AN ACT GENERALLY REVISING PHARMACY LAWS; UPDATING AND CLARIFYING DEFINITIONS; REVISING THE DEFINITION OF A PHARMACY TECHNICIAN; REMOVING THE UTILIZATION PLAN REQUIREMENT FOR IN-STATE PHARMACIES AND OUT-OF-STATE MAIL ORDER PHARMACIES; CLARIFYING THE POWERS AND DUTIES OF THE BOARD OF PHARMACY; PROVIDING RULEMAKING AUTHORITY; REQUIRING AN ENDORSEMENT TO PRACTICE AS A CLINICAL PHARMACIST PRACTITIONER; REMOVING OUTDATED NOTIFICATION PRACTICES REGARDING BIOSIMILAR PRODUCT SELECTION; REMOVING OUTDATED GENERIC DRUG SIGNAGE REQUIREMENTS; CLARIFYING PHARMACY WHOLESALE DISTRIBUTION LICENSES; AMENDING SECTIONS 2-18-704, 37-7-101, 37-7-105, 37-7-201, 37-7-301, 37-7-306, 37-7-502, 37-7-505, 37-7-601, 37-7-602, 37-7-603, 37-7-604, 37-7-701, 37-7-702, 37-7-703, 37-7-704, 37-7-705, 37-7-706, 39-71-727, AND 53-6-1002, MCA; AND REPEALING SECTIONS 37-7-307, 37-7-308, 37-7-309 AND 37-7-506, MCA."

BE IT ENACTED BY THE LEGISLATURE OF THE STATE OF MONTANA:

Section 1. Section 2-18-704, MCA, is amended to read:

"**2-18-704. Mandatory provisions.** (1) An insurance contract or plan issued under this part must contain provisions that permit:

(a) the member of a group who retires from active service under the appropriate retirement provisions of a defined benefit plan provided by law or, in the case of the defined contribution plan provided in Title 19, chapter 3, part 21, a member with at least 5 years of service and who is at least age 50 while in covered employment to remain a member of the group until the member becomes eligible for medicare under the federal Health Insurance for the Aged Act, 42 U.S.C. 1395, unless the member is a participant in another group plan with substantially the same or greater benefits at an equivalent cost or unless the member is employed and, by virtue of that employment, is eligible to participate in another group plan with substantially the

same or greater benefits at an equivalent cost;

(b) the surviving spouse of a member to remain a member of the group as long as the spouse is eligible for retirement benefits accrued by the deceased member as provided by law unless the spouse is eligible for medicare under the federal Health Insurance for the Aged Act or unless the spouse has or is eligible for equivalent insurance coverage as provided in subsection (1)(a);

(c) the surviving children of a member to remain members of the group as long as they are eligible for retirement benefits accrued by the deceased member as provided by law unless they have equivalent coverage as provided in subsection (1)(a) or are eligible for insurance coverage by virtue of the employment of a surviving parent or legal guardian.

(2) An insurance contract or plan issued under this part must contain the provisions of subsection (1) for remaining a member of the group and also must permit:

(a) the spouse of a retired member the same rights as a surviving spouse under subsection (1)(b);

(b) the spouse of a retiring member to convert a group policy as provided in 33-22-508; and

(c) continued membership in the group by anyone eligible under the provisions of this section, notwithstanding the person's eligibility for medicare under the federal Health Insurance for the Aged Act.

(3) (a) A state insurance contract or plan must contain provisions that permit a legislator to remain a member of the state's group plan until the legislator becomes eligible for medicare under the federal Health Insurance for the Aged Act if the legislator:

(i) terminates service in the legislature and is a vested member of a state retirement system provided by law; and

(ii) notifies the department of administration in writing within 90 days of the end of the legislator's legislative term.

(b) A former legislator may not remain a member of the group plan under the provisions of subsection (3)(a) if the person:

(i) is a member of a plan with substantially the same or greater benefits at an equivalent cost; or

(ii) is employed and, by virtue of that employment, is eligible to participate in another group plan with substantially the same or greater benefits at an equivalent cost.

