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


NOTICE OF PUBLIC HEARING ON PROPOSED AMENDMENT AND REPEAL

TO: All Concerned Persons

1. On July 26, 2019, at 10:00 a.m., a public hearing will be held in the Basement Conference Room #B-07, 301 South Park Avenue, Helena, Montana, to consider the proposed amendment and repeal of the above-stated rules.

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 July 19, 2019, 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 dlibsdpha@mt.gov (board's e-mail).

3. The rules proposed to be amended are as follows, stricken matter interlined, new matter underlined:

24.174.401 FEE SCHEDULE (1) through (13) remain the same.
(14) Pharmacy technician and technician-in-training registration fee 35
(15) through (23) remain the same.

AUTH: 37-1-134, 37-7-201, 50-32-314, MCA
IMP: 37-1-134, 37-1-305, 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 technicians-in-training (TTR) license type has been in place since 2002. However, when reviewing a TTR extension request, legal staff concluded that statute does not authorize the board to issue TTR licenses. Therefore, the board determined it is reasonably necessary to remove the TTR license type and corresponding references related to pharmacy technicians from this rule, ARM 24.174.701, and 24.174.703.

In lieu of the TTR license, the board is further amending ARM 24.174.701 and 24.174.703 to issue temporary certified pharmacy technician licenses valid for 12 months per 37-1-305, MCA. The only outstanding application requirement for these temporary licenses is completion of a certification exam administered and issued by one of the pharmacy technician certification authorities listed in rule. If the board receives proof of certification from the applicant within the 12-month timeline, a full pharmacy technician license will be issued that is subject to annual license renewal requirements. Importantly, license renewal requirements will continue to remain separate from the requirements for maintaining certification as determined by certifying entities. Because the same pharmacy technician applicants will pay the same fee but simply receive a different temporary license, there is no fiscal impact to board revenue. The board is amending the implementation citations to include 37-1-305, MCA.

To correlate with the TTR changes, the board is also repealing ARM 24.174.702 but incorporating the technician scope of practice language into relevant rules and removing the TTR reference in the listing of application fees.

24.174.507 MILITARY TRAINING OR EXPERIENCE (1) and (2) remain the same.
(3) An applicant must submit satisfactory evidence of receiving military training, service, or education that is equivalent to relevant licensure requirements of the Board of Pharmacy. At a minimum, satisfactory evidence shall include:
   (a) a copy of the applicant's military discharge document (DD 214 or other discharge documentation);
   (b) through (4) remain the same.

AUTH: 37-1-145, MCA
IMP: 37-1-145, MCA

REASON: The board determined it is necessary to amend the rule to reflect feedback received since adopting this rule. The board has become aware that certain military personnel (reservists and national guardsmen who have never been activated) in fact do not receive a DD 214 form upon discharge from the military.
Because the current rule may be interpreted to require a DD 214 from all applicants who submit evidence of relevant military training, service, or education as part of the licensure process, the board is amending the rule to allow consideration of other evidence of military discharge in addition to or in lieu of a DD 214 form.

24.174.524 COLLABORATIVE PRACTICE AGREEMENT REQUIREMENTS
(1) Prior to initially engaging in collaborative practice, a pharmacist must provide the board with an executed written and electronic copy of the collaborative practice agreement.
(1) A pharmacist engaged in collaborative practice must:
(a) maintain an executed written copy of the collaborative practice agreement at the pharmacy and any other location in which the practice is occurring; and
(b) make the agreement available for inspection by the board.
(2) and (2)(a) remain the same.
(i) the practitioner as defined in 37-2-101, MCA, must be licensed in good standing in Montana; and
(ii) the practitioner must be in active practice in the community in which the collaborating pharmacist practices. A request for an exception to this provision must be in writing and will be decided by the board.
(b) through (4) remain the same.

AUTH: 37-7-201, MCA
IMP: 37-7-101, 37-7-201, MCA

REASON: The board is amending (1) to no longer require that pharmacists annually submit copies of their collaborative drug therapy management (CDTM) agreements to the board and simply require the agreements be available for inspection. The board’s inspectors routinely request pharmacy records during inspections and requiring CDTM agreements at the time of inspection comports with current practice and reduces the board staff’s administrative burden of maintaining the copies. It is important that pharmacies maintain records onsite, including CDTM agreements, and doing so enables the board’s inspectors to determine compliance with all requirements at the time of inspection.

