MONTANA STATUTES AND RULES COMBINED- updated 5/30/2012

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Laws are represented by dashes (37-7-101) and rules by periods (24.174.301)

Without Wholesaler, designer drug and medical marijuana rules.

DEFINITIONS-STATUTE

37-7-101. Definitions. As used in this chapter, the following definitions apply: (1) (a) "Administer" means the direct application of a drug to the body of a patient by injection, inhalation, ingestion, or any other means.
(b) Except as provided in [section 2], the term does not include immunization by injection for children under 18 years of age.
Section 2. Administration of influenza vaccine. A pharmacist may administer immunization against the influenza virus by injection or inhalation for individuals who are 12 years of age or older.
(2) "Board" means the board of pharmacy provided for in 2-15-1733.
(3) "Cancer drug" means a prescription drug used to treat:
(a) cancer or its side effects; or
(b) the side effects of a prescription drug used to treat cancer or its side effects.
(4) "Chemical" means medicinal or industrial substances, whether simple, compound, or obtained through the process of the science and art of chemistry, whether of organic or inorganic origin.
(5) "Clinical pharmacist practitioner" means a licensed pharmacist in good standing who meets the requirements specified in 37-7-306.
(6) "Collaborative pharmacy practice" means the practice of pharmacy by a pharmacist who has agreed to work in conjunction with one or more prescribers, on a voluntary basis and under protocol, and who may perform certain patient care functions under certain specified conditions or limitations authorized by the prescriber.
(7) "Collaborative pharmacy practice agreement" means a written and signed agreement between one or more pharmacists and one or more prescribers that provides for collaborative pharmacy practice for the purpose of drug therapy management of patients.
(8) "Commercial purposes" means the ordinary purposes of trade, agriculture, industry, and commerce, exclusive of the practices of medicine and pharmacy.
(9) "Compounding" means the preparation, mixing, assembling, packaging, or labeling of a drug or device based on:
(a) a practitioner's prescription drug order;
(b) a professional practice relationship between a practitioner, pharmacist, and patient;
(c) research, instruction, or chemical analysis, but not for sale or dispensing; or
(d) the preparation of drugs or devices based on routine, regularly observed prescribing patterns.
(10) "Confidential patient information" means privileged information accessed by, maintained by, or transmitted to a pharmacist in patient records or that is communicated to the patient as part of patient counseling.
(11) “Controlled substance” means a substance designated n Schedule II through V of Title 50, chapter 32, part 2.
(12)"Department" means the department of labor and industry provided for in Title 2, chapter 15, part 17.
(13) "Device" has the same meaning as defined in 37-2-101.
(14) "Dispense" or "dispensing" means the interpretation, evaluation, and implementation of a prescription drug order, including the preparation and delivery of a drug or device to a patient or patient's agent in a suitable container appropriately labeled for administration to or use by a patient.
(15) "Distribute" means the delivery of a drug or device by means other than administering or dispensing.
(16) "Drug" means a substance:
(a) recognized as a drug in any official compendium or supplement;
(b) intended for use in diagnosis, cure, mitigation, treatment, or prevention of disease in humans or animals;
(c) other than food, intended to affect the structure or function of the body of humans or animals; and
(d) intended for use as a component of a substance specified in subsection (15)(a), (15)(b), or (15)(c).
(17) "Drug utilization review" means an evaluation of a prescription drug order and patient records for duplication of therapy, interactions, proper utilization, and optimum therapeutic outcomes. The term includes but is not limited to the following evaluations:
(a) known allergies;
(b) rational therapy contraindications;
(c) reasonable dose and route administration;
(d) reasonable directions for use;
(e) drug-drug interactions;
(f) drug-food interactions;

(g) drug-disease interactions; and
(h) adverse drug reactions.
(18) "Equivalent drug product" means a drug product that has the same established name, active ingredient or ingredients, strength or concentration, dosage form, and route of administration and meets the same standards as another drug product as determined by any official compendium or supplement. Equivalent drug products may differ in shape, scoring, configuration, packaging, excipients, and expiration time.
(19) "Health care facility" has the meaning provided in 50-5-101.
(20) (a) "Health clinic" means a facility in which advice, counseling, diagnosis, treatment, surgery, care, or services relating to preserving or maintaining health are provided on an outpatient basis for a period of less than 24 consecutive hours to a person not residing at or confined to the facility.
(b) The term includes an outpatient center for primary care and an outpatient center for surgical services, as those terms are defined in 50-5-101, and a local public health agency as defined in 50-1-101.
(c) The term does not include a facility that provides routine health screenings, health education, or immunizations.
(21) "Hospital" has the meaning provided in 50-5-101.
(22) "Intern" means:
(a) a person who is licensed by the state to engage in the practice of pharmacy while under the personal supervision of a preceptor and who is satisfactorily progressing toward meeting the requirements for licensure as a pharmacist;
(b) a graduate of an accredited college of pharmacy who is licensed by the state for the purpose of obtaining practical experience as a requirement for licensure as a pharmacist;
(c) a qualified applicant awaiting examination for licensure; or
(d) a person participating in a residency or fellowship program.
(23) "Long-term care facility" has the meaning provided in 50-5-101.
(24) (a) "Manufacturing" means the production, preparation, propagation, conversion, or processing of a drug or device, either directly or indirectly, by extraction from substances of natural origin or independently by means of chemical or biological synthesis.
(b) Manufacturing includes:
(i) any packaging or repackaging;
(ii) labeling or relabeling;
(iii) promoting or marketing; and
(iv) preparing and promoting commercially available products from bulk compounds for resale by pharmacies, practitioners, or other persons.
(25) "Medicine" means a remedial agent that has the property of curing, preventing, treating, or mitigating diseases or which is used for this purpose.
(26) "Participant" means a physician's office, pharmacy, hospital, or health clinic that has elected to voluntarily participate in the cancer drug repository program provided for in 37-7-1403 and that accepts donated cancer drugs or devices under rules adopted by the board.
(27) "Patient counseling" means the communication by the pharmacist of information, as defined by the rules of the board, to the patient or caregiver in order to ensure the proper use of drugs or devices.
(28) "Person" includes an individual, partnership, corporation, association, or other legal entity.
(29) "Pharmaceutical care" means the provision of drug therapy and other patient care services intended to achieve outcomes related to the cure or prevention of a disease, elimination or reduction of a patient's symptoms, or arresting or slowing of disease process.
(30) "Pharmacist" means a person licensed by the state to engage in the practice of pharmacy and who may affix to the person's name the term "R.Ph.".
(31) "Pharmacy" means an established location, either physical or electronic, registered by the board where drugs or devices are dispensed with pharmaceutical care or where pharmaceutical care is provided.
(32) "Pharmacy technician" means an individual who assists a pharmacist in the practice of pharmacy.
(33) "Poison" means a substance that, when introduced into the system, either directly or by absorption, produces violent, morbid, or fatal changes or that destroys living tissue with which it comes in contact.
(34) "Practice of pharmacy" means:
(a) interpreting, evaluating, and implementing prescriber orders;
(b) administering drugs and devices pursuant to a collaborative practice agreement and compounding, labeling,

dispensing, and distributing drugs and devices, including patient counseling;
(c) properly and safely procuring, storing, distributing, and disposing of drugs and devices and maintaining proper records;
(d) monitoring drug therapy and use;
(e) initiating or modifying drug therapy in accordance with collaborative pharmacy practice agreements established and approved by health care facilities or voluntary agreements with prescribers;
(f) participating in quality assurance and performance improvement activities;
(g) providing information on drugs, dietary supplements, and devices to patients, the public, and other health care providers; and
(h) participating in scientific or clinical research as an investigator or in collaboration with other investigators.
(35) "Practice telepharmacy" means to provide pharmaceutical care through the use of information technology to patients at a distance.
(36) "Preceptor" means an individual who is registered by the board and participates in the instructional training of a pharmacy intern.
(37) "Prescriber" has the same meaning as provided in 37-7-502.
(38) "Prescription drug" means any drug that is required by federal law or regulation to be dispensed only by a prescription subject to section 503(b) of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. 353.
(39) "Prescription drug order" means an order from a prescriber for a drug or device that is communicated directly or indirectly by the prescriber to the furnisher by means of a signed order, by electronic transmission, in person, or by telephone. The order must include the name and address of the prescriber, the prescriber's license classification, the name and address of the patient, the name, strength, and quantity of the drug, drugs, or device prescribed, the directions for use, and the date of its issue. These stipulations apply to written, oral, electronically transmitted, and telephoned prescriptions and orders derived from collaborative pharmacy practice.
(40) "Provisional community pharmacy" means a pharmacy that has been approved by the board, including but not limited to federally qualified health centers, as defined in 42 CFR 405.2401, where prescription drugs are dispensed to appropriately screened, qualified patients.
(41) "Qualified patient" means a person who is uninsured, indigent, or has insufficient funds to obtain needed prescription drugs or cancer drugs.
(42)”Registry” means the prescription drug registry provided for in [section 3].
(43) "Utilization plan" means a plan under which a pharmacist may use the services of a pharmacy technician in the practice of pharmacy to perform tasks that:
(a) do not require the exercise of the pharmacist's independent professional judgment; and
(b) are verified by the pharmacist.
(44) "Wholesale" means a sale for the purpose of resale.

24.174.301 DEFINITIONS-REGULATION

(1) "Biological safety cabinet" means a contained unit suitable for the preparation of low to moderate risk agents and where there is a need for protection of the product, personnel, and environment according to National Sanitation Foundation Standard 49.
(2) "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.
(3) "Clean room" means a room in which the concentration of airborne particles is controlled.
(4) "Contingency kit" means a secured kit 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.
(5) "Cytotoxic" means a pharmaceutical agent capable of killing living cells.
(6) “DEA” means the Drug Enforcement Administration of the United States Department of Justice.
(7) "Deliver" or "delivery" means the actual, constructive, or attempted transfer of a drug or device from one person to another, whether or not for a consideration.

(8) "Device" is defined in 37-2-101, 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."
(9) "Drug order" means a written or electronic order issued by an authorized practitioner, or a verbal order promptly reduced to writing, for the compounding and dispensing of a drug or device to be administered to patients within the facility.
(10) "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.
(11) "Electronic signature" means a confidential personalized method of affixing a signature to an electronic document that will guarantee the identity of the prescriber.
(12) "Emergency drug cart" or "crash cart" means a secure lockable cart containing drugs and devices necessary to meet the immediate therapeutic needs of inpatients or outpatients and which cannot be obtained from any other authorized source in sufficient time to prevent risk or harm or death to patients.
(13) "Emergency kits" are sealed kits containing those drugs which may be required to meet the immediate therapeutic needs of patients within an institution not having an in-house pharmacy, and which would not be available from any other authorized source in sufficient time to prevent risk or harm or death to patients.
(14) "Facility" means an outpatient center for surgical services, a hospital and/or long-term care facility, or a home infusion facility.
(15) "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.
(16) "Formulary" means a current compilation of pharmaceuticals authorized for use within the institution by representatives of the medical staff and pharmacy department.
(17) "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.
(18) "Institutional pharmacy" means that physical portion of an institutional facility where drugs, devices and other material used in the diagnosis and treatment of injury, illness, and disease are dispensed, compounded, and distributed to other healthcare professionals for administration to patients within or outside the facility, and pharmaceutical care is provided.
(19) "Labeling" means the process of preparing and affixing a label to any drug container exclusive, however, of the labeling by a manufacturer, packer, or distributor of a nonprescription drug or commercially packaged legend drug or device. Any such label shall include all information required by federal and Montana law or rule.
(20) "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.
(21) “Medical gas” means any gaseous substance that meets medical purity standards and has application in a medical environment. Examples of medical gases include, but are not limited to, oxygen, carbon dioxide, nitrous oxide, cyclopropane, helium, nitrogen, and air.
(22) “Medical gas distributor” is a person engaged I the manufacture, processing, packaging, labeling, or distribution of a medical gas to a person other than a consumer or patient.
(23) “Medical gas supplier” is a person engaged in selling, transferring, or delivering to a patient or a patient’s agent one or more doses of medical gas in the manufacturer’s or distributor’s original container for subsequent use by the patient.
(24) "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.
(25) "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.
(26) “Outpatient center for surgical services” is as defined in 50-5-101, MCA.
(27) "Parenteral" means a sterile preparation of drugs for injection through one or more layers of skin.
(28) "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 pharmacy does not have to be licensed in Montana.
(29) "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.
(30) "Qualified patients" means patients who are uninsured, indigent, or have insufficient funds to obtain needed prescription drugs.
(31) "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.
(32) "Remote telepharmacy dispensing machine site" means a licensed site containing prescription inventory which is secured in an automated dispensing device and which has access to its parent pharmacy and registered pharmacists via computer, video, and audio link at all times during business hours.
(33) "Remote telepharmacy site" means a licensed site staffed by a registered pharmacy technician with access to its parent pharmacy and registered pharmacists via computer, video, and audio link at all times during business hours.
(34) "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.
(35) "Security" or "secure system" means a system to maintain the confidentiality and integrity of patient records, which are being sent electronically.
(36) "Sterile pharmaceutical" means any dosage form containing no viable microorganisms including, but not limited to, parenterals and ophthalmics.
(37) "Verification audit" means a comparison and verification of written patient orders with medications removed for that patient.

BOARD OF PHARMACY

2-15-1733. Board of pharmacy. (1) There is a board of pharmacy.
(2) The board consists of seven members appointed by the governor with the consent of the senate. Four members must be licensed pharmacists, one member must be a registered pharmacy technician, and two members must be from the general public.
(a) Each licensed pharmacist member must have graduated and received the first professional undergraduate degree from the school of pharmacy of the university of Montana-Missoula or from an accredited pharmacy degree program that has been approved by the board. Each licensed pharmacist member must have at least 5 consecutive years of practical experience as a pharmacist immediately before appointment to the board. A licensed pharmacist member who, during the member's term of office, ceases to be actively engaged in the practice of pharmacy in this state must be automatically disqualified from membership on the board.
(b) A registered pharmacy technician member must have at least 5 consecutive years of practical experience as a pharmacy technician immediately before appointment to the board. A registered pharmacy technician member who, during the member's term of office, ceases to be actively engaged as a pharmacy technician in this state must be automatically disqualified from membership on the board.
(c) Each public member of the board must be a resident of the state and may not be or ever have been:
(i) a member of the profession of pharmacy or the spouse of a member of the profession of pharmacy;
(ii) a person having any material financial interest in the providing of pharmacy services; or
(iii) a person who has engaged in any activity directly related to the practice of pharmacy.
(3) Members shall serve staggered 5-year terms. A member may not serve more than two consecutive full terms. For the purposes of this section, an appointment to fill an unexpired term does not constitute a full term.
(4) A member must be removed from office by the governor:
(a) upon proof of malfeasance or misfeasance in office, after reasonable notice of charges against the member and after a hearing; or
(b) upon refusal or inability to perform the duties of a board member in an efficient, responsible, and professional manner.

37-1-101. Duties of department. In addition to the provisions of 2-15-121, the department shall: (1) establish and provide all the administrative, legal, and clerical services needed by the boards within the department, including corresponding, receiving and processing routine applications for licenses as defined by a board, issuing and renewing routine licenses as defined by a board, disciplining licensees, setting administrative fees, preparing agendas and meeting notices, conducting mailings, taking minutes of board meetings and hearings, and filing;
(2) standardize policies and procedures and keep in Helena all official records of the boards;
(3) make arrangements and provide facilities in Helena for all meetings, hearings, and examinations of each board or elsewhere in the state if requested by the board;
(4) contract for or administer and grade examinations required by each board;
(5) investigate complaints received by the department of illegal or unethical conduct of a member of the profession or occupation under the jurisdiction of a board or a program within the department;
(6) assess the costs of the department to the boards and programs on an equitable basis as determined by the department;
(7) adopt rules setting administrative fees and expiration, renewal, and termination dates for licenses;
(8) issue a notice to and pursue an action against a licensed individual, as a party, before the licensed individual's board after a finding of reasonable cause by a screening panel of the board pursuant to 37-1-307(1)(d);
(9) (a) provide notice to the board and to the appropriate legislative interim committee when a board cannot operate in a cost-effective manner;
(b) suspend all duties under this title related to the board except for services related to renewal of licenses;
(c) review the need for a board and make recommendations to the legislative interim committee with monitoring responsibility for the boards for legislation revising the board's operations to achieve fiscal solvency; and
(d) notwithstanding 2-15-121, recover the costs by one-time charges against all licensees of the board after providing notice and meeting the requirements under the Montana Administrative Procedure Act;
(10) monitor a board's cash balances to ensure that the balances do not exceed two times the board's annual appropriation level and adjust fees through administrative rules when necessary;
(11) establish policies and procedures to set fees for administrative services, as provided in 37-1-134, commensurate with the cost of the services provided. Late penalty fees may be set without being commensurate with the cost of services provided.
(12) adopt uniform rules for all boards and department programs to comply with the public notice requirements of 37-1-311 and 37-1-405. The rules may require the posting of only the licensee's name and the fact that a hearing is being held when the information is being posted on a publicly available website prior to a decision leading to a suspension or revocation of a license or other final decision of a board or the department. (5) The board is allocated to the department for administrative purposes only as prescribed in 2-15-121.

37-1-104. Standardized forms. The department shall adopt standardized forms and processes to be used by the boards and department programs. The standardization is to streamline processes, expedite services, reduce costs and waste, and facilitate computerization.

37-1-105. Reporting disciplinary actions against licensees. The department has the authority and shall require that all licensing boards within the department require all applicants for licensure or renewal to report any legal or disciplinary actions against them that relate to the propriety of the applicants' practice of or their fitness to practice the profession or occupation for which they seek licensure. Failure to furnish the required information, except pursuant to 37-1-138, or the filing of false information is grounds for denial or revocation of a license.

37-1-106. Biennial report. The department, in cooperation with each licensing board, shall prepare a biennial report. The biennial report of the department shall contain for each board a summary of the board's activities, the board's goals and objectives, a detailed breakdown of board revenues and expenditures, statistics illustrating board activities concerning licensing, summary of complaints received and their disposition, number of licenses revoked or suspended, legislative or court action affecting the board, and any other information the department or board considers relevant. The department shall submit the report to the office of budget and program planning as a part of the information required by 17-7-111.

37-1-121. Duties of commissioner. In addition to the powers and duties under 2-15-112 and 2-15-121, the commissioner of labor and industry shall: (1) at the request of a party, appoint an impartial hearings examiner to conduct hearings whenever any board or department program holds a contested case hearing. The hearings examiner shall conduct hearings in a proper and legal manner.
(2) establish the qualifications of and hire all personnel to perform the administrative, legal, and clerical functions of the department for the boards. Boards within the department do not have authority to establish the qualifications of, hire, or terminate personnel. The department shall consult with the boards regarding recommendations for qualifications for executive or executive director positions.
(3) approve all contracts and expenditures by boards within the department. A board within the department may not enter into a contract or expend funds without the approval of the commissioner.

37-1-130. Definitions. As used in this part, the following definitions apply: (1) "Administrative fee" means a fee established by the department to cover the cost of administrative services as provided for in 37-1-134.
(2) "Board" means a licensing board created under Title 2, chapter 15, that regulates a profession or occupation and that is administratively attached to the department as provided in 2-15-121.
(3) "Board fee" means:
(a) a fee established by the board to cover program area costs as provided in 37-1-134; and
(b) any other legislatively prescribed fees specific to boards and department programs.
(4) "Department" means the department of labor and industry established in 2-15-1701.
(5) "Department program" means a program administered by the department pursuant to this title and not affiliated with a board.
(6) "Expired license" means a license that is not reactivated within the period of 46 days to 2 years after the renewal date for the license.
(7) "Lapsed license" means a license that is not renewed by the renewal date and that may be reactivated within the first 45-day period after the renewal date for the license.
(8) "License" means permission granted under a chapter of this title to engage in or practice at a specific level in a profession or occupation, regardless of the specific term used for the permission, including permit, certificate, recognition, or registration.
(9) "Terminated license" means a license that is not renewed or reactivated within 2 years of the license lapsing.

37-1-131. Duties of boards -- quorum required. (1) A quorum of each board within the department shall:
(a) set and enforce standards and rules governing the licensing, certification, registration, and conduct of the members of the particular profession or occupation within the board's jurisdiction;
(b) sit in judgment in hearings for the suspension, revocation, or denial of a license of an actual or potential member of the particular profession or occupation within the board's jurisdiction. The hearings must be conducted by a hearings examiner when required under 37-1-121.
(c) suspend, revoke, or deny a license of a person who the board determines, after a hearing as provided in subsection (1)(b), is guilty of knowingly defrauding, abusing, or aiding in the defrauding or abusing of the workers' compensation system in violation of the provisions of Title 39, chapter 71;
(d) pay to the department the board's pro rata share of the assessed costs of the department under 37-1-101(6);
(e) consult with the department before the board initiates a program expansion, under existing legislation, to determine if the board has adequate money and appropriation authority to fully pay all costs associated with the proposed program expansion. The board may not expand a program if the board does not have adequate money and appropriation authority available.
(2) A board, board panel, or subcommittee convened to conduct board business must have a majority of its members, which constitutes a quorum, present to conduct business.
(3) A board that requires continuing education or continued state, regional, or national certification for licensees shall require licensees reactivating an expired license to submit proof of meeting the requirements of this subsection for the renewal cycle.
(4) The board or the department program may:
(a) establish the qualifications of applicants to take the licensure examination;
(b) determine the standards, content, type, and method of examination required for licensure or reinstatement of a

license, the acceptable level of performance for each examination, and the standards and limitations for reexamination if an applicant fails an examination;
(c) examine applicants for licensure at reasonable places and times as determined by the board or enter into contracts with third-party testing agencies to administer examinations; and
(d) require continuing education for licensure, as provided in 37-1-306, or require continued state, regional, or national certification for licensure. Except as provided in subsection (3), if the board or department requires continuing education or continued state, regional, or national certification for continued licensure, the board or department may not audit or require proof of continuing education or continued state, regional, or national certification requirements as a precondition for renewing the license, certification, or registration. The board or department may conduct random audits after the lapsed date of up to 50% of all licensees with renewed licenses for documentary verification of the continuing education requirement.
(5) A board may, at the board's discretion, request the applicant to make a personal appearance before the board for non-routine license applications as defined by the board.
(6) A board shall adopt rules governing the provision of public notice as required by 37-1-311.

37-1-132. Nominees for appointment to licensing and regulatory boards. Private associations and members of the public may submit to the governor lists of nominees for appointment to professional and occupational licensing and regulatory boards. The governor may consider nominees from the lists when making appointments to such boards.

37-1-133. Board members' compensation and expenses. Unless otherwise provided by law, each member of a board allocated to the department is entitled to receive $50 per day compensation and travel expenses, as provided for in 2-18-501 through 2-18-503, for each day spent on official board business. Board members who conduct official board business in their city of residence are entitled to receive a midday meal allowance, as provided for in 2-18-502. Ex officio board members may not receive compensation but shall receive travel expenses.

37-1-136. Disciplinary authority of boards -- injunctions. (1) Subject to 37-1-138, each licensing board allocated to the department has the authority, in addition to any other penalty or disciplinary action provided by law, to adopt rules specifying grounds for disciplinary action and rules providing for:
(a) revocation of a license;
(b) suspension of its judgment of revocation on terms and conditions determined by the board;
(c) suspension of the right to practice for a period not exceeding 1 year;
(d) placing a licensee on probation;
(e) reprimand or censure of a licensee; or
(f) taking any other action in relation to disciplining a licensee as the board in its discretion considers proper.
(2) Any disciplinary action by a board shall be conducted as a contested case hearing under the provisions of the Montana Administrative Procedure Act.
(3) Notwithstanding any other provision of law, a board may maintain an action to enjoin a person from engaging in the practice of the occupation or profession regulated by the board until a license to practice is procured. A person who has been enjoined and who violates the injunction is punishable for contempt of court.
(4) An action may not be taken against a person who is in compliance with Title 50, chapter 46.
(5) Rules adopted under subsection (1) must provide for the provision of public notice as required by 37-1-311.

37-1-137. Grounds for disciplinary action as grounds for license denial -- conditions to new licenses. (1) Unless otherwise provided by law, grounds for disciplinary action by a board allocated to the department of labor and industry against a holder of an occupational or professional license may be, under appropriate circumstances, grounds for either issuance of a probationary license for a period not to exceed 1 year or denial of a license to an applicant.
(2) The denial of a license or the issuance of a probationary license under subsection (1) must be conducted as a contested case hearing under the provisions of the Montana Administrative Procedure Act.

37-1-138. Protection of professional licenses for activated military reservists -- rulemaking authority -- definitions. (1)For purposes of this section, the following definitions apply:
(a) "Activated reservist" means a member of a reserve component who has received federal military orders to report for federal active duty for at least 90 consecutive days.
(b) "License" has the meaning provided in 37-1-302.
(c) "Reserve component" means the Montana national guard or the military reserves of the United States armed forces.
(2) An activated reservist who holds an occupational or professional license may report the reservist's activation to the appropriate professional licensing board or to the department of labor and industry if the licensing requirements are administered by the department. The report must, at a minimum, include a copy of the reservist's orders to federal active duty. The report may request that the reservist's professional license revert to an inactive status.
(3) If an activated reservist has requested that the reservist's license revert to inactive status pursuant to subsection (2), then for the duration of the reservist's active duty service under the orders submitted, the department or licensing board may not:
(a) require the collection of professional licensing fees or continuing education fees from the activated reservist;
(b) require that the activated reservist take continuing education classes or file a report of continuing education classes completed; or
(c) revoke or suspend the activated reservist's professional license, require the license to be forfeited, or allow the license to lapse for failure to pay licensing fees or continuing education fees or for failure to take or report continuing education classes.
(4) (a) Upon release from federal active duty service, the reservist shall send a copy of the reservist's discharge documents to the appropriate professional licensing board or to the department.
(b) The board or department shall evaluate the discharge documents, consider the military position held by the reservist and the duties performed by the reservist during the active duty, and compare the position and duties to the licensing requirements for the profession. The board or department shall also consider the reservist's length of time on federal active duty.
(c) Based on the considerations pursuant to subsection (4)(b) and subject to subsection (5):
(i) the license must be fully restored;
(ii) conditions must be attached to the reservist's continued retention of the license; or
(iii) the license must be suspended or revoked.
(5) (a) A licensing board or the department may adopt rules concerning what conditions may be attached to a reservist's professional license pursuant to subsection (4)(c)(ii).
(b) If conditions are attached pursuant to subsection (4)(c)(ii) or the license is suspended or revoked pursuant to subsection (4)(c)(iii), the affected reservist may, within 90 days of the decision to take the action, request a hearing by writing a letter to the board or department. The board or department shall conduct a requested hearing within 30 days of receiving the written request.

37-1-307. Board authority. (1) A board may:
(a) hold hearings as provided in this part;
(b) issue subpoenas requiring the attendance of witnesses or the production of documents and administer oaths in connection with investigations and disciplinary proceedings under this part. Subpoenas must be relevant to the complaint and must be signed by a member of the board. Subpoenas may be enforced as provided in 2-4-104.
(c) authorize depositions and other discovery procedures under the Montana Rules of Civil Procedure in connection with an investigation, hearing, or proceeding held under this part;
(d) establish a screening panel to determine whether there is reasonable cause to believe that a licensee has violated a particular statute, rule, or standard justifying disciplinary proceedings. A screening panel shall specify in writing the particular statute, rule, or standard that the panel believes may have been violated. The screening panel shall also state in writing the reasonable grounds that support the panel's finding that a violation may have occurred. The assigned board members may not subsequently participate in a hearing of the case. The final decision on the case must be made by a majority of the board members who did not serve on the screening panel for the case.
(e) grant or deny a license and, upon a finding of unprofessional conduct by an applicant or license holder, impose a sanction provided by this chapter.

(2) Each board is designated as a criminal justice agency within the meaning of 44-5-103 for the purpose of obtaining confidential criminal justice information, as defined in 44-5-103, regarding the board's licensees and license applicants and regarding possible unlicensed practice, but the board may not record or retain any confidential criminal justice information without complying with the provisions of the Montana Criminal Justice Information Act of 1979, Title 44, chapter 5.
(3) A board may contact and request information from the department of justice, which is designated as a criminal justice agency within the meaning of 44-5-103, for the purpose of obtaining criminal history record information regarding the board's licensees and license applicants and regarding possible unlicensed practice.
(4) (a) A board that is statutorily authorized to obtain a criminal background check as a prerequisite to the issuance of a license shall require the applicant to submit fingerprints for the purpose of fingerprint checks by the Montana department of justice and the federal bureau of investigation.
(b) The applicant shall sign a release of information to the board and is responsible to the department of justice for the payment of all fees associated with the criminal background check.
(c) Upon completion of the criminal background check, the department of justice shall forward all criminal history record information, as defined in 44-5-103, in any jurisdiction to the board as authorized in 44-5-303.
(d) At the conclusion of any background check required by this section, the board must receive the criminal background check report but may not receive the fingerprint card of the applicant. Upon receipt of the criminal background check report, the department of justice shall promptly destroy the fingerprint card of the applicant.
[(5) Each board shall require a license applicant to provide the applicant's social security number as a part of the application. Each board shall keep the social security number from this source confidential, except that a board may provide the number to the department of public health and human services for use in administering Title IV-D of the Social Security Act.] *(Bracketed language terminates on occurrence of contingency--sec. 1, Ch. 27, L. 1999.)*

37-1-319. Rules. A board may adopt rules: (1) under the guidelines of 37-1-306, regarding continuing education and establishing the number of hours required each year, the methods of obtaining education, education topics, and carrying over hours to subsequent years;
(2) regarding practice limitations for temporary practice permits issued under 37-1-305 and designed to ensure adequate supervision of the practice until all qualifications for licensure are met and a license is granted;
(3) regarding qualifications for inactive license status that may require compliance with stated continuing education requirements and may limit the number of years a person may remain on inactive status without having to reestablish qualifications for licensure;
(4) regarding maintenance and safeguarding of client funds or property possessed by a licensee and requiring the funds or property to be maintained separately from the licensee's funds and property; and
(5) defining acts of unprofessional conduct, in addition to those contained in 37-1-316, that constitute a threat to public health, safety, or welfare and that are inappropriate to the practice of the profession or occupation.

37-7-104. Qualifications of employee hired to assist board. A person hired by the department to enter and inspect an establishment under this chapter must be: (1) a citizen of the United States and a resident of this state; and
(2) a pharmacist registered under this chapter.

37-7-201. Organization -- powers and duties. (1) The board shall meet at least once a year to transact its business. The board shall annually elect from its members a president, vice president, and secretary.
(2) The board shall regulate the practice of pharmacy in this state, including but not limited to:
(a) establishing minimum standards for:
(i) equipment necessary in and for a pharmacy;
(ii) the purity and quality of drugs, devices, and other materials dispensed within the state through the practice of pharmacy, using an official compendium recognized by the board or current practical standards;
(iii) specifications for the facilities, environment, supplies, technical equipment, personnel, and procedures for the storage, compounding, or dispensing of drugs and devices;
(iv) monitoring drug therapy; and
(v) maintaining the integrity and confidentiality of prescription information and other confidential patient information;

(b) requesting the department to inspect, at reasonable times:
(i) places where drugs, medicines, chemicals, or poisons are sold, vended, given away, compounded, dispensed, or manufactured; and
(ii) the appropriate records and the license of any person engaged in the practice of pharmacy for the purpose of determining whether any laws governing the legal distribution of drugs or devices or the practice of pharmacy are being violated. The board shall cooperate with all agencies charged with the enforcement of the laws of the United States, other states, or this state relating to drugs, devices, and the practice of pharmacy. It is a misdemeanor for a person to refuse to permit or otherwise prevent the department from entering these places and making an inspection.
(c) regulating:
(i) the training, qualifications, employment, licensure, and practice of interns;
(ii) the training, qualifications, employment, and registration of pharmacy technicians; and
(iii) under therapeutic classification, the sale and labeling of drugs, devices, medicines, chemicals, and poisons;
(d) examining applicants and issuing and renewing licenses of:
(i) applicants whom the board considers qualified under this chapter to practice pharmacy;
(ii) pharmacies and certain stores under this chapter;
(iii) wholesale drug distributors; and
(iv) persons engaged in the manufacture and distribution of drugs or devices;
(e) in concurrence with the board of medical examiners, defining the additional education, experience, or certification required of a licensed pharmacist to become a certified clinical pharmacist practitioner;
(f) issuing certificates of "certified pharmacy" under this chapter;
(g) establishing and collecting license and registration fees;
(h) approving pharmacy practice initiatives that improve the quality of, or access to, pharmaceutical care but that fall outside the scope of this chapter. This subsection (2)(h) may not be construed to expand on the definition of the practice of pharmacy.
(i) making rules for the conduct of its business;
(j) performing other duties and exercising other powers as this chapter requires;
(k) adopting and authorizing the department to publish rules for carrying out and enforcing parts 1 through 7 of this chapter, including but not limited to:
(i) requirements and qualifications for the transfer of board-issued licenses;
(ii) minimum standards for pharmacy internship programs and qualifications for licensing pharmacy interns;
(iii) qualifications and procedures for registering pharmacy technicians; and
(iv) requirements and procedures necessary to allow a pharmacy licensed in another jurisdiction to be registered to practice telepharmacy across state lines.
(3) The board may:
(a) join professional organizations and associations organized exclusively to promote the improvement of standards of the practice of pharmacy for the protection of the health and welfare of the public and whose activities assist and facilitate the work of the board; and
(b) establish standards of care for patients concerning health care services that a patient may expect with regard to pharmaceutical care.

37-7-202. Salaries and expenses of board members. Each member of the board shall receive compensation and travel expenses as provided for in 37-1-133

24.174.101 BOARD ORGANIZATION (1) The board of pharmacy hereby adopts and incorporates the organizational rules of the department of labor and industry as listed in chapter 1 of this title.

24.174.201 PROCEDURAL RULES (1) The board of pharmacy hereby adopts and incorporates the procedural rules of the department of labor and industry as listed in chapter 2 of this title.

24.174.202 PUBLIC PARTICIPATION RULES (1) The board of pharmacy hereby adopts and incorporates by this reference the public participation rules of the department of commerce as listed in chapter 2 of this title.

INTERNSHIP REGULATIONS

24.174.303 INTERNSHIP PROGRAM DEFINITIONS (1) "Approved program" means that time credited toward the training period which begins from the date of intern registration and continues under the requirements of the approved program.
(2) "Approved training area" means a place for instructing an intern for licensure subject to requirements of the board.
(3) "Computed time" means that time credited toward the training period which begins from the date of intern registration and continues under the requirements of the approved program.
(4) "Intern" means a qualified [under ARM 24.174.602] pharmacy student, or a graduate from an accredited school of pharmacy, and registered in an approved program of supervised training.
(5) "Intern certificate of registration" means that certificate furnished by the board upon approval of the intern application form, received from the intern applicant.
(6) "Internship period" means 1500 hours of practical experience in an approved pharmacy, hospital, or other facility. The intern may acquire a maximum of 48 hours experience per calendar week.. The student may acquire up to 1500 hours concurrently with school attendance in approved courses, introductory pharmacy practice experience, and advanced pharmacy practice experience, or demonstration projects in the Pharm.D. program.
(7) "Preceptor" means a pharmacist or other approved individual who meets those requirements for the supervision and training of an intern.
(8) "Reporting period" means at the completion of internship or introductory pharmacy practice experience in a given site or after 500 hours, whichever comes first, or at the completion of advanced pharmacy practice experience.
(9) “Supervising Pharmacist” means the registered pharmacist who is in charge of the day-to-day supervision of the intern.
(10)"Supervision" means that all drug distribution or dispensing activities shall be performed by the intern under the direction of a registered pharmacist and that the preceptor shall have overall responsibility for the required training of the intern.

