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

| | | |
|---|---|---|
| In the matter of the amendment of ARM 24.174.301, 24.174.401, 24.174.407, 24.174.503, 24.174.526, 24.174.602, 24.174.604, 24.174.701, 24.174.712, 24.174.801, 24.174.802, 24.174.803, 24.174.804, 24.174.805, 24.174.806, 24.174.807, 24.174.814, 24.174.819, 24.174.823, 24.174.830, 24.174.831, 24.174.832, 24.174.833, 24.174.835, 24.174.836, 24.174.840, 24.174.901, 24.174.903, 24.174.1412, 24.174.1501, 24.174.1503, 24.174.1505, 24.174.1506, 24.174.1603, 24.174.1604, 24.174.1605, 24.174.1606, 24.174.1702, 24.174.1706, 24.174.1708, 24.174.1709, 24.174.1711, 24.174.2104, and 24.174.2301, the adoption of NEW RULE I, and the repeal of ARM 24.174.303, 24.174.402, 24.174.504, 24.174.507, 24.174.525, 24.174.527, 24.174.528, 24.174.601, 24.174.603, 24.174.605, 24.174.611. 24.174.612, 24.174.613, 24.174.817, 24.174.818, 24.174.834, 24.174.902, 24.174.1206, 24.174.1502, 24.174.1504, 24.174.1507, 24.174.1508, 24.174.1509, 24.174.1510, 24.174.1601, 24.174.1602, 24.174.1607, 24.174.1608, 24.174.1609, 24.174.1703, 24.174.1704, 24.174.1705, 24.174.1713, and 24.174.1715 pertaining to the Board of Pharmacy | ) | NOTICE OF PUBLIC HEARING ON PROPOSED AMENDMENT, ADOPTION, AND REPEAL |

TO: All Concerned Persons

1. On August 15, 2024, at 10:00 a.m., a public hearing will be held via remote conferencing to consider the proposed changes to the above-stated rules. There will be no in-person hearing. Interested parties may access the remote conferencing platform in the following ways:

a. Join Zoom Meeting, https://mt-gov.zoom.us/j/81896489120

Meeting ID: 818 9648 9120, Passcode: 344863
-OR-
b. Dial by telephone, +1 406 444 9999 or +1 646 558 8656
Meeting ID: 818 9648 9120, Passcode: 344863

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 department no later than 5:00 p.m., on August 8, 2024, to advise us of the nature of the accommodation that you need. Please contact the department at P.O. Box 1728, Helena, Montana 59624-1728; telephone (406) 444-5466; Montana Relay 711; or e-mail laborlegal@mt.gov.

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

24.174.301 DEFINITIONS (1) through (3) remain the same.

(4) "Board of Pharmaceutical Specialties" (BPS) means an independent nongovernmental certification body that provides recognition of persons involved in the advanced practice of pharmacy specialties through development and administration and a certification process that is consistent with public policy regarding the credentialing of healthcare professionals.

(5) "Chart order" means a lawful order entered on the chart or a medical record of a patient or resident of a facility by a practitioner, or his or her designated agent, for a drug or device and shall be considered a prescription.

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

~~(5)~~ (7) "Clean room" means ~~a room~~ an environment in which the concentration of airborne particles is controlled and monitored with parameters including high efficiency particulate air (HEPA) filtered airflow, pressurization, temperature, and humidity.

(8) "Clinical practice experience," for purposes of issuing a clinical pharmacist practitioner endorsement, means working in a pharmacy practice setting which includes at least 50 percent of time spent in:

(a) communication with healthcare professionals and patients regarding drug therapy, wellness, and health promotion;

(b) designing, implementing, monitoring, evaluating, and modifying or recommending modifications in drug therapy to optimize patient care;

(c) identifying, assessing, and solving medication-related problems and providing a clinical judgment as to the continuing effectiveness of the therapeutic plan;

(d) conducting physical assessment applicable to the area of practice, evaluating patient problems, and ordering and monitoring medications, and/or laboratory tests in accordance with established standards of practice;

(e) referring patients to other healthcare professionals as appropriate;

(f) integrating relevant diet, exercise, and other non-drug therapy with pharmaceutical care;

(g) retrieving, evaluating, utilizing, and managing data and professional resources;

(h) documenting interventions and evaluating outcomes; and

(i) integrating national standards for the quality of healthcare.

(9) "Collaborative practice agreement" is defined as set forth in ARM 24.174.524.

(6) through (11) remain the same but are renumbered (10) through (15).

~~(12)~~ (16) "Drug order" means a written or electronic order issued by an authorized practitioner, or a verbal order promptly transcribed, for the compounding and dispensing of a drug or device to be administered to patients within ~~the~~ a facility and shall be considered a prescription.

(13) remain the same but is renumbered (17).

(18) "Electronic prescription" means a prescription that is generated on an electronic application and is transmitted to a pharmacy as an electronic data file. Controlled substance prescriptions for Schedules II through V shall be transmitted in accordance with DEA requirements as outlined in 21 CFR Part 1300.

(14) through (21) remain the same but are renumbered (19) through (26).

(27) "Internship" means the practical experiences required to provide an intern, as defined in 37-7-101, MCA, with the knowledge and practical experience necessary for professional licensure as a pharmacist.

(28) "Internship period" means 300 Introductory Pharmacy Practice Experience (IPPE) hours, and 1,440 Advanced Pharmacy Practice Experience (APPE) hours of practical experience in an approved pharmacy, hospital, or other facility or location relevant to the pharmacy profession. The intern may acquire the internship 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. The intern may acquire a maximum of 48 hours experience per calendar week.

(22) through (33) remain the same but are renumbered (29) through (40).

(41) "Preceptor" means a pharmacist or other approved individual who meets those requirements for the supervision and training of an intern. A preceptor shall have overall responsibility for the required training of the intern.

(34) through (44) remain the same but are renumbered (42) through (52).

(53) "Supervising pharmacist" means the registered pharmacist who is serving as the pharmacist on duty and is in charge of the day-to-day supervision of the pharmacy personnel.

(54) "Supervision" means that all drug distribution or dispensing activities, immunizations, or other activities performed by pharmacy personnel are under the direction of a registered pharmacist.

(45) remains the same but is renumbered (55).

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

IMP: 37-7-102, 37-7-201, 37-7-301, 37-7-306, 37-7-321, 37-7-406, 37-7-603, 37-7-604, 37-7-605, 50-32-314, MCA

REASON: The board is combining multiple definition rules into a single rule for ease of understanding. The board is updating the definition of "clean room" for clarity and

is adding a new definition for "electronic prescription" to clarify ARM 24.174.840. The board is updating the definition of "drug order" to clearly state that a drug order is a prescription and removing unnecessary references to "drug order" throughout this rule package. The board is also expanding the definition of "preceptor" to include other approved individuals who meet training requirements and adding reference to a preceptor's overall responsibility that had previously been in the definition of "supervision." In addition, the board is revising the definition of "supervising pharmacist" to include all pharmacy personnel, not just interns. This change reflects practice and the supervising pharmacist having oversight of all pharmacy personnel, including pharmacy technicians, as outlined in ARM 24.174.705, 24.174.711, and 24.174.712, and interns, clerks, and other individuals authorized to assist the pharmacist.

24.174.401 FEE SCHEDULE

(1) Application for pharmacist licensure transfer $180

(2) ~~Original registration for pharmacist~~ Pharmacist initial license 70

(3) remains the same.

(4) ~~Original registration for clinical~~ Clinical pharmacist practitioner initial endorsement/registration and annual renewal fee 25

~~(5) Clinical pharmacist practitioner annual renewal fee 25~~

~~(6)~~ (5) Community and institutional pharmacy ~~original certification~~ initial license (includes ~~original~~ initial license, change in location, and change in ownership) 240

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

~~(8)~~ (7) ~~Family planning limited~~ Limited service pharmacy facility, ~~certified pharmacy license~~ (~~original~~ initial license and annual renewal) 45

(9) through (11) remain the same but are renumbered (8) through (10).

~~(12)~~ (11) Utilization plan ~~approval~~ initial endorsement and annual renewal fee 75

~~(13) Annual utilization plan renewal fee 75~~

(14) and (15) remain the same but are renumbered (12) and (13).

~~(16)~~ (14) Wholesale distributor initial license and annual renewal fee 240

~~(17) Annual wholesale distributor renewal 240~~

~~(18)~~ (15) Out-of-state mail service pharmacy~~/telepharmacy~~ initial license and annual renewal fee 240

~~(19) Out-of-state mail service pharmacy/telepharmacy renewal 240~~

(20) remains the same but is renumbered (16).

~~(21) Inactive pharmacist annual renewal fee 15~~

~~(22)~~ (17) Outpatient center for surgical services (~~original~~ initial or renewal) 45

~~(23)~~ (18) Drugs dispensed by a medical practitioner ~~original~~ initial registration 240

(24) through (29) remain the same but are renumbered (19) through (24).

(25) The fees to be assessed for registration to manufacture, distribute,

dispense, conduct research on, or analyze a dangerous drug shall be assessed the following fees upon application and annual renewal:

| | |
|---|---|
| (a) manufacture | 100 |
| (b) distribute | 100 |
| (c) dispense – pharmacy | 75 |
| (d) dispense – outpatient centers for surgical services | 75 |

(26) The fees for registration to manufacture, distribute, or supply medical gases shall be assessed according to the following annual fee:

| | |
|---|---|
| (a) medical gas distributor | 75 |
| (b) medical gas supplier | 75 |

AUTH: 37-1-134, 37-2-104, 37-7-201, 37-7-604, 37-7-610, 37-18-803, 50-32-314, MCA
IMP: 37-1-134, 37-2-104, 37-7-201, 37-7-306, 37-7-321, 37-7-604, 37-7-605, 37-7-703, 37-18-803, 50-32-314, MCA

REASON: The board is combining all fee rules into a single rule for standardization purposes, including the fees listed in ARM 24.174.402 for dangerous drug fee schedule, and ARM 24.174.1206 for medical gas fee schedule. The board is also taking the opportunity to combine initial licensure and annual renewal fees where the fees are identical. See also ARM 24.174.504 REASON.

