

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

In the matter of the proposed amendment	)	NOTICE OF PUBLIC HEARING
of ARM 24.174.301 definitions, 24.174.303	)	ON PROPOSED AMENDMENT,
internship, 24.174.401 and 24.174.402 fee	)	ADOPTION, AND REPEAL
schedules, 24.174.501 examination,	)	
24.174.502 transfer, 24.174.503 vaccines,	)	
24.174.524 collaborative practice,	)	
24.174.602 internship, 24.174.604	)	
preceptor requirements, 24.174.801	)	
general licensure, 24.174.804 ownership,	)	
24.174.1122 ambulatory facilities,	)	
24.174.1201 and 24.174.1202 wholesale	)	
licensing, and the adoption of NEW RULE	)	
I pharmacy closure, NEW RULE II change	)	
in location, NEW RULE III change in	)	
ownership, NEW RULE IV, NEW RULE V,	)	
and NEW RULE VI medical gas, NEW	)	
RULE VII change in location, NEW RULE	)	
VIII ownership, NEW RULE IX foreign	)	
interns, NEW RULE X technicians, and	)	
NEW RULE XI centralized prescription	)	
and drug orders, and repeal of 24.174.822	)	
central filling by hub pharmacies	)	

TO: All Concerned Persons

1. On June 14, 2007, at 9:30 a.m., a public hearing will be held in room 439, 301 South Park Avenue, Helena, Montana to consider the proposed amendment, adoption, 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 June 8, 2007, to advise us of the nature of the accommodation that you need. Please contact Evie Martin, Board of Pharmacy, 301 South Park Avenue, P.O. Box 200513, Helena, Montana 59620-0513; telephone (406) 841-2355; Montana Relay 1-800-253-4091; TDD (406) 444-2978; facsimile (406) 841-2305; e-mail dlibsdp@mt.gov.

3. GENERAL STATEMENT OF REASONABLE NECESSITY: The board is proposing to amend and repeal existing rules and adopt new rules to clarify or add detail to unclear or vague rules, to substitute gender neutral for gender specific terms, and to update obsolete terminology for current usage. It is reasonably

necessary to amend the rules further to address contemporary issues in pharmacy practice not previously addressed in rule, and to correct unintentional omissions. Punctuation and grammar are being amended throughout to comply with ARM formatting requirements. Authority and implementation cites are also being amended throughout to accurately reflect all statutes implemented through the rules, to provide the complete sources of the board's rulemaking authority, and to delete references to repealed statutes. Accordingly, the board believes that there is reasonable necessity to generally amend certain existing rules, repeal one existing rule, and adopt new rules at this time. Where additional specific bases for a proposed action exist, the board will identify those reasons immediately following that rule.

4. 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) remains the same.

(2) "Biological safety cabinet" means a contained unit suitable for the preparation of low to moderate risk agents and where there is a need for protection of the product, personnel, and environment according to National Sanitation Foundation Standard 49.

(3) through (6) remain the same.

(7) "Deliver" or "delivery" means the actual, constructive, or attempted transfer of a drug or device from one person to another, whether or not for a consideration.

(8) through (17) remain the same.

(18) "Institutional pharmacy" means that physical portion of an institutional facility where drugs, devices, and other material used in the diagnosis and treatment of injury, illness, and disease are dispensed, compounded, and distributed to other health care professionals for administration to patients within or outside the facility, and pharmaceutical care is provided.

(19) "Labeling" means the process of preparing and affixing a label to any drug container exclusive, however, of the labeling by a manufacturer, packer, or distributor of a nonprescription drug or commercially packaged legend drug or device. Any such label shall include all information required by federal and Montana law or rule.

(20) remains the same.

(21) "Medical gas" means any gaseous substance that meets medical purity standards and has application in a medical environment. Examples of medical gases include but are not limited to oxygen, carbon dioxide, nitrous oxide, cyclopropane, helium, nitrogen, and air.

(22) "Medical gas distributor" is a person engaged in the manufacture, processing, packaging, labeling, or distribution of a medical gas to a person other than a consumer or patient.

(23) "Medical gas supplier" is a person engaged in selling, transferring, or delivering to a patient or a patient's agent one or more doses of medical gas in the

manufacturer's or distributor's original container for subsequent use by the patient.  
 (21) through (25) remain the same but are renumbered (24) through (28).  
~~(26)~~ (29) "Qualified patients" mean patients who are uninsured, indigent, or have insufficient funds to obtain needed prescription drugs.  
 (27) through (33) remain the same but are renumbered (30) through (36).

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: It is reasonably necessary to define three new terms to comply with and clarify terminology used in proposed New Rules IV through VIII, addressing the regulation of distributors and suppliers of medical gases.

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

(4) "Intern" means a qualified [under ARM 24.174.602~~(8)~~] pharmacy student, or a graduate from an accredited school of pharmacy, and registered in an approved program of supervised training.