24.174.601 SUMMARY OF OBJECTIVES (1) The practical experience required prior to professional licensure shall be referred to as internship. The purpose of pharmacy internship is to provide an intern with the knowledge and practical experience necessary for professional licensure.

24.174.602 INTERNSHIP REQUIREMENTS (1) The experience required to obtain licensure as a pharmacist shall be that instruction period composed of computed time obtained under the supervision of the preceptor in an approved site. An intern may practice only under the immediate personal supervision of a registered pharmacist.
(2) An intern may practice only under the immediate personal supervision of a supervising pharmacist.
(3) Application shall be made on the intern application form prescribed by the board. Registration must be obtained prior to commencing work as an intern.
(4) The intern shall make such reports and certifications as required under the approved program and or as required by the board.
(5) The intern is responsible for the knowledge and observation of the extent of the intern’s legal liability and legal restrictions applicable under the federal, state, and municipal laws and rules.
(6) The intern shall be responsible for ensuring that the preceptor has proper certification.
(7) The intern is responsible for properly submitting all forms and hour reports under the approved program.
(8) Employment and the intern training periods are not to be interpreted as being the same. An intern may work in excess of the computed time.
(9)An intern shall be:
a. a student currently enrolled in an accredited pharmacy program;
b. a graduate of an accredited pharmacy program serving an internship; or
c. a graduate of a pharmacy program located outside the United States of America which is not accredited and who has successfully passed equivalency examinations approved by the board.
Intern registration based on enrollment in or graduation from an accredited pharmacy program shall expire not later than 12 months after the date of graduation or at the time of professional licensure, whichever comes first. Intern

registration based on graduation from a pharmacy program located outside of the United States of America which is not accredited shall expire not later than 12 months after the date of issuance of the registration or at the time of professional licensure, whichever comes first.
An intern registration may be issued to a student currently enrolled in an accredited pharmacy program at any time
a)after they have completed 30 days of study;
b)submitted a completed application to the board; and
c)paid the required fee.
(10) The intern shall notify the board of any change of address, employment or preceptor within 10 days.
(11) Intern certificate of registration shall be displayed in the approved training area.
(12) An intern registration may be extended, subject to approval by the board, upon application by the intern, if extenuating circumstances are present.

24.174.603 OUT-OF-STATE INTERNSHIP REQUIREMENTS (1) Written request by the intern must be made to the board prior to commencing training at an out-of-state site.
(2) The intern must comply with the rules relating to internship and the approved program.
(3) The intern must obtain certification of the training area and the preceptor from the out-of-state's board and must submit the same directly to the Montana board of pharmacy.

24.174.604 PRECEPTOR REQUIREMENTS (1) Each pharmacist preceptor shall:
(a) apply for board approval to be a preceptor;
(b) have been actively engaged in:
(i) the practice of pharmacy for one year unless otherwise approved by the board; or
(ii) other approved disciplines;
(c) be engaged in active pharmacy practice WHILE ACTING AS A PRECEPTOR;
(d) not have been convicted of violation of any statutes or rules relating to pharmacy within three years prior to application;
(e) be acutely aware of the responsibilities governing professional conduct in this state;
(f) have current knowledge of developments in the profession by exhibiting such attendances, readings, and actions, which conform to the best traditions of pharmacy;
(g) make such reports and certifications as required under the approved program;
(h) notify the board of any change of address or employment within 30 days. Change of employment shall serve to suspend preceptor approval until such time as re-evaluation is made by the board;
(i) not be permitted to leave an intern work alone to assume the responsibility of a pharmacist; and
(j) complete a training course as approved by the board.
(2) The repackaging, labeling and dispensing of drugs for distribution shall be under the supervision of a supervising pharmacist.
(3) A supervising pharmacist may only supervise one student in introductory pharmacy practice experience (IPPE) at any time.
(4) A supervising pharmacist may supervise no more than three persons at one time (including technicians, interns, and students), unless an exception is specifically granted by the board.
(5) A pharmacist preceptor may supervise two students at a time if the students are completing an advanced pharmacy practice experience (APPE) through an approved school of pharmacy.
(6) A preceptor may serve as a preceptor for no more than one intern at a time.

24.174.611 APPROVED TRAINING AREAS (1) Approved training areas will include licensed pharmacy settings plus other health care and research settings approved by the board.

24.174.612 REQUIRED FORMS AND REPORTS (1) Forms shall be furnished by the board, the cost of which is included in the application for internship registration.
(a) The "intern application" must be filed by the intern before computed time is credited.
(b) The "internship experience affidavit", provided by the board, must be filed by the intern at the end of the internship experience in a given site or after 500 hours, whichever comes first.

(c) The "evaluation of internship site" must be filed by the intern at the completion of internship or externship experience in a given site or after 500 hours, whichever comes first.
(d) The "clerkship experience affidavit", provided by the board, must be filed by the intern at the end of the academic year.

24.174.613 REVOCATION OR SUSPENSION OF CERTIFICATE (1) An intern certificate may be suspended or revoked by the board for violation of any statute or rule, or failure to comply with the approved program after due notice.
(2) Suspension of an intern from university or college attendance concurrently suspends an intern's certificate of registration.

24.174.605 FOREIGN INTERN REQUIREMENTS (1) A graduate of a foreign school of pharmacy seeking licensure to practice as a pharmacy intern in the state of Montana shall:
(a) take the Foreign Pharmacy Graduate Equivalency Exam (FPGEE);
(b) take the Test of Spoken English (TSE); and one of the following:
(i) take the computer-based Test of English as a Foreign Language (TOEFL);
(ii) take the paper-based TOEFL; or
(iii) take the internet-based TOEFL;
(c) achieve NABP minimum passing scores on all tests and examinations;
(d) have an internship practice site identified and that practice site must be a licensed pharmacy in good standing with the board; and
(e) have an internship preceptor identified and that preceptor must:
(i) be a licensed pharmacist in good standing with the board; and
(ii) be a registered preceptor in good standing with the board.
(2) The intern and their preceptor must appear before the board.
(3) The intern shall comply with the internship requirements as set forth in ARM 24.174.602.
(4) A graduate of a foreign school of pharmacy must complete 1500 hours of internship in the United States in order to be eligible for pharmacist licensure in Montana.

FEES

24.174.401 FEE SCHEDULE

(1) Application for licensure transfer	$300
(2) Original registration for pharmacist	120
(3) Pharmacist annual renewal fee	110
(4) Original registration for clinical pharmacist practitioner	25
(5) Clinical pharmacist practitioner annual renewal fee	25
(6) Certified pharmacy original certification (includes original, change in location, and change in ownership)	400
(7) Certified pharmacy annual renewal fee	25
(8) Family Planning limited pharmacy facility, certified pharmacy license, (original and renewal)	75
(9) Intern registration	80
(10) NAPLEX examination processing fee (paid to board)	35
(11) Montana multistate pharmacy jurisprudence examination (MPJE) exam fee (a separate exam fee is paid directly to NABP)	25
(12) Utilization plan approval fee	200
(13) Annual utilization plan renewal fee	100
(14) Pharmacy technician and technician-in-training registration fee	60
(15) Pharmacy technician renewal fee	50
(16) Wholesale drug distributor license	400
(17) Annual wholesale drug distributor renewal	400
(18) Out-of-state mail service pharmacy/telepharmacy initial license	400

(19) Out-of-state mail service pharmacy/telepharmacy renewal	400
(20) Certification of grades/transfer of internship hours	20
(21) Inactive pharmacist annual renewal fee	25
(22) Outpatient center for surgical services (original or renewal)	75

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

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

REGISTRATION ANNUAL FEE
(a) manufacture $100
(b) distribute $100
(c) dispense –
i. pharmacies $75
ii. outpatient centers for surgical services $75
(d) conduct research/analyze $100

24.174.403 CHANGE IN ADDRESS AND/OR EMPLOYMENT (1) All licensees shall notify the board in writing within 30 days of any change in employment and/or any change of business or personal address.

24.174.404 FEE ABATEMENT (1) The Board of Pharmacy adopts and incorporates by reference the fee abatement rule of the Department of Labor and Industry found at ARM 24.101.301.

24.101.404 Posting Disciplinary Orders On Licensee Lookup Database (1) Unless the exceptions in (2) and (3) are applicable, any final order imposing a sanction against a professional or occupational license holder that is based on competence to practice issues or based on an allegation that generally or specifically is a violation of law or regulation, is a "disciplinary action" that must be published and noted on the licensee lookup.
(2) If a final order is based only upon a failure to file or complete in a timely manner a minor administrative requirement that is in rule or law, the order affecting the licensee is not a "disciplinary action" for the purposes of publication and notice on the licensee lookup.
(3) A final order of license denial based solely upon an applicant's failure to meet minimum licensure qualifications and not based on competence to practice issues or involving the applicant's past disciplinary or legal actions is not a "disciplinary action" for the purposes of publication and notice on the licensee lookup.

PHARMACIST MEAL/REST BREAKS

24.174.411 PHARMACIST MEAL/REST BREAKS (1) In any pharmacy staffed by a single pharmacist, the pharmacist shall take a meal/rest break 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 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.
(5) When authorized by the pharmacist, only registered technicians directly involved in the process of filling prescriptions may remain in the prescription department to perform nondiscretionary duties as delineated by the pharmacist.
(6) Upon returning, the pharmacist shall review any work performed in the pharmacist's absence.

(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.
(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.

REGISTRATION FOR OUT-OF-STATE VOLUNTEER PROFESSIONALS

24.174.417 REGISTRATION FOR OUT-OF-STATE VOLUNTEER PROFESSIONALS (1) As provided in 10-3-118, MCA, a volunteer professional may practice in Montana when a state of emergency or disaster, as defined in 10-3-103, MCA, is in effect.
(2) A volunteer professional shall not accept remuneration for services provided during a state of emergency or disaster as a volunteer professional.
(3) A professional volunteer shall successfully register with the appropriate licensing agency in Montana. To register, a volunteer professional shall hold an active, unrestricted license in another state.
(4) An applicant for registration shall submit a completed, signed department registration form, to include the following:
(a) applicant's full name;
(b) applicant's complete mailing address;
(c) applicant's e-mail address;
(d) applicant's correct social security number;
(e) applicant's birth date;
(f) occupation(s) for which the applicant holds a current license;
(g) state or states in which the applicant holds or has ever held a professional license;
(h) an affirmation that the applicant currently holds an active, unrestricted license in another state(s);
(i) an affirmation that the statements contained in the form are true and accurate to the best of the applicant's knowledge.
(5) A volunteer professional must practice within the scope and standards of the professional's license and in compliance with the licensing statutes and administrative rules of Montana governing the profession.
(6) A volunteer professional is subject to administrative sanctions for unprofessional conduct as described in 37-1-316, MCA, and the specific professional licensing board's administrative rules.

LICENSING

37-1-134. Licensing boards to establish fees commensurate with costs. All licensing boards allocated to the department shall set fees reasonably related to the respective program area costs. Unless otherwise provided by law, each board within the department may establish fees including but not limited to fees for program areas such as application, examination, renewal, reciprocity, late renewal, and continuing education. Board costs not related to a specific program area may be equitably distributed to program areas as determined by the board. Each board shall maintain records sufficient to support the fees charged for each program area.

37-1-135. Licensing investigation and review -- record access. Any person, firm, corporation, or association that performs background reviews, complaint investigations, or peer reviews pursuant to an agreement or contract with a

state professional or occupational licensing board shall make available to the board and the legislative auditor, upon request, any and all records or other information gathered or compiled during the course of the background review, complaint investigation, or peer review.

24.174.501 EXAMINATION FOR LICENSURE AS A REGISTERED PHARMACIST (1) The board has selected the national association of boards of pharmacy (NABP) licensure examination (NAPLEX) to be administered to candidates for licensure in Montana. The examination shall be prepared to measure the competence of the applicant to engage in the practice of pharmacy. A score of 75 shall be a passing score for this examination. A candidate who does not attain this score may retake the examination after a 90-day waiting period from the date of the exam.
(2) In addition the NABP shall administer a multi-state pharmacy jurisprudence examination (MPJE). This examination shall be prepared to measure the competence of the applicant regarding the statutes and rules governing the practice of pharmacy. A score of not less than 75 shall be a passing score for this examination. A candidate who does not attain this score may retake the examination after a 30-day waiting period from the date of the exam.
(3) Pharmacy graduates from outside the 50 states, the District of Columbia, or Puerto Rico, who seek certification of educational equivalency in order to sit for the North American pharmacist licensure examination must also complete the following:
(a) A successful interview before the Board of Pharmacy or its designee;
(b) the Foreign Pharmacy Graduate Equivalency Examination (FPGEE);
(c) 1500 hours of internship in the United States;
(d) the Test of Spoken English (TSE); and one of the following:
(i) the computer-based Test of English as a Foreign Language (TOEFL);
(ii) the paper-based TOEFL;
(iii) the internet-based TOEFL.
(4) The board may waive the provisions of (3)(d) upon request of the applicant, if the board determines the applicant is able to communicate in the English language.
(5)NABP minimum passing scores must be achieved on all tests and examinations.

24.174.502 TRANSFER OF LICENSE FROM ANOTHER STATE (1) Applicants seeking a license on the basis of having taken the NAPLEX examination and then issued a license by another state shall submit the following information to the board:
(a) NABP transfer of licensure application;
(b) proof of passing examination score on the NAPLEX examination;
(c) verification of current licensure in good standing from all other states where licensed; and
(d) appropriate fees.
(2) An applicant who has been registered as a pharmacist by examination in another state but who has not taken the NAPLEX examination shall appear before the board for consideration of transfer of licensure and submit the following information to the board:
(a) transfer of licensure application;
(b) proof of passing examination score;
(c) verification of current licensure in good standing from all other states where licensed; and
(d) appropriate fees.
(3) In addition to the above requirements in (1) and (2), the applicant will be required to pass the MPJE, to measure the competence of the applicant regarding the statutes and rules governing the practice of pharmacy. A score of not less than 75 shall be a passing score for this examination.
(4) The applicant has one year from the date of the NABP application in which to complete the licensure process. An applicant who does not obtain a license in one year will be required to file a new application and pay the appropriate fees.

37-1-141. License renewal -- lapse -- expiration -- termination. (1) The renewal date for a license must be set by department rule. The department shall provide notice prior to the renewal date.
(2) To renew a license, a licensee shall submit a completed renewal form, comply with all certification and continuing education requirements, and remit renewal fees before the end of the renewal period.

(3) A licensee may reactivate a lapsed license within 45 days after the renewal date by following the process in subsection (5) and complying with all certification and educational requirements.
(4) A licensee may reactivate an expired license within 2 years after the renewal date by following the process in subsection (5) and complying with all certification and education requirements that have accrued since the license was last granted or renewed as prescribed by board or department rule.
(5) To reactivate a lapsed license or an expired license, in addition to the respective requirements in subsections (3) and (4), a licensee shall:
(a) submit the completed renewal form;
(b) pay the late penalty fee provided for in subsection (7); and
(c) pay the current renewal fee as prescribed by the department or the board.
(6) (a) A licensee who practices with a lapsed license is not considered to be practicing without a license.
(b) A licensee who practices after a license has expired is considered to be practicing without a license.
(7) The department may assess a late penalty fee for each renewal period in which a license is not renewed. The late penalty fee need not be commensurate with the costs of assessing the fee.
(8) Unless otherwise provided by statute or rule, an occupational or professional license that is not renewed within 2 years of the most recent renewal date automatically terminates. The terminated license may not be reactivated, and a new original license must be obtained.
(9) The department or board responsible for licensing a licensee retains jurisdiction for disciplinary purposes over the licensee for a period of 2 years after the date on which the license lapsed.
(10) This section may not be interpreted to conflict with 37-1-138

24.174.504 INACTIVE LICENSE (1) A pharmacist may obtain an inactive license through a written request to the board, if the pharmacist holds an active Montana pharmacist license in good standing, and will not practice in Montana for the period of inactive licensure.
(2) A pharmacist with an inactive status of three years or less, whether or not the pharmacist has been in practice in another state, wishing to return to active status in Montana shall:
(a) submit a written request for status change to the board;
(b) pay either:
(i) the difference between the current inactive and active license renewal fees if the change occurs between renewal periods; or
(ii) the full active license renewal fee if the change occurs during the regular renewal period;
(c) certify that:
(i) no disciplinary action has been taken by any state or federal jurisdiction which would prevent or restrict the pharmacist's practice of the profession; and
(ii) the pharmacist has not surrendered any credential or privilege in the practice of the profession in lieu of or to avoid formal action;
(d) submit verification of active practice from the state(s) in which practice occurred; and
(e) provide proof that continuing education requirements for the period of inactive licensure have been satisfied.
(3) A pharmacist with an inactive status of three to five years, who has not been in active practice in another U.S. state, wishing to return to active status in Montana shall:
(a) comply with the requirements of (2);
(b) complete an appropriate internship of 300 hours or take and pass the North American Pharmacist Licensure Examination (NAPLEX); and
(c) take and pass the Multistate Pharmacy Jurisprudence Examination (MPJE) for the state of Montana.
(4) A pharmacist with an inactive status of five years or more, who has not been in active practice in another U.S. state, wishing to return to active status in Montana shall:
(a) comply with the requirements of (2);
(b) complete an appropriate internship of 300 hours;
(c) take and pass the NAPLEX; and
(d) take and pass the MPJE for the state of Montana.
(5) A pharmacist with an inactive status for more than three years, who has been in active practice in another U.S. state, wishing to return to active status in Montana shall:

(a) comply with the requirements of (2); and
(b) take and pass the MPJE for the state of Montana.

Part 2 -- Licensure of Criminal Offenders

37-1-201. Purpose. It is the public policy of the legislature of the state of Montana to encourage and contribute to the rehabilitation of criminal offenders and to assist them in the assumption of the responsibilities of citizenship. The legislature finds that the public is best protected when such offenders are given the opportunity to secure employment or to engage in a meaningful occupation, while licensure must be conferred with prudence to protect the interests of the public.

37-1-202. Intent and policy. It is the intent of the legislature and the declared policy of the state that occupational licensure be granted or revoked as a police power of the state in its protection of the public health, safety, and welfare.

37-1-203. Conviction not a sole basis for denial. Criminal convictions shall not operate as an automatic bar to being licensed to enter any occupation in the state of Montana. No licensing authority shall refuse to license a person solely on the basis of a previous criminal conviction; provided, however, where a license applicant has been convicted of a criminal offense and such criminal offense relates to the public health, welfare, and safety as it applies to the occupation for which the license is sought, the licensing agency may, after investigation, find that the applicant so convicted has not been sufficiently rehabilitated as to warrant the public trust and deny the issuance of a license.

37-1-204. Statement of reasons for denial. When a licensing agency prohibits an applicant from being licensed wholly or partially on the basis of a criminal conviction, the agency shall state explicitly in writing the reasons for the decision.

37-1-205. Licensure on completion of supervision. Completion of probation or parole supervision without any subsequent criminal conviction is evidence of rehabilitation. However, the facts surrounding the situation that led to the probation or parole supervision may be considered as they relate to the occupation for which a license is sought, and this chapter may not be construed to prohibit licensure of a person while the person is under state supervision if the licensing agency finds insufficient evidence to preclude licensure.

37-7-301. Unlawful practice. Except as provided in 37-7-307 through 37-7-309, it is unlawful for a person to:
(1) engage in the practice of pharmacy unless licensed by the board; or
(2) assist in the practice of pharmacy unless registered by the board as a pharmacy technician.

37-7-302. Qualifications -- display of license. (1) To be entitled to examination as a pharmacist, the applicant must be of good moral character and must have graduated and received the first professional undergraduate degree from the school of pharmacy of the university of Montana-Missoula or have received an accredited pharmacy degree that has been approved by the board. However, an applicant may not receive a registered pharmacist's license until the applicant has complied with the internship requirements established by the board.
(2) Each person licensed and registered under this chapter must receive from the department an appropriate license. The license must be conspicuously displayed at all times in the place of business.

37-1-305. Temporary practice permits. (1) A board may issue a temporary practice permit to a person licensed in another state that has licensing standards substantially equivalent to those of this state if the board determines that there is no reason to deny the license under the laws of this state governing the profession or occupation. The person may practice under the permit until a license is granted or until a notice of proposal to deny a license is issued. The permit may not be issued until the board receives verification from the state or states in which the person is licensed that the person is currently licensed and is not subject to pending charges or final disciplinary action for

unprofessional conduct or impairment.
(2) A board may issue a temporary practice permit to a person seeking licensure in this state who has met all licensure requirements other than passage of the licensing examination. Except as provided in 37-68-311 and 37-69-306, a permit is valid until the person either fails the first license examination for which the person is eligible following issuance of the permit or passes the examination and is granted a license.

37-1-317. Practice without license -- investigation of complaint -- injunction -- penalties. (1) The department shall investigate complaints or other information received concerning practice by an unlicensed person of a profession or occupation for which a license is required by this title.
(2) (a) Unless otherwise provided by statute, a board may file an action to enjoin a person from practicing, without a license, a profession or occupation for which a license is required by this title. In addition to the penalty provided for in 37-1-318, a person violating an injunction issued pursuant to this section may be held in contempt of court.
(b) A person subject to an injunction for practicing without a license may also be subject to criminal prosecution. In a complaint for an injunction or in an affidavit, information, or indictment alleging that a person has engaged in unlicensed practice, it is sufficient to charge that the person engaged in the unlicensed practice of a licensed profession or occupation on a certain day in a certain county without averring further or more particular facts concerning the violation.
(3) Unless otherwise provided by statute, a person practicing a licensed profession or occupation in this state without complying with the licensing provisions of this title is guilty of a misdemeanor punishable by a fine of not less than $250 or more than $1,000, imprisonment in the county jail for not less than 90 days or more than 1 year, or both. Each violation of the provisions of this chapter constitutes a separate offense.
(4) The department may issue a citation to and collect a fine, as provided in 37-68-316 and 37-69-310, from a person at a job site who is performing plumbing or electrical work and who fails to display a license or proof of licensure at the request of an employee of the department who bears responsibility for compliance with licensure requirements.

37-1-318. Violation of injunction -- penalty. A person who violates an injunction issued under 37-1-317 shall pay a civil penalty, as determined by the court, of not more than $5,000. Fifty percent of the penalty must be deposited in the general fund of the county in which the injunction is issued, and 50% must be deposited in the state general fund.

37-1-320. Mental intent -- unprofessional conduct. A licensee may be found to have violated a provision of 37-1-316 or a rule of professional conduct enacted by a governing board without proof that the licensee acted purposefully, knowingly, or negligently.

37-1-331. Correctional health care review team. (1)There is a correctional health care review team process in the department. The purpose of a review team is to review complaints filed by an inmate against a licensed or certified provider of health care or rehabilitative services for services that were provided to the person while the person was detained or confined in a county detention center or incarcerated under legal custody of the department of corrections. The inmate may file a complaint directly with the correctional health care review team for review or, if a board receives a complaint that has not been reviewed, the board shall forward the complaint to the review team. If the review team has reason to believe that there has been a violation of this part arising out of health care or rehabilitative services provided to a person detained or confined in a county detention center, the review team shall report the possible violation to the department for appropriate action under 37-1-308.
(2) Each health care licensing board shall solicit and submit to the department a list of licensed or certified health care or rehabilitative service professionals who have correctional health care experience and who are interested in participating on a team. A current board member may not participate on a review team. The department shall solicit from the administrators of the county detention centers and from the department of corrections names of licensed or certified health care or rehabilitative service providers who have correctional health care or rehabilitative services experience and are interested in participating on a review team. Each member of a review team must have at least 2 years of experience in providing health care or rehabilitative services in a correctional facility or program.
(3) Each correctional health care review team is composed of three members who shall represent health care and rehabilitative service providers who have provided health care or rehabilitative services to incarcerated persons. Two members of the review team must be providers of the same discipline and scope of practice as the provider against

whom a complaint was filed, and the third member may be a provider of any other health care or rehabilitative services discipline. The members must be willing to serve without compensation. If available, a correctional health care professional employed by the department of corrections and appointed by the director of the department of corrections may participate on the review team, except when the provider against whom the complaint was filed was employed by the department of corrections.
(4) The members of a review team are appointed by the department from the listing of health care and rehabilitative service providers with correctional experience who have been submitted by each respective board, a county detention center administrator, or the department of corrections as provided in subsection (2). A review team shall meet at least twice a year. Any travel, lodging, meal, or miscellaneous costs incurred by a review team may be recovered through a memorandum of understanding with the agencies who provide medical services to inmates or may be assessed to the licensing or certifying boards of health care and rehabilitative service providers.
(5) The review team shall review each complaint with regard to the health care or rehabilitative services provider's scope of practice. A decision on whether or not to forward the complaint must be made by the majority of the review team. The review team shall submit a written response regarding the decision to the inmate, the county detention center administrator or the department of corrections, and the health care or rehabilitative services provider. If the decision is to not forward the complaint for action under 37-1-308, a record of the complaint may not be forwarded to any licensing or certifying board, but must be retained by the department.

37-2-201. Non-liability -- evidential privilege -- application to nonprofit corporations. (1) A member of a utilization review or medical ethics review committee of a hospital or long-term care facility or of a professional utilization committee, peer review committee, medical ethics review committee, or professional standards review committee of a society composed of persons licensed to practice a health care profession is not liable in damages to any person for any action taken or recommendation made within the scope of the functions of the committee if the committee member acts without malice and in the reasonable belief that the action or recommendation is warranted by the facts known to the member after reasonable effort to obtain the facts of the matter for which the action is taken or a recommendation is made.
(2) The proceedings and records of professional utilization, peer review, medical ethics review, and professional standards review committees are not subject to discovery or introduction into evidence in any proceeding. However, information otherwise discoverable or admissible from an original source is not to be construed as immune from discovery or use in any proceeding merely because it was presented during proceedings before the committee, nor is a member of the committee or other person appearing before it to be prevented from testifying as to matters within the individual's knowledge, but the individual may not be questioned about the individual's testimony or other proceedings before the committee or about opinions or other actions of the committee or any member of the committee.
(3) This section also applies to any member, agent, or employee of a nonprofit corporation engaged in performing the functions of a peer review, medical ethics review, or professional standards review committee.

37-7-1101. Nonliability for peer review. No member, employee, or volunteer intervenor of the Montana pharmaceutical association in its peer review program is liable in damages to any person for any action taken or recommendation made within the scope of the program if the member, employee, or volunteer acts in good faith in accordance with the rules of the association

DISPENSING OF PRECRIPTION DRUGS

50-31-307. Dispensing of prescription drugs. (1) A drug intended for use by humans that is included in one of the categories in subsection (2) may be dispensed only:
(a) upon a written prescription of a practitioner licensed by law to administer the drug;
(b) upon an oral prescription of the practitioner that is reduced promptly to writing and filed by the pharmacist; or
(c) by refilling a written or oral prescription if the refilling is authorized by the practitioner, either in the original prescription or by an oral order that is reduced promptly to writing and filed by the pharmacist.
(2) A drug must be dispensed as provided in subsection (1) if the drug:
(a) is a habit-forming drug to which 50-31-306(1)(d) applies;

(b) because of its toxicity or other potentiality for harmful effect, the method of its use, or the collateral measures necessary to its use, is not safe for use except under the supervision of a practitioner licensed by law to administer the drug; or
(c) is limited by an approved application under section 505 of the federal act (21 U.S.C. 355) or 50-31-311 to use under the professional supervision of a practitioner licensed by law to administer the drug.
(3) If the drug is a factory prepackaged contraceptive, other than mifepristone, it may be dispensed as provided in subsection (1) or by a registered nurse employed by a family planning clinic under contract with the department of public health and human services pursuant to a physician's written protocol specifying the circumstances under which dispensing is appropriate and pursuant to the board of pharmacy's rules concerning labeling, storage, and recordkeeping of drugs.
(4) The act of dispensing a drug contrary to the provisions of this section is considered an act that results in a drug being misbranded while held for sale.

24.174.510 PRESCRIPTION REQUIREMENTS (1) Prescriptions [or drug orders] shall include, but not be limited to:
(a) patient's name;
(b) name of drug, device, or biological;
(c) strength of drug or biological, if applicable;
(d) dosage form of drug or biological, if applicable;
(e) quantity of drug, device, or biological prescribed;
(f) directions for use;
(g) date of issuance;
(h) prescriber's name;
(i) if the prescription is written, it must contain the prescriber's hand-written signature and the name of the prescriber stamped, typed, printed, or clearly handwritten in addition to the signature;
(j) if the prescription is written, it must be tamper-resistant and contain all of the following characteristics:
(a) one or more industry-recognized features designed to prevent unauthorized copying of a completed or blank prescription form;
(b) one or more industry-recognized features designed to prevent the erasure or modification of information written on the prescription pad by the prescriber; and
(c) one or more industry-recognized features designed to prevent the use of counterfeit prescription forms.
(k) number of refills authorized;
(a) when the refill designation on the prescription is prn or Pro re nata, such designation, unless otherwise limited, means a refill for one year;
(b) if a prescription is for a controlled substance in Schedules III, IV, or V, refill five times in the six months from the date of issuance;
(c) if a prescription is for a noncontrolled drug, device, or biological, refill for 12 months from the date of issuance;
(d) controlled substances in Schedule II cannot be refilled and a refill designation for a controlled substance in Schedule II has no meaning.
(l) if the prescription is for a controlled substance, the following additional information is required to be on the prescription:
(a) patient's address;
(b) prescriber's address; and
(c) prescriber's Drug Enforcement Administration (DEA) registration number.
(2) Prescription or refill authorization issued by a prescriber may be communicated to a pharmacist or a pharmacist intern by an employee or agent of the prescriber.
(3) “Brand name medically necessary” shall be handwritten (or printed if electronically generated) on the face of the prescription if it is medically necessary that an equivalent drug product not be selected.

24.174.511 LABELING FOR PRESCRIPTIONS (1) On prescription drugs, the label shall contain the name, address and phone number of the dispenser, name of prescriber, name of patient, name and strength of the drug, directions for use and date of filling.

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

24.174.512 RECORDS OF DISPENSING (1) Records of dispensing for original and refill prescriptions are to be made and kept by pharmacies for at least two years and shall include, but not be limited to:
(a) quantity dispensed, if different;
(b) date of dispensing;
(c) serial number [or equivalent if an institution];
(d) the identification of the pharmacist responsible for dispensing;
(e) documentation of satisfaction of state requirements for drug product selection;
(f) records of refills to date.
(Note: Information presented in brackets [] represents institutional pharmacy requirements.)

24.174.513 COPY OF PRESCRIPTION (1) A pharmacist giving a copy of a prescription, must issue the same on a prescription blank showing the name and address of the pharmacy. It must be an accurate and correct copy and have the original number and date of the prescription on it.

24.174.522 ALTERNATE DELIVERY OF PRESCRIPTIONS (1) Under the provisions of 37-7-301, MCA, it shall be deemed a violation of the pharmacy law for any person or corporation holding a pharmacy license to participate in any arrangement or agreement whereby prescriptions may be left at, picked up from, accepted by or delivered to any store, shop or any other establishment not licensed by the board as a pharmacy.
(a) Nothing in this rule shall prohibit a licensed pharmacy from picking up prescriptions or delivering prescriptions at the office or home of the prescriber, and at the residence of the patient or at the hospital in which a patient is confined, by means of an employee or a common carrier.
(b) Nothing in this rule shall prohibit a registered pharmacist from installing an appropriate secure device as an alternate delivery system, when the pharmacy is closed. The system and counseling methods must have the prior approval of the board or its designee.

TRANSFER OF PRESCRIPTIONS

24.174.514 TRANSFER OF PRESCRIPTIONS (1) The manual transfer of original prescription information for the purpose of refill dispensing is permissible between pharmacies subject to the following requirements:
(a) the transfer is communicated directly between two licensed pharmacists and the transferring pharmacist records the following information:
(i) write the word 'VOID' on the face of the invalidated prescription,
(ii) record on the reverse of the invalidated prescription the name and address of the pharmacy to which it was transferred and the name of the pharmacist receiving the prescription information,
(iii) record the date of the transfer and the name of the pharmacist transferring the information.
(b) The pharmacist receiving the transferred prescription information shall reduce to writing the following:
(i) write the word 'TRANSFER' on the face of the transferred prescription,
(ii) provide all information required to be on a prescription pursuant to state and federal laws and regulations and include:
(A) date of issuance of original prescription,
(B) original number of refills authorized on original prescription,
(C) date of original dispensing,
(D) number of valid refills remaining and date of last refill,
(E) pharmacy's name, address and original prescription number from which the prescription information was transferred,
(F) name of transferor pharmacist.
(2) The manual transfer of original prescription information for a controlled (dangerous) substance listed in Schedules III, IV or V for the purpose of refill dispensing is permissible between pharmacies on a one time basis only, by following the procedures listed above. In addition:

(a) the transferring pharmacist shall record on the reverse of the invalidated prescription the DEA registration number of the pharmacy to which it was transferred; and
(b) the pharmacist receiving the transferred prescription shall record the DEA registration number of the pharmacy from which the prescription information was transferred.
(3) The electronic transfer of prescription information for the purpose of refill dispensing is permissible between pharmacies subject to the following requirements:
(a) the transferring pharmacy shall:
(i) render the prescription void;
(ii) enter the name, address, and DEA number of the receiving pharmacy into the database of the transferring pharmacy;
(iii) inform the receiving pharmacy of:
(A) the date on which the prescription was written;
(B) the original number of refills;
(C) the number of refills remaining; and
(D) the date of the most recent refill; and
(iv) maintain a retrievable audit trail, including the date of transfer and initials or code of the transferring party, for a period of two years; and
(b) the receiving pharmacy shall maintain documentation including:
(i) a notation that the prescription was received by transfer;
(ii) the date on which the prescription was written;
(iii) the original prescription number of the transferred prescription;
(iv) the original number of refills, number of refills remaining, and the date of the most recent refill;
(v) the name, address, and DEA number of the transferring pharmacy;
(vi) all other prescription information required by state and federal laws and regulations;
(vii) a retrievable audit trail, including the date of transfer and initials or code of the receiving party, for a period of two years; and
(viii) a nonfading hard copy record of each prescription drug order transferred
(4) The electronic transfer of original prescription information for a controlled (dangerous) substance listed in Schedules III, IV or V for the purpose of refill dispensing is permissible between pharmacies on a one time basis only, by following the procedures listed above.
(5) Pharmacies accessing a common or shared electronic file or database used to maintain required dispensing information are not required to transfer prescription drug orders or information for dispensing purposes between or among pharmacies participating in the common or shared prescription file, provided, however, that any such common or shared file shall contain complete records of each prescription drug order and refill dispensed. A hard copy record of each prescription drug order accessed for purposes of refilling shall be generated if necessary and maintained at the refilling pharmacy. An easily retrievable audit trail which documents the location of each filling must be maintained and provisions must be made to assure that the number of authorized refills is not exceeded.
(a) Any pharmacy which establishes an electronic file for prescription records, which is shared with or accessible to other pharmacies, shall post in a place conspicuous to and readily readable by prescription drug consumers a notice in substantially the following form:
"NOTICE TO CONSUMERS:
This pharmacy maintains its prescription information in an electronic file which is shared by or accessible to the following pharmacies: (list names of all pharmacies which share the prescription information).
By offering this service, your prescriptions may also be refilled at the above locations. If for any reason you do not want your prescriptions to be maintained this way, please notify the pharmacist-in-charge."
(b) Whenever a consumer objects to their prescription records being made accessible to other pharmacies through the use of electronic prescription files, it is the duty of the pharmacy to assure that the consumer's records are not shared with or made accessible to another pharmacy except as provided in (1), (2) and (4) of this rule. The pharmacist to whom the consumer communicated the objection shall ask the consumer to sign a form which reads substantially as follows: "I hereby notify (name of pharmacy) that my prescription drug records may not be made accessible to other pharmacies through a common or shared electronic file." The pharmacist shall date and co-sign the form and shall

deliver a copy thereof to the patient. The original shall be maintained by the pharmacy for three years from the date of the last filling or refilling of any prescription in the name of the consumer.
(6) In an emergency, a pharmacy may transfer original prescription drug order information for a noncontrolled substance to a second pharmacy for the purpose of dispensing up to seven days supply without voiding the original prescription drug order.
(7) Both the original and transferred prescription must be maintained for a period of at least two years from the date of last refill.
(8) Pharmacies utilizing automated data processing systems must satisfy all information requirements of the manual mode for all prescription transferral and be certain that their system can void the original prescription once it is transferred, yet maintain the information on file.