24.174.407 QUALITY ASSURANCE PROGRAM REQUIREMENTS (1) Each pharmacy or other facility licensed by the board shall ~~implement or~~ have in place a quality assurance program to detect, identify, and prevent ~~prescription~~ errors, for improving public safety, or both. The quality assurance program shall include necessary documentation, internal reporting, and assessment of ~~prescription~~ errors to determine the root cause and contributing factors, such as system or process failures, provide an appropriate response, and communicate the findings to all pharmacy personnel.

~~(2) The primary purpose of the quality assurance program shall be to advance error prevention by analyzing, individually and collectively, investigative and other pertinent data collected in response to a prescription error to assess the cause and any contributing factors such as system or process failures.~~

~~(3) Each pharmacy, corporation, or health system shall use the findings of its quality assurance program to develop pharmacy systems and workflow processes designed to prevent prescription errors, as well as communicate those findings to all pharmacy personnel.~~

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

REASON: The board is consolidating the rule into a single section to reduce repeated language and clarify expectations for quality assurance programs.

24.174.503 ADMINISTRATION OF VACCINES BY PHARMACISTS, INTERNS, AND PHARMACY TECHNICIANS (1) through (4) remain the same.

(5) ~~The authority of a pharmacist to administer immunizations may not be delegated; however, a~~ An immunization-certified pharmacist may delegate the administration of immunizations to a pharmacy intern or a pharmacy technician ~~pharmacy intern may immunize~~ under the direct supervision of ~~an immunization-certified pharmacist or other healthcare provider qualified in vaccine administration and deemed appropriate by the preceptor~~ the pharmacist upon meeting the ~~immunization-certified~~ immunization certification requirements listed in 37-7-105, MCA, and this rule. The board shall issue an immunization endorsement on the license of an intern or pharmacy technician upon receipt of qualifications being met.

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

AUTH: 37-7-201, MCA
IMP: 37-7-101, 37-7-105, 37-7-201, MCA

REASON: The board is updating this rule to reflect pharmacy intern and pharmacy technician immunization authority in 37-7-105, MCA, pursuant to 2023 House Bill 710. For auditing, pharmacy technicians are added to the audit procedure but not interns as they do not renew their license, and the school of pharmacy has additional oversight of their practice experience.

24.174.526 ~~REQUIREMENTS TO BECOME A~~ CLINICAL PHARMACIST PRACTITIONER QUALIFICATIONS AND REQUIREMENTS (1) An applicant for a clinical pharmacist practitioner registration shall:

(a) remains the same.

(b) pay a required registration fee ~~as prescribed by the board~~ and annual renewal fee;

(c) through (2) remain the same.

(3) A clinical pharmacist practitioner shall complete an annual renewal of a pharmacist's license and pay the clinical pharmacist practitioner endorsement renewal fee.

(4) The board shall audit clinical pharmacist practitioners for compliance with continued registration.

AUTH: 37-7-201, MCA
IMP: 37-7-201, 37-7-306, MCA

REASON: The board is combining ARM 24.174.526 and 24.174.527 regarding clinical pharmacist practitioner requirements to consolidate information and to standardize rule format for listing qualifications, requirements, and renewals, similar to Subchapter 18 for medical practitioner dispensers.

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~~ a site approved by the school in which the intern is enrolled.

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

~~(3) Application shall be made on the intern application form prescribed by the board. Registration must be obtained prior to commencing work as an intern.~~

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

(3) An intern registration may be issued to an individual who:

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

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

(c) is a graduate of a pharmacy program located outside the United States of America which is not accredited and who is licensed pursuant to (14).

(4) All intern applicants must:

(a) submit a completed application to the board;

(b) pay the required fee; and

(c) complete at least one day of the accredited pharmacy program.

(5) remains the same.

~~(6) The intern shall be responsible for ensuring that the preceptor has proper certification.~~

~~(7) The intern is responsible for properly submitting all forms and hour reports under the approved program directly to the school of pharmacy.~~

(6) Intern and internship documentation, hours, and forms shall be furnished by the school of pharmacy and filed directly to the school of pharmacy.

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

(7) An out-of-state intern must register with the board and comply with rules related to internship and this chapter.

(8) remains the same.

~~(9) 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 is licensed pursuant to ARM 24.174.605.~~

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

~~(11) An intern registration may be issued to a student who:~~

~~(a) is currently enrolled in an accredited pharmacy program;~~

~~(b) has submitted a completed application to the board;~~

~~(c) has paid the required fee; and~~

~~(d) has completed at least one day of the accredited pharmacy program.~~

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

~~(13)~~ (11) Intern certificate of registration shall be displayed ~~in the approved training area~~ at any experiential or employment location.

(14) remains the same but is renumbered (12).

(13) Suspension of an intern from university or college attendance concurrently suspends an intern's certificate of registration.

(14) A graduate of a foreign school of pharmacy seeking licensure to practice as a pharmacy intern in the state of Montana shall:

(a) submit proof of a Foreign Pharmacy Graduate Examination Committee (FPGEC) Certification from the National Association of Boards of Pharmacy (NABP), which includes the following:

(i) Test of Spoken English (TSE);

(ii) Test of English as a Foreign Language (TOEFL); and

(iii) Foreign Pharmacy Graduate Equivalency Exam (FPGEE);

(b) achieve NABP minimum passing scores on all tests and examinations;

(c) have an internship practice site identified and that practice site must be a licensed pharmacy in good standing with the board;

(d) 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;

(e) appear before the board with their preceptor; and

(f) complete 1,740 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: The board is revising this rule to consolidate multiple intern rules (ARM 24.174.601, 24.174.602, 24.174.605, 24.174.611, 24.174.612, and 24.174.613) and to reconcile current procedures based on school of pharmacy operations and oversight of intern requirements.

24.174.604 PRECEPTOR REQUIREMENTS (1) Each ~~pharmacist~~ preceptor shall:

(a) apply for board approval to be a preceptor when the preceptor is a pharmacist. For pharmacists, the board shall issue an endorsement on the pharmacist's license when requirements are met;

(b) remains the same.

(c) be actively engaged in ~~active practice~~ the pharmacy profession or other approved discipline or healthcare profession while acting as preceptor;

(d) through (f) remain the same.

(g) make ~~such~~ reports and certifications as required ~~under the approved program~~ by a school of pharmacy;

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

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

~~(j)~~ (i) complete a training course as approved by the ~~board~~ ACPE or the school of pharmacy prior to applying for a pharmacist preceptor endorsement.

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

(3) remains the same.

AUTH: 37-7-201, MCA

IMP: 37-7-201, MCA

REASON: The board is revising this rule to be more flexible and reflect current preceptor procedures, expectations, use of other healthcare providers as appropriate, and the variety of experiential locations utilized by a school of pharmacy for intern activity. The board is also clarifying its role in issuing a preceptor endorsement only to pharmacist licensees. The board is removing reference to preceptor address change notification as duplicative to ARM 24.174.403.

24.174.701 PHARMACY TECHNICIAN REGISTRATION REQUIREMENTS

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

~~(a) be at least 18 years old;~~

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

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

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

(e) and (f) remain the same but are renumbered (c) and (d).

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

(3) remains the same.

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

REASON: The board is amending this rule to remove barriers to pharmacy technician licensure and limitations on staff recruitment. Removing the requirements of being 18 years old and having a high school diploma or equivalent will allow for greater opportunities to engage with or employ high school students and others who may be interested in the pharmacy profession but currently do not meet licensure requirements. In addition, extending the temporary practice permit (provisional registration) from one year to two years will better accommodate the timeline individuals have to complete more complex training and practice requirements to be eligible to take pharmacy technician certification exams. These changes also reduce burden on pharmacy managers as they recruit, provide training programs, provide practice experiences, assist in technician certification exam preparation, and try to retain pharmacy technicians in a competitive work environment.

24.174.712 APPLICATION FOR APPROVAL OF UTILIZATION PLAN

(1) The pharmacist-in-charge may apply to the board for approval to use the services of a pharmacy technician, including the use of authorized healthcare licensees, as described in ARM 24.174.701(1)~~(f)~~(d), to assist pharmacists in the admission of vaccines, in compliance with state and federal requirements, by submitting to the board:

(a) through (c) remain the same

(d) any changes in the technician utilization plan, including technician training and use of other healthcare licensees for administration of vaccines, as described in

ARM 24.174.701(1)~~(f)~~(d), must be ~~resubmitted to the board for approval before implementation of the changes by the supervising pharmacist~~ provided upon inspection by the board.

(2) through (4) remain the same.

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

REASON: The board is updating this rule to reduce paperwork burden on licensees and provide for a revised technician utilization plan to be reviewed by the board through the inspection process, rather than submitting updates directly to the board.

24.174.801 GENERAL LICENSE REQUIREMENTS (1) The board shall ~~grant~~ issue a license for the operation of a pharmacy in the state of Montana when ~~it is plainly shown that~~:

(a) through (3) remain the same.

(4) No license may be issued whose intended place of business is a personal residence.

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

REASON: The board is amending this rule to standardize with wholesale drug distributor license requirements and to update language.

24.174.802 NEW PHARMACY (1) and (2) remain the same.

(3) All new pharmacies shall be in compliance with ARM 24.174.801 and ARM 24.174.814 at the time the pharmacy is opened for business.

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

REASON: The board is amending this rule to address questions staff receive regularly from new pharmacy applicants as to expectations upon opening.

24.174.803 CHANGE IN LOCATION (1) Whenever a ~~pharmacy~~ facility licensed by the board changes its physical location, including within the existing business location, it shall submit a new schematic or floor plan, for board approval.

(2) Whenever a ~~pharmacy~~ facility changes its physical location outside of its then existing business location, its original license becomes void and must be surrendered. ~~The pharmacy shall submit a~~ A new license application, including a new schematic and floor plan of the new location, shall be submitted for the board's approval at least 30 days before such change occurs.

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

REASON: The board is updating this rule for clarity purposes due to questions staff receive from licensees regarding change in location requirements for any facility license.

24.174.804 CHANGE IN OWNERSHIP (1) When a pharmacy, or other facility licensed by the board, changes ownership, ~~the original license becomes void and must be surrendered to the board, and~~ a new license must be 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. The original license will expire at the time of license renewal unless the board is notified of an alternative closure date.

(2) remains the same.