The board is amending (2) to remove the requirement for a practitioner to be in active practice in the community in which a collaborating pharmacist practices. The board determined this amendment is reasonably necessary because the provision does not reflect current practice, potentially limits the opportunity for collaboration, and prevents flexibility in how pharmacists and practitioners collaborate across a variety of practice settings and locations.

24.174.602 INTERNSHIP REQUIREMENTS (1) through (6) remain the same.

(7) The intern is responsible for properly submitting all forms and hour reports under the approved program directly to the school of pharmacy.
(8) remains the same.
(9) An intern shall be:
(a) and (b) remain the same.
(c) a graduate of a pharmacy program located outside the United States of America which is not accredited and who has successfully passed equivalency examinations approved by the board is licensed pursuant to ARM 24.174.605.
(10) and (11) remain the same.
(12) The intern shall notify the board of any change of permanent address, employment, or preceptor within 30 days.
(13) and (14) remain the same.

AUTH:  37-7-201, MCA
IMP:     37-7-201, MCA

REASON: The board is amending several provisions in this rule, ARM 24.174.604, and 24.174.612 regarding pharmacist interns, their educational opportunities with preceptors and supervising pharmacists, and the procedures for interns to obtain pharmacy school credit and complete the 1,500 hours to meet pharmacist licensure requirements.

In evaluating administrative efficiencies, board and licensing staff identified the reporting and tracking of intern hours to be an unnecessary burden on licensees, preceptors, and staff. Pharmacy schools collect and verify intern hours and use experiential program computer program technologies to improve such procedures and improve efficiency. For example, interns can now input hours directly into the school's system which is more efficient and can replace the forms and procedures currently required by the board for tracking and/or verifying intern hours. In addition, other states seeking to verify intern hours can receive confirmation directly from the school rather than the board, a practice already in place in other states. A pharmacy school also verifies successful completion of intern hours to issue a certificate of completion required in the application for pharmacist licensure. Therefore, the board is amending these rules to no longer require pharmacist interns to submit hours to the board as it is duplicative and unnecessary.

To improve educational opportunities, the board is removing limitations on the number of pharmacist interns that a preceptor and/or supervising pharmacist can precept at one time. By allowing for greater flexibility in accommodating educational experiences at different pharmacy practice locations, the amendment will ensure more opportunities for pharmacist interns and removes potential challenges with rotation and clerkship placements, a change requested by the school of pharmacy. The amendments also correlate with proposed amendments to ARM 24.174.711 to remove interns from counting against the pharmacist to pharmacy technician ratio and therefore expand the ratio.

24.174.604  PRECEPTOR REQUIREMENTS  (1) and (2) remain the same.
(3) A supervising pharmacist may only supervise one student in introductory pharmacy practice experience (IPPE) at any time.
(4) A supervising pharmacist may supervise no more than three persons at one time (including technicians, interns, and students), unless an exception is specifically granted by the board.
(5) A pharmacist preceptor may supervise two students at a time if the students are completing an advanced pharmacy practice experience (APPE) through an approved school of pharmacy.

(6) A supervising pharmacist or preceptor may precept more than one intern at a time.

AUTH:  37-7-201, MCA
IMP:  37-7-201, MCA


24.174.612  INTERNSHIP REQUIRED FORMS AND REPORTS

(1) Forms Intern and internship documentation, hours, and forms shall be furnished by the board, the cost of which is included in the application for internship registration school of pharmacy and filed directly to the school of pharmacy.

(a) The "intern application" must be filed by the intern An intern must be licensed by the board before computed time is credited.

(b) The "internship experience affidavit", provided by the board, must be filed by the intern at the end of the internship experience in a given site or after 500 hours, whichever comes first.

(c) The "evaluation of internship site" must be filed by the intern at the completion of internship or externship experience in a given site or after 500 hours, whichever comes first.

(d) The "clerkship experience affidavit", provided by the board, must be filed by the intern at the end of the academic year.

