MONTANA
ADMINISTRATIVE
REGISTER

BOARD OF PHARMACY
DEPARTMENT OF LABOR AND INDUSTRY

NOTICE OF PROPOSED RULEMAKING

MAR NOTICE NO. 2025-174.1

Summary

Implementing House Bills (HB) 246, 414, and 794 and Senate Bill (SB) 456

Hearing Date and Time

Friday, October 31, 2025, at 11:00 a.m.

Virtual Hearing Information

A public hearing will be held via remote conferencing to consider the proposed changes to the agency's rules. There will be no in-person hearing. Interested parties may access the remote conferencing platform in the following ways:

Join Zoom Meeting: https://mt-gov.zoom.us/j/81718023198

Meeting ID: 817 1802 3198; Password: 1487061148

Dial by Telephone: +1 646 558 8656

Meeting ID: 817 1802 3198; Password: 1487061148

Comments

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 by Friday, November 7, 2025, at 5:00 p.m.

Accommodations

The agency will make reasonable accommodations for persons with disabilities who wish to participate in this rulemaking process or need an alternative accessible format of this notice. Requests must be made by Friday, October 24, 2025, at 5:00 p.m.

Contact

Department of Labor and Industry
(406) 444-5466
laborlegal@mt.gov
Montana Relay: 711

General Reasonable Necessity Statement

The Board of Pharmacy is implementing several bills passed by the 2025 Legislature. The 2025 Legislature passed House Bills 246, 414, and 794 and Senate Bill 456. HB 246 amends the definition of substantial equivalency for licensing purposes and requires boards to review and adopt standards for substantial equivalency.

HB 414 standardizes licensing terms for provisional and temporary licenses across all licensing boards. The board is updating its technician licensing requirements to comply with the passage of HB 414 and clarifying provisional licensing for pharmacy technicians under the age of 18.

HB 794 amends the pharmacy practice act, repealing requirements that pharmacies using technicians file utilization plans and changes with the board, incorporating the amended definition of wholesale distribution regarding the four distributor license types, allowing for nonpharmacy facilities to dispense medical devices, and modernizing language.

SB 456 amended the medical practitioner dispensing statutes. More specific reasonable necessity statements follow the rules.

Rulemaking Actions

AMEND

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

24.174.301 DEFINITIONS

(1) "Airborne particulate cleanliness classification" means the level of cleanliness defined by the maximum allowable number of particles per cubic meter of air as specified in the International Organization of Standardization (ISO) "Classification of Air Cleanliness" (ISO 14644-1) for Class 5, Class 7, and Class 8.

(a) ISO Class 5 is an atmospheric environment that contains less than 3,520 particles 0.5 microns in diameter per cubic meter of air;

(b) ISO Class 7 is an atmospheric environment that contains less than 352,000 particles 0.5 microns in diameter per cubic meter of air; and

(c) ISO Class 8 is an atmospheric environment that contains less than 3,520,000 particles 0.5 microns in diameter per cubic meter of air.

(2) "Beyond use date" (BUD) means the date after which the preparation may not be dispensed or administered to a patient. BUD also means expiration date.

(3) "Biological safety cabinet" means a ventilated cabinet with an inward airflow for personnel protection; a downward, High Efficiency Particulate Arresting (HEPA) filtered, laminar airflow for product protection; and HEPA filtered exhaust system for environmental protection.

(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.

(6) "Class 100 environment" means an atmospheric environment which contains fewer than 100 particles 0.5 microns in diameter per cubic foot of air, according to Federal Standard 209E.

(7) "Clean room" means 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.

(10) "Compounded sterile preparation" (CSP) means:

(a) a preparation prepared according to the manufacturer's labeled instructions and other manipulations when preparing sterile products that expose the original contents to potential contamination, and includes all preparations compounded in a sterile environment; or

(b) a preparation containing nonsterile ingredients or employing nonsterile components and devices that must be sterilized before administration.

(11) "Cytotoxic" means a pharmaceutical agent capable of killing living cells.

(12) "DEA" means the Drug Enforcement Administration of the United States Department of Justice.

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

(14) "Device" is defined in ~~37-2-101,~~ 37-7-101, MCA~~, and is required under federal law to bear the label "Caution: Federal law requires dispensing by or on the order of a physician" or "Rx only."~~

(15) "Drug kit" means a secured kit stored outside of a pharmacy containing those drugs which may be required to meet the short-term therapeutic need of patients within an institution not having an in-house pharmacy or 24-hour access to dispensing services, and which would not be available from any other authorized source in

sufficient time, and without which would compromise the quality of care of the patient.

(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 a facility and shall be considered a prescription.

(17) "Drug room" means a secure, lockable temperature-controlled location within a facility that does not have an institutional pharmacy and which contains drugs and devices for administration to patients within the facility pursuant to a valid drug order.

(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.

(19) "Electronic signature" means a confidential personalized method of affixing a signature to an electronic document that will guarantee the identity of the prescriber.

(20) "Emergency drug cart" or "crash cart" means a secure lockable cart or container in an inpatient setting that stores drugs and devices necessary to meet the immediate therapeutic needs of a patient and which cannot be obtained from any other authorized source in sufficient time to prevent harm.

(21) "Facility" means an outpatient center for surgical services, a hospital and/or long-term care facility, or a home infusion facility.

(22) "Floor stock" means prescription drugs not labeled for a specific patient, which are maintained at a nursing station or other hospital department other than the pharmacy, and which are administered to patients within the facility pursuant to a valid drug order. Floor stock shall be maintained in a secure manner pursuant to written policies and procedures, which shall include, but not be limited to, automated dispensing devices.

(23) "Formulary" means a current compilation of pharmaceuticals authorized for use within the institution by representatives of the medical staff and pharmacy department.

(24) "Home infusion facility" means a facility where parenteral solutions are compounded and distributed to outpatients for home infusion pursuant to a valid prescription or drug order.

(25) "Immediate use" means a preparation compounded pursuant to the conditions in ARM ~~24.174.1121~~ 24.174.841 and whose administration must begin within one hour of preparation.

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

(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.

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

(30) "Laminar airflow hood" (LAF) means a workspace where the work surface is subjected to a constant HEPA filtered airflow that is directed towards the user.

(31) "Long-term care facility" has the same meaning as provided in 50-5-101, MCA, and means a facility or part of a facility that provides skilled nursing care, residential care, intermediate nursing care, or intermediate developmental disability care to a total of two or more individuals, or that provides personal care.

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

(33) "Medical gas distributor" is a person engaged in the manufacture, processing, packaging, labeling, or wholesale distribution, as defined in 37-7-602, MCA, of a medical gas to a person other than a consumer or patient.

(34) "Medical gas supplier" is a person engaged in selling, transferring, dispensing, or delivering to a patient or a patient's agent one or more doses of medical gas in the manufacturer's or distributor's original container for subsequent use by the patient.

(35) "Multi-dose vial" means a vial of liquid medication intended for parenteral administration, whether by injection or infusion, that contains more than one dose of medication; is labeled as containing more than one dose of medication by the

manufacturer; and typically contains an antimicrobial preservative to help prevent the growth of bacteria.

(36) "Night cabinet" means a secure locked cabinet or other enclosure located outside the pharmacy, containing drugs which authorized personnel may access in the absence of a pharmacist.

(37) "Nonprescription drug" means a drug which may be sold without a prescription and which is labeled for consumer use in accordance with the requirements of the laws and rules of Montana and the federal government.

(38) "Outpatient center for surgical services" is as defined at 50-5-101, MCA.

(39) "Parenteral" means a sterile preparation of drugs for injection through one or more layers of skin.

(40) "Pharmacist-in-charge" means a pharmacist licensed in Montana who accepts responsibility for the operation of a pharmacy in conformance with all laws and rules pertinent to the practice of pharmacy, who assures that the pharmacy and all pharmacy personnel working in the pharmacy have current and appropriate licensure and certification, and who is personally in full and actual charge of such pharmacy. The pharmacist-in-charge at an out-of-state mail ~~service~~ order pharmacy does not have to be licensed in Montana.

(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.

(42) "Provisional pharmacy" means a pharmacy licensed by the Montana Board of Pharmacy and includes, but is not limited to, federally qualified health centers as defined in 42 CFR 405.2401, where prescription drugs are dispensed to appropriately screened, qualified patients.

(43) "Qualified patients" mean patients who are uninsured, indigent, or have insufficient funds to obtain needed prescription drugs.

(44) "Remote pharmacy" means a licensed pharmacy at which prescriptions may be filled or transmitted to a central hub pharmacy for filling and subsequent delivery to the remote site or the patient's home. Patient counseling by a pharmacist may occur at this site.

(45) "Remote telepharmacy dispensing machine site" means a licensed site containing prescription inventory which is secured in an automated dispensing ~~device~~ machine or system and which has access to its parent pharmacy and ~~registered~~ licensed pharmacists via computer, video, and audio link at all times during business hours.

(46) "Remote telepharmacy site" means a licensed site staffed by a ~~registered~~ licensed pharmacy technician with access to its parent pharmacy and ~~registered~~ licensed pharmacists via computer, video, and audio link at all times during business hours.

