

BEFORE THE BOARD OF PHARMACY
AND THE BOARD OF VETERINARY MEDICINE
DEPARTMENT OF LABOR AND INDUSTRY
STATE OF MONTANA

In the matter of the amendment of)
ARM 24.174.401, 24.174.2301,)
24.225.301, 24.225.401, and)
24.225.550 and the adoption of NEW)
RULES I through IV pertaining to)
veterinary retail dispensing)

TO: All Concerned Persons

1. On November 28, 2023, at 10:00 a.m., a public hearing will be held via remote conferencing to consider the proposed changes to the above-stated rules. There will be no in-person hearing. Interested parties may access the remote conferencing platform in the following ways:

- a. Join Zoom Meeting, <https://mt-gov.zoom.us/j/85705820322>
Meeting ID: 857 0582 0322, Passcode: 499885
-OR-
- b. Dial by telephone, +1 406 444 9999 or +1 646 558 8656
Meeting ID: 857 0582 0322, Passcode: 499885

2. The Department of Labor and Industry (department) will make reasonable accommodations for persons with disabilities who wish to participate in this public hearing or need an alternative accessible format of this notice. If you require an accommodation, contact the department no later than 5:00 p.m., on November 21, 2023, to advise us of the nature of the accommodation that you need. Please contact the department at P.O. Box 1728, Helena, Montana 59624-1728; telephone (406) 444-5466; Montana Relay 711; or e-mail laborlegal@mt.gov.

3. GENERAL REASON: The 2023 Montana Legislature passed Senate Bill 561, requiring licensing of veterinary retail facilities and veterinary dispensing technicians. The Board of Pharmacy and the Board of Veterinary Medicine are proposing to amend certain rules and adopt new rules to implement the provisions of the bill by setting fees and application requirements and establishing scopes of practice and unprofessional conduct applicable to these new license types. Where necessary, more specific reasons are given following the individual rule.

4. The rules as proposed to be amended provide as follows, new matter underlined, deleted matter interlined:

BOARD OF PHARMACY

24.174.401 FEE SCHEDULE
(1) through (27) remain the same.

(28) Veterinary retail facility initial license and annual renewal fee

150

(28) remains the same but is renumbered (29).

AUTH: 37-1-134, 37-2-104, 37-7-201, 37-7-604, 37-18-803, 50-32-314, MCA
IMP: 37-1-134, 37-2-104, 37-7-201, 37-7-306, 37-7-321, 37-7-604, 37-7-605, 37-7-703, 37-18-803, 50-32-314, MCA

REASON: It is reasonably necessary to set a fee to cover the costs of initial licensure and renewal of veterinary retail facilities. The board estimates that approximately 25 facilities will be initially impacted by this new fee, resulting in \$3,750 in additional annual revenue.

24.174.2301 UNPROFESSIONAL CONDUCT

(1) through (1)(t) remain the same.

(u) failure to comply with an agreement the licensee has entered into with the impaired pharmacist program; and

(v) failure to follow policies or procedures defined in the practice situation to safeguard patient care.

AUTH: 37-1-319, 37-7-201, MCA

IMP: 37-1-316, MCA

REASON: The board is adding (1)(v) as requested by department prosecutors to facilitate cases and reduce the necessity for expert witnesses. Pharmacies are required to utilize and maintain procedure manuals for the pharmacies' operations. It is reasonable to clarify that failure to follow the procedures is unprofessional conduct and subject to discipline.

BOARD OF PHARMACY
PAUL BRAND, PHARMACIST, PRESIDENT

BOARD OF VETERINARY MEDICINE

24.225.301 DEFINITIONS

(1) through (12) remain the same.

