

Emergency Rules

Title 20—DEPARTMENT OF INSURANCE, FINANCIAL INSTITUTIONS AND PROFESSIONAL REGISTRATION

Division 2220—State Board of Pharmacy Chapter 2—General Rules

EMERGENCY AMENDMENT

20 CSR 2220-2.400 Compounding Standards of Practice. The board is adding a new section (13), renumbering as necessary, and amending sections (12) and (14) of the rule.

PURPOSE: This board is amending sections (12) and (14) of this rule and adding section (13) to delineate requirements for compounding medication for office use/administration by a Missouri licensed veterinarian for animal patients.

EMERGENCY STATEMENT: This emergency amendment is being promulgated to protect the lives of Missouri animals by ensuring the continued availability of emergency compounded medication for veterinarian use in this state. Compounding of medication generally involves the mixing or preparation of medication by combining one (1) or more ingredients to meet the specific needs of the individual client/patient. Compounded preparations play a critical role in veterinary medicine. Unlike human practitioners, veterinarians treat a large variety of breeds and species, each of which have their own set of health challenges and diseases. The vast differences in species, breed, and size among patients requires specific amounts, dosages, and dosage forms to meet the needs of individual patients. As a result, veterinarians routinely prescribe or administer compounded medication where no commercial product is available, where the patient is allergic to the commercially available product, or where the drug does not come in the appropriate dose form for a particular animal.

Currently, the Missouri Board of Pharmacy's Rule 20 CSR 2220-2.400(12) prohibits a pharmacist from providing veterinarians with compounded preparations for office administration. Instead, a patient-specific prescription is required that includes the precise species of the patient. However, veterinarians perform a significant amount of emergency care where medication cannot be prescribed in advance due to the emergency nature of the use. Particularly in the rural parts of the state, veterinarians often travel long distances and perform much of their work in service to the state's agriculture industry in barns, pastures, and stables and may not know what medication is needed in an emergency situation until after the patient is seen/evaluated. As a result, veterinarians need to keep life-saving drugs on hand and in their trucks to meet uncertain and often emergent patient needs. Many of these compounded products such as Apomorphine and fomepazole are life-saving drugs and must be kept on hand for immediate administration when needed. Under the board's current rule, these necessary medications cannot be dispensed by a pharmacy unless the specific name and species of the patient is provided to the pharmacy in advance which, once again, the veterinarian may not have or know.

Compounding for office administration is specifically vital for animal shelters. Across Missouri, shelters take in mass numbers of pets on short notice, often when law enforcement raids puppy mills or other cat hoarding situations. These animals are often diseased and are held in close confines where outbreaks can easily spread. Shelter veterinarians have to treat large numbers on intake, often without any advance warning of which pets they will be treating, and in emergent conditions. Absence of the required compounded medication threatens the lives of not only the applicable pet/animal, but also other animals/pets being housed.

In September 2018, the Missouri Veterinary Medical Association (MVMA) asked the Missouri Board of Pharmacy to take emergency

action to allow pharmacies to compound for veterinarian medication. MVMA informed the board that an increasing number of veterinarians were unable to find needed emergency medication to treat Missouri's agricultural population. Significantly, MVMA reported a number of these medications were unavailable from any other source due to manufacturer backorders or voluntary discontinuation of a proprietary veterinary drug from the market. The Board of Pharmacy was subsequently contacted by a number of veterinarians in November and December of 2018 who indicated they were unable to find needed emergency medication and asked the board to allow an exemption to the compounding for office use/administration restriction. In many cases, veterinarians reported agricultural patients were unable to get medical care because the practitioner did not have access to the compounded drugs they needed for office administration. In at least one (1) instance, a patient/animal death was suspected.

The Board of Pharmacy subsequently consulted with the Missouri Veterinary Medical Board to identify the appropriate solution to meet the emergency need resulting in the following emergency amendment. This emergency amendment is necessary to protect and preserve the lives of Missouri veterinary patients by allowing pharmacists to compound medication needed for emergency office use/administration. A corresponding emergency rule filed by the Missouri Veterinary Medical Board would limit the amount of compounded medication dispensed by a veterinarian to no more than a seven- (7-) day supply. Adoption of these amendments through the ordinary rulemaking process will leave veterinarians in the state of Missouri without the ability to provide immediate and emergency treatment for patients in need of compounded medication.

As a result, the Missouri Veterinary Medical Board and the Missouri State Board of Pharmacy jointly find that there is an immediate danger to the public health, safety, and/or welfare and a compelling governmental interest that requires this emergency action. The scope of this emergency amendment is limited to the circumstances creating the emergency and complies with the protections extended in the Missouri and United States Constitutions. The Missouri Veterinary Medical Board and the Missouri Board of Pharmacy believe this emergency amendment is fair to all interested persons and parties under the circumstances. This emergency amendment was filed March 20, 2019, becomes effective March 30, 2019, and expires January 8, 2020.

(12) Except as provided by law, [P]pharmacists shall not offer or provide compounded [drug products] preparations to other pharmacies, practitioners, or [commercial] entities for subsequent dispensing, distribution, resale, or administration, except in the course of professional practice for a prescriber to administer to an individual patient by a prescription dispensed by the pharmacy. A pharmacist or pharmacy may advertise or otherwise provide information concerning the provision of compounding services; however, no pharmacist or pharmacy shall attempt to solicit business by making specific claims about compounded [products] preparations.

(13) Pharmacies may provide non-patient specific compounded preparations for veterinary use to a Missouri-licensed veterinarian to administer and dispense to the veterinarians's animal patients, provided the following:

(A) The preparation container is labeled with:

1. Pharmacy name, address, and telephone number;
2. Date of distribution;
3. Veterinarian's name;
4. Preparation name, strength, dosage form, and quantity;
5. Name of each active or therapeutic ingredient included in the preparation;
6. Preparation lot/batch number;
7. Preparation beyond-use date; and

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8. Statement: “Office Stock Compounded Preparation”;

(B) The pharmacy maintains a record of the distribution to the veterinarian;

(C) The pharmacy can retrieve distribution records by specific veterinarian, if requested;

(D) In lieu of (7)(A)7., the veterinarian’s name may be recorded on the compounding log; and

(E) The pharmacy complies with all applicable controlled substance laws and regulations.

[(13)](14) In addition to the requirements outlined in this rule, all standards and requirements as outlined in *[4 CSR 220-2.020]* **20 CSR 2220-2.200 Sterile [Pharmaceuticals] Compounding** must be adhered to whenever compounding involves the need for aseptic procedures or requires the use of or results in an intended steril pharmaceutical product.

AUTHORITY: section[s] 338.010, RSMo Supp. 2018, and sections 338.140, 338.240, and 338.280, RSMo [2000] 2016. This rule originally filed as 4 CSR 220-2.400. Original rule filed Aug. 25, 1995, effective April 30, 1996. Amended: Filed Dec. 3, 2002, effective July 30, 2003. Moved to 20 CSR 2220-2.400, effective Aug. 28, 2006. Emergency amendment filed March 20, 2019, effective March 30, 2019, expires Jan. 8, 2020. An emergency amendment and a proposed amendment covering the same material will be published in the May 1, 2019, issue of the Missouri Register.