(47) "Risk levels for sterile preparations" means the three risk levels of CSP recognized by the United States Pharmacopeia (USP) in USP Chapter 797 "Pharmaceutical Compounding - Sterile Preparations" that are based on the probability of contamination by microbial, chemical, or physical agents. Pursuant to the conditions set forth in ARM ~~24.174.1121~~ 24.174.841, the three risk levels are low-risk, medium-risk, and high-risk.

(48) "Same-day use" means that the administration of the preparation shall commence within 24 hours from the time of preparation.

(49) "Satellite pharmacy" means a specialized inpatient pharmacy staffed by a pharmacist which is adjacent to or near the department served and is connected via computer to the central institutional pharmacy.

(50) "Security" or "secure system" means a system to maintain the confidentiality and integrity of patient records, which are being sent electronically.

(51) "Single-dose vial" means a sterile medication in a vial without preservatives.

(52) "Sterile pharmaceutical" means any dosage form containing no viable microorganisms including, but not limited to, parenterals and ophthalmics.

(53) "Supervising pharmacist" means the ~~registered~~ licensed 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~~ licensed pharmacist.

(55) "Tech-Check-Tech (TCT)" means a program in a community or institutional pharmacy with an endorsement, in which a pharmacy technician or pharmacist intern performs the final check or product verification of medications prepared by another technician or pharmacist intern in compliance with TCT program requirements in ARM 24.174.715.

~~(55)~~(56) "Verification audit" means a comparison and verification of written patient orders with medications removed for that patient.

Authorizing statute(s): 37-7-201, 37-7-602, 50-32-314, MCA

Implementing statute(s): 37-7-101, 37-7-102, 37-7-201, 37-7-301, 37-7-306, 37-7-321, 37-7-406, 37-7-602, 37-7-603, 37-7-604, 37-7-605, 50-32-314, MCA

Reasonable Necessity Statement

The board is amending definitions after the passage of HB 794, which amends the pharmacy practice act. The board is referring to statutory definitions where necessary, and updating language and outdated references in "immediate use" and "risk levels for sterile preparations."

With the addition of a new device license type, the board is updating existing definitions using the term "device" to reduce confusion between the new license type, and the generally understood meaning of device outside the practice of pharmacy.

Due to the changes in technician usage reporting requirements in HB 794, the board is adding a definition of "Tech-Check-Tech" indicating a need for an endorsement and providing notice to the public as to the requirements for a pharmacy to use the "tech-check-tech" program. The board is further updating authorizing and implementation citations.

24.174.401 FEE SCHEDULE

(1) Application for pharmacist licensure transfer - $180.

(2) Pharmacist initial license - $70.

(3) Pharmacist annual renewal fee - $65.

(4) Clinical pharmacist practitioner initial endorsement~~/registration~~ application and annual renewal fee - $25.

(5) Community and institutional pharmacy initial license (includes initial license, change in location, and change in ownership) - $240.

(6) Community and institutional pharmacy annual renewal fee - $150.

(7) Limited service pharmacy facility, (initial license and annual renewal) - $45.

(8) Intern ~~registration~~ license - $50.

(9) Montana NAPLEX examination processing fee (a separate exam fee is paid directly to NABP) - $35.

(10) Montana multistate pharmacy jurisprudence examination (MPJE) exam fee (a separate exam fee is paid directly to NABP) - $25.

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

~~(12)~~(11) Pharmacy technician ~~registration~~ license fee - $35.

~~(13)~~(12) Pharmacy technician renewal fee - $30.

~~(14)~~(13) Wholesale distributor initial license and annual renewal fee - $240.

~~(15)~~(14) Out-of-state mail ~~service~~ order pharmacy initial license and annual renewal fee - $240.

~~(16)~~(15) Certification of grades/transfer of internship hours - $20.

~~(17)~~(16) Outpatient center for surgical services (initial or renewal) - $45.

~~(18)~~(17) Drugs dispensed by a medical practitioner initial registration - $240.

~~(19)~~(18) Drugs dispensed by a medical practitioner annual renewal fee - $150.

~~(20)~~(19) Third-party logistics provider (3PL) initial license and annual renewal fee - $240.

~~(21)~~(20) Repackager initial license and annual renewal fee - $240.

~~(22)~~(21) Manufacturer initial license and annual renewal fee - $240.

~~(23)~~(22) Veterinary retail facility initial license and annual renewal fee - $150.

~~(24)~~(23) Additional standardized fees are specified in ARM 24.101.403.

~~(25)~~(24) The fees to be assessed for ~~registration~~ the endorsement to manufacture, distribute, dispense, conduct research on, or analyze ~~a~~ dangerous drugs (controlled substances) 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)~~(25) The fees for ~~registration~~ the endorsement 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.

(26) Device non-pharmacy facility initial license and annual renewal fee - $240.

Authorizing statute(s): 37-1-134, 37-2-104, 37-7-201, 37-7-604, 37-7-610, 37-18-803, 50-32-314, MCA

Implementing statute(s): 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

Reasonable Necessity Statement

The board is removing the fee for utilization plans for technicians after HB 794 repealed the requirement that utilization plans be filed with the board. The board is also updating the terminology relating to mail order pharmacies after HB 794 passed. Additionally, the board is adding a new license type for non-pharmacy facilities who sell devices, as the term is defined in HB 794.

The board anticipates a loss in revenue from the 309 utilization plans currently on file with the board. At $75 per each renewal, revenue will decline roughly $23,175 to the board, but licensees will save $75 annually. For the new license type, the board anticipates 100 new applicants based on polling existing licensees, for a new revenue of $24,000.

24.174.411 PHARMACIST MEAL/REST BREAKS

(1) In any pharmacy staffed by a single pharmacist, the pharmacist shall take a meal/rest break on the premises for a period of up to 30 minutes per shift without closing the pharmacy and removing support personnel, provided the pharmacist reasonably believes that the security of prescription drugs will be maintained in the pharmacist's absence.

(2) The pharmacist-in-charge shall develop written policies and procedures for operation of the pharmacy in the temporary absence of the pharmacist.

~~(2)~~(3) A sign indicating that no pharmacists is on duty and the ~~The~~ time of the meal/rest break will be conspicuously posted in clear view of patients approaching the prescription area.

~~(3) In the pharmacist's absence a sign indicating that no pharmacist is on duty will be conspicuously displayed in clear view of patients approaching the prescription area.~~

(4) ~~The pharmacist will remain on the premises if the prescription area is to remain open, and be available for emergencies.~~ New prescriptions may be accepted and processed by pharmacy technicians and interns in the pharmacist's absence. These prescriptions may not be dispensed until the pharmacist has performed prospective drug review and completed the final check.

(5) ~~When authorized by the pharmacist, only registered technicians and interns directly involved in the process of filling prescriptions may remain in the prescription department to perform nondiscretionary duties as delineated by the pharmacist.~~ Telephoned new prescriptions may not be accepted in the pharmacist's absence unless identified in the pharmacy's policies and procedures.

(6) ~~Upon returning, the pharmacist shall review any work performed in the pharmacist's absence.~~ At the discretion of the pharmacist, new prescriptions may

be dispensed, provided that the final check has been completed and the prescriptions are waiting to be dispensed, unless counseling is requested by the patient or required by the pharmacist.

(7) ~~In the pharmacist's absence there may be no dispensing of new prescriptions that the pharmacist has checked and that are waiting to be picked up, nor may counseling be provided.~~ At the discretion of the pharmacist, previously checked medication refills may be dispensed in the pharmacist's absence, provided the offer to counsel is made. If the patient requests counseling, the patient may wait for the pharmacist to return or may leave a telephone number for the pharmacist to call upon return.

~~(8) At the discretion of the pharmacist, previously checked medication refills may be handed to patients or their agents by registered technicians in the pharmacist's absence, and the technicians must offer the patient counseling by the pharmacist. If the patient desires counseling, the patient may wait for the pharmacist to return or may leave a telephone number for the pharmacist to call upon return.~~

~~(9) Telephoned new prescriptions must not be accepted by support personnel in the pharmacist's absence.~~

~~(10) New hardcopy prescriptions may be accepted and processed by registered technicians in the pharmacist's absence. These prescriptions may not be dispensed until the pharmacist has performed prospective drug review and completed the final check.~~

~~(11) If two or more pharmacists are on duty, the pharmacists shall stagger their breaks so that the prescription department is not left without a pharmacist on duty.~~

~~(12) The pharmacist-in-charge shall develop written policies and procedures for operation of the prescription department in the temporary absence of the pharmacist.~~

Authorizing statute(s): 37-7-201, MCA

Implementing statute(s): 37-1-101, 37-7-201, MCA

Reasonable Necessity Statement

The board is amending this rule to implement legislative changes in HB 794. HB 794 repealed the requirement of licensees to submit technician utilization plans to the board. As that requirement has gone away, the board is amending this rule to require pharmacies to update internal policies and procedures to describe allowable functions of technicians in the absence of a pharmacist during a meal break.

