stringent quality standards that traditional manufacturers are held to, and several procedures critical for an office-use product are required by CGMP that are not required of traditional pharmacy compounders under USP or state regulations. Several state boards allow for veterinary dispensing of 503B products that do not allow for the dispensing of 503A products, and FDA has acknowledged and allows outsourcing facilities to compound products for animal health. For all of these reasons, Kentucky should require veterinarians to purchase their office-use stock from a 503B outsourcing facility.

Please let us know if you have any questions,

Aaron

Aaron R Lopez, JD, FCLS
Political Capital LLC

Hadley, Larry A (KY Board of Pharmacy)

From: Jerry Johnson <jhjdvm@aol.com>
Sent: Sunday, June 30, 2019 9:56 AM
To: Hadley, Larry A (KY Board of Pharmacy)
Subject: Compounded medications

Dear Sir:

Veterinarians need to retain the ability to dispense compounded medications.

We see horses at all times of the day and night. Compounding pharmacies may not be open for the client to pick up prescriptions.

Not all horse facilities are convenient to the location of the Compounding pharmacies

Compounds are often compounded at the time the order is placed, rather than being available in pharmacy stock. Therefore, there is a lag time between the prescription being placed and being available.

Most prescriptions are necessary for immediate implementation for the health and well being of the patient (eg antibiotics, pain medications), and even the lag time between prescription and driving to the pharmacy to pick up the prescription is inappropriate.

We are required by law to offer prescriptions directly to the client instead of dispensing from stock, so the opportunity is already there for the client to pick up, or have the compounds shipped if there is no immediate pressing need.

Thank you for your attention to this matter.

Sincerely,

Jerry H. Johnson, D.V.M.

Sent from my iPhone

WILDERNESS TRACE VETERINARY CLINIC

276A HENRY STREET JUNCTION CITY KY 40440

PHONE 859-854-5055

FAX 859-854-5988

FROM: Stephanie Raispis

TO: Larry Hadley

FAX #: 502-696-3806

NUMBER OF PAGES INCLUDING COVER: 4

SUBJECT: Compounded medications regulations

6/28/2019

Roundcube Webmail :: Important news for Kentucky veterinarians

Subject **Important news for Kentucky veterinarians**
From Wedgewood Pharmacy <info@wedgewoodpharmacy.com>
To <ann-maria@wildernesstracevetclinic.com>
Reply-To <info@wedgewoodpharmacy.com>
Date 2019-06-26 12:52



The Kentucky Board of Pharmacy is proposing to amend the language in their regulations regarding compounded medications for office use by veterinarians. While the Board of Pharmacy has always allowed pharmacies to compound medications for veterinary office use, the proposed language clarifies that this practice is restricted to veterinary use and that compounded medications for veterinary office use may only be administered in the veterinary facility and may not be dispensed to the pet owner.

A hearing was scheduled for June 21st, but was cancelled because no one requested an opportunity to speak prior to the 5-day notice cut off. Nevertheless, the Board will accept written comments through June 30th. This is an opportunity for veterinarians to let the Board of Pharmacy know how important it is to be able to dispense compounded medications from office stock and the negative impact not being able to dispense has had on patient care.

Written comments can be sent via mail, fax or email to:

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

All comments should be courteous and concise. Comments should include stories or examples of how the inability to dispense compounded medication from office stock has negatively affected patient care. A constructive, information-rich comment that clearly communicates and supports its claims is more likely to have an impact on regulatory decision making. Be sure to reference **Proposed Amendments: 201 KAR 2:310.**

Compounding for a veterinarian's office or institutional administration for veterinary use.

Please feel free to contact Michael Blaire, Vice President of Government and Regulatory Affairs at mblaire@wedgewoodpharmacy.com if you have any questions.

Wilderness Trace Veterinary Clinic**276 Henry Street****Junction City, Ky 40440**

To the Committee,

My name is Stephanie Raispis and I have been a small animal veterinarian for 27 years. I own Wilderness Trace Veterinary Clinic and have recently felt much pressure and anxiety concerning the prescription drug business and its affect on my business and my ability to practice the best medicine and surgery for my patients. When I read that the Board of Pharmacy is planning to keep veterinary clinics from being able to sell compounded medicines to our clients it added another layer of concern.

Compounded medications have become a life saver for many of our clients for many reasons. First, many medications have become unavailable through our veterinary distributors because of back order and discontinuance of production. One drug in particular, Aminopentamide, was commonly available for years under the name Centrline. Centrline was a wonder drug for small animal diarrhea and vomiting because it was safe and effective. All of a sudden it went off of the market. We were told that the demand for it was decreasing and the company that bought the rights to it were not interested in veterinary products because they could not make enough money from manufacturing the product compared to human drug manufacturing. Several compounding pharmacies began to make Aminopentamide tiny tabs. This was such a relief! Now we could help our vomiting and diarrhea cases right away because we have Aminopentamide back. We keep it on hand at our clinic for dosing in house and dispensing. When a pet is having watery blow out diarrhea our clients do not want to wait 3-4 days for a mail in prescription. By the time it gets to their home in the mail either the diarrhea is cleared up, the carpet is a mess or the pet has been hospitalized because it is dehydrated. Simply sending the meds home when needed offers the pet immediate treatment for the condition and the client the peace of mind that their pet is getting better and their home will not be a diarrhea ward for a week.

Another medication Metronidazole is commonly used to treat small intestinal disease and liver disease and some parasitic diseases. The smallest dose available on the market is a 250 mg tablet. This is fine for a 50 pound dog but a 4 pound puppy or kitten would be overdosed using this size. Overdosing can cause neurological problems and seizures. Before compounding we had to cut a 250 mg tablet into 8-10 pieces and administer to tiny pets. In fact, we had turned into compounders in order to treat the tiny patients. Now we have compounded Metronidazole Tiny Tabs which are 50 mg tablets which can be scored for efficient and accurate dosing. However, just like Centrline we need to be able to keep it on hand and dispense it to clients on an outpatient basis in order to treat the condition immediately and not have to wait for up to a week to get the medication in the mail.

I could go on and on listing the medication needed for pets that are not commercially available to our clients any more. However I am running out of time as I have just been made aware of this committee reviewing the need for veterinary compounding. Please consider the patients in our care and know that veterinarians are in this field to supply compassionate care to our animal family members. We need to be able to dispense compounded medications in order to keep our pets healthy!! Just consider this ... would you want to see your child have uncontrollable diarrhea for 3 days while awaiting a safe

medication to be delivered or would you feel immediate relief when the doctor sends you home with medication that will immediately begin to bring healing to your baby? The choice is in your hands!

