

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

In the matter of the amendment of )  
ARM 24.174.401 and the adoption of )  
New Rules I through III pertaining to )  
dispenser registration for medical )  
practitioners )

NOTICE OF PUBLIC HEARING ON  
PROPOSED AMENDMENT AND  
ADOPTION

TO: All Concerned Persons

1. On October 15, 2021, at 10:00 a.m., a public hearing will be held via remote conferencing to consider the proposed amendment and adoption of 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/82087767178>

Meeting ID: 820 8776 7178, Passcode: 997924

-OR-

b. Dial by telephone, +1 406 444 9999 or +1 646 558 8656

Meeting ID: 820 8776 7178, Passcode: 997924

The hearing will begin with a brief introduction by department staff to explain the use of the videoconference and telephonic platform. All participants will be muted except when it is their time to speak.

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 Board of Pharmacy no later than 5:00 p.m., on October 8, 2021, to advise us of the nature of the accommodation that you need. Please contact Marcie Bough, Board of Pharmacy, 301 South Park Avenue, P.O. Box 200513, Helena, Montana 59620-0513; telephone (406) 841-2371; Montana Relay 1 (800) 253-4091; TDD (406) 444-2978; facsimile (406) 841-2305; or [dlibspha@mt.gov](mailto:dlibspha@mt.gov) (board's e-mail).

3. GENERAL REASON: The board determined it is reasonably necessary to amend one existing rule and adopt three new rules to implement the statutory amendments of Chapter 454, Laws of 2021 (Senate Bill 374). The bill allows medical practitioners, as defined in 37-2-101(7), MCA, to dispense drugs under the standards of 37-2-104(1) through (7), MCA, when registered to dispense by the board. The bill becomes effective October 1, 2021.

Once registered, dispensing medical practitioners must comply with statutory dispensing standards in the bill, existing board rules, state and federal requirements for dispensing prescription drugs, and the proposed new rules. Registrants must also follow board requirements for labeling, storage, and recordkeeping, are subject to board inspection, and are prohibited from dispensing controlled substances.

In drafting the new rules, the board reviewed similar dispensing authorities in other states and gathered feedback from medical, pharmacy, and public stakeholders involved in the legislative process. The board reviewed rule discussion drafts and included stakeholder input during meetings on June 18, July 22, and July 29, 2021, at which time proposed language was finalized.

Noting the new dispensing authority provides opportunities for more flexibility in patient care and access to prescription drugs, the board is adopting the new rules to ensure patient safety and that dispensing requirements are maintained. To help ensure patient safety, the new rules establish requirements for registrants that are similar to patient safety provisions required of pharmacists in pharmacy settings. Such requirements include provisions on patient drug utilization review, prescription order and patient labeling, dispensing records, patient counseling, overall recordkeeping, and inspections.

The board is adopting NEW RULES I, II, and III to establish dispensing registration qualifications, practice requirements for dispensing, and recordkeeping requirements. When applicable, the rules reference board statutes and rules to comprehensively provide all related provisions.

4. The rule proposed to be amended is as follows, stricken matter interlined, new matter underlined:

24.174.401 FEE SCHEDULE (1) through (22) remain the same.  
(23) Drugs dispensed by a medical practitioner original registration 240  
(24) Drugs dispensed by a medical practitioner annual renewal fee 150  
(23) remains the same but is renumbered (25).

AUTH: 37-1-134, 37-2-104, 37-7-201, 50-32-314, MCA

IMP: 37-1-134, ~~37-1-305~~, 37-2-104, 37-7-201, ~~37-7-302~~, 37-7-306, 37-7-321, 37-7-604, 37-7-605, 37-7-703, 50-32-314, MCA

REASON: The board is amending this rule to implement SB 374 by setting fees for original dispenser registration and the annual renewal. The proposed fees are the same as the current fees for certified pharmacy licenses. The board estimates 49 applicants and renewing registrants for a \$9,600 cumulative impact to annual revenue. The board also projects \$6,000 in expenses related to annual inspections by board inspectors.

Authority and implementation citations are being amended to reflect all statutes implemented through the rule, including the SB 374 changes, and provide the complete sources of the board's rulemaking authority.