(3) A change due to corporate restructuring or business structure for legal or tax purposes does not constitute an ownership change unless the provisions of (2) are met. The licensee shall notify the board of the change but a new application and license are not required.

~~(3)~~ (4) The board must be notified in writing when five to 50 percent of the equitable ownership of a facility business license 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: The board is updating this rule for clarity purposes due to questions staff receive from licensees regarding ownership change requirements and when a new application is required.

24.174.805 CHANGE OF PHARMACIST-IN-CHARGE OR PERSON-IN-CHARGE (1) When service as the pharmacist-in-charge of a pharmacy ends ~~ceases to be the pharmacist-in-charge~~, the pharmacist ~~will be held~~ is responsible for notifying the board in writing of such termination of services.

(2) Within ~~72 hours~~ 10 days of termination of services of the pharmacist-in-charge, a new pharmacist-in-charge must be designated in writing on the appropriate board-approved form and filed with the board.

(3) The requirements in (1) and (2) apply to a person-in-charge for other facilities licensed by the board for which a pharmacist is not required to be the person-in-charge.

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

REASON: The board is updating this rule for clarity purposes due to questions staff receive from licensees and to include facilities which are not required to have a pharmacist-in-charge but a person-in-charge. The timeline to update the board of a change is extended from 72 hours to 10 days to better accommodate the logistics of

such notifications and align with other provisions. Failure to comply is addressed in ARM 24.174.2301.

24.174.806 FACILITY LICENSES TO BE POSTED (1) The pharmacy license or other facility license issued by the board must be posted in a conspicuous place in the ~~pharmacy~~ facility.

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

REASON: The board is updating this rule for clarity purposes due to questions received by staff and for consolidation purposes.

24.174.807 CLOSURE OF A ~~PHARMACY~~ FACILITY (1) Upon permanent closure of a pharmacy or other facility licensed by the board, the original license becomes void ~~and must be surrendered to the board within ten days~~.

(2) Whenever a ~~pharmacy~~ facility 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~~ of closure;

(b) remains the same

(c) the names and addresses of any persons who will acquire any ~~legend~~ prescription drugs from the closing ~~pharmacy~~ facility, if known at the time the notice is filed~~.~~; and

(d) the name and phone number of the property owner.

(3) No later than 15 days after the ~~pharmacy~~ facility has closed, the owner shall submit to the board written confirmation that:

(a) all ~~legend~~ prescription drugs have been either:

(i) remains the same.

(ii) transferred to an authorized person(s), including the names and addresses of the person(s) to whom the ~~legend~~ prescription drugs were transferred.

(b) and (c) remain the same.

(d) all ~~pharmacy~~ facility labels and blank prescriptions which were in the possession of the ~~pharmacy~~ facility were destroyed; ~~and~~

(e) all signs and symbols indicating the presence of the ~~pharmacy~~ facility have been removed~~.~~; and

(f) all contents of medication collection receptacles or disposal kiosks, if any, have been shipped and the containers have been removed.

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

REASON: The board is updating this rule for clarity purposes due to questions received by staff and for consolidation purposes. The board is adding (3)(f) to address federal requirements and to include needed information upon a closure.

24.174.814 SECURITY OF PHARMACY AND RECORDS (1) through (3)

remain the same.

(4) ~~Sections (1) and (2) of this rule shall be effective February 1, 2004~~ An automated prescription record keeping system(s) (system) may be employed for prescription record keeping.

(a) The system shall contain adequate safeguards or security of the records to maintain the confidentiality and accuracy of the prescription or drug order information. Safeguards against unauthorized changes in data after the information has been entered and verified by the registered pharmacist shall be provided by the system.

(b) The system must comply with all applicable state and federal privacy and security requirements.

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

REASON: The board is combining ARM 24.174.817 and 24.174.818 into this security rule for standardization purposes, and to repeal outdated language and unnecessary detail that is part of standard operating procedures for pharmacy dispensing systems.

24.174.819 SANITATION AND EQUIPMENT REQUIREMENTS

(1) Pharmacies shall at all times be operated by a registered pharmacist in a sanitary manner, pursuant to 50-31-103 and 50-31-305, MCA. There must be in use a safe and pure water supply and facilities for the proper storage and handling of supplies and stocks.

(2) and (3) remain the same.

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

REASON: The board is adding this reference at the request of staff to address questions from licensees.

24.174.823 CENTRALIZED ~~PRESCRIPTION~~ FILLING AND REMOTE ORDER PROCESSING OF PRESCRIPTIONS ~~DRUG ORDERS~~ IN COMMUNITY PHARMACIES ~~(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.~~

(1) Central or remote prescription processing services may be utilized by a licensed pharmacy if the following conditions have been met:

(a) remote licensed staff must be licensed in Montana as a pharmacist or a pharmacy technician or, if located out-of-state, be licensed in their home state and work under the authority of a pharmacy licensed in Montana pursuant to (8); and

(b) policies and procedures must be in place for remote licensed staff working off-site to process prescriptions or other applicable duties to ensure appropriate tasks, security, and privacy provisions are met. The policies and procedures shall:

(i) be reviewed and documented annually;

(ii) include a continuous quality improvement program;

(iii) comply with federal and state statutes and regulations; and

(iv) be available for inspection by the board.

(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 and accommodate patient choice not to have the prescription outsourced;

(b) and (c) remain the same.

~~(3) The patient shall have the choice not to have the prescription outsourced.~~

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

~~(5)~~ (4) The delivering pharmacy is responsible for providing patient counseling.

~~(6)~~ All central filling ~~or processing~~ of prescriptions ~~drug orders~~ must be completed in a licensed pharmacy.

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

~~(8)~~ (6) 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)~~ (7) ~~A policy and procedure manual~~ Policies and procedures 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~~ and 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.~~

(a) include the annual review of the competencies of pharmacists providing remote and/or centralized prescription processing or filling services;

(b) be reviewed and documented annually;

(c) include a continuous quality improvement program;

(d) comply with federal and state statutes and regulations; and

(e) be available for inspection by the board.

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

REASON: The board is amending this rule to distinguish between remote licensed staff performing central/remote services remotely, not at the physical location of the pharmacy, versus pharmacies as described in (2), at the request of staff after numerous questions from licensees. The board is further updating language and striking duplicative language from other provisions of Subchapter 8.

24.174.830 LIMITED SERVICE PHARMACY (1) A limited service pharmacy is defined as a family planning clinic:

(a) operating under contract with the ~~Department of Public Health and Human Services (DPHHS)~~ state to provide such services; or

(b) providing pharmaceutical care under the review of a consulting pharmacist and dispensing ~~legend~~ prescription drugs, but which is not under contract with ~~DPHHS~~ the state.

(2) Each limited service pharmacy must apply for a license from the board and submit the required fee for each separate location.

~~(3) The board shall grant a license to operate a limited service pharmacy to qualified applicants. A licensed family planning clinic may operate satellite locations under the same license if identified on the application.~~

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

~~(6)~~ (5) A limited service pharmacy dispensing ~~legend~~ prescription drugs other than factory, prepackaged contraceptives must disclose the name, address, telephone number, and title of the designated ~~person in charge~~ person-in-charge of the limited service pharmacy.

(a) The ~~person in charge~~ person-in-charge is responsible for the limited service pharmacy's compliance with all applicable state and federal statutes and rules.

(b) A ~~person in charge~~ person-in-charge may be responsible for multiple sites.

~~(7)~~ (6) The board may annually inspect limited service pharmacies~~, including any satellite locations~~. The board may inspect more often for cause. Such inspections must include assurance that the limited service pharmacy provides adequate:

(a) through (e) remain the same.

~~(8)~~ (7) Nothing in this rule is meant to limit or restrict the authority of a registered nurse employed by a family planning clinic, operating under contract with ~~DPHHS~~ the state, from dispensing factory, prepackaged contraceptives as authorized by 37-2-104, 37-7-103, or 50-31-307, MCA.

~~(9)~~ (8) A registered nurse or provider with prescriptive authority, employed by a family planning clinic operating with ~~DPHHS~~ the state, may dispense ~~oral antibiotics~~ medications used to treat ~~Chlamydia~~ sexually transmitted diseases, including but not limited to conditions listed in 50-16-1004 and 50-18-101, MCA, ~~to a patient diagnosed with Chlamydia~~ and to a sexual contact or partner of a patient diagnosed with ~~Chlamydia~~ a sexually transmitted disease. All appropriate records shall be maintained on-site.

(9) The ~~antibiotics~~ medications dispensed must:

(a) through (c) remain the same.

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

REASON: The board is amending this rule to standardize language, and to address questions staff have received from numerous licensees regarding which facilities require licenses and for clarity with the inspection process. After consultation with the Department of Public Health and Human Services, the board also is including all sexually transmitted infections and updating language to better address public health efforts.

24.174.831 PRESCRIPTION REQUIREMENTS (1) Prescriptions ~~[or drug orders]~~ shall include, but not be limited to:

(a) through (h) remain the same.

(i) number of refills authorized.

(2) A prescription and any refills for a non-controlled drug, device, or biologic are valid for one year from date of issuance.

(3) Prescriptions shall comply with all federal DEA requirements for prescriptions, dispensing, and refills of controlled substance in Schedules II, III, IV, and V, pursuant to 21 CFR 1306.

~~(i)~~ (4) ~~if~~ 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, must be tamper-resistant, and contain:~~;~~

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

(A) through (C) remain the same but are renumbered (a) through (c).

~~(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)~~ (5) ~~if~~ If the prescription is for a controlled substance, all state and federal requirements must be met, and the following additional information is required to be on the prescription:

(i) and (ii) remain the same but are renumbered (a) and (b).

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

(2) and (3) remain the same but are renumbered (6) and (7).

~~(4) "Chart order" means a lawful order entered on the chart or a medical record of a patient or resident of a facility by a practitioner, or his or her designated agent, for a drug or device and shall be considered a prescription.~~

(8) Prescription records may be electronically stored and maintained if they remain legible and are in a readily retrievable format, and if federal law does not require them to be kept in a hard copy format, pursuant to DEA requirements in 21 CFR 1304.06.

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

REASON: The board is striking definitions from this rule, as necessary definitions have been moved to ARM 24.174.301. The board is further updating references to DEA requirements and striking provisions made unnecessary with DEA requirements. The board is adding (8) to clarify use of technology, to better accommodate receipt and storage of electronic prescriptions, and to reduce burden in pharmacies and other facilities.