The board is also amending this rule to address common questions received by the board and inspectors to combine and standardize language for ease of reading.

24.174.503 ADMINISTRATION OF VACCINES BY PHARMACISTS, INTERNS, AND PHARMACY TECHNICIANS

(1) An immunization-certified pharmacist may prescribe and administer those immunizations listed in 37-7-105, MCA, without a collaborative practice agreement in place, as required by the statute.

(2) An immunization-certified pharmacist must have a collaborative practice agreement with a practitioner authorized to prescribe drugs to administer immunizations not listed in 37-7-105, MCA, to persons seven years of age or older, as provided in the most recent guidelines by vaccine and age group published by the U.S. Centers for Disease Control and Prevention (CDC) and as determined within a collaborative practice agreement; or, in the case of a public health emergency, a directive from the State Medical Officer of the Montana Department of Public Health and Human Services.

(3) An immunization-certified pharmacist, as defined in 37-7-101, MCA, shall:

(a) provide a copy of the immunization certificate and current basic cardiopulmonary resuscitation (CPR) certification to the board for initial endorsement on license; and

(b) maintain documentation of immunization endorsement and current CPR certification on file at the practice site.

(4) In order to administer immunizations, with or without a collaborative practice agreement, an immunization-certified pharmacist must meet the requirements of 37-7-105, MCA, and:

(a) administer vaccinations in accordance with established protocol that includes site-specific emergency measures;

(b) have access to a current edition of the CDC reference "Epidemiology and Prevention of Vaccine-Preventable Diseases";

(c) maintain the following:

(i) written policies and procedures for the types of immunizations administered;

(ii) specific description of the procedures, methods, and decision criteria to follow for administering the immunization;

(iii) a detailed description of the procedures and patient activities to follow in the course of administering immunizations;

(iv) training for staff procedures and record keeping requirements; and

(v) disposal of used or contaminated supplies; and

(d) maintain the following information in the patient's medical records as required by 37-7-105, MCA, which shall be considered confidential information:

(i) the patient's name, address, allergies, and date of birth;

(ii) the product's name, dose, manufacturer, lot number, and expiration date;

(iii) the date of administration;

(iv) the site and route of administration; and

(v) the administering pharmacist's name or identifiable initials and the pharmacy's address.

(5) An immunization-certified pharmacist may delegate the administration of immunizations to a pharmacy intern or a pharmacy technician under the direct supervision of the pharmacist upon meeting the 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.~~ Verification and compliance of requirements listed in this rule, including certification, recordkeeping, and collaborative practice agreements, must be available for inspection by the board.

Authorizing statute(s): 37-7-201, MCA

Implementing statute(s): 37-7-101, 37-7-105, 37-7-201, MCA

Reasonable Necessity Statement

HB 794 clarifies the board's inspection authority. The board is moving the review and verification of certification and recordkeeping requirements from the department's audit unit

to the board's inspectors to take advantage of the inspectors' subject matter expertise, and to allow for discussion with inspectors and more immediate addressing of concerns.

24.174.526 CLINICAL PHARMACIST PRACTITIONER QUALIFICATIONS AND REQUIREMENTS

(1) An applicant for a clinical pharmacist practitioner ~~registration~~ endorsement shall:

(a) submit an application on a form prescribed by the board for approval by the board and the Board of Medical Examiners (BME);

(b) pay a required ~~registration~~ endorsement fee and annual renewal fee;

(c) hold an active, unrestricted Montana pharmacist license;

(d) have completed the years of clinical practice experience that meet the requirements for Board of Pharmacy Specialties (BPS) certification or other equivalent national certification, and hold one of the following active certifications:

(i) BPS certification; or

(ii) nationally recognized certification equivalent to BPS certification standards in an area of practice as approved by the board and ~~the Board of Medical Examiners (~~BME~~)~~.

(e) submit a signed collaborative practice agreement with the application to the board that includes a description of the type of supervision the collaborating practitioner will exercise over the clinical pharmacist practitioner; and

(f) ~~following approval of the board, submit the application and collaborative practice agreement to the BME for approval; and~~ appear before the board and/or BME if requested.

~~(g) appear before the board and/or BME if requested.~~

(2) Within ten days of discontinuing work under an approved collaborative drug therapy agreement, the pharmacist shall notify the board and the clinical pharmacist practitioner's ~~registration~~ endorsement shall be inactive, until such time as a new application is approved.

(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~~ endorsement.

Authorizing statute(s): 37-7-201, MCA

Implementing statute(s): 37-7-201, 37-7-306, MCA

Reasonable Necessity Statement

HB 794 amends the requirements for clinical pharmacist practitioners (CPP) and indicates that the CPP is an endorsement on the pharmacist's license. The board is therefore amending the rule to reflect technical changes in the bill. The board is further amending the rule to update language to standardize with statute, and for ease of understanding by licensees and the general public.

24.174.701 PHARMACY TECHNICIAN ~~REGISTRATION~~ LICENSE REQUIREMENTS

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

~~(a) be of good moral character;~~

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

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

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

(i) The board recognizes other Montana health care licensing boards as certifying entities for which licensees can assist the pharmacist(s) in administering vaccines, in compliance with state and federal requirements, under the supervision of a pharmacist, pursuant to the following restrictions:

(A) The health care licensee is in good standing with their licensing board and is authorized to administer vaccines under their own scope of practice. The health care licensee does not need a separate pharmacy technician license issued by the board.

(B) The pharmacist(s) is authorized to prescribe, dispense, and administer vaccines, pursuant to 37-7-105, MCA, and ARM 24.174.503, and in compliance with state and federal requirements.

(ii) The ~~technician utilization plan must~~ pharmacy must have policies and procedures to reflect use of health care licensees to assist pharmacists

in administration of vaccines as authorized in (i) and their license must be conspicuously displayed at the pharmacy.

(2) An applicant for ~~registration~~ licensure as a pharmacy technician in this state ~~may apply for a temporary practice permit~~ who is not yet certified, or does not meet the age or training requirements for certification may be issued a certified pharmacy technician provisional license, as authorized by ~~37-1-305, MCA,~~ [HB 414, Chapter 279], valid for two years from the date the ~~permit~~ provisional license was issued or after the applicant is eligible for certification.

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

Authorizing statute(s): 37-1-131, 37-7-201, MCA

Implementing statute(s): 37-1-305, 37-7-101, 37-7-201, MCA

Reasonable Necessity Statement

HB 794 amended the definition of "pharmacy technician" to "means an individual who assists a pharmacist in the practice of pharmacy and performs tasks delegated to the technician by a pharmacist that do not require a pharmacist's independent professional judgment." HB 794 also repealed the requirement that a pharmacy submit a technician utilization plan or changes to the board. The proposed amendments to the rules in subchapter 7 incorporate delegation of duties and use of technicians into a facility's policies and procedures as a replacement to the previous details and restrictions of technician utilization plans. Policies and procedures for how a technician will be utilized can be customized by a facility's scope of practice and based on the education, competencies, and training of the pharmacy technician staff, pursuant to supervision by a pharmacist.

HB 414 standardized terminology relating to provisional licensure, and the board is updating the provisional licensure for technicians accordingly. The board is further amending the rule to reflect that there is no age restriction under Montana law to get a provisional license but the third party certifying bodies for technicians require an individual to be 18 to sit for the exam and to have completed qualifying training/education courses.

24.174.703 USE AND TRAINING OF PHARMACY TECHNICIANS

(1) A pharmacy technician, as defined in 37-7-101, MCA, may perform tasks as delegated by the supervising pharmacist and may not perform tasks which require the exercise of the pharmacist's independent professional judgment, including but not limited to, patient counseling, drug product selection, drug interaction review or drug regimen review.

(2) An initial training program must include on-the-job practical training and didactic education that is commensurate with the tasks and functions a pharmacy technician may perform. Pharmacy technician training materials must be available for inspection by the board.

~~(2)~~(3) A pharmacy must have policies and procedures directing how a pharmacy technician will be utilized based on the technician's training, experience, education, skills, competencies, and applicable scope of practice. ~~must work under the provisions of a technician utilization plan and the plan~~ The policies and procedures must be made available for inspection by the board.

~~(3)~~(4) When a pharmacist is not in the ~~prescription department~~ pharmacy, ~~there shall be no dispensing of new prescriptions that the pharmacist has checked and that are waiting to be picked up, nor shall counseling be provided by the pharmacy technician~~ new prescriptions may be dispensed, provided that the final check has been completed and the prescriptions are waiting to be dispensed, unless counseling is requested by the patient or required by the pharmacist. Pharmacy technicians may not provide counseling.

~~(4)~~(5) No medication may be ~~released~~ dispensed to a patient without review by a ~~registered~~ pharmacist for the accuracy and appropriateness of the prescription drug order.

(6) All compounded medications must be verified by the supervising pharmacist including but not limited to checking: the original order, additives, dosages, and clarity of IV solution, where appropriate.