5. The proposed new rules are as follows:

NEW RULE I QUALIFICATIONS FOR DISPENSER REGISTRATION

(1) An applicant for a registration to dispense drugs as a medical practitioner, pursuant to 37-2-104, MCA, shall:

- (a) be a licensed medical practitioner as defined in 37-2-101(7), MCA;
- (b) be in good standing as that term is defined in this chapter;

- (c) complete the application on a form supplied by the board;
- (d) pay the required application fee and renewal fee; and
- (e) be located in Montana.
- (2) The applicant shall:
  - (a) state each location in Montana at which prescription drugs will be dispensed; and
  - (b) grant permission to the board to inspect each location at which prescription drugs will be dispensed during the normal business hours.
- (3) Registrants must conspicuously display the dispenser license at all times in the place of business for which the license is issued.

AUTH: 37-7-201, MCA

IMP: 37-2-104, 37-7-201, MCA

NEW RULE II DISPENSING REQUIREMENTS (1) A dispenser registrant shall:

- (a) create a written or electronic prescription drug order for each drug dispensed and maintain such information in the patient's chart or record, pursuant to ARM 24.174.831, and 37-7-101(43) and 50-31-307, MCA, which shall include the following, but not be limited to:
  - (i) patient's name;
  - (ii) name of drug;
  - (iii) strength;
  - (iv) dosage form;
  - (v) quantity;
  - (vi) directions for use;
  - (vii) date of issuance; and
  - (viii) prescriber's name;
- (b) perform in person the final verification check of each drug prior to dispensing that, at a minimum, includes the following:
  - (i) ensuring the prescription drug product and label match the prescription drug order and the information on the manufacturer's label with respect to drug, dosage form, strength, quantity, and drug identification number;
  - (ii) verifying the prescription product label matches the prescription drug information with respect to prescription requirements in ARM 24.174.831;
  - (iii) verifying the drug has not expired and will not expire within the duration of use;
  - (iv) ensuring the registrant has completed a prospective drug utilization review after reviewing the patient profile; and
  - (v) documenting that the final verification check was completed by the registrant; and
- (c) directly prepare, dispense, and deliver the drug, including subsequent fills or refills, in person to their patient(s) pursuant to the provisions in 37-2-104(2) and 50-31-307, MCA. The drug may not be dispensed or delivered by mail or common carrier.

(2) A registrant shall comply with all federal and state statutes and regulations regarding dispensing of prescription drugs, including all requirements for the registrant to:

(a) perform a prospective drug utilization review, pursuant to 37-7-101(17) and 37-7-406, MCA, and ARM 24.174.902;

(b) provide patient labeling, pursuant to 37-7-101(14), MCA, and ARM 24.174.301(23), 24.174.832, and 24.174.833, including:

(i) the prescription label shall contain the name, address, and phone number of the registrant, name of patient, name and strength of drug, directions for use, and date of filling;

(ii) the prescription label must be securely attached to the outside of the container in which the drug is dispensed; and

(iii) the registrant shall provide Medication Guides and/or Patient Package Inserts, comply with Risk Evaluation and Mitigation Strategies, and/or other labeling requirements as required by the U.S. Food and Drug Administration;

(c) develop a protocol to manage, store, and secure prescription drug dispensing inventory, pursuant to ARM 24.174.301(43), 24.174.814, 24.174.818, and 24.174.819, including:

(i) operating in a sanitary manner;

(ii) restricting access only to authorized individuals as determined by the registrant;

(iii) assuring that physical access to prescription drugs for dispensing is denied to all individuals at all times when a registrant is not on the premises, except with regard to dispensing pursuant to 37-2-104(8), MCA;

(d) maintain recordkeeping, pursuant to ARM 24.174.833, with records available for inspection by the board;

(e) compound drug products, including non-sterile and sterile products, pursuant to ARM 24.174.841;

(f) provide patient counseling, pursuant to 37-7-101(31) and 37-7-406, MCA, and ARM 24.174.903;

(g) provide notification that the patient may request dispensing of a less expensive therapeutically equivalent generic or interchangeable biologic product pursuant to 37-7-502 and 37-7-506, MCA, if applicable; and

(h) implement and have in place a quality assurance program to detect, identify, and prevent prescription errors, pursuant to ARM 24.174.407.

(3) With regard to inspections by the board or its designee, a registrant shall resolve conditions identified in an inspection report, if applicable.

(4) Prescription drugs dispensed by a registrant may not be transferred to another practitioner or pharmacist for subsequent filling or refills.