24.174.832 LABELING FOR PRESCRIPTIONS (1) remains the same.

(2) The prescription label must be securely attached to the outside of the container in which the prescription is dispensed, with the exception of medical oxygen.

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

REASON: The board is updating this rule to reflect limitations on medical oxygen canisters and current practice.

24.174.833 RECORDS OF DISPENSING, PURCHASES, AND DISTRIBUTION (1) Records of dispensing for original and refill prescriptions are to

be made and kept by pharmacies for at least two years and shall include, but not be limited to:

(a) and (b) remain the same.

(c) ~~serial number~~ prescription number ~~[~~or equivalent if an institution~~]~~;

(d) and (e) remain the same.

(f) records of refills to date; and

(g) if the pharmacy is distributing to another licensee through wholesale distribution activities, the invoice number and invoice, and, pursuant to 21 CFR 205.50, retain distribution records for three years.

(2) All records must be available for printing and available for inspection by the board.

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

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

REASON: The board is amending this rule to include purchasing and dispensing records to address questions from licensees. The board is also removing outdated terminology and to align with record keeping requirements from FDA for pharmacies that conduct wholesale activity.

24.174.835 TRANSFER OF PRESCRIPTIONS (1) The transfer of prescription information for the purpose of dispensing is permissible between pharmacies subject to DEA regulations and the following requirements:

(a) the transfer is communicated directly between two licensed pharmacists/interns, or is faxed or electronically transmitted by a pharmacy technician under the direct supervision of a pharmacist; ~~and~~

(b) a retrievable audit trail, including the date of transfer and initials or code of the transferring parties, is maintained for a period of two years~~.~~; and

(c) the transfer of pertinent and necessary patient records to another licensed pharmacy, when requested by the patient or the patient's legally designated representative, is completed in a timeline that meets patient safety and health needs, subject to the pharmacist's professional judgment.

(2) The transferring pharmacy shall:

(a) render the prescription void; and

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

~~(c) inform the receiving pharmacy of:~~

~~(i) the date on which the prescription was written;~~

~~(ii) the original number of refills;~~

~~(iii) the number of refills or quantity remaining; and~~

~~(iv) the date of the most recent refill.~~

(3) The receiving pharmacy shall maintain documentation including:

(a) through (f) remain the same.

(g) a ~~nonfading hard copy~~ record of each prescription ~~drug order~~ transferred.

(4) ~~Pharmacies accessing a common or shared electronic file or database used to maintain required dispensing information are not required to transfer prescription drug orders or information for dispensing purposes between or among pharmacies participating in the common or shared prescription file, provided, however, that any such common or shared file shall contain complete records of each prescription drug order and refill dispensed. A hard copy record of each prescription drug order accessed for purposes of refilling shall be generated if necessary and maintained at the refilling pharmacy. An easily retrievable audit trail which documents the location of each filling must be maintained and provisions must be made to assure that the number of authorized refills is not exceeded.~~ Two or more pharmacies sharing common electronic files to maintain dispensing information are not required to transfer prescription information between these pharmacies, provided all common electronic files maintain complete and accurate records of each prescription and refill dispensed, and the total number of refills authorized is not exceeded.

~~(a) Any pharmacy which establishes an electronic file for prescription records, which is shared with or accessible to other pharmacies, shall post in a place conspicuous to and readily readable by prescription drug consumers a notice in substantially the following form:~~

~~"NOTICE TO CONSUMERS:~~

~~This pharmacy maintains its prescription information in an electronic file which is shared by or accessible to the following pharmacies: (list names of all pharmacies which share the prescription information).~~

~~By offering this service, your prescriptions may also be refilled at the above locations. If for any reason you do not want your prescriptions to be maintained this way, please notify the pharmacist-in-charge."~~

~~(b)~~ (a) ~~Whenever a consumer objects to their prescription records being made accessible to other pharmacies through the use of electronic prescription files, it is the duty of the pharmacy to assure that the consumer's records are not shared with or made accessible to another pharmacy except as provided in this rule.~~ Pharmacies sharing common electronic files shall have policies and procedures in place for handling patient exceptions.

(5) In an emergency, a pharmacy may transfer original prescription ~~drug order~~ information for a noncontrolled substance to a second pharmacy for the purpose of dispensing up to a seven-day supply, without voiding the original prescription ~~drug order~~.

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

REASON: The board is amending this rule to include a reference to technicians faxing or electronically transmitting prescription transfers to address questions received by staff, to align with current practice, and to comply with DEA requirements. The board is further amending this rule to clarify that pharmacies are expected to transfer records in a timeline that meets patient safety and health needs, and to address questions received regarding ARM 24.174.2301(1)(t). The board is removing duplicative language and standardizing language with ARM 24.174.840.

Finally, the board is removing the requirement of sign posting with specific language as unnecessary to state in rule after determining electronic record keeping is a common element in pharmacy practice and patients may address concerns with pharmacy staff.

24.174.836 EMERGENCY PRESCRIPTION REFILLS (1) remains the same.

(2) If a prescription is not refillable, a pharmacist dispensing an emergency refill:

(a) may exercise professional judgment to dispense a minimum sufficient quantity until authorization can be obtained from a prescriber~~.~~;

~~(i) for drugs which must be dispensed in their original containers, the pharmacist may dispense the smallest trade size available;~~

(b) may not dispense a controlled substance prescription medication listed in Schedule II through Schedule V;

(c) and (d) remain the same.

(e) must comply with all applicable record-keeping requirements.

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

REASON: The board is amending this rule to align with current practices after reports from board inspectors. The board is striking (2)(a)(i) as unnecessary, given the requirement in (2)(a) that the pharmacist exercise professional judgment as to the quantity needed.

24.174.840 ELECTRONIC TRANSMISSION OF PRESCRIPTIONS ~~BY ELECTRONIC MEANS~~ ~~(1) A pharmacist may dispense directly any legend drug, which requires a prescription to dispense (except as provided in (2) and (3) below for Schedule II, III, IV, and V, controlled substances) pursuant to either a written prescription signed by a practitioner or a prescription transmitted by the practitioner or the practitioner's agent to the pharmacy by electronic means, or pursuant to an oral prescription made by an individual practitioner and promptly reduced to hardcopy by the pharmacist, containing all information required. The prescription shall be maintained in accordance with ARM 24.174.512.~~

~~(2) A pharmacist may dispense directly a controlled substance in Schedule II, which is a prescription drug as determined by the Federal Food, Drug, and Cosmetic Act (FD&C Act), pursuant to a written prescription signed by the practitioner. In addition, a prescription for a Schedule II controlled substance may be transmitted by the practitioner or the practitioner's agent to a pharmacy by electronic means, provided the original written, signed prescription is presented to the pharmacist for review prior to the actual dispensing of the controlled substance or by electronic means that meet all of the federal guidelines for controlled substances that are electronically prescribed. The original prescription shall be maintained in accordance with ARM 24.174.512.~~

~~(a) A signed prescription for a Schedule II narcotic substance to be compounded for the direct administration to a patient by parenteral, intravenous, intramuscular, subcutaneous, or intraspinal infusion may be transmitted by the~~

~~practitioner or the practitioner's agent to the pharmacy by electronic means. The electronic transmission serves as the original written prescription for the purpose of this rule and it shall be maintained in accordance with ARM 24.174.512.~~

~~(b) A signed prescription for a Schedule II substance for a resident of a long-term care facility may be transmitted by the practitioner or the practitioner's agent to the dispensing pharmacy by electronic means. The electronic transmission serves as the original written prescription for purposes of this rule and it shall be maintained in accordance with ARM 24.174.512.~~

~~(c) A signed prescription for a Schedule II substance for a patient enrolled in a hospice care program, certified and/or paid for by Medicare under Title XVIII of the Social Security Act, or a hospice program which is licensed by the state of Montana, may be transmitted by the practitioner or the practitioner's agent to the dispensing pharmacy by electronic means. The practitioner or the practitioner's agent shall note on the prescription that the patient is a hospice patient. The electronic transmission serves as the original written prescription for purposes of this rule and it shall be maintained in accordance with ARM 24.174.512.~~

~~(3) A pharmacist may dispense directly a controlled substance listed in Schedule III, IV, or V, which is a prescription drug as determined under the FD&C Act, only pursuant to either a written prescription signed by a practitioner or a copy of a written, signed prescription transmitted by the practitioner or the practitioner's agent to the pharmacy by electronic means, or pursuant to an oral prescription made by an individual practitioner and promptly reduced to hardcopy by the pharmacist, containing all information required or by electronic means that meet all of the federal guidelines for controlled substances that are electronically prescribed. The prescription shall be maintained in accordance with ARM 24.174.512.~~

~~(4) Prescriptions may be transmitted electronically directly from an authorized prescriber or his/her authorized agent to the pharmacy of the patient's choice without alteration by any other party, providing the following requirements are met:~~

~~(a) Both prescriber and pharmacist must have a secure (encrypted or encoded) system for electronic transmission from computer to computer that ensures patient confidentiality;~~

~~(b) The receiving electronic device shall be located within the pharmacy department to ensure security and confidentiality;~~

~~(c) An electronically transmitted prescription shall contain all information required by state and federal law, including the date and time of transmission, the prescriber's telephone number for verbal confirmation, and the name of the prescriber's agent transmitting the order, if other than the prescriber;~~

~~(d) The prescriber's electronic signature or other secure (encrypted or encoded) method of validation shall be provided with the electronically transmitted order. Faxed prescription orders shall contain the identifying number of the sending fax machine;~~

~~(e) A printed, nonfading copy of an electronically transcribed prescription will be maintained in the pharmacy for a period of two years;~~

~~(f) The prescription shall be marked "electronically transmitted prescription" or be otherwise identified for easy retrieval;~~

~~(g) An electronically transmitted prescription shall be transmitted only to the pharmacy of the patient's choice;~~

~~(h) The pharmacist is responsible for assuring the validity of the electronically transmitted prescription;~~

~~(i) A pharmacist or pharmacy shall not enter into any agreement to provide or receive a computer or computer modem, personal digital assistant, facsimile machine, or any other electronic device which would adversely affect a patient's freedom to select the pharmacy of the patient's choice; and~~

~~(j) A pharmacist or pharmacy shall not provide a computer or computer modem, personal digital assistant, facsimile machine, or any other electronic device to a prescriber or healthcare facility for the purpose of providing an incentive to refer patients to a particular pharmacy.~~

(1) Unless otherwise prohibited by law, an electronic prescription may be transmitted from the prescriber or an authorized agent directly to the dispensing pharmacy and must contain all information required by state and federal law.