~~(5)~~(7) All pharmacy technicians and auxiliary staff shall be made visually identifiable by name and job title utilizing letters of 16 point or larger on a name badge.

(8) All pharmacy technicians must properly identify themselves as a pharmacy technician when they answer the telephone, accept verbal prescription orders for new or refill prescriptions from medical practitioners with prescriptive authority or their designated agents, and initiate refill requests to a prescriber. Delegated activities related to pharmacy technicians accepting verbal prescription orders or initiating refill requests must be outlined in the policies and procedures.

~~(6)~~(9) All pharmacy technician licenses must be conspicuously displayed at all times in the place of business.

(10) Pursuant to ARM 24.174.411, regarding pharmacist meal/rest breaks, a pharmacy technician may act as agent in charge of the pharmacy to ensure its integrity when

a licensed pharmacist is not physically present but remains on the premises. The pharmacy technician may not perform any duties which require the exercise of the pharmacist's independent professional judgment. The technician may not be left in charge for more than 30 minutes.

Authorizing statute(s): 37-7-201, MCA

Implementing statute(s): 37-7-101, 37-7-201, 37-7-301, ~~37-7-307,~~ MCA

Reasonable Necessity Statement

See the REASON for ARM 24.174.701.

24.174.711 RATIO OF PHARMACY TECHNICIANS AND INTERNS TO SUPERVISING PHARMACISTS

(1) The ratio of pharmacy technicians to pharmacist(s) on duty is to be determined by the pharmacist-in-charge. A pharmacist intern does not count against the pharmacist to pharmacy technician ratio.

(2) The pharmacist-in-charge will ensure that the number of pharmacy technicians on duty can be satisfactorily supervised by the pharmacist(s) on duty to ensure patient safety and a safe work environment, provided:

(a) in the professional judgment of the pharmacist on duty, the ratio and supervision of pharmacy technicians is adequate and manageable based on the technician's scope of practice, training, education, skill and experience, the policy and procedures of the pharmacy must allow for safe and accurate filling and labeling of prescriptions, and the ratio must be assessed with regard to the pharmacy's quality assurance program , pursuant to ARM 24.174.407;

(b) ~~a technician utilization plan, as described in ARM 24.174.712, must include the policy~~ the pharmacy's policies and procedures ~~and~~ shall be reviewed annually. All affected supervising pharmacists and pharmacy technicians must be familiar with the contents and ~~any changes made must be reported to the board; and~~ the policies and procedures must be available for inspection by the board.

~~(c) a copy of the policy and procedures must be available for inspection by the board.~~

~~(3) No pharmacy shall modify a board-approved technician utilization plan without the prior written approval of the board.~~

Authorizing statute(s): 37-7-201, MCA

Implementing statute(s): 37-7-101, 37-7-201, ~~37-7-307, 37-7-308, 37-7-309,~~ MCA

Reasonable Necessity Statement

See the REASON for ARM 24.174.701.

24.174.715 ~~TECHNICIAN~~ TECH-CHECK-TECH~~NICIAN~~ PROGRAM

(1) ~~To participate in a technician check technician (TCT) program an institutional pharmacy within a hospital must meet the following requirements:~~ To participate in a TCT program, a pharmacy must be licensed by the board as an institutional pharmacy or a community pharmacy and must submit an application for an endorsement on the pharmacy's license, renew the endorsement annually, and submit a description of the types of services that will be provided through the TCT program. There is no cost for the endorsement.

~~(a) the pharmacy must include TCT as a technician duty, submitted to the Board of Pharmacy by the pharmacist-in-charge as part of the technician utilization plan;~~

~~(b) develop a site-specific training program tailored to the patient population and medication distribution system;~~

~~(c) designate one pharmacist to be responsible for meeting the TCT program training and validation requirements;~~

~~(d) staffing must be adequate to support a consistent utilization of the TCT program;~~

~~(e) a pharmacist must review all orders against a medication profile containing pertinent clinical information about the patient (allergies, current medication, etc.);~~

~~(f) the medication description on the batch fill list must contain the same description as the labeling on the unit dose package;~~

~~(g) the drug distribution system must be structured so that at least one additional check of dispensed medications is completed prior to administration;~~

~~(h) develop policies and procedures which include a list of the types of work that a technician may check and the types of work that are excluded from being checked by a technician; and~~

~~(i) utilize the TCT program as a tool to redirect pharmacists from distributive tasks to cognitive and patient centered activities.~~

(2) ~~In order to participate in a TCT program a technician must:~~ No medications utilized in a TCT program, as defined in 37-7-101, MCA, may be administered or dispensed to a patient without the prescription drug order or chart order first being reviewed by a licensed pharmacist for clinical evaluation and drug utilization.

~~(a) be a registered pharmacy intern in good standing with the board with at least three months experience in unit dose filling; or~~

~~(b) be a certified pharmacy technician in good standing with the board working full or part time with six months equivalent experience in unit dose filling; and~~

~~(c) complete site specific training in the TCT program.~~

(3) ~~A TCT training program must include:~~ Pursuant to the definition of "pharmacy technician" in 37-7-101, MCA, a pharmacist may delegate tasks to a certified pharmacy technician, a provisional pharmacy technician (not yet certified), or a pharmacist intern through a TCT program who may be used to perform tasks associated with the physical preparation and processing of prescription drug orders or chart orders. In delegating these activities, the supervising pharmacist shall ensure that authorized activities do not include tasks which require a pharmacist's clinical evaluation or independent professional judgment.

~~(a) didactic lecture (or equivalent training with a self-learning packet);~~

~~(b) practical sessions (one-on-one training) which consist of observation of a pharmacist checking a unit dose medication batch and/or cart;~~

~~(c) initial validation (and revalidation if needed); and~~

~~(d) regular quality assurance audits performed quarterly for the first year then every six months thereafter.~~

(4) ~~Approval from the Board of Pharmacy or designee is required prior to program implementation.~~ The TCT program may include a second certified pharmacy technician or a pharmacist intern who verifies the work of the first pharmacy technician (certified or provisional) or pharmacist intern to:

(a) perform final product verification, excluding compounded products;

(b) utilize bar code or other technology to perform verification of each medication product stored in a unit dose cart or automated pharmacy system when such medication will be administered to the patient by a licensed health care professional; and

(c) verify repackaging of medications from bulk to unit dose for administration or dispensing.

(5) ~~If at any time a technician loses their validation, that individual must not function as a TCT until they are retrained and revalidated.~~ For any TCT program, a second verification of work cannot be performed by a provisional pharmacy technician.

(6) ~~All TCT program materials should be readily retrievable for review by the board inspector.~~ The written policies and procedures must identify how technicians will be utilized in a TCT program, describe steps for safe and accurate filling and labeling of prescription drug orders and chart orders, and specifically describe the participating technician's training, education, competencies, and experiences related to the TCT program activities. In addition, the TCT program policies and procedures must:

(a) include and maintain a current record of a technician's training who participates in the TCT program;

(b) reflect current activities and be reviewed annually;

(c) be available for inspection by the board;

(d) include the review of all quality related events or errors with documentation of corrective action measures pursuant to the quality assurance program requirements in ARM 24.174.407; and

(e) identify specific monitoring, review, and quality assurance parameters instituted if high-risk or high-alert medications are used in the TCT program. Additional information is available on the Institute for Safe Medication Practices (ISMP) website at https://home.ecri.org/pages/ismp.

~~(7) Any facility that is not within an institutional pharmacy within a hospital must come before the board.~~

Authorizing statute(s): 37-7-201, MCA

Implementing statute(s): 37-7-101, 37-7-201, 37-7-301, 37-7-307, MCA

Reasonable Necessity Statement

See the REASON for ARM 24.174.301 and 24.174.701.

24.174.803 CHANGE IN LOCATION

(1) Whenever a 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 facility changes its physical location outside of its then existing business location, its original license becomes void and must be surrendered. 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.

Authorizing statute(s): 37-7-201, 37-7-610, 37-7-712, MCA

Implementing statute(s): 37-7-321, 37-7-604, 37-7-605, 37-7-610, 37-7-701, 37-7-702, 37-7-703, 37-7-704, 37-7-706, MCA

Reasonable Necessity Statement

The board is consolidating all facility changes in location into ARM 24.174.803 and ownership changes into ARM 24.174.804. This amendment further updates outdated language for mail order pharmacies in ARM 24.174.1004 to refer to ARM 24.174.803 and 24.174.804, and repeals of ARM 24.174.1005. For wholesale drug distributors, ARM 24.174.1207 is amended to refer to ARM 24.174.803 and 24.174.804, and ARM 24.174.1208 is repealed.

The board is also updating authorizing and implementing citations to note the changes from HB 794.

24.174.804 CHANGE IN OWNERSHIP

(1) When a pharmacy, or other facility licensed by the board, changes ownership, 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, or as soon as change in ownership information is available. 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) A change in ownership for the purposes of this rule shall be deemed to occur when more than 50 percent of the equitable ownership of a business is transferred in a single transaction or in a related series of transactions to one or more persons or any other legal entity.

(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.

(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.

