

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

Division 2220-State Board of Pharmacy

Chapter 2-General Rules

ORDER OF RULEMAKING

By the authority vested in the Missouri Board of Pharmacy under sections 338.056, 338.059, 338.196, 338.250, 338.280, and 338.343, RSMo 2000 and sections 338.010, 338.055, 338.140, 338.150, 338.210, 338.220, and 338.240, RSMo Supp. 2011, the Missouri Board of Pharmacy adopts a rule as follows:

20 CSR 2220-2.675 Standards of Operation/Licensure for Class L Veterinary Pharmacies is adopted.

PURPOSE: This rule defines standards for a Class L veterinary pharmacy.

(1) A Class A or a Class L pharmacy permit shall be required for any entity engaged in the sale, dispensing, or filling of a legend drug for use in animals that must only be dispensed by prescription under state or federal law. For purposes of this rule, a legend drug shall be defined as provided by 21 USC section 353.

(2) Class A Pharmacies. Class A permit holders shall comply with all laws/rules applicable to Class A pharmacies, provided a Class A pharmacy shall comply with sections (7) and (8) of this rule when legend drugs are dispensed for animal use.

(3) Class L Pharmacies. A Class L pharmacy shall dispense, sell, or provide legend drugs only for animal use. Except as otherwise provided in this rule, a Class L pharmacy shall comply with all applicable state and federal pharmacy and controlled substance laws/rules including, but not limited to, all applicable provisions of Chapter 338, RSMo, and the rules of the board.

(4) Pharmacy Operations. A Class L pharmacy shall comply with 20 CSR 2220-2.010, with the following allowed modifications:

(A) The pharmacy permit shall be displayed in plain view at the pharmacy location;

(B) The pharmacy shall maintain sufficient space, equipment, and storage capabilities as necessary to carry out its operations;

(C) Legend drugs shall be properly identified and stored in a defined area within the pharmacy;

(D) Legend drugs shall be stored in a clean and sanitary designated area and within temperature requirements as provided for by the manufacturer or the latest edition of the United States Pharmacopoeia (USP);

(E) The pharmacy shall maintain a current reference manual related to veterinary drugs that complies with 20 CSR 2220-2.010(1)(D);

(F) Appropriate sewage disposal must be available within the pharmacy and a hot and cold water supply shall be accessible to pharmacy staff. If compounding is performed, the hot and cold water supply shall be located within the pharmacy;

(G) Pharmacy compounding shall comply with 20 CSR 2220-2.200, 20 CSR 2220-2.400, and all other applicable provisions of state/federal law;

(H) All dispensing errors shall be documented in the pharmacy's records;

(I) Animals shall not be allowed in the designated area where legend drugs are stored or maintained; and

(J) The pharmacist-in-charge shall be notified within twenty-four (24) hours after a dispensing error is learned by pharmacy staff. Documentation of notification shall be maintained in the pharmacy's prescription records.

(5) A Class L pharmacy shall designate a pharmacist-in-charge as required by 20 CSR 2220-2.010(1)(M). The pharmacist-in-charge shall be responsible for supervising pharmacy operations and ensuring compliance with the provisions of this rule and all applicable state/federal laws. Except as otherwise provided in this rule, the pharmacist-in-charge shall also-

(A) Ensure legend drugs are only sold, dispensed, or filled by the pharmacy for animal use;

(B) Ensure legend drugs have been ordered/prescribed by an authorized prescriber; and

(C) Maintain a policy and procedure manual for pharmacy operations. The policy and procedure manual shall be reviewed annually by the pharmacist-in-charge. The manual shall be available for inspection by board personnel and shall include policies and procedures for:

1. Accepting, compounding, dispensing, or filling prescriptions;
2. Accepting, dispensing, or filling prescriptions in the pharmacist's absence;
3. Drug storage and security;
4. Handling drug recalls;
5. Procedures for offering patient/client counseling;
6. If applicable, procedures for dispensing or providing prescriptions in a pharmacist's absence pursuant to section (8) of this rule;

7. Contacting the pharmacist-in-charge for consultation during the pharmacy's business operations or in the event of an emergency; and

8. Reporting and handling dispensing errors. The pharmacist-in-charge shall be notified of a dispensing error within twenty-four (24) hours after the error is learned by pharmacy staff. Policies/procedures shall include the manner of notification.