(2) Electronic prescriptions for Schedules II through V controlled substances shall comply with DEA requirements, as outlined in 21 CFR 1311.120, and any security or other requirements of federal law.

(3) All electronic prescriptions shall comply with all security requirements of state and federal law related to privacy of protected health information.

(4) A pharmacy receiving an electronic prescription shall maintain the prescription record in accordance with ARM 24.174.833.

(5) An electronic prescription shall be transmitted only to the pharmacy of the patient's choice.

~~(5)~~ (6) Computer-generated, electronically signed prescriptions for controlled substances that are handed directly to a patient or to a patient's agent ~~must be authenticated by the prescriber with the prescription hand-signed, with~~, or faxed to a pharmacy, must contain the actual signature of the prescriber, and comply with prescription requirements outlined in ARM 24.174.831 if a hard copy prescription. Computer-generated, electronically signed prescriptions for noncontrolled substances do not require an additional wet signature.

~~(6) Two or more pharmacies sharing common electronic files to maintain dispensing information are not required to transfer prescription information between these pharmacies, providing all common electronic files maintain complete and accurate records of each prescription and refill dispensed, and the total number of refills authorized is not exceeded.~~

~~(a) Any pharmacy sharing a common electronic file for prescription records shall post the following notice in readily readable form in a conspicuous place within the pharmacy:~~

~~"This pharmacy maintains its prescription information in a secure electronic file that is shared by the following pharmacies: (list names of pharmacies which share the prescription information). If refills are authorized, your prescriptions may be refilled at any of the above locations. If you do not want your prescriptions to be maintained in this way, please notify the pharmacist at the time of filling."~~

~~(b) Pharmacies sharing common electronic files will have policies and procedures in place for handling these exceptions.~~

AUTH: 37-7-201, 50-32-103, MCA
IMP: 37-1-101, 37-7-102, 37-7-201, 50-32-208, MCA

REASON: The board is amending this rule to simplify and more clearly explain electronic prescription requirements and correlate with the definition added to ARM 24.174.301. The board is further striking (6), regarding sharing common electronic files, as it is now included in ARM 24.174.835. Also, the board is adding reference to compliance with ARM 24.174.831, if the electronically generated prescription is printed and presented as a hard copy prescription for a controlled substance.

24.174.901 PATIENT RECORDS AND DRUG UTILIZATION REVIEW (1) A patient record system shall be maintained by all pharmacies for patients for whom prescriptions ~~drug orders~~ are dispensed. The patient record system shall provide for the immediate retrieval of information necessary for the dispensing pharmacist to identify previously dispensed drugs at the time a prescription ~~drug order~~ is presented for dispensing. The pharmacist or pharmacy technician ~~under a board-approved utilization plan,~~ shall make a reasonable effort to obtain, record, and maintain the following information:

(a) full name of the patient ~~for whom the drug is intended~~;

(b) through (d) remain the same.

(e) known allergies or drug intolerances;

(f) chronic conditions;

(g) other prescription or non-prescription medications; and

(e) remains the same but is renumbered (h).

~~(2) The pharmacist or pharmacy technician under a board-approved utilization plan, shall make a reasonable effort to obtain from the patient or the patient's agent and shall record any known allergies, drug reactions, idiosyncrasies, and chronic conditions or disease status of the patient and the identity of any other drugs, including over-the-counter drugs, or devices currently being used by the patient which may relate to prospective drug review.~~

(2) A pharmacist shall review the patient record and complete a drug utilization review as defined in 37-7-101, MCA. Upon recognizing any potential therapeutic problems, the pharmacist shall take appropriate steps to avoid or resolve the problem which shall, if necessary, include consultation with the prescriber.

(3) A patient record shall be maintained for a period of not less than ~~three~~ two years from the date of the last entry in the profile record. This record may be a hard copy or a computerized form.

AUTH: 37-7-201, MCA
IMP: 37-7-406, MCA

REASON: The board is amending this rule to strike unnecessary language and to incorporate relevant provisions from ARM 24.174.902. The board is further updating the patient retention record requirements to two years to align with other provisions.

24.174.903 PATIENT COUNSELING (1) Upon receipt of a new, refill, or transfer prescription ~~drug order or refill prescription drug order~~ if deemed necessary by the pharmacist, ~~and following a review of the patient's record, a pharmacist~~ each patient or caregiver, agent, or representative of the patient shall be offered

~~personally offer~~ the opportunity to discuss matters which will enhance or optimize drug therapy with ~~each patient or caregiver of such patient~~ the pharmacist. The discussion shall be in person, whenever practicable, or by telephone, and shall include appropriate elements of patient counseling. ~~Such elements may include the following:~~ Pharmacy personnel may make the offer to counsel, but the pharmacist must personally conduct the counseling.

~~(a) the name and description of the drug;~~

~~(b) the dosage form, dose, route of administration, and duration of drug therapy;~~

~~(c) intended use of the drug and expected action;~~

~~(d) special directions and precautions for preparation, administration, and use by the patient;~~

~~(e) common severe side or adverse effects or interactions and therapeutic contraindications that may be encountered, including their avoidance, and the action required if they occur;~~

~~(f) techniques for self-monitoring drug therapy;~~

~~(g) proper storage;~~

~~(h) prescription refill information;~~

~~(i) action to be taken in the event of a missed dose; and~~

~~(j) pharmacist comments relevant to the individual's drug therapy, including any other information peculiar to the specific patient or drug.~~

(2) remains the same.

(3) Alternative forms of patient information shall be used to supplement patient counseling when appropriate and when required. Examples include written information leaflets, pictogram labels, video programs, QR codes, etc. The pharmacy shall provide medication guides or confirm patient access to the medication guides and/or patient package inserts, comply with risk evaluation and mitigation strategies, and/or other labeling requirements as required by the U.S. Food and Drug Administration.

(4) remains the same.

(5) A pharmacist shall not be required to counsel a patient or caregiver when the patient or caregiver refuses ~~such~~ consultation. A record of the refusal shall be maintained ~~by the pharmacist~~.

AUTH: 37-7-201, MCA
IMP: 37-7-406, MCA

REASON: The board is amending this rule to strike unnecessary details which are taught in pharmacy school and are known elements of counseling and recognized as standard of pharmacy practice. The board is including QR codes in (3) to address questions received from licensees, is adding reference to FDA labeling/dispensing requirements in (3), and is amending (5) to provide flexibility in workflow and pharmacy staff operations.

24.174.1412 ADDITIONS, DELETIONS, AND RESCHEDULING OF DANGEROUS DRUGS (1) In addition to those dangerous drugs scheduled in 50-32-222, 50-32-224, 50-32-226, 50-32-229, and 50-32-232, MCA, the board adds the

following to dangerous drug schedules after considering federal regulations and/or the criteria enumerated in Title 50, chapter 32, part 2, MCA:

(a) remains the same.

(b) Schedule II:

(i) ~~norfentanyl~~ none at this time;

(c) remains the same.

(d) Schedule IV:

~~(i) brexanolone, allopregnanolone~~ none at this time;

~~(ii) soriamfetol;~~

~~(iii) lemborexant;~~

(e) Schedule V:

~~(i) lasmiditan;~~ none at this time.

~~(ii) cenobamate.~~

(2) The board deletes the following dangerous drugs from the schedules in 50-32-222, 50-32-224, 50-32-226, 50-32-229, and 50-32-232, MCA, after considering federal regulations and/or the criteria enumerated in Title 50, chapter 32, part 2, MCA:

(a) remains the same.

(b) Schedule II:

(i) ~~6β-naltrexol~~ none at this time;

(c) and (d) remain the same.

(e) Schedule V:

~~(i) approved cannabidiol drugs. A drug product in finished dosage formulation that has been approved by the United States Food and Drug Administration that contains cannabidiol, also known as (2-[1R-3-methyl-6R-(1-methylethenyl)-2-cyclohexen-1-yl]-5-pentyl-1,3-benzenediol), derived from cannabis and no more than 0.1% (w/w) residual tetrahydrocannabinols, and as authorized by the Agriculture Improvement Act of 2018 (P.L. 115-334)~~ none at this time.

(3) remains the same.

AUTH: 50-32-103, 50-32-203, MCA

IMP: 50-32-103, 50-32-202, 50-32-203, 50-32-209, 50-32-222, 50-32-223, 50-32-224, 50-32-225, 50-32-226, 50-32-228, 50-32-229, 50-32-231, 50-32-232, MCA

REASON: The board is amending this rule to remove duplicate language that is now listed in statute pursuant to 2023 Senate Bill 67.

24.174.1501 PARTICIPATION AND REGISTRATION (1) remains the same.

~~(2) A pharmacy or facility may withdraw from participation in the cancer drug repository program at any time, upon notification to the board. A notice to withdraw shall be in writing.~~

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

~~(4) Cancer drugs may be donated to a pharmacy or facility.~~

~~(5)~~ (3) ~~Participation in the~~ The program is voluntary, and any pharmacy or facility must notify the board of their interest in participating in the program.

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

(5) Any person or entity (donor) may donate cancer drugs to the program. The donor must contact a pharmacy or facility to obtain a form on which the donor must specify the drug(s) to be donated. The board will supply the form to be used which will include the provisions of 37-7-1405, MCA, and the:

(a) name and quantity of the drug; and

(b) name of the person the drug was originally prescribed, their relationship with the donor, the signature of the donor, and the date the form was signed.

(6) The board may inspect a pharmacy or facility participating in the program for compliance with the storage and record-keeping requirements. The board may terminate participation in the program for noncompliance.

(7) The board shall establish and maintain a list of any pharmacy or facility participating in the program by issuing an endorsement on the license at no cost. The endorsement application information must include the entity's name, address, telephone number, and if it is a practitioner's office, pharmacy, clinic, or hospital, in compliance with 37-7-1403, MCA. The pharmacy or facility must notify the board of any changes to their registration information, including when they stop participating in the program.