Authorizing statute(s): 37-7-201, 37-7-610, MCA, 37-7-712, MCA

Implementing statute(s): 37-7-201, 37-7-321, 37-7-604, 37-7-605, 37-7-610, 37-7-701, 37-7-702, 37-7-703, 37-7-704, 37-7-706, MCA

Reasonable Necessity Statement

See the reason for ARM 24.174.803. The board is further amending this rule based on questions from licensees based on corporate ownership changes that are not public 30 days prior to such a change.

24.174.823 CENTRALIZED FILLING AND REMOTE ORDER PROCESSING OF PRESCRIPTIONS IN COMMUNITY PHARMACIES

(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)~~(6); 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 filling or processing to another pharmacy shall, prior to outsourcing a prescription:

(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) provide the name of the pharmacy that will be filling or processing the prescription or, if the pharmacy is part of a network of pharmacies under common ownership and any of the network pharmacies may fill or process the prescription, the patient shall be notified of this fact; and

(c) clearly show the name, address, and telephone number of the delivering pharmacy on the prescription container.

(3) Each pharmacy engaging in centralized prescription processing shall be jointly responsible for properly filling the prescription.

(4) The delivering pharmacy is responsible for providing patient counseling. All central filling of prescriptions must be completed in a licensed pharmacy.

(5) Pharmacies providing central processing or central filling services to pharmacies in the state of Montana must be licensed in Montana.

(6) An out-of-state pharmacy providing central processing or central filling services to pharmacies in the state of Montana must be ~~registered~~ licensed as an out-of-state mail ~~service~~ order pharmacy and comply with all Montana statutes and rules.

(7) Policies and procedures relating to centralized filling or processing activities shall be maintained at all pharmacies involved in centralized filling or processing and shall be available for inspection by the board. The policies and procedures shall:

(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.

Authorizing statute(s): 37-7-201, MCA

Implementing statute(s): 37-7-201, 37-7-321, MCA

Reasonable Necessity Statement

The board is amending this rule to correct a renumbering error missed in 2024. The board is further amending this rule to update terminology referring to mail order pharmacies after the passage of HB 794.

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~~;~~. A pharmacy technician may initiate the transfer if reflected in the pharmacy's policies and procedures; 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.

(3) The receiving pharmacy shall maintain documentation including:

(a) a notation that the prescription was received by transfer;

(b) the date on which the prescription was written;

(c) the original prescription number of the transferred prescription;

(d) the original number of refills, number of refills or quantity remaining, and the date of the most recent refill;

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

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

(g) a record of each prescription transferred.

(4) 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) 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 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.

Authorizing statute(s): 37-7-201, MCA

Implementing statute(s): 37-7-201, MCA

Reasonable Necessity Statement

The board is amending this rule to reflect changes in HB 794, including that a pharmacy technician may initiate transfers if the policies and procedures allow for such duties.

24.174.1001 ~~REGISTRATION~~ LICENSURE OF OUT-OF-STATE MAIL ~~SERVICE~~ ORDER PHARMACIES

(1) No out-of-state pharmacy shall ship, mail, or deliver prescription drugs and/or devices to a patient in this state unless ~~registered~~ licensed in the home-state location and by the Montana Board of Pharmacy.

(2) As conditions of licensure, the out-of-state mail order pharmacy must comply with the following:

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

(b) be registered and in good standing with the National Association of Boards of Pharmacy Digital Pharmacy Accreditation program, if applicable and if eligible based on offering at least one interactive pharmacy practice component;

(c) maintain, in readily retrievable form, records of legend drugs and/or devices dispensed to Montana patients;

(d) supply upon request, all information needed by the Montana Board of Pharmacy to carry out the board's responsibilities under the statutes and regulations pertaining to out-of-state mail order pharmacies, including information on the use of pharmacy technicians;

(e) maintain pharmacy hours that permit the timely dispensing of drugs to Montana patients and provide reasonable access for the Montana patients to consult with a licensed pharmacist about such patients' medications; and

(f) provide toll-free telephone communication consultation between a Montana patient and a pharmacist at the pharmacy who has access to the patient's records, and ensure that the telephone number(s) will be placed upon the label affixed to each drug or device container or in the educational materials included with the product. A toll-free telephone number shall also be provided to the board to allow for compliance with all information requests by the board.

Authorizing statute(s): 37-7-712, MCA

Implementing statute(s): 37-7-703, MCA

Reasonable Necessity Statement

HB 794 amends the terminology of “out-of-state mail service pharmacy” to “out-of-state mail order pharmacy.” This is reflected throughout the mail order pharmacy rules, ARM 24.174.1001 through 24.174.1009. The board is further amending and consolidating mail order pharmacy rules for simplification and ease of reading, repealing an outdated reference to VIPPS, and adding new language to reference devices.

24.174.1003 IDENTIFICATION OF PHARMACIST-IN-CHARGE OF DISPENSING TO MONTANA

(1) Each out-of-state mail ~~service~~ order pharmacy that ships, mails, or delivers prescription drugs ~~and/~~or devices and oversees the pharmacy services provided to patients in Montana shall identify a pharmacist-in-charge of dispensing

prescriptions for shipment to Montana and oversee the pharmacy services provided. Each pharmacist so identified shall meet the following requirements:

(a) be licensed in good standing in the state in which the out-of-state mail ~~service~~ order pharmacy is located;

(b) be properly listed on the application form prescribed by the board;

(c) comply with all applicable Montana laws and rules; and

(d) notify the Montana board promptly in writing of any changes in the licensure status of the pharmacist-in-charge and any disciplinary actions initiated and/or finalized against the pharmacist's license.

(2) When the pharmacist-in-charge of an out-of-state mail ~~service~~ order pharmacy ceases to be the pharmacist-in-charge, the pharmacist will be held responsible for notifying the board in writing of such termination of services.

(3) Within ~~72 hours~~ ten 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.

Authorizing statute(s): 37-7-201, 37-7-712, MCA

Implementing statute(s): 37-7-101, 37-7-201, 37-7-703, MCA

Reasonable Necessity Statement

HB 794 amends the terminology of "out-of-state mail service pharmacy" to "out-of-state mail order pharmacy." This is reflected throughout the mail order pharmacy rules, ARM 24.174.1001 through 24.174.1009. The board is further amending and consolidating mail order pharmacy rules for simplification and ease of reading, repealing an outdated reference to VIPPS, and adding new language to reference devices.

The board is amending this rule to allow pharmacies ten days to designate a new pharmacist-in-charge to align with amendments to ARM 24.174.805.

24.174.1004 CHANGE IN LOCATION AND CHANGE IN OWNERSHIP

(1) ~~Whenever a mail service pharmacy changes its physical location outside of its then existing business location, its original license becomes void and must be surrendered. The mail service pharmacy shall submit a new license application for~~

~~the new location at least 30 days before such change occurs.~~ For a facility change in location requirements, see ARM 24.174.803.

(2) For a facility change in ownership requirements, see ARM 24.174.804.

Authorizing statute(s): 37-7-201, 37-7-712, MCA

Implementing statute(s): 37-7-701, 37-7-702, 37-7-703, 37-7-704, 37-7-706, MCA

Reasonable Necessity Statement

See the REASON for ARM 24.174 803.

24.174.1009 COMPLIANCE

(1) Each out-of-state mail ~~service~~ order pharmacy shall comply with the following:

(a) all statutory and regulatory requirements of the state of Montana for controlled substances, including those that are different from federal law or regulation, unless compliance would violate the pharmacy drug laws or regulations of the state in which the pharmacy is located;

(b) all statutory and regulatory requirements of the state of Montana regarding drug product selection laws, unless compliance would violate the laws or regulations of the state in which the pharmacy is located;

(c) labeling of all prescriptions dispensed, to include but not be limited to identification of the product and quantity dispensed;

(d) all the statutory and regulatory requirements of the state of Montana for dispensing prescriptions in accordance with the quantities indicated by the prescriber, unless compliance would violate laws or regulations of the state in which the pharmacy is located.

Authorizing statute(s): 37-7-712, MCA

Implementing statute(s): 37-7-701, 37-7-703, MCA

Reasonable Necessity Statement

See the REASON for ARM 24.174.1001.

24.174.1201 WHOLESALE DISTRIBUTOR AND THIRD-PARTY LOGISTICS PROVIDER LICENSING

(1) Every person ~~engaged in wholesale distribution of drugs or prescription devices, which includes reverse wholesale distribution and medical gases, or engaged as a third-party logistics provider (3PL), as defined in 37-7-602, MCA, shall be licensed annually by the board~~ seeking licensure as a wholesale distributor or third-party logistics provide (3PL), as defined in 37-7-602, MCA, must be licensed annually by the board for the purposes of wholesale distribution, as defined in 37-7-602, MCA. The licensure requirement includes those engaged in wholesale distribution of drugs or prescription devices, reverse whole distribution, and medical gases. Each applicant shall:

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

(b) file an application on a form prescribed by the board;

(c) pay the appropriate licensing and ~~registration~~ annual renewal fees;

(d) meet the requirements of 37-7-604, MCA; and

(e) designate a person-in-charge of the facility and for purposes of meeting requirements of 37-7-611, MCA, regarding a criminal background check at time of initial licensure or any change in person-in-charge, complete the requirements included on a form prescribed by the board.