Sincerely,

Dr Stephanie Raispls

Auburn 1991 Graduate

Hadley, Larry A (KY Board of Pharmacy)

From: James Slaughter <jlsdvm@aol.com>
Sent: Sunday, June 30, 2019 2:05 PM
To: Hadley, Larry A (KY Board of Pharmacy)
Subject: Compounded medications for veterinarians

I am concerned about the new proposals concerning compounded medication I use on a daily basis. We see horses at all times of the day and night. Compounding pharmacies may not be open for the client to pick up prescriptions. Not all horse facilities are convenient to the location of the Compounding pharmacies Compounds are often compounded at the time the order is placed, rather than being available in pharmacy stock. Therefore, there is a lag time between the prescription being placed and being available. Most prescriptions are necessary for immediate implementation for the health and well being of the patient (eg antibiotics, pain medications), and even the lag time between prescription and driving to the pharmacy to pick up the prescription is inappropriate We are required by law to offer prescriptions directly to the client instead of dispensing from stock, so the opportunity is already there for the client to pick up, or have the compounds shipped if there is no immediate pressing need. I will be unable to attend, but I am against these changes Thank you, James L Slaughter, DVM

Hadley, Larry A (KY Board of Pharmacy)

From: Frank Vice <fgvice@yahoo.com>
Sent: Sunday, June 30, 2019 11:08 PM
To: Hadley, Larry A (KY Board of Pharmacy)
Subject: Re: Dispensing Compounded Medication for Veterinarians (Proposed Amendment :201KAR 2:310)

Thank you ,,I look forward to hearing from you

Frank G, Vice DVM
Alternate Delegate
Kentucky

On Jun 30, 2019, at 10:52 PM, Hadley, Larry A (KY Board of Pharmacy) <Larry.Hadley@ky.gov> wrote:

Frank,
I will call you Tuesday and we can talk about the process of getting a regulation amended and the timelines required.
Regards,
Larry

[Get Outlook for iOS](#)

From: Frank Vice <fgvice@yahoo.com>
Sent: Sunday, June 30, 2019 10:26:33 PM
To: Hadley, Larry A (KY Board of Pharmacy)
Subject: Re: Dispensing Compounded Medication for Veterinarians (Proposed Amendment :201KAR 2:310)

Dear Larry

It is wonderful to hear from you and have this opportunity to work on these issues together, I am well ,,and yes I continue to practice large animal medicine even though I sold the small animal portion, I am committed to helping maintain a relationship with people that still need me,, and yes I work as a dispensing pharmacist for Lewis County Primary Plus, I just have to say for me personally this has been a career of a lifetime ,,in addition, Recently the KVMA allowed me to move deeper into organized veterinary and this too has been a challenge, My cell number is 606-748-1821, just a note ,,I am in the prescription department tomorrow dispensing medicine but Tuesday is a free day unless I have large animal calls, please feel free to call me as we progress.

Frank G, Vice DVM
Alternate Delegate
Kentucky

On Jun 30, 2019, at 9:57 PM, Hadley, Larry A (KY Board of Pharmacy) <Larry.Hadley@ky.gov> wrote:

Frank,

Good to hear from you. Hope you are doing well. Are you still practicing both DVM and RPh?

I appreciate all of the comments we have received from veterinarians. I will contact you soon to discuss how we will proceed. What is your best contact number? My office number is 502-564-7913 and my cell is 502-330-4398

Thanks,
Larry

Get Outlook for iOS

From: Frank Vice <fgvice@yahoo.com>
Sent: Sunday, June 30, 2019 9:38:49 PM
To: Hadley, Larry A (KY Board of Pharmacy)
Cc: Debra Hamelback
Subject: Re: Dispensing Compounded Medication for Veterinarians (Proposed Amendment :201KAR 2:310)

On Sunday, June 30, 2019, 8:30:12 PM EDT, Frank Vice <fgvice@yahoo.com> wrote:

Mr. Larry Hadley, Executive Director
Kentucky Board of Pharmacy
125 Holmes Street Suite 300
State Office Building Annex
Frankfort, Kentucky 40601

Dear Mr. Hadley

Thanks always for your help and consideration with concerns in veterinary medicine. In addition, I want to personally thank you for your rapid response with regard to the potential amendment of 201 KAR 2:310. During the past few days, I have been in conversation with the KVMA and they indicate that some additional veterinary stakeholders should be in attendance during any follow up meeting.

In addition, I am writing to you tonight about the amendment language change in 201KAR2:310. In reading the potential amendment, the proposed language change suggests restricting all available compounded medication inventory for administration and dispensing, to only the veterinary clinic, thus preventing these medicinals from use at other practice locations. While I can appreciate and support maintaining medicinal inventory control, the dilemma this restrictive language presents in veterinary medicine reduces, in some practice types, the benefit that could be gained in dispensing compounded medication by a larger group of veterinary practitioners. Some veterinary practice locations extend beyond the doors of a fixed clinic, due to the ambulatory practice many rural veterinary practitioners continue to maintain in service to owners of large animals unable to be transported to a fixed location. The logistics of acute therapy in many of these animal patients would be interrupted if needed medication was not available.

Therefore, is it possible to withhold the final decision on any regulatory language, thus avoiding any commitment by the BOP toward amending 201 KAR 2:310, until after additional review? While your quick response to this regulatory change is greatly appreciated, this brief delay would give all stakeholders an opportunity to consider the implications these changes represent.

Sincerely
Frank G. Vice



Kentucky Veterinary Medical Association

P. O. Box 4067 • 108 Consumer Lane • Frankfort, KY 40604-4067
502-226-5862 • Fax: 502-226-6177 • info@kvma.org

June 29, 2019

Larry Hadley, Executive Director
Kentucky Board of Pharmacy
125 Holmes Street, Suite 300
State Office Building Annex
Frankfort, KY 40601

To the Members of the Kentucky Board of Pharmacy;

On behalf of the Kentucky Veterinary Medical Association, we would like to comment on the proposed amendments to 201KAR 2:310. We would like to suggest that changes are considered for veterinarians to be able to dispense compounded medications not only be able to utilize them within a clinic setting and office use. In Kentucky, we have equine and livestock veterinarians that are ambulatory veterinarians and do not necessarily have a clinic setting as they use their home as a base, and they travel to the patient. This would limit their ability to treat a horse properly. We realize this is a unique situation, but it is important to consider all factors of veterinary practice in the state of Kentucky. There will be times that a pet will need to be sent home after veterinary care with a compounded product, therefore in the best interest of the health and welfare of the animal it would be necessary to be able to dispense a product.

Dr. Frank Vice whom is on our KVMA Board as the Alternate Delegate for the AVMA is a licensed veterinarian as well as a licensed pharmacist in Kentucky. Dr. Vice has been in communication with Katie Busroe, whom is the Pharmacy Inspections and Investigations Supervisor on this same subject matter.

The Kentucky Veterinary Medical Association would welcome further dialogue regarding this important matter to ensure the accessibility for proper treatment of animals regarding safe, quality compounded medication. The KVMA appreciates the opportunity to be in on-going dialogue concerning the proposed amendment 201KAR 2:310.

Respectfully,

Jennifer K Quammen DVM, MPH

Dr. Jennifer Quammen
KVMA President

Hadley, Larry A (KY Board of Pharmacy)

From: Frank Marcum <fdmdvm@me.com>
Sent: Sunday, June 30, 2019 6:34 PM
To: Hadley, Larry A (KY Board of Pharmacy)
Cc: Frank Dwayne Marcum, DVM
Subject: Porposed Amendment: 201 KAR 2:310

Mr. Hadley:

I am contacting you regarding the proposed amendment 201 KAR 2:310.
In advance, thank you for your time in considering this.

Below is a set of points from the Veterinarian's perspective that have been complied in support of continuing the regulations as they are in place now.

You may have already seen this within other correspondence to you.

1. We see horses at all times of the day and night. Compounding pharmacies may not be open for the client to pick up prescriptions.
2. Not all horse facilities are convenient to the location of the Compounding pharmacies
3. Compounds are often compounded at the time the order is placed, rather than being available in pharmacy stock. Therefore, there is a lag time between the prescription being placed and being available.
4. Most prescriptions are necessary for immediate implementation for the health and well being of the patient (eg antibiotics, pain medications), and even the lag time between prescription and driving to the pharmacy to pick up the prescription is inappropriate.
5. We are required by law to offer prescriptions directly to the client instead of dispensing from stock, so the opportunity is already there for the client to pick up, or have the compounds shipped if there is no immediate pressing need.