(5) through (7) remain the same.

(8) "Reporting period" means at the completion of internship or ~~externship experience~~ introductory pharmacy practice experience in a given site or after 500 hours, whichever comes first, or at the completion of ~~the clerkship experience~~ advanced pharmacy practice experience.

(9) remains the same.

AUTH: 37-7-201, MCA

IMP: 37-7-201, MCA

24.174.401 FEE SCHEDULE (1) through (7) remain the same.

<del>(8) NAPLEX examination fee (paid directly to exam service)</del>	<del>465</del>
<u>(8) Montana NAPLEX examination processing fee (a separate exam fee is paid directly to NABP)</u>	<u>35</u>
<del>(9) NAPLEX examination processing fee (paid to board)</del>	<del>35</del>
<del>(10) Multistate pharmacy jurisprudence examination (MPJE) exam fee (NABP - \$185; board - \$25)</del>	<del>210</del>
<u>(9) Montana multistate pharmacy jurisprudence examination (MPJE) exam fee (a separate exam fee is paid directly to NABP)</u>	<u>25</u>
(11) through (22) remain the same but are renumbered (10) through (21).	

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

IMP: 37-1-134, 37-7-201, 37-7-302, 37-7-321, 37-7-604, 37-7-605, 37-7-703, 50-32-314, MCA

REASON: It is reasonable and necessary to amend this rule to clarify the rule and lessen confusion among applicants regarding fees paid to the board and those paid directly to NABP. The fees paid to the board are not being changed, but the board

decided to restate these fees for the purpose of clarity. Additionally, the board is amending the rule to no longer list the NABP fee amounts because the board does not set these fees and to avoid having to amend this rule whenever the NABP changes its fees.

24.174.402 DANGEROUS DRUG FEE SCHEDULE (1) The fees to be assessed for registration to manufacture, distribute, dispense, conduct research, or analyze, a dangerous drug shall be assessed according to the following schedule:

<u>REGISTRATION</u>	<u>ANNUAL FEE</u>
(a) manufacture	\$150 <u>100</u>
(b) distribute	450 <u>100</u>
(c) dispense -- pharmacies	75
<u>(i) pharmacies</u>	<u>75</u>
<u>(ii) ambulatory surgical facilities</u>	<u>75</u>
(d) conduct research or analyze	100

AUTH: 37-1-134, 37-7-201, 50-32-103, 50-32-314, MCA

IMP: 37-1-134, 37-7-201, 37-7-321, 50-32-103, 50-32-314, MCA

REASON: The board determined it is reasonably necessary to amend this rule to decrease the registration fee for the manufacturers and distributors of dangerous drugs to \$100. It was discovered through a legislative audit that the current fee exceeded the maximum allowed by statute at 50-32-103, MCA, and the board is amending the fee to comply with audit recommendations. The board estimates that the change will affect 263 licensees and will result in a decrease in annual revenue of approximately \$13,150.

The board is also adding a fee for registration of ambulatory surgical facilities. Ambulatory surgical facilities must register with the board as a dangerous drug dispenser and with the Drug Enforcement Administration (DEA) to assure accountability for the security of controlled substances stored and administered within the facility. The board estimates that this change will affect 15 of these facilities and will result in an estimated annual increase in revenue of \$1,125.

24.174.501 EXAMINATION FOR LICENSURE AS A REGISTERED PHARMACIST (1) and (2) remain the same.

~~(3) A successful interview before the Board of Pharmacy or its designee, the test of English as a foreign language, test of spoken English and the foreign pharmacy graduate equivalency exam provided by the National Association of Boards of Pharmacy will be required for pharmacy graduates from outside the 50 states, the District of Columbia, or Puerto Rico, who seek certification of educational equivalency in order to sit for the North American pharmacist licensure examination. must complete the following: A scaled score of 75 or greater will be the passing score for this examination. A candidate who does not attain this score may retake the examination after a 91-day waiting period.~~

- (a) a successful interview before the Board of Pharmacy or its designee;
- (b) the Foreign Pharmacy Graduate Equivalency Examination (FPGEE);

- (c) 1500 hours of internship in the United States;
- (d) the Test of Spoken English (TSE); and one of the following:
  - (i) the computer-based Test of English as a Foreign Language (TOEFL);
  - (ii) the paper-based TOEFL;
  - (iii) the internet-based TOEFL.
- (4) NABP minimum passing scores must be achieved on all tests and examinations.

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

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

**REASON:** It is reasonable and necessary to amend this rule to require that foreign pharmacy graduates complete 1500 hours of internship in the United States to sit for the licensure examination. The practice of pharmacy in a foreign country may vary significantly from the practice of pharmacy in the United States and therefore in the interest of public and patient safety, the board concluded that a foreign pharmacist should receive supervised internship training prior to being licensed and practicing independently in Montana.