AUTH:  37-7-201, MCA
IMP:  37-7-201, MCA


24.174.701  PHARMACY TECHNICIAN REGISTRATION REQUIREMENTS

(1) In order to To be registered as a pharmacy technician in this state, the applicant shall:

(a) submit application on a form prescribed by the board;

(b) pay application fees as prescribed by the board; and

(c) submit a copy of proof of certification by the Pharmacy Technician Certification Board (PTCB), National Healthcareer Association (ExCPT), or other board-approved certifying entity.

(a) be at least 18 years old;

(b) be a high school graduate or have attained an equivalent degree;

(c) be of good moral character;

(d) submit application on a form prescribed by the board;

(e) pay application fees as prescribed by the board; and

(f) submit a copy of proof of certification by the Pharmacy Technician Certification Board (PTCB), National Healthcareer Association (ExCPT), or other board-approved certifying entity.
(2) In order to be registered as a technician-in-training in this state, the applicant shall:
   (a) apply to the board for a permit on an application supplied by the board;
   (b) pay the fee required;
   (c) provide the name and address of the pharmacy in which the technician-in-training is employed. A change in place of employment will require submission of updated information within 30 working days of the change.

(2) An applicant for registration as a pharmacy technician in this state may apply for a temporary practice permit as authorized by 37-1-305, MCA, valid for one year from the date the permit was issued.

(3) The permit to practice as a technician-in-training shall be valid for a period of not longer than 18 months. A technician-in-training applicant who has not passed the Pharmacy Technician Certification Board (PTCB), ExCPT, or other board-approved certifying exam within the 18 months due to extenuating circumstances may file a written request to the board for an extension of his or her technician-in-training license. The board will then determine when the license will expire. A technician-in-training whose license has expired but who did not pass the requisite exam may not apply for a technician-in-training license a second time.

(3) No pharmacist or intern whose license has been denied, revoked, suspended, or restricted for disciplinary purposes shall be eligible to be registered as a pharmacy technician.

(4) Working as a technician-in-training with an expired license is cause for disciplinary action against the licensee.

AUTH: 37-1-131, 37-7-201, MCA
IMP: 37-1-305, 37-7-201, MCA

REASON: See REASON for ARM 24.174.401. Authority and implementation citations are being amended to accurately reflect all statutes implemented through the rule and provide the complete sources of the board's rulemaking authority.

24.174.703 USE OF PHARMACY TECHNICIAN (1) remains the same.

(2) A pharmacy technician must work under the provisions of a technician utilization plan and the plan must be made available for inspection by the board.

(2) through (4) remain the same but are renumbered (3) through (5).

(5) (6) All pharmacy technician licenses and technician-in-training permits must be conspicuously displayed at all times in the place of business.

AUTH: 37-7-201, MCA
IMP: 37-7-101, 37-7-201, 37-7-301, 37-7-307, MCA


24.174.711 RATIO OF PHARMACY TECHNICIANS AND INTERNS TO SUPERVISING PHARMACISTS (1) A registered pharmacist in good standing may supervise the services of no more than three pharmacy technicians at any time. The 1:3 1:4 pharmacist to pharmacy technician ratio may be revised by the board at
any time for good cause. A pharmacist intern does not count against the pharmacist to pharmacy technician ratio.

(2) Registered pharmacists in good standing in the state of Montana may supervise a maximum of three four registered pharmacy technicians, provided:
   (a) through (c) remain the same.

(3) If a pharmacy desires more than three four technicians to work under the supervision, direction, and control of one pharmacist, the pharmacy shall obtain the prior written approval of the board. To apply for approval, the pharmacist-in-charge shall submit a pharmacy services plan to the board. The pharmacy services plan submitted shall demonstrate how the plan facilitates the provision of pharmaceutical care and shall include, but shall not be limited to the following:
   (a) through (6) remain the same.

AUTH:  37-7-201, MCA
IMP:     37-7-101, 37-7-201, 37-7-307, 37-7-308, 37-7-309, MCA

REASON: The board determined it is reasonably necessary to amend this rule to expand the pharmacist to pharmacy technician ratio from 1:3 to 1:4 to better reflect changing pharmacy practice and procedures and address the consistent number of ratio variance requests the board receives. The board considered options for making no ratio change, expanding the ratio to 4 through 6 (or more) pharmacy technicians per pharmacist, or removing the ratio and allowing pharmacy practice locations to determine their own staffing levels. The board also considered a comparison of ratios in other states. The board concluded that expanding the ratio to 1:4 addresses current requests by pharmacies for a ratio waiver or for an increase in the ratio, while also maintaining adequate pharmacist oversight and supervision of technician duties to ensure patient safety and compliance with technician utilization plans.