TRANSMISSION BY ELECTRONIC MEANS

24.174.523 TRANSMISSION OF PRESCRIPTIONS BY ELECTRONIC MEANS (1) A pharmacist may dispense directly any legend drug which requires a prescription to dispense (except as provided in (2) and (3) below for Schedule II, III, IV, and V, controlled substances) only pursuant to either a written prescription signed by a practitioner or a prescription transmitted by the practitioner or the practitioner's agent to the pharmacy by electronic means, or pursuant to an oral prescription made by an individual practitioner and promptly reduced to hardcopy by the pharmacist, containing all information required. The prescription shall be maintained in accordance with ARM 24.174.512.
(2) A pharmacist may dispense directly a controlled substance in Schedule II, which is a prescription drug as determined by the Federal Food, Drug, and Cosmetic Act (FD&C Act), only pursuant to a written prescription signed by the practitioner. A prescription for a Schedule II controlled substance may be transmitted by the practitioner or the practitioner's agent to a pharmacy by electronic means, provided the original written, signed prescription is presented to the pharmacist for review prior to the actual dispensing of the controlled substance. The original prescription shall be maintained in accordance with ARM 24.174.512.
(a) A signed prescription for a Schedule II narcotic substance to be compounded for the direct administration to a patient by parenteral, intravenous, intramuscular, subcutaneous, or intraspinal infusion may be transmitted by the practitioner or the practitioner's agent to the pharmacy by electronic means. The electronic transmission serves as the original written prescription for the purpose of this rule and it shall be maintained in accordance with ARM 24.174.512.
(b) A signed prescription for a Schedule II substance for a resident of a long-term care facility may be transmitted by the practitioner or the practitioner's agent to the dispensing pharmacy by electronic means. The electronic transmission serves as the original written prescription for purposes of this rule and it shall be maintained in accordance with ARM 24.174.512.
(c) A signed prescription for a Schedule II substance for a patient enrolled in a hospice care program certified and/or paid for by Medicare under Title XVIII of the Social Security Act or a hospice program which is licensed by the state of Montana may be transmitted by the practitioner or the practitioner's agent to the dispensing pharmacy by electronic means. The practitioner or the practitioner's agent shall note on the prescription that the patient is a hospice patient. The electronic transmission serves as the original written prescription for purposes of this rule and it shall be maintained in accordance with ARM 24.174.512.
(3) A pharmacist may dispense directly a controlled substance listed in Schedule III, IV or V which is a prescription drug as determined under the Federal Food, Drug and Cosmetic Act, only pursuant to either a written prescription signed by a practitioner or a copy of a written, signed prescription transmitted by the practitioner or the practitioner's agent to the pharmacy by electronic means or pursuant to an oral prescription made by an individual practitioner and promptly reduced to hard copy by the pharmacist containing all information required. The prescription shall be maintained in accordance with ARM 24.174.512.
(4) Prescriptions may be transmitted electronically directly from an authorized prescriber or his/her authorized agent to the pharmacy of the patient's choice without alteration by any other party, providing the following requirements are met:
(a) Both prescriber and pharmacist must have a secure (encrypted or encoded) system for electronic transmission from computer to computer that ensures patient confidentiality;

(b) The receiving electronic device shall be located within the pharmacy department to ensure security and confidentiality;
(c) An electronically transmitted prescription shall contain all information required by state and federal law, including the date and time of transmission, the prescriber's telephone number for verbal confirmation and the name of the prescriber's agent transmitting the order, if other than the prescriber;
(d) The prescriber's electronic signature or other secure (encrypted or encoded) method of validation shall be provided with the electronically transmitted order. Faxed prescription orders shall contain the identifying number of the sending fax machine;
(e) A printed, nonfading copy of an electronically transcribed prescription will be maintained in the pharmacy for a period of two years;
(f) The prescription shall be marked "electronically transmitted prescription" or be otherwise identified for easy retrieval;
(g) An electronically transmitted prescription shall be transmitted only to the pharmacy of the patient's choice;
(h) The pharmacist is responsible for assuring the validity of the electronically transmitted prescription;
(i) A pharmacist or pharmacy shall not enter into any agreement to provide or receive a computer or computer modem, personal digital assistant, facsimile machine, or any other electronic device which would adversely affect a patient's freedom to select the pharmacy of the patient's choice; and
(j) A pharmacist or pharmacy shall not provide a computer or computer modem, personal digital assistant, facsimile machine, or any other electronic device to a prescriber or healthcare facility for the purpose of providing an incentive to refer patients to a particular pharmacy.
(5) Computer-generated, electronically signed prescriptions that are handed directly to a patient or to a patient’s agent must be authenticated by the prescriber with the prescription hand-signed, with the actual signature of the prescriber.
(6) Two or more pharmacies sharing common electronic files to maintain dispensing information are not required to transfer prescription information between these pharmacies, providing all common electronic files maintain complete and accurate records of each prescription and refill dispensed, and the total number of refills authorized is not exceeded.
(a) Any pharmacy sharing a common electronic file for prescription records shall post the following notice in readily readable form in a conspicuous place within the pharmacy:
"This pharmacy maintains its prescription information in a secure electronic file that is shared by the following pharmacies: (list names of pharmacies which share the prescription information) . If refills are authorized, your prescriptions may be refilled at any of the above locations. If you do not want your prescriptions to be maintained in this way, please notify the pharmacist at the time of filling."
(b) Pharmacies sharing common electronic files will have policies and procedures in place for handling these exceptions.

VACCINE ADMINISTRATION

24.174.503 ADMINISTRATION OF VACCINES BY PHARMACISTS (1) In order to administer or prescribe vaccinations, a pharmacist must have a collaborative practice agreement with a practitioner authorized to prescribe drugs, or in the case of a public health emergency, a directive from the state medical office of the Montana Department of Public Health and Human Services.
(2) A pharmacist may administer vaccines to persons 18 years of age or older and administer influenza vaccine to persons 12 years of age or older provided that:
(a) the pharmacist has successfully completed a course of training approved by the Centers for Disease Control and Prevention (CDC), a provider accredited by the Accreditation Counsel on Pharmacy Education (ACPE), or other authority approved by the board;
(b) the pharmacist holds a current basic cardiopulmonary resuscitation certification issued by the American Heart Association, the American Red Cross or other recognized provider, and documentation is on file at the practice site;
(c) the pharmacist and the pharmacist intern must provide a copy of the immunization certificate and CPR certification of the board for initial specialty recognition;

(d) the vaccines are administered in accordance with an established protocol that includes site-specific emergency measures; and
(e) the pharmacist has either a current copy of or online access to the most recent edition of the CDC reference "Epidemiology and Prevention of Vaccine-Preventable Diseases."
(3) The pharmacist must give a copy of the most current vaccine information statement (VIS) to the patient or the patient's legal representative for those vaccines which have them, and counsel the patient accordingly.
(4) The pharmacist must maintain written policies and procedures for disposal of used or contaminated supplies.
(5) The pharmacist must report any significant adverse events to the primary care provider if one is identified by the patient, and to the Vaccine Adverse Events Reporting System (VAERS), if applicable.
(6) A pharmacist administering any vaccine shall maintain the following information in the patient's medical records for a period of at least three years:
(a) the name, address, allergies, and date of birth of the patient;
(b) the date of administration;
(c) the name, manufacturer, dose, lot number, and expiration date of the vaccine;
(d) the vaccine information statement provided;
(e) the site and route of administration;
-(f) the name or identifiable initials of the administering pharmacist; and
(g) any adverse events encountered.
(7) The authority of a pharmacist to administer immunizations may not be delegated, however, an immunization-certified intern may immunize under the direct supervision of a pharmacist or other health care provider qualified in vaccine administration and deemed appropriate by the preceptor.
(8) The pharmacist must provide a certified true copy of the immunization certificate and CPR certification to the board for initial endorsement on their pharmacist license.
(9) In order to maintain the immunization endorsement on their pharmacist license, an immunization certified pharmacist must:
(a) maintain a current CPR certification.
(10) The board shall randomly select renewal notice forms of immunization-certified pharmacists for audit and verification of the requirements listed in this rule.

EMERGENCY PRESCRIPTION REFILLS

24.174.515 EMERGENCY PRESCRIPTION REFILLS (1) A pharmacist may refill a prescription without practitioner authorization when: (a) the pharmacist is unable to contact the practitioner after reasonable effort; and (b)in the professional judgment of the pharmacist, failure to refill the prescription may result in an interruption of a therapeutic regimen or cause patient suffering.
(2) If a prescription is not refillable, a pharmacist dispensing an emergency refill:
(a)may exercise professional judgment to dispense a minimum sufficient quantity until authorization can be obtained from a prescriber:
(i)for drugs which must be dispensed in their original containers, the pharmacist may dispense the smallest trade size available;
(b) may not dispense a prescription medication listed in Schedule II;
(c) must inform the patient or the patient's representative at the time of dispensing that the refill is being provided without the practitioner's authorization, and that practitioner authorization is required for any future refill;
(d) must inform the practitioner of the emergency refill at the earliest reasonable time; and
(e) comply with all applicable record-keeping requirements.

CLINICAL PHARMACIST PRACTITIONER

37-7-306. Clinical pharmacist practitioner qualifications. (1) A clinical pharmacist practitioner is a licensed pharmacist in good standing who:
(a) is certified by the board, in concurrence with the board of medical examiners, to provide drug therapy

management, including initiating, modifying, or discontinuing therapies, identifying and managing drug-related problems, or ordering tests under the direction or supervision of a prescriber;
(b) has additional education, experience, or certification as required by the board in concurrence with the board of medical examiners; and
(c) has in place a collaborative pharmacy practice agreement.
(2) Only a pharmacist certified by the board may legally be identified as a clinical pharmacist practitioner.

COLLABORTATIVE AGREEMENTS

24.174.524 COLLABORATIVE PRACTICE AGREEMENT REQUIREMENTS (1) Prior to initially engaging in collaborative practice, a pharmacist must provide the board with an executed written and electronic copy of the collaborative practice agreement.
(2) The collaborative practice agreement must include:
(a) the identification and signature of individual practitioner(s) authorized to prescribe drugs and responsible for the delegation of drug therapy management;
(i) the practitioner as defined in 37-2-101, MCA, must be licensed in good standing in Montana; and
(ii) the practitioner must be in active practice in the community in which the collaborating pharmacist practices. A request for an exception to this provision must be in writing and will be decided by the board.
(b) the identification and signature of individual pharmacist(s) authorized to dispense drugs and engage in drug therapy management;
(c) the types of drug therapy management decisions that the pharmacist is allowed to make which may include:
(i) a specific description of the types of diseases and drugs involved, and the type of drug therapy management allowed in each case; and
(ii) a specific description of the procedures and methods, decision criteria and plan the pharmacist is to follow.
(d) a detailed description of the procedures and patient activities the pharmacist is to follow in the course of the protocol, including the method for documenting decisions made and a plan or mechanism for communication, feedback and reporting to the practitioner concerning specific decisions made. Documentation shall be recorded within 24 hours following each intervention and may be recorded on the patient medication record, patient medical chart, or a separate log book. Documentation of drug therapy management must be kept as part of the patient's permanent record and shall be considered confidential information;
(e) a method by which adverse events shall be reported to the practitioner;
(f) a method for the practitioner to monitor clinical outcomes and intercede when necessary;
(g) a provision that allows the practitioner to override protocol agreements when necessary;
(h) a provision that allows either party to cancel the agreement by written notification;
(i) the effective date of the protocol. The duration of each protocol shall not exceed one year;
(j) the annual date by which review, renewal, and revision, if necessary, will be accomplished;
(k) the addresses where records of collaborative practice are maintained; and
(l) the process for obtaining the patient's written consent to the collaborative practice agreement.
(3) Patient records shall be maintained by the pharmacist for a minimum of seven years and may be maintained in an automated system pursuant to ARM 24.174.817.
(4) Collaborative practice agreements approved by an institutional committee such as the pharmacy and therapeutics committee and that will be used solely for inpatients are exempt.

24.174.525 DEFINITIONS (1) "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, a certification process that is consistent with public policy regarding the credentialing of healthcare professionals.
(2) "Clinical practice experience" 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, 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.
(3) "Collaborative practice agreement" is defined as set forth in ARM 24.174.524.

24.174.526 REQUIREMENTS TO BECOME A CLINICAL PHARMACIST PRACTITIONER (1) An applicant for a clinical pharmacist practitioner registration shall:
(a) submit an application on a form prescribed by the board;
(b) pay a registration fee as prescribed by the board;
(c) hold an active, unrestricted Montana pharmacist license;
(d) have completed five years of clinical practice experience or have completed a pharmacy residency and two years clinical practice experience and hold one of the following active certifications:
(i) BPS certification; or
(ii) nationally recognized certification in an area of practice as approved by the board and Board of Medical Examiners (BME).
(e) submit a signed collaborative practice agreement to the board that includes a description of the type of supervision the collaborating physician will exercise over the clinical pharmacist practitioner;
(f) following approval of the board, submit the application and collaborative practice agreement to the BME for approval; and
(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 shall be inactive, until such time as a new application is approved.

24.174.527 REQUIREMENTS TO MAINTAIN CLINICAL PHARMACIST PRACTITIONER REGISTRATION
(1) In addition to completing the annual renewal requirements for a pharmacist's license, a clinical pharmacist practitioner must pay a clinical pharmacist practitioner annual renewal fee to the board.
(2) The board shall randomly select renewal notice forms of clinical pharmacist practitioners for audit of current certification and requirements for continued registration.

24.174.528 UNPROFESSIONAL CONDUCT (1) A clinical pharmacist practitioner's registration may be disciplined by the board for unprofessional conduct as defined by the board in ARM 24.174.2301.
(2) The BME may take appropriate action for the unlicensed practice of medicine under 37-3-101 and 37-1-317, MCA, if a clinical pharmacist practitioner exceeds the scope of practice as defined in 37-7-306, MCA.

TECHNICIANS

37-7-307. Utilization plan -- contents -- responsibility of pharmacist. (1) A utilization plan must set forth:
(a) the name and qualifications of the supervising pharmacist or pharmacists;
(b) the nature and location of the supervising pharmacist's pharmacy practice;
(c) a summary of the tasks delegated by the pharmacist and the methods by which a supervising pharmacist may verify and document the tasks. "Verify" means the personal confirmation by a supervising pharmacist of the correctness of the tasks undertaken by the pharmacy technician.
(d) any other information the board considers relevant.

(2) The board shall approve a utilization plan if it determines that the duties to be delegated are:
(a) assigned, verified, and documented by the supervising pharmacist; and
(b) within the scope of the training and competence of the person to whom the authority is delegated.
(3) A supervising pharmacist is responsible for the actions of a pharmacy technician or auxiliary who performs services for the pharmacist under the terms of a utilization plan.

37-7-308. Preparation and approval of utilization plan -- revocation of or refusal to renew plan – contested case hearing. (1) A supervising pharmacist shall:
(a) prepare the utilization plan and submit a summary of the plan to the board for approval;
(b) keep on file in the pharmacy a copy of the utilization plan for inspection by the board; and
(c) annually review the utilization plan and provide documentation to the board that the plan accurately reflects the current use of the services of a pharmacy technician or auxiliary.
(2) The board shall refuse to approve or shall revoke or fail to renew approval of a utilization plan if it does not conform to the provisions of 37-7-307 through 37-7-309 and rules adopted under those sections.
(3) One year after the board revokes approval of a utilization plan, the supervising pharmacist may reapply for approval by complying with the requirements of 37-7-307 through 37-7-309 and with rules adopted under those sections.
(4) Before refusing to approve or before revoking or failing to renew approval of a utilization plan, the board shall provide the supervising pharmacist a reasonable time in which to supply additional information demonstrating compliance with the requirements of 37-7-307 through 37-7-309 and with rules adopted under those sections and the opportunity to request a hearing.
(5) If a supervising pharmacist requests a hearing, the board shall conduct the hearing in accordance with the contested case procedures in Title 2, chapter 4, part 6.

37-7-309. Utilization plan approval fee -- renewal of approval -- renewal fee. (1) A pharmacy in which a pharmacist uses the services of a pharmacy technician or auxiliary under an approved utilization plan shall pay to the board a utilization plan approval fee in an amount set by the board as provided in 37-1-134. Payment must be made when the utilization plan is submitted and is not refundable.
(2) Approval of a utilization plan expires 1 year from the date of approval. The board shall grant renewal of approval upon payment of a renewal fee in an amount set by the board and documentation as required by 37-7-308(1)(c).
(3) The board may adopt fees, as provided in 37-1-134, for other costs associated with implementation of 37-7-307 through 37-7-309, including the costs of onsite inspection of the utilization plan at the participating pharmacy.
(4) The board shall deposit fees received in the state special revenue fund for use by the board in administration of 37-7-307 through 37-7-309, subject to 37-1-101(6).

24.174.701 REGISTRATION REQUIREMENTS (1) In order to be registered as a pharmacy technician in this state, the applicant shall:
(a) submit application on a form prescribed by the board;
(b) pay application fees as prescribed by the board; and (c) submit a copy of proof of certification by PTCB or other board approved certifying entity.
(2) In order to be registered as a technician-in-training in this state, the applicant shall:
(a) apply to the board for a permit on an application supplied by the board;
(b) pay the fee required;
(c) provide the name and address of the pharmacy in which the technician-in-training is employed. A change in place of employment will require submission of updated information within 10 working days of the change.
(3) The permit to practice as a technician-in-training shall be valid for a period of not longer than 18 months. A technician-in-training applicant who has not passed the pharmacy Technician Certification Board (PTCB), ExCPT, or other board-approved certifying exam within the 18 months due to extenuating circumstances may file a written request to the board for an extension of his or her technician-in-training license. The board will then determine when the license will expire. A technician-in-training whose license has expired but who did not pass the requisite exams may not apply for a technician-in-training license a second time.
(4) Working as a technician-in-training with an expired license is cause for disciplinary action against the licensee.

24.174.702 QUALIFICATIONS OF PHARMACY TECHNICIAN (1) A person who acts as a pharmacy technician under the provisions of a utilization plan must be:
(a) at least 18 years old;
(b) a high school graduate or have attained an equivalent degree;
(c) of good moral character; and
(d) certified by the pharmacy technician certification board (PTCB) or other board approved certifying entity.
(2) No pharmacist whose license has been denied, revoked, suspended, or restricted for disciplinary purposes shall be eligible to be registered as a pharmacy technician.

24.174.703 USE OF PHARMACY TECHNICIAN (1) A pharmacy technician 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) When a pharmacist is not in the prescription department, 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.
(3) No medication may be released to a patient without review by a registered pharmacist for the accuracy and appropriateness of the prescription drug order.
(4) All 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.
(5) All pharmacy technician licenses and technician-in-training permits must be conspicuously displayed at all times in the place of business.

24.174.704 PHARMACY TECHNICIAN TRAINING (1) A supervising pharmacist shall:
(a) provide initial training to a pharmacy technician that relates to the tasks the technician may perform pursuant to the supervising pharmacist's utilization plan; and
(b) prepare and maintain a written record of initial and in-service training for on-site inspection by the board. The record shall contain the following information:
(i) name and signature of the person receiving the training;
(ii) dates of the training;
(iii) general description of the topics covered; and
(iv) name and signature of the person supervising the training.
(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. A supervising pharmacist must obtain the board's approval of an initial training program prior to undertaking the training of a pharmacy technician pursuant to the program.
(3) Verification of completion of training, by test or otherwise, shall be recorded by the supervising pharmacist, and shall be available for inspection with the training record.

24.174.705 TASKS AND FUNCTIONS OF PHARMACY TECHNICIAN (1) Only a registered pharmacy technician may perform the following tasks or functions under the provisions of an approved utilization plan:
(a) remove a stock bottle from the shelf and count or pour the contents into a suitable container. The stock bottle must be quarantined together with the prescription until the supervising pharmacist performs a final check or bar coding or other available technology verifies the bottle contents;
(b) type a prescription label and affix it and auxiliary labels to a prescription bottle, with final review by the registered pharmacist;
(c) enter prescription information into an automated system under the supervision of a pharmacist who must be able to check all entries;
(d) maintain prescription records, including prescription numbers, refill data and other information on the patient profile system;

(e) prepackage unit dose drugs for internal distribution. These prepackage unit dose drugs must be quarantined together with bulk containers until the supervising pharmacist performs a final check and maintains appropriate records.
(f) answer the telephone, properly identify themselves as a technician, accept verbal orders for refill prescriptions from medical practitioners or their designated agents and issue refill requests to the prescriber;
(g) a pharmacy technician may act as agent in charge of the pharmacy to assure its integrity when a registered pharmacist is not physically present, but 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; and
(h) compounding if a mechanism for verification by the supervising pharmacist exists that includes checking of: the original order; additives; dosages; and clarity of IV solution, where appropriate.
(2) The board reserves the right to evaluate and amend the functions allowable by a pharmacy technician, with final determination in the sole discretion of the board.

24.174.711 RATIO OF PHARMACY TECHNICIANS TO SUPERVISING PHARMACISTS (1) A registered pharmacist in good standing may supervise the services of no more than three technicians at any time. The 1:3 pharmacist to pharmacy technician ratio may be revised by the board at any time for good cause.
(2) Registered pharmacists in good standing in the state of Montana may supervise a maximum of three registered pharmacy technicians, provided:
(a) in the professional judgment of the pharmacist on duty, the policy and procedures of the pharmacy must allow for safe and accurate filling and labeling of prescriptions;
(b) the policy and procedures 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
(c) a copy of the policy and procedures must be available for inspection by the board compliance officer.
(3) If a pharmacy desires more than three technicians to work under the supervision, direction, and control of one pharmacist, the pharmacy shall obtain the prior written approval of the board. To apply for approval, the pharmacist-in-charge shall submit a pharmacy services plan to the board. The pharmacy services plan submitted shall demonstrate how the plan facilitates the provision of pharmaceutical care and shall include, but shall not be limited to the following:
(a) design and equipment;
(b) information systems;
(c) work flow; and
(d) quality assurance procedures.
(4) The board shall grant approval of a pharmacy service plan only when the board is satisfied that the provision of pharmaceutical care by the pharmacy will be enhanced by the increased use of technicians. An exception may be revoked by the board at any time for good cause.
(5) No pharmacy shall modify a board approved pharmacy service plan without the prior written approval of the board.
(6) Nothing in this rule shall prevent a pharmacy from terminating a service plan upon written notification to the board.

24.174.712 APPLICATION FOR APPROVAL OF UTILIZATION PLAN (1) A registered pharmacist in good standing in the state of Montana may apply to the board for permission to use the services of a pharmacy technician by submitting to the board:
(a) an application on a form prescribed by the board;
(b) a summary of the utilization plan, to include information showing compliance with all requirements set forth in these rules, plus all other requirements of 37-7-307, 37-7-308, and 37-7-309, MCA, and this chapter;
(c) the appropriate fee for initial approval of the plan;
(d) any changes in the utilization plan, including technician training, must be re-submitted to the board for approval before implementation of the changes by the supervising pharmacist.
(2) Any number of registered pharmacists employed in the same pharmacy may sign as supervising pharmacist of a pharmacy technician on a single utilization plan submitted for approval to the board by that pharmacy.

(3) A registered pharmacist in good standing in the state of Montana may apply to the board to designate that pharmacy as a technician training site for a board-approved academic program curriculum. If the pharmacy training site does not have an approved technician utilization plan in place, the pharmacy may substitute an academic program training plan, assessment criteria and periodic contact plan for board approval, for the purpose of providing on-the-job experience for technician trainees.

24.174.713 CONTENTS OF TRAINING COURSE (1) A pharmacy technician training course must include instruction in:
(a) orientation to the practice of pharmacy;
(b) pharmacy terminology and basic pharmaceutics;
(c) state and federal laws relating to the practice of pharmacy;
(d) pharmaceutical calculations;
(e) processing prescription drug orders;
(f) telephone procedure and communication including taking refill requests;
(g) pharmaceutical compounding;
(h) intravenous admixture, if applicable; and
(i) use of pharmacy computer systems, if applicable.

24.174.714 INSPECTION OF UTILIZATION PLAN AND TRAINING RECORD (1) The supervising pharmacist shall make the utilization plan available for inspection by the board during the normal business hours of the pharmacy.
(2) The pharmacy technician shall make their training record available for inspection by the board during the normal business hours of the pharmacy.

24.174.715 TECHNICIAN CHECK TECHNICIAN PROGRAM (1) To participate in a technician check technician (TCT) program an institutional pharmacy within a hospital must meet the following requirements:
(a) the pharmacy must include TCT as a technician duty, submitted to the Board of Pharmacy by the pharmacist-in-charge as part of the technician utilization plan;
(b) develop a site-specific training program tailored to the patient population and medication distribution system;
(c) designate one pharmacist to be responsible for meeting the TCT program training and validation requirements;
(d) staffing must be adequate to support a consistent utilization of the TCT program;
(e) a pharmacist must review all orders against a medication profile containing pertinent clinical information about the patient (allergies, current medication, etc.);
(f) the medication description on the batch fill list must contain the same description as the labeling on the unit dose package;
(g) the drug distribution system must be structured so that at least one additional check of dispensed medications is completed prior to administration;
(h) develop policies and procedures which include a list of the types of work that a technician may check and the types of work that are excluded from being checked by a technician; and
(i) utilize the TCT program as a tool to redirect pharmacists from distributive tasks to cognitive and patient centered activities.
(2) In order to participate in a TCT program a technician must:
(a) be a registered pharmacy intern in good standing with the board with at least three months experience in unit dose filling; or
(b) be a certified pharmacy technician in good standing with the board working full or part time with six months equivalent experience in unit dose filling; and
(c) complete site specific training in the TCT program.
(3) A TCT training program must include:
(a) didactic lecture (or equivalent training with a self-learning packet);
(b) practical sessions (one-on-one training) which consist of observation of a pharmacist checking a unit dose medication batch and/or cart;

(c) initial validation (and revalidation if needed); and
(d) regular quality assurance audits performed quarterly for the first year then every six months thereafter.
(4) Approval from the Board of Pharmacy or designee is required prior to program implementation.
(5) If at any time a technician loses their validation, that individual must not function as a TCT until they are retrained and revalidated.
(6) All TCT program materials should be readily retrievable for review by the board inspector.

DISPENSING RESTRICTIONS

37-2-101. Definitions. As used in this part, the following definitions apply: (1) "Community pharmacy", when used in relation to a medical practitioner, means a pharmacy situated within 10 miles of any place at which the medical practitioner maintains an office for professional practice.
(2) "Device" means any instrument, apparatus, or contrivance intended:
(a) for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in humans;
(b) to affect the structure or any function of the body of humans.
(3) "Drug" has the same meaning as provided in 37-7-101.
(4) "Drug company" means any person engaged in the manufacturing, processing, packaging, or distribution of drugs. The term does not include a pharmacy.
(5) "Medical practitioner" means any person licensed by the state of Montana to engage in the practice of medicine, dentistry, osteopathy, podiatry, optometry, or a nursing specialty as described in 37-8-202 and in the licensed practice to administer or prescribe drugs.
(6) "Person" means any individual and any partnership, firm, corporation, association, or other business entity.
(7) "Pharmacy" has the same meaning as provided in 37-7-101.
(8) "State" means the state of Montana or any political subdivision of the state.

37-2-102. Practices declared unlawful between drug companies and medical practitioners. It is unlawful:
(1) for a drug company to give or sell to a medical practitioner any legal or beneficial interest in the company or in the income of the company with the intent or for the purpose of inducing the medical practitioner to prescribe to patients the drugs of the company. The giving or selling of an interest by the company to a medical practitioner without the interest first having been publicly offered to the general public is prima facie evidence of the intent or purpose.
(2) for a medical practitioner to acquire or own a legal or beneficial interest in any drug company, provided it is not unlawful for a medical practitioner to acquire or own an interest solely for investment, and the acquisition of an interest that is publicly offered to the general public is prima facie evidence of its acquisition solely for investment;
(3) for a medical practitioner to solicit or to knowingly receive from a drug company or for a drug company to pay or to promise to pay to a medical practitioner any rebate, refund, discount, commission, or other valuable consideration for, on account of, or based upon the volume of wholesale or retail sales, at any place, of drugs manufactured, processed, packaged, or distributed by the company.

37-2-103. Practices declared unlawful between medical practitioners and pharmacies. (1) It is unlawful for a medical practitioner to own, directly or indirectly, a community pharmacy. This subsection does not prohibit a medical practitioner from dispensing a drug that the medical practitioner is permitted to dispense under 37-2-104.
(2) It is unlawful for a medical practitioner, directly or indirectly, to solicit or to knowingly receive from a community pharmacy or for a community pharmacy knowingly to pay or promise to pay to a medical practitioner any rebate, refund, discount, commission, or other valuable consideration for, on account of, or based upon income received or resulting from the sale or furnishing by the community pharmacy of drugs to patients of a medical practitioner.

37-2-104. Dispensing of drugs by medical practitioners unlawful -- exceptions. (1) Except as otherwise provided by this section, it is unlawful for a medical practitioner to engage, directly or indirectly, in the dispensing of drugs.
(2) This section does not prohibit:
(a) a medical practitioner from furnishing a patient any drug in an emergency;

(b) the administration of a unit dose of a drug to a patient by or under the supervision of a medical practitioner;
(c) dispensing a drug to a patient by a medical practitioner whenever there is no community pharmacy available to the patient;
(d) the dispensing of drugs occasionally, but not as a usual course of doing business, by a medical practitioner;
(e) a medical practitioner from dispensing drug samples;
(f) the dispensing of factory prepackaged contraceptives, other than mifepristone, by a registered nurse employed by a family planning clinic under contract with the department of public health and human services if the dispensing is in accordance with:
(i) a physician's written protocol specifying the circumstances under which dispensing is appropriate; and
(ii) the drug labeling, storage, and recordkeeping requirements of the board of pharmacy;
(g) a contract physician at an urban Indian clinic from dispensing drugs to qualified patients of the clinic. The clinic may not stock or dispense any dangerous drug, as defined in 50-32-101, or any controlled substance. The contract physician may not delegate the authority to dispense any drug for which a prescription is required under 21 U.S.C. 353(b).
(h) a medical practitioner from dispensing a drug if the medical practitioner has prescribed the drug and verified that the drug is not otherwise available from a community pharmacy. A drug dispensed pursuant to this subsection (2)(h) must meet the labeling requirements of the board of pharmacy.

37-2-105. Duty of county attorneys. It shall be the duty of the county attorneys in the counties of the state, under the direction of the attorney general, to institute appropriate proceedings to prevent and restrain such violations. Such proceedings may be by way of complaint setting forth the case and praying that such violation shall be enjoined or otherwise prohibited. Upon the filing of a complaint under this section and the service thereof upon the defendants named therein, the court shall proceed as soon as possible to the hearing and determination of the action.

37-2-106. Existing ownership of pharmacy. The provisions of 37-2-103(1) do not apply to a medical practitioner with respect to any interest that the medical practitioner owns on July 1, 1971. However, transfer of this interest to another person results in immediate termination of the exemption.

37-2-107. Civil penalty for unreadable prescription. (1) A medical practitioner may not issue a written prescription, to be delivered to a patient or pharmacy, in such a manner that the name of the drug, the dosage, the instructions for use, the printed name or other identifying letters or numbers unique to the medical practitioner, and, if required, the federal drug enforcement agency identifying number cannot be read by a registered pharmacist licensed to practice in this state.
(2) Any person may file a complaint alleging a violation of subsection (1) with the board that licensed the medical practitioner who issued the prescription. The board may investigate the complaint and take any action and impose any sanction allowed by the statutes relating to the board and rules adopted by the board. Each board licensing a medical practitioner shall adopt rules to implement this section.
(3) The board may refer the complaint to the county attorney of the county in which the prescription was issued, whether or not the board itself has taken any action or imposed any sanction. A county attorney may not file an action alleging a violation of subsection (1) unless a complaint has been referred to the county attorney by the medical practitioner's licensing board.
(4) A medical practitioner who violates subsection (1) is guilty of a civil offense and may be punished by a civil penalty of not more than $500 for each prescription.

REPORTING OBLIGATIONS

37-2-301. Duty to report cases of communicable disease. (1) If a physician or other practitioner of the healing arts examines or treats a person who the physician or other practitioner believes has a communicable disease or a disease declared reportable by the department of public health and human services, the physician or other practitioner shall immediately report the case to the local health officer. The report must be in the form and contain the information prescribed by the department.
(2) A person who violates the provisions of this section or rules adopted by the department under the provisions of

this section is guilty of a misdemeanor. On conviction, the person shall be fined not less than $10 or more than $500, imprisoned for not more than 90 days, or both. Each day of violation constitutes a separate offense. Fines, except those collected by a justice's court, must be paid to the county treasurer of the county in which the violation occurs.

37-2-302. Gunshot or stab wounds to be reported. The physician, nurse, or other person licensed to practice a health care profession treating the victim of a gunshot wound or stabbing shall make a report to a law enforcement officer by the fastest possible means. Within 24 hours after initial treatment or first observation of the wound, a written report shall be submitted, including the name and address of the victim, if known, and shall be sent by regular mail.

37-2-303. Immunity from liability. A physician or other person reporting pursuant to 37-2-302 is presumed to be acting in good faith and in reporting is immune from any liability, civil or criminal, unless the individual acted in bad faith or with malicious purpose.

