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

In the matter of the amendment of ARM 24.174.303 definitions, 24.174.501 examination for licensure, 24.174.503 administration of vaccines, 24.174.510 prescription requirements, 24.174.602 internship requirements, 24.174.604 preceptor requirements, 24.174.2104 and 24.174.2106 registered pharmacist continuing education, and the repeal of ARM 24.174.1010 disciplinary action	)))))))))))	NOTICE OF PUBLIC HEARING ON PROPOSED AMENDMENT AND REPEAL

TO: All Concerned Persons

1. On April 4, 2011, at 9:00 a.m., a public hearing will be held in room 439, 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 March 30, 2011, to advise us of the nature of the accommodation that you need. Please contact Ronald 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 dlibsdpha@mt.gov.

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

24.174.303 INTERNSHIP PROGRAM DEFINITIONS (1) through (3) remain the same.

(4) "Intern" means a qualified [under ARM 24.174.602] pharmacy student~~,~~ or a graduate from an accredited school of pharmacy, and registered in an approved program of supervised training.

(5) remains the same.

(6) "Internship period" means 1500 hours of practical experience in an approved pharmacy, hospital, or other facility. The intern ~~must acquire a minimum of 20 hours experience per calendar week and~~ may acquire a maximum of 48 hours experience per calendar week. The student may acquire up to 1500 hours concurrently with school attendance in approved courses, introductory pharmacy

practice experience, and advanced pharmacy practice experience, or demonstration projects in the Pharm.D. program.

(7) and (8) remain the same.

(9) "Supervising Pharmacist" means the registered pharmacist who is in charge of the day-to-day supervision of the intern.

(9) remains the same but is renumbered (10).

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

REASON: The board is amending the definition of internship period to repeal an outdated 20-hour per week minimum requirement and align with the shift of pharmacy education to a doctor of pharmacy degree. The board is adding a definition of supervising pharmacist to clarify the supervision requirements in accord with current pharmacy accreditation recommendations.

24.174.501 EXAMINATION FOR LICENSURE AS A REGISTERED PHARMACIST (1) remains the same.

(2) In addition, the NABP shall administer a multistate pharmacy jurisprudence examination (MPJE). This examination shall be prepared to measure the competence of the applicant regarding the statutes and rules governing the practice of pharmacy. A score of not less than 75 shall be a passing score for this examination. A candidate who does not attain this score may retake the examination after a 30-day waiting period from the date of the exam.

(3) through (3)(d)(iii) remain the same.

(4) The board may waive the provisions of (3)(d) upon request of the applicant, if the board determines the applicant is able to communicate in the English language.

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

AUTH: 37-1-131, 37-7-201, MCA
IMP: 37-1-131, 37-7-201, 37-7-302, MCA

REASON: The board determined this rule is burdensome and unnecessarily rigid for foreign pharmacy graduates who are native English speakers. The amendment will allow the board flexibility to waive the English testing requirements and thus save these applicants and the board unnecessary expenses.

24.174.503 ADMINISTRATION OF VACCINES BY PHARMACISTS (1) ~~A~~ In order to administer or prescribe vaccinations, a pharmacist must have a collaborative practice agreement with a practitioner authorized to prescribe drugs, or in the case of a public health emergency, a directive from the chief medical officer of the Montana Department of Public Health and Human Services ~~in order to administer and/or prescribe vaccinations~~.

(2) remains the same.

(a) the pharmacist has successfully completed ~~an accredited~~ a course of training ~~provided~~ approved by the Centers for Disease Control and Prevention

(CDC), ~~the American Council on Pharmaceutical Education~~ a provider accredited by the Accreditation Counsel on Pharmacy Education (ACPE), or other authority approved by the board;

(b) the pharmacist holds a current basic cardiopulmonary resuscitation certification issued by the American Heart Association, the American Red Cross, or other recognized provider, and documentation is on file at the practice site;

(c) the pharmacist and the pharmacist intern must provide a copy of the immunization certificate and CPR certification to the board for initial specialty recognition;

~~(c)~~ (d) the vaccines are administered in accordance with an established protocol that includes site-specific emergency measures; and

~~(d)~~ (e) the pharmacist has either a current copy of or ~~on-site~~ online access to the most recent edition of the ~~Centers for Disease Control and Prevention~~ CDC reference "Epidemiology and Prevention of Vaccine-Preventable Diseases."

(3) The pharmacist must give ~~the appropriate~~ a copy of the most current vaccine information statement (VIS) to the patient or the patient's legal representative for those vaccines which have them, ~~with each dose of vaccine covered by these forms~~ and counsel the patient accordingly.

(4) remains the same.

(5) The pharmacist must report any significant adverse events to the primary care provider if one is identified by the patient, and to the ~~CDC~~ Vaccine Adverse Events Reporting System (VAERS), if applicable.

