

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

In the matter of the amendment of) NOTICE OF PUBLIC HEARING ON
ARM 24.174.301 definitions,) PROPOSED AMENDMENT AND
24.174.503 administration of) REPEAL
vaccines, 24.174.510 prescriptions,)
24.174.523 transmission of)
prescriptions, 24.174.601 objectives,)
24.174.602 internship, 24.174.701)
registration requirements, 24.174.703)
pharmacy technician, 24.174.817)
record keeping, 24.174.1002)
registration conditions, 24.174.1114)
emergency drug kit, 24.174.2102 and)
24.174.2103 renewal, 24.174.2301)
unprofessional conduct, and repeal of)
24.174.1007 agent of records)

TO: All Concerned Persons

1. On August 6, 2009, at 9:00 a.m., a public hearing will be held in 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 (board) no later than 5:00 p.m., on July 31, 2009, to advise us of the nature of the accommodation that you need. Please contact Ronald J. Klein, 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; e-mail pharmacy@mt.gov.

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

24.174.301 DEFINITIONS In addition to the terms defined in 37-7-101, MCA, the following definitions apply to the rules in this chapter.

(1) through (26) remain the same.

(27) "Pharmacist-in-charge" means a pharmacist licensed in Montana who accepts responsibility for the operation of a pharmacy in conformance with all laws and rules pertinent to the practice of pharmacy, who assures that the pharmacy and all pharmacy personnel working in the pharmacy have current and appropriate

licensure and certification, and who is personally in full and actual charge of such pharmacy.

(28) through (36) remain the same.

AUTH: 37-1-131, 37-7-201, 50-32-314, MCA

IMP: 37-7-102, 37-7-201, 37-7-301, 37-7-321, 37-7-406, 37-7-603, 37-7-604, 37-7-605, 50-32-314, MCA

REASON: The board determined it is reasonably necessary to amend this definition to address recent questions addressing the responsibility of pharmacists-in-charge regarding licensure. Although the board's intent has been for pharmacists-in-charge to ensure proper licensure of pharmacies and employees, the requirement was not previously set forth in rule.

24.174.503 ADMINISTRATION OF VACCINES BY PHARMACISTS (1) through (7) remain the same.

(8) The pharmacist must provide a certified true copy of the immunization certificate and CPR certification to the board for initial endorsement on their ~~pharmacy~~ pharmacist license.

(9) In order to maintain the immunization endorsement on their ~~pharmacy~~ pharmacist license, an immunization certified pharmacist must:

(a) through (10) remain the same.

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

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

REASON: The board is amending this rule to correct an inadvertent error discovered during the October 2008 meeting. Immunization endorsements are attached to pharmacist licenses, not pharmacy licenses. Authority cites are being amended to accurately reflect the statutory sources of the board's rulemaking authority.

24.174.510 PRESCRIPTION REQUIREMENTS (1) remains the same.

(2) "Brand name medically necessary" shall be handwritten (or printed if electronically generated) on the face of the prescription if it is medically necessary that an equivalent drug product not be selected.

(Note: Information presented in brackets [] represents institutional pharmacy requirements.)

AUTH: 37-7-201, MCA

IMP: 37-7-201, 37-7-505, MCA

REASON: It is reasonable and necessary to amend this rule to clarify that "brand name medically necessary" must be handwritten or printed on the prescription. The board determined that checking a box or signing on a specified line is not a reliable method to communicate this information because it is frequently done unintentionally by the prescriber. Many third party payers require that "brand name medically

necessary" be handwritten on the prescription for payment and audit pharmacies to assure compliance. The handwritten requirement will give pharmacists a tool to inform and educate prescribers on what is currently an industry standard.

Implementation cites are being amended to accurately reflect all statutes implemented through this rule.

24.174.523 TRANSMISSION OF PRESCRIPTIONS BY ELECTRONIC MEANS (1) through (4) remain the same.

(5) Computer-generated, electronically signed prescriptions that are handed directly to a patient or to a patient's agent must be authenticated by the prescriber by one of the following methods:

(a) the prescription must be hand signed with the actual signature of the prescriber; or

(b) a prescription that is electronically signed by the prescriber must include an additional security feature on the prescription that cannot be reproduced.

(i) It is the prescriber's responsibility to identify the security feature on the face of the prescription.

(ii) It is the prescriber's responsibility to indicate on the face of the prescription that the prescription is not valid without the security feature.