PRESCRIPTION RESTRICTIONS

37-7-401. Restrictions on prescriptions. (1) An authorized prescriber may not sell, give to, or prescribe for any person any opium, morphine, alkaloid-cocaine, alpha or beta eucaine, codeine, heroin, or any derivative, mixture, or preparation of any of them, except to a patient believed in good faith to require opium, morphine, alkaloid-cocaine, alpha or beta eucaine, codeine, heroin, or any derivative, mixture, or preparation of the enumerated substances for medical use and in quantities proportioned to the needs of the patient.
(2) A prescription must be written so that the prescription can be compounded by any registered pharmacist. The coding of any prescription is a violation of this section.
(3) A prescription marked "non repetatur", "non rep", or "N.R." cannot be refilled. A prescription marked to be refilled may be filled by any registered pharmacist the number of times marked on the prescription. A prescription not bearing any refill instructions may not be refilled without first obtaining permission from the prescriber. A prescription may not be refilled for more than 1 year from the date the prescription was originally written. A Schedule II prescription may not be refilled.

37-7-402. Penalty for violation of provisions on sale or prescription of opiates, coding, refilling. Any person found guilty of the violation of 37-7-401 shall be punished for each separate offense (and each and every individual case shall constitute a separate offense) by a fine of not less than $50 or more than $500 or by imprisonment in the county jail for a period of not less than 60 days or more than 100 days or by both such fine and imprisonment.

DRUG PRODUCT SELECTION (GENERIC SUBSTITUTION)

37-7-501. Short title. This part may be cited as the "Montana Drug Product Selection Act".

37-7-502. Definitions. As used in this part, the following definitions apply: (1) "Bioavailability" means the extent and rate of absorption from a dosage form as reflected by the time-concentration curve of the administered drug in the systemic circulation.
(2) "Bioequivalent" means a chemical equivalent which, when administered to the same individual in the same dosage regimen, will result in comparable bioavailability.
(3) "Brand name" means the proprietary or the registered trademark name given to a drug product by its manufacturer, labeler, or distributor and placed upon the drug, its container, label, or wrapping at the time of packaging.
(4) "Chemical equivalent" means drug products that contain the same amounts of the same therapeutically active ingredients in the same dosage forms and that meet present compendium standards.
(5) "Drug product" means a dosage form containing one or more active therapeutic ingredients along with other substances included during the manufacturing process.
(6) "Generic name" means the chemical or established name of a drug product or drug ingredient published in the

latest edition of an official compendium recognized by the board.
(7) "Person" has the same meaning as provided in 37-7-101.
(8) "Prescriber" means a medical practitioner, as defined in 37-2-101, licensed under the professional laws of the state to administer and prescribe medicine and drugs.
(9) "Present compendium standard" means the official standard for drug excipients and drug products listed in the latest revision of an official compendium recognized by the board.
(10) "Product selection" means to dispense without the prescriber's express authorization a different drug product in place of the drug product prescribed.
(11) "Therapeutically equivalent" means those chemical equivalents which, when administered in the same dosage regimen, will provide essentially the same therapeutic effect as measured by the control of a symptom or a disease and/or toxicity.

37-7-503. Rulemaking. The board of pharmacy may adopt, amend, or repeal rules necessary for the implementation, continuation, and enforcement of this part in accordance with the Montana Administrative Procedure Act.

37-7-504. General prohibition of drug substitution. No person may substitute a drug different from the one ordered or deviate in any manner from the requirements of an order or prescription, except as provided in this part.

37-7-505. Product selection permitted -- limitation. (1) Except as limited by subsection (2) and unless instructed otherwise by the purchaser, the pharmacist who receives a prescription for a specific drug product by brand or proprietary name may select a less expensive drug product with the same generic name, strength, quantity, dose, and dosage form as the prescribed drug that is, in the pharmacist's professional opinion, therapeutically equivalent, bioequivalent, and bioavailable.
(2) If, in the professional opinion of the prescriber, it is medically necessary that an equivalent drug product not be selected, the prescriber may so indicate by certifying that the specific brand-name drug product is medically necessary for that particular patient. In the case of a prescription transmitted orally, the prescriber must expressly indicate to the pharmacist that the brand-name drug product prescribed is medically necessary.

37-7-506. Notice to purchaser. (1) A pharmacist who selects a drug product, as provided in 37-7-505, shall notify the person presenting the prescription that the person may refuse the product selection as provided in 37-7-505.
(2) Each pharmacy shall display in a prominent place that is in clear and unobstructed public view, at or near the place where prescriptions are dispensed, a sign stating: "This pharmacy may be able to select a less expensive drug product that is equivalent to the one prescribed by your physician unless you or your physician request otherwise." The printing on the sign must be in block letters not less than 1 inch in height.

37-7-507. Savings passed on. (1) A pharmacist selecting a less expensive drug product must pass on to the purchaser the full amount of the savings realized by the product selection. In no event may the pharmacist charge a different professional fee for dispensing a different drug product than the drug product originally prescribed.
(2) If the prescriber prescribes a drug product by its generic name, the pharmacist must, consistent with reasonable judgment, dispense the lowest retail priced, therapeutically equivalent brand which is in stock.

3**7-7-508. Product selection not practice of medicine.** The selection of a drug product by a registered pharmacist under the provisions of this part does not constitute the practice of medicine.

37-7-509. Limitations on liability. (1) A pharmacist making a product selection under the provisions of this part assumes no greater responsibility for selecting the dispensed drug product than the pharmacist would incur in filling a prescription for a drug product prescribed by a generic name.
(2) When a pharmacist selects a drug product, the prescriber may not be held liable in an action for loss, damage, injury, or death to a person caused by the use of the selected drug product, except that if the original drug product was incorrectly prescribed, the prescriber is not relieved of liability.

PRICING

37-7-204. Posting of prescription drug prices -- adoption of list by rule. If the board of pharmacy finds after a public hearing that the interests of consumers will be furthered by its action, the board shall annually adopt by rule a list of 20 prescription drugs frequently prescribed for outpatient dispensing in Montana. A licensed pharmacy, other than in a hospital or nursing home, that sells prescription drugs shall monthly post its prices for the drugs on the list adopted by the board. The list must show the drugs by brand name and retail price and by generic name and retail price.

PHARMACIES, COMMUNITY

37-7-102. Practice subject to regulation. The practice of pharmacy is a professional practice affecting the public health, safety, and welfare and is subject to regulation and control in the public interest.

24.174.801 GENERAL LICENSE REQUIREMENTS (1) The board shall grant a license for the operation of a pharmacy in the state of Montana when it is plainly shown that:
(a) the owner of the pharmacy is a registered pharmacist in good standing in the state of Montana; or
(b) the manager or supervisor of the pharmacy is a registered pharmacist in good standing in the state of Montana and that the pharmacist will be actively and regularly engaged and employed in, and responsible for the management, supervision and operation of such pharmacy.
(2) The license registers the pharmacy to which it is issued and is not transferable. It is issued on the application of the registered pharmacist in charge, and which contains the sworn statement that the pharmacy will be operated in accordance with the provisions of the law.
(3) To operate, maintain, open, or establish more than one pharmacy, separate applications shall be made and separate licenses issued for each.

24.174.802 NEW PHARMACY (1) Prior to conducting business, a pharmacy must secure a license and be registered with the board. Application for a license to operate a new pharmacy must be reviewed by the board or its designee before the license may be issued.
(2) A corporation or unregistered owner, may secure a license on the affidavit of the registered pharmacist charged with the management and supervision of the pharmacy.
(3) All new pharmacies shall be in compliance with ARM 24.174.814 at the time the pharmacy is opened for business.

24.174.803 CHANGE IN LOCATION (1) Whenever a pharmacy changes its physical location, including within the existing business location, it shall submit a new schematic or floor plan, for board approval.
(2) Whenever a pharmacy changes its physical location outside of its then existing business location, its original license becomes void and must be surrendered. The pharmacy shall submit a new license application, including a new schematic and floor plan of the new location, for the board's approval at least 30 days before such change occurs.

24.174.804 CHANGE IN OWNERSHIP (1) When a pharmacy changes ownership, the original license becomes void and must be surrendered to the board, and a new license obtained by the new owner or owners. The owner shall submit a new license application at least 30 days prior to the change in ownership. The application must be reviewed by the board or its designee before the license may be issued.
(2) A change in ownership for the purposes of this rule shall be deemed to occur when more than 50 percent of the equitable ownership of a business is transferred in a single transaction or in a related series of transactions to one or more persons or any other legal entity.
(3) The board must be notified in writing when five to 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.

24.174.805 CHANGE OF PHARMACIST-IN-CHARGE (1)When the pharmacist-in-charge of a 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.
(2) Within 72 hours 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.

24.174.806 LICENSES TO BE POSTED (1)The pharmacy license must be posted in a conspicuous place in the pharmacy.

24.174.807 CLOSURE OF A PHARMACY (1) Upon permanent closure of a pharmacy, the original license becomes void and must be surrendered to the board within ten days.
(2) Whenever a pharmacy permanently closes, the owner shall notify the board of the closing no later than 15 days prior to the anticipated date of closing. The notice shall be submitted in writing and shall include the following information:
(a) the date the pharmacy will close;
(b) the names and addresses of the persons who will have custody of the closing pharmacies:
(i) prescription files;
(ii) bulk compounding records;
(iii) repackaging records; and
(iv) controlled substance inventory records.
(c) the names and addresses of any persons who will acquire any legend drugs from the closing pharmacy, if known at the time the notice is filed.
(3) No later than 15 days after the pharmacy has closed, the owner shall submit to the board written confirmation that:
(a) all legend drugs have been either:
(i) destroyed; or
(ii) transferred to an authorized person(s), including the names and addresses of the person(s) to whom the legend drugs were transferred.
(b) controlled substances were transferred, including:
(i) names and addresses of the person(s) to whom the substances were transferred;
(ii) the substances transferred;
(iii) the amount of each substance transferred; and
(iv) the date on which the transfer took place.
(c) the DEA registration and all unused DEA 222 forms (order forms) were returned to the DEA;
(d) all pharmacy labels and blank prescriptions which were in the possession of the pharmacy were destroyed; and
(e) all signs and symbols indicating the presence of the pharmacy have been removed.

24.174.814 SECURITY OF PHARMACY (1) Each pharmacist, while on duty, shall be responsible for the security of the pharmacy, including provisions for effective control against theft or diversion of drugs.
(a) A Schedule II controlled substance perpetual inventory shall be maintained and routinely reconciled in all pharmacies.
(2) The pharmacy shall be secured at all times by either a physical barrier with suitable locks and/or an electronic barrier to detect entry by unauthorized persons at any time. Such barrier shall be approved by the board or its designee before being put into use.
(3) Prescription and other patient health care information shall be maintained in a manner that protects the integrity and confidentiality of such information as provided by the rules of the board.
(4) Sections (1) and (2) of this rule shall be effective February 1, 2004.

24.174.817 AUTOMATED RECORD KEEPING SYSTEMS (1) An automated system may be employed for the record keeping system, if the following conditions have been met:
(a) The system shall have the capability of producing legible documents of all original and refilled prescription information. During the course of an on-site inspection the records must be accessible for viewing or printing.

(b) The individual pharmacist responsible for completeness and accuracy of the entries to system must provide documentation of the fact that prescription information entered into the computer is correct. In documenting this information, the pharmacy shall have the option to either:
(i) maintain a bound log book, or separate file, in which each individual pharmacist involved in such dispensing shall sign a statement each day, attesting to the fact that the prescription information entered into the computer that day has been reviewed and is correct as shown. Such a book or file must be maintained at the pharmacy employing such a system for a period of at least two years after the date of last dispensing; or
(ii) provide a printout of each day's prescription information. That printout shall be verified, dated and signed by the individual pharmacist verifying that the information indicated is correct and then sign this document in the same manner as signing a check or legal document (e.g., J. H. Smith, or John H. Smith). Such printout must be maintained at least two years from the date of last dispensing; or
(iii) utilize a software system which requires a unique log in for each function such that it can be easily and accurately determined who performed every function within the prescription dispensing process. The records must be readily accessible for viewing or printing at the request of the board.
(c) An auxiliary recordkeeping system shall be established for the documentation of refills if the automated system is inoperative for any reason. The auxiliary system shall insure that all refills are authorized by the original prescription and that the maximum number of refills is not exceeded. When this automated system is restored to operation, the information regarding prescriptions filled and refilled during the inoperative period shall be entered into the automated system within 96 hours. However, nothing in this section shall preclude the pharmacist from using his professional judgment for the benefit of a patient's health and safety.
(d) Any pharmacy using an automated system must comply with all applicable state and federal laws and regulations.

24.174.818 SECURITY (1)The system shall contain adequate safeguards or security of the records to maintain the confidentiality and accuracy of the prescription or drug order information. Safeguards against unauthorized changes in data after the information has been entered and verified by the registered pharmacist shall be provided by the system.

24.174.819 SANITATION AND EQUIPMENT REQUIREMENTS (1) Pharmacies shall at all times be operated by a registered pharmacist in a sanitary manner. There must be in use a safe and pure water supply and facilities for the proper storage and handling of supplies and stocks.
(2) Pharmacies shall have adequate space where prescriptions are filled or drugs compounded, containing suitable equipment in order to provide for an efficient pharmacy operation.
(3) Pharmacies shall contain and have ready for use all up-to-date items which are necessary in filling prescriptions, compounding drugs and the efficient operation of the pharmacy.

PHARMACIES, HUB

24.174.823 CENTRALIZED PRESCRIPTION FILLING AND PROCESSING OF DRUG ORDERS (1) A pharmacy may outsource prescription drug order filling or processing to a central filling or processing pharmacy provided the pharmacies:
(a) have the same owner or have entered into a written contract or agreement that outlines the services to be provided and the responsibilities and accountabilities of each pharmacy in compliance with federal and state laws, rules, and regulations; and
(b) share a common electronic file.
(2) A pharmacy that outsources prescription drug order filling or processing to another pharmacy shall, prior to outsourcing a prescription drug order:
(a) notify the patient or the patient's agent that prescription filling or processing may be outsourced to another pharmacy;
(b) provide the name of the pharmacy that will be filling or processing the prescription or, if the pharmacy is part of a network of pharmacies under common ownership and any of the network pharmacies may fill or process the prescription, the patient shall be notified of this fact; and

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

LIMITED SERVICE PHARMACY

24.174.830 LIMITED SERVICE PHARMACY

(1) A limited service pharmacy is defined as a family planning clinic:
(a) operating under contract with the Department of Public Health and Human Services (DPHHS); or
(b) providing pharmaceutical care under the review of a consulting pharmacist and dispensing legend drugs, but which is not under contract with DPHHS.
(2) Each limited service pharmacy must apply for a license from the board and submit the required fee.
(3) The board shall grant a license to operate a limited service pharmacy to qualified applicants. A licensed family planning clinic may operate satellite locations under the same license if identified on the application.
(4) A limited service pharmacy must display its license in a conspicuous place at the facility.
(5) A limited service pharmacy is not required to employ a licensed pharmacist.
(6) A limited service pharmacy dispensing legend drugs other than factory, prepackaged contraceptives must disclose the name, address, telephone number, and title of the designated person in charge of the limited service pharmacy. The person in charge is responsible for the limited service pharmacy's compliance with all applicable state and federal statutes and rules. A person in charge may be responsible for multiple sites.

(7) The board may annually inspect limited service pharmacies, including any satellite locations. The board may inspect more often for cause. Such inspections must include assurance that the limited service pharmacy provides adequate:
(a) drug labeling;
(b) counseling materials to all patients, including the name of the limited service pharmacy's consulting pharmacist, where required;
(c) contact information of a knowledgeable individual at the clinic in the event of an adverse reaction;
(d) records maintenance and retention; and
(e) drug storage and security.
(8) Nothing in this rule is meant to limit or restrict the authority of a registered nurse employed by a family planning clinic, operating under contract with DPHHS, from dispensing factory, prepackaged contraceptives as authorized by 37-2-104, 37-7-103, or 50-31-307, MCA.
(9) A registered nurse or provider with prescriptive authority, employed by a family planning clinic operating under contract with DPHHS, may dispense oral antibiotics used to treat Chlamydia to a patient diagnosed with Chlamydia and to a sexual contact or partner of a patient diagnosed with Chlamydia. All appropriate records shall be maintained on-site. The antibiotics dispensed must:
(a) be prepackaged and properly labeled in accordance with state law;
(b) include appropriate counseling materials informing the patient of the potential risks involved in taking the drug; and
(c) contain contact information for the healthcare provider or a consulting pharmacist to provide advice or answer questions.

37-7-103. Exemptions. Subject only to 37-7-401 and 37-7-402, this chapter does not:
(1) subject a person who is licensed in this state to practice medicine, dentistry, or veterinary medicine to inspection by the board, prevent the person from compounding or using drugs, medicines, chemicals, or poisons in the person's practice, or prevent a person who is licensed to practice medicine from furnishing to a patient drugs, medicines, chemicals, or poisons that the person considers proper in the treatment of the patient;
(2) prevent the sale of drugs, medicines, chemicals, or poisons at wholesale;
(3) prevent the sale of drugs, chemicals, or poisons at either wholesale or retail for use for commercial purposes or in the arts;
(4) change any of the provisions of this code relating to the sale of insecticides and fungicides;
(5) prevent the sale of common household preparations and other drugs if the stores selling them are licensed under the terms of this chapter;
(6) apply to or interfere with manufacture, wholesaling, vending, or retailing of flavoring extracts, toilet articles, cosmetics, perfumes, spices, and other commonly used household articles of a chemical nature for use for non-medicinal purposes;
(7) prevent a registered nurse employed by a family planning clinic under contract with the department of public health and human services from dispensing factory prepackaged contraceptives, other than mifepristone, if the dispensing is in accordance with a physician's written protocol specifying the circumstances under which dispensing is appropriate and is in accordance with the board's requirements for labeling, storage, and recordkeeping of drugs; or
(8) prevent a certified agency from possessing, or a certified euthanasia technician or support personnel under the supervision of the employing veterinarian from administering, any controlled substance authorized by the board of veterinary medicine for the purpose of euthanasia pursuant to Title 37, chapter 18, part 6.

37-7-321. Certified pharmacy license -- display. The board shall provide for the original certification and renewal by the board of every pharmacy doing business in this state. On presentation of evidence satisfactory to the board, on application on a prescribed form, and on the payment of an original certification fee prescribed by the board, the board shall issue a license to a pharmacy as a certified pharmacy. However, the license may be granted only to pharmacies operated by registered pharmacists qualified under this chapter. The license must be displayed in a conspicuous place in the pharmacy for which it is issued. A person may not operate a pharmacy, use the word

"pharmacy" to identify the business, or use the word "pharmacy" in advertising unless a license has been issued and is in effect.

37-7-322. Use of words pharmacy, apothecary, drug store, or chemist shop for advertising. It is unlawful for a person to carry on, conduct, or transact a retail business under a name which contains as a part of the business the words "pharmacy", "apothecary", "drug store", or "chemist shop" or any abbreviation, translation, extension, or variation of those terms or in any manner by advertisement circular or poster, sign, or otherwise to describe or refer to the place of business conducted by that person by the term, abbreviation, translation, extension, or variation unless the business conducted is a pharmacy within the meaning of this chapter and licensed and in the charge of a licensed pharmacist.

37-7-323. Penalty -- enforcement. (1) A person, firm, partnership, or corporation violating any of the provisions of parts 1 through 3 of this chapter is guilty of a misdemeanor and upon conviction for each violation shall automatically lose any license issued by the board.
(2) In addition to the penalty provided in subsection (1), the board may withdraw its approval of a utilization plan previously approved for a supervising pharmacist who:
(a) violates any provision of 37-7-307 through 37-7-309 or rules adopted under those sections;
(b) obtained the approval of the utilization plan through fraud; or
(c) acts in a manner contrary to the terms of the utilization plan.
(3) The board may seek an injunction to enforce the provisions of subsection (2).

50-31-303. Certain drug advertisements considered false. (1)For the purpose of this chapter, the advertisement of a drug or device representing it to have any effect in albuminuria, appendicitis, arteriosclerosis, blood poison, bone disease, Bright's disease, cancer, carbuncles, cholecystitis, diabetes, diphtheria, dropsy, erysipelas, gallstones, heart and vascular diseases, high blood pressure, mastoiditis, measles, meningitis, mumps, nephritis, otitis media, paralysis, pneumonia, poliomyelitis (infantile paralysis), prostate gland disorders, pyelitis, scarlet fever, sexual impotence, sinus infection, smallpox, tuberculosis, tumors, typhoid, uremia, or a sexually transmitted disease shall also be deemed to be false, except that no advertisement not in violation of 50-31-107(1) shall be deemed to be false under this section if it is disseminated only to members of the medical, dental, or veterinary professions or appears only in the scientific periodicals of these professions or is disseminated only for the purpose of public health education by persons not commercially interested, directly or indirectly, in the sale of such drugs or devices.
(2) Whenever the department determines that an advance in medical science has made any type of self-medication safe as to any of the diseases named above, the department shall by regulation authorize the advertisement of drugs having curative or therapeutic effect for such disease, subject to such conditions and restrictions as the department may deem necessary in the interests of public health.
(3) This section shall not be construed as indicating that self-medication for diseases other than those named herein is safe or efficacious.

PROSPECTIVE DRUG UTILIZATION REVIEW AND PATIENT COUNSELING

37-7-406. Standards for prospective drug utilization review and patient counseling. (1) The board may by rule set standards for the provision of prospective drug utilization review information from a pharmacist to a patient before a prescription is dispensed to the patient or the patient's representative. The review may include, when applicable, an appropriate level of screening for potential drug therapy problems due to therapeutic duplication, drug disease contraindications, drug interactions, incorrect drug dosage or duration of drug treatment, drug-allergy interactions, and clinical abuse or misuse.
(2) Under the standards provided for in this section, the pharmacist should offer to discuss those matters that, in the pharmacist's professional judgment, the pharmacist considers significant to the patient's safe and proper use of the prescribed drug. The patient counseling should encompass the topics set forth in 42 U.S.C. 1396r-8 of the Social Security Act and administrative rules established by the board.
(3) Communications between a pharmacist and a patient pursuant to the standards provided for in this section constitute health care information for the purposes of Title 50, chapter 16, part 5.

(4) Standards established by the board under this section apply to all patients seen by a pharmacist or to categories of patients as the board may designate. However, standards provided for in this section may not apply to inpatients of a health care facility in which a nurse or other licensed health care professional is authorized to administer the prescribed drug.

37-7-407. Penalty. In addition to all other penalties provided by law, a person violating 37-7-406 shall be fined not more than $250 for each violation.

24.174.901 PATIENT RECORDS (1) A patient record system shall be maintained by all pharmacies for patients for whom prescription drug orders are dispensed. The patient record system shall provide for the immediate retrieval of information necessary for the dispensing pharmacist to identify previously dispensed drugs at the time a prescription drug order is presented for dispensing. The pharmacist or pharmacy technician under a board-approved utilization plan, shall make a reasonable effort to obtain, record, and maintain the following information:
(a) full name of the patient for whom the drug is intended;
(b) address and telephone number of the patient;
(c) patient's age or date of birth;
(d) patient's gender;
(e) pharmacist comments relevant to the individual's drug therapy, including any other information peculiar to the specific patient or drug.
(2) The pharmacist or pharmacy technician under a board-approved utilization plan, shall make a reasonable effort to obtain from the patient or the patient's agent and shall record any known allergies, drug reactions, idiosyncrasies, and chronic conditions or disease status of the patient and the identity of any other drugs, including over-the-counter drugs, or devices currently being used by the patient which may relate to prospective drug review.
(3) A patient record shall be maintained for a period of not less than three years from the date of the last entry in the profile record. This record may be a hard copy or a computerized form.

24.174.902 PROSPECTIVE DRUG REVIEW (1) A pharmacist shall review the patient record and each prescription drug order presented for dispensing for purposes of promoting therapeutic appropriateness by identifying:
(a) over-utilization or under-utilization;
(b) therapeutic duplication;
(c) drug-disease contraindications;
(d) drug-drug interactions;
(e) incorrect drug dosage or duration of drug treatment;
(f) drug-allergy interactions;
(g) clinical abuse/misuse.
(2) Upon recognizing any of the above, the pharmacist shall take appropriate steps to avoid or resolve the problem which shall, if necessary, include consultation with the prescriber.

24.174.903 PATIENT COUNSELING (1) Upon receipt of a new prescription drug order or refill prescription drug order if deemed necessary by the pharmacist, and following a review of the patient's record, a pharmacist shall personally offer to discuss matters which will enhance or optimize drug therapy with each patient or caregiver of such patient. Such discussion shall be in person, whenever practicable, or by telephone and shall include appropriate elements of patient counseling. Such elements may include the following:
(a) the name and description of the drug;
(b) the dosage form, dose, route of administration, and duration of drug therapy;
(c) intended use of the drug and expected action;
(d) special directions and precautions for preparation, administration, and use by the patient;
(e) common severe side or adverse effects or interactions and therapeutic contraindications that may be encountered, including their avoidance, and the action required if they occur;
(f) techniques for self-monitoring drug therapy;
(g) proper storage;
(h) prescription refill information;

(i) action to be taken in the event of a missed dose; and
(j) pharmacist comments relevant to the individual's drug therapy, including any other information peculiar to the specific patient or drug.
(2) Each pharmacy shall have at least one area that offers appropriate visual and auditory patient confidentiality for patient counseling. This requirement shall go into effect three years from the date of enactment.
(3) Alternative forms of patient information shall be used to supplement patient counseling when appropriate. Examples to include written information leaflets, pictogram labels, video programs, etc.
(4) Patient counseling, as described above and defined in this Act shall not be required for inpatients of a hospital or institution where other licensed health care professionals are authorized to administer the drug(s). Any pharmacist dispensing medication to be self-administered outside an institution shall comply with all patient counseling statutes and rules.
(5) A pharmacist shall not be required to counsel a patient or caregiver when the patient or caregiver refuses such consultation. A record of the refusal shall be maintained by the pharmacist.

PHARMACIES, OUT OF STATE

37-7-701. Legislative declaration. The legislature recognizes that with the proliferation of alternate methods of health care delivery, there has arisen among third-party payors and insurance companies the desire to control the cost and use of pharmacy services through a variety of mechanisms, including the use of mail service pharmacies located outside this state. As a result, the legislature finds and declares that to continue to protect the consumer-patients of this state, all out-of-state mail service pharmacies that provide services to this state's residents must be registered with the board, shall disclose specific information about their services, shall meet the same standards for utilization of technicians as an in-state pharmacy, and shall provide pharmacy services at a high level of competence.

37-7-702. Out-of-state mail service pharmacy defined. "Out-of-state mail service pharmacy" means a pharmacy located outside this state that: (1) ships, mails, or delivers by any lawful means a dispensed legend drug to a resident in this state pursuant to a legally issued prescription;
(2) provides to a resident of this state information on drugs or devices that may include but is not limited to advice relating to therapeutic values, potential hazards, and uses; or
(3) counsels pharmacy patients residing in this state concerning adverse and therapeutic effects of drugs.

37-7-703. Registration requirements. Each out-of-state mail service pharmacy must be registered with the board of pharmacy. In order to be registered with the board to do business in this state and for the renewal of its registration, an out-of-state mail service pharmacy:
(1) (a) shall submit a certificate from the appropriate licensing authority with which it is currently licensed and in good standing in the state in which its dispensing facilities are located; and
(b) shall comply with all applicable laws, regulations, and standards of that state and the United States and, if requested by the board, provide evidence that it has complied;
(2) shall register with the board and provide information on ownership and location, including the names and titles of the corporate officers, of the out-of-state mail service pharmacy and the identity of a pharmacist licensed in the state in which the pharmacy is located who is in charge of dispensing prescriptions for shipment to Montana from the out-of-state mail service pharmacy;
(3) shall submit a utilization plan for the employment of pharmacy technicians if allowed by the state where the mail service pharmacy is located. If the state in which the pharmacy is located does not establish a ratio of technicians to pharmacists for determining the number of pharmacy technicians or otherwise define the role of the pharmacist in compounding or dispensing drugs at the pharmacy, then the out-of-state mail service pharmacy may not allow a pharmacist to supervise more than one supportive person at any one time in the compounding or dispensing of prescription drugs, unless approved by the board as provided in 37-7-307 through 37-7-309.
(4) shall submit to the board proof of the pharmacist's good standing with the licensing authority in the state where the pharmacist is employed and the pharmacist's written commitment to comply with the utilization plan, if any, for each pharmacist identified under subsection (2) and shall provide to the board the same toll-free telephone service referenced in 37-7-706 in order to comply with all information requests by the board; and

(5) shall pay an initial registration fee and a periodic renewal fee in an amount to be determined by the board and at a time established by the department by rule.

37-7-704. Inspections. If the licensing or regulatory agency of the state in which an out-of-state mail service pharmacy is domiciled fails or refuses to inspect the out-of-state mail service pharmacy after receiving a request for an inspection from the board of this state, the board may cancel the out-of-state pharmacy's right to do business in this state unless the out-of-state pharmacy agrees to an onsite inspection by the board of this state.

37-7-705. Product selection of prescribed drugs -- notification. 1) An out-of-state mail service pharmacy may not substitute a prescription drug unless the substitution is made in compliance with the laws of this state and the rules and regulations of the board.
(2) An out-of-state mail service pharmacy may not dispense a substitute drug product to a resident of this state without notifying the patient of the substitution either by telephone or in writing.

37-7-706. Patient communication -- telephone service. Every out-of-state mail service pharmacy shall provide a toll-free telephone service, available at least 6 days a week and for 40 hours a week, to facilitate communication as may be required under this part, between patients in this state and a pharmacist who has access to the patients' records at the out-of-state mail service pharmacy. The toll-free telephone number must be affixed to all drug product containers dispensed to patients in this state.

37-7-711. Penalty. In addition to all other penalties provided by law, a person violating 37-7-703 through 37-7-706 shall be fined not more than $250 for each violation.

37-7-712. Rulemaking authority. The board of pharmacy may adopt rules to implement this part.

24.174.1001 REGISTRATION OF OUT-OF-STATE MAIL SERVICE 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 by the Montana board of pharmacy.

24.174.1002 CONDITIONS OF REGISTRATION (1) As conditions of registration, the out-of-state mail service 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 verified internet pharmacy practice sites (VIPPS) if registered after June 1, 2001;
(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 service pharmacies;
(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;
(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 said telephone number(s) will be placed upon the label affixed to each legend drug container. A toll-free telephone number shall also be provided to the board to allow for compliance with all information requests by the board.

24.174.1003 IDENTIFICATION OF PHARMACIST IN CHARGE OF DISPENSING TO MONTANA (1)Each out-of-state mail service pharmacy that ships, mails, 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 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 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 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.

24.174.1008 USE OF PHARMACY TECHNICIANS BY OUT-OF-STATE MAIL SERVICE PHARMACIES (1) Any application for out-of-state mail service pharmacy registration from a facility located in a state which does not regulate the use of pharmacy technicians may not allow a pharmacist to supervise more than one supportive person at any one time in the compounding or dispensing of prescription drugs, unless approved by the board.
(2) Any application for out-of-state mail service pharmacy licensure from a facility located in a state which does regulate the use of pharmacy technicians shall provide information on the supervisor to technician ratio allowed in the resident state, and submit a utilization plan for the employment of pharmacy technicians.

24.174.1009 COMPLIANCE (1) Each out-of-state mail service 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.

24.174.1004 CHANGE IN LOCATION (1) Whenever a mail service pharmacy changes its physical location outside of its then existing business location, its original license becomes void and must be surrendered. The mail service pharmacy shall submit a new license application for the new location at least 30 days before such change occurs.

24.174.1005 CHANGE IN OWNERSHIP (1) When a mail service pharmacy changes ownership, the original license becomes void and must be surrendered to the board, and a new license obtained by the new owner. The owner shall submit a new license application at least 30 days prior to the change in ownership.
(2) A change in ownership for the purposes of this rule shall be deemed to occur when more than 50 percent of the equitable ownership of a business is transferred in a single transaction or in a related series of transactions to one or more persons or any other legal entity.
(3)The board must be notified in writing when five to 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.

PHARMACIES, INSTITUTIONAL

24.174.1101 PERSONNEL (1) Each institutional pharmacy must be directed by a pharmacist-in-charge who is licensed to engage in the practice of pharmacy in the state of Montana and who is responsible for the storage, compounding, repackaging, dispensing and distribution of drugs within the facility. Depending upon the needs of the facility, pharmacy services may be provided on a full or part-time basis, with a mechanism for emergency service provided at all times. Contractual providers of pharmacy services shall meet the same requirements as pharmacies located within the institution.

(2) Registered pharmacy technicians or technicians-in-training may be utilized pursuant to the written policies and procedures of the institutional pharmacy. Exemptions to established ratios as defined in ARM 24.174.711 may be granted with board approval.

24.174.1104 INSTITUTIONAL PHARMACIST AND PHARMACIST-IN-CHARGE RESPONSIBILITY (1) The pharmacy director/pharmacist-in-charge shall provide for applicable policies and procedures to ensure:
(a) mechanisms for receiving and verifying drug orders from prescribers and evaluating them for safety and therapeutic appropriateness based on patient parameters and dosing guidelines;
(b)appropriate filling and proper labeling of all containers from which drugs are to be dispensed or administered on an inpatient or outpatient basis;
(c) a system for the admixture of parenteral products accomplished within the pharmacy, and verification that the facility's department of nursing will provide education and training of nursing personnel regarding sterile technique, stability and compatibility of parenteral products not mixed within the pharmacy;
(d)appropriate clinical services and monitoring of outcomes, and the development of new areas of pharmaceutical care appropriate for that institution;
(e) a policy by which an offer is made to convey the discharge medication regimen to a patient’s pharmacies;
(f) maintaining and distributing a list of emergency drugs, antidotes, and their doses throughout the institution;
(g) pharmacy participation in formulary development;
(h)participation in drug utilization review and monitoring of adverse drug reactions and development of procedures to avoid problems identified;
(i) evaluation of reported medication errors and development of procedures to prevent those errors;
(j) proper acquisition and secure, temperature-controlled storage of all prescription drugs;
(k)quality control of sterile and non-sterile pharmaceutical products, including procedures for identifying, removing and destroying outdated products;
(l) pharmacy safety and security;
(m)utilization of registered technicians or technicians in training;
(n)accurate distribution systems and secure, temperature-controlled storage of pharmaceutical products throughout the institution;
(o) unit-dosing of bulk pharmaceuticals, compounding and sterilization of drug products if applicable;
(p) the appropriate use, security and accountability of controlled substances;
(q) staff development and competency evaluation;
(r) maintenance of all required records; and
(s) compliance with all other requirements of the Montana board of pharmacy.

24.174.1107 ABSENCE OF PHARMACIST IN INSTITUTIONAL SETTINGS (1) During times that an institutional pharmacy does not have a pharmacist in attendance, arrangements must be made in advance by the pharmacist-in-charge for provision of drugs to the medical staff and other authorized personnel by use of night cabinets, floor stock and, in emergency circumstances, by access to the pharmacy. A mechanism for providers and nursing to obtain pharmacy consultation must be available at all times in accordance with ARM 24.174.1101.
(2) If night cabinets are used to store drugs in the absence of a pharmacist, they must be locked and sufficiently secure to deny access to unauthorized persons, and must be located outside of the pharmacy area. Contents of night cabinets must be prepackaged. Only specifically authorized personnel may obtain access by key or combination, pursuant to a valid prescription order. The pharmacist-in-charge shall, in conjunction with the appropriate committee of the facility, develop inventory listings of drugs included in these cabinets and determine who may have access.
(3) A complete verification audit of all inpatient orders and activity concerning the night cabinet or after-hours pharmacy entry must be conducted by a pharmacist, pharmacy technician, or other licensed designee of that pharmacist within 72 hours of the drugs having been removed from the night cabinet or pharmacy
4) Whenever any drug is not available from floor stock or night cabinets, and that drug is required to treat the immediate needs of a patient whose health would otherwise be jeopardized, the drug may be obtained from the pharmacy by an authorized registered nurse or licensed practical nurse in accordance with established policies and procedures. The responsible nurse shall be designated by the appropriate committee of the institutional facility.