I have recently retired from my career as a racetrack practitioner of some 25+ years.
From this, I would like to cite an example of how I customarily performed my practice.

As ambulatory practitioners, we utilize vehicles equipped to handle regular daily calls, stocked with diagnostic equipment, drugs and supplies, as well as emergency equipment that might be needed. A routine day consists of leaving the home or office before daylight and spending most of the day attending to numerous clients (trainers) having training horses under their oversight and management. This process is a continuum most often times only returning the office for resupply once a day, or restocking the trucks/vehicles at the end of the day if operating out of a home office. It is much similar to the "route of milk man" whom had to make his daily runs serving the customers with fresh products. Difference being with us, each of our clients and patients have to be seen personally almost each and every day. Treating these animals can be be from an individual daily requirement (i.e antibiotic injections) to medications that are oral or topical and can be managed by the trainer/custodian then followed up on by the attending DVM.

The crux of all of this is that we need to be able to have medications in our hands, on the vehicle, for ready use, should the need arise. The logistics of anything less will be terribly burdensome

and will compromise the care and welfare of our patients. We, quite simply, operate a mini-hospital out of our vehicles and need to have supplies (drugs/compounds) that support this. In many ways, our vehicle is our office....even to the point that reports and bills can now be generated from the vehicle.

It would be virtually impossible to operate an ambulatory practice without the benefit of the law as it is now written. Additionally, to not be allowed to dispense medications (compounds) to the owners or trainers (legal custodians) could severely compromise the welfare of the patient.

I've attempted to be brief and not over-burdensome, but this is a very important benefit we now have in practicing the art of medicine. Unfortunately, we have lost many of our practice rights in the near past. I hope we don't lose another important benefit in treating our patients to the best of our ability.

If you have any questions, please feel free to call or respond to this mail. I would appreciate the opportunity to better explain what I have presented.

Most respectfully and kindly,
frank dwayne marcum, dvm.
859-227-0879

Hadley, Larry A (KY Board of Pharmacy)

From: twodocsfarm@gmail.com
Sent: Sunday, June 30, 2019 5:12 PM
To: Hadley, Larry A (KY Board of Pharmacy)
Subject: Compounding

Dear Mr Hadley,

Please refrain from further restrictions on compounding for Kentucky's Equine Veterinarians. The ability to use and script out medication is often on an emergency basis. My compounding pharmacy in Lexington is available M-F 9 to 4:30. Many of the medications I need to use are outside of these hours, and may not even be "on the shelf" at the pharmacy requiring an even longer delay. In addition, many of the conditions I need to treat simply cannot wait. If a critically ill patient needs antibiotics, time is of the essence!

In my practice I have a fair number of patients that suffer from exercise induced myopathy. The ability to use dantrolene liquid (only available compounded) makes a large number of horses able to compete. Time is of critical essence for these patients.

I am more than happy to have clients pick up medication (or have it shipped) directly from the pharmacy when possible.

This issue probably affects every veterinarian in the state at some level. Please consider the wishes of the KVMA and the KBVME before issuing any further restrictions on Kentucky's veterinarians. We all support fair accurate regulations for the health and safety of our patients.

Andrew M Roberts DVM
KAEP Past President (2017)

Sent from my iPhone

Hadley, Larry A (KY Board of Pharmacy)

From: Kate Hammer <katehammer@hotmail.com>
Sent: Sunday, June 30, 2019 2:24 PM
To: Hadley, Larry A (KY Board of Pharmacy)
Subject: 201 KAR 2:310. Compounding for a veterinarian's office or institutional administration for veterinary use.

Re: 201 KAR 2:310. Compounding for a veterinarian's office or institutional administration for veterinary use.

Veterinarians need to retain the ability to dispense compounded medications for the following reasons:

1. We see horses at all times of the day and night. Compounding pharmacies may not be open for the client to pick up prescriptions.
2. Not all horse facilities are convenient to the location of the Compounding pharmacies
3. Compounds are often compounded at the time the order is placed, rather than being available in pharmacy stock. Therefore, there is a lag time between the prescription being placed and being available.
4. Most prescriptions are necessary for immediate implementation for the health and well being of the patient (eg antibiotics, pain medications), and even the lag time between prescription and driving to the pharmacy to pick up the prescription is inappropriate
5. We are required by law to offer prescriptions directly to the client instead of dispensing from stock, so the opportunity is already there for the client to pick up, or have the compounds shipped if there is no immediate pressing need.

Kate Hammer, DVM
KY licensed veterinarian
817-771-2550

Hadley, Larry A (KY Board of Pharmacy)

From: jtberk5@aol.com
Sent: Sunday, June 30, 2019 1:18 PM
To: Hadley, Larry A (KY Board of Pharmacy)
Cc: dfoley@aaep.org; kenton.morgan@zoetis.com; jpmorehead@eqmedical.com; jtberk5@aol.com
Subject: Proposed amendment to compounded medication regulations
Attachments: AAEP Compounding letter.pdf

****CAUTION** PDF attachments may contain links to malicious sites. Please contact the COT Service Desk ServiceCorrespondence@ky.gov for any assistance.**

Dear Mr. Hadley,

I have attached a letter to you as the Executive Director of the Kentucky Board of Pharmacy outlining the AAEP position on the proposal to amend the language in the regulations regarding compounded medications for office use by veterinarians. Please feel free to contact me at any time if you have any questions or comments. My contact information is listed below.

Best regards,

Jeffrey T. Berk, VMD, MRCVS
President | American Association of Equine Practitioners
Equine Medical Associates
Lexington, KY USA
(352) 843-3030 cell
jtberk5@aol.com



June 28, 2019

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.

Dear Mr. Hadley,

The AAEP (American Association of Equine Practitioners) is providing the following comments regarding proposed regulatory changes contained within "201 KAR 2:310. Compounding for a veterinarian's office or institutional administration for veterinary use".

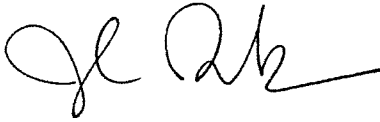
The AAEP recognizes there are times when it is necessary for veterinarians to use compounded products to treat a specific need of an individual patient when an approved medication is either unavailable in the market or the product which is available is not in an appropriate dosage form for the specific needs of that individual patient. However, we do have concerns with what appears to be very widespread use of compounded products when many times (not always) there are FDA approved products available in the appropriate dosage form available to treat the disease/condition of the equine patient. This type of activity is not in the best interests of the health and welfare of the horse.

Regarding the proposed regulatory changes, the AAEP does recognize there may be instances when it is necessary to dispense compounded medications to a client, however, these instances are rare and should only be done within the confines of a valid veterinarian client patient relationship (VCPR). As you know, right here in Kentucky, there was a very tragic example of illegitimate compounding and dispensing. A local Lexington compounding pharmacy formulated a drug combination product for the treatment of EPM (Equine Protozoal Myeloencephalopathy). The components of the product were miscalculated/formulated with the end result being toxic levels of one of the active ingredients. Four horses died as a result of receiving this product. One of the active ingredients of that product, toltrazuril, is not approved for use in any species here in the US. And what makes this example even more tragic is the fact that at the time this compounded product was formulated and sold, there were three FDA approved medications available on the market for the treatment of EPM. This incident led to changes in the Kentucky pharmacy regulations.