AUTH: 37-7-201, MCA

IMP: 37-2-104, 37-7-201, MCA

### NEW RULE III DISPENSER RECORDKEEPING REQUIREMENTS

(1) A registrant shall keep readily retrievable at each dispensing location records of dispensing and inventory, pursuant to ARM 24.174.833:

(a) a copy of the registrant's dispenser license;

- (b) a record of each final verification check by the registrant;
- (c) the registrant's protocols for handling drug recalls, including the arrangements for notifying patients;
- (d) the registrant's protocols for disposal of drugs;
- (e) with respect to a supplier from whom the registrant purchased prescription drugs:
  - (i) the name, address, and phone number of each wholesale drug distributor supplier, as defined in 37-7-602(8), MCA, and ARM 24.174.1201; and
  - (ii) documentation including:
    - (A) for each wholesale drug distributor supplier, the number and the expiration date of the license issued by the board; and
    - (B) for any pharmacy supplier acting as a wholesale drug distributor, the number and the expiration date of the pharmacy license issued by the board;
  - (f) any other purchasing, inventory, and dispensing records required by state or federal statutes or regulations;
  - (g) a manual or electronic dispensing record must be maintained separately from the patient medical record and kept for a minimum of two years. If an electronic health information system, as defined in 37-7-101(22), MCA, is utilized, the system must be able to produce a separate dispensing record; and
  - (h) the dispensing record must show, at a minimum, the following for original and subsequent fills or refills, in compliance with ARM 24.174.833:
    - (i) name of patient;
    - (ii) unique identifier;
    - (iii) dose, dosage form, quantity dispensed, and either the brand name of drug or generic name and name of manufacturer;
    - (iv) directions for use;
    - (v) date of dispensing; and
    - (vi) initials of registrant dispensing the prescription.
- (2) In addition to meeting the requirements of [NEW RULE II], the registrant shall comply with any other state or federal law or regulation relating to dispensing of prescription drugs.
- (3) Records must be available for inspection by the board.

AUTH: 37-7-201, MCA

IMP: 37-2-104, 37-7-201, MCA

6. Concerned persons may present their data, views, or arguments either orally or in writing at the hearing. Written data, views, or arguments may also be submitted to the Board of Pharmacy, 301 South Park Avenue, P.O. Box 200513, Helena, Montana 59620-0513, by facsimile to (406) 841-2305, or e-mail to [dlibsdp@mt.gov](mailto:dlibsdp@mt.gov), and must be received no later than 5:00 p.m., October 22, 2021.

7. An electronic copy of this notice of public hearing is available at [www.pharmacy.mt.gov](http://www.pharmacy.mt.gov) (department and board's web site). Although the department strives to keep its web sites accessible at all times, concerned persons should be aware that web sites may be unavailable during some periods, due to system

maintenance or technical problems, and that technical difficulties in accessing a web site do not excuse late submission of comments.

8. The board maintains a list of interested persons who wish to receive notices of rulemaking actions proposed by this board. Persons who wish to have their name added to the list shall make a written request that includes the name, e-mail, and mailing address of the person to receive notices and specifies that the person wishes to receive notices regarding all board administrative rulemaking proceedings or other administrative proceedings. The request must indicate whether e-mail or standard mail is preferred. Such written request may be sent or delivered to the Board of Pharmacy, 301 South Park Avenue, P.O. Box 200513, Helena, Montana 59620-0513; faxed to the office at (406) 841-2305; e-mailed to [dlibsdpba@mt.gov](mailto:dlibsdpba@mt.gov); or made by completing a request form at any rules hearing held by the agency.

9. The bill sponsor contact requirements of 2-4-302, MCA, apply and have been fulfilled. The primary bill sponsor was contacted on July 16, 2021, by telephone.

10. Regarding the requirements of 2-4-111, MCA, the board has determined that the amendment of ARM 24.174.401 will not significantly and directly impact small businesses.

Regarding the requirements of 2-4-111, MCA, the board has determined that the adoption of New Rules I through III will not significantly and directly impact small businesses.

Documentation of the board's above-stated determinations is available upon request to the Board of Pharmacy, 301 South Park Avenue, P.O. Box 200513, Helena, Montana 59620-0513; telephone (406) 841-2371; facsimile (406) 841-2305; or to [dlibsdpba@mt.gov](mailto:dlibsdpba@mt.gov).

11. Marcie Bough, Executive Officer, has been designated to preside over and conduct this hearing.

BOARD OF PHARMACY  
TONY KING, RPh  
PRESIDENT

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

/s/ LAURIE ESAU  
Laurie Esau, Commissioner  
DEPARTMENT OF LABOR AND INDUSTRY

Certified to the Secretary of State September 14, 2021.