(a) Removal of any drug from the pharmacy, floor stock, or night cabinet by an authorized nurse must be recorded on a suitable form showing the following information:
(i) patient name;
(ii) the patient's room number if applicable;
(iii) the name, strength, and quantity of drug removed;
(iv) the date and time the drug was removed;
(v) the signature of the nurse removing the drug; and
(vi) documentation of pharmacy review.
(b) in cases of medication not unit-dosed, the NDC number of the drug removed must also be recorded.
(5) The pharmacist-in-charge shall ensure that:
(a) written policies and procedures are established to implement the requirements of this rule;
(b) all drugs are properly labeled; and
(c) only prepackaged drugs are available, in amounts sufficient for immediate therapeutic requirements.
(6) A copy of the original drug order with the NDC number or other identifying code of the drug(s) provided may be faxed to the pharmacist. If the patient is an inpatient, a patient profile containing the patient's name, location, allergies, current medication regimen, and relevant laboratory values must be reviewed by a pharmacist within 72 hours.

24.174.1111 DRUG DISTRIBUTION AND CONTROL IN AN INSTITUTUIONAL FACILITY (1) The pharmacist-in-charge shall establish written policies and procedures for the safe and efficient distribution of drugs and provision of pharmaceutical care, including the mechanism by which drug review will be accomplished and documented. A current copy of such procedures must be on hand for inspection by the board of pharmacy.
(2) Automated dispensing devices must be stocked with drugs only by or under the supervision of a registered pharmacist. At the time of removal of any drug, the device must automatically make an electronic record indicating the date of removal, the name, strength, and quantity of drug removed, name of the patient for whom the drug was ordered, and the name or other identification of the person removing the drug. These records must be maintained for a period of two years.
(3) Drugs or herbal/alternative food supplement products brought into an institutional facility by a patient must not be administered unless they can be identified and their quality assured by a pharmacist, and their use has been authorized by the attending physician. If such drugs are not to be administered, the pharmacist-in-charge shall develop policies and procedures for storing them for return to the patient upon discharge or transferring them to an adult member of the patient’s immediate family.
(4) Investigational drugs must be stored in and dispensed from the pharmacy only pursuant to written policies and procedures. Complete information regarding these drugs and their disposition must be maintained in the facility. The drug monograph and a signed patient consent form must be obtained and made available in accordance with federal guidelines.
(5) A Sample drug policy must be established if samples are used.
(6) The safe handling, storage, and administration of medications within jails, correctional facilities, and detention facilities without onsite pharmacies shall be regulated as follows:
(a) Jails, correctional facilities, and detention facilities must have written policies and procedures in place, written by the responsible practitioner or authority, for the safe handling, storage, and administration of medications. Such policies shall address security of medications, procurement, proper storage and disposal of medications, training for those administering medication, methods for documenting that medications were given or refused, procedures for confirming that the inmate has ingested each medication, and the disposition of medications at discharge. Medications brought by or with an inmate upon admission to the jail, correctional facility, or detention facility must not be used unless specifically authorized by a physician at the jail, correctional facility, or detention facility or that physician's designee, and medication identity has been confirmed by a licensed health care professional. Prescription medications brought by an inmate from outside must be recorded on the inmate property record. If they are not used while the patient is incarcerated, they must be stored in a secure area until the inmate's release.
(b) Patient medications may be transferred from one jail, correctional facility, or detention facility to another if there is a secure method for ensuring that individual inmate prescriptions are not tampered with between locations and that containers are properly labeled. During transfer, medications requiring storage at room temperature should be

subjected to external temperatures no greater than 86 degrees Fahrenheit. A method of transferring refrigerated medications from one jail, correctional facility, or detention facility to another must be addressed in policy and procedure. Medications transferred pursuant to the above regulations, in control of the transferring official at all time, may continue to be used for that patient.
(c) Emergency kits supplied and maintained by a registered pharmacist may be utilized if policies and procedures regulating their use are in place. Such emergency kits will comply with the requirements of ARM 24.174.1114.
(d) Jails, correctional facilities, and detention facilities without an on-site pharmacy that procures, stores, and administers prescription medications may request technical assistance from the board.

REMOTE MEDICATION ORDER PROCESSING SERVICES

24.174.1112 REMOTE MEDICATION ORDER PROCESSING SERVICES
(1) A hospital pharmacy may outsource medication order processing to another pharmacy provided the pharmacies have the same owner or the pharmacy has entered into a written contract or agreement with an outsourcing company that outlines the services to be provided and the responsibilities and accountabilities of each party to the contract or agreement in compliance with federal and state statutes and regulations.
(2) The hospital pharmacy must provide a copy of the contract or agreement to the board and receive approval from the board or its designee prior to initiation of remote order entry services.
(3) A hospital pharmacy utilizing remote order entry shall ensure that all pharmacists providing such services have been trained on the pharmacy's policies and procedures relating to medication order processing. The training of each pharmacist shall be documented. Such training shall include, but is not limited to, policies on drug and food allergy documentation, abbreviations, administration times, automatic stop orders, substitution, and formulary compliance. The pharmacy and the pharmacy/outsourcing company shall jointly develop a procedure to communicate changes in formulary and changes in policies and procedures related to medication order processing.
(4) A hospital pharmacy utilizing a remote order entry pharmacist shall maintain a record of the name and address of such pharmacist, evidence of current licensure in Montana, and the address of each location where the pharmacist will be providing remote order entry services.
(5) The director of pharmacy shall ensure that any remote order entry pharmacist shall have secure electronic access to the hospital pharmacy's patient information system and to other electronic systems that the on-site pharmacist has access to when the pharmacy is open.
(6) The remote order entry pharmacist must be able to contact the prescribing practitioner to discuss any concerns identified during the pharmacist's review of patient information and the drug order. A procedure must be in place to communicate any problems identified with the practitioner and the nursing staff providing direct patient care.
(7) Each remote entry record must comply with all recordkeeping requirements and shall identify by name or other unique identifier, the pharmacist involved in the review and verification of the drug order.
(8) A pharmacy utilizing remote order entry processing services is responsible for maintaining records of all orders entered into their information system, including orders entered from a remote location. The system shall have the ability to audit the activities of the individuals remotely processing medication orders.
(9) All records shall be readily available upon request by the board, its designee, or agent of the board for inspection, copying, or production.
(10) A pharmacy utilizing remote order entry processing services shall maintain a policy and procedure manual. A remote pharmacy/order processing company shall maintain a copy of those portions of the policy and procedure manual that relate to that pharmacy's operations. Each manual shall:
(a) outline the responsibilities of the pharmacy and the remote pharmacy/order processing company;
(b) include a list of the names, addresses, telephone numbers, and all license numbers of the pharmacies/pharmacists involved in remote order entry processing; and
(c) include policies and procedures for:
(i) protecting the confidentiality and integrity of patient information;
(ii) maintaining appropriate records of each pharmacist involved in order processing;
(iii) complying with federal and state statutes and regulations;
(iv) annually reviewing the written policies and procedures and documentation of the annual review; and
(v) annually reviewing the competencies of pharmacists providing remote order entry processing services

24.174.1114 USE OF EMERGENCY DRUG KITS IN CERTAIN INSTITUTIONAL FACILITIES (1) In an institutional facility that does not have an in-house pharmacy; drugs may be provided for use by authorized personnel through emergency kits prepared by the registered pharmacist providing pharmaceutical services to the facility. Such emergency drug kits must meet all of the following requirements:
(a) a registered pharmacist shall prepare and seal the kit;
(b) the supplying pharmacist and the designated practitioner or appropriate committee of the institutional facility shall jointly determine the identity and quantity of drugs to be included in the kit. Such drugs shall then be approved in advance of placement in the emergency kit by the board; unless such drugs are included on a general list of drugs preciously approved by the board for use in emergency kits;
(c) the kit must be locked and stored in a secure area to prevent unauthorized access and to ensure a proper storage environment for the drugs contained therein. The kit shall be secured with a seal to be of such a nature that it can be easily identified if it has been broken;
(d) all drugs in the kit must be properly labeled, including lot number and expiration date, and shall possess any additional information that may be required to prevent risk of harm to the patient;
(e) the exterior of the kit must be clearly labeled to indicate:
(i) its use and expiration date of its contents;
(ii) the name, address and telephone number of the supplying pharmacist; and
(iii) a statement indicating that the kit is to be used in emergency situations only pursuant to a valid drug order.
(2) Drugs shall be removed from emergency kits only by the supplying pharmacist or by authorized personnel pursuant to a valid drug order.
(3) Upon notice of any entry into the kit, the supplying pharmacist or another pharmacist designated by the supplying pharmacist shall restock and refill the kit, reseal the kit, and update the drug listing on the exterior of the kit within 72 hours.
(4) The expiration date of a kit must be the earliest date of expiration of any drug supplied in the kit. On or before the expiration date, the supplying pharmacist shall replace the expired drug.
(5) The supplying pharmacist shall, in conjunction with the appropriate institutional committee, be responsible for development of policies and procedures for safe and appropriate use and maintenance of emergency drug kits.

CONTINGENCY KITS

24.174.1115 USE OF CONTINGENCY KITS IN CERTAIN INSTITUTIONAL FACILITIES (1) In an institutional facility that does not have an in-house pharmacy or 24-hour access to dispensing services, medications may be provided for use by authorized personnel through contingency kits, prepared by the registered pharmacist, providing pharmaceutical services to the facility. Such contingency kits must meet all of the following requirements:
(a) the supplying or consultant pharmacist and director of nursing shall designate nursing personnel who may obtain access to the drug supply;
(b) the supplying or consultant pharmacist and the designated practitioner or appropriate committee of the institutional facility shall jointly determine the contents and quantity of drugs to be included in the kit;
(c) the kit must be locked and stored in a secure area to prevent unauthorized access and to ensure a proper storage environment for the drugs contained therein;
(d) the supplying pharmacist and director of nursing will provide adequate controls to prevent drug diversion;
(e) medications in the kit must be prepackaged and properly labeled, including lot number and expiration date, and shall possess any additional information that may be required to prevent risk of harm to the patient; and
(f) the exterior of the kit must be clearly labeled to indicate:
(i) its contents and expiration date; and
(ii) the name, address, and telephone number of the supplying pharmacist pharmacy.
(2) Drugs shall be removed from kits only: by the supplying pharmacist or by authorized nursing personnel pursuant to a valid drug order or during inspection of the kit.
(a) by the supplying pharmacist; or
(b) by authorized nursing personnel pursuant to a valid drug order and reviewed by a pharmacist; or
(c) during inspection of the kit.

(3) Removal of any drug from the contingency kit by authorized nursing or pharmacy personnel must be recorded on a suitable form showing the following information:
(a) patient name;
(b) name, strength, and quantity of drug removed;
(c) date and time the drug was removed; and
(d) signature of the authorized personnel removing the drug.
(4) The supplying pharmacist shall ensure that:
(a) written policies and procedures are established to implement the requirements of this rule;
(b) all drugs are properly labeled;
(c) only prepackaged drugs are available in amounts sufficient for short-term therapeutic requirements to meet the needs of the facility when dispensing pharmacy services are unavailable;
(d) replacement of medications is performed in a timely manner by authorized personnel;
(e) at a minimum, the kit shall be inspected annually; and
(f) at least one copy of the documentation for all drugs that have been removed from the contingency kit shall be kept at the long-term care facility and one copy at the supplying pharmacy.
(5) The expiration date of a kit must be the earliest date of expiration of any drug supplied in the kit. On or before the expiration date, the supplying pharmacist shall replace the expired drug.
(6) All documentation must be readily available for inspection by the board.

24.174.1121 STERILE PRODUCTS (1) Policies and procedures must be prepared for the compounding, dispensing, delivery, administration, storage and use of sterile pharmaceutical products. The policies must include a quality assurance program for monitoring personnel qualifications and training in sterile technique, product storage, stability standards, and infection control. Policies and procedures must be current and available for inspection by a designee of the board of pharmacy.
(2) An institutional pharmacy compounding sterile products must have an isolated area designed to avoid unnecessary traffic and airflow disturbances.
(3) An institutional pharmacy compounding sterile products must utilize an appropriate aseptic environmental control device such as a laminar flow biological safety cabinet capable of maintaining Class 100 conditions during normal activity, or have polices and procedures in place limiting the pharmacy's scope of sterile product preparation.
(4) An institution preparing Cytotoxic drugs must have a vertical flow Class II biological safety cabinet. Cytotoxic drugs must be prepared in a vertical flow class II biological safety cabinet.
(a) Protective apparel including non-vinyl gloves, gowns and masks must be available, and gloves must be worn at all times.
(b) Appropriate containment techniques must be used in addition to aseptic techniques required for sterile product preparation.
(c) Prepared doses of Cytotoxic drugs must be clearly identified, labeled with proper precautions and dispensed in a manner to minimize risk of Cytotoxic spills.
(d) Disposal of Cytotoxic waste must comply with all applicable local, state and federal laws.
(e) Written procedures for handling Cytotoxic spills must be included in the policies and procedures manual.
(5) All parenteral admixtures must be labeled with date of preparation and expiration date clearly indicated, patient name and room number, name and strength and/or amount of drug and base solution, and any special handling or storage instructions.
(6) All aseptic environmental control devices must be certified by an independent contractor for operational efficiency at least every 12 months or when relocated, according to federal standard 209E. Pre-filters must be inspected periodically and replaced if needed.
(7) Inspection and replacement dates must be documented and maintained for a period of at least two years.
(8) Documented records of ongoing quality assurance programs, justification of expiration dates chosen, and employee training records and technique audits must be available for inspection by the board of pharmacy.

OUTPATIENT CENTERS FOR SURGICAL SERVICES

24.174.1122 OUTPATIENT CENTERS FOR SURGICAL SERVICES (1) The board shall annually register and inspect all outpatient centers for surgical services in Montana, regardless of pharmacy status.
(2) In an outpatient center for surgical services without an on-site pharmacy, drug distribution must be directed by a physician or consulting pharmacist licensed to practice in Montana and who is responsible for the security, storage, and distribution of drugs within the facility.
(3) The physician director or consulting pharmacist shall provide for applicable policies and procedures to ensure:
(a) proper acquisition and secure, temperature-controlled storage of all pharmaceuticals;
(b) security and accountability of controlled substances;
(c) quality control of sterile and nonsterile pharmaceutical products including procedures for identifying, removing, and destroying outdated products;
(d) evaluation of reported medication errors and development of procedures to prevent those errors;
(e) maintenance of all required records; and
(f) compliance with all requirements of the board.
(4) Ambulatory surgical centers that store and/or administer controlled substances shall register with the board and with the DEA, and shall comply with all applicable state, local, and DEA regulations.

PHARMACIES, TELEPHARMACY

24.174.1302 TELEPHARMACY OPERATIONS (1) A remote telepharmacy site shall be connected to its parent pharmacy via computer, video, and audio link.
(2) A site cannot be licensed as a remote telepharmacy site if it is located within a twenty mile radius of an existing pharmacy.
(3) A remote telepharmacy site manned by a registered pharmacy technician shall access and use the parent pharmacy's central processing unit or common database.
(4) A remote telepharmacy site shall comply will all the requirements of pharmacy rules and statutes of Montana. The remote telepharmacy site is considered to be under the personal charge of the pharmacist at the parent pharmacy.
(a) The remote telepharmacy site must have a registered pharmacy technician present and a working computer, video, and audio link to a pharmacist at the parent pharmacy to have the prescription area open.
(b) The technician at the remote telepharmacy site must:
(i) be currently registered with the board;
(ii) be currently certified with the Pharmacy Technician Certification Board (PTCB), or Exam for the Certification of Pharmacy Technicians (ExCPT), or other board-approved certifying entity; and
(iii) have at least 500 hours of active experience as a pharmacy technician, technician-in-training, or experience deemed as equivalent by the board.
(c) The technician may unlock the prescription and storage areas. While the technician is on duty, the prescription area may remain open. Security standards for pharmacies shall be maintained at all times pursuant to ARM 24.174.814.
(d) The technician will be subject to all rules of ARM 24.174.701 through 24.174.714.
(e) All prescription records and consecutive prescription numbers must be maintained at the parent pharmacy or remote site. The remote telepharmacy site must transmit copies of new prescriptions via secure electronic means to the parent pharmacy, keeping the original prescription blank at the remote telepharmacy site.
(f) Prescriptions filled at the remote telepharmacy site must be distinguishable in some manner from those filled at the parent pharmacy.
(g) Daily reports for both the parent pharmacy and remote telepharmacy site must be maintained at the parent pharmacy or telepharmacy site.
(h) The remote telepharmacy site may have a prescription inventory. Prescription medications including controlled substances shall be securely maintained at the remote telepharmacy site in accordance with current Montana pharmacy statutes and rules.
(i) If controlled substances are dispensed or handled, both the remote telepharmacy site and the parent pharmacy must be registered with the DEA and must obtain individual DEA numbers.
(j) All records must be stored at the parent pharmacy or telepharmacy site, except those required by DEA to be at a DEA registered site.

k) The software system utilized must be able to generate labels from the parent pharmacy or at the remote telepharmacy site.
(l) The input of drug information may be done by a pharmacist at the parent pharmacy or a technician at either location if verified by a pharmacist.
(m) New prescriptions may be received at the parent pharmacy and entered there with a label printing at the remote telepharmacy site.
(n) New prescriptions received at the remote telepharmacy site may be entered into the computer system at the remote telepharmacy site. The pharmacist at the parent pharmacy remains responsible for all verification, interaction checking, and profile review.
(o) All filled prescriptions must have a label meeting the requirements of ARM 24.174.511 attached to the final drug container before the pharmacist verifies the dispensing process.
(p) Unless the remote telepharmacy site is a remote telepharmacy dispensing machine site, a pharmacist shall compare via video link the stock bottle, drug dispensed, and strength. The entire label must be checked for accuracy on the video link.
(q) The computer, video, and audio link must be operational at all times. In the event of connectivity loss to the parent location, no new prescriptions may be processed, filled, or dispensed from the telepharmacy site until connectivity is reestablished. Refill prescriptions that have a final check by the pharmacy may be dispensed.
(r) A code containing both the pharmacist's and technician's initials must appear on the fill screen, patient profile, and prescription label.
(s) No prescription medication may be released to a patient until approved by a pharmacist in person or via the computer, video, and audio link.
(t) The pharmacist shall offer to counsel the patient or the patient's agent via video and/or audio link on all new prescriptions.
(u) When the technician is not present, dispensing and counseling via video and audio link may be done using a secure alternate delivery system with prior approval of the board.
(v) The license holder, agent of the parent pharmacy, or the pharmacist-in-charge of the parent pharmacy, or the pharmacist-in-charge of the remote site, if different from the parent pharmacist-in-charge shall apply for a license for the remote telepharmacy site.
(w) As dispensing is considered to be done by the pharmacist, the pharmacist shall be responsible for and held accountable for dispensing at the remote telepharmacy site.
(x) Policies and procedures must be in place to ensure the safe and effective distribution of pharmaceutical products and delivery of required pharmaceutical care.
(y) The pharmacist at the parent pharmacy shall perform an ongoing analysis of incident reports and outcomes, with appropriate corrective action taken when necessary to ensure patient safety.
(z) The pharmacist at the parent pharmacy or that person's designee shall conduct and complete monthly inspections of the remote telepharmacy site. Inspection criteria must be included in the policies and procedures for the site. The inspection report must be available for review at the next board inspection.

24.174.1303 REMOTE TELEPHARMACY DISPENSING MACHINE SITES (1) Remote telepharmacy dispensing machine sites contain prescription inventory which is secured in an automated dispensing device connected to the central processing unit at the parent pharmacy.
(2) A site cannot be licensed as a remote telepharmacy dispensing machine site if it is located within a ten mile radius of an existing pharmacy.
(3) A pharmacist must approve all outpatient prescriptions before they are dispensed, unless the prescription is directly dispensed by a person authorized to prescribe.
(4) All filled prescriptions must have a label that meets the requirements of ARM 24.174.511 attached to the final drug container.
(5) A licensed pharmacist at the parent site shall perform counseling and professional consultation via audio and video link as required by ARM 24.174.903, unless the prescription is directly dispensed by a person authorized to prescribe.

(6) Registered technicians involved in stocking and removal of prescription medications under this rule must have at least 80 hours of pretraining in bar coding technology. All requirements of ARM 24.174.701 through 24.174.714 will apply, excluding the technician certification requirement of ARM 24.174.702.
(7) Policies and procedures of the parent pharmacy and the remote telepharmacy dispensing machine site must address all aspects of the telepharmacy operation, including stocking procedures and removal of outdated prescription medications.
(8) The pharmacist at the parent pharmacy shall perform an ongoing analysis of incident reports and outcomes, with appropriate corrective action taken when necessary to ensure patient safety.
(9) The pharmacist-in-charge of the parent pharmacy or that person's designee shall conduct and complete monthly inspections of the remote telepharmacy dispensing machine site. Inspection criteria must be included in the policies and procedures for the site. The inspection reports must be available for review at the next board inspection.
(10) Remote telepharmacy dispensing machine sites must be licensed with the board by November 30 of each year, and will be subject to random inspection by board inspectors.
(11) This rule does not apply to institutional satellite pharmacies as defined in ARM 24.174.301.

DONATED DRUG PROGRAM

37-7-1401. Programs for donation of unused prescription drugs, cancer drugs, and devices -- rulemaking required. (1) The board of pharmacy shall, in consultation and cooperation with the department of public health and human services, create a program for the donation of prescription drugs collected from long-term care facilities to qualified patients.
(2) For the purposes of the program created pursuant to subsection (1), prescription drugs, except those drugs defined as a dangerous drug in 50-32-101 or a drug designated as a precursor to a controlled substance in 50-32-401, unneeded by a resident or former resident of a long-term care facility may be donated by the long-term care facility to a provisional community pharmacy that provides or may provide prescription drugs to individuals who are qualified patients for transfer free of charge or at a reduced charge to those individuals.
(3) This section does not amend or otherwise change the law applicable to the prescribing of prescription drugs, the sale of those drugs, or the licensing of long-term care facilities or pharmacies.

(4) The board of pharmacy shall adopt rules to implement this part. The rules must address:
(a) the collection, receipt, and storage of donated drugs and devices;
(b) the transfer of prescription drugs donated by a long-term care facility to provisional community pharmacies;
(c) which pharmacies may be considered provisional community pharmacies that may sell or give the prescription drugs donated by long-term care facilities to others;
(d) eligibility criteria and other standards and procedures for participants that accept and distribute or dispense donated cancer drugs or devices;
(e) the forms needed for the administration of the donated drug programs;
(f) categories of cancer drugs and devices that the cancer drug repository program will accept for dispensing and categories it will not accept, including the reason that a cancer drug or device will not be accepted;
(g) the price for which the prescription drugs donated by a long-term care facility may be sold; and
(h) the maximum handling fee that may be charged by participants that accept and distribute or dispense a cancer drug or device.
(5) In adopting the rules, the board of pharmacy shall consider the ability of persons to pay for the drugs and the existence and operation of similar programs in other states.

37-7-1402. Identifying information to be deleted from donated drugs or devices. A person or entity donating a prescription drug, a cancer drug, or a device pursuant to the programs created under this part shall delete from the container in which the drug or device is held any information by which the person for whom the drug or device was prescribed may be identified.

37-7-1403. Cancer drug repository program -- donations -- registry. (1) The board shall establish a cancer drug repository program for accepting donated cancer drugs and devices and dispensing the drugs and devices to qualified

patients. Participation in the program is voluntary.
(2) Any person or entity, including but not limited to a health care facility or the manufacturer of a cancer drug or device, may donate cancer drugs or devices to a participant pursuant to the provisions of 37-7-1403 through 37-7-1405.
(3) The board shall establish and maintain a registry of participants in the cancer drug repository program. The participant registry must:
(a) include the participant's name, address, and telephone number; and
(b) identify whether the participant is a physician's office, pharmacy, hospital, or health clinic.
(4) The board shall make the participant registry available to a person or entity wishing to donate a cancer drug or device to the cancer drug repository program.

37-7-1404. Cancer drugs or devices accepted or dispensed -- conditions. (1) (a) Unless otherwise prohibited by law, a cancer drug or device may be accepted or dispensed under the cancer drug repository program established under 37-7-1403 if the drug or device is in its original, unopened, sealed, and tamper-evident unit dose packaging.
(b) A cancer drug packaged in single-unit doses may be accepted and dispensed if the outside packaging is opened but the single-unit dose packaging is unopened.
(2) A cancer drug may not be accepted or dispensed under this section if the drug:
(a) bears an expiration date that is earlier than 6 months after the date the drug was donated;
(b) is considered adulterated or misbranded under the provisions of Title 50, chapter 31, part 3; or
(c) is subject to restricted distribution pursuant to 21 CFR 314.520.
(3)Subject to the limitations provided in this section, an unused cancer drug or device dispensed under the Medicaid program provided for in Title 53, chapter 6, may be accepted and dispensed under the cancer drug repository program.
(4) A cancer drug or device donated under this program must be stored:
(a) separately from other prescription drugs or stock;
(b) according to the manufacturer's recommended storage conditions; and
(c) in the compounding or dispensing area if stored in a pharmacy.
(5) In dispensing a donated cancer drug or device, a participant shall give first priority to a qualified patient in the participant's service area. Other cancer patients may receive donated cancer drugs or devices if a qualified patient is not available.
(6) A participant shall notify a patient if the patient is receiving a cancer drug or device that has been donated.

37-7-1405. Participants -- duties -- fee authorized. (1) A participant shall comply with all applicable provisions of state and federal law relating to the storage, distribution, and dispensing of a donated cancer drug or device and shall inspect all donated drugs and devices before dispensing them to determine if they are adulterated or misbranded.
(2) A cancer drug or device may be:
(a) dispensed only pursuant to a prescription issued by a prescriber authorized to prescribe cancer drugs or devices; or
(b) distributed to another participant for dispensing.
(3) A cancer drug or device donated to the cancer drug repository program may not be resold.
(4) A participant may charge a handling fee for distributing or dispensing a cancer drug or device.
(5) A participant shall maintain records of donated drugs and devices and the distribution of the drugs and devices.
(6) (a) For cancer drugs or devices that are donated to the participant, records maintained pursuant to subsection (5) must include but are not limited to the following information:
(i) the date the participant received the cancer drug or device;
(ii) the drug name, strength, and amount;
(iii) the prescription number;
(iv) the expiration date of the drug;
(v) the manufacturer's name and lot number; and
(vi) the name and address of the person or entity donating the drug.
(b) For cancer drugs or devices that are distributed or dispensed by the participant, records maintained pursuant to subsection (5) must include but are not limited to the following information:

(i) the name and address of the receiving person or entity;
(ii) the name, strength, and quantity of the drug;
(iii) the dosage form, if applicable;
(iv) the name and address of the participant who distributed or dispensed the drug or device;
(v) the date the participant distributed or dispensed the drug or device;
(vi) the manufacturer's name and lot number; and
(vii) the expiration date of the drug.

37-7-1408. Donated drugs and devices -- immunity. (1) A resident or former resident of a long-term care facility and the long-term care facility donating a prescription drug, a cancer drug, or a device as part of the programs created pursuant to this part are not liable for simple negligence in the donation of a drug or device if the requirements of this part and the rules implementing this part have been complied with.
(2) Except as provided in subsection (3):
(a) a person or entity, including the manufacturer of a cancer drug or device that exercises reasonable care in donating, accepting, distributing, or dispensing a cancer drug or device under the provisions of 37-7-1403 through 37-7-1405 and rules adopted by the board, is immune from civil or criminal liability or professional disciplinary action of any kind for an injury, death, or loss to a person or property relating to the accepting, distributing, or dispensing of the cancer drug or device;
(b) a person or entity, unless directly negligent, is not liable for the negligence or lack of care of other persons or entities and is entitled to the immunity of this part.
(3) (a) The donation of a cancer drug or device by the manufacturer of the drug or device does not absolve the manufacturer from criminal or civil liability or increase a liability that would have existed had the drug or device not been donated.
(b) The civil immunity provisions of subsection (2) do not apply to a person employed by or an entity operated by the state or a political subdivision of the state.

24.174.1141 RETURN OF MEDICATION FROM LONG TERM CARE FACILITIES -- DONATED DRUG PROGRAM (1) In facilities licensed by the Montana department of health and human services where United States pharmacopoeia storage requirements are assured, unit-dosed legend drugs, with the exception of controlled substances, no longer needed by the patient for whom they were prescribed, may be transferred to a provisional permitted pharmacy for relabeling and dispensing free of charge to patients who are uninsured, indigent or have insufficient funds to obtain needed prescription drugs. Prescription medications may be dispensed pursuant to a valid prescription order. A usual and customary dispensing fee may be charged at the pharmacist’s discretion.
(2) The pharmacist-in-charge of the provisional permitted pharmacy shall be responsible for determining the suitability of the legend drug for use. Medications must be unopened in sealed, unaltered unit dose containers that meet USP standards for light, moisture and air permeation. No product in which drug integrity cannot be assured shall be accepted for re-dispensing by the pharmacist.
(3) A re-dispensed prescription medication must be assigned the expiration date stated on the unit dose packaging. Medications packaged in unit dose form within a pharmacy must be given an expiration date of one year or actual date of expiration of the medication, whichever comes first, and must not be repackaged.
(4) No medication can be redistributed more than once.
(5) Only authorized personnel shall carry out the physical transfer of medication in either facility, pursuant to established policies and procedures.
(6) The patient’s name and other identifying marks must be obliterated from packaging prior to transfer. The drug name, strength, lot number and expiration date must remain clearly visible on the packaging.
(7) An inventory list of drugs transferred, including expiration dates, must accompany the drugs, and must be maintained in the provisional permitted pharmacy for a period of two years.
(8) Policies and procedures to document safe storage and transfer of unneeded medications must be written and adhered to by the facilities involved, and must be available for inspection by an authorized representative of the Montana board of pharmacy or public health and human services.

CANCER DRUG REPOSITORY

24.174.1501 PARTICIPATION (1) A pharmacy or facility may fully participate in the cancer drug repository program by accepting, storing and dispensing, or administering donated drugs and supplies, or may limit its participation to only accepting and storing donated drugs and supplies. If a pharmacy or facility chooses to limit its participation, the pharmacy or facility shall distribute any donated drugs to a fully participating repository.
(2) A pharmacy or facility may withdraw from participation in the cancer drug repository program at any time, upon notification to the board. A notice to withdraw shall be in writing.
(3) Any patient who is diagnosed with cancer is eligible to receive drugs or supplies under the cancer drug repository program.
(4) Cancer drugs may be donated to a pharmacy or facility.
(5) Participation in the program is voluntary.
(6) There is no limitation on the number of doses that can be donated to the program as long as the donated drugs meet the requirements of these regulations.

24.174.1502 DONATION OF CANCER DRUGS (1) Any person or entity may donate cancer drugs to the program. Any person or entity who donates to the program must contact a pharmacy or facility to obtain a form on which the donor must specify the cancer drug to be donated. The board will supply the form to be used which will include:
(a) name of the cancer drug;
(b) quantity of the cancer drug;
(c) the name of the person to whom the cancer drug was originally prescribed;
(d) the relationship between the person or entity donating the cancer drug and the person to whom the drug was prescribed;
(e) signature of the person donating the cancer drug; and
(f) date the form was signed.

24.174.1503 ACCEPTABLE CANCER DRUGS (1) The following categories of drugs are acceptable for dispensing or distribution under the program:
(a) a cancer drug that is in its original, unopened, sealed, and tamper-evident packaging;
(b) a cancer drug packaged in single unit doses if the outside packaging is opened, but the single unit dose packaging is unopened;
(c) a cancer drug that does not require refrigeration, freezing, or other special temperature requirements beyond controlled room temperature; and
(d) an injectable cancer drug if it does not have temperature requirements other than controlled room temperature.
(2) Any cancer drug donated to the program cannot be used past its expiration date.

24.174.1504 NONACCEPTABLE CANCER DRUGS (1) The following categories of drugs are not acceptable for dispensing or distribution under the program, because the effectiveness and safety of the cancer drug cannot be ensured or is otherwise prohibited:
(a) a cancer drug that is adulterated or misbranded;
(b) a cancer drug in packaging that has been opened, unsealed, or tampered with, or that is no longer in its original container;
(c) a cancer drug packaged in single unit doses if the outside packaging is opened and the single unit dose packaging is also opened;
(d) a cancer drug that requires refrigeration, freezing, or other special temperature requirements beyond controlled room temperature;
(e) controlled substances; and
(f) a cancer drug that has expired before dispensing to the patient.

24.174.1505 DISPENSING AND DISTRIBUTION OF CANCER DRUGS
(1) A pharmacy or facility must comply with all applicable provisions of state and federal law relating to the storage, distribution, and dispensing of donated cancer drugs.

(2) A pharmacy or facility must inspect all such drugs prior to dispensing or distributing to determine if they are adulterated, misbranded, or expired.
(3) The following are authorized to dispense drugs:
(a) practitioners with prescriptive authority; and
(b) licensed pharmacists.
(4) Cancer drugs may only be dispensed pursuant to a prescription issued by a prescribing practitioner. Cancer drugs may be:
(a) dispensed to an ultimate user of the cancer drug; or
(b) distributed to another pharmacy or facility for dispensing.
(5) Cancer drugs donated under the program may not be resold.
(6) Patients for whom cancer drugs are dispensed under the program must be notified by the prescribing practitioner that the cancer drugs they received were originally dispensed to another patient and were returned for re-dispensing through the program.

24.174.1506 STORAGE REQUIREMENTS (1) The pharmacy or facility that receives donated cancer drugs for dispensing or distribution must:
(a) provide equipment for the storage of cancer drugs donated to the program at controlled room temperature;
(b) maintain the inventory of donated cancer drugs separate from all other drug inventory of the pharmacy or facility; and
(c) establish a secure location for the storage of the donated cancer drugs.

24.174.1507 RECORD-KEEPING REQUIREMENTS (1) A pharmacy or facility must maintain a perpetual inventory log book of all donated cancer drugs received, dispensed, or distributed.
(2) The perpetual inventory log book must contain the following information regarding all donated cancer drugs received, dispensed, or distributed:
(a) name of the cancer drug;
(b) quantity of the cancer drug;
(c) expiration date of the cancer drug;
(d) lot number of the cancer drug;
(e) name of pharmacy or facility;
(f) name of person who donated the cancer drug;
(g) name of the person to whom the cancer drug was dispensed;
(h) date the cancer drug was dispensed;
(i) name of the prescribing practitioner who wrote the prescription for the cancer drug to be dispensed under the program;
(j) name of the pharmacy or facility which the cancer drug was distributed;
(k) date the cancer drug was distributed to another pharmacy or facility;
(l) date of destruction of the expired cancer drug; and
(m) the amount of the handling fee charged, if any.

24.174.1508 HANDLING FEE (1) A pharmacy or facility that receives donated cancer drugs may charge a handling fee to the patient for dispensing or distribution of cancer drugs under the program.
(2) The handling fee must not exceed the applicable Medicaid dispensing fee.