~~(13) "Veterinary prescription drugs" means those drugs restricted by federal law to use by or on the order of a licensed veterinarian (section 503(f) Food, Drug and Cosmetic Act). The law requires that such drugs be labeled with the statement: "Caution: Federal law restricts this drug to use by or on the order of a licensed veterinarian."~~

AUTH: 37-18-202, 37-18-603, 37-18-701, MCA

IMP: 37-18-102, 37-18-104, 37-18-603, 37-18-701, MCA

REASON: Section 1 of Senate Bill 561 (37-18-801, MCA) defines "veterinary prescription drugs," and it is unnecessary to repeat the definition in rule.

24.225.401 FEE SCHEDULE

(1) through (4) remain the same.

(5) Veterinary dispensing technician

(a) application

35

(b) renewal

35

(5) and (6) remain the same but are renumbered (6) and (7).

AUTH: 37-1-134, 37-18-202, 37-18-603, 37-18-701, 37-18-806, MCA

IMP: 37-1-134, 37-1-141, 37-1-304, 37-1-305, 37-18-302, 37-18-603, 37-18-701, 37-18-806, MCA

REASON: It is reasonably necessary to set a fee for initial licensure and renewal of veterinary dispensing technicians. The board estimates that approximately 35 individuals will be initially impacted by this new fee, resulting in \$1,225 in additional annual revenue.

24.225.550 UNPROFESSIONAL CONDUCT

(1) through (3) remain the same.

(4) In addition to 37-18-804, MCA, it is unprofessional conduct for a veterinary dispensing technician to:

(a) dispense a product without consulting with the prescribing veterinarian regarding questions and/or other needs for clarification;

(b) alter prescriptions or other records which the law requires; and

(c) dispense an outdated or damaged product.

AUTH: 37-1-131, 37-1-136, 37-1-319, 37-18-202, MCA

IMP: 37-1-131, 37-1-136, 37-1-316, 37-1-319, 37-18-309, MCA

REASON: It is reasonably necessary to amend the unprofessional conduct rule to include standards of practice for registered veterinary dispensing technicians.

5. The proposed new rules are as follows:

NEW RULE I VETERINARY DISPENSING TECHNICIAN REGISTRATION

(1) Applicants for registration must:

(a) submit a completed application form;

(b) pay the required fee;

(c) provide the name and license number of the veterinary retail facility where the technician is working; and

(d) review and attest to understanding the board's educational materials.

(2) A person licensed as an LVT does not require a separate license to work as a dispensing technician but must provide the board with the name and license number of the veterinary retail facility where the LVT is employed and attest to review of the board's educational materials.

AUTH: 37-18-806, MCA

IMP: 37-18-805, 37-18-806, MCA

NEW RULE II VETERINARY RETAIL FACILITY LICENSE REQUIREMENTS

- (1) Applicants for licensure as a veterinary retail facility must:
 - (a) submit a completed application form;
 - (b) pay the required application fee or renewal fee;
 - (c) designate a registered veterinary dispensing technician as person-in-charge; and
 - (d) comply with the provisions of 37-18-803, MCA.
- (2) Veterinary retail facilities must notify the board within 30 days of the following changes:
 - (a) designated person-in-charge; and
 - (b) termination in service.

AUTH: 37-18-803, MCA

IMP: 37-18-803, MCA

NEW RULE III VETERINARY RETAIL FACILITY REQUIREMENTS

- (1) A veterinary retail facility may dispense veterinary prescription drugs as defined in 37-18-801, MCA, upon receipt of a Montana licensed veterinarian's prescription, standing order, or other order for use in livestock. Drugs must be dispensed by a veterinary dispensing technician registered with the Board of Veterinary Medicine.
- (2) A veterinary retail facility may refill a prescription only if the initial prescription authorizes a specific number of refills, or as identified in a standing order or other appropriate authorization from the prescribing veterinarian.
- (3) All licensed veterinary retail facilities shall:
 - (a) for two years, maintain readily accessible written or electronic records of veterinary prescription drug inventory and prescriptions received, and make the records available for board inspection;
 - (b) provide for secure storage of and accurate recordkeeping for veterinary prescription medications, records, and drug inventory;
 - (c) limit access to veterinary prescription medications and records to the facility's person-in-charge and registered veterinary dispensing technician(s) only;
 - (d) store veterinary prescription drugs separately from over-the-counter drugs and as recommended by the manufacturer;
 - (e) operate in a sanitary manner;
 - (f) purchase veterinary prescription drugs, as defined in 37-18-801, MCA, from a wholesale distributor or pharmacy licensed by the board;
 - (g) maintain policies and procedures to manage and dispose of outdated, expired, damaged, or returned drugs to prevent such drugs from being dispensed, distributed, or resold. Facilities may utilize a reverse distributor licensed as a wholesale distributor by the board; and
 - (h) create and maintain a dispensing record and a client information sheet that includes the following:
 - (i) name, address, and telephone number of the Montana licensed prescribing veterinarian;
 - (ii) client name;