Excessive office stock of product is another concern. It is recognized that potency and stability of the vast majority of compounded products is unknown. Therefore, excessive office stock of compounded products which may sit on shelves for extended periods of time can have a negative impact on these important drug parameters. In a day and age of "next day" product transport and delivery, it is difficult to justify significant amounts of office stock of compounded products and rarely are these products needed in an "emergency" situation.

The AAEP appreciates the opportunity to comment on the proposed regulatory changes. The mission of our organization is simple, the health and welfare of the horse. We believe that while there are certainly times when using compounded products is appropriate, there are also many times when illegitimate compounding and dispensing is a very significant concern when it comes to the health and welfare of our patients.

Sincerely,

A handwritten signature in black ink, appearing to read 'J. Berk', with a long horizontal flourish extending to the right.

Jeffrey T. Berk, VMD, MRCVS
2019 AAEP President

Hadley, Larry A (KY Board of Pharmacy)

From: Fred Sprinkle <fpsdvm3@gmail.com>
Sent: Sunday, June 30, 2019 12:20 PM
To: Hadley, Larry A (KY Board of Pharmacy)
Subject: Board Of Pharmacy Proposed amendments: 201 KAR 2:310

Sir: In my equine ambulatory practice I see horses of all ages, at farms, training centers, rehab centers, riding and show barns and calls come at hours of the day and night. It is necessary for me to have these compounded drugs with me when I am there to provide the care and service required and expected on me. F. P. Sprinkle MS DVM

Hadley, Larry A (KY Board of Pharmacy)

From: Dr. William Baker <baker@woodfordequine.com>
Sent: Sunday, June 30, 2019 9:19 AM
To: Hadley, Larry A (KY Board of Pharmacy)
Subject: Re: [Track-Vets] KY ALERT: Compounded medication rules

1. We see horses at all times of the day and night. Compounding pharmacies may not be open for the client to pick up prescriptions.
2. Not all horse facilities are convenient to the location of the Compounding pharmacies
3. Compounds are often compounded at the time the order is placed, rather than being available in pharmacy stock. Therefore, there is a lag time between the prescription being placed and being available.
4. Most prescriptions are necessary for immediate implementation for the health and well being of the patient (eg antibiotics, pain medications), and even the lag time between prescription and driving to the pharmacy to pick up the prescription is inappropriate
5. We are required by law to offer prescriptions directly to the client instead of dispensing from stock, so the opportunity is already there for the client to pick up, or have the compounds shipped if there is no immediate pressing need.

On Sun, Jun 30, 2019 at 8:02 AM Clara Fenger <drfng@gmail.com> wrote:

All KY vets, Please email comments by TONIGHT!!!! Veterinarians need to retain the ability to dispense compounded medications

Important points:

1. We see horses at all times of the day and night. Compounding pharmacies may not be open for the client to pick up prescriptions.
2. Not all horse facilities are convenient to the location of the Compounding pharmacies
3. Compounds are often compounded at the time the order is placed, rather than being available in pharmacy stock. Therefore, there is a lag time between the prescription being placed and being available.
4. Most prescriptions are necessary for immediate implementation for the health and well being of the patient (eg antibiotics, pain medications), and even the lag time between prescription and driving to the pharmacy to pick up the prescription is inappropriate
5. We are required by law to offer prescriptions directly to the client instead of dispensing from stock, so the opportunity is already there for the client to pick up, or have the compounds shipped if there is no immediate pressing need.

You can cut and paste the above list if you don't have time to write your own letter. Please email comments TODAY!!!

Clara Fenger, DVM, PhD, DACVIM

Sent from Mail for Windows 10

From: Eric Kates

Sent: Wednesday, June 26, 2019 6:28 AM

To: track-vets@googlegroups.com

Subject: Re: [Track-Vets] KY ALERT: Compounded medication rules

This is an important issue that could significantly affect all of us and our patients. Antibiotic paste comes to mind immediately. Thanks for the heads up.

On Wed, Jun 26, 2019 at 6:15 AM Clara Fenger <drfngr@gmail.com> wrote:

All Kentucky Veterinarians need to write to the Board of Pharmacy. I will draft sample Verbiage and post so that you can see an example of how the letters might read. We are fortunate in Kentucky in that we are able to use office use compounded medications. Let's band together to continue to be able to use and dispense compounded medications for the benefit of our patients.

The Kentucky Board of Pharmacy is proposing to amend the language in their regulations regarding compounded medications for office use by veterinarians. While the Board of Pharmacy has always allowed pharmacies to compound medications for veterinary office use, the proposed language clarifies that this practice is restricted to veterinary use and that compounded medications for veterinary office use may only be administered in the veterinary facility and may not be dispensed to the pet owner.

A hearing was scheduled for June 21, but was cancelled because no one requested an opportunity to speak prior to the 5-day notice cut off. Nevertheless, the Board will accept written comments through June 30. This is an opportunity for veterinarians to let the Board of Pharmacy know how important it is to be able to dispense compounded medications from office stock and the negative impact not be able to do so has had on patient care.

Written comments can be sent via mail, fax or email to:

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.

All comments should be courteous and concise. Comments should include stories or examples of how the inability to dispense compounded medication from office stock has negatively affected patient care. A constructive, information-rich comment that clearly communicates and supports its claims is more likely to have an impact on regulatory decision making. Be sure to reference Proposed Amendments: 201 KAR 2:310. Compounding for a veterinarian's office or institutional administration for veterinary use.

Please feel free to contact Michael Blaire, Vice President of Government and Regulatory Affairs at mblaire@wedgewoodpharmaacy.com if you have any questions.

--

You received this message because you are subscribed to the Google Groups "Track Vets" group. To unsubscribe from this group and stop receiving emails from it, send an email to track-vets+unsubscribe@googlegroups.com.

To post to this group, send email to track-vets@googlegroups.com.

Visit this group at <https://groups.google.com/group/track-vets>.

To view this discussion on the web visit https://groups.google.com/d/msgid/track-vets/CAJrFFDE4uJuET0S1T%3DKBTcu5kmCeI6uUskxegZf4FK5_NRQMSg%40mail.gmail.com.

For more options, visit <https://groups.google.com/d/optout>.

--

Eric Kates, DVM

Colts Neck Equine Associates, P.C.

office 732-938-4240

cell 732-547-5591

erickates@gmail.com

--

You received this message because you are subscribed to the Google Groups "Track Vets" group.

To unsubscribe from this group and stop receiving emails from it, send an email to track-vets+unsubscribe@googlegroups.com.

To post to this group, send email to track-vets@googlegroups.com.

Visit this group at <https://groups.google.com/group/track-vets>.

To view this discussion on the web visit [https://groups.google.com/d/msgid/track-](https://groups.google.com/d/msgid/track-vets/CANd2JafYtYHMHSfChyx0oxxoVHNRu7%2BdGZqaYw%2B0PLn_PA2duA%40mail.gmail.com)

[vets/CANd2JafYtYHMHSfChyx0oxxoVHNRu7%2BdGZqaYw%2B0PLn_PA2duA%40mail.gmail.com](https://groups.google.com/d/msgid/track-vets/CANd2JafYtYHMHSfChyx0oxxoVHNRu7%2BdGZqaYw%2B0PLn_PA2duA%40mail.gmail.com).

For more options, visit <https://groups.google.com/d/optout>.

--

You received this message because you are subscribed to the Google Groups "Track Vets" group.