(c) A legislator who remains a member of the group under the provisions of subsection (3)(a) and

subsequently terminates membership may not rejoin the group plan unless the person again serves as a legislator.

(4) (a) A state insurance contract or plan must contain provisions that permit continued membership in the state's group plan by a member of the judges' retirement system who leaves judicial office but continues to be an inactive vested member of the judges' retirement system as provided by 19-5-301. The judge shall notify the department of administration in writing within 90 days of the end of the judge's judicial service of the judge's choice to continue membership in the group plan.

(b) A former judge may not remain a member of the group plan under the provisions of this subsection (4) if the person:

(i) is a member of a plan with substantially the same or greater benefits at an equivalent cost;

(ii) is employed and, by virtue of that employment, is eligible to participate in another group plan with substantially the same or greater benefits at an equivalent cost; or

(iii) becomes eligible for medicare under the federal Health Insurance for the Aged Act.

(c) A judge who remains a member of the group under the provisions of this subsection (4) and subsequently terminates membership may not rejoin the group plan unless the person again serves in a position covered by the state's group plan.

(5) A person electing to remain a member of the group under subsection (1), (2), (3), or (4) shall pay the full premium for coverage and for that of the person's covered dependents.

(6) An insurance contract or plan issued under this part that provides for the dispensing of prescription drugs by an out-of-state mail ~~service~~ order pharmacy, as defined in 37-7-702:

(a) must permit any member of a group to obtain prescription drugs from a pharmacy located in Montana that is willing to match the price charged to the group or plan and to meet all terms and conditions, including the same professional requirements that are met by the mail ~~service~~ order pharmacy for a drug, without financial penalty to the member; and

(b) may only be with an out-of-state mail ~~service~~ order pharmacy that is registered with the board under Title 37, chapter 7, part 7, and that is registered in this state as a foreign corporation.

(7) An insurance contract or plan issued under this part must include coverage for:

(a) treatment of inborn errors of metabolism, as provided for in 33-22-131;

(b) therapies for Down syndrome, as provided in 33-22-139;

(c) treatment for children with hearing loss as provided in 33-22-128(1) and (2);

(d) fertility preservation services as required under 33-22-2103;

(e) the care and treatment of mental illness in accordance with the provisions of Title 33, chapter 22, part 7;

(f) telehealth services, as provided for in 33-22-138; and

(g) refills of prescription eyedrops as provided in 33-22-154.

(8) (a) An insurance contract or plan issued under this part that provides coverage for an individual in a member's family must provide coverage for well-child care for children from the moment of birth through 7 years of age. Benefits provided under this coverage are exempt from any deductible provision that may be in force in the contract or plan.

(b) Coverage for well-child care under subsection (8)(a) must include:

(i) a history, physical examination, developmental assessment, anticipatory guidance, and laboratory tests, according to the schedule of visits adopted under the early and periodic screening, diagnosis, and treatment services program provided for in 53-6-101; and

(ii) routine immunizations according to the schedule for immunization recommended by the advisory committee on immunization practices of the U.S. department of health and human services.

(c) Minimum benefits may be limited to one visit payable to one provider for all of the services provided at each visit as provided for in this subsection (8).

(d) For purposes of this subsection (8):

(i) "developmental assessment" and "anticipatory guidance" mean the services described in the Guidelines for Health Supervision II, published by the American academy of pediatrics; and

(ii) "well-child care" means the services described in subsection (8)(b) and delivered by a physician or a health care professional supervised by a physician.

(9) Upon renewal, an insurance contract or plan issued under this part under which coverage of a dependent terminates at a specified age must continue to provide coverage for any dependent, as defined in the insurance contract or plan, until the dependent reaches 26 years of age. For insurance contracts or plans issued under this part, the premium charged for the additional coverage of a dependent, as defined in the

insurance contract or plan, may be required to be paid by the insured and not by the employer.