(i) The person-in-charge must notify the board of any changes or termination of services.

(ii) Within 30 days of termination of services, a new person-in-charge must be designated in writing on the appropriate board-approved forms and filed with the board.

(2) The board will independently verify the applicant's standing through the National Practitioner Data Bank (NPDB) and National Association of Boards of Pharmacy Clearinghouse.

(3) The license shall be posted in a conspicuous place in the wholesaler's place of business for which it is issued.

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

(5) Wholesale distributors located in Montana, applying for initial licensure, shall pass an inspection by a pharmacy inspector or other agent of the Board of Pharmacy before a license is issued.

(6) A separate license is required for each separate location, in-state and/or out-of-state, where drugs or devices are stored and directly distributed to Montana.

(7) ~~Wholesale distributors~~ Licensees shall operate in compliance with applicable federal, state, and local laws and regulations. ~~Wholesale distributors~~ Licensees who distribute controlled substances shall ~~register with~~ be licensed by the board, to obtain an appropriate dangerous drug endorsement, and register with the DEA.

(8) Wholesale distributors shall submit proof of surety bond upon initial licensure and at time of renewal as identified on forms prescribed by the board in compliance with state and federal requirements.

Authorizing statute(s): 37-7-201, 37-7-610, MCA

Implementing statute(s): 37-7-603, 37-7-604, 37-7-605, 37-7-606, 37-7-611, 37-7-612, MCA

Reasonable Necessity Statement

HB 794 amended the definition of "wholesale distribution" that includes the board's four facility license types. The board is updating these rules to reflect the amended definition, and to align with the statutory term "license" rather than registration.

24.174.1202 MANUFACTURER AND REPACKAGER LICENSING

(1) Every person seeking licensure ~~or renewa~~l as a manufacturer or repackager, for the purposes of wholesale distribution, as defined in 37-7-602, MCA, shall:

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

(b) file an application on a form prescribed by the board;

(c) pay the appropriate licensing and ~~registration~~ annual renewal fees;

(d) meet the requirements of 37-7-604, MCA; and

(e) designate a person-in-charge of the facility.

(i) The person-in-charge must notify the board of any changes or termination of services.

(ii) Within 30 days of termination of services, a new person-in-charge must be designated in writing on the appropriate board-approved forms and filed with the board.

(2) The board will independently verify the applicant's standing through the National Practitioner Data Bank (NPDB) and National Association of Boards of Pharmacy Clearinghouse.

(3) The license shall be posted in a conspicuous place in the place of business for which it is issued.

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

(5) Applicants located in Montana, applying for initial licensure, shall pass an inspection by a pharmacy inspector or other agent of the Board of Pharmacy before a license is issued.

(6) A separate license is required for each separate location where drugs or devices are stored, repackaged, and/or directly distributed to Montana. For manufacturers, a license shall be issued to a facility meeting the requirements that is located in Montana.

(7) Licensees shall operate in compliance with applicable federal, state, and local laws and regulations. Licensees who distribute controlled substances shall ~~register with~~ <u>be licensed by</u> the board, obtain an appropriate dangerous drug endorsement, register with the DEA, and shall comply with all applicable state, local, and DEA regulations.

Authorizing statute(s): 37-7-201, 37-7-610, MCA

Implementing statute(s): 37-7-201, 37-7-604, 37-7-605, 37-7-610, MCA

Reasonable Necessity Statement

See the REASON for ARM 24.174.1201.

24.174.1204 MEDICAL GAS DISTRIBUTOR

(1) Every person engaged in the manufacture or distribution of medical gases other than to the consuming public or a patient, in the state of Montana, shall ~~register annually with~~ be licensed by the board. Each applicant shall:

(a) if a medical gas manufacturer, provide proof of registration with the Food and Drug Administration (FDA) as a medical gas manufacturer ~~and~~, comply with all FDA requirements, and be licensed by the board as a manufacturer, pursuant to ARM 24.174.1203;

(b) ~~register~~ if a medical gas distributor, be licensed by ~~with~~ the board as a wholesale drug distributor;

(c) file an application ~~to register as a~~ for the medical gas distributor/manufacturer endorsement on a form prescribed by the board; and

(d) pay the appropriate ~~registration~~ endorsement application and annual renewal fees.

(2) The ~~wholesale drug distributor~~ license with the medical gas distributor/manufacturer endorsement shall be posted in a conspicuous place in the ~~wholesaler's~~ licensee's place of business for which it is issued to the wholesaler, manufacturer, or both if in the same location.

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

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

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

Authorizing statute(s): 37-1-134, 37-7-201, 37-7-610, MCA

Implementing statute(s): 37-7-604, 37-7-605, MCA

Reasonable Necessity Statement

HB 794 clarified wholesale distribution authority specific to a manufacturer. Medical gas distributor/manufacturer endorsement is a single endorsement. The board is amending this

rule to distinguish the activity by the license type issued—wholesale drug distributor or manufacturer.

24.174.1205 MEDICAL GAS SUPPLIER

(1) Every person engaged in ~~supplying~~ dispensing medical gases, including associated medical gas supplies, to the consuming public, or to a patient or a patient's agent, in the state of Montana that is not a licensed pharmacy shall ~~register annually with the board~~ obtain a medical gas supplier endorsement. Each applicant shall:

(a) ~~register~~ be licensed by ~~with~~ the board as a wholesale drug distributor;

(b) file an application t~~o register as a medical gas supplier~~ on a form prescribed by the board; and

(c) pay the appropriate ~~registration fee~~ endorsement application and annual renewal fees.

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

(3) A medical gas supplier shall not:

(a) ~~supply~~ dispense prescription medications, except medical gases, without appropriate licensure as a pharmacy;

(b) manufacture or distribute medical gases without appropriate licensure and endorsement as a medical gas distributor; ~~or~~

(c) instruct patients regarding clinical use of equipment, or provide any monitoring, assessment, or other evaluation of therapeutic effects without appropriate licensure as a respiratory care practitioner~~.~~; or

(d) dispense any device that requires a prescription for dispensing that is not a medical gas or medical gas supply, without licensure as a non-pharmacy device facility pursuant to [NEW RULE 1] and [NEW RULE 2].

(4) A medical gas supplier shall ~~supply~~ dispense medical gas only pursuant to prescription order by an authorized prescriber.

(5) A medical gas supplier must label each medical gas container with the name, address, and telephone number of the supplier.

(6) A medical gas supplier shall establish and implement written procedures for maintaining records pertaining to the acquisition and ~~supply~~ dispensing of, and complaints related to, medical gases.

(7) Records shall be retained for at least three years, as required by the FDA, after ~~supply~~ dispensing to a patient or one year after the expiration date of the medical gas, whichever is longer.

(8) Records shall be readily available for ~~review~~ inspection by the board ~~or its inspector~~.

Authorizing statute(s): 37-1-134, 37-7-201, 37-7-610, MCA

Implementing statute(s): 37-7-604, 37-7-605, MCA

Reasonable Necessity Statement

The board is amending this rule after passage of HB 794 related to NEW RULE 1 for devices and related clarifications to the endorsement rather than using the term "register." The board is also taking the opportunity to simplify language and align rule language with statutory language.

24.174.1207 CHANGE IN LOCATION AND CHANGE IN OWNERSHIP

(1) ~~Whenever a facility licensed under this subchapter changes its physical location outside of its then existing business location, its original license becomes void and must be surrendered. The facility shall submit a new license application for the new location at least 30 days before such change occurs.~~ For change in facility location requirements, see ARM 24.174.803.

(2) For change in facility ownership requirements, see ARM 24.174.804.

Authorizing statute(s): 37-7-201, 37-7-610, MCA

Implementing statute(s): 37-7-604, 37-7-605, 37-7-610, MCA

Reasonable Necessity Statement

See the REASON for ARM 24.174.803.

24.174.1801 QUALIFICATIONS FOR DISPENSER REGISTRATION

(1) An applicant for a registration to dispense drugs as a medical practitioner, pursuant to 37-2-104, MCA, shall:

(a) be a licensed medical practitioner as defined in 37-2-101~~(7)~~(8), MCA, or a naturopathic physician as defined in 37-2-101(9), MCA;

(b) be in good standing as that term is defined in this chapter;

(c) complete the application on a form supplied by the board;

(d) pay the required application fee and renewal fee; and

(e) be located in Montana.

(2) The applicant shall:

(a) state each location in Montana at which prescription drugs will be dispensed; and

(b) grant permission to the board to inspect each location at which prescription drugs will be dispensed during the normal business hours.

(3) Registrants must conspicuously display the dispenser license at all times in the place of business for which the license is issued.

Authorizing statute(s): 37-7-201, MCA

Implementing statute(s): 37-2-104, 37-7-201, MCA

Reasonable Necessity Statement

The board is amending this rule to include naturopathic physicians, who were added after the 2023 legislative session.