The board is also amending this rule to reflect the currently available testing methods for the Test of English as a Foreign Language (TOEFL) to an internet-based examination with four scored components including writing, speaking, listening, and reading.

#### 24.174.502 TRANSFER OF LICENSE FROM ANOTHER STATE

(1) Applicants seeking a license on the basis of having been examined taken the NAPLEX examination and then issued a license by another state shall submit the following information to the board:

- (a) remains the same.
- (b) proof of passing examination score on the ~~NABP~~ NAPLEX examination;
- (c) and (d) remain the same.

(2) An applicant who has been registered as a pharmacist by examination in another state but who has not taken the NAPLEX examination shall appear before the board for consideration of transfer of licensure and submit the following information to the board:

- (a) transfer of licensure application;
- (b) proof of passing examination score;
- (c) verification of current licensure in good standing from all other states where licensed; and
- (d) appropriate fees.

(2)(3) In addition to the above requirements in (1) and (2), the applicant will be required to pass the MPJE, 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.

- (3) remains the same but is renumbered (4).

AUTH: 37-7-201, MCA

IMP: 37-1-304, MCA

REASON: The board determined it is reasonably necessary to amend this rule to clearly delineate the requirements for applicants regarding the transfer of licensure from states that do not, or previously did not utilize the NAPLEX examination. The amended rule will also address potential applicants who took their licensure examination prior to creation of the NAPLEX examination.

24.174.503 ADMINISTRATION OF VACCINES BY PHARMACISTS (1) A pharmacist must have a collaborative practice agreement with a practitioner authorized to prescribe drugs in order to administer and/or prescribe vaccinations.

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

(a) through (c) remain the same.

(d) the pharmacist has a current copy of or on-site access to the Centers for Disease Control and Prevention reference "Epidemiology and Prevention of Vaccine-Preventable Diseases."

(2) through (5) remain the same but are renumbered (3) through (6).

(a) the name, address, allergies, and date of birth of the patient;

(b) remains the same.

(c) the name, manufacturer, dose, lot number, and expiration date of the vaccine;

(d) through (i) remain the same.

(6) remains the same but is renumbered (7).

~~(7)~~(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 license.

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

(a) maintain current CPR certification;

(b) participate in two hours of ACPE or CME accredited continuing education on immunizations every year; and

(c) maintain competency in vaccine administration technique by:

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

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

(10) The board shall randomly select renewal notice forms of immunization-certified pharmacists for audit and verification of the requirements listed in this rule.

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

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

REASON: It is reasonable and necessary to amend this rule to clarify that a collaborative practice agreement is needed to administer and/or prescribe vaccinations under the delegated prescriptive authority of a licensed prescriber.

Licensed pharmacists expressed confusion regarding this requirement and the board is amending the rule to address and alleviate the uncertainty.

It is necessary to amend the rule to require that immunization-certified pharmacists obtain continuing education and ongoing competency in vaccine administration in the interest of public health and safety. Currently the board does not require the reassessment of immunization certified pharmacists' skills in vaccine administration after initial certification, nor are they required to submit evidence of continuing professional development in the area of vaccine administration and epidemiology. Since vaccine administration requires hands-on patient care that is currently not in the usual course of practice for a pharmacist, and since the board is providing a special endorsement on the license, it is reasonable for the board to require continuing professional development and competency in support of this specialty practice.

24.174.524 COLLABORATIVE PRACTICE AGREEMENT REQUIREMENTS

(1) through (2)(a) remain the same.

(i) the practitioner 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.

(b) through (i) remain the same.

(j) the annual date by which review, renewal, and revision, if necessary, will be accomplished;

(k) and (l) remain the same.

(3) Patient records shall be maintained by the pharmacist for a minimum of seven years and may be maintained in an automated system pursuant to ARM ~~24.174.818(3)~~ 24.174.817.

(4) remains the same.

AUTH: 37-7-201, MCA

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

REASON: It is reasonable and necessary to amend this rule to require that the sponsoring physician be licensed in good standing in Montana and actively practicing in the same community as the collaborating pharmacist. The rules for collaborative practice require periodic physician oversight and communication which are optimally completed when the physician and the pharmacist have an established professional relationship and both professionals practice in the same community.

24.174.602 INTERNSHIP REQUIREMENTS (1) The experience required ~~for 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.

(2) through (4) remain the same.

(5) The intern is responsible for the knowledge and observation of the extent of ~~his~~ the intern's legal liability and legal restrictions applicable under the federal, state, and municipal laws and rules.

(6) and (7) remain the same.

(8) Employment and the intern training periods are not to be interpreted as being the same. An intern may work in excess of his the computed time.

(9) remains the same.

(10) The intern shall notify the board of any change of address, employment, or preceptor within ten days.

(11) remains the same.

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

AUTH: 37-7-201, MCA

IMP: 37-7-201, MCA

REASON: It is necessary to amend this rule to address confusion by clarifying that the internship experience is a requirement for licensure as a pharmacist, not licensure as an intern.