(8) The board will make the pharmacy or facility registry information available to any person or entity wishing to donate cancer drugs to the program, and will make the information available on the board webpage or by contacting the board office.

AUTH: 37-7-1401, MCA
IMP: 37-7-1401, 37-7-1403, 37-7-1405, MCA

REASON: The board is combining ARM 24.174.1501, 24.174.1502, 24.174.1508, 24.174.1509, and 24.174.1510 for standardization purposes and to simplify listing of requirements.

24.174.1503 ACCEPTABLE AND NONACCEPTABLE CANCER DRUGS

(1) The following categories of cancer drugs are acceptable for dispensing or distribution under the program, if in compliance with 37-7-1404, MCA, the cancer drug:

(a) ~~a cancer drug that~~ is in its original, unopened, sealed, and tamper-evident packaging;

(b) ~~a cancer drug~~ is packaged in single unit doses if the outside packaging is opened, but the single unit dose packaging is unopened; and

~~(c) a cancer drug that does not require refrigeration, freezing, or other special temperature requirements beyond controlled room temperature; and~~

~~(d)~~ (c) ~~an injectable cancer drug if it~~ does not have temperature or storage requirements other than controlled room temperature.

(2) remains the same.

(3) The following categories of cancer drugs are not acceptable for dispensing or distribution under the program, because the effectiveness and safety of the cancer drugs cannot be ensured or is otherwise prohibited if the cancer drugs:

(a) are adulterated or misbranded;

(b) do not comply with the requirements in (1);

(c) are controlled substances; and

(d) have expired before dispensing to the patient.

AUTH: 37-7-1401, MCA
IMP: 37-7-1401, 37-7-1404, 37-7-1405, MCA

REASON: The board is consolidating rules ARM 24.174.1503 and 24.174.1504 for clarity and simplification in the listing of acceptable and nonacceptable cancer drugs for the donation program, and added a reference to 37-7-1404, MCA.

24.174.1505 DISPENSING AND DISTRIBUTION OF CANCER DRUGS

(1) remains the same.

~~(2) A pharmacy or facility must inspect all such drugs prior to dispensing or distributing to determine if they are adulterated, misbranded, or expired.~~

~~(3) The following are authorized to dispense drugs:~~

~~(a) practitioners with prescriptive authority; and~~

~~(b) licensed pharmacists.~~

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

(a) dispensed to ~~an ultimate user of the cancer drug~~ a cancer drug patient or to a patient's agent or caregiver; or

(b) remains the same.

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

~~(6)~~ (4) Patients for whom cancer drugs are dispensed under the program must be notified by the prescribing practitioner or dispensing pharmacy that the cancer drugs they received were originally dispensed to another patient and were returned for redispensing through the program.

AUTH: 37-7-1401, MCA
IMP: 37-7-1401, 37-7-1405, MCA

REASON: The board is striking (2) as redundant. Pharmacies may not dispense or distribute adulterated, misbranded, or expired drugs generally, so it is unnecessary to restate here. The board is also adding clarification for dispensing to a patient's agent or caregiver.

24.174.1506 STORAGE AND RECORD-KEEPING REQUIREMENTS

(1) The pharmacy or facility that receives donated cancer drugs for dispensing or distribution must:

(a) ~~provide equipment for~~ ensure the proper and secure storage of cancer drugs donated to the program ~~at controlled room temperature~~; and

(b) maintain the inventory of donated cancer drugs separate from all other drug inventory of the pharmacy or facility~~; and~~

~~(c) establish a secure location for the storage of the donated cancer drugs~~.

(2) A pharmacy or facility must maintain a perpetual inventory log book of all donated cancer drugs received, dispensed, or distributed that must include the information outlined in 37-7-1405, MCA, including:

(a) name, quantity, expiration date, dosage form, and lot number;

(b) name of pharmacy or facility;

(c) name of person or entity who donated the cancer drug;

(d) name of the person to whom the cancer drug was dispensed and date dispensed;

(e) name of the prescribing practitioner who wrote the prescription for the cancer drug to be dispensed under the program;

(f) name of the pharmacy or facility which the cancer drug was distributed and date distributed;

(g) date of destruction of the expired cancer drug; and

(h) the amount of the handling fee charged, if any.

AUTH: 37-7-1401, MCA
IMP: 37-7-1401, 37-7-1404, 37-7-1405, MCA

REASON: The board is combining ARM 24.174.1506 and 24.174.507 for clarity and to simplify listing of requirements as outlined in 37-7-1405, MCA.

24.174.1603 PROTOCOL FOR SELF-REPORTING TO A ~~BOARD-ESTABLISHED MEDICAL~~ PROFESSIONAL ASSISTANCE PROGRAM (1) If a licensee or license applicant chooses to self-report to the ~~board-established medical~~ assistance program, and the ~~medical assistance~~ program has determined that the licensee or license applicant needs assistance or supervision, the licensee or license applicant shall be required to:

(a) and (b) remain the same.

(2) Self-reporting by a licensee or license applicant may still result in disciplinary action by the board if:

(a) the medical assistance program determines that the self-reporting licensee or license applicant poses a danger to themselves or to the public;

(b) the licensee or license applicant is noncompliant with a contractual agreement with the medical assistance program;

(c) the licensee or license applicant has not completed evaluation, treatment, or aftercare monitoring as recommended by the medical assistance program; or

(d) remains the same.

(3) ~~The medical assistance program shall notify the board, disclose the identity of the licensee involved, and provide all facts and documentation to the board whenever:~~ The program shall notify and disclose to the board the identity of a new license applicant who is determined by the program to have significant impairment issues.

~~(a) the licensee:~~

~~(i) has committed an act described in ARM 24.174.2301;~~

~~(ii) is noncompliant with a recommendation of the medical assistance program for evaluation, treatment, or aftercare monitoring contract; or~~

~~(iii) is the subject of credible allegations that the licensee has put a patient or the public at risk or harm; or~~

~~(b) the screening panel otherwise determines disciplinary action is warranted.~~

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

REASON: The board is amending this rule to repeal unnecessary sections that repeat statute, and to include license applicants to align with current practices and other boards.

24.174.1604 RESPONSIBILITIES OF ~~MEDICAL~~ PROFESSIONAL ASSISTANCE PROGRAM (1) The ~~medical~~ professional assistance program established by the board as set forth in 37-7-201, MCA, shall ~~fulfill the terms of its contract with the board, which will include, but not be limited to, the following~~:

(a) ~~providing~~ provide two tracks for assistance of licensees:

(i) and (ii) remain the same.

(b) ~~providing~~ provide recommendations to licensees or license applicants for appropriate evaluation and treatment facilities;

(c) ~~recommending to the board~~ recommend terms and conditions of treatment, rehabilitation, and monitoring of licensees or license applicants known to the board; and

(d) remains the same.

(e) report to the board the discharge of a participant, and if applicable, provide to the board:

(i) verification of the participant's satisfactory completion of monitoring and program requirements as appropriate for public safety;

(ii) verification of the participant's completion of board final order terms and conditions with recommendation of the program for discharge; and/or

(iii) notification that the participant is transferring to another jurisdiction.

(2) and (3) remain the same.

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

REASON: The board is amending this rule to include the responsibilities of the assistance program to manage intake, monitoring, and discharge, as well as the reporting to the board requirements. These requirements were previously contained in multiple rules, so the board is combining for ease of understanding and repealing the extraneous rules.

24.174.1605 PROTOCOL FOR DISCIPLINARY TRACK (1) All licensees who participate in the ~~medical~~ assistance program under the disciplinary track shall be reported to the board by name.

(2) A licensee or license applicant is placed in the disciplinary track by one or more of the following:

(a) remains the same.

(b) as a result of a sanction imposed by a board final order~~;~~.

~~(c) as a result of noncompliance with the licensee's contractual agreement with the program; or~~

~~(d) pursuant to an agreement between the licensee and the screening panel or the full board upon licensure.~~

(3) The program shall also report licensees who have discharged from the

program.

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

REASON: The board is striking (2)(c) and (d) as a requirement to participate in the disciplinary track is a sanction, which can only be imposed after a board final order either as a disciplinary action or as a licensing decision. The board is further amending the rule to include discharged participants.

24.174.1606 PROTOCOL FOR NONDISCIPLINARY TRACK (1) A licensee or license applicant who participates in the medical assistance program under the nondisciplinary track shall be reported to the board by participant number.

(2) and (3) remain the same.

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

REASON: The board is adding license applicants for standardization with other boards and to reflect current practice.

24.174.1702 REQUIREMENTS FOR SUBMITTING PRESCRIPTION REGISTRY INFORMATION TO THE BOARD ~~INFORMATION REQUIRED FOR SUBMISSION~~ (1) All prescription information for controlled substances shall be submitted to the board pursuant to this subchapter.

~~(1)~~ (2) Each ~~entity~~ facility licensed by the board as a community pharmacy or as an out-of-state mail service pharmacy that dispenses to patients in Montana shall provide ~~the following~~ controlled substances dispensing information or zero report by no later than the close of the next business day to the board~~:~~ as outlined in the Montana Prescription Drug Registry (MPDR) Data Submission Guide available on the Board of Pharmacy's MPDR website at www.mpdr.mt.gov.

(3) Each facility licensed by the board as an institutional pharmacy shall provide controlled substance dispensing information if they dispense controlled substances in an outpatient, discharge, starter packet, or other related capacity in which the controlled substance(s) leaves their premises. Institutional pharmacies are not required to submit zero reports.

(4) Controlled substance dispensing information reported to the MPDR must include the following:

(a) through (h) remain the same.

(i) ~~prescription~~ number assigned to the prescription ~~order~~; and

(j) remains the same.

~~(2) Each entity licensed by the board as an institutional pharmacy shall comply with the reporting requirements listed in this rule if they dispense controlled substances in an outpatient, discharge, starter packet, or other related capacity in which the controlled substance(s) leaves their premises. Institutional pharmacies are not required to submit zero reports.~~

(5) All prescription information submitted to the board must be transmitted in the format specified by the American Society for Automation in Pharmacy (ASAP), version 4.2A, dated 2016, at a minimum, which is adopted and incorporated by reference. ASAP 4.2A specifications are available in the MPDR Data Submission Guide available at the board's MPDR website at www.mpdr.mt.gov.