24.174.1802 DISPENSING REQUIREMENTS

(1) A dispenser registrant shall:

(a) create a written or electronic prescription drug order for each drug dispensed and maintain such information in the patient's chart or record, pursuant to ARM 24.174.831, and 37-7-101(43) and 50-31-307, MCA, which shall include the following, but not be limited to:

(i) patient's name;

(ii) name of drug;

(iii) strength;

(iv) dosage form;

(v) quantity;

(vi) directions for use;

(vii) date of issuance; and

(viii) prescriber's name;

(b) perform in person the final verification check of each drug prior to dispensing that, at a minimum, includes the following:

(i) ensuring the prescription drug product and label match the prescription drug order and the information on the manufacturer's label with respect to drug, dosage form, strength, quantity, and drug identification number;

(ii) verifying the prescription product label matches the prescription drug information with respect to prescription requirements in ARM 24.174.831;

(iii) verifying the drug has not expired and will not expire within the duration of use;

(iv) ensuring the registrant has completed a prospective drug utilization review after reviewing the patient profile; ~~and~~

(v) documenting that the final verification check was completed by the registrant; and

(vi) offer counseling to the patient;

(c) ~~directly~~ prepare, dispense, and deliver the drug, including subsequent fills or refills, ~~in person~~ to their own patient(s) pursuant to the provisions in 37-2-104(2) and 50-31-307, MCA. In addition:

(i) Health care staff members in the office, or place of practice of the registrant, may convey or dispense the drug on behalf of the registrant if:

(A) the drugs are prepared and sealed with two forms of identification written on the package by the registrant; and

(B) the health care staff member verifies the identity of the patient.

(ii) The drug may not be dispensed, conveyed, or delivered by mail or common carrier.

(2) A registrant shall comply with all federal and state statutes and regulations regarding dispensing of prescription drugs, including all requirements for the registrant to:

(a) perform a prospective drug utilization review, pursuant to 37-7-101(17) and 37-7-406, MCA, and ARM ~~24.174.902~~ 24.174.901;

(b) provide patient labeling, pursuant to 37-7-101(14), MCA, and ARM 24.174.301(23), 24.174.832, and 24.174.833, including:

(i) the prescription label shall contain the name, address, and phone number of the registrant, name of patient, name and strength of drug, directions for use, and date of filling;

(ii) the prescription label must be securely attached to the outside of the container in which the drug is dispensed; and

(iii) the registrant shall provide 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;

(c) develop a protocol to manage, store, and secure prescription drug dispensing inventory, pursuant to ARM ~~24.174.301(43),~~ 24.174.814~~, 24.174.818,~~ and 24.174.819, including:

(i) operating in a sanitary manner;

(ii) restricting access only to authorized individuals as determined by the registrant;

(iii) assuring that physical access to prescription drugs for dispensing is denied to all individuals at all times when a registrant is not on the premises, except with regard to dispensing pursuant to 37-2-104(8), MCA;

(d) maintain recordkeeping, pursuant to ARM 24.174.833, with records available for inspection by the board;

(e) compound drug products, including non-sterile and sterile products, pursuant to ARM 24.174.841;

(f) dispense with the offer to provide patient counseling, pursuant to 37-2-104(2), 37-7-101(31), and 37-7-406, MCA, and ARM 24.174.903; and

~~(g) provide notification that the patient may request dispensing of a less expensive therapeutically equivalent generic or interchangeable biologic product pursuant to 37-7-502 and 37-7-506, MCA, if applicable; and~~

~~(h)~~(g) implement and have in place a quality assurance program to detect, identify, and prevent prescription errors, pursuant to ARM 24.174.407.

(3) With regard to inspections by the board or its designee, a registrant shall resolve conditions identified in an inspection report, if applicable.

(4) Prescription drugs dispensed by a registrant may not be transferred to another practitioner or pharmacist for subsequent filling or refills.

Authorizing statute(s): 37-7-201, MCA

Implementing statute(s): 37-2-104, 37-7-201, MCA

Reasonable Necessity Statement

SB 456 allows staff members to provide the dispensed products to patients. The board is amending this rule to include the new language here for clarity and as part of the comprehensive rule. HB 794 removed the requirement for biologic notification to a patient and the requirement for notice to a purchaser for less expensive generic drugs, so the board is repealing that language in rule.

24.174.1803 DISPENSER RECORDKEEPING REQUIREMENTS

(1) A registrant shall keep readily retrievable at each dispensing location records of dispensing and inventory, pursuant to ARM 24.174.833:

(a) a copy of the registrant's dispenser license;

(b) a record of each final verification check by the registrant;

(c) the registrant's protocols for handling drug recalls, including the arrangements for notifying patients;

(d) the registrant's protocols for disposal of drugs;

(e) with respect to a supplier from whom the registrant purchased prescription drugs:

(i) the name, address, and phone number of each wholesale drug distributor supplier, as defined in 37-7-602(8), MCA, and ARM 24.174.1201; and

(ii) documentation including:

(A) for each wholesale ~~drug distributor~~ distribution supplier, the number and the expiration date of the license issued by the board; and

(B) for any pharmacy supplier acting as a wholesale drug distributor, the number and the expiration date of the pharmacy license issued by the board;

(f) any other purchasing, inventory, and dispensing records required by state or federal statutes or regulations;

(g) a manual or electronic dispensing record must be maintained separately from the patient medical record and kept for a minimum of two years. If an electronic health information system, as defined in 37-7-101(22), MCA, is utilized, the system must be able to produce a separate dispensing record; and

(h) the dispensing record must show, at a minimum, the following for original and subsequent fills or refills, in compliance with ARM 24.174.833:

(i) name of patient;

(ii) unique identifier;

(iii) dose, dosage form, quantity dispensed, and either the brand name of drug or generic name and name of manufacturer;

(iv) directions for use;

(v) date of dispensing; and

(vi) initials of registrant dispensing the prescription.

(2) In addition to meeting the requirements of ARM 24.174.1802, the registrant shall comply with any other state or federal law or regulation relating to dispensing of prescription drugs.

(3) Records must be available for inspection by the board.

Authorizing statute(s): 37-7-201, MCA

Implementing statute(s): 37-2-104, 37-7-201, MCA

Reasonable Necessity Statement

The board is amending this rule after the passage of HB 794, which updated the terminology to "wholesale distribution."

ADOPT

The rules proposed to be adopted are as follows:

NEW RULE 1 DEVICE, DURABLE MEDICAL EQUIPMENT, AND MEDICAL GAS SUPPLIER LICENSURE REQUIREMENTS FOR A NON-PHARMACY FACILITY

(1) A facility must obtain a device facility license from the board when the facility exclusively dispenses products that are devices, durable medical equipment (DME), medical gas, including medical gas supplies, directly to a patient in Montana pursuant to a prescription drug order, as defined in 37-7-101, MCA.

(2) If the scope of practice is limited to (1), and does not include the dispensing of prescription drugs, then a device facility license type is sufficient and a separate pharmacy, out-of-state mail-order pharmacy, or wholesale distributor license is not required.

(3) Facilities that comply with (1) and supply medical gas and/or medical gas supplies must apply for a medical gas supplier endorsement.

(4) A device facility must identify a person-in-charge responsible for complying with board laws and regulations. The person-in-charge does not need to be a pharmacist. If a person-in-charge changes, the board must be notified of a new person-in-charge within 30 days.

(5) A device facility must:

(a) submit an application and pay the required application, endorsement, and annual renewal fees as required by the board;

(b) submit with the application a description of the device facility's scope of service, floor plan, security measures, list of device types or categories to be dispensed, list of policies and procedures in place necessary to comply with the provisions listed in [NEW RULE 2(3)], and product storage;

(c) apply for separate licenses to operate, maintain, open, or establish more than one device facility at separate locations;

(d) provide a toll-free telephone number in the information dispensed to a patient to the location that has access to the patient's records. A toll-free telephone number shall also be provided to the board to allow for compliance with all information requests by the board;

(e) comply with board rules related to:

(i) location change, ARM 24.174.803;

(ii) ownership change, ARM 24.174.804;

(iii) license posting, ARM 24.174.806; and

(iv) closure, ARM 24.174.807;

(f) comply with all applicable state and federal laws and regulations.

(6) No license may be issued to any device facility whose intended place of business is a personal residence.

Authorizing statute(s): 37-7-201, MCA

Implementing statute(s): 37-7-101, 37-7-102, 37-7-201, MCA

Reasonable Necessity Statement

The board is proposing this rule after passage of HB 794, which allows for the licensure of non-pharmacy facilities for purposes of selling devices, durable medical equipment, and medical gas suppliers. Since HB 794 indicates these non-pharmacy facilities are separate licenses than pharmacies, the board is using its rulemaking authority in 37-7-201, MCA, to set up the qualifications for licensure.

The board received input from stakeholders and prospective licensees in developing the requirements for the new license type, including requiring submission of a floor plan, security requirements, policies and procedures, expected inventory, and customer service expectations. The board is further establishing requirements for a person in charge, and outlining when a device non-pharmacy license is sufficient or if a facility requires a mail order pharmacy license.