24.174.604 PRECEPTOR REQUIREMENTS (1) Each pharmacist preceptor shall:

(a) through (e) remain the same.

(f) have current knowledge of developments in the profession by exhibiting such attendances, readings, and actions, which conform to the best traditions of pharmacy;

(g) through (i) remain the same.

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

~~(3) A preceptor may supervise one intern or one extern and one pharmacy technician at any time. A pharmacist preceptor may, however, supervise two students at a time if the students are completing a clerkship experience through an approved school of pharmacy. A pharmacist preceptor may only supervise one student in internship or one student in introductory pharmacy practice experience (IPPE) at any time.~~

(4) A pharmacist preceptor may supervise no more than three persons at one time (including technicians 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.

AUTH: 37-7-201, MCA

IMP: 37-7-201, MCA

REASON: It is reasonably necessary to amend this rule to specify that the preceptor requirements apply only to pharmacist preceptors. The board recognizes that there are elective advanced pharmacy practice experience sites where the preceptor is

not a pharmacist and the board and the school of pharmacy agree that it is not feasible or necessary to have these nonpharmacist preceptors register with the board. It is also necessary to update the rule to reflect the changes in the technician ratio and in the terminology used by schools of pharmacy for the experiential portion of the pharmacy curriculum. Externship is now called introductory pharmacy practice experience (IPPE) and clerkship is now called advanced pharmacy practice experience (APPE).

24.174.801 GENERAL LICENSE REQUIREMENTS (1) and (2) remain the same.

(3) To operate, maintain, open, or establish more than one pharmacy, separate applications shall be made and separate licenses issued for each.

~~(4) Upon closure of a certified pharmacy, the original license becomes void and must be surrendered to the board within ten days.~~

AUTH: 37-7-201, MCA

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

REASON: It is reasonably necessary to delete (4) and include the provision in New Rule I that is proposed to expand upon and clarify procedures for pharmacy closure.

24.174.804 CHANGE IN OWNERSHIP (1) When a pharmacy changes ownership, the original license becomes void and must be surrendered to the board, and a new license obtained by the new owner or owners. The owner shall submit a new license application at least 30 days prior to the change in ownership. The application must be reviewed by the board or its designee before the license may be issued.

(2) A change in ownership for the purposes of this rule shall be deemed to occur when more than 50 percent of the equitable ownership of a business is transferred in a single transaction or in a related series of transactions to one or more persons or any other legal entity.

AUTH: 37-7-201, MCA

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

REASON: It is necessary to amend this rule to specifically define the meaning of "change of ownership." The board has received numerous inquiries regarding co-owner family members taking over pharmacy management due to a pharmacist's death or illness, and whether this rule applied. The board is amending this rule to address those questions and clarify the board's intent behind a change in ownership.

24.174.1122 AMBULATORY SURGICAL FACILITIES (1) through (3) remain the same.

(4) Ambulatory surgical centers that store and/or administer controlled substances shall register with the board and with the DEA, and shall comply with all applicable state, local, and DEA regulations.

AUTH: 50-32-314, MCA

IMP: 50-32-314, MCA

REASON: It is necessary to amend this rule to clarify that ambulatory surgical facilities must register as dangerous drug dispensers with the board and with the DEA to assure the security of controlled substances stored and administered within the facilities.

24.174.1201 WHOLESALE DRUG DISTRIBUTOR LICENSING (1) Every person engaged in manufacturing, wholesale distribution, or selling of drugs, medicines, chemicals, or poisons for medicinal purposes, medical gases, or legend devices other than to the consuming public or patient, in the state of Montana, shall be licensed annually by the board. Each applicant shall:

(a) be a legal entity registered and in good standing with the Montana Secretary of State;

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

(b)(c) pay the appropriate licensing and registration fees; and

(c) remains the same but is renumbered (d).

(2) through (5) remain the same.

(6) Manufacturers, distributors, and suppliers of medical gases shall operate in compliance with applicable federal, state, and local laws and regulations. Manufacturers, distributors, and suppliers of medical gases shall register with the board to obtain the appropriate endorsement on their wholesale drug distributor license.

AUTH: 37-7-201, 37-7-610, MCA

IMP: 37-7-603, 37-7-604, 37-7-605, 37-7-606, MCA

REASON: It is reasonable and necessary to amend the rule for licensing wholesale drug distributors to include distributors of legend devices and medical gases. Devices, as defined in 37-2-101, MCA, are included in the definition of the "practice of pharmacy" in 37-7-101, MCA, and a medical gas is a drug as defined in 37-7-101, MCA. An endorsement on a license as a distributor or supplier of medical gases is necessary so that the board can readily identify those wholesalers engaged in the distribution or supply of medical gases.

It is also necessary to amend the rule to clarify that wholesale drug distributors doing business in Montana must register with the Secretary of State's office because any entity doing business in Montana must be registered with the Secretary of State's office.