To unsubscribe from this group and stop receiving emails from it, send an email to track-vets+unsubscribe@googlegroups.com.

To post to this group, send email to track-vets@googlegroups.com.

Visit this group at <https://groups.google.com/group/track-vets>.

To view this discussion on the web visit [https://groups.google.com/d/msgid/track-](https://groups.google.com/d/msgid/track-vets/5d18a4ca.1c69fb81.295fc.33d0%40mx.google.com)

[vets/5d18a4ca.1c69fb81.295fc.33d0%40mx.google.com](https://groups.google.com/d/msgid/track-vets/5d18a4ca.1c69fb81.295fc.33d0%40mx.google.com).

For more options, visit <https://groups.google.com/d/optout>.

Hadley, Larry A (KY Board of Pharmacy)

From: Katherine Baker <Tbaker4674@aol.com>
Sent: Sunday, June 30, 2019 9:16 AM
To: Hadley, Larry A (KY Board of Pharmacy)

1. We see horses at all times of the day and night. Compounding pharmacies may not be open for the client to pick up prescriptions.
2. Not all horse facilities are convenient to the location of the Compounding pharmacies
3. Compounds are often compounded at the time the order is placed, rather than being available in pharmacy stock. Therefore, there is a lag time between the prescription being placed and being available.
4. Most prescriptions are necessary for immediate implementation for the health and well being of the patient (eg antibiotics, pain medications), and even the lag time between prescription and driving to the pharmacy to pick up the prescription is inappropriate
5. We are required by law to offer prescriptions directly to the client instead of dispensing from stock, so the opportunity is already there for the client to pick up, or have the compounds shipped if there is no immediate pressing need.

Sent from my iPad

Hadley, Larry A (KY Board of Pharmacy)

From: z522 <z522@aol.com>
Sent: Sunday, June 30, 2019 8:39 AM
To: Hadley, Larry A (KY Board of Pharmacy)
Subject: Compounded medications

As a practicing veterinarian I consider it crucial for me to stock certain medications, including some compounded medications, so that I can provide my patients with immediate and high quality health care.

I see horses at all times of the day and night. Compounding pharmacies may not be open for the client to pick up prescriptions.

Not all horse facilities are convenient to the location of the Compounding pharmacies

Compounds are often compounded at the time the order is placed, rather than being available in pharmacy stock. Therefore, there is a lag time between the prescription being placed and being available.

Most prescriptions are necessary for immediate implementation for the health and well being of the patient (eg antibiotics, pain medications), and even the lag time between prescription and driving to the pharmacy to pick up the prescription is inappropriate

We are required by law to offer prescriptions directly to the client instead of dispensing from stock, so the opportunity is already there for the client to pick up, or have the compounds shipped if there is no immediate pressing need.

Please continue to allow us to have compounded medications on hand for immediate use and distribution.

Thank you for your time and consideration.

Patricia Ziefle, DVM
Lexington, KY

Sent from my Verizon 4G LTE smartphone

Hadley, Larry A (KY Board of Pharmacy)

From: Foster Northrop <fosternorthrop@gmail.com>
Sent: Sunday, June 30, 2019 8:20 AM
To: Hadley, Larry A (KY Board of Pharmacy)
Subject: Compounded Drugs

Dear Sir,

I'm expressing my opinion that our compounding laws should not change. As a mobile equine veterinarian it is vital I have access to compounded medications. I am a member of the KY Horse Racing Commission and I also sit on the board of the AAEP. I currently serve on the scientific advisory committee for the RMTC. As you see I'm well versed in all the issues we have in equine veterinary medicine.

These following points illustrate our needs to have the ability to get compounded drugs to our patients when they need them, not a week or more later.

1. We see horses at all times of the day and night. Compounding pharmacies may not be open for the client to pick up prescriptions.
2. Not all horse facilities are convenient to the location of the Compounding pharmacies
3. Compounds are often compounded at the time the order is placed, rather than being available in pharmacy stock. Therefore, there is a lag time between the prescription being placed and being available.
4. Most prescriptions are necessary for immediate implementation for the health and well being of the patient (eg antibiotics, pain medications), and even the lag time between prescription and driving to the pharmacy to pick up the prescription is inappropriate
5. We are required by law to offer prescriptions directly to the client instead of dispensing from stock, so the opportunity is already there for the client to pick up, or have the compounds shipped if there is no immediate pressing need.

Thank you for your consideration.

Foster Northrop DVM

--

Sent from Gmail Mobile

Hadley, Larry A (KY Board of Pharmacy)

From: Clara Fenger <drfng@gmail.com>
Sent: Sunday, June 30, 2019 8:07 AM
To: Hadley, Larry A (KY Board of Pharmacy)
Subject: Veterinary Compounding

As the Pharmacy Board seeks to clarify the compounding regulations for Kentucky, I urge you to consider the health and well being of the patients treated by the veterinarians of Kentucky.

1. We see horses at all times of the day and night. Compounding pharmacies may not be open for the client to pick up prescriptions.
2. Not all horse facilities are convenient to the location of the Compounding pharmacies
3. Compounds are often compounded at the time the order is placed, rather than being available in pharmacy stock. Therefore, there is a lag time between the prescription being placed and being available.
4. Most prescriptions are necessary for immediate implementation for the health and well being of the patient (eg antibiotics, pain medications), and even the lag time between prescription and driving to the pharmacy to pick up the prescription is inappropriate
5. We are required by law to offer written prescriptions directly to the client instead of dispensing from stock, so the opportunity is already there for the client to pick up, or have the compounds shipped if there is no immediate pressing need.

For these reasons, we need the ability to dispense compounded medications out of "Office Use" stock.

Clara Fenger, DVM, PhD, DACVIM
Equine Integrated Medicine, PLC
4904 Ironworks Rd.
Georgetown, KY 40324
(859)983-0737

Sent from [Mail](#) for Windows 10

Hadley, Larry A (KY Board of Pharmacy)

From: Michael Blaire <mblaire@wedgewoodpharmacy.com>
Sent: Friday, June 28, 2019 5:15 PM
To: Hadley, Larry A (KY Board of Pharmacy)
Subject: Proposed Amendments to 201 KAR 2:310
Attachments: KY BOP Comments Final.pdf

****CAUTION** PDF attachments may contain links to malicious sites. Please contact the COT Service Desk ServiceCorrespondence@ky.gov for any assistance.**

Dear Mr. Hadley,

Attached please find comments to the proposed changes to language regarding compounding for veterinary office use. We appreciate the board's recognition of the importance of this practice to the provision of quality veterinary medical care and appreciate the opportunity to comment.

Please feel free to contact me if you require additional information.

Yours truly,

Michael Blaire

Michael Blaire, R.Ph., FIACP

Vice President - Government and Regulatory Affairs

Wedgewood Pharmacy

480-221-8511



GREAT CARE. DELIVERED.

Larry Hadley, Executive Director
Kentucky Board of Pharmacy
125 Holmes Street, Suite 300
State Office Building Annex
Frankfort, Kentucky 40601

June 24, 2019

Re: Proposed Amendments to 201KAR 2:310

To The Members of the Kentucky Board of Pharmacy:

I write on behalf of Wedgewood Village Pharmacy, LLC, a Kentucky licensed, non-resident pharmacy engaged in the practice of compounding sterile and non-sterile medications for animal use. I appreciate the opportunity to comment on the proposed amendments to 201 KAR 2:310 currently scheduled for a hearing on June 21, 2019. We are writing to request changes to the proposed amendments that, we believe, will meet the need of veterinarians to have wider access to the compounded medications they require for their patients, but at the same time ensure that these medications are provided in a manner consistent with the Board's mission to protect the public safety.