(6) through (6)(e) remain the same.

~~(f) the name and address of the patient's primary health care provider;~~

~~(g) the date on which the vaccination information was reported to the patient's primary health care provider under the provisions of the National Vaccine Injury Compensation Program;~~

~~(h)~~ (f) the name or identifiable initials of the administering pharmacist; and

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

(7) The authority of a pharmacist to administer immunizations may not be delegated~~;~~, however, an immunization-certified intern may immunize under the direct supervision of a pharmacist or other health care provider qualified ~~under this chapter~~ in vaccine administration and deemed appropriate by the preceptor.

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

~~(9)~~ (8) In order to maintain ~~the immunization endorsement on their pharmacist license~~ specialty recognition, an immunization certified pharmacist must~~:~~

~~(a)~~ maintain a current CPR certification~~;~~.

~~(b) participate in a minimum of two hours of continuing education on immunizations or vaccine-preventable diseases every year. The continuing education must be American Council on Pharmaceutical Education (ACPE), Continuing Medical Education (CME), or Continuing Education Advisory Council (CEAC) approved; and~~

~~(c) maintain competency in vaccine administration technique by:~~

~~(i) professionally administering vaccinations to humans in the previous 12 months; or~~

~~(ii) having a Montana licensed health care provider authorized to prescribe or administer vaccines or an immunization-certified pharmacist witness and validate the pharmacist's vaccine administration technique every year.~~

(10) remains the same but is renumbered (9).

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

REASON: This board determined it is reasonably necessary to amend this rule throughout to clarify education requirements, references, documentation, and recordkeeping for a pharmacist to administer vaccines, as the present rule is unclear and confusing. During the 2009 H1N1 swine flu epidemic, the board was called upon to coordinate with federal health agencies to facilitate the timely distribution and administration of vaccines to the public. To be more responsive to similar future health emergencies, the board is amending (1) to allow qualified pharmacists to administer vaccinations upon the directive of the department of public health and human services chief medical officer.

24.174.510 PRESCRIPTION REQUIREMENTS (1) remains the same.

~~(a) date of issuance;~~

~~(b) name and address of patient [or patient location if an institution];~~

~~(c) name and address of prescriber [if not a staff physician of institution];~~

~~(d) DEA number of prescriber in the case of controlled substances;~~

~~(e) name, strength, dosage form and quantity [or stop date, and route of administration] of drug prescribed;~~

~~(f) refills authorized;~~

~~(g) directions of use for patient.~~

(a) patient's name;

(b) name of drug, device, or biological;

(c) strength of drug or biological, if applicable;

(d) dosage form of drug or biological, if applicable;

(e) quantity of drug, device, or biological prescribed;

(i) the quantity for residents of long-term care facilities must be for 60 days, unless otherwise limited by the prescriber.

(f) directions for use;

(g) date of issuance;

(h) prescriber's name;

(i) if the prescription is written, it must contain the prescriber's hand-written signature and the name of the prescriber stamped, typed, printed, or clearly handwritten in addition to the signature;

(ii) if the prescription is written, it must be tamper-resistant and contain all of the following characteristics:

(A) one or more industry-recognized features designed to prevent unauthorized copying of a completed or blank prescription form;

(B) one or more industry-recognized features designed to prevent the erasure or modification of information written on the prescription pad by the prescriber; and

(C) one or more industry-recognized features designed to prevent the use of counterfeit prescription forms.

(i) number of refills authorized;

(i) when the refill designation on the prescription is prn or Pro re nata, such designation, unless otherwise limited, means a refill for one year;

(ii) if a prescription is for a controlled substance in Schedules III, IV, or V, refill five times in the six months from the date of issuance;

(iii) if a prescription is for a noncontrolled drug, device, or biological, refill for 12 months from the date of issuance;

(iv) controlled substances in Schedule II cannot be refilled and a refill designation for a controlled substance in Schedule II has no meaning.

(j) if the prescription is for a controlled substance, the following additional information is required to be on the prescription:

(i) patient's address;

(ii) prescriber's address; and

(iii) prescriber's Drug Enforcement Administration (DEA) registration number.

(k) prescriber's employee or agent;

(i) prescription or refill authorization issued by a prescriber may be communicated to a pharmacist or a pharmacist intern by an employee or agent of the prescriber.

(2) remains the same.

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

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

REASON: The board is amending this rule to update the prescription requirements to conform to new Federal Drug Administration (FDA) rules. The board concluded that the amendments will also clarify obsolete prescription requirements.

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.

(2) An intern may practice only under the immediate personal supervision of a ~~registered~~ supervising pharmacist.

(2) remains the same but is renumbered (3).

~~(3) The intern shall receive instruction in only one approved area and under only one preceptor concurrently, except in unusual and extenuating circumstances approved by the board upon written request.~~

(4) through (14) remain the same.