(5) remains the same but is renumbered (6).

AUTH: 37-7-201, 50-32-103, MCA

IMP: 37-7-102, 37-7-201, 50-32-208, MCA

REASON: The board is amending this rule to address the security of electronically generated prescriptions that are handed directly to patients rather than transmitted to a pharmacy by electronic means. The board has received requests to consider options other than hand signing to authenticate these electronically generated prescriptions. The board concluded that a method to authenticate these prescriptions is needed to ensure that the prescriptions have not been reproduced. This amendment provides the flexibility of an alternative to hand signing as long as the alternative is clearly marked on the prescription, such as, "prescription invalid if not stamped with a red seal" or "prescription not valid without watermark."

24.174.601 SUMMARY OF OBJECTIVES (1) ~~Internship training, using academic training as a foundation, provides a learning experience in real life situations that will result in a professional who is competent to practice pharmacy and render professional services on their own, without supervision at the time of licensure. The objectives shall be:~~

~~(a) a practically, accurately and safely trained intern;~~

~~(b) an ethically trained intern; and~~

(c) a legally trained intern The practical experiences required prior to professional licensure shall be referred to as internship. The purpose of pharmacy internship is to provide an intern with the knowledge and practical experience necessary for professional licensure.

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 national internship standards. Noting that this internship rule is outdated, the board is amending it to reflect what is happening in current national practice standards as promoted by the National Association of Boards of Pharmacy (NABP).

24.174.602 INTERNSHIP REQUIREMENTS (1) The experience required to obtain licensure as a pharmacist shall be that instruction period composed of computed time obtained under the supervision of the preceptor in an approved site. ~~An intern may not work alone and assume the responsibility of a registered pharmacist practice only under the immediate personal supervision of a registered pharmacist.~~

(2) and (3) remain the same.

(4) The intern shall make such reports and certifications as required under the approved program and as required by the board.

(5) through (8) remain the same.

~~(9) Only those students who have completed the first professional year (third year) of the pharmacy curriculum may begin their internship.~~ An intern shall be:

(a) a student currently enrolled in an accredited pharmacy program;

(b) a graduate of an accredited pharmacy program serving an internship; or

(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.

(10) Intern registration based on enrollment in or graduation from an accredited pharmacy program shall expire not later than 12 months after the date of graduation or at the time of professional licensure, whichever comes first. Intern registration based on graduation from a pharmacy program located outside of the United States of America which is not accredited shall expire not later than 12 months after the date of issuance of the registration or at the time of professional licensure, whichever comes first.

(11) An intern registration may be issued to a student currently enrolled in an accredited pharmacy program at any time after they have completed 30 days of study, submitted a completed application to the board, and paid the required fee.

(10) and (11) remain the same but are renumbered (12) and (13).

~~(12) (14) An intern will be allowed six months after taking the NAPLEX examination to complete requirements for licensure. The time may be extended, subject to the approval of the board, if extenuating circumstances prohibit completion in the prescribed time.~~ An intern registration may be extended, subject to approval by the board, upon application by the intern, if extenuating circumstances are present.

AUTH: 37-7-201, MCA

IMP: 37-7-201, MCA

REASON: The board is amending this rule to comport with current national standards as promoted by the National Association of Boards of Pharmacy (NABP).

The board notes that these standards are more directly reflective of current internship requirements on a national level. The board is amending language from negative, prohibitive language to more positive, directive language. The changes also help to adapt the rule to recognize the transition of pharmacy education from a baccalaureate program to a doctor of pharmacy program in many institutions, including the University of Montana. The board is also amending this rule to increase the time for pharmacy graduates to complete examination requirements. The board concluded that six months is often insufficient due to the number of interns that apply to the board for an extension of this time.

24.174.701 REGISTRATION REQUIREMENTS (1) and (2) remain the same.

(3) The permit to practice as a technician-in-training shall be valid for a period of not longer than 18 months, and may not be renewed. 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.

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

AUTH: 37-7-201, MCA

IMP: 37-7-201, MCA

REASON: It is reasonably necessary to amend this rule to clarify that technician-in-training permits are not renewable and that licensees cannot get around this by continuing to reapply once the 18-month permit period has passed. The board is amending the process for extending permit length to address numerous requests by technicians-in-training who have not passed their exam yet. The board concluded that an extension would benefit technicians-in-training who, due to particular circumstances, were not able to take or pass the exam, but wanted to continue to work.