(a) The acceptable methods of electronic reporting are Secure File Transfer Protocol (SFTP), file upload, and manual data entry of prescription information via the secure web-based interface provided by the system vendor maintained by the board.

(6) In the event that a pharmacy cannot submit the required information as described in this rule, the pharmacy must timely notify the board on or before the date the submission is due. Upon notification, the board may grant an extension, at their discretion.

(7) It is the responsibility of the submitting pharmacy to address any errors or questions about information that the pharmacy has submitted to the prescription drug registry and resubmit corrected data within seven days after the date of notification of the error.

(8) A pharmacy that does not dispense controlled substances may notify the board by submitting an appropriate board-approved form attesting that the pharmacy does not dispense controlled substances to Montana patients. A pharmacy is not exempt from reporting requirements until it receives approval from the board.

(a) The board-approved form submitted by a pharmacy that does not dispense controlled substances shall be maintained on file with the board.

(b) A pharmacy's exempt status does not expire unless the pharmacy is issued a new license number or the pharmacy dispenses a controlled substance.

AUTH: 37-7-1512, MCA
IMP: 37-7-1502, 37-7-1503, 37-7-1512, 37-7-1513, MCA,

REASON: The board is combining ARM 24.174.1702, 24.174.1703, and 24.174.1704 to simplify and streamline the rules, and updating language to reflect current practice and questions from licensees.

24.174.1706 REGISTRY INFORMATION REVIEW AND UNSOLICITED PATIENT PROFILES (1) remains the same.

(2) ~~In instances of possible misuse or diversion, the executive director will promptly report by telephone, e-mail, or postal mail the patient's profile information to practitioners and pharmacists who have provided care to that patient~~ Registered prescribers and pharmacists will be notified electronically, through vendor functionality, of instances of possible misuse or diversion for patients under their care.

(3) remains the same.

AUTH: 37-7-1512, MCA
IMP: 37-7-1502, 37-7-1504, MCA

REASON: The board is amending this rule to reflect a new vendor's notifications operating differently. Prescribers get notified directly when they log in and can see a queue of alerts for patients that fill a prescription from that prescriber; pharmacists are notified if an alteration is included in the search result for a specific patient.

24.174.1708 ACCESS TO PRESCRIPTION DRUG REGISTRY INFORMATION (1) The following persons may have direct online access to prescription drug registry information:

(a) licensed practitioners having authority to prescribe ~~controlled substances~~ prescription drugs, or that practitioner's authorized agent, for the purpose of providing medical and/or pharmaceutical care for their patients, or for patients referred for medical care and/or pharmaceutical care;

(b) licensed pharmacists authorized to dispense ~~controlled substances~~ prescription drugs, or that pharmacist's ~~authorize~~ authorized agent, for the purpose of providing pharmaceutical care for their patients or for patients referred for care;

(c) remains the same.

(d) board staff~~, including executive director, inspectors, and program manager~~ for administrative and compliance purposes; and

(e) remains the same.

(2) To access registry information, each user must first:

~~(a) successfully complete the board's educational program~~;

~~(b)~~ complete the registration form, terms of use or equivalent agreement, and confidentiality agreement provided by the board~~;~~. The board will provide educational material about the MPDR program online at www.mpdr.mt.gov.

~~(c) complete a written agreement assuring that the user's access and use of the prescription drug registry is limited to that authorized by law;~~

(3) Access for users is restricted:

~~(i)~~ (a) in the case of a licensed practitioner having authority to prescribe ~~controlled substances~~ prescription drugs, or that practitioner's authorized agent, ~~access is restricted~~ to:

~~(A)~~ (i) the practitioner's own prescribing information; or

~~(B)~~ (ii) prescription records for a patient of the practitioner to whom the practitioner is providing or considering providing medical and/or pharmaceutical care;

~~(ii)~~ (b) in the case of a licensed pharmacist, ~~pharmacy intern, or certified pharmacy technician, access is restricted~~ or that pharmacist's authorized agent, to prescription records for a patient for whom the ~~pharmacy~~ pharmacist is ~~actually~~ providing pharmaceutical care, dispensing, or considering dispensing a prescription;

~~(iii)~~ (c) in the case of a designated representative of the Montana Medicare or Medicaid programs, Tribal Health, Indian Health Service, and Veterans Affairs, ~~access is restricted~~ to prescription records related to a participant in the program;

~~(iv)~~ (d) in the case of authorized representatives of the board, ~~access is restricted~~ to:

~~(A)~~ (i) that necessary to respond to legitimate inquiries; or

~~(B)~~ (ii) that necessary for legitimate inquiries under ARM 24.174.1706;

~~(v)~~ (e) in the case of an authorized vendor or contractor, ~~access is restricted~~ to technical work necessary to establish or maintain the prescription drug registry databank~~; or~~.

~~(vi)~~ (4) For each user ~~in every user's case~~:

~~(A)~~ (a) information accessed from the prescription drug registry must be kept confidential;

~~(B)~~ (b) information accessed from the prescription drug registry must not be disclosed to any unauthorized person; and

~~(C)~~ (c) user account information, login names, and passwords must not be shared with any person, regardless of whether that person is also an authorized user of the prescription drug registry.

~~(3)~~ (5) Prior to granting access to the registry, the board shall verify that the applicant is licensed to prescribe or dispense ~~controlled substances or legend drugs~~ prescription drugs, or in the case of an agency applicant, the board shall verify that the applicant is the designated representative of the Montana Medicare or Medicaid programs, Tribal Health, Indian Health Service, or Veterans Affairs.

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

~~(5)~~ (7) Upon ~~receipt of written~~ notification that an authorized user no longer possesses authority to prescribe, dispense, or represent Medicare or Medicaid programs, Tribal Health, Indian Health Services, Veterans Affairs, or the board, the board shall terminate the user's access to the prescription drug information.

(6) remains the same but is renumbered (8).

(a) ~~completing the form provided by the board and returning the completed form, along with proof of identification and authorization required by the board, to the board's office~~ completing the registration form, terms of use or equivalent agreement, and confidentiality agreement provided by the board and provide appropriate credentialing; or

(b) remains the same.

~~(7)~~ (9) Individual patients may request their own prescription registry information from the board or their provider. If requesting from the board, the ~~requestor~~ requester shall ~~personally appear at the program office and produce a positive photo identification at the time of their request~~ complete and return the form provided by the board. A ~~single~~ copy of the information will be provided at no charge to the individual.

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

AUTH: 37-7-1506, 37-7-1512, MCA
IMP: 37-7-1506, 37-7-1512, MCA

REASON: The board is amending this rule to reflect that the MPDR program is operated by a new vendor, and to align terminology with statutory language.

24.174.1709 REGISTRY INFORMATION RETENTION (1) remains the same.

(2) Pursuant to 37-7-1508, MCA, a government entity or law enforcement agency may request that specific information in the registry, related to an open

investigation, be retained beyond the three-year destruction requirement by submitting a ~~written~~ request to the board ~~on a form provided by the board~~.

AUTH: 37-7-1512, MCA
IMP: 37-7-1508, MCA

24.174.1711 ADVISORY GROUP (1) The board shall establish a prescription drug registry advisory group, to provide information and ~~advice~~ recommendations about the development ~~and~~, operation, enhancement, and clinical application of the prescription drug registry.

~~(2) The advisory group shall consist of, but is not limited to, representatives of:~~

~~(a) Montana boards of pharmacy, medical examiners, nursing, and dentistry;~~

~~(b) Montana pharmacy associations, medical associations, nursing associations, dental associations, and associations that advocate for patients;~~

~~(c) tribal health, Medicaid and Medicare, and public health agencies;~~

~~(d) the Department of Justice; and~~

~~(e) the Montana Legislature.~~

~~(3) The members of the advisory group shall serve at the pleasure of their respective appointing authorities.~~

~~(4) The members of the advisory group shall elect a chair and a vice chair whose duties shall be established by the advisory group.~~

~~(5) The advisory group shall establish policies and procedures necessary to carry out duties.~~

~~(6) The board shall establish a time and a place for regular meetings of the advisory group, which shall meet at least once a year.~~

AUTH: 37-7-1510, 37-7-1512, MCA
IMP: 37-7-1510, MCA

REASON: The board is amending this rule to remove language repeating statute, and to reflect that board staff manages and chairs meetings. The board is not repealing the entire rule as 37-7-1711, MCA requires that the board set rules for the conduct of the advisory group.

24.174.2104 REGISTERED PHARMACIST CONTINUING EDUCATION - REQUIREMENTS (1) through (5) remain the same.

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

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

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

REASON: The board is striking (6) as duplicative of 37-1-306, MCA, and is moving (7) to NEW RULE I to align with standard administrative suspension procedures within the department.

24.174.2301 UNPROFESSIONAL CONDUCT (1) The board defines "unprofessional conduct" as follows:

(a) through (s) remain the same

(t) failure to transfer pertinent and necessary patient records to another licensed pharmacy, the patient or the patient's representative when requested to do so by the patient or the patient's legally designated representative in a timeline that meets patient safety and health needs;

(u) failure to comply with an agreement the licensee has entered into with the ~~impaired pharmacist~~ assistance program; ~~and~~

(v) failure to follow policies and procedures defined in the practice situation to safeguard patient care~~.~~;

(w) failure to comply with the scope of practice of a clinical pharmacist practitioner and the authority of a collaborative practice agreement, as authorized in 37-7-306, MCA;

(x) failure to submit controlled substance dispensing information to the prescription drug registry, pursuant to 37-7-1503, MCA; and

(y) filling a prescription from a pharmacy-produced copy as a pharmacy-produced copy of a prescription cannot be used to fill or dispense a prescription.

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

REASON: The board is incorporating (w), (x) and (y) after relocating them from other rules, including ARM 24.174.528, 24.174.1705, and 24.174.834. The board is also revising (t) to reflect revisions to ARM 24.174.835.