24.174.1509 PHARMACY OR FACILITY REGISTRY (1) The board shall establish and maintain a pharmacy or facility registry for the program.
(2) The pharmacy or facility registry shall include:
(a) pharmacy's or facility's name;
(b) pharmacy's or facility's address;
(c) pharmacy's or facility's telephone number; and
(d) whether the pharmacy or facility is in a practitioner's office, a pharmacy, a clinic, or a hospital.
(3) It is the responsibility of the pharmacy or facility to:

(a) notify the board of the desire to participate in the program; and
(b) provide the required registry information to the board.
(4) Any pharmacy or facility in the program will be entered on the pharmacy or facility registry by the board.
(5) It is the responsibility of the pharmacy or facility to notify the board:
(a) of any change of name, address, telephone number; and
(b) when it no longer wants to participate in the program.
(6) The board will make the pharmacy or facility registry information available to any person or entity wishing to donate cancer drugs to the program.
(7) The board will provide public access to the pharmacy or facility registry information on the board web site, or by contacting the board office.

24.174.1510 INSPECTIONS AND TERMINATION FROM PROGRAM (1) The board may, in its discretion, inspect pharmacy or facilities in the program for compliance with the storage and record-keeping requirements of this subchapter.
(2) In the event of noncompliance with the storage and record-keeping requirements of this subchapter, the board may terminate the pharmacy's or facility's participation in the program.

CONTROLLED SUBSTANCES

50-32-101. Definitions. As used in this chapter, the following definitions apply: (1) "Administer" means the direct application of a dangerous drug, whether by injection, inhalation, ingestion, or other means, to the body of a patient or research subject by:
(a) a practitioner or by the practitioner's authorized agent; or
(b) the patient or research subject at the direction and in the presence of the practitioner.
(2) (a) "Agent" means an authorized person who acts on behalf of or at the direction of a manufacturer, distributor, or dispenser.
(b) The term does not include a common or contract carrier, public warehouse operator, or employee of the carrier or warehouse operator.
(3) "Board" means the board of pharmacy provided for in 2-15-1733.
(4) "Bureau" means the drug enforcement administration, United States department of justice, or its successor agency.
(5) "Counterfeit substance" means a dangerous drug or the container or labeling of a dangerous drug without authorization that bears the trademark, trade name, or other identifying mark, imprint, number, or device or a likeness of an identifying mark, imprint, number, or device of a manufacturer, distributor, or dispenser other than the person who in fact manufactured, distributed, or dispensed the drug.
(6) "Dangerous drug" means a drug, substance, or immediate precursor in Schedules I through V set forth in part 2.
(7) "Deliver" or "delivery" means the actual, constructive, or attempted transfer from one person to another of a dangerous drug, whether or not there is an agency relationship.
(8) "Department" means the department of labor and industry provided for in Title 2, chapter 15, part 17.
(9) "Dispense" means to deliver a dangerous drug to an ultimate user or research subject by or pursuant to the lawful order of a practitioner, including the prescribing, administering, packaging, labeling, or compounding necessary to prepare the drug for that delivery.
(10) "Dispenser" means a practitioner who dispenses.
(11) "Distribute" means to deliver other than by administering or dispensing a dangerous drug.
(12) "Distributor" means a person who distributes.
(13) "Drug" has the same meaning as provided in 37-7-101.
(14) "Hashish", as distinguished from marijuana, means the mechanically processed or extracted plant material that contains tetrahydrocannabinol (THC) and is composed of resin from the cannabis plant.
(15) "Immediate precursor" means a substance that the board finds to be and by rule designates as being the principal compound commonly used or produced primarily for use and that is an immediate chemical intermediary used or likely to be used in the manufacture of a dangerous drug, the control of which is necessary to prevent, curtail, or limit manufacture.

(16) (a) "Manufacture" means the production, preparation, propagation, compounding, conversion, or processing of a dangerous drug either directly or indirectly by extraction from substances of natural origin, independently by means of chemical synthesis, or by a combination of extraction and chemical synthesis and includes the packaging or repackaging of the drug or labeling or relabeling of its container.
(b) Manufacture does not include the preparation or compounding of a dangerous drug by an individual for personal use or the preparation, compounding, packaging, or labeling of a dangerous drug:
(i) by a practitioner as an incident to the administering or dispensing of a dangerous drug in the course of a professional practice; or
(ii) by a practitioner or the practitioner's authorized agent under the practitioner's supervision for the purpose of or as an incident to research, teaching, or chemical analysis and not for sale.
(17) "Marijuana (marihuana)" means all plant material from the genus cannabis containing tetrahydrocannabinol (THC) or seeds of the genus capable of germination.
(18) "Narcotic drug" means any of the following, whether produced directly or indirectly by extraction from substances of vegetable origin, independently by means of chemical synthesis, or by a combination of extraction and chemical synthesis:
(a) opium and opiate and a salt, compound, derivative, or preparation of opium or opiate;
(b) a salt, compound, isomer, derivative, or preparation of a salt, compound, isomer, or derivative that is chemically equivalent or identical with any of the drugs referred to in subsection (18)(a), but not including the isoquinoline alkaloids of opium;
(c) opium poppy and poppy straw; or
(d) coca leaves and a salt, compound, derivative, or preparation of coca leaves and a salt, compound, isomer, derivative, or preparation of a salt, compound, isomer, or derivative that is chemically equivalent or identical with any of these drugs, but not including decocainized coca leaves or extractions of coca leaves that do not contain cocaine or ecgonine.
(19) "Opiate" means a drug having an addiction-forming or addiction-sustaining liability similar to morphine or being capable of conversion into a drug having addiction-forming or addiction-sustaining liability. The term does not include, unless specifically designated as a dangerous drug under 50-32-202, the dextrorotatory isomer of 3-methoxy-n-methylmorphinan and its salts (dextromethorphan). The term does include its racemic and levorotatory forms.
(20) "Opium poppy" means the plant of the species papaver somniferum L., except its seeds.
(21) "Person" means an individual, corporation, government or governmental subdivision or agency, business trust, estate, trust, partnership, association, or any other legal entity.
(22) "Poppy straw" means all parts, except the seeds, of the opium poppy after mowing.
(23) "Practitioner" means:
(a) a physician, dentist, veterinarian, scientific investigator, or other person licensed, registered, or otherwise permitted to distribute, dispense, or conduct research with respect to or to administer a dangerous drug in the course of professional practice or research in this state;
(b) a pharmacy or other institution licensed, registered, or otherwise permitted to distribute, dispense, or conduct research with respect to or to administer a dangerous drug in the course of professional practice or research in this state; and
(c) a physician licensed to practice medicine or a dentist licensed to practice dentistry in another state.
(24) "Prescription" means an order given individually for the person for whom prescribed, directly from the prescriber to the furnisher or indirectly to the furnisher, by means of an order signed by the prescriber and bearing the name and address of the prescriber, the prescriber's license classification, the name of the patient, the name and quantity of the drug or drugs prescribed, the directions for use, and the date of its issue. These stipulations apply to written, electronically transmitted, and telephoned prescriptions.
(25) "Production" includes the manufacture, planting, cultivation, growing, or harvesting of a substance or drug regulated under the provisions of this chapter.
(26) "State", when applied to a part of the United States, includes a state, district, commonwealth, territory, insular possession of the United States, and any area subject to the legal authority of the United States of America.
(27) "Ultimate user" means a person who lawfully possesses a dangerous drug for personal use or for the use of a

member of the person's household or for administering to an animal owned by the person or by a member of the person's household.

50-32-103. Board to administer chapter. (1) The board shall administer this chapter and may add drugs to or delete or reschedule all drugs enumerated in the schedules in 50-32-222, 50-32-224, 50-32-226, 50-32-229, or 50-32-232 pursuant to the rulemaking procedures of the Montana Administrative Procedure Act.
(2) The board shall promulgate rules for its administration which are not inconsistent with this chapter and specifically shall levy and the department shall collect reasonable registration fees relating to the registration and control of the manufacture, distribution, and dispensing of dangerous drugs within the state. The maximum fee for any registration shall not exceed $100 per year.

50-32-104. Board's authority limited. Authority to control under 50-32-103 does not extend to distilled spirits, liquor, wine, malt beverages, beer, porter, ale, stout, or tobacco.

50-32-105. Board to conduct educational programs. (1) The board shall carry out educational programs designed to prevent and deter misuse and abuse of dangerous drugs.
(2) In connection with these programs, it may:
(a) promote better recognition of the problems of misuse and abuse of dangerous drugs within the regulated industry and among interested groups and organizations;
(b) assist the regulated industry and interested groups and organizations in contributing to the reduction of misuse and abuse of dangerous drugs;
(c) consult with interested groups and organizations to aid them in solving administrative and organizational problems;
(d) evaluate procedures, projects, techniques, and controls conducted or proposed as part of educational programs on misuse and abuse of dangerous drugs;
(e) disseminate the results of research on misuse and abuse of dangerous drugs to promote a better public understanding of what problems exist and what can be done to combat them; and
(f) assist in the education and training of state and local law enforcement officials in their efforts to control misuse and abuse of dangerous drugs.

50-32-106. Board to encourage research. (1) The board shall encourage research on misuse and abuse of dangerous drugs.
(2) In connection with the research and in furtherance of the enforcement of this chapter, it may:
(a) establish methods to assess accurately the effects of dangerous drugs and identify and characterize those with potential for abuse;
(b) make studies and undertake programs of research to:
(i) develop new or improved approaches, techniques, systems, equipment, and devices to strengthen the enforcement of this chapter;
(ii) determine patterns of misuse and abuse of dangerous drugs and the social effects thereof; and
(iii) improve methods for preventing, predicting, understanding, and dealing with the misuse and abuse of dangerous drugs; and
(c) request the department to enter into contracts with public agencies, institutions of higher education, and private organizations or individuals for the purpose of conducting research, demonstrations, or special projects which bear directly on misuse and abuse of dangerous drugs.
(3) The board may authorize persons engaged in research on the use and effects of dangerous drugs to withhold the names and other identifying characteristics of individuals who are the subjects of the research. Persons who obtain this authorization are not compelled in any civil, criminal, administrative, legislative, or other proceeding to identify the individuals who are the subjects of research for which the authorization was obtained.
(4) The board may authorize the possession and distribution of dangerous drugs by persons engaged in research. Persons who obtain this authorization are exempt from state prosecution for possession and distribution of dangerous drugs to the extent of the authorization.

50-32-201. General criteria to be considered. In making a determination regarding a drug, the board shall consider the following:
(1) the actual or relative potential for abuse;
(2) the scientific evidence of its pharmacological effect, if known;
(3) the state of current scientific knowledge regarding the drug;
(4) the history and current pattern of abuse;
(5) the scope, duration, and significance of abuse;
(6) the risk to the public health;
(7) the potential of the drug to produce psychic or physiological dependence liability; and
(8) whether the drug is an immediate precursor of a drug already controlled under this chapter

50-32-202. Designation of drug as dangerous drug. After considering the factors enumerated in 50-32-201, the board shall make findings with respect thereto, and if it finds the drug has a potential for abuse, it shall designate such drug a dangerous drug in the manner set forth in the Montana Administrative Procedure Act.

50-32-203. Effect of rescheduling under federal law. If any drug is designated, rescheduled, or deleted as a "controlled substance" under federal law and notice thereof is given to the board, the board shall similarly control the drug under this chapter after the expiration of 30 days from publication in the federal register of a final order designating a drug as a "controlled substance" or rescheduling or deleting a drug unless, within that 30-day period, the board objects to inclusion, rescheduling, or deletion. In that case, the board shall cause the reasons for objection to be published and afford all interested parties an opportunity to be heard. At the conclusion of the hearing, the department shall publish the board's decision which shall be final unless altered thereafter by the board or by statute. Upon publication of objection to inclusion, rescheduling, or deletion under this chapter by the board, control under this chapter is stayed until the board's decision is published.

50-32-204. Immediate precursors. If the board designates a drug as an immediate precursor, drugs which are precursors of the controlled precursor shall not be subject to control solely because they are precursors of the controlled precursor.

50-32-205. Nonprescription drugs not to be scheduled. The board shall exclude any nonnarcotic drug from a schedule if the drug may, under the Federal Food, Drug, and Cosmetic Act and 50-31-307(2)(b) of the Montana Food, Drug, and Cosmetic Act, be lawfully sold over the counter without a prescription.

24.174.520 PRESCRIPTION REQUIRED FOR SCHEDULE V (1) All products which are presently defined as exempt narcotics (Schedule V) of the Comprehensive Controlled Substances Act, Public Law (91-513) shall require a prescription from one with the authority to prescribe.

50-32-206. Use of names of scheduled drugs. The dangerous drugs listed or to be listed in the schedules in 50-32-222, 50-32-224, 50-32-226, 50-32-229, and 50-32-232 are included by whatever official, common, usual, chemical, or trade name designated.

50-32-207. Order forms for drugs in Schedules I and II. Dangerous drugs in Schedules I and II shall be distributed by a registrant to another registrant only pursuant to an order form. Compliance with the provisions of federal law respecting order forms shall be deemed compliance with this section unless the board prescribes particular forms to be used.

50-32-208. Prescription and medical requirements for scheduled drugs -- penalty. (1) No dangerous drug in Schedule II may be dispensed without the written prescription of a practitioner.
(2) In emergency situations, as defined by rule of the board, Schedule II drugs may be dispensed upon a practitioner's oral prescription reduced promptly to writing and filed by the pharmacy. Prescriptions shall be retained in conformity with the requirements of 50-32-309. No prescription for a Schedule II drug may be refilled.

(3) A dangerous drug included in Schedule III or IV, which is a prescription drug as determined under the federal or Montana food, drug, and cosmetic acts, shall not be dispensed without a written or oral prescription of a practitioner. The prescription shall not be filled or refilled more than 6 months after the date thereof or be refilled more than five times unless renewed by the practitioner.
(4) A dangerous drug included in Schedule V shall not be distributed or dispensed other than for a medical purpose.
(5) Any person who violates the provisions of this section is guilty of a misdemeanor and upon conviction may be fined not to exceed $1,000 or be imprisoned in county jail for a term not to exceed 1 year, or both fined and imprisoned.

50-32-209. Republication of schedules. The board shall revise and the department shall republish additions, deletions, or other changes to the schedules of dangerous drugs at times determined by the board. For the purposes of this section, the mandate to republish additions, deletions, or other changes is satisfied by publication in the Administrative Rules of Montana pursuant to Title 2, chapter 4.

50-32-221. Criteria for placement of drug in Schedule I. The board shall place a drug in Schedule I if it finds that the drug:
(1) has high potential for abuse; and
(2) has no accepted medical use in treatment in the United States or lacks accepted safety for use in treatment under medical supervision.

50-32-222. Specific dangerous drugs included in Schedule I. Schedule I consists of the drugs and other substances, by whatever official, common, usual, chemical, or brand name designated, listed in this section.
(1) Opiates.
(2) For the purposes of subsection (1)(hh), the term "isomer" includes the optical, position, and geometric isomers.
(3) Opium derivatives. Unless specifically excepted or listed in another schedule, any of the following are opium derivatives, including salts, isomers, and salts of isomers whenever the existence of those salts, isomers, and salts of isomers is possible within the specific chemical designation:
(4) Hallucinogenic substances. Unless specifically excepted or listed in another schedule, any material, compound, mixture, or preparation that contains any quantity of the following is a hallucinogenic substance, including salts, isomers, and salts of isomers whenever the existence of those salts, isomers, and salts of isomers is possible within the specific chemical designation:
(5) For the purposes of subsection (4), the term "isomer" includes the optical, position, and geometric isomers.
(6) Depressants. Unless specifically excepted or listed in another schedule, any material, compound, mixture, or preparation that contains any quantity of the following substances is a depressant having a depressant effect on the central nervous system, including salts, isomers, and salts of isomers whenever the existence of those salts, isomers, and salts of isomers is possible within the specific chemical designation:
(a) mecloqualone; and
(b) methaqualone.
(7) Stimulants. Unless specifically excepted or listed in another schedule, any material, compound, mixture, or preparation that contains any quantity of the following substances is a stimulant having a stimulant effect on the central nervous system, including its salts, isomers, and salts of isomers:
(8) Substances subject to emergency scheduling. Any material, compound, mixture, or preparation that contains any quantity of the following substances is included in this category:
(9) If prescription or administration is authorized by the Federal Food, Drug and Cosmetic Act, then any material, compound, mixture, or preparation containing tetrahydrocannabinols listed in subsection (4) must automatically be rescheduled from Schedule I to Schedule II.

50-32-223. Criteria for placement of drug in Schedule II. The board shall place a drug in Schedule II if it finds that: (1) the drug has high potential for abuse;
(2) the drug has currently accepted medical use in treatment in the United States or currently accepted medical use with severe restrictions; and
(3) the abuse of the drug may lead to severe psychic or physical dependence.

50-32-224. Specific dangerous drugs included in Schedule II. Schedule II consists of the drugs and other substances, by whatever official, common, usual, chemical, or brand name designated, listed in this section.
(1) Substances, vegetable origin or chemical synthesis. Unless specifically excepted or listed in another schedule, any of the following substances, whether produced directly or indirectly by extraction from substances of vegetable origin, independently by means of chemical synthesis, or by a combination of extraction and chemical synthesis, are included in this category:
(a) opium and opiate and any salt, compound, derivative, or preparation of opium or opiate, excluding apomorphine, thebaine-derived butorphanol, dextrorphan, nalbuphine, nalmefene, naloxone, and naltrexone and their respective salts, but including the following:
(b) any salt, compound, derivative, or preparation of them that is chemically equivalent or identical with any of the substances referred to in subsection (1)(a), except that these substances do not include the isoquinoline alkaloids of opium;
(c) opium poppy and poppy straw;
(d) coca leaves and any salt, compound, derivative, or preparation of coca leaves, including cocaine and ecgonine and their salts, isomers, derivatives, and salts of isomers, and derivatives, and any salt, compound, derivative, or preparation of them that is chemically equivalent or identical with any of these substances, except that these substances do not include decocainized coca leaves or extraction of coca leaves, which extractions do not contain cocaine or ecgonine; and
(e) concentrate of poppy straw, the crude extract of poppy straw in either liquid, solid, or powder form that contains the phenanthrene alkaloids of the opium poppy.
(2) Opiates. Unless specifically excepted or listed in another schedule, any of the following are opiates, including isomers, esters, ethers, salts, and salts of isomers, esters, and ethers whenever the existence of those isomers, esters, ethers, and salts is possible within the specific chemical designation, dextrorphan and levopropoxyphene excepted:
(3) Stimulants. Unless specifically excepted or listed in another schedule, any material, compound, mixture, or preparation that contains any quantity of the following substances is a stimulant having a stimulant effect on the central nervous system:
(4) Depressants. Unless specifically excepted or listed in another schedule, any material, compound, mixture, or preparation that contains any quantity of the following substances is a depressant having a depressant effect on the central nervous system, including salts, isomers, and salts of isomers whenever the existence of those salts, isomers, and salts of isomers is possible within the specific chemical designation:
(5) Hallucinogenic substances include the following:
(6) Immediate precursors. Unless specifically excepted or listed in another schedule, any material, compound, mixture, or preparation that contains any quantity of the following substances is an immediate precursor:
(a) phenylacetone, an immediate precursor to amphetamine and methamphetamine. Trade or other names for phenylacetone include phenyl-2-propanone, P2P, benzyl methyl ketone, and methyl benzyl ketone.
(b) 1-phenylcyclohexylamine and 1-piperidinocyclohexanecarbonitrile (PCC), immediate precursors to phencyclidine (PCP).

50-32-225. Criteria for placement of drug in Schedule III. The board shall place a drug in Schedule III if it finds that: (1) the drug has a potential for abuse less than the drugs listed in Schedules I and II;
(2) the drug has currently accepted medical use in treatment in the United States; and
(3) abuse of the drug may lead to moderate or low physical dependence or high psychological dependence.

50-32-226. Specific dangerous drugs included in Schedule III. Schedule III consists of the drugs and other substances, by whatever official, common, usual, chemical, or brand name designated, listed in this section.
(1) Stimulants. Unless specifically excepted or listed in another schedule, any material, compound, mixture, or preparation that contains any quantity of the following substances is a stimulant having a stimulant effect on the central nervous system, including salts, isomers (whether optical, position, or geometric), and salts of isomers whenever the existence of those salts, isomers, and salts of isomers is possible within the specific chemical designation:
(2) Depressants. Unless specifically excepted or listed in another schedule, any material, compound, mixture, or preparation that contains any quantity of the following substances is a depressant having a depressant effect on the

central nervous system:
(3) Nalorphine.
(4) Narcotic drugs. Unless specifically excepted or listed in another schedule, any material, compound, mixture, or preparation containing any of the following is a narcotic drug, including its salts calculated as the free anhydrous base or alkaloid in the following limited quantities:
(a) not more than 1.8 grams of codeine per 100 milliliters or not more than 90 milligrams per dosage unit, with an equal or greater quantity of an isoquinoline alkaloid of opium;
(b) not more than 1.8 grams of codeine per 100 milliliters or not more than 90 milligrams per dosage unit, with one or more active, nonnarcotic ingredients in recognized therapeutic amounts;
(c) not more than 300 milligrams of dihydrocodeinone (hydrocodone) per 100 milliliters or not more than 15 milligrams per dosage unit, with a fourfold or greater quantity of an isoquinoline alkaloid of opium;
(d) not more than 300 milligrams of dihydrocodeinone (hydrocodone) per 100 milliliters or not more than 15 milligrams per dosage unit, with one or more active, nonnarcotic ingredients in recognized therapeutic amounts;
(e) not more than 1.8 grams of dihydrocodeine per 100 milliliters or not more than 90 milligrams per dosage unit, with one or more active, nonnarcotic ingredients in recognized therapeutic amounts;
(f) not more than 300 milligrams of ethylmorphine per 100 milliliters or not more than 15 milligrams per dosage unit, with one or more active, nonnarcotic ingredients in recognized therapeutic amounts;
(g) not more than 500 milligrams of opium per 100 milliliters or per 100 grams or not more than 25 milligrams per dosage unit, with one or more active, nonnarcotic ingredients in recognized therapeutic amounts; or
(h) not more than 50 milligrams of morphine per 100 milliliters or per 100 grams, with one or more active, nonnarcotic ingredients in recognized therapeutic amounts.
(5) Anabolic steroids. The term "anabolic steroid" means any drug or hormonal substance, chemically and pharmacologically related to testosterone, other than estrogens, progestins, and corticosteroids, that promotes muscle growth. Unless specifically excepted or listed in another schedule, any material, compound, mixture, or preparation containing any quantity of the following substances is an anabolic steroid, including salts, isomers, and salts of isomers whenever the existence of those salts of isomers is possible within the specific chemical designation:
50-32-227. Board authorized to exempt certain compounds, mixtures, or preparations from Schedule III. The board may except by rule any compound, mixture, or preparation containing any stimulant or depressant drug listed in 50-32-226(1) and (2) from the application of all or any part of this chapter if the compound, mixture, or preparation contains one or more active medicinal ingredients not having a stimulant or depressant effect on the central nervous system and if the admixtures are included therein in combinations, quantity, proportion, or concentration that vitiate the potential for abuse of the drugs which have a stimulant or depressant effect on the central nervous system.

50-32-228. Criteria for placement of drug in Schedule IV. The board shall place a drug in Schedule IV if it finds that: (1) the drug has a low potential for abuse relative to drugs in Schedule III;
(2) the drug has currently accepted medical use in treatment in the United States; and
(3) abuse of the drug may lead to limited physical dependence or psychological dependence relative to the drugs in Schedule III.

50-32-229. Specific dangerous drugs included in Schedule IV. Schedule IV consists of the drugs and other substances, by whatever official, common, usual, chemical, or brand name designated, listed in this section.
(1) Narcotic drugs. Unless specifically excepted or listed in another schedule, any material, compound, mixture, or preparation containing any of the following narcotic is a drug, including its salts calculated as the free anhydrous base or alkaloid in the following limited quantities:
(a) not more than 1 milligram of difenoxin and not less than 25 micrograms of atropine sulfate per dosage unit; and
(b) dextropropoxyphene (alpha-(+)-4-dimethylamino-1,2-diphenyl-3-methyl-2-propionoxybutane).
(2) Depressants. Unless specifically excepted or listed in another schedule, any material, compound, mixture, or preparation that contains any quantity of the following substances is a depressant, including salts, isomers, and salts of isomers whenever the existence of those salts, isomers, and salts of isomers is possible within the specific chemical designation:
(3) Fenfluramine. Any material, compound, mixture, or preparation that contains any quantity of fenfluramine,

including its salts, isomers (whether optical, position, or geometric), and salts of isomers whenever the existence of those salts, isomers, and salts of isomers is possible.
(4) Stimulants. Unless specifically excepted or listed in another schedule, any material, compound, mixture, or preparation that contains any quantity of the following substances is a stimulant having a stimulant effect on the central nervous system, including its salts, isomers, and salts of isomers:
(5) Ephedrine.
(a) Except as provided in subsection (5)(b), any material, compound, mixture, or preparation that contains any quantity of ephedrine having a stimulant effect on the central nervous system, including its salts, enantiomers (optical isomers), and salts of enantiomers (optical isomers) when ephedrine is the only active medicinal ingredient or is used in combination with therapeutically insignificant quantities of another active medicinal ingredient.
(b) Ephedrine does not include materials, compounds, mixtures, or preparations labeled in compliance with the Dietary Supplement Health and Education Act of 1994, 21 U.S.C. 321, et seq., that contain only natural ephedra alkaloids or extracts of natural ephedra alkaloids.
(c) Ephedrine may be immediately accessible for use by a licensed physician in a patient care area if it is under the physician's direct supervision.
(6) Other substances. Unless specifically excepted or listed in another schedule, any material, compound, mixture, or preparation that contains any quantity of pentazocine, including its salts.

50-32-230. Board authorized to exempt certain compounds, mixtures, or preparations from Schedule IV. The board may except by rule any compound, mixture, or preparation containing any depressant drug listed in 50-32-229 from the application of all or any part of this chapter if the compound, mixture, or preparation contains one or more active medicinal ingredients not having a depressant effect on the central nervous system and if the admixtures are included therein in combinations, quantity, proportion, or concentration that vitiate the potential for abuse of the drugs which have a depressant effect on the central nervous system.

50-32-231. Criteria for placement of drug in Schedule V. The board shall place a drug in Schedule V if it finds that: (1) the drug has low potential for abuse relative to the controlled drugs listed in Schedule IV;
(2) the drug has currently accepted medical use in treatment in the United States; and
(3) the drug has limited physical dependence or psychological dependence liability relative to the dangerous drugs listed in Schedule IV.

50-32-232. Specific dangerous drugs included in Schedule V. Schedule V consists of the drugs and other substances, by whatever official, common, usual, chemical, or brand name designated, listed in this section.
(1) Narcotic drugs. Unless specifically excepted or unless listed in another schedule, any material, compound, mixture, or preparation containing buprenorphine and its salts is included in this category.
(2) Narcotic drugs containing nonnarcotic active medicinal ingredients. Any compound, mixture, or preparation containing any of the following is a narcotic drug, including its salts, calculated as the free anhydrous base or alkaloid in limited quantities as set forth in subsections (2)(a) through (2)(f), which include one or more nonnarcotic, active medicinal ingredients in sufficient proportion to confer upon the compound, mixture, or preparation valuable medicinal qualities other than those possessed by narcotic drugs alone:
(a) not more than 200 milligrams of codeine per 100 milliliters or per 100 grams;
(b) not more than 100 milligrams of dihydrocodeine per 100 milliliters or per 100 grams;
(c) not more than 100 milligrams of ethylmorphine per 100 milliliters or per 100 grams;
(d) not more than 2.5 milligrams of diphenoxylate and not less than 25 micrograms of atropine sulfate per dosage unit;
(e) not more than 100 milligrams of opium per 100 milliliters or per 100 grams; and
(f) not more than 0.5 milligram of difenoxin and not less than 25 micrograms of atropine sulfate per dosage unit.
(3) Stimulants. Unless specifically exempted or excluded or unless listed in another schedule, any material, compound, mixture, or preparation that contains any quantity of pyrovalerone is a stimulant having a stimulant effect on the central nervous system, including its salts, isomers, and salts of isomers.

50-32-233. Exempt anabolic steroid products. The following anabolic steroid-containing compounds, mixtures, or preparations are exempt from this chapter:
(1) androgyn L.A.;
(2) andro-estro 90-4;
(3) depandrogyn;
(4) DEPO-T.E.;
(5) deptestrogen;
(6) duomone;
(7) duratestrin;
(8) duo-span II;
(9) estratest;
(10) estratest HS;
(11) pan estra test;
(12) premarin with methyltestosterone;
(13) synovex H pellets in process;
(14) synovex H pellets in process granulation;
(15) test-estro cypionates;
(16) testagen;
(17) testosterone cyp 50 estradiol cyp 2;
(18) testosterone, cypionate-estradiol, cypionate injection;
(19) testosterone, enanthate-estradiol, valerate injection; and
(20) tilapia sex reversal feed (investigational).

45-9-101. Criminal distribution of dangerous drugs. (1) A person commits the offense of criminal distribution of dangerous drugs if the person sells, barters, exchanges, gives away, or offers to sell, barter, exchange, or give away any dangerous drug, as defined in 50-32-101.
(2) A person convicted of criminal distribution of a narcotic drug, as defined in 50-32-101(18)(d), or an opiate, as defined in 50-32-101(19), shall be imprisoned in the state prison for a term of not less than 2 years or more than life and may be fined not more than $50,000, except as provided in 46-18-222.
(3) A person convicted of criminal distribution of a dangerous drug included in Schedule I or Schedule II pursuant to 50-32-222 or 50-32-224, except marijuana or tetrahydrocannabinol, who has a prior conviction for criminal distribution of such a drug shall be imprisoned in the state prison for a term of not less than 10 years or more than life and may be fined not more than $50,000, except as provided in 46-18-222. Upon a third or subsequent conviction for criminal distribution of such a drug, the person shall be imprisoned in the state prison for a term of not less than 20 years or more than life and may be fined not more than $50,000, except as provided in 46-18-222.
(4) A person convicted of criminal distribution of dangerous drugs not otherwise provided for in subsection (2), (3), or (5) shall be imprisoned in the state prison for a term of not less than 1 year or more than life or be fined an amount of not more than $50,000, or both.
(5) A person who was an adult at the time of distribution and who is convicted of criminal distribution of dangerous drugs to a minor shall be sentenced as follows:
(a) If convicted pursuant to subsection (2), the person shall be imprisoned in the state prison for not less than 4 years or more than life and may be fined not more than $50,000, except as provided in 46-18-222.
(b) If convicted of the distribution of a dangerous drug included in Schedule I or Schedule II pursuant to 50-32-222 or 50-32-224 and if previously convicted of such a distribution, the person shall be imprisoned in the state prison for not less than 20 years or more than life and may be fined not more than $50,000, except as provided in 46-18-222.
(c) If convicted of the distribution of a dangerous drug included in Schedule I or Schedule II pursuant to 50-32-222 or 50-32-224 and if previously convicted of two or more such distributions, the person shall be imprisoned in the state prison for not less than 40 years or more than life and may be fined not more than $50,000, except as provided in 46-18-222.
(d) If convicted pursuant to subsection (4), the person shall be imprisoned in the state prison for not less than 2 years or more than life and may be fined not more than $50,000, except as provided in 46-18-222.

(6) Practitioners, as defined in 50-32-101, and agents under their supervision acting in the course of a professional practice are exempt from this section.

45-9-102. Criminal possession of dangerous drugs. (1) A person commits the offense of criminal possession of dangerous drugs if the person possesses any dangerous drug, as defined in 50-32-101.
(2) A person convicted of criminal possession of marijuana or its derivatives in an amount the aggregate weight of which does not exceed 60 grams of marijuana or 1 gram of hashish is, for the first offense, guilty of a misdemeanor and shall be punished by a fine of not less than $100 or more than $500 and by imprisonment in the county jail for not more than 6 months. The minimum fine must be imposed as a condition of a suspended or deferred sentence. A person convicted of a second or subsequent offense under this subsection is punishable by a fine not to exceed $1,000 or by imprisonment in the county jail for a term not to exceed 1 year or in the state prison for a term not to exceed 3 years or by both.
(3) A person convicted of criminal possession of an anabolic steroid as listed in 50-32-226 is, for the first offense, guilty of a misdemeanor and shall be punished by a fine of not less than $100 or more than $500 or by imprisonment in the county jail for not more than 6 months, or both.
(4) A person convicted of criminal possession of an opiate, as defined in 50-32-101(19), shall be imprisoned in the state prison for a term of not less than 2 years or more than 5 years and may be fined not more than $50,000, except as provided in 46-18-222.
(5) A person convicted of criminal possession of dangerous drugs not otherwise provided for in subsection (2), (3), or (4) shall be imprisoned in the state prison for a term not to exceed 5 years or be fined an amount not to exceed $50,000, or both.
(6) A person convicted of a first violation under this section is presumed to be entitled to a deferred imposition of sentence of imprisonment.
(7) Ultimate users and practitioners, as defined in 50-32-101, and agents under their supervision acting in the course of a professional practice are exempt from this section.

45-9-103. Criminal possession with intent to distribute. (1) A person commits the offense of criminal possession with intent to distribute if the person possesses with intent to distribute any dangerous drug as defined in 50-32-101.
(2) A person convicted of criminal possession of an opiate, as defined in 50-32-101(19), with intent to distribute shall be imprisoned in the state prison for a term of not less than 2 years or more than 20 years and may be fined not more than $50,000, except as provided in 46-18-222.
(3) A person convicted of criminal possession with intent to distribute not otherwise provided for in subsection (2) shall be imprisoned in the state prison for a term of not more than 20 years or be fined an amount not to exceed $50,000, or both.
(4) Practitioners, as defined in 50-32-101, and agents under their supervision acting in the course of a professional practice are exempt from this section.

45-9-104. Fraudulently obtaining dangerous drugs. A person commits the offense of fraudulently obtaining dangerous drugs if he obtains or attempts to obtain a dangerous drug, as defined in 50-32-101, by: (1) fraud, deceit, misrepresentation, or subterfuge;
(2) falsely assuming the title of or representing himself to be a manufacturer, wholesaler, practitioner, pharmacist, owner of a pharmacy, or other person authorized to possess dangerous drugs;
(3) the use of a forged, altered, or fictitious prescription;
(4) the use of a false name or a false address on a prescription; or
(5) the concealment of a material fact;
(6) knowingly or purposefully failing to disclose to a practitioner, as defined in 50-32-101, that the person has received the same or a similar dangerous drug or prescription for a dangerous drug from another source within the prior 30 days; or
(7) knowingly or purposefully communicating false or incomplete information to a practitioner with the intent to procure the administration of or a prescription for a dangerous drug. A communication of this information for the purpose provided in this subsection is not a privileged communication."

45-9-105. Altering labels on dangerous drugs. A person commits the offense of altering labels on dangerous drugs if he affixes a false, forged, or altered label to or otherwise misrepresents a package or receptacle containing a dangerous drug, as defined in 50-32-101.