The board notes that a large number of extension requests were submitted after the 18-month permit deadline. Therefore, the board is also amending this rule to clarify that the board considers anyone who practices past the deadline to be practicing without a valid and current license which may result in disciplinary action by the board.

24.174.703 USE OF PHARMACY TECHNICIAN (1) through (4) remain the same.

(5) 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

REASON: The board is amending this rule to require the posting of technician licenses to reduce the number of technicians working with expired licenses and to make it easier for the pharmacy inspector to check licenses during inspections. The board concluded that it is important for the public to have knowledge of the registered pharmacy technicians as well as the pharmacists in a practice and therefore all licenses should be posted for public view.

24.174.817 AUTOMATED RECORD KEEPING SYSTEMS (1) through (1)(b)(i) remain the same.

(ii) provide a printout of each day's prescription information. That printout shall be verified, dated, and signed by the individual pharmacist verifying that the information indicated is correct and then sign this document in the same manner as signing a check or legal document (e.g., J. H. Smith, or John H. Smith). Such printout must be maintained at least two years from the date of last dispensing; or

(iii) utilize a software system which requires a unique log in for each function such that it can be easily and accurately determined who performed every function within the prescription dispensing process. The records must be readily accessible for viewing or printing at the request of the board.

(c) and (d) remain the same.

AUTH: 37-7-201, MCA

IMP: 37-7-201, MCA

REASON: The board determined it is reasonable and necessary to amend this rule to reflect the advancements in record-keeping computer software that provides the highest level of accuracy and real time information on individuals performing each step of the prescription filling process. The board is amending this rule to allow software systems in pharmacies that document the accountability of the pharmacists involved in and/or supervising the dispensing process including systems that require a biometric log on and off for each step in the prescription process.

24.174.1002 CONDITIONS OF REGISTRATION (1) remains the same.

(a) be a legal entity registered and in good standing with the Montana Secretary of State with a registered agent in Montana for service of process designated;

(b) through (f) remain the same.

AUTH: 37-7-201, 37-7-712, MCA

IMP: ~~2-48-704~~, 37-7-701, 37-7-702, 37-7-703, 37-7-704, 37-7-706, MCA

REASON: The board is amending this rule to maintain the requirement that mail order pharmacies designate a registered agent in Montana. The board is repealing ARM 24.174.1007, the rule that currently contains this requirement, in this notice.

Authority and implementation cites are being amended to accurately reflect

the statutes implemented through the rule and to provide the complete sources of the board's rulemaking authority.

24.174.1114 USE OF EMERGENCY DRUG KITS IN CERTAIN INSTITUTIONAL FACILITIES (1) and (1)(a) remain the same.

(b) the supplying pharmacist and the designated practitioner or appropriate committee of the institutional facility shall jointly determine the identity and quantity of drugs to be included in the kit. Such drugs shall then be approved in advance of placement in the emergency kit by the board; unless such drugs are included on a general list of drugs previously approved by the board for use in emergency kits;

(c) the kit must be locked and stored in a secure area to prevent unauthorized access and to ensure a proper storage environment for the drugs contained therein. The kit shall be secured with a seal to be of such a nature that it can be easily identified if it has been broken;

(d) through (2) remain the same.

~~(3) The supplying pharmacist shall be notified of any entry into the kit. The supplying pharmacist shall have a mechanism defined in policy to restock and reseal the kit within a reasonable time so as to prevent risk of harm to patients.~~ Upon notice of any entry into the kit, the supplying pharmacist or another pharmacist designated by the supplying pharmacist shall restock and refill the kit, reseal the kit, and update the drug listing on the exterior of the kit within 72 hours.

(4) and (5) remain the same.

AUTH: 37-7-201, MCA

IMP: 37-7-201, MCA

REASON: The board is amending this rule regarding use of emergency drug kits in institutional facilities. The board concluded that the current requirements are vague, and allow for emergency drug kits of unlimited size which are not true emergency kits. Further, the board's pharmacy inspector has encountered apparent instances of abuse regarding these kits. The proposed amendments will allow the board to adopt a list of drugs which are truly used in emergency situations for use in emergency drug kits.