Background

Compounded medication is essential to the practice of veterinary medicine because, unlike medical doctors, veterinarians treat a wide variety of species, all of varying sizes, each of which face their own unique set of health conditions and diseases and which require specific types, amounts, dosages, and dosage forms of medications. Inherently, commercially available drugs cannot satisfy the wide variety of animal patient needs. As a result, compounded drugs are used where, in the judgment of veterinarians, there is no suitable commercially manufactured drug product available to appropriately treat their animal patients.

PHONE: 800.331.8272

FAX: 800.589.4250

ADDRESS: 405 HERON DRIVE, STE 300 | SWEDESBORO, NJ 08085

WEDGEWOODPETRX.COM

The necessity of compounded medication to treat animal patients is buttressed by the unique nature of veterinary practice. Unlike human medical doctors, veterinarians' offices often serve as emergency rooms, hospitals and pharmacy for animal patients. Veterinarians must, in many instances, travel to their animal patients for on-site treatment. For example, veterinarians treating horses at a barn or animals in a zoo must do so on-site as such animals cannot travel to a veterinary office for treatment. As a result, the unique nature of veterinary medicine requires not only access to compounded medication, but immediate access to compounded medications for "office use," *i.e.* compounded medication that is readily available, in the veterinarian's office or to travel with the veterinarian, to treat animal patients in emergent situations or off-site. Without access to compounded medications for office use animal patients would not receive the medical treatment they often desperately need.

A coalition of animal-health pharmacies, the American Veterinary Medical Association (AVMA) and several state veterinary medical associations have conducted surveys of veterinarians to understand the role that compounded medications play in their practices and in the health of their patients. The most recent survey (March 2019) confirmed that having access to compounded medications when they believe they are medically necessary is "very important" to 90% of veterinarians and "important" to 82%. For 94%, their ability to maintain office stock of compounded medications is important, "very important" for 77% of them. We appreciate the fact that the Kentucky Board of Pharmacy has long recognized that compounding medications for veterinary office use is essential for optimum patient care.

Section 5. The compounded drug shall be administered in the veterinarian's office or institution and shall not be dispensed.

In addition to permitting veterinarians to purchase compounded medications for office use, we believe that veterinarians should be permitted to dispense these products to patients. In the March 2019 survey mentioned above, 89% of respondent veterinarians order compounded medications that they later *administer* to a patient, and 77% *dispense compounded medications to animals from office stock*. In states that do not allow office use of compounded medications, 78% report that this has had a negative impact on their ability to practice medicine. Not allowing veterinarians to *dispense* compounded medications from office use stock to pet owners threatens uninterrupted treatment and can present risk to human health.

In August 2017, the National Association of Boards of Pharmacy (NABP) convened a Task Force to determine Best Practices for Veterinary Compounding. Among the ideas discussed, the Task Force members concluded that a new definition of veterinary dispensing should be added to the *Model State Pharmacy Practice Act* to recognize the importance of this emerging role in pharmacist care services. Furthermore, the members also recommended that a new section be added to the Model Rules for Compounded or Repackaged Pharmaceuticals identifying appropriate instances for compounding for office use by veterinarians and subsequent dispensing for emergency situations.

(b) It is acceptable for any licensed Pharmacy to compound veterinary drug preparations to be used by veterinarians in their office for Administration to client's animals.

(c) Compounded office use preparations may be Dispensed by a veterinarian to clients only in an urgent or emergency situation for use in a single course of treatment, not to exceed 120-hour supply.

This language was approved and incorporated into the NABP Model State Pharmacy Practice Act in 2018.

The states of Florida and Illinois have passed regulations allowing pharmacies to compound medications for veterinary office use administration and dispensing without restrictions on quantities sold or dispensed. California and Ohio passed similar legislation, although with some limits on the days of supply of dispensed medication. Most recently, the State Boards of Pharmacy in Missouri, Georgia and Mississippi have amended their regulations to allow for veterinarians to both stock and dispense medications compounded for office use. Legislation containing similar language awaits the Governor's signature in Minnesota. We believe that these regulatory developments greatly increase the likelihood of animal patients receiving the medication their veterinarian prefers in a timely manner. We are hopeful that Kentucky will join this trend of allowing veterinarians to dispense compounded medications from office stock, thereby giving veterinarians significant flexibility to treat patients in the manner they best see fit.

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

Opioids in animal medicine are the foundation, and often the only method, of pain control and anesthesia. They are critical for the treatment of animals that have been hit by a car, shot by a gun, mauled by another animal, undergone surgery, or suffer from a severe disease or other trauma. Veterinarians often require dosage forms and concentrations of drugs that differ from commercially available products. This requirement increases during times of shortage, as veterinarians are the last health professionals to receive allocations of available products.

In September 2018, Wedgewood Pharmacy conducted a nationwide survey of veterinarians' experiences obtaining controlled substances for use in their practices. Of the approximately 1100 veterinary professionals who responded to the survey, 88% consider hydromorphone and 79% consider morphine important to their ability to practice. Of those respondents, 73% reported difficulty obtaining hydromorphone and 57% reported difficulty obtaining morphine. As a result, 83% of respondents were forced to use less effective therapies, 26% were forced to postpone procedures, 71% reported increased suffering and 3% reported patient deaths.

A handful of compounding pharmacies in the United States have been permitted by the Drug Enforcement Administration to distribute compounded, non-patient specific controlled substances, including morphine and hydromorphone. Obtaining these permits requires months of preparation and close work with the local DEA field office. There are numerous security requirements that must be addressed, and systems must be developed to obtain customer profiles

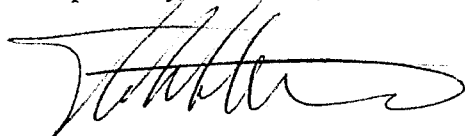
and to address excessive and/or suspicious orders. Active ingredients are subject to quota allocation, and all transactions are reported to the DEA via ARCOS and the Year End Reporting System (YERS). These transactions can also be reported to the state CSPMP programs if required.

While we appreciate the tremendous pressure placed on the Board of Pharmacy to address controlled substance diversion and opioid abuse, we believe that complete prohibition of compounded controlled substances for veterinary office use is inconsistent with the Board's mission to protect the public. Access to required medications is a vital component of public safety. If a pharmacy has fulfilled the requirements to distribute compounded preparations under the Federal Controlled Substances Act, the Kentucky Board of Pharmacy should not deny veterinarians access to those medications.

Conclusion

We very much appreciate the opportunity to comment on the Kentucky Board of Pharmacy's proposed amendments to 201 KAR 2:310 and we hope that the board finds the information herein to be useful in its discussions. We would be happy to appear before the board or provide additional information or comments. We respectfully ask that 201 KAR 2:310 be amended to ensure complete access to safe, quality compounded medications, from pharmacies, for office use and dispensing by veterinarians.

Respectfully Submitted,

A handwritten signature in black ink, appearing to read "Michael Blaire", with a long, sweeping horizontal stroke extending to the right.

Michael Blaire, R. Ph., FIACP
Vice President: Government and Regulatory Affairs

Hadley, Larry A (KY Board of Pharmacy)

From: Town and Country <townandcountryvet@att.net>
Sent: Thursday, June 27, 2019 2:09 PM
To: Hadley, Larry A (KY Board of Pharmacy)
Subject: compounding pharmacy changes

Mr. Hadley,

We just received an email from Wedgewood Pharmacy regarding the proposed change regarding compounded drugs.