45-9-106. Penalty for fraudulently obtaining dangerous drugs or altering the labels of dangerous drugs. (1) A person convicted of altering labels on dangerous drugs shall be imprisoned in the county jail for a term not to exceed 6 months.
(2) A person convicted of fraudulently obtaining dangerous drugs included in Schedule I, Schedule II, Schedule III, Schedule IV, or Schedule V in 50-32-222, 50-32-224, 50-32-226, 50-32-229, or 50-32-232 shall:
(a) upon his first conviction be imprisoned in the state prison for a term of not less than 1 year or not more than 5 years or fined an amount not to exceed $50,000, or both;
(b) upon his second conviction be imprisoned in the state prison for a term of not less than 5 years or not more than 10 years or fined an amount not to exceed $50,000, or both.

45-9-107. Criminal possession of precursors to dangerous drugs. (1) A person commits the offense of criminal possession of precursors to dangerous drugs if the person possesses any material, compound, mixture, or preparation that contains any combination of the following with intent to manufacture dangerous drugs:
(a) phenyl-2-propanone (phenylacetone);
(b) piperidine in conjunction with cyclohexanone;
(c) ephedrine;
(d) lead acetate;
(e) methylamine;
(f) methylformamide;
(g) n-methylephedrine;
(h) phenylpropanolamine;
(i) pseudoephedrine;
(j) anhydrous ammonia;
(k) hydriodic acid;
(l) red phosphorus;
(m) iodine in conjunction with ephedrine, pseudoephedrine, or red phosphorus;
(n) lithium in conjunction with anhydrous ammonia.
(2) A person convicted of criminal possession of precursors to dangerous drugs shall be imprisoned in the state prison for a term not less than 2 years or more than 20 years or be fined an amount not to exceed $50,000, or both.

45-9-108. Exemptions. (1) The provisions of 45-9-107 do not apply to:
(a) a drug manufacturer licensed by the state;
(b) a person authorized by rules adopted by the board of pharmacy to possess the combination of substances;
(c) a person employed by or enrolled as a student in a college or university within the state who possesses any combination of substances listed in 45-9-107 for the purposes of teaching or research that is authorized by the college or university.
(2) The board of pharmacy shall adopt, amend, or repeal rules in accordance with the Montana Administrative Procedure Act to authorize the processing of any combination of the substances listed in 45-9-107 whenever it determines that there is a legitimate need and that the substances will be used for a lawful purpose.
(3) The provisions of 45-9-102, 45-9-103, and 45-9-110 do not apply to 80-18-102.

45-9-109. Criminal distribution of dangerous drugs on or near school property -- penalty -- affirmative defense. (1) A person commits the offense of criminal distribution of dangerous drugs on or near school property if the person violates 45-9-101 in, on, or within 1,000 feet of the real property comprising a public or private elementary or secondary school.
(2) Except as provided in 46-18-222, a person convicted of criminal distribution of dangerous drugs on or near school property:
(a) shall be imprisoned in the state prison for a term of not less than 3 years or more than life; and

(b) may be fined an amount of not more than $50,000.
(3) It is not a defense to prosecution under subsection (1) that the person did not know the distance involved.
(4) It is an affirmative defense to prosecution for a violation of this section that:
(a) the prohibited conduct took place entirely within a private residence; and
(b) no person 17 years of age or younger was present in the private residence at any time during the commission of the offense.

45-9-110. Criminal production or manufacture of dangerous drugs. (1) A person commits the offense of criminal production or manufacture of dangerous drugs if the person knowingly or purposely produces, manufactures, prepares, cultivates, compounds, or processes a dangerous drug, as defined in 50-32-101.
(2) A person convicted of criminal production or manufacture of a narcotic drug, as defined in 50-32-101(18)(d), or an opiate, as defined in 50-32-101(19), shall be imprisoned in the state prison for a term of not less than 5 years or more than life and may be fined not more than $50,000, except as provided in 46-18-222.
(3) A person convicted of criminal production or manufacture of a dangerous drug included in Schedule I of 50-32-222 or Schedule II of 50-32-224, except marijuana or tetrahydrocannabinol, who has a prior conviction that has become final for criminal production or manufacture of a Schedule I or Schedule II drug shall be imprisoned in the state prison for a term of not less than 20 years or more than life and may be fined not more than $50,000, except as provided in 46-18-222. Upon a third or subsequent conviction that has become final for criminal production or manufacture of a Schedule I or Schedule II drug, the person shall be imprisoned in the state prison for a term of not less than 40 years or more than life and may be fined not more than $50,000, except as provided in 46-18-222.
(4) A person convicted of criminal production or manufacture of marijuana, tetrahydrocannabinol, or a dangerous drug not referred to in subsections (2) and (3) shall be imprisoned in the state prison for a term not to exceed 10 years and may be fined not more than $50,000, except that if the dangerous drug is marijuana and the total weight is more than a pound or the number of plants is more than 30, the person shall be imprisoned in the state prison for not less than 2 years or more than life and may be fined not more than $50,000. "Weight" means the weight of the dry plant and includes the leaves and stem structure but does not include the root structure. A person convicted under this subsection who has a prior conviction that has become final for criminal production or manufacture of a drug under this subsection shall be imprisoned in the state prison for a term not to exceed twice that authorized for a first offense under this subsection and may be fined not more than $100,000.
(5) Practitioners, as defined in 50-32-101, and agents under their supervision acting in the course of a professional practice are exempt from this section.

45-9-111. Imitation dangerous drugs -- definitions. As used in 45-9-111 through 45-9-116 and 45-9-202, the following definitions apply: (1) "Dangerous drug" has the meaning given to that term in 50-32-101.
(2) "Imitation dangerous drug" means a substance that is not a dangerous drug but that is expressly or impliedly represented to be a dangerous drug or to simulate the effect of a dangerous drug and the appearance of which, including the color, shape, size, and markings, would lead a reasonable person to believe that the substance is a dangerous drug.
(3) "Person" includes any individual, business association, partnership, or corporation.

45-9-112. Criminal distribution of imitation dangerous drug -- penalty. (1) A person commits the offense of criminal distribution of an imitation dangerous drug if the person knowingly or purposely sells, barters, exchanges, gives away, or offers to sell, barter, exchange, or give away any imitation dangerous drug.
(2) A person convicted of criminal distribution of an imitation dangerous drug to a person 18 years of age or older shall be imprisoned in the state prison for a term of not more than 5 years and may be fined not more than $50,000.
(3) A person convicted of criminal distribution of an imitation dangerous drug to a person under the age of 18 shall be imprisoned in the state prison for a term of not more than 10 years and may be fined not more than $50,000.

45-9-113. Criminal possession of imitation dangerous drug with the purpose to distribute -- penalty. (1) A person commits the offense of criminal possession of an imitation dangerous drug with the purpose to distribute if the person possesses with the purpose to distribute any imitation dangerous drug.
(2) A person convicted of criminal possession of an imitation dangerous drug with the purpose to distribute shall be

imprisoned in the state prison for a term of not more than 5 years and may be fined not more than $50,000.
(3) A person under 18 years of age convicted of a first violation under this section is presumed to be entitled to a deferred imposition of sentence.

45-9-114. Criminal advertisement of imitation dangerous drug -- penalty. (1) A person commits the offense of criminal advertisement of an imitation dangerous drug if he knowingly or purposely places in any newspaper, magazine, handbill, or other publication or posts or distributes any advertisement or solicitation to promote the manufacture, sale, exchange, or distribution of an imitation dangerous drug.
(2) A person convicted of criminal advertisement of an imitation dangerous drug under this section is punishable by a fine not to exceed $100,000 or by imprisonment in the state prison for a term of not more than 10 years or by both such fine and imprisonment.

45-9-115. Criminal manufacture of imitation dangerous drug -- penalty. (1) A person commits the offense of criminal manufacture of an imitation dangerous drug if he knowingly or purposely manufactures, prepares, or cultivates any imitation dangerous drug.
(2) A person convicted of criminal manufacture of an imitation dangerous drug under this section is punishable by a fine not to exceed $100,000 or by imprisonment in the state prison for a term of not more than 10 years or by both such fine and imprisonment.

45-9-116. Imitation dangerous drugs -- exemptions -- rules. (1)Sections 45-9-111 through 45-9-115 do not apply to: (a) a person authorized by rules adopted by the board of pharmacy to possess with purpose to sell or sell imitation dangerous drugs;
(b) law enforcement personnel selling or possessing with purpose to sell imitation dangerous drugs while acting within the scope of their employment; and
(c) a person registered under the provisions of Title 50, chapter 32, part 3, who sells, or possesses with purpose to sell an imitation dangerous drug for use as a placebo, by that person or any other person so registered, in the course of professional practice or research.
(2) The board of pharmacy shall adopt, amend, or repeal rules in accordance with the Montana Administrative Procedure Act to authorize the possession with purpose to sell or sale of imitation dangerous drugs whenever it determines that there is a legitimate need and that the drugs will be used for a lawful purpose.

45-9-131. Definitions. As used in 45-9-132 and this section, the following definitions apply:
(1) "Booby trap" means any concealed or camouflaged device designed to cause bodily injury when triggered by any action of a person making contact with the device. "Booby trap" includes:
(a) guns, ammunition, or explosive devices that are attached to trip wires or other triggering mechanisms;
(b) sharpened stakes, nails, spikes, electrical devices, lines, or wires with hooks attached; and
(c) devices for the production of toxic fumes or gases.
(2) "Equipment" or "laboratory equipment" means all products, components, or materials of any kind when used, intended for use, or designed for use in the manufacture, preparation, production, compounding, conversion, or processing of a dangerous drug as defined in 50-32-101. Equipment or laboratory equipment includes but is not limited to:
(a) a reaction vessel;
(b) a separatory funnel or its equivalent;
(c) a glass condensor;
(d) an analytical balance or scale; or
(e) a heating mantle or other heat source.
(3) "Precursor to dangerous drugs" means any material, compound, mixture, or preparation that contains any combination of the items listed in 45-9-107(1), except as exempted by 45-9-108.

45-9-132. Operation of unlawful clandestine laboratory -- penalties. (1) A person commits the offense of operation of an unlawful clandestine laboratory if the person purposely or knowingly engages in:
(a) the procurement, possession, or use of chemicals, precursors to dangerous drugs, supplies, equipment, or a

laboratory location for the criminal production or manufacture of dangerous drugs as prohibited by 45-9-110;
(b) the transportation of or arranging for the transportation of chemicals, precursors to dangerous drugs, supplies, or equipment for the criminal production or manufacture of dangerous drugs as prohibited by 45-9-110; or
(c) the setting up of equipment or supplies in preparation for the criminal production or manufacture of dangerous drugs as prohibited by 45-9-110.
(2) Except as provided in subsections (3) and (4), a person convicted of operation of an unlawful clandestine laboratory shall be fined an amount not to exceed $25,000, be imprisoned in a state prison for a term not to exceed 40 years, or both.
(3) A person convicted of operation of an unlawful clandestine laboratory shall be fined an amount not to exceed $50,000, be imprisoned in a state prison for a term not to exceed 50 years, or both, if 46-1-401 is complied with and the operation of an unlawful clandestine laboratory or any phase of the operation:
(a) created a substantial risk of death of or serious bodily injury to another;
(b) took place within 500 feet of a residence, business, church, or school; or
(c) took place in the presence of a person less than 18 years of age.
(4) A person convicted of operation of an unlawful clandestine laboratory shall be fined an amount not to exceed $100,000, be imprisoned in a state prison for a term not to exceed 50 years, or both, if 46-1-401 is complied with and the operation of an unlawful clandestine laboratory or any phase of the operation involved the use of a firearm or booby trap.

45-9-208. Mandatory dangerous drug information course. A person who is convicted of an offense under this chapter and given a sentence that makes the offense a misdemeanor, as defined in 45-2-101, shall, in addition to any other sentence imposed, be sentenced to complete a dangerous drug information course offered by a chemical dependency facility approved by the department of public health and human services under 53-24-208. The sentencing judge may include in the sentencing order a condition that the person shall undergo chemical dependency treatment if a licensed addiction counselor working with the person recommends treatment.

50-32-401. Report required for precursor to controlled substance. (1) A manufacturer, wholesaler, retailer, or other person who sells, transfers, or otherwise furnishes any of the following substances to a person in this state shall submit a report to the department of justice detailing all transactions:
(a) phenyl-2-propanone;
(b) methylamine;
(c) d-lysergic acid;
(d) ergotamine tartrate;
(e) diethyl malonate;
(f) malonic acid;
(g) ethyl malonate;
(h) barbituric acid; and
(i) piperidine.
(2) The department of justice may adopt, amend, or repeal rules in accordance with the Montana Administrative Procedure Act that add or delete substances on the list of regulated substances in subsection (1) if the substance is a precursor to a dangerous drug as defined in 50-32-101.
(3) This section does not apply to any of the following:
(a) a pharmacist or other authorized person who sells or furnishes the substance upon the prescription of a physician, dentist, podiatrist, or veterinarian;
(b) a physician, dentist, podiatrist, or veterinarian who administers or furnishes the substance to patients;
(c) a manufacturer or wholesaler licensed by the board of pharmacy who sells, transfers, or otherwise furnishes the substance to a licensed pharmacist, physician, dentist, podiatrist, or veterinarian;
(d) transfers of the substances listed in subsection (1) within any college or university to an employee or student of the college or university for the purpose of teaching or research authorized by the college or university.

24.174.1401 REQUIREMENTS FOR REGISTRATION (1)The board shall register a person to manufacture dangerous drugs (as defined in 50-32-101, MCA) included in Schedules I through V upon the following conditions:

(a) applicant is registered for such purposes pursuant to the Federal Controlled Substances Act of 1970;
(b) the applicant has made proper application and has paid the applicable fee; and
(c) the category of manufacturer as above-stated shall include only those applicants who are engaged in the manufacturing of dangerous drugs within the state of Montana.
(2) The board shall register a person or entity to distribute dangerous drugs included in Schedules I through V under the following conditions:
(a) applicant is registered for such purpose pursuant to the Federal Controlled Substances Act of 1970;
(b) the applicant has made proper application and paid the applicable fee;
(c) the category of distributor as above-stated shall include any person or entity who distributes dangerous drugs or samples thereof within the state of Montana and may include a manufacturer not otherwise required to be registered if such manufacturer also distributes dangerous drugs or samples thereof within the state of Montana; and
(d) representatives of drug manufacturers who distribute controlled substance samples to licensed practitioners shall be exempt from the requirement of registration.
(3) The board shall register a person to analyze or conduct research with narcotic dangerous drugs in Schedules II through V upon making proper application and paying the applicable fee.
(4) The board shall register a person to analyze or conduct research with dangerous drugs in Schedule I, if:
(a) the applicant is a practitioner licensed under the laws of this state;
(b) the applicant has furnished the board evidence of registration for such purpose pursuant to the Federal Controlled Substances Act of 1970;
(c) the applicant has furnished the board a complete resume of all research proposed relative to any dangerous drugs. Such resume must be a duplicate of an application submitted to the DEA; and
(d) the applicant has made proper application and paid the applicable fee.

24.174.1402 APPLICATION FOR REGISTRATION OR RENEWAL (1) All applications for registration shall be made on forms provided by the board and shall be filed with the board.
(2) Forms for renewal will be mailed to each registered person or entity 60 days before the expiration date of the registration at the last known address. The applicant is required to notify the board of current changes of address within 10 days.
(3) The registrant shall prominently display the certificate of registration to be visible to the public.

24.174.1403 APPLICATION FORMS (1) If any person is required to be registered and is not so registered and is applying for registration to manufacture or distribute dangerous drugs in Schedules I through V, the person shall apply on a form prescribed by the board.
(2) If any person is required to be registered and is not so registered and is applying for registration to dispense dangerous drugs in Schedules II through V, the person shall apply on a form prescribed by the board.
(3) If any person is required to be registered and is not so registered and is applying for registration to analyze or conduct research with dangerous drugs in Schedules I through V, the person shall apply on a form prescribed by the board.
(4) Any licensee applying for renewal of registration to manufacture or distribute dangerous drugs in Schedules I through V, the licensee shall apply on a form prescribed by the board.
(5) Any licensee applying for renewal to dispense dangerous drugs in Schedules II through V, the licensee shall apply on a form prescribed by the board.

24.174.1404 REQUIRED RECORDS (1) As used in this sub- chapter, the term "records" means:
(a) those records and inventories maintained by persons registered to manufacture, distribute, analyze or dispense dangerous drugs or samples thereof in conformance with record keeping and inventory requirements of federal statute and regulation, (21 CFR 304), and as they may be amended from time to time.
(2) Manufacturers and distributors shall be required to keep such records as are required by federal statutes and regulations, (21 CFR 304), and as they may be amended from time to time.
(3) Separate records required:
(a) registrants' inventories and records of dangerous drugs listed in Schedules I and II shall be maintained separately from all records of the registrant; and

(b) Registrants' inventories and records of dangerous drugs listed in Schedules III through V shall be maintained according to federal statutes and regulations as they may be amended from time to time.

24.174.1411 SECURITY REQUIREMENT (1) All applicants and registrants shall establish and maintain effective written controls and procedures to guard against theft and diversion of dangerous drugs into other than legitimate medical, scientific or industrial channels.
(2) The registrant shall not employ as an agent or employee any person who has access to dangerous drugs, who has had a federal or state application for registration denied or his registration revoked at any time, or has been convicted of a felony offense under any state or federal law relating to dangerous drugs or convicted of any other felony.
(3) The registrant shall notify the Board of Pharmacy in writing by forwarding a copy of the applicable DEA form reporting the theft or loss of any dangerous drugs upon discovery of such theft or loss. The notification shall contain a list of all dangerous drugs stolen or lost.
(4) The registrant shall notify law enforcement officials of any theft or loss of any dangerous drug promptly upon discovery of such theft or loss.

24.174.1412 ADDITIONS, DELETIONS AND RESCHEDULING OF DANGEROUS DRUGS (1) The board of pharmacy adopts the most current schedule of dangerous drugs as defined in 21 CFR 1308, et. seq. April 1, 2009. Copies are available from the Board of Pharmacy, 301 South Park Avenue, P.O. Box 200513, Helena, Montana 59620-0513.

PSEUDOEPHEDRINE RESTRICTIONS

50-32-501. Restricted possession, purchase, or other transfer of ephedrine or pseudoephedrine -- exceptions -- penalties. (1) Except as provided in subsection (2), a person may not purchase, receive, or otherwise acquire more than 9 grams of any product, mixture, or preparation containing any detectable quantity of ephedrine or pseudoephedrine, any of their salts or optical isomers, or salts of optical isomers within any 30-day period.
(2) This section does not apply to any quantity of a product, mixture, or preparation dispensed pursuant to a valid prescription or as provided in 50-32-502.
(3) Possession of more than 9 grams of a drug product containing any detectable quantity of ephedrine, pseudoephedrine, their salts or optical isomers, or salts of optical isomers constitutes a rebuttable presumption of the intent to use the product as a precursor to methamphetamine or another controlled substance.
(4) The rebuttable presumption in subsection (3) does not apply to:
(a) a retail distributor of drug products;
(b) a wholesale drug distributor, or its agents, licensed by the board of pharmacy;
(c) a manufacturer of drug products or its agents;
(d) a pharmacist licensed by the board of pharmacy; or
(e) a licensed health care professional possessing the drug products in the course of carrying out the profession.
(5) A person who knowingly or negligently violates any provision of this section is guilty of a misdemeanor and shall be punished by a fine of not less than $100 or more than $500 and by imprisonment in the county jail for not more than 1 year.

50-32-502. Restricted sale and access to ephedrine or pseudoephedrine products -- exceptions -- penalties. (1) The retail sale of a product that contains any detectable quantity of ephedrine or pseudoephedrine, their salts or optical isomers, or salts of optical isomers may be made only in a pharmacy licensed pursuant to Title 37, chapter 7, or a retail establishment that is certified by the department of justice pursuant to subsection (2).
(2) (a) If there is not a licensed community pharmacy within a county, then a retail establishment may apply to the department of justice for certification as an establishment that is allowed to sell products that contain any detectable quantity of ephedrine or pseudoephedrine, their salts or optical isomers, or salts of optical isomers.
(b) The department of justice shall adopt rules to establish criteria for the certification of retail establishments with the intent to limit the available supply of ephedrine and pseudoephedrine to prevent the manufacture of

methamphetamine.
(c) The department of justice may certify a retail establishment based on the criteria adopted by rule.
(3) Except as provided in subsection (5), a licensed pharmacy or certified retail establishment provided for in subsection (1) that dispenses, sells, or distributes products containing ephedrine or pseudoephedrine shall:
(a) display the products containing ephedrine or pseudoephedrine behind the store counter in an area that is not accessible to customers or in a locked case so that a customer is required to ask an employee of the licensed pharmacy or certified retail establishment for assistance in purchasing the product;
(b) limit sales to packages containing no more than a total of 9 grams;
(c) require the person purchasing, receiving, or otherwise acquiring any product, mixture, or preparation containing ephedrine or pseudoephedrine to produce a driver's license or other form of photo identification and sign a record of sale or acquisition that includes the date of the transaction, the name of the person purchasing or acquiring the ephedrine or pseudoephedrine, and the number of grams of the product, mixture, or preparation purchased or acquired;
(d) take action as necessary to ensure that a person does not purchase or acquire more than 9 grams of ephedrine or pseudoephedrine from the licensed pharmacy or certified retail establishment provided for in subsection (1) in any 30-day period.
(4) A licensed pharmacy or certified retail establishment provided for in subsection (1) that dispenses, sells, or distributes products containing ephedrine or pseudoephedrine shall maintain all records made under subsection (3) in a secure, centralized location. Each record must be maintained by the licensed pharmacy or certified retail establishment provided for in subsection (1) for 2 years. The licensed pharmacy or certified retail establishment provided for in subsection (1) shall provide access to sales records by law enforcement officials.
(5) This section does not apply to:
(a) any quantity of a product, mixture, or preparation dispensed pursuant to a valid prescription;
(b) products containing ephedrine or pseudoephedrine that are in liquid, liquid capsule, or gel capsule form if ephedrine or pseudoephedrine is not the only active ingredient;
(c) a product that the board, upon application by a manufacturer, exempts from this section by rule because the product has been formulated in a manner as to effectively prevent the conversion of the active ingredient into methamphetamine or its salts or precursors.
(6) A person who knowingly or negligently violates any provision of this section is guilty of a misdemeanor and shall be punished by a fine of not less than $100 or more than $500 and by imprisonment in the county jail for not more than 1 year.

MEDICAL ASSISTANCE PROGRAM

24.174.1601 MEDICAL ASSISTANCE PROGRAM PURPOSE

(1) The Montana Board of Pharmacy has established a medical assistance program which provides assistance, rehabilitation, and aftercare monitoring to pharmacists, pharmacist interns, certified pharmacy technicians, and pharmacy technicians-in-training under the jurisdiction of the board, who are suspected and/or found to be physically or mentally impaired by habitual intemperance or the excessive use of addictive drugs, alcohol, or any other drug or substance, or by mental or chronic physical illness.
(2) The board encourages and shall permit the rehabilitation of licensees if, in the board's opinion, public health, safety, and welfare can be assured. Early intervention and referral are paramount to promoting public health, safety, and welfare.

24.174.1602 REPORTING OF SUSPECTED IMPAIRMENT

(1) Individuals, entities, or associations may report information to the board of suspected impairment of a licensee or license applicant, as provided in 37-7-201, MCA.
(2) Individuals, entities, or associations may report information of suspected impairment of a licensee or license applicant to the appropriate personnel of the medical assistance program established by the board, in lieu of reporting to the board, as provided in 37-7-201, MCA.
(3) Reports received by the board of suspected impaired licensees may be referred to the medical assistance program at the board's discretion through the nondisciplinary track, without formal disciplinary action against the licensee.

24.174.1603 PROTOCOL FOR SELF-REPORTING TO A BOARD-ESTABLISHED MEDICAL ASSISTANCE PROGRAM (1) If a licensee chooses to self-report to the board-established medical assistance program, and the medical assistance program has determined that the licensee needs assistance or supervision, the licensee shall be required to:
(a) enter into a contractual agreement with the medical assistance program for the specified length of time determined by the medical assistance program; and
(b) abide by all the requirements set forth by the medical assistance program.
(2) Self-reporting by a licensee may still result in disciplinary action by the board if:
(a) the medical assistance program determines that the self-reporting licensee poses a danger to themselves or to the public;
(b) the licensee is noncompliant with a contractual agreement with the medical assistance program;
(c) the licensee has not completed evaluation, treatment, or aftercare monitoring as recommended by the medical assistance program; or
(d) the screening panel otherwise determines that disciplinary action is warranted.
(3) The medical assistance program shall notify the board, disclose the identity of the licensee involved, and provide all facts and documentation to the board whenever:
(a) the licensee:
(i) has committed an act described in ARM 24.174.2301;
(ii) is noncompliant with a recommendation of the medical assistance program for evaluation, treatment, or aftercare monitoring contract; or
(iii) is the subject of credible allegations that the licensee has put a patient or the public at risk or harm; or
(b) the screening panel otherwise determines disciplinary action is warranted.

24.174.1604 RESPONSIBILITIES OF MEDICAL ASSISTANCE PROGRAM (1) The medical assistance program established by the board as set forth in 37-7-201, MCA, shall fulfill the terms of its contract with the board, which will include, but not be limited to, the following:
(a) providing two tracks for assistance of licensees:
(i) a disciplinary track; and
(ii) a nondisciplinary track;
(b) providing recommendations to licensees for appropriate evaluation and treatment facilities;
(c) recommending to the board terms and conditions of treatment, rehabilitation, and monitoring of licensees known to the board; and
(d) monitoring all aftercare of participants under contract to ensure public safety and compliance with agreed treatment recommendations propounded by one or more of the following:
(i) the board, through stipulations and/or final orders;
(ii) treatment centers; or
(iii) the medical assistance program established by the board.
(2) The medical assistance program shall consult with the board regarding medical assistance program processes and procedures to ensure program responsibilities are met, consistent with board orders, requests, and contract terms.
(3) The medical assistance program shall provide information to and consult with the board upon the board's request.

24.174.1605 PROTOCOL FOR DISCIPLINARY TRACK (1) All licensees who participate in the medical assistance program under the disciplinary track shall be reported to the board by name.
(2) A licensee is placed in the disciplinary track by one or more of the following:
(a) as a condition of licensure imposed by a board final order;
(b) as a result of a sanction imposed by a board final order;
(c) as a result of noncompliance with the licensee's contractual agreement with the program; or
(d) pursuant to an agreement between the licensee and the screening panel or the full board upon licensure.

24.174.1606 PROTOCOL FOR NONDISCIPLINARY TRACK

(1) A licensee who participates in the medical assistance program under the nondisciplinary track shall be reported to the board by participant number.
(2) The identity of the participant who is noncompliant or refuses a reasonable request by the medical assistance program shall be reported to the board.
(3) If the board determines that a participant does not abide by all terms and conditions of the medical assistance program, the participant will be referred to the screening panel of the board for appropriate action under the disciplinary track.

24.174.1607 REPORTING TO THE BOARD (1) The screening panel of the board must receive a written compliance status report from the medical assistance program at intervals established by the contract between the program and the board regarding each program participant:
(a) under a monitoring agreement;
(b) referred to the program; or
(c) in the process of evaluation or treatment.
(2) The full board shall receive a written compliance status report from the medical assistance program at intervals established by contract between the program and the board regarding each participant:
(a) under a monitoring agreement;
(b) referred to the program; or
(c) in the process of evaluation or treatment.
(3) The identity of a participant in the nondisciplinary track must be reported to the full board by participant number except as required by 24.174.1603 and 24.174.1606.
(4) The identity of a participant in the disciplinary track must be reported to the full board by name.

24.174.1608 PARTICIPANT DISCHARGE REQUIREMENTS (1) The medical assistance program shall facilitate participant discharge from the program.
(2) The discharge criteria must be determined by the board in conjunction with the recommendations of the medical assistance program.
(3) The following are required upon discharge of a participant from the endorsed medical assistance program:
(a) report of the discharge of the participant to the board:
(i) verification of satisfactory completion of monitoring, program requirements, and appropriate assurance of public safety;
(ii) completion of board final order terms and conditions with medical assistance program recommendation for discharge and release; and
(iii) request by a participant to transfer assistance into an appropriate endorsed medical assistance program in another jurisdiction; such transfer to be confirmed by the program.

24.174.1609 RELAPSE REPORTING (1) The medical assistance program shall define what constitutes "relapse" for each particular participant and determine if and when relapse has occurred.
(a) A participant who has a single episode of relapse and/or early detection of relapse with nominal substance abuse may be reported to the board by the medical assistance program.
(b) A participant who has a second or severe relapse must be reported by the medical assistance program to the board screening panel for review.
(c) The board shall take disciplinary action against the license of a person in a medical assistance program if, in the period under contract, the licensee has on three separate occasions returned to the use of a prohibited or proscribed substance.
(2) Any of the following may be required by the board upon the recommendation of the medical assistance program when a participant suffers a relapse:
(a) the participant may be required to withdraw from practice;
(b) the participant may undergo further recommended evaluation and/or treatment as determined by the medical assistance program;
(c) the participant's monitoring agreement required by the medical assistance program must be reassessed and may be modified;

(d) the participant may be required to comply with other recommendations of the medical assistance program; or
(e) the participant may be subject to discipline as imposed by a board final order.

PRESCRIPTION DRUG REGISTRY

37-7-1502. Prescription drug registry -- purpose. (1) The board shall establish and maintain a prescription drug registry for the purpose of improving patient safety by:
(a) making a list of controlled substances prescribed to a patient available to the patient or to the patient's health care provider; and
(b) allowing authorized staff of the board who have signed appropriate confidentiality agreements to review the registry for possible misuse and diversion of controlled substances.
(2) The board shall electronically collect information on prescription drug orders involving controlled substances pursuant to 37-7-1503 and shall disseminate information as provided in 37-7-1504 through 37-7-1506.

37-7-1503. Prescription drug registry -- reporting requirements. (1) Except as provided in subsection (2), each entity licensed by the board as a certified pharmacy or as an out-of-state mail order pharmacy that dispenses drugs to patients in Montana shall provide prescription drug order information for controlled substances to the registry by:
(a) electronically transmitting the information in a format established by the board unless the board has granted a waiver allowing the information to be submitted in a nonelectronic manner; and
(b) submitting the information in accordance with time limits set by the board unless the board grants an extension because:
(i) the pharmacy has suffered a mechanical or electronic failure or cannot meet the deadline for other reasons beyond its control; or
(ii) the board is unable to receive electronic submissions.
(2) This section does not apply to:
(a) a prescriber who dispenses or administers drugs to the prescriber's patients; or
(b) a prescription drug order for a controlled substance dispensed to a person who is hospitalized.

37-7-1504. Prescription drug registry review. The board may review the information in the registry for possible misuse and diversion of controlled substances prescribed and dispensed to a patient. The board may provide information about possible misuse or diversion to prescribers and dispensers as allowed by rule.

37-7-1505. Confidentiality. Patient information that is collected, recorded, transmitted, and stored for the registry is protected and may not be disclosed except as allowed in 37-7-1506. The board shall adopt rules to protect the confidentiality of the registry and to ensure that only authorized individuals have access to the registry.

37-7-1506. Providing prescription drug registry information. (1) Registry information is health care information as defined in 50-16-504 and is confidential. Except as provided in 37-7-1504, the board is authorized to provide data from the registry, upon request, only to the following:
(a) a person authorized to prescribe or dispense prescription drugs if the person certifies that the information is needed to provide medical or pharmaceutical treatment to a patient who is the subject of the request and who is under the person's care or has been referred to the person for care;
(b) a prescriber who requests information relating to the prescriber's own prescribing information if the prescriber certifies that the requested information is for a purpose in accordance with board rule;
(c) an individual requesting the individual's registry information if the individual provides evidence satisfactory to the board that the individual requesting the information is the person about whom the data entry was made;
(d) a designated representative of a government agency responsible for licensing, regulating, or disciplining licensed

health care professionals who are authorized to prescribe, administer, or dispense drugs, in order to conduct investigations related to a health care professional who is the subject of an active investigation for drug misuse or diversion;
(e) a county coroner or a peace officer employed by a federal, state, tribal, or local law enforcement agency if the county coroner or peace officer has obtained an investigative subpoena;
(f) an authorized individual under the direction of the department of public health and human services for the purpose of reviewing and enforcing that department's responsibilities under the public health, medicare, or medicaid laws; or
(g) a prescription drug registry in another state if the data is subject to limitations and restrictions similar to those provided in 37-7-1502 through 37-7-1513.
(2) The board shall maintain a record of each individual or entity that requests information from the registry and whether the request was granted pursuant to this section.
(3) The board may release information in summary, statistical, or aggregate form for educational, research, or public information purposes. The information may not identify a person or entity.
(4) Information collected by or obtained from the registry may not be used:
(a) for commercial purposes; or
(b) as evidence in any civil or administrative action, except in an investigation and disciplinary proceeding by the department or the agency responsible for licensing, regulating, or disciplining licensed health care professionals who are authorized to prescribe, administer, or dispense prescription drugs.
(5) Information obtained from the registry in accordance with the requirements of this section may be used in the course of a criminal investigation and subsequent criminal proceedings.
(6) The board shall adopt rules to ensure that only authorized individuals have access to the registry and only to appropriate information from the registry. The rules must be consistent with:
(a) the privacy provisions of the Health Insurance Portability and Accountability Act of 1996, 42 U.S.C. 1320d, et seq.;
(b) administrative rules adopted in connection with that act;
(c) Article II, section 10, of the Montana constitution; and
(d) the privacy provisions of Title 50, chapter 16.
(7) The procedures established by the board under this section may not impede patient access to prescription drugs for legitimate medical purposes.

37-7-1507. Prescription drug registry -- immunity. (1) A person or entity that complies with the reporting requirements of 37-7-1503 is not subject to civil liability or other legal or equitable relief for reporting the information to the board.
(2) Unless a court of competent jurisdiction finds that a person or entity committed an unlawful act pursuant to 37-7-1513, a person or entity in proper possession of information pursuant to this part is not subject to civil liability or other legal or equitable relief for any of the following acts or omissions:
(a) furnishing information pursuant to 37-7-1502 through 37-7-1506;
(b) receiving, using or relying on, or not using or relying on information received pursuant to 37-7-1502 through 37-7-1506; or
(c) relying on information that was entered into the registry in error, was factually incorrect, or was released by the board to the wrong person or entity.
(3) The immunity provisions of this section do not apply to the board, a state agency, or any political subdivision of the state.

37-7-1508. Registry information retention -- destruction. The board shall retain the information collected for the registry for up to 3 years, as established by rule. After 3 years, the board shall destroy the information unless it is being used as part of an active investigation.

37-7-1509. Administration of prescription drug registry. The board may hire or contract for other professional, technical, or clerical staff as necessary to operate the registry. A contractor shall comply with the provisions regarding confidentiality of prescription information in 37-7-1505 and 37-7-1506 and is subject to the penalties specified in 37-7-1513 for unlawful acts.

37-7-1510. Prescription drug registry -- advisory group. (1) The board shall establish an advisory group to provide information and advice about the development and operation of the registry, including but not limited to information on:
(a) the criteria for reporting information from the registry to prescribers and pharmacists;
(b) the design and implementation of educational courses about the registry;
(c) standards for evaluating the effectiveness of the registry; and
(d) administrative rules for establishing and maintaining the registry.
(2) The advisory group consists of but is not limited to representatives of:
(a) health care licensing boards that oversee health care providers who have authority to prescribe or dispense drugs;
(b) associations that represent health care professionals who have authority to prescribe or dispense drugs;
(c) associations that advocate for patients;
(d) entities involved in tribal health services or issues; and
(e) the department of justice provided for in 2-15-2001.
(3) The advisory group may identify other individuals for appointment to the group.
(4) The board shall establish rules for the conduct of advisory group business.
(5) The advisory group may not receive or access confidential health care information contained in the registry.