NEW RULE 2 DEVICE NON-PHARMACY FACILITY REQUIREMENTS

(1) In-state device facilities shall be inspected by the board and the board reserves the right to inspect out-of-state device facilities for cause.

(2) Out-of-state device facilities must comply with the following:

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

(b) maintain, in readily retrievable form, records of products dispensed to Montana patients pursuant to a prescription drug order;

(c) supply, upon request, all information needed by the board to carry out the board's responsibilities; and

(d) upon application, provide verification of licensure in the state in which the facility is located and provide the home-state inspection report.

(3) A device facility must establish and implement policies and procedures for compliance with the following and be available upon inspection:

(a) maintaining records pertaining to the acquisition and supply of, and complaints related to, devices, DME, and/or medical gases;

(b) facility security;

(c) product storage and security;

(d) copy of prescription and records of dispensing pursuant to ARM 24.174.833;

(e) labeling of a dispensed product pursuant to ARM 24.174.832 that includes on the device, container, or in the educational information the name, address, and telephone number of the facility;

(f) providing directions and/or educational information to the patient regarding the dispensed product;

(g) procedures for ensuring patient safety for the appropriate patient care, treatment, and service response requirements for devices dispensed to a patient. The device facility must address how it will perform the following functions for a device provided to a patient:

(i) provide all supplies necessary to operate the equipment, and provide information on appropriate storage;

(ii) deliver, unpack, and assemble equipment and perform safety and operational checks for a device;

(iii) adapt, fit, or adjust medical equipment to meet patient need; and

(iv) maintain, inspect, and test medical equipment;

(h) provide emergency maintenance, replacement, or backup of medical equipment when needed; and

(i) for ventilators, life-sustaining infusions, or oxygen, the device facility must provide a backup system, means to provide a duplicate, or a power supply that provides a minimum of three times the licensee's response time to a patient.

Authorizing statute(s): 37-7-201, MCA

Implementing statute(s): 37-7-101, 37-7-102, 37-7-201, MCA

Reasonable Necessity Statement

The board is proposing this rule after passage of HB 794, which allows for the licensure of non-pharmacy facilities for purposes of selling devices, durable medical equipment, and medical gas supplies. Since HB 794 indicates these non-pharmacy facilities are separate licenses than pharmacies, the board is using its rulemaking authority in 37-7-201, MCA, to set up the requirements for facilities wishing to conduct business in Montana. The board received input from stakeholders and prospective licensees in developing the requirements for the facilities, including registration requirements, recordkeeping, and policy and procedure requirements. The board is also proposing inspection requirements and expectations of facilities.

NEW RULE 3 SUBSTANTIAL EQUIVALENCY

(1) The board adopts and incorporates by reference the 2025 substantial equivalency list for the Board of Pharmacy publication. The publication is available on the board's website.

(2) The board intends to review the publication annually. However, failure to review or adopt a new list does not change the effectiveness of the adoption in this rule.

(3) License applications from individuals licensed in substantially equivalent states are routine applications as to the education, examination, and experience requirements for licensure. Applications may be nonroutine on other bases.

Authorizing statute(s): 37-1-131, MCA

Implementing statute(s): 37-1-304, MCA

Reasonable Necessity Statement

The 2025 Montana Legislature passed House Bill 246 which was signed by the Governor April 3, 2025, and will become effective October 1, 2025. The bill standardizes substantial equivalency determinations in professional licensing and eliminates duplicative statutory sections regarding equivalency and reciprocity.

While historically available to applicants licensed in other states or jurisdictions, licensure by substantial equivalency has never been consistent among the professional licensing boards and programs. House Bill 246 creates a standard definition for determining substantial equivalency to be uniformly utilized by all the boards and programs when processing endorsement applications. This will create overall efficiencies in processing endorsement applications and reduce licensing wait times for applicants and employers.

To implement the legislation and further the endorsement licensing process, the board is proposing to adopt NEW RULE 3. The board has compared current licensure standards of the fifty United States for Board of Pharmacy licensees and determined those that are substantially equivalent per the definition in 37-1-302, MCA. This new rule will adopt and incorporate by reference the board's initial approved list of states having substantially equivalent licensing standards. The list will be published on the board's website. The board will analyze other states' licensing standards annually, and update the published list as needed.

REPEAL

The rules proposed to be repealed are as follows:

24.174.704 PHARMACY TECHNICIAN TRAINING

Authorizing statute(s): 37-7-201, MCA

Implementing statute(s): 37-7-201, 37-7-307, MCA

Reasonable Necessity Statement

See the REASON for ARM 24.174.701 and 24.174.703. Necessary provisions of this repealed rule are included in ARM 24.174.703.

24.174.705 TASKS AND FUNCTIONS OF PHARMACY TECHNICIAN

Authorizing statute(s): 37-7-201, MCA

Implementing statute(s): 37-7-101, 37-7-201, 37-7-301, 37-7-307, MCA

Reasonable Necessity Statement

See the REASON for ARM 24.174.701 and 24.174.703. Necessary provisions of this repealed rule are included in ARM 24.174.703.

24.174.712 APPLICATION FOR APPROVAL OF UTILIZATION PLAN

Authorizing statute(s): 37-7-201, MCA

Implementing statute(s): 37-7-201, 37-7-308, 37-7-309, MCA

Reasonable Necessity Statement

See the REASON for ARM 24.174.701.

24.174.713 CONTENTS OF TRAINING COURSE

Authorizing statute(s): 37-7-201, MCA

Implementing statute(s): 37-7-201, 37-7-307, MCA

Reasonable Necessity Statement

See the REASON for ARM 24.174.701.

24.174.714 INSPECTION OF UTILIZATION PLAN AND TRAINING RECORD

Authorizing statute(s): 37-7-201, MCA

Implementing statute(s): 37-7-201, 37-7-308, MCA

Reasonable Necessity Statement

See the REASON for ARM 24.174.701.

24.174.1002 CONDITIONS OF REGISTRATION

Authorizing statute(s): 37-7-201, 37-7-712, MCA

Implementing statute(s): 37-7-701, 37-7-702, 37-7-703, 37-7-704, 37-7-706, MCA

Reasonable Necessity Statement

See the reason for ARM 24.174.1001. The board is repealing this rule after consolidating necessary provisions into ARM 24.174.1001.

24.174.1005 CHANGE IN OWNERSHIP

Authorizing statute(s): 37-7-201, 37-7-712, MCA

Implementing statute(s): 37-7-701, 37-7-702, 37-7-703, 37-7-704, 37-7-706, MCA

Reasonable Necessity Statement

See the REASON for ARM 24.174.803.

24.174.1008 USE OF PHARMACY TECHNICIANS BY OUT-OF-STATE MAIL SERVICE PHARMACIES

Authorizing statute(s): 37-7-712, MCA

Implementing statute(s): 37-7-703, MCA

Reasonable Necessity Statement

The board is repealing this rule after the passage of HB 794, which repeals the requirement for pharmacies to submit utilization plans to the board. The board has also repealed the ratio requirements for technicians, and this rule is therefore unnecessary. ARM 24.174.1001(2)(d) proposes to require the mail order pharmacy to maintain policies and procedures regarding the use of pharmacy technicians.

24.174.1208 CHANGE IN OWNERSHIP

Authorizing statute(s): 37-7-201, 37-7-610, MCA

Implementing statute(s): 37-7-604, 37-7-605, 37-7-610, MCA

Reasonable Necessity Statement

See the REASON for ARM 24.174.803.

Small Business Impact

The board anticipates a loss in revenue from the 309 utilization plans currently on file with the board. At $75 per each renewal, revenue will decline roughly $23,175 to the board, but licensees will save $75 annually. For the new non-pharmacy facility license type, the board anticipates 100 new applicants based on polling existing licensees, for a new revenue of $24,000. Although it is a new license type, existing licensees may opt to move from an existing type to the new type. As the fee for all facility license types is the same, existing licensees will not see a change in costs. New licensees can expect a change of $240 annually.

The board has determined the class of people likely to be affected by these rules changes are people seeking to do business as device non-pharmacy facility sales. The board has set a licensing fee that is commensurate with its other facility costs and reflects the costs to the board in processing the application and issuing the license. The fee is direct, but is not significant.

The board's other proposed changes are necessary to implement legislation, and reflect amendments designed to make existing rules more clear to licensees and the general public, and to ensure public safety while reducing an administrative burden on licensees in submitting technician utilization plans to the board.

Documentation of the small business impact analysis is available upon request.

Bill Sponsor Notification

The primary bill sponsors were contacted by electronic mail for HB 414 on August 14, 2025, HB 794 on May 28, 2025, SB 456 on June 9, 2025, and HB 246 on August 19, 2025.

Interested Persons

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.

Rule Reviewer

Jennifer Stallkamp

Approval

Sarah Swanson, Commissioner

Approval

Jeff Nikolaisen, Pharmacist, Presiding Officer, Board of Pharmacy