To be honest, it's difficult to find a starting point in how to explain just how negatively this will affect our practice, because it is so broad of an effect. With the changes in healthcare regulations (Obamacare) it has affected what drugs we can find, afford, and use. Drugs that were once relatively easy to buy and dispense have become scarce, gone and exorbitantly expensive. I estimate that 10% of our drug purchasing is through compounding pharmacies, and losing this option negatively affects our business and our patients/clients.

Compound pharmacies offer us the ability to find drugs in specific strengths, vehicles (liquid vs chewable tablets, topical cream) to facilitate client/owner administration. In many cases, compounded drugs offers an owner a cost effective method of purchasing drugs. It offers us the ability to even find certain drugs!

Let me give you just one example: Itraconazole:DMSO ophthalmic ointment. This compound is used in certain equine eye cases. We have to be able to dispense it to an owner to use at home, there is no way that it can be feasibly used only in the office. The only way to purchase it is through a compounding pharmacy, it cannot even be purchased at any of our veterinary drug distributors.

Before passing legislation that affects so many people negatively, we would sincerely ask that the Board members spend a little time with their own personal veterinarians and see what the impact this legislation would be on our patients, and clients.

Thank you for your time,

Jack Jones, DVM
Justin Murray, DVM

Town & Country Animal Clinic
993 Ben Ali Dr
Danville, KY 40422

Hadley, Larry A (KY Board of Pharmacy)

From: Jerry Allen <drjmallen@gmail.com>
Sent: Thursday, June 27, 2019 10:54 AM
To: Hadley, Larry A (KY Board of Pharmacy)
Subject: Proposed Amendments: 201 KAR 2:310. Compounding for a veterinarian's office or institutional administration for veterinary use.

Mr. Hadley,

It has come to my attention that a change involving compounded products is being considered. I have practiced for over 36 years and can state without any reservation that preventing dispensing these medications will SEVERELY impact the state of animal health in this Commonwealth. Many therapies only exist in compounded form due to manufacturers discontinuing production due to lack of profit, long term back orders or just flat out doesn't exist in the form or concentrations we need for our huge range of patients. Human medicine only uses 1-2 sizes or forms of a medicine while in Veterinary medicine we may need 5 or more.

Some treatments are needed for long term, possibly life time treatment, how can we NOT dispense to the owner? Trying to tie our hands by requiring only in office treatment will result in needless suffering and in some cases preventable death in households that cannot bring the animal in every day and would either not treat or decide to end the animals life.

I suspect most in the pharmacy field have little to no real practical knowledge of the problems in Veterinary medicine. Experience in the human field is of very LIMITED value in determining what is needed in Veterinary medicine. I would highly recommend obtaining a Veterinary consultant to help determine the best solutions of pharmaceutical matters that involve Veterinary medicine, either as a full time employee or a regular on-call source. In fact, should you be in need of someone to fulfill this important niche, I would consider retiring from active practice and working full time (for a reasonable salary) to help the Board and other State offices in regard to Veterinary related changes.

At least then, I and other Veterinarians in the state would know someone who has extensive experience "from the trenches" is looking out for their interests.

In summary, we NEED these compounded medications, we need to be able to dispense them as our unique knowledge and experience sees the need. Please don't treat the Veterinary profession as "the red headed step child" of the medical field in KY. Please realize what works in the narrow margins of human medicine seldom is appropriate for the wide range (every other species on the planet) of patients the Veterinarian is faced with on a daily basis.

Thank you for your time and attention.

Jerry Allen, DVM
Science Hill , KY

"Outside of a dog, a book is man's best friend. Inside a dog, it's too dark to read.!" Julius "Groucho" Marx

Hadley, Larry A (KY Board of Pharmacy)

From: Eric Greenwell <2vets@windstream.net>
Sent: Wednesday, June 26, 2019 11:21 PM
To: Hadley, Larry A (KY Board of Pharmacy)
Subject: Poposed Amendment 201 KAR 2:310 Compounding for a veterinarian's office of institutional administration for veterinary use

Dear Kentucky Pharmacy Board Members,

I am a veterinarian in Somerset, KY and I would like to offer my comment regarding the proposed amendment to clarify the use of compounded medications by veterinarians.

As a veterinarian in a rural region of KY I do not have access to a local pharmacy which is able or willing to compound any of the medications that my patients need. This causes a hardship for my clients because they have to drive over 50 miles to a pharmacy that maintains an inventory of pharmaceuticals and is able to make the compounded medication. Being able to dispense such compounded medications to my clients from the in-house pharmacy would avoid the hardship of driving to Lexington or further to get these medication. Many of my clients are elderly and driving out of town is not an option for them. If these clients choose to deal with mail order pharmacies they have wait more than a week to get the medication causing serious delays in starting time critical treatments.

I make every effort to use commercially available preparations for the treatment of my patients, but when compounded medications are needed, I could save my clients much hardship and better treat my patients by dispensing compounded medications from my in-house stock.

I appreciate your consideration of these comments when deciding your action on amendment 201 KAR 2:310.

Thank you,
Eric D. Greenwell DVM

Hadley, Larry A (KY Board of Pharmacy)

From: Stacey Hutchison <stacey.hutchison@hotmail.com>
Sent: Wednesday, June 26, 2019 8:33 PM
To: Hadley, Larry A (KY Board of Pharmacy)
Subject: Compounding Veterinary drugs

I'm writing in regard to the importance compounded drugs have in veterinary medicine. We treat multiple species that cover a wide range of sizes and call for numerous differences in drug dosages. Not only does this limit the options of standard drug sizes being appropriate for these animals but the feasibility of stocking the drugs in all these sizes economically is non-existent! The onslaught of mega-online pharmacies has already negatively impacted our profession. We have so many obstacles facing us that being able to provide quality care to our patients affordably is fading. We need to be able to have medications on our shelves that are appropriate for the species and size so that we can practice veterinary medicine effectively and efficiently.

Thank you,
Stacey Hutchison DVM
Sent from my iPhone

Hadley, Larry A (KY Board of Pharmacy)

From: Tony Sheets <drsheets@lexanimalclinic.com>
Sent: Wednesday, June 26, 2019 3:48 PM
To: Hadley, Larry A (KY Board of Pharmacy)
Subject: Proposed Amendments: 201 KAR 2:310. Compounding for a veterinarian's office or institutional administration for veterinary use

The Kentucky Board of Pharmacy,

I am writing in reference to **Proposed Amendments: 201 KAR 2:310. Compounding for a veterinarian's office or institutional administration for veterinary use.** Some disease processes like keratitis conjunctiva sicca or dry eye can be painful. Medications like tacrolimus ophthalmic solution must be compounded as it cannot be purchased in an ophthalmic solution. I purchase such medication from a pharmacy located outside of Kentucky. If I order this medication and have the pharmacy mail it to the client, at best, there is a two 2 day wait. These pets need this medication at diagnosis.

Felids sometime need antibiotics like doxycycline for respiratory infections. Common medical knowledge tells us that using a capsulated form of doxycycline would almost guarantee a medical malpractice suite. Since this medication is not produced in a flavored solution that cats prefer, compounding is mandatory. Again, these pet's need medication two days ago. Not tomorrow.