(10) Prior to issuance of an insurance contract or plan under this part, written informational materials describing the contract's or plan's cancer screening coverages must be provided to a prospective group or plan member.

(11) The state employee group benefit plans and the Montana university system group benefits plans must provide coverage for hospital inpatient care for a period of time as is determined by the attending physician and, in the case of a health maintenance organization, the primary care physician, in consultation with the patient to be medically necessary following a mastectomy, a lumpectomy, or a lymph node dissection for the treatment of breast cancer.

(12) (a) (i) The state employee group benefit plans and the Montana university system group benefits plans must provide coverage for medically necessary and prescribed outpatient self-management training and education for the treatment of diabetes. Any education must be provided by a licensed health care professional with expertise in diabetes. At a minimum, the benefit must consist of:

(A) 20 visits of training and education in diabetes self-management provided in either an individual or group setting if the person has not received the training and education previously; and

(B) 12 visits of followup diabetes self-management training and education services in subsequent years for an insured who has previously received and exhausted the initial 20 visits of education.

(ii) For the purposes of this subsection (12)(a), the term "visit" refers to a period of 30 minutes.

(b) The state employee group benefit plans and the Montana university system group benefits plans must provide coverage for diabetic equipment and supplies that at a minimum includes insulin, syringes, injection aids, devices for self-monitoring of glucose levels (including those for the visually impaired), test strips, visual reading and urine test strips, one insulin pump for each warranty period, accessories to insulin pumps, one prescriptive oral agent for controlling blood sugar levels for each class of drug approved by the United States food and drug administration, and glucagon emergency kits.

(c) Nothing in subsection (12)(a) or (12)(b) prohibits the state or the Montana university group benefit plans from providing a greater benefit or an alternative benefit of substantially equal value, in which case subsection (12)(a) or (12)(b), as appropriate, does not apply.

(d) Annual copayment and deductible provisions are subject to the same terms and conditions

applicable to all other covered benefits within a given policy.

(e) This subsection (12) does not apply to disability income, hospital indemnity, medicare supplement, accident-only, vision, dental, specific disease, or long-term care policies offered by the state or the Montana university system as benefits to employees, retirees, and their dependents.

(13) (a) Except as provided in subsection (16), the state employee group benefit plans and the Montana university system group benefits plans that provide coverage to the spouse or dependents of a peace officer as defined in 45-2-101, a game warden as defined in 19-8-101, a firefighter as defined in 19-13-104, or a volunteer firefighter as defined in 19-17-102 shall renew the coverage of the spouse or dependents if the peace officer, game warden, firefighter, or volunteer firefighter dies within the course and scope of employment. Except as provided in subsection (13)(b), the continuation of the coverage is at the option of the spouse or dependents. Renewals of coverage under this section must provide for the same level of benefits as is available to other members of the group. Premiums charged to a spouse or dependent under this section must be the same as premiums charged to other similarly situated members of the group. Dependent special enrollment must be allowed under the terms of the insurance contract or plan. The provisions of this subsection (13)(a) are applicable to a spouse or dependent who is insured under a COBRA continuation provision.

(b) The state employee group benefit plans and the Montana university system group benefits plans subject to the provisions of subsection (13)(a) may discontinue or not renew the coverage of a spouse or dependent only if:

(i) the spouse or dependent has failed to pay premiums or contributions in accordance with the terms of the state employee group benefit plans and the Montana university system group benefits plans or if the plans have not received timely premium payments;

(ii) the spouse or dependent has performed an act or practice that constitutes fraud or has made an intentional misrepresentation of a material fact under the terms of the coverage; or

(iii) the state employee group benefit plans and the Montana university system group benefits plans are ceasing to offer coverage in accordance with applicable state law.

(14) The state employee group benefit plans and the Montana university system group benefits plans must comply with the provisions of 33-22-153.