24.174.1202 MINIMUM INFORMATION REQUIRED FOR LICENSURE

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

(c) addresses, telephone numbers, and the name, address, telephone number, and title of the designated person in charge of the facility of contact persons for all facilities used by the licensee for the storage, handling, and distribution of drugs;

(d) whether the ownership or operation is a partnership, corporation, or sole proprietorship, and;

~~(e) the name, address, and telephone number of the owner and operator of the licensee, including:~~

~~(i) if an individual, the name, address, and telephone number of the individual;~~

~~(ii) if a partnership, the name, address, telephone number, and ownership percentage of each partner, and the name of the partnership;~~

~~(iii) if a corporation, the name, address, telephone number, and ownership percentage and title of each corporate officer and director, the corporate names, and the name of the state of incorporation; and~~

~~(iv) if a sole proprietorship, the full name, address, and telephone number of the sole proprietor, and the name of the business entity;~~

~~(f) the name and address of the five highest-ranking employees responsible for daily operations;~~

~~(g) the name and address of the five largest shareholders owning at least 5 percent of the total shares;~~

(e) proof of registration with the Montana Secretary of State;

(h) through (j) remain the same but are renumbered (f) through (h).

(2) Any changes in information contained in items (1)(a) through (e)(f) above shall be submitted to the board within 30 days of the change. Any changes in location or ownership require that a new license application be filed with the board.

AUTH: 37-7-201, 37-7-610, MCA

IMP: 37-7-604, 37-7-605, MCA

REASON: It is reasonable and necessary to amend this rule to comply with proposed New Rules VII and VIII that will require a separate license for each location where drugs are stored or distributed and any changes in location or ownership would necessitate a new license.

The board currently lacks a mechanism to collect and store information about the corporate structure of a wholesale drug distributor business even though board rule requires the information be provided. It is reasonable to delete these requirements from this rule as this information will be readily available and more accessible when the business is required to register with the Secretary of State.

5. The new rules proposed to be adopted provide as follows:

NEW RULE I CLOSURE OF A PHARMACY (1) Upon permanent closure of a pharmacy, the original license becomes void and must be surrendered to the board within ten days.

(2) Whenever a pharmacy permanently closes, the owner shall notify the board of the closing no later than 15 days prior to the anticipated date of closing. The notice shall be submitted in writing and shall include the following information:

(a) the date the pharmacy will close;

(b) the names and addresses of the persons who will have custody of the closing pharmacy's:

- (i) prescription files;
  - (ii) bulk compounding records;
  - (iii) repackaging records; and
  - (iv) controlled substance inventory records.
- (c) the names and addresses of any persons who will acquire any legend drugs from the closing pharmacy, if known at the time the notice is filed.
- (3) No later than 15 days after the pharmacy has closed, the owner shall submit to the board written confirmation that:
- (a) all legend drugs have been either:
    - (i) destroyed; or
    - (ii) transferred to an authorized person(s), including the names and addresses of the person(s) to whom the legend drugs were transferred.
  - (b) controlled substances were transferred, including:
    - (i) names and addresses of the person(s) to whom the substances were transferred;
    - (ii) the substances transferred;
    - (iii) the amount of each substance transferred; and
    - (iv) the date on which the transfer took place.
  - (c) the DEA registration and all unused DEA 222 forms (order forms) were returned to the DEA;
  - (d) all pharmacy labels and blank prescriptions which were in the possession of the pharmacy were destroyed; and
  - (e) all signs and symbols indicating the presence of the pharmacy have been removed.

AUTH: 37-7-201, MCA

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

REASON: It is reasonable and necessary to adopt this rule to expand upon and clarify procedures for pharmacy closure. The board notes that pharmacies have closed with no advance notice to the general public, creating patient safety issues when prescription refills cannot be obtained and the timing of previous refills is not readily available to the patient's physician or other provider. Under law, pharmacies are required to maintain prescription and patient refill history for a minimum amount of time, and prescription information must be available to authorized board inspectors even though a pharmacy may have recently closed. The board acknowledges that a closed pharmacy's stock of prescription medications, including controlled substances and the related orders forms, could pose a significant risk of public harm if diverted. The board determined that adopting a new rule to clearly delineate the required pharmacy closure procedures would further the goal of ensuring patient and public health and safety.

NEW RULE II CHANGE IN LOCATION (1) Whenever a mail service pharmacy changes its physical location outside of its then existing business location, its original license becomes void and must be surrendered. The mail service pharmacy shall submit a new license application for the new location at least 30 days before such change occurs.

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

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

REASON: It is reasonable and necessary to adopt New Rules II and III to clarify that a change in location or ownership of a mail service pharmacy requires that a new application for licensure be submitted to the board. The new rules will also achieve consistency among the change of location or ownership requirements for general pharmacies, mail order pharmacies, and wholesale drug distributors.