Lastly, ask yourself what it will harm for veterinarian to have the ability to compounded medication that are needed, when they are needed, in a formulation that reduces stress during administration.

Best,

Tony L. Sheets DVM
drsheets@lexanimalclinic.com
Lexington Animal Clinic
3090 Helmsdale Place Suite 220
Lexington, KY 40509
P: 859-447-9442
F: 859-447-9443
www.lexanimalclinic.com

This e-mail and any attachments may contain confidential information and is intended solely for the use of the individual or entity to which it is addressed. If you are not the intended recipient of this e-mail, you are hereby notified that any copying, distribution, dissemination or action taken in relation to the content of this e-mail or attachments is strictly prohibited and may be unlawful. If you have received this e-mail in error, please notify the sender by reply e-mail delete the original e-mail and destroy any copies or printouts as well as any attachments

Hadley, Larry A (KY Board of Pharmacy)

From: Karen Goss <griggsandkidder@yahoo.com>
Sent: Wednesday, June 26, 2019 1:55 PM
To: Hadley, Larry A (KY Board of Pharmacy)
Cc: Kvma Info
Subject: 201 KAR 2:310 Compounding

Mr. Hadley,

I am writing about the proposed language changes concerning Compounded medications; Proposed Amendments: 201 KAR 2:310. This change would adversely affect Ambulatory Veterinary Practices. Our patients (livestock) are not referred to as pets. An exemption should be made for Ambulatory Veterinarians. As an Ambulatory Veterinarian traveling the county to different farms, it would be impossible to dispense Compounded medications under the proposed amendment. I sincerely urge you to reconsider this Proposed Amendment.

Regards,

Charles L. Kidder, DVM

Griggs Kidder and Williams, PLLC
1901 Ferguson Road
Lexington, KY 40511
Phone (859) 299-0919
Fax (859) 293-1347

Hadley, Larry A (KY Board of Pharmacy)

From: Aaron Lopez <aaron@politicalcapitalllc.com>
Sent: Friday, June 21, 2019 1:24 PM
To: Hadley, Larry A (KY Board of Pharmacy)
Subject: Kentucky Proposed Rule Amendment Comments
Attachments: Traditional and Outsourcing Facilities.pdf; Kentucky Board of Pharmacy - Office Use Vet Compounding.docx

****CAUTION** PDF attachments may contain links to malicious sites. Please contact the COT Service Desk ServiceCorrespondence@ky.gov for any assistance.**

Mr. Hadley,


Thank you so much for the opportunity to send in comments before your upcoming meeting on proposed rule changes on veterinary office use compounding. We represent a group of Federally Registered Outsourcing Facilities and feel it is important to preserve FDA's current thought and feelings of requiring vet products for office use to be produced at a cGMP level and produced by outsourcing facilities.

Please see the attached supporting documents and our comments. If you have any questions please feel free to reach out and use us as a resource.

Kindest regards,

Aaron

Aaron R. Lopez, JD, FCLS

 Political Capital LLC
1300 Pennsylvania 190-604
Washington DC, 20004
Work: (202) 753-7975

Differences Between a 503A vs 503B Facilities

<i>Note: Text in red explained below</i>	503A		503B	
Type of Pharmacy	Traditional compounding pharmacy		Outsourcing Facility	
Main Regulatory Oversight	State Board of Pharmacy		FDA	
Regulations	USP <795>, <797>, <800>, SBOP		FDA 21 CFR Part 210 and 211 (cGMP)	
FDA Inspections?	For cause (approx. 3k compounding pharmacies)	<input checked="" type="checkbox"/>	Random inspections (approx. 75 facilities)	<input checked="" type="checkbox"/>
Engineering Control Smoke Studies to Assess Proper Air Flow?	Yes, per area	<input checked="" type="checkbox"/>	Yes, per area and for each process	<input checked="" type="checkbox"/>
Stability Testing of Formulation to Assign Expiration/Beyond-Use Date?	No	<input type="checkbox"/>	Yes	<input checked="" type="checkbox"/>
Sterility Testing as Release Test for finished product testing? (USP General Chapter <71>)	Limited - Only with extended dating and high-risk batches	<input type="checkbox"/>	Yes	<input checked="" type="checkbox"/>
Finished Product Testing (Potency, Endotoxins)	No	<input type="checkbox"/>	Yes	<input checked="" type="checkbox"/>
Cleaning Validation (equipment and environmentally controlled areas)?	No	<input type="checkbox"/>	Yes	<input checked="" type="checkbox"/>
Continuous non-viable particle monitoring during aseptic processing?	No	<input type="checkbox"/>	Yes	<input checked="" type="checkbox"/>
Viable Monitoring to determine microbial control?	Air-twice yearly Surface-routinely Personnel- initially & 1-2/yr	<input type="checkbox"/>	Daily (Air, surface, personnel) and every batch	<input checked="" type="checkbox"/>
Sterile Garb during aseptic processing?	Only gloves are monitored	<input type="checkbox"/>	Yes, gloves & gown are monitored	<input checked="" type="checkbox"/>
Reserve Samples?	No	<input type="checkbox"/>	Yes	<input checked="" type="checkbox"/>
High level of documentation to ensure process traceability and tracking?	No; no batch record	<input type="checkbox"/>	Yes by batch record	<input checked="" type="checkbox"/>
Processes and equipment validations?	No	<input type="checkbox"/>	Yes	<input checked="" type="checkbox"/>
Independent Quality Department (Separate of Production)	No	<input type="checkbox"/>	Yes	<input checked="" type="checkbox"/>

Please note: this is not an all-inclusive list of the differences between 503A vs 503B

Explanation

Smoke Study - dynamic airflow visualization testing which is used to demonstrate unidirectional airflow within aseptic processing areas. The goal of smoke studies is to show that areas are designed to prevent microbiological contamination of products and provide adequate assurance of product sterility.

Sterility Testing - to provide assurance that the batch of product is sterile or free from the presence of viable microorganisms.

Stability Testing - the combination of physical, chemical and microbiological tests and acceptance criteria that demonstrates finished product integrity throughout its shelf life.

Non-viable particle monitoring (form of environmental monitoring) - this verifies that the cleanroom is operating within the required classifications and that particulate matter is at a level to ensure aseptic processes remain aseptic.

Viable monitoring (form of environmental monitoring) - a program designed to demonstrate microbial control of aseptic processing areas. Viable monitoring refers to testing for the detection and enumeration of bacteria, yeast and mold. It includes the monitoring of personnel, air and area surfaces for microbial contamination.

Reserve samples - the representative samples of each lot or batch of APIs, excipients, packaging material, intermediates and finished products which are kept for purpose of future reference. The purpose of this would be for future evaluation of materials and/or finished product.

Batch record - Batch manufacturing record is a written document of the batch, prepared during pharmaceutical manufacturing process. It contains all material, equipment, and procedural steps utilized in the manufacturing of each batch. Batch manufacturing record is proof that batches were properly made and checked by quality control personnel.

Product tracking and traceability- the process that enables you to track the movement of finished product across the supply chain. You can trace backwards to identify the history of the transfers and locations of a product, from the point of manufacturing onwards. And you can track forwards to see the intended route of the product.

Process and equipment validations - Processes and equipment are validated to ensure intended results are achieved. They also help identify variable and risks prior to implementations, establish working parameters and provide documented evidence and a high level of assurance for consistency.

Quality Department- Functions as as an independent group within the company; oversees all processes and departments; established investigation and program; testing of raw materials, components and product; performs vendor audits to establish individual quality standards.