   The board is also amending (1) to no longer count pharmacist interns against the pharmacist to pharmacy technician ratio and allow for additional educational/training opportunities for interns, and supervisory/mentorship opportunities for pharmacists. This amendment further correlates with proposed changes to ARM 24.174.604 removing limitations on the number of pharmacist interns a preceptor or supervising pharmacist can precept.

   The board offers the following example of how combining the ratio and intern amendments may impact staffing: a pharmacist who currently uses one spot of the 1:3 ratio for a pharmacist intern will have an opportunity to utilize two additional pharmacy technicians, maintain compliance with the 1:4 ratio, and still serve as a preceptor or supervising pharmacist for one or more pharmacist interns. Furthermore, the board expects the amendments to decrease the number of ratio variance requests it receives.

24.174.835 TRANSFER OF PRESCRIPTIONS (1) The transfer of prescription information for the purpose of refill dispensing is permissible between pharmacies subject to DEA regulations and the following requirements:
   (a) the transfer is communicated directly between two licensed pharmacists/interns; and
(b) a retrievable audit trail, including the date of transfer and initials or code of the transferring parties, is maintained for a period of two years.

(b) controlled substances may only be transferred from the original pharmacy to which it was presented; and

(c) for a period of not less than two years, a retrievable audit trail must be maintained that includes the date of transfer and initials or code of the transferring party.

(2) The manual transfer of original prescription information for a controlled (dangerous) substance listed in Schedules III, IV, or V for the purpose of refill dispensing is permissible between pharmacies on a one-time basis only, by following the procedures listed in (1). In addition:

(a) the transferring pharmacist shall record on the reverse of the invalidated prescription the DEA registration number of the pharmacy to which it was transferred; and

(b) the pharmacist receiving the transferred prescription shall record the DEA registration number of the pharmacy from which the prescription information was transferred.

(3) The electronic transfer of prescription information for the purpose of refill dispensing is permissible between pharmacies subject to the following requirements:

(a) The transferring pharmacy shall:

(i) remain the same but is renumbered (a).

(ii) enter the name, address, and DEA number if required of the receiving pharmacy into the database of the transferring pharmacy;

(iii) remain the same but is renumbered (c).

(A) through (C) remain the same but are renumbered (i) through (iii).

(D) (iv) maintain a retrievable audit trail, including the date of transfer and initials or code of the transferring party, for a period of two years; and

(b) The receiving pharmacy shall maintain documentation including:

(i) through (iv) remain the same but are renumbered (a) through (d).

(v) the name, address, and DEA number if required of the transferring pharmacy;

(vi) all other prescription information required by state and federal laws and regulations; and

(vii) a retrievable audit trail, including the date of transfer and initials or code of the receiving party, for a period of two years; and

(viii) remains the same but is renumbered (g).

(4) The electronic transfer of original prescription information for a controlled (dangerous) substance listed in Schedules III, IV, or V for the purpose of refill dispensing is permissible between pharmacies on a one-time basis only, by following the procedures listed in (1) and (3).

(5) and (5)(a) remain the same but are renumbered (4) and (4)(a).

(b) Whenever a consumer objects to their prescription records being made accessible to other pharmacies through the use of electronic prescription files, it is the duty of the pharmacy to assure that the consumer's records are not shared with or made accessible to another pharmacy except as provided in (1), (2), and (4) this rule.
(6) remains the same but is renumbered (5).

(7) Both the original and transferred prescription must be maintained for a period of at least two years from the date of last refill.

(8) Pharmacies utilizing automated data processing systems must satisfy all information requirements of the manual mode for all prescription transferral and be certain that their system can void the original prescription once it is transferred, yet maintain the information on file.