4. The proposed new rule is as follows:

NEW RULE I ADMINISTRATIVE SUSPENSION (1) The board authorizes the department to:

(a) administratively suspend licenses for deficiencies set forth in 37-1-321(1)(a) though (e), MCA; or

(b) file a complaint pertaining to the deficiencies in (1) that are based on repeated or egregious conduct, or that have co-occurring misconduct allegations that directly implicate public safety and may warrant formal disciplinary action.

(2) An administrative suspension is not a negative, adverse, or disciplinary action under Title 37, MCA, and is not reportable under federal law and regulations implementing the Healthcare Practitioner Databank or the department's licensee lookup and license verification databank.

AUTH: 37-1-131, MCA
IMP: 37-1-321, MCA

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

24.174.303 INTERNSHIP PROGRAM DEFINITIONS

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

REASON: The board is repealing this rule after moving the definitions into ARM 24.174.301, as revised, and to align with revisions in Subchapter 6 Internship Requirements.

24.174.402 DANGEROUS DRUG FEE SCHEDULE

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 is repealing this rule after moving the fees into ARM 24.174.401.

24.174.504 INACTIVE LICENSE

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

REASON: The board is repealing the pharmacist inactive license status after discussing the Board of Nursing's repeal of inactive status in 2017, determining that a license should be active or should not exist, unless the status changes due to a disciplinary action. The board determined inactive status is minimally used and is an administrative burden for licensees and staff. It is also not necessary to keep for purposes of the professional assistance program. The board currently has approximately 50 inactive status licensees. The resulting increase in revenue of approximately $2500 is not significant to the board's overall budget.

24.174.507 MILITARY TRAINING OR EXPERIENCE

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

REASON: The board is repealing this rule to reflect military training or experience authority in 37-1-145, MCA, pursuant to 2023 House Bill 583, which outlines specific obligations for the board to accept military experience for granting licensure.

24.174.525 DEFINITIONS

AUTH: 37-7-201, MCA
IMP: 37-7-201, 37-7-306, MCA

REASON: The board is moving the definitions for collaborative practice agreement requirements into ARM 24.174.301 to have one definition rule.

24.174.527 REQUIREMENTS TO MAINTAIN CLINICAL PHARMACIST PRACTITIONER REGISTRATION

AUTH: 37-7-201, MCA
IMP: 37-7-201, 37-7-306, MCA

REASON: The board is combining ARM 24.174.526 and 24.174.527 regarding clinical pharmacist practitioner requirements to consolidate information and to standardize rule format for listing qualifications, requirements, and renewals, similar to Subchapter 18 for medical practitioner dispensers.

24.174.528 UNPROFESSIONAL CONDUCT

AUTH: 37-1-319, 37-7-201, MCA
IMP: 37-1-316, 37-7-306, MCA

REASON: The board is repealing this rule as an unnecessary duplication of ARM 24.174.2301. The Board of Medical Examiners remains free to take action against any person alleged to have practiced medicine without the appropriate license.

24.174.601 SUMMARY OF OBJECTIVES

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

REASON: The board is repealing this rule and adding the intern practice experience provision to ARM 24.174.301.

24.174.603 OUT-OF-STATE INTERNSHIP REQUIREMENTS

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

REASON: See REASON for ARM 24.174.602.

24.174.605 FOREIGN INTERN REQUIREMENTS

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

REASON: See REASON for ARM 24.174.602.

24.174.611 APPROVED TRAINING AREAS

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

REASON: The board is revising this rule to consolidate multiple intern rules, ARM 24.174.601, 24.174.602, 24.174.605, 24.174.611, 24.174.612, and 24.174.613, and to reconcile current procedures based on school of pharmacy operations and oversight of intern requirements.

24.174.612 INTERNSHIP REQUIRED FORMS AND REPORTS

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

REASON: See REASON for ARM 24.174.602.

24.174.613 REVOCATION OR SUSPENSION OF CERTIFICATE

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

REASON: See REASON for ARM 24.174.602.

24.174.817 AUTOMATED RECORD KEEPING SYSTEMS

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

REASON: The board is combining ARM 24.174.817 and 24.174.818 into ARM 24.174.814 for standardization purposes, and to repeal outdated language and unnecessary detail that is part of standard operating procedures for pharmacy dispensing systems.

24.174.818 SECURITY

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

REASON: The board is combining ARM 24.174.817 and 24.174.818 into ARM 24.174.814 for standardization purposes, and to repeal outdated language and unnecessary detail that is part of standard operating procedures for pharmacy dispensing systems.

24.174.834 COPY OF PRESCRIPTION

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

REASON: The board is repealing this rule after including necessary provisions in ARM 24.174.831 and ARM 24.174.2301.

24.174.902 PROSPECTIVE DRUG REVIEW

AUTH: 37-7-201, MCA
IMP: 37-7-406, MCA

REASON: The board is repealing this rule after relocating provisions into ARM 24.174.901.

24.174.1206 MEDICAL GAS FEE SCHEDULE

AUTH: 37-1-134, 37-7-201, 37-7-610, MCA
IMP: 37-7-604, 37-7-605, MCA

REASON: The board is repealing this rule after moving the fees into ARM 24.174.401.

24.174.1502 DONATION OF CANCER DRUGS

AUTH: 37-7-1401, MCA
IMP: 37-7-1401, 37-7-1403, MCA

REASON: The board is combining ARM 24.174.1501, 24.174.1502, 24.174.1508, 24.174.1509, and 24.174.1510 for standardization purposes and to simplify listing of requirements.

24.174.1504 NONACCEPTABLE CANCER DRUGS

AUTH: 37-7-1401, MCA
IMP: 37-7-1401, 37-7-1404, 37-7-1405, MCA

REASON: See reason for ARM 24.174.1503.

24.174.1507 RECORD-KEEPING REQUIREMENTS

AUTH: 37-7-1401, MCA
IMP: 37-7-1401, 37-7-1405, MCA

REASON: See reason for ARM 24.174.1506.

24.174.1508 HANDLING FEE

AUTH: 37-7-1401, MCA
IMP: 37-7-1401, 37-7-1405, MCA

REASON: The board is repealing this rule to consolidate the fee into ARM 24.174.1506.

24.174.1509 PHARMACY OR FACILITY REGISTRY

AUTH: 37-7-1401, MCA
IMP: 37-7-1401, 37-7-1403, MCA

REASON: The board is repealing this rule to consolidate and simplify into ARM 24.174.1501.

24.174.1510 INSPECTIONS AND TERMINATION FROM PROGRAM

AUTH: 37-7-1401, MCA
IMP: 37-7-1401, MCA

REASON: The board is repealing this rule as it was consolidated into ARM 24.174.1501.

24.174.1601 MEDICAL ASSISTANCE PROGRAM PURPOSE

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

REASON: The board is repealing this rule as unnecessary repetition of statute, 37-7-201, MCA.

24.174.1602 REPORTING OF SUSPECTED IMPAIRMENT

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

REASON: The board is repealing this rule as unnecessary repetition of statute, 37-7-201, MCA.

24.174.1607 REPORTING TO THE BOARD

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

REASON: The board is repealing this rule as unnecessary, as the reporting requirements are in ARM 24.174.1604, 24.174.1605, and 24.174.1606, and covered by the contract with the assistance program.

24.174.1608 PARTICIPANT DISCHARGE REQUIREMENTS

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

REASON: The board is repealing this rule as unnecessary after moving the discharge reporting requirements to ARM 24.174.1604, which already contained the program's reporting requirements to the board.

24.174.1609 RELAPSE REPORTING

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

REASON: The board is repealing this rule as unnecessary. The assistance program's contract requires monitoring of licensees. Spelling out the requirements for the handling of relapses takes away from the professional judgment of the monitoring program and does not allow for individual circumstances of the monitored licensees.

24.174.1703 ELECTRONIC FORMAT REQUIRED FOR THE TRANSMISSION OF INFORMATION

AUTH: 37-7-1512, MCA
IMP: 37-7-1503, 37-7-1512, MCA

REASON: See reason for ARM 24.174.1702.

24.174.1704 REQUIREMENTS FOR SUBMITTING PRESCRIPTION REGISTRY INFORMATION TO THE BOARD

AUTH: 37-7-1512, MCA
IMP: 37-7-1503, 37-7-1512, MCA

REASON: See reason for ARM 24.174.1702.

24.174.1705 FAILURE TO REPORT PRESCRIPTION INFORMATION

AUTH: 37-1-319, 37-7-1512, MCA
IMP: 37-1-312, 37-7-1513, MCA

REASON: The board is incorporating this rule into its unprofessional conduct rule, ARM 24.174.2301.

24.174.1713 RELEASE OF PRESCRIPTION DRUG REGISTRY INFORMATION TO OTHER ENTITIES

AUTH: 37-7-1512, MCA
IMP: 37-7-1506, MCA

REASON: The board is repealing this rule as duplicating 37-7-1506(3), MCA. The board is further repealing this rule as it has not historically charged a fee for these uncomplicated reports.

24.174.1715 INTERSTATE EXCHANGE OF REGISTRY INFORMATION

AUTH: 37-7-1512, MCA
IMP: 37-7-1506, MCA

REASON: The board is repealing this rule as it duplicates 37-7-1506(1)(g), MCA.

6. Concerned persons may present their data, views, or arguments at the hearing. Written data, views, or arguments may also be submitted at dli.mt.gov/rules or P.O. Box 1728, Helena, Montana 59624. Comments must be received no later than 5:00 p.m., August 23, 2024.

7. An electronic copy of this notice of public hearing is available at dli.mt.gov/rules and rules.mt.gov.

8. The agency maintains a list of interested persons who wish to receive notices of rulemaking actions proposed by the agency. Persons wishing to have their name added to the list may sign up at dli.mt.gov/rules or by sending a letter to P.O. Box 1728; Helena, Montana 59624 and indicating the program or programs about which they wish to receive notices.

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

10. Pursuant to 2-4-111, MCA, the agency has determined that the rule changes proposed in this notice will not have a significant and direct impact upon small businesses.

11. Department staff has been designated to preside over and conduct this hearing.

BOARD OF PHARMACY, JEFF NIKOLAISEN, CHAIR

/s/ JENNIFER STALLKAMP
Jennifer Stallkamp
Rule Reviewer

/s/ SARAH SWANSON
Sarah Swanson, Commissioner
DEPARTMENT OF LABOR AND INDUSTRY

Certified to the Secretary of State July 16, 2024.