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

REASON: The board is amending this rule to repeal outdated language regarding intern supervision and reflect current pharmacy practice and accreditation standards for schools of pharmacy.

24.174.604 PRECEPTOR REQUIREMENTS (1) through (1)(b) remain the same.

(i) the practice of pharmacy for ~~two years~~ one year, unless otherwise approved by the board; or

(ii) through (1)(g) remain the same.

(h) notify the board of any change of address or employment within ~~ten~~ 30 days. Change of employment shall serve to suspend preceptor approval until such time as reevaluation is made by the board; ~~and~~

(i) not be permitted to leave an intern work alone to assume the responsibility of a pharmacist~~.~~; and

(j) complete a training course as approved by the board.

(2) The repackaging, labeling, and dispensing of drugs for distribution shall be under the supervision of a ~~registered~~ supervising pharmacist ~~or pharmacist preceptor~~.

(3) A supervising pharmacist ~~preceptor~~ may only supervise ~~one student in internship or~~ one student in introductory pharmacy practice experience (IPPE) at any time.

(4) A supervising pharmacist ~~preceptor~~ 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) remains the same.

(6) A preceptor may serve as a preceptor for no more than one intern at a time.

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

REASON: A number of licensees recently petitioned the board for exemptions from the requirement for two years of active pharmacist practice to become preceptors. The board determined it is reasonable to amend the rule and allow a pharmacist to become a preceptor with just one year of practice plus an additional board-approved training course. With the greater pharmacy education offered to current doctor of pharmacy graduates (versus former bachelor of science in pharmacy), pharmacists are prepared to become preceptors after a shorter period of active pharmacy practice. The board is amending (1)(h) to require that preceptors notify the board of address or employment changes within 30 days to align with similar requirements within board rules.

The board recognizes that recent market trends are moving away from pharmacies with just one or two pharmacists. Even though larger pharmacies with a number of pharmacists are more common, the board notes that not all pharmacists in a larger pharmacy will be preceptors. Therefore, the board is amending (2) through (6) to allow a supervising pharmacist to stand in the place of the named preceptor during those times when the preceptor is not on duty or is unavailable.

24.174.2104 REGISTERED PHARMACIST CONTINUING EDUCATION - REQUIREMENTS (1) remains the same.

(2) The board will require: ~~1.5 CEU for each fiscal year.~~

(a) 1.5 CEU for each fiscal year if a pharmacist takes at least 0.5 CEU in an approved group program; or

(b) 2.0 CEU for each fiscal year if a pharmacist does not take at least 0.5 CEU in an approved group program.

~~(a)~~ (3) ~~This requirement~~ The annual CEU requirement will not pertain to a pharmacist applying as a new graduate for his or her first license renewal.

(b) remains the same but is renumbered (4).

~~(c) A minimum of 0.5 CEU is to be obtained in approved group program.~~

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

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

REASON: The board has received a number of complaints that the group continuing education (CE) requirement is burdensome and unnecessary, especially for rural and out-of-state pharmacists. The board is amending this rule to allow licensees to meet the CE requirement without having to take any group CEU.

Pharmacists have also asked whether the exemption for first-time renewal applies to experienced pharmacists moving to Montana. The board is amending this rule to clarify that only new pharmacist graduates, not pharmacists licensed in other states, are exempt from the CE requirement for the first renewal period.

24.174.2106 REGISTERED PHARMACIST CONTINUING EDUCATION - APPROVED PROGRAMS (1) through (1)(c) remain the same.

(2) Pharmacists may receive CEU for programs other than those on the ACPE list of providers by applying for prior approval by the board or its designee on board-approved forms. ~~The forms and guidelines for applying for approval are available from the board office.~~

(3) remains the same.

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

REASON: The board is amending this rule to specify that CE approval must be requested on board-approved forms to reduce the number of obsolete and inadequate CE forms received in the board office.

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

24.174.1010 DISCIPLINARY ACTION found at ARM page 24-19746.

AUTH: 37-7-712, MCA
IMP: 37-7-703, 37-7-704, 37-7-711, MCA

REASON: The board's screening panel has been unable to institute disciplinary proceedings in recent cases because this rule requires that the board defer action until the out-of-state mail service pharmacy's home state reviews the matter. The board concluded that it should be able to take appropriate action where it possesses jurisdiction over a licensee concerning a matter of public health, safety, or welfare, and is proposing to repeal this rule.

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 dlibsdpha@mt.gov, and must be received no later than 5:00 p.m., April 12, 2011.

6. An electronic copy of this Notice of Public Hearing is available through the department and board's 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 dlibsdpha@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. Mike Fanning, attorney, has been designated to preside over and conduct this hearing.

BOARD OF PHARMACY
LEE ANN BRADLEY, 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 February 28, 2011