37-7-1511. Prescription drug registry -- funding. (1) Each person licensed under Title 37 who prescribes, dispenses, or distributes controlled substances shall pay to the board a nonrefundable fee that is set by rule and that may not exceed $15.
(2) The board may apply for any available grants and may accept gifts, grants, or donations to assist in establishing and maintaining the registry.
(3) Funds collected pursuant to this part must be deposited into a state special revenue account to the credit of the department. The money must be used to defray the expenses of the board in establishing and maintaining the registry and in discharging its administrative and regulatory duties under this part. *(Subsection (1) terminates July 1, 2015--sec. 20, Ch. 241, L. 2011.)*

37-7-1512. Rulemaking authority. The board shall adopt rules to carry out and enforce this part, including but not limited to rules that:
(1) specify the type of information to be reported on prescription drug orders involving controlled substances;
(2) establish the requirements for transmitting from a pharmacy to the board prescription drug order information involving controlled substances;
(3) define the electronic format for submission of information;
(4) define the circumstances under which a pharmacy may receive a waiver from the requirement to submit information electronically;
(5) specify the procedure through which a pharmacy may request an extension of the time limit for submitting information;
(6) establish how a person or entity authorized to receive information from the registry may submit a request for the information;
(7) specify the ways in which the board may use records involving requests for registry information to document and report on statistics involving the registry;
(8) set the fees to be charged for establishing and maintaining the registry; and
(9) establish confidentiality provisions to ensure that the privacy of patient information is maintained.

37-7-1513. Unlawful acts -- sanctions -- civil penalties. (1) A pharmacist who fails to submit prescription drug order information to the board as required by 37-7-1503 or who willfully submits incorrect prescription drug order information must be referred to the board for consideration of administrative sanctions.
(2) A person or entity authorized to possess registry information pursuant to 37-7-1504 through 37-7-1506 who willfully discloses or uses the registry information in violation of 37-7-1504 through 37-7-1506 or a rule adopted pursuant to this part must be referred to the appropriate licensing board or regulatory agency for consideration of administrative sanctions.
(3) In addition to the administrative sanction provided in subsection (2), a person or entity who willfully discloses or uses information from the registry in violation of 37-7-1504 through 37-7-1506 or a rule adopted pursuant to this part is liable for a civil penalty of up to $10,000 for each violation.
(4) The board may institute and maintain in the name of the state any enforcement proceedings under this section. Upon request of the department, the attorney general shall petition the district court to impose, assess, and recover the civil penalty.
(5) An action under subsection (3) or to enforce this part or a rule adopted under this part may be brought in the district court of any county where a violation occurs or, if mutually agreed on by the parties in the action, in the district court of the first judicial district.
(6) Civil penalties collected pursuant to this part must be deposited into the state special revenue account created pursuant to 37-7-1511 and must be used to defray the expenses of the board in establishing and maintaining the registry and in discharging its administrative and regulatory duties in relation to this part.

37-7-1514. Report to legislature. The board shall provide a report to the appropriate interim committees of the legislature each interim, including but not limited to information on:
(1) the cost of establishing and maintaining the registry;
(2) any grants, gifts, or donations received to assist in establishing and maintaining the registry;
(3) how registry information was used; and
(4) how quickly the board was able to answer requests for information from the registry.

24.174.1701 DEFINITIONS (1) "Authorized user" means a prescriber, pharmacist, Board of Pharmacy staff, Montana Medicare or Medicaid programs, Tribal Health, Indian Health Service, and Veterans Affairs.
(2) "Authorized agent" means a designated person authorized access by an authorized user. An authorized agent for a pharmacist must be a pharmacy intern or certified pharmacy technician.

24.174.1702 INFORMATION REQUIRED FOR SUBMISSION (1) Each entity registered by the board as a certified pharmacy or as an out-of-state mail service pharmacy that dispenses to patients in Montana shall provide the following controlled substances dispensing information to the board:
(a) pharmacy name, address, telephone number, and drug enforcement administration number;
(b) full name, address, telephone number, gender, and date of birth for whom the prescription was written;
(c) full name, address, telephone number, and drug enforcement administration registration number of the prescriber;
(d) date the prescription was issued by the prescriber;
(e) date the prescription was filled by the pharmacy;
(f) indication of whether the prescription dispensed is new or a refill;
(g) name, national drug code number, strength, quantity, dosage form, and days' supply of the actual drug dispensed;
(h) prescription number assigned to the prescription order; and
(i) source of payment for the prescription that indicates one of the following:
(i) cash;
(ii) insurance; or
(iii) government subsidy.

24.174.1703 ELECTRONIC FORMAT REQUIRED FOR THE TRANSMISSION OF INFORMATION (1) All prescription information submitted to the board pursuant to [New Rule III], must be transmitted in the format specified by the American Society for Automation in Pharmacy (ASAP), version 4.1, dated 2009, which is adopted

and incorporated by reference. A copy of the ASAP standards may be obtained through the Board of Pharmacy, 301 South Park Avenue, P.O. Box 200513, Helena, Montana, 59620-0513.

24.174.1704 REQUIREMENTS FOR SUBMITTING PRESCRIPTION REGISTRY INFORMATION TO THE BOARD (1) All prescription dispensing information submitted under this subchapter shall be submitted at least weekly.
(2) The information submitted shall be consecutive and complete from the date and time of the submitting pharmacy's last submission, and shall be reported no later than eight days after the date of dispensing.
(3) If a pharmacy has dispensed no reportable controlled substances during a reporting period, the pharmacy shall submit a timely "zero report."
(4) For the purposes of establishing a data history at the initiation of the prescription drug registry, each certified pharmacy and out-of-state mail service pharmacy shall submit a one-time batch submission of controlled substances, dispensed to Montana patients from July 1, 2011 forward to the date the registry is operational.
(5) In the event that a pharmacy cannot submit the required information as described in this rule, the pharmacy must report that fact on the appropriate board-approved form. This form is due to the board on or before the date that the weekly submission is otherwise due. The board office may grant an extension, at their discretion, when a pharmacy notifies the board that they are unable to submit their report.
(6) It is the responsibility of the submitting pharmacy to address any errors or questions about information that the pharmacy has submitted to the prescription drug registry.

24.174.1705 FAILURE TO REPORT PRESCRIPTION INFORMATION
(1) A pharmacy that fails to submit prescription information to the board as required is deemed to have committed unprofessional conduct for which discipline may be imposed under 37-1-312, MCA.

24.174.1706 REGISTRY INFORMATION REVIEW AND UNSOLICITED PATIENT PROFILES (1) The board or their designee(s) may review and compile information contained in the registry to identify evidence of possible misuse or diversion of controlled substances.
(2) In instances of possible misuse or diversion, the executive director will promptly report by telephone, e-mail, or postal mail the patient's profile information to practitioners and pharmacists who have provided care to that patient.
(3) The following factors are suggestive, but not conclusive evidence of misuse or diversion:
(a) four or more prescribers in a 60-day period; or
(b) four or more pharmacies in a 60-day period.

24.174.1708 ACCESS TO PRESCRIPTION DRUG REGISTRY INFORMATION (1) The following persons may have direct online access to prescription drug registry information:
(a) licensed practitioners having authority to prescribe controlled substances, or that practitioner's authorized agent, for the purpose of providing medical and/or pharmaceutical care for their patients, or for patients referred for medical care and/or pharmaceutical care;
(b) licensed pharmacists authorized to dispense controlled substances, or that pharmacist's authorize agent, for the purpose of providing pharmaceutical care for their patients or for patients referred for care;
(c) designated representatives from the Montana Medicare or Medicaid programs, Tribal Health, Indian Health Service, and Veterans Affairs regarding program recipients;
(d) board staff, including executive director, inspectors, and program manager; and
(e) any vendor or contractor establishing or maintaining the prescription drug registry.
(2) To access registry information, each user must first:
(a) successfully complete the board's educational program;
(b) complete the registration form and confidentiality agreement provided by the board;
(c) complete a written agreement assuring that the user's access and use of the prescription drug registry is limited to that authorized by law;
(i) in the case of a licensed practitioner having authority to prescribe controlled substances, or that practitioner's authorized agent, access is restricted to:
(A) the practitioner's own prescribing information; or

(B) prescription records for a patient of the practitioner to whom the practitioner is providing or considering providing medical and/or pharmaceutical care;
(ii) in the case of a licensed pharmacist, pharmacy intern, or certified pharmacy technician, access is restricted to prescription records for a patient for whom the pharmacy is actually dispensing or considering dispensing a prescription;
(iii) in the case of a designated representative of the Montana Medicare or Medicaid programs, Tribal Health, Indian Health Service, and Veteran Affairs, access is restricted to prescription records related to a participant in the program;
(iv) in the case of authorized representatives of the board, access is restricted to:
(A) that necessary to respond to legitimate inquiries; or
(B) that necessary for legitimate inquiries under ARM 24.174.1706;
(v) in the case of an authorized vendor or contractor, access is restricted to technical work necessary to establish or maintain the prescription drug registry databank; or
(vi) in every user's case:
(A) information accessed from the prescription drug registry must be kept confidential;
(B) information accessed from the prescription drug registry must not be disclosed to any unauthorized person; and
(C) user account information, login names, and passwords must not be shared with any person, regardless of whether that person is also an authorized user of the prescription drug registry.
(3) Prior to granting access to the registry, the board shall verify that the applicant is licensed to prescribe or dispense controlled substances or legend drugs, or in the case of an agency applicant, the board shall verify that the applicant is the designated representative of the Montana Medicare or Medicaid programs, Tribal Health, Indian Health Service, or Veterans Affairs.
(4) Upon verification of all requirements, the board shall issue the appropriate information necessary for online access to the prescription drug registry.
(5) Upon receipt of written notification that an authorized user no longer possesses authority to prescribe, dispense, or represent Medicare or Medicaid programs, Tribal Health, Indian Health Services, Veterans Affairs, or the board, the board shall terminate the user's access to the prescription drug information.
(6) Persons authorized in [HB 83 section 7(1)(d)(e)], MCA, to obtain information from the prescription drug registry must apply for that information by:
(a) completing the form provided by the board and returning the completed form, along with proof of identification and authorization required by the board, to the board's office; or
(b) serving upon the board or its designee, an investigative subpoena directing the board to release a profile to the county coroner or a peace officer employed by a federal, state, tribal, or local law enforcement agency.
(7) Individual patients may request their own prescription registry information from the board or their provider. If requesting from the board, the requestor shall personally appear at the program office and produce a positive photo identification at the time of their request. A single copy of the information will be provided at no charge to the individual.
(8) If the prescription drug registry receives evidence of inappropriate or unlawful use or disclosure of prescription registry information by an authorized user, the board shall file a complaint with the user's licensing board.

24.174.1709 REGISTRY INFORMATION RETENTION (1) Patient information contained in the registry shall be destroyed three years after the original date of submission of the information to the registry.
(2) Pursuant to 37-7-1508, MCA, a government entity or law enforcement agency may request that specific information in the registry, related to an open investigation, be retained beyond the three-year destruction requirement by submitting a written request to the board on a form provided by the board.

24.174.1711 ADVISORY GROUP (1) The board shall establish a prescription drug registry advisory group, to provide information and advice about the development and operation of the prescription drug registry.
(2) The advisory group shall consist of, but is not limited to, representatives of:
(a) Montana boards of pharmacy, medical examiners, nursing, and dentistry;
(b) Montana pharmacy associations, medical associations, nursing associations, dental associations, and associations that advocate for patients;

(c) tribal health, Medicaid and Medicare, and public health agencies;
(d) the Department of Justice; and
(e) the Montana Legislature.
(3) The members of the advisory group shall serve at the pleasure of their respective appointing authorities.
(4) The members of the advisory group shall elect a chair and a vice chair whose duties shall be established by the advisory group.
(5) The advisory group shall establish policies and procedures necessary to carry out duties.
(6) The board shall establish a time and a place for regular meetings of the advisory group, which shall meet at least once a year.

24.174.1712 PRESCRIPTION DRUG REGISTRY FEE (1) Every person licensed under Title 37, MCA, who is authorized to prescribe or dispense controlled substances, shall pay a fee to the board for the purpose of establishing and maintaining the prescription drug registry.
(2) The fee shall be paid annually to the board.
(3) Upon payment of the fee, the board shall issue authorized prescribers and dispensers a controlled substances registration.
(4) The annual prescription drug registry fee is $15.

24.174.1713 RELEASE OF PRESCRIPTION DRUG REGISTRY INFORMATION TO OTHER ENTITIES (1) The board shall provide prescription registry information to public or private entities for public research, policy, or educational purposes, but only after removing information that identifies or could reasonably be used to identify individuals or entities whose information is contained in the registry.
(2) The board may charge a fee to a person who requests information under this rule.

24.174.1715 INTERSTATE EXCHANGE OF REGISTRY INFORMATION
(1) The board may enter into agreements with other states to exchange prescription drug registry information if the other states restrict disclosure and maintain confidentiality to the same extent as provided in 37-7-1506, MCA, and this subchapter.

LICENSE RENEWAL

24.174.2101 PHARMACIES - RENEWAL (1)All pharmacies must renew their license annually with the board, in accordance with ARM 8.2.208. No pharmacy is allowed to operate without a currently renewed license.

24.174.2102 PHARMACY TECHNICIAN - RENEWAL (1) Pharmacy technicians will be required to renew each year on the date set forth in ARM 24.101.413.
(2) To assure the continuing competence of a pharmacy technician, in order to renew a license, the pharmacy technician must be in compliance with all certification requirements at the time of renewal.

24.174.2103 RENEWALS (1) Renewal notices will be sent as specified in ARM 24.101.414 prior to the renewal date set by ARM 24.101.413.
(a) The notice will state the annual pharmacist's license renewal fee.
(b) The notice will state the continuing education requirements and any other information considered pertinent for the licensee's understanding of the renewal requirements.
(c) Notice will be considered as properly mailed when addressed to the current address on file with the board.
(2) The annual renewal notice shall be returned to the board with the appropriate fee and a representation of having satisfactorily completed continuing education requirements signed by the licensee. Incomplete renewal applications will not be processed and will be returned to the applicant.
(3) The board shall randomly select submitted renewal notice forms for audit and verification of the continuing education requirements. It will be the responsibility of each pharmacist to maintain his or her own records of attendance or completion and make such documents available upon request.

(a) The board shall randomly select submitted renewal notice forms for audit and verification of current pharmacy technician certification from a board-approved certifying entity. It shall be the responsibility of each pharmacy technician to maintain his or her current pharmacy technician cortication and make such certification available upon request.
(4) The provisions of ARM 24.101.408 apply.

CONTINUING EDUCATION

37-1-306. Continuing education. A board may require licensees to participate in flexible, cost-efficient, effective, and geographically accessible continuing education.

24.174.2104 Registered Pharmacist Continuing Education - Requirements (1) The nationally accepted measurement of continuing education, the continuing education unit (CEU), will be the measurement employed by the board. Ten hours of approved continuing education credit equal one CEU.
(2) The board will require:
(a) 1.5 CEU for each fiscal year if a pharmacy takes at least 0.5 CEU in an approved group program; or
(b) 2.0 CEU for each fiscal year is a pharmacist does not take at least 0.5 CEU in an approved group program.
(3) The annual CEU requirement will not pertain to a pharmacist applying as a new graduate for his or her first license renewal.
(4) Only an additional 1.5 CEU may be accumulated and applied to the following year.
(5) In order to receive Montana license renewal, any Montana-licensed pharmacist residing in another state shall meet Montana's requirements for continuing education.

24.174.2105 Registered Pharmacist Continuing Education -Subjects (1) Continuing pharmaceutical education will include, but will not be limited to, appropriate professional post graduate education in any of the following subjects:
(a) properties and actions of drugs and dosage forms;
(b) etiology, pathophysiology, clinical course, therapy and prognosis of diseases;
(c) pharmacy practice; and
(d) legal, psychological and socio-economic aspects of health care delivery.

24.174.2106 Registered Pharmacist Continuing Education - Approved Programs (1) Continuing education programs sponsored by providers that are approved by the following organizations will automatically qualify for continuing education credit.
a)The American Council on Pharmaceutical Education (ACPE)
b)Programs that have been approved for continuing medical education (CME) by a state board of medical examiners or its equivalent or
c)The American board of medical specialties.
(2) Pharmacists may receive CEU for programs other than those on the ACPE list of providers by applying for prior approval by the board or its designee on board-approved forms.
(3) Pharmacists participating in programs that have not received prior approval risk disallowance of credit.

24.174.2107 Registered Pharmacist Continuing Education – Noncompliance
A pharmacist who submits a renewal application, but who has not completed the required continuing education requirements as set forth in ARM 24.101.413 and 24.174.2104, will have sixty days, following the end of the renewal period, to complete the requirements. The pharmacist shall:
(a) notify the board of the continuing education deficiency by checking the appropriate box on the renewal application;
(b) pay a fee equal to one hundred percent of the annual fee for licensure. This fee is in addition to the regular fee for licensure; and
(c) submit to the board office documentation of completion of continuing education requirements.
(2) Failure to complete continuing education requirements may be cause for disciplinary action by the board.

(3) An action taken under (2) is not a "disciplinary action" under ARM 24.101.404, for the purposes of publication and notice on the licensee look-up.

REGISTERED PHARMACIST-UNPROFESSIONAL CONDUCT

37-1-308. Unprofessional conduct -- complaint -- investigation -- immunity -- exceptions.
(1) Except as provided in subsections (4) and (5), a person, government, or private entity may submit a written complaint to the department charging a licensee or license applicant with a violation of this part and specifying the grounds for the complaint.
(2) If the department receives a written complaint or otherwise obtains information that a licensee or license applicant may have committed a violation of this part, the department may, with the concurrence of a member of the screening panel established in 37-1-307, investigate to determine whether there is reasonable cause to believe that the licensee or license applicant has committed the violation.
(3) A person or private entity, but not a government entity, filing a complaint under this section in good faith is immune from suit in a civil action related to the filing or contents of the complaint.
(4) A person under legal custody of a county detention center or incarcerated under legal custody of the department of corrections may not file a complaint under subsection (1) against a licensed or certified provider of health care or rehabilitative services for services that were provided to the person while detained or confined in a county detention center or incarcerated under legal custody of the department of corrections unless the complaint is first reviewed by a correctional health care review team provided for in 37-1-331.
(5) A board member may file a complaint with the board on which the member serves or otherwise act in concert with a complainant in developing, authoring, or initiating a complaint to be filed with the board if the board member determines that there are reasonable grounds to believe that a particular statute, rule, or standard has been violated.

37-1-309. Notice -- request for hearing. (1) If a reasonable cause determination is made pursuant to 37-1-307 that a violation of this part has occurred, a notice must be prepared by department legal staff and served on the alleged violator. The notice may be served by certified mail to the current address on file with the board or by other means authorized by the Montana Rules of Civil Procedure. The notice may not allege a violation of a particular statute, rule, or standard unless the board or the board's screening panel, if one has been established, has made a written determination that there are reasonable grounds to believe that the particular statute, rule, or standard has been violated.
(2) A licensee or license applicant shall give the board the licensee's or applicant's current address and any change of address within 30 days of the change.
(3) The notice must state that the licensee or license applicant may request a hearing to contest the charge or charges. A request for a hearing must be in writing and received in the offices of the department within 20 days after the licensee's receipt of the notice. Failure to request a hearing constitutes a default on the charge or charges, and the board may enter a decision on the basis of the facts available to it.

37-1-310. Hearing -- adjudicative procedures. The procedures in Title 2, chapter 4, governing adjudicative proceedings before agencies; the Montana Rules of Civil Procedure; and the Montana Rules of Evidence govern a hearing under this part. A board has all the powers and duties granted by Title 2, chapter 4.

37-1-311. Findings of fact -- order -- report. (1) If the board decides by a preponderance of the evidence, following a hearing or on default, that a violation of this part occurred, the department shall prepare and serve the board's findings of fact and an order as provided in Title 2, chapter 4. If the licensee or license applicant is found not to have violated this part, the department shall prepare and serve the board's findings of fact and an order of dismissal of the charges.
(2) The department may report the issuance of a notice and final order to:
(a) the person or entity who brought to the department's attention information that resulted in the initiation of the proceeding;
(b) appropriate public and private organizations that serve the profession or occupation; and
(c) the public.

37-1-312. Sanctions -- stay -- costs -- stipulations. (1) Upon a decision that a licensee or license applicant has violated this part or is unable to practice with reasonable skill and safety due to a physical or mental condition or upon stipulation of the parties as provided in subsection (3), the board may issue an order providing for one or any combination of the following sanctions:
(a) revocation of the license;
(b) suspension of the license for a fixed or indefinite term;
(c) restriction or limitation of the practice;
(d) satisfactory completion of a specific program of remedial education or treatment;
(e) monitoring of the practice by a supervisor approved by the disciplining authority;
(f) censure or reprimand, either public or private;
(g) compliance with conditions of probation for a designated period of time;
(h) payment of a fine not to exceed $1,000 for each violation. Fines must be deposited in the state general fund.
(i) denial of a license application;
(j) refund of costs and fees billed to and collected from a consumer.
(2) A sanction may be totally or partly stayed by the board. To determine which sanctions are appropriate, the board shall first consider the sanctions that are necessary to protect or compensate the public. Only after the determination has been made may the board consider and include in the order any requirements designed to rehabilitate the licensee or license applicant.
(3) The licensee or license applicant may enter into a stipulated agreement resolving potential or pending charges that includes one or more of the sanctions in this section. The stipulation is an informal disposition for the purposes of 2-4-603.
(4) A licensee shall surrender a suspended or revoked license to the board within 24 hours after receiving notification of the suspension or revocation by mailing it or delivering it personally to the board.

37-1-313. Appeal. A person who is disciplined or denied a license may appeal the decision to the district court as provided in Title 2, chapter 4.

37-1-314. Reinstatement. A licensee whose license has been suspended or revoked under this part may petition the board for reinstatement after an interval set by the board in the order. The board may hold a hearing on the petition and may deny the petition or order reinstatement and impose terms and conditions as provided in 37-1-312. The board may require the successful completion of an examination as a condition of reinstatement and may treat a licensee whose license has been revoked or suspended as a new applicant for purposes of establishing the requisite qualifications of licensure.

37-1-315. Enforcement of fine. (1) If payment of a fine is included in an order and timely payment is not made as directed in the order, the board may enforce the order for payment in the district court of the first judicial district.
(2) In a proceeding for enforcement of an order of payment of a fine, the order is conclusive proof of the validity of the order of payment and the terms of payment.

37-1-316. Unprofessional conduct. The following is unprofessional conduct for a licensee or license applicant governed by this chapter:
(1) conviction, including conviction following a plea of nolo contendere, of a crime relating to or committed during the course of the person's practice or involving violence, use or sale of drugs, fraud, deceit, or theft, whether or not an appeal is pending;
(2) permitting, aiding, abetting, or conspiring with a person to violate or circumvent a law relating to licensure or certification;
(3) fraud, misrepresentation, deception, or concealment of a material fact in applying for or assisting in securing a license or license renewal or in taking an examination required for licensure;
(4) signing or issuing, in the licensee's professional capacity, a document or statement that the licensee knows or reasonably ought to know contains a false or misleading statement;
(5) a misleading, deceptive, false, or fraudulent advertisement or other representation in the conduct of the profession

or occupation;
(6) offering, giving, or promising anything of value or benefit to a federal, state, or local government employee or official for the purpose of influencing the employee or official to circumvent a federal, state, or local law, rule, or ordinance governing the licensee's profession or occupation;
(7) denial, suspension, revocation, probation, fine, or other license restriction or discipline against a licensee by a state, province, territory, or Indian tribal government or the federal government if the action is not on appeal, under judicial review, or has been satisfied.
(8) failure to comply with a term, condition, or limitation of a license by final order of a board;
(9) revealing confidential information obtained as the result of a professional relationship without the prior consent of the recipient of services, except as authorized or required by law;
(10) addiction to or dependency on a habit-forming drug or controlled substance as defined in Title 50, chapter 32, as a result of illegal use of the drug or controlled substance;
(11) use of a habit-forming drug or controlled substance as defined in Title 50, chapter 32, to the extent that the use impairs the user physically or mentally;
(12) having a physical or mental disability that renders the licensee or license applicant unable to practice the profession or occupation with reasonable skill and safety;
(13) engaging in conduct in the course of one's practice while suffering from a contagious or infectious disease involving serious risk to public health or without taking adequate precautions, including but not limited to informed consent, protective gear, or cessation of practice;
(14) misappropriating property or funds from a client or workplace or failing to comply with a board rule regarding the accounting and distribution of a client's property or funds;
(15) interference with an investigation or disciplinary proceeding by willful misrepresentation of facts, by the use of threats or harassment against or inducement to a client or witness to prevent them from providing evidence in a disciplinary proceeding or other legal action, or by use of threats or harassment against or inducement to a person to prevent or attempt to prevent a disciplinary proceeding or other legal action from being filed, prosecuted, or completed;
(16) assisting in the unlicensed practice of a profession or occupation or allowing another person or organization to practice or offer to practice by use of the licensee's license;
(17) failing to report the institution of or final action on a malpractice action, including a final decision on appeal, against the licensee or of an action against the licensee by a:
(a) peer review committee;
(b) professional association; or
(c) local, state, federal, territorial, provincial, or Indian tribal government;
(18) conduct that does not meet the generally accepted standards of practice. A certified copy of a malpractice judgment against the licensee or license applicant or of a tort judgment in an action involving an act or omission occurring during the scope and course of the practice is conclusive evidence of but is not needed to prove conduct that does not meet generally accepted standards.

24.174.2301 UNPROFESSIONAL CONDUCT (1) The board defines "unprofessional conduct" as follows:
(a) engaging in any activity which violates state and federal statutes and rules governing the practice of pharmacy;
(b) dispensing an outdated or questionable product;
(c) dispensing a cheaper product and charging for a more expensive product;
(d) charging for more dosage units than are actually dispensed;
(e) altering prescriptions or other records which the law requires pharmacies and pharmacists to maintain;
(f) dispensing medication without proper authorization;
(g) defrauding any persons or government agency receiving pharmacy services;
(h) placing a signature on any affidavit pertaining to any phase of the practice of pharmacy which the pharmacist knows to contain false information;
(i) any act performed in the practice of pharmacy which is hostile to the public health and which is knowingly committed by the holder of a license;

(j) buying, selling, purchasing or trading any prescription drug samples or offering to sell, purchase or trade drug samples. A "drug sample," as used herein, is defined to mean a unit of a prescription drug which is not intended to be sold and is intended to promote the sale of a drug;
(k) conviction, including conviction following a plea of nolo contendere, of an offense involving moral turpitude, whether misdemeanor or felony, and whether or not an appeal is pending;
(l) fraud, misrepresentation, deception or concealment of a material fact in applying for or securing a license, or license renewal, or in taking an examination required for licensure; as used herein, "material" means any false or misleading statement or information;
(m) use of a false, fraudulent or deceptive statement in any document connected with the practice of pharmacy;
(n) having been subject to disciplinary action of another state or jurisdiction against a license or other authorization to practice pharmacy, based upon acts or conduct by the licensee similar to acts or conduct that would constitute grounds for disciplinary actions under Title 37, chapter 7, MCA or these rules; a certified copy of the record of the action taken by the other state or jurisdiction is evidence of unprofessional conduct.
(o) willful disobedience of a rule adopted by the board, or an order of the board regarding evaluation or enforcement of discipline of a licensee;
(p) habitual intemperance or excessive use of an addictive drug, alcohol or any other substance to the extent that the use impairs the user physically or mentally;
(q) failing to furnish to the board or its investigators or representatives information legally requested by the board.
(r) failing to cooperate with a lawful investigation conducted by the board;
(s) conviction or violation of a federal or state law regulating the possession, distribution or use of a controlled substance, as defined by the federal food and drug administration or successors, whether or not an appeal is pending;
(t) failure to transfer pertinent and necessary patient records to another licensed pharmacy, the patient or the patient's representative when requested to do so by the patient or the patient's legally designated representative;
(u) failure to comply with an agreement the licensee has entered into with the impaired pharmacist program.

DISCIPLINARY/COMPLAINT PROCEDURES

24.174.2401 SCREENING PANEL (1) The board screening panel shall consist of three board members, including the two pharmacist members who have served longest on the board, and one other member as appointed by the board president. The board president may reappoint screening panel members as necessary at the president's discretion.

24.174.2402 COMPLAINT PROCEDURE (1) A person, government or private entity may submit a written complaint to the board charging a licensee or license applicant with a violation of board statutes or rules, and specifying grounds for the complaint.
(2) Complaints must be in writing, and shall be filed on the proper complaint form prescribed by the board.
(3) Upon receipt of the written complaint form, the board office shall log in the complaint and assign it a complaint number. The complaint shall then be sent to the licensee or license applicant complained about for a written response. Upon receipt of the licensee's or license applicant's written response, both complaint and response shall be considered by the screening panel of the board for appropriate action including dismissal, investigation or a finding of reasonable cause of violation of a statute or rule. The board office shall notify both complainant and licensee or license applicant of the determination made by the screening panel.
(4) If a reasonable cause violation determination is made by the screening panel, the Montana Administrative Procedure Act shall be followed for all disciplinary proceedings.

24.174.2403 LEGAL SUSPENSION OR REVOCATION (1) All licensed pharmacists and operators of pharmacies in the state of Montana must adhere to all the laws of the state of Montana and the rules of the board pertaining to pharmacists and operators of pharmacies and any violation thereof may constitute a cause for the revocation of such licenses.
(2) If an intern pharmacist is found or allowed to work in a pharmacy without the supervision of a registered pharmacist, meaning that the intern is allowed to work a shift by himself/herself, it may be cause for the board to cancel his or her internship in said pharmacy and may be cause for suspension or revocation of his or her intern

pharmacist license. The board may in its discretion ask for surrender, suspension or revocation of the pharmacy license of the pharmacy in which the intern has violated this section of the pharmacy law.
(3) The board may, upon notice and after a hearing, temporarily suspend or permanently revoke or refuse to renew any license of any registered pharmacist, or intern pharmacist, found to have been employed in any establishment which:
(a) does not have a license required by the pharmacy laws of the state of Montana, 37-7-321, MCA.

Still pending:

NEW RULE XVII QUALITY IMPROVEMENT PROGRAM DEFINITIONS
(1) "Continuous Quality Improvement Program" or CQI program means a system of standards and procedures to identify and evaluate quality-related events and improve patient care.
(2) "Quality-related event" or QRE means the incorrect dispensing of a prescribed medication that is received by a patient including:
(a) a variation from the prescriber's prescription order including, but not limited to:
(i) dispensing an incorrect drug;
(ii) dispensing an incorrect drug strength;
(iii) dispensing an incorrect dosage form;
(iv) dispensing a drug to the wrong patient; or
(v) providing inadequate or incorrect packaging, labeling, or directions;
(b) failure to identify and manage:
(i) overutilization;
(ii) therapeutic duplication;
(iii) drug-disease contraindications;
(iv) drug-drug interactions;
(v) incorrect drug dosage or duration of drug treatment;
(vi) drug allergy interactions; or
(vii) clinical abuse or misuse.
(3) "Near-miss QRE" means that an error occurred at some point in the dispensing process, but it was caught and corrected before being given to a patient.
(4) "Pharmacy" means a pharmacy or a group of pharmacies under common ownership and control of one entity licensed by the board.
(5) "Pharmacy personnel" mean pharmacist, pharmacist intern, and pharmacy technician.

NEW RULE XVIII CONTINUOUS QUALITY IMPROVEMENT PROGRAM
(1) Each pharmacy shall establish a Continuous Quality Improvement (CQI) program for the purpose of detecting, documenting, assessing, and preventing quality-related events (QREs). At a minimum, a CQI program shall include provisions to:
(a) identify and document QREs;
(b) minimize impact of QREs on patients;
(c) analyze data collected in response to QREs to assess causes and any contributing factors;
(d) use the findings of the analysis to formulate an appropriate response and develop pharmacy systems and workflow processes designed to prevent QREs; and
(e) provide ongoing education and feedback to pharmacy personnel in the area of CQI, and specific findings from the CQI program.
(2) The pharmacist-in-charge (PIC) is responsible for monitoring CQI program compliance.
(3) CQI program requirements shall be implemented by each pharmacy within six months of the effective date of this rule.

NEW RULE XIX QUALITY-RELATED EVENT DISCOVERY, NOTIFICATION, AND DOCUMENTATION (1) All pharmacy personnel shall be trained to bring any quality-related event (QRE) to the attention of the pharmacist

on duty or the pharmacist-in-charge (PIC) immediately upon discovery. The pharmacist who has discovered or been informed of a QRE shall immediately provide:
(a) notification to the patient or patient's representative;
(b) notification of the prescriber and other members of the healthcare team if indicated in the professional judgment of the pharmacist;
(c) directions for correcting the error; and
(d) instructions for minimizing the negative impact on the patient.
(2) A QRE shall be initially documented by the pharmacist who has discovered or been informed of the QRE on the same day the QRE is discovered by or described to the pharmacist.
(3) QRE documentation shall include a description of the event that is sufficient to permit categorization and analysis of the event. QRE documentation shall include:
(a) the date when the pharmacist discovered or received notification of the QRE and the names of the persons who notified the pharmacy;
(b) the names and titles of the persons recording the QRE information and performing the QRE analysis;
(c) a description of the QRE reviewed; and
(d) documentation of the contact with the patient or patient's representative and the prescribing practitioner and other members of the healthcare team (if indicated in the professional judgment of the pharmacist).

NEW RULE XX QUALITY-RELATED EVENT ANALYSIS AND RESPONSE
(1) The investigative and other pertinent data collected in response to a quality-related event (QRE) shall be analyzed individually and collectively to assess the cause and any contributing factors such as system or process failures. The QRE analysis and assessment shall include:
(a) consideration of the effects on quality assurance related to workflow processes, technological support, personnel training, and staffing levels; and
(b) any recommended remedial changes to pharmacy policies, procedures, systems, or processes.
(2) Each pharmacy shall inform pharmacy personnel of changes to pharmacy policies, procedures, systems, or processes resulting from recommendations generated by the Continuous Quality Improvement Program.

NEW RULE XXI DUTY TO REPORT (1) A pharmacy licensed by the board is required to report any quality-related event (QRE) to the Institute for Safe Medication Practices (ISMP). Near-miss QREs are encouraged to be treated as a QRE and reported to the ISMP.

NEW RULE XXII RECORDS (1) Each pharmacy shall maintain a copy of its Continuous Quality Improvement Program (CQI) description on the pharmacy premises. The CQI program description shall be readily available to all pharmacy personnel.
(2) Each pharmacy shall maintain a record of all quality-related event (QRE) documentation for a minimum period of two years from the date of the QRE report.
(3) QRE records shall be maintained in an orderly manner and accessible for the pharmacy compliance officer.
(4) The date and name of the person filing the Institute for Safe Medication Practices report will be kept as part of the QRE record.