(6) A pharmacist shall not be required to be physically present onsite during the business operations of a Class L pharmacy if the pharmacist-in-charge reviews the activities and records of the pharmacy operations on a monthly basis to ensure compliance with this rule. This exemption shall not apply if the pharmacy sells, dispenses, or otherwise provides controlled substances. The date of the pharmacist-in-charge review shall be documented and maintained at the pharmacy.

(7) To be valid for purposes of dispensing, legend drug prescriptions for animal use shall conform to all requirements of sections 338.056 and 338.196, RSMo, and shall contain the following:

(A) The date issued;

(B) The client's/owner's name and the class, species, or identification of the animal, herd, flock, pen, lot, or other group being treated;

(C) The prescriber's name, if an oral prescription, or signature, if a written prescription;

(D) Name, strength, and dosage form of drug and directions for use;

(E) The number of refills, when applicable;

(F) The quantity prescribed in weight, volume, or number of units;

(G) The address of the prescriber and the patient when the prescription is for a controlled substance;

(H) Whether generic substitution has been authorized;

(I) The prescriber's Drug Enforcement Administration (DEA) number when the prescription is for a controlled substance; and

(J) Controlled substance prescriptions shall comply with all requirements of federal and state controlled substance laws.

(8) Dispensing. A Class L pharmacy may accept, fill, enter, dispense, or otherwise provide non-controlled legend drugs for animal use in the absence of a pharmacist, provided the pharmacist-in-charge shall review the prescription record for each such prescription on a monthly basis. The review shall be documented as provided in section (6) of this rule. For purposes of 20 CSR 2220-

2.010(3), the dispensing pharmacist shall be identified as the pharmacist-in-charge unless dispensed by another licensed pharmacist.

(A) Legend drugs may only be compounded for use in animals when a pharmacist is present on site.

(B) Clients must be offered an opportunity to consult with a pharmacist as required by 20 CSR 2220-2.190. If the pharmacist is not present on site, a written offer to counsel with a contact telephone number for a pharmacist shall be supplied with the medication.

(9) Labeling. Prescriptions must be labeled as required by section 338.059, RSMo. Prescription labels may be manually written or numbered and shall include:

(A) The class, species, or identification of the animal, herd, flock, pen, lot, or other group being treated; and

(B) If applicable, the veterinarian's specified withdrawal, withholding, or discard time for meat, milk, eggs, or any other food which might be derived from the treated animal(s).

(10) Records. Class L pharmacy records shall be maintained as required by Chapter 338, RSMo, and the rules of the board, including 20 CSR 2220-2.018 and 20 CSR 2220-2.080.

(A) The information specified in section (7) of this rule shall be required and recorded on all handwritten, telephone, oral, and electronically produced prescriptions that are processed for dispensing by a pharmacist/pharmacy. If applicable, prescription records shall also include the veterinarian's specified withdrawal, withholding, or discard time identified in section (9) of this rule.

(B) Any change or alteration made to the prescription dispensed based on contact with the prescriber shall be documented in the pharmacy's prescription records. This shall include, but is not limited to, a change in quantity, directions, number of refills, or authority to substitute a drug.

(C) The pharmacy's prescription records shall identify any prescription dispensed in a pharmacist's absence pursuant to subsection (8)(B) of this rule.

(11) A Class L pharmacy shall comply with all applicable state or federal controlled substance laws.

(12) The provisions of this rule shall not be applicable to the sale of medication for use in animals that may lawfully be dispensed without a prescription nor shall this rule be construed to require licensure for entities solely engaged in selling, dispensing, or providing medications authorized for dispensing without a prescription.

(13) The provisions of this rule shall not prohibit or interfere with any legally registered practitioner of veterinary medicine in the compounding, administering, prescribing, or

dispensing of their own prescriptions, medicine, drug, or pharmaceutical product to be used for animals.

AUTHORITY: sections 338.056, 338.059, 338.196, 338.250, 338.280, and 338.343, RSMo 2000, and sections 338.010, 338.055, 338.140, 338.150, 338.210, 338.220, and 338.240, HB 412 and SB 325, First Regular Session, Ninety-sixth General Assembly, 2011. Emergency rule filed Aug. 29, 2011, effective Sept. 8, 2011, expires March 5, 2012. Original rule filed Aug. 29, 2011.