NEW RULE III CHANGE IN OWNERSHIP (1) When a mail service pharmacy changes ownership, the original license becomes void and must be surrendered to the board, and a new license obtained by the new owner. The owner shall submit a new license application at least 30 days prior to the change in ownership.

(2) A change in ownership for the purposes of this rule shall be deemed to occur when more than 50 percent of the equitable ownership of a business is transferred in a single transaction or in a related series of transactions to one or more persons or any other legal entity.

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

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

NEW RULE IV MEDICAL GAS DISTRIBUTOR (1) Every person engaged in the manufacture or distribution of medical gases other than to the consuming public or a patient, in the state of Montana, shall register annually with the board. Each applicant shall:

- (a) provide proof of registration with the Food and Drug Administration (FDA) as a medical gas manufacturer and comply with all FDA requirements;
- (b) register with the board as a wholesale drug distributor;
- (c) file an application to register as a medical gas distributor on a form prescribed by the board; and
- (d) pay the appropriate registration fee.

(2) The wholesale drug distributor license with the medical gas distributor endorsement shall be posted in a conspicuous place in the wholesaler's place of business for which it is issued.

(3) A medical gas distributor shall establish and implement written procedures for maintaining records pertaining to medical gas production, processing, labeling, packaging, quality control, distribution, complaints, and any information required by federal or state law.

(a) Records shall be retained for at least two years after distribution or one year after the expiration date of the medical gas, whichever is longer.

(b) Records shall be readily available for review by the board, its inspector, or the FDA.

AUTH: 37-1-134, 37-7-201, 37-7-610, MCA

IMP: 37-7-604, 37-7-605, MCA

REASON: It is reasonably necessary to adopt New Rules IV, V, and VI to set forth the registration requirements for medical gas distributors and suppliers in the interest of patient and public safety. Although an exact number is not available, information provided by the National Association of Boards of Pharmacy indicates that because medical gases are considered to be prescription drugs, most states and boards of pharmacy license these entities as wholesale distributors. A medical gas is a drug as defined in 37-7-101, MCA, but current board rules do not clearly define how distributors and suppliers of medical gases are regulated. These proposed new rules will help to ensure the safe manufacture, distribution, and supply of medical gases to Montana patients. The board estimates that this change will affect 15 licensees and will result in an estimated annual increase in revenue of \$1,125.

NEW RULE V MEDICAL GAS SUPPLIER (1) Every person engaged in supplying medical gases to the consuming public, or to a patient or a patient's agent, in the state of Montana that is not a licensed pharmacy shall register annually with the board. Each applicant shall:

- (a) register with the board as a wholesale drug distributor;
  - (b) file an application to register as a medical gas supplier on a form prescribed by the board; and
  - (c) pay the appropriate registration fee.
- (2) The wholesale drug distributor license with the medical gas supplier endorsement shall be posted in a conspicuous place in the wholesaler's place of business for which it is issued.
- (3) A medical gas supplier shall not:
- (a) supply prescription medications, except medical gases, without appropriate licensure as a pharmacy;
  - (b) manufacture or distribute medical gases without appropriate licensure as a medical gas distributor; or
  - (c) instruct patients regarding clinical use of equipment, or provide any monitoring, assessment, or other evaluation of therapeutic effects without appropriate licensure as a respiratory care practitioner.
- (4) A medical gas supplier shall supply medical gas only pursuant to prescription order by an authorized prescriber.
- (5) A medical gas supplier must label each medical gas container with the name, address, and telephone number of the supplier.
- (6) A medical gas supplier shall establish and implement written procedures for maintaining records pertaining to the acquisition and supply of, and complaints related to, medical gases.
- (7) Records shall be retained for at least three years after supply to a patient or one year after the expiration date of the medical gas, whichever is longer.
- (8) Records shall be readily available for review by the board or its inspector.

AUTH: 37-1-134, 37-7-201, 37-7-610, MCA

IMP: 37-7-604, 37-7-605, MCA

NEW RULE VI MEDICAL GAS FEE SCHEDULE (1) The fees for registration to manufacture, distribute, or supply medical gases shall be assessed according to the following schedule:

<u>REGISTRATION</u>	<u>ANNUAL FEE</u>
(a) medical gas distributor	\$75
(b) medical gas supplier	75

AUTH: 37-1-134, 37-7-201, 37-7-610, MCA

IMP: 37-7-604, 37-7-605, MCA

NEW RULE VII CHANGE IN LOCATION (1) Whenever a wholesale drug distributor facility changes its physical location outside of its then existing business location, its original license becomes void and must be surrendered. The wholesale drug distributor facility shall submit a new license application for the new location at least 30 days before such change occurs.

AUTH: 37-7-201, 37-7-610, MCA

IMP: 37-7-604, 37-7-605, MCA

REASON: It is reasonable and necessary to adopt New Rules VII and VIII to clarify that a change in location or ownership of a wholesale drug distributor requires that a new application for licensure be submitted to the board. The new rules will also achieve consistency among the change of location or ownership requirements for general pharmacies, mail order pharmacies, and wholesale drug distributors.