- (iii) identification of animals or herds treated;
- (iv) date(s) each prescription was written, and the drugs dispensed;
- (v) name and quantity of dispensed drug;
- (vi) directions for the drug's dosage, frequency, and duration for use;
- (vii) manufacturer's cautionary statements; and
- (viii) manufacturer's expiration date.

(4) If the information in (3)(h) is included on the manufacturer's label, it is unnecessary to repeat the same information on the client's information sheet, but it must be included in the dispensing record.

AUTH: 37-18-803, MCA

IMP: 37-18-803, 37-18-804, MCA

NEW RULE IV VETERINARY DISPENSING TECHNICIAN SCOPE OF PRACTICE (1) A veterinary dispensing technician, working in a veterinary retail facility licensed by the Board of Pharmacy, must:

- (a) create a written or electronic client record;
- (b) dispense veterinary prescription drugs upon receipt of a prescription order, standing order, or other order as authorized by a licensed veterinarian;
- (c) consult with the prescribing veterinarian in order to clarify a prescription and/or other relevant information necessary to dispense the veterinary prescription drug;
- (d) dispense veterinary prescription drugs based on package size and quantity as provided by the manufacturer;
- (e) perform inventory control to remove expired or damaged drugs from stock, prevent returned drugs from being returned to stock, and ensure such drugs are not dispensed, distributed, or resold;
- (f) ensure the drug product and client information sheet match the prescription order and the information on the manufacturer's labeling with respect to drug, dosage form, strength, and quantity; and
- (g) comply with prescription labeling, recordkeeping, storage, security, and inventory control required of veterinary retail facilities, per [NEW RULE III].

AUTH: 37-1-131, MCA

IMP: 37-1-131, MCA

BOARD OF VETERINARY MEDICINE
TIA NELSON, DVM, PRESIDENT

6. Concerned persons may present their data, views, or arguments at the hearing. Written data, views, or arguments may also be submitted at dli.mt.gov/rules or P.O. Box 1728; Helena, Montana 59624. Comments must be received no later than 5:00 p.m., December 1, 2023.

7. An electronic copy of this notice of public hearing is available at dli.mt.gov/rules and sosmt.gov/ARM/register.

8. The agency maintains a list of interested persons who wish to receive notices of rulemaking actions proposed by the agency. Persons wishing to have their name added to the list may sign up at dli.mt.gov/rules or by sending a letter to P.O. Box 1728; Helena, Montana 59624 and indicating the program or programs about which they wish to receive notices.

9. The bill sponsor contact requirements of 2-4-302, MCA, apply and have been fulfilled. The primary bill sponsor was contacted on May 23, 2023, by electronic mail.

10. Pursuant to 2-4-111, MCA, the agency has determined that the rule changes proposed in this notice will not have a significant and direct impact upon small businesses.

11. Department staff has been designated to preside over and conduct this hearing.

/s/ DARCEE L. MOE
Darcee L. Moe
Rule Reviewer

/s/ SARAH SWANSON
Sarah Swanson, Commissioner
DEPARTMENT OF LABOR AND INDUSTRY

Certified to the Secretary of State October 24, 2023.