This rule was designed to limit access to the drugs only to authorized individuals and include a provision that the kit remain sealed. The purpose of the seal is to guarantee the integrity of the kit so the practitioner can be assured of a complete inventory of drugs in an emergency situation. The drugs in an emergency kit amount to an extension of the pharmacy. No drug may be dispensed without a prescription and a prescription must be issued to account for the reduction in inventory. The board is further amending this rule to clarify the nature of the required seal which had not been addressed previously, and specify that emergency kits must be resealed timely following every entry.

24.174.2102 PHARMACY TECHNICIAN - RENEWAL (1) remains the same.

(2) To assure the continuing competence of a pharmacy technician, ~~proof of continued certification will be required~~ in order to renew a license, the pharmacy

technician must be in compliance with all certification requirements at the time of renewal.

AUTH: 37-7-201, MCA

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

REASON: It is reasonably necessary to amend this rule to delete the requirement of proof of certification as it conflicts with 37-1-131, MCA. The requirement regarding meeting the certification requirements has replaced that language and is in accordance with statute. Implementation cites are being amended to accurately reflect all statutes implemented through the rule.

24.174.2103 RENEWALS (1) and (2) remain the same.

~~(3) The annual renewal notice shall be returned to the board with the appropriate fee and a representation of having satisfactorily completed continuing education requirements signed by the licensee. Incomplete renewal applications will not be processed and will be returned to the applicant.~~

~~(a) (3)~~ The board shall randomly select submitted renewal notice forms for audit and verification of the ~~approved~~ continuing education ~~programs listed~~ requirements. It will be the responsibility of each pharmacist to maintain his or her own records of attendance or completion and make ~~them~~ such documents available upon request.

(a) The board shall randomly select submitted renewal notice forms for audit and verification of current pharmacy technician certification from a board-approved certifying entity. It shall be the responsibility of each pharmacy technician to maintain his or her current pharmacy technician certification and make such certification available upon request.

(4) remains the same.

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

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

REASON: The board determined it is reasonably necessary to amend this rule to delete (3), which unnecessarily repeats (2), and to renumber the rule accordingly.

The board is also amending the rule to specify that the board will conduct random audits of pharmacy technician renewals. Continued certification is a requirement for pharmacy technician registration and the board concluded that auditing is necessary to ensure the continued competence of pharmacy technicians.

Authority and implementation cites are being amended to accurately reflect all statutes implemented through the rule and to provide the complete sources of the board's rulemaking authority.

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; or

(v) engaging in the practice of pharmacy or assisting in the practice of pharmacy when the licensee's license has been suspended or revoked, or is expired or terminated.

AUTH: 37-1-319, 37-7-201, MCA
IMP: 37-1-316, 37-7-201, MCA

REASON: It is necessary to amend the rules on unprofessional conduct because it is unlawful to engage in the practice of pharmacy without a current, valid license. The board is adding (1)(v) to delineate this unlicensed pharmacy practice as unprofessional conduct. Implementation cites are being amended to accurately reflect all statutes implemented through the rule.

4. The rule proposed to be repealed is as follows:

24.174.1007 AGENT OF RECORD found at ARM page 24-19745.

AUTH: 37-7-712, MCA
IMP: 37-7-703, MCA

REASON: It is reasonably necessary to repeal this rule addressing agent of record to eliminate inaccurate terminology and unnecessary and improper processes. The requirement to designate an agent of record in Montana is being added to ARM 24.174.1002 in this notice.

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 by e-mail to pharmacy@mt.gov, and must be received no later than 5:00 p.m., August 14, 2009.

6. An electronic copy of this Notice of Public Hearing is available through the department and board site on the World Wide Web at www.pharmacy.mt.gov. The department strives to make the electronic copy of this Notice conform to the official version of the Notice, as printed in the Montana Administrative Register, but advises all concerned persons that in the event of a discrepancy between the official printed text of the Notice and the electronic version of the Notice, only the official printed text will be considered. In addition, although the department strives to keep its web site accessible at all times, concerned persons should be aware that the web site may be unavailable during some periods, due to system maintenance or technical problems, and that technical difficulties in accessing or posting to the e-mail address 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 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 pharmacy@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.

9. Michael L. Fanning, attorney, has been designated to preside over and conduct this hearing.

BOARD OF PHARMACY
WILLIAM BURTON, RPH, PRESIDENT

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

/s/ KEITH KELLY
Keith Kelly, Commissioner
DEPARTMENT OF LABOR AND INDUSTRY

Certified to the Secretary of State July 6, 2009