NEW RULE VIII CHANGE IN OWNERSHIP (1) When a wholesale drug distributor changes ownership, the original license becomes void and must be surrendered to the board, and a new license obtained by the new owner. The owner shall submit a new license application at least 30 days prior to the change in ownership.

(2) A change in ownership for the purposes of this rule shall be deemed to occur when more than 50 percent of the equitable ownership of a business is transferred in a single transaction or in a related series of transactions to one or more persons or any other legal entity.

AUTH: 37-7-201, 37-7-610, MCA

IMP: 37-7-604, 37-7-605, MCA

NEW RULE IX FOREIGN INTERN REQUIREMENTS (1) A graduate of a foreign school of pharmacy seeking licensure to practice as a pharmacy intern in the state of Montana shall:

- (a) take the Foreign Pharmacy Graduate Equivalency Exam (FPGEE);
- (b) take the Test of Spoken English (TSE); and one of the following:
  - (i) take the computer-based Test of English as a Foreign Language (TOEFL);
  - (ii) take the paper-based TOEFL; or
  - (iii) take the internet-based TOEFL;

- (c) achieve NABP minimum passing scores on all tests and examinations;
- (d) have an internship practice site identified and that practice site must be a licensed pharmacy in good standing with the board; and
- (e) have an internship preceptor identified and that preceptor must:
  - (i) be a licensed pharmacist in good standing with the board; and
  - (ii) be a registered preceptor in good standing with the board.
- (2) The student and their preceptor must appear before the board.
- (3) The intern shall comply with the internship requirements as set forth in ARM 24.174.602.
- (4) A graduate of a foreign school of pharmacy must complete 1500 hours of internship in the United States in order to be eligible for pharmacist licensure in Montana.

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

IMP: 37-7-201, MCA

REASON: It is reasonable and necessary to adopt New Rule IX because the current internship rules do not adequately and clearly address foreign students. The board receives numerous inquiries from foreign students seeking pharmacy internships in Montana. This new rule will provide clear, consistent, and fair guidelines for foreign students who wish to intern in Montana.

NEW RULE X TECHNICIAN CHECK TECHNICIAN PROGRAM (1) To participate in a technician check technician (TCT) program an institutional pharmacy must meet the following requirements:

- (a) the pharmacy must include TCT as a technician duty, submitted to the Board of Pharmacy by the pharmacist-in-charge as part of the technician utilization plan;
  - (b) develop a site-specific training program tailored to the patient population and medication distribution system;
  - (c) designate one pharmacist to be responsible for meeting the TCT program training and validation requirements;
  - (d) staffing must be adequate to support a consistent utilization of the TCT program;
  - (e) a pharmacist must review all orders against a medication profile containing pertinent clinical information about the patient (allergies, current medication, etc.);
  - (f) the medication description on the batch fill list must contain the same description as the labeling on the unit dose package;
  - (g) the drug distribution system must be structured so that at least one additional check of dispensed medications is completed prior to administration;
  - (h) develop policies and procedures which include a list of the types of work that a technician may check and the types of work that are excluded from being checked by a technician; and
  - (i) utilize the TCT program as a tool to redirect pharmacists from distributive tasks to cognitive and patient centered activities.
- (2) In order to participate in a TCT program a technician must:

- (a) be a registered pharmacy intern in good standing with the board with at least three months experience in unit dose filling; or
  - (b) be a certified pharmacy technician in good standing with the board working full or part time with six months equivalent experience in unit dose filling; and
  - (c) complete site specific training in the TCT program.
- (3) A TCT training program must include:
- (a) didactic lecture (or equivalent training with a self-learning packet);
  - (b) practical sessions (one-on-one training) which consist of observation of a pharmacist checking a unit dose medication batch and/or cart;
  - (c) initial validation (and revalidation if needed); and
  - (d) regular quality assurance audits performed quarterly for the first year then every six months thereafter.
- (4) Approval from the Board of Pharmacy or designee is required prior to program implementation.
- (5) If at any time a technician loses their validation, that individual must not function as a TCT until they are retrained and revalidated.
- (6) All TCT program materials should be readily retrievable for review by the board inspector.

AUTH: 37-7-201, MCA

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

REASON: It is reasonably necessary to adopt New Rule X allowing for the implementation of technician check technician (TCT) programs so that hospital pharmacies can utilize technicians for distributive functions and redirect pharmacists to more cognitive, patient care activities. Studies have demonstrated that clinical pharmacy services improve patient care and reduce medication errors and that TCT programs have helped to facilitate clinical pharmacy services by freeing pharmacists from distributive tasks. Studies have also demonstrated that qualified pharmacy technicians are as accurate as pharmacists in checking unit dose cassettes. Currently there are two TCT pilot programs in the state with another pending before the board. The adoption of rules for TCT programs will provide consistent program guidelines and help to facilitate the implementation of TCT programs in hospital pharmacies across the state.