AUTH: 37-7-201, MCA
IMP: 37-7-201, MCA

REASON: The board determined it is reasonably necessary to amend this rule to align with current pharmacy practice and address questions from licensees and the public by clarifying prescription transfers. Removing the term "refill" better reflects current practice in which original, unfilled prescriptions may need to be transferred to a different pharmacy because of patient choice and/or when a prescription is sent to the wrong pharmacy. The board believes the amendments will improve patient access to medications incorrectly e-prescribed, faxed, and/or phoned to the wrong pharmacy. Additionally, the changes eliminate redundant and conflicting provisions relative to federal Drug Enforcement Administration (DEA) regulations for the transfer of controlled substance prescriptions. Lastly, the board is amending this rule to eliminate redundant record retention language and outdated references to automated data processing systems and clarify record keeping requirements for prescription transfers.

24.174.2104 REGISTERED PHARMACIST CONTINUING EDUCATION—REQUIREMENTS (1) through (4) remain the same.

(5) In order to receive Montana license renewal, any Montana-licensed pharmacist residing in another state shall meet Montana's requirements for continuing education. All licensees shall affirm an understanding of their recurring duty to comply with CE requirements as a part of annual license renewal.

(6) The board may randomly audit up to 50 percent of renewed licensees' CE hours.

(7) Licensees found to be in noncompliance with CE requirements may be subject to administrative suspension.

AUTH: 37-1-319, MCA
IMP: 37-1-306, MCA

REASON: The board is amending this rule to align with and further facilitate the department's standardized renewal, administrative suspension, and audit procedures.

Following a recommendation by department legal staff, the board is amending (5) to align the affirmation of CE requirements at renewal with the provisions of 37-1-306, MCA. The amendments fall within standardized department procedures that licensees with mandatory CE affirm an understanding of their CE requirements, as part of a complete renewal application, instead of affirming CE completion.
The board is adding (6) to allow flexibility in conducting random CE audits. This amendment will allow the board to respond to staffing and budget issues by adjusting the number of licensees audited, while remaining consistent with the statutory maximum of 50 percent in 37-1-306, MCA.

The board is adding (7) to clarify that licensees not in compliance with CE requirements may be subject to administrative suspension per 37-1-321, MCA, and in accordance with standardized department audit processes.

4. The rules proposed to be repealed are as follows:

24.174.702 QUALIFICATIONS OF PHARMACY TECHNICIAN

AUTH: 37-7-201, MCA
IMP: 37-7-201, 37-7-301, 37-7-307, MCA

REASON: The board is repealing this rule to eliminate duplication and confusion with ARM 24.174.701, pharmacy technician registration. The board is relocating relevant provisions on scope of practice to ARM 24.174.703, as a more appropriate location.

24.174.2101 PHARMACIES–ANNUAL RENEWAL

AUTH: 37-7-201, MCA
IMP: 37-7-321, MCA

REASON: The board is repealing this rule and ARM 24.174.2102, 24.174.2103, and 24.174.2107 because they are unnecessarily duplicative of the department's continuing education and renewal rules and standardized procedures.

24.174.2102 PHARMACY TECHNICIAN–RENEWAL

AUTH: 37-7-201, MCA
IMP: 37-1-141, 37-7-201, MCA

24.174.2103 RENEWALS

AUTH: 37-1-319, 37-7-201, MCA
IMP: 37-1-131, 37-1-141, 37-1-306, 37-7-201, MCA

24.174.2107 REGISTERED PHARMACIST CONTINUING EDUCATION–NONCOMPLIANCE

AUTH: 37-1-319, MCA
IMP: 37-1-141, 37-1-306, MCA

5. 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 dlibsdphamgov@mt.gov, and must be received no later than 5:00 p.m., August 2, 2019.

6. An electronic copy of this notice of public hearing is available at 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.

7. 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 dlibsdphamgov@mt.gov; or made by completing a request form at any rules hearing held by the agency.

8. The bill sponsor contact requirements of 2-4-302, MCA, do not apply.


Regarding the requirements of 2-4-111, MCA, the board has determined that the repeal of ARM 24.174.702, 24.174.2101, 24.174.2102, 24.174.2103, and 24.174.2107 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 dlibsdphamgov@mt.gov.

10. Marcie Bough, Executive Officer, has been designated to preside over and conduct this hearing.
-/s/ DARCEE L. MOE    /s/ GALEN HOLLENBAUGH
Darcee L. Moe    Galen Hollenbaugh, Commissioner
Rule Reviewer    DEPARTMENT OF LABOR AND INDUSTRY

Certified to the Secretary of State June 25, 2019.