NEW RULE XI CENTRALIZED PRESCRIPTION FILLING AND PROCESSING OF DRUG ORDERS (1) A pharmacy may outsource prescription drug order filling or processing to a central filling or processing pharmacy provided the pharmacies:

- (a) have the same owner or have entered into a written contract or agreement that outlines the services to be provided and the responsibilities and accountabilities of each pharmacy in compliance with federal and state laws, rules, and regulations; and
  - (b) share a common electronic file.
- (2) A pharmacy that outsources prescription drug order filling or processing to another pharmacy shall, prior to outsourcing a prescription drug order:

- (a) notify the patient or the patient's agent that prescription filling or processing may be outsourced to another pharmacy;
  - (b) provide the name of the pharmacy that will be filling or processing the prescription or, if the pharmacy is part of a network of pharmacies under common ownership and any of the network pharmacies may fill or process the prescription, the patient shall be notified of this fact; and
  - (c) clearly show the name, address, and telephone number of the delivering pharmacy on the prescription container.
- (3) The patient shall have the choice not to have the prescription outsourced.
  - (4) Each pharmacy engaging in centralized prescription processing shall be jointly responsible for properly filling the prescription.
  - (5) The delivering pharmacy is responsible for providing patient counseling.
  - (6) All central filling or processing of prescription drug orders must be completed in a licensed pharmacy.
  - (7) Pharmacies providing central processing or central filling services to pharmacies in the state of Montana must be licensed in Montana.
  - (8) An out-of-state pharmacy providing central processing or central filling services to pharmacies in the state of Montana must be registered as an out-of-state mail service pharmacy and comply with all Montana statutes and rules regulating mail order pharmacies.
  - (9) A policy and procedure manual relating to centralized filling or processing activities shall be maintained at all pharmacies involved in centralized filling or processing. An electronic copy of the policy and procedure manual shall be submitted to the board. Thereafter the manual shall be available for inspection and copying by the board. The policies and procedures shall:
    - (a) outline the responsibilities of each of the pharmacies which must include but is not limited to:
      - (i) receiving, interpreting, or clarifying prescription orders;
      - (ii) entering data and transferring prescription information;
      - (iii) obtaining refill and substitution authorization information;
      - (iv) performing drug regimen review;
      - (v) interpreting clinical data for prior authorization dispensing;
      - (vi) performing therapeutic interventions; and
      - (vii) providing drug information.
    - (b) include a list of the name, address, telephone numbers, and license or registration number of the pharmacies participating in central filling or processing; and
    - (c) include policies and procedures for:
      - (i) protection of the confidentiality and integrity of patient information;
      - (ii) maintenance of appropriate records to identify the names, initials, or identification codes and specific activities of each of the pharmacists and/or technicians who performed any processing; and
      - (iii) compliance with federal, DEA, and state laws and regulations;
      - (iv) operation of a continuous quality improvement program for pharmacy services designed to objectively and systematically monitor and evaluate the quality and appropriateness of patient care, pursue opportunities to improve patient care, and resolve identified problems; and

(v) annual review of the written policies and procedures and documentation of such review.

AUTH: 37-7-201, MCA

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

REASON: It is reasonably necessary to adopt this new rule to provide for the accurate, safe, and confidential outsourcing of prescription drug order filling or processing. Pharmacies and institutions are utilizing central filling and processing of prescriptions as a method to manage workload and costs, decrease wait time to enhance customer service, or in the case of hospitals without a 24/7 pharmacist, improve pharmaceutical care to patients. The board concluded that having well-regulated central filling or processing of prescriptions has the potential to be a safe and effective method of providing pharmacy services after hours for both pharmacies and institutions.

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

24.174.822 CENTRAL FILLING BY HUB PHARMACIES found at ARM page 24-19691.

AUTH: 37-7-201, MCA

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

REASON: It is reasonable and necessary to repeal this rule because New Rule XI is proposed to address both central filling and central processing of prescriptions.

7. 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](mailto:dlibsdpha@mt.gov), and must be received no later than 5:00 p.m., June 22, 2007.

8. 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](http://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.

9. The Board of Pharmacy 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 which includes the name and mailing address of the person to receive notices and specifies that the person wishes to receive notices regarding all Board of Pharmacy administrative rulemaking proceedings or other administrative proceedings. Such written request may be mailed 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 [dlibsdp@mt.gov](mailto:dlibsdp@mt.gov), or made by completing a request form at any rules hearing held by the agency.

10. The bill sponsor notice requirements of 2-4-302, MCA, do not apply.

11. Anjeanette Christiansen, attorney, has been designated to preside over and conduct this hearing.

BOARD OF PHARMACY  
MARK MEREDITH, Pharm. D.

/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 May 14, 2007