(15) An insurance contract or plan issued under this part and a group benefits plan issued by the

Montana university system must provide mental health coverage that meets the provisions of Title 33, chapter 22, part 7.

(16) The employing state agency of a law enforcement officer as defined in 2-15-2040 who is covered under the state employee group benefit plan shall:

(a) if the officer is catastrophically injured in the line of duty as defined in 2-15-2040, enroll the officer and the officer's covered spouse or dependent children in COBRA continuation coverage when that officer is terminated from employment as a result of the catastrophic injury. The officer and the officer's spouse or dependent children may opt out of COBRA continuation coverage within 60 days of enrollment.

(b) enroll the officer's covered spouse or dependent children in COBRA continuation coverage if the officer dies in the line of duty as defined in 2-15-2040. The officer's spouse or dependent children may opt out of COBRA coverage within 60 days of the date of enrollment.

(c) pay the COBRA premium for 4 months of COBRA continuation coverage for the officer and the officer's covered spouse or dependent children enrolled in COBRA continuation coverage pursuant to subsections (16)(a) or (16)(b), after which time the officer and the officer's spouse or dependent children shall pay the COBRA premium. (See compiler's comments for contingent termination of certain text.)"

Section 2. Section 37-7-101, MCA, is amended to read:

"**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 37-7-105, the term does not include immunization by injection for children under 18 years of age.

(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; or

(e) the preparation of drugs based on a facility being registered as an outsourcing facility with the FDA.

(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 in Schedules 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~~ the term "prescription device" as

defined in 21 CFR 801.109.

(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" or "distribution" means the sale, purchase, trade, delivery, handling, storage, or receipt of a drug or device and does not include:

(a) administering or dispensing a prescription drug, pursuant to section 353(b)(1), ~~or~~ ;

(b) a new animal drug, pursuant to section 360b(b) of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. 301, et seq.; or

(c) dispensing a device other than medical gas and supplies.

(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 (16)(a), (16)(b), or (16)(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) "FDA" means the United States food and drug administration.

(20) "Health care facility" has the meaning provided in 50-5-101.

(21) (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.

(22) "Health information system" means one of the following systems used to compile and manage patient health care information:

(a) an electronic health record system;

(b) a health information exchange approved by the board;

(c) a pharmacy dispensing system; or

(d) a system defined by the board by rule.

(23) "Hospital" has the meaning provided in 50-5-101.

(24) "Immunization-certified pharmacist" means a pharmacist who:

(a) has successfully completed an immunization delivery course of training that is approved by the accreditation council for pharmacy education or by an authority approved by the board and that, at a minimum, includes instruction in hands-on injection technique, clinical evaluation of indications and contraindications of immunizations, storage and handling of immunizations, and documentation and reporting; and

(b) holds a current basic cardiopulmonary resuscitation certification issued by the American heart association, the American red cross, or another recognized provider.

(25) "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.

(26) "Long-term care facility" has the meaning provided in 50-5-101.

(27) "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.

(28) "Medicine" means a remedial agent that has the property of curing, preventing, treating, or mitigating diseases or which is used for this purpose.

(29) "Outsourcing facility" means a facility at one geographic location or address that:

(a) engages in compounding of sterile drugs;

(b) has elected to register as an outsourcing facility with FDA; and

(c) complies with all the requirements of section 353b of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. 301 et seq.

(30) "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.

(31) "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.

(32) "Person" includes an individual, partnership, corporation, association, or other legal entity.

(33) "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 a disease process.

(34) "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.".

(35) "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.

(36) "Pharmacy technician" means an individual who assists a pharmacist in the practice of pharmacy and performs tasks delegated to the technician by a pharmacist that do not require a pharmacist's independent professional judgment.

(37) "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.

(38) "Practice of pharmacy" means:

(a) interpreting, evaluating, and implementing prescriber orders;

(b) administering drugs and devices pursuant to a collaborative practice agreement, except as provided in 37-7-105, 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) prescribing drugs and devices in accordance with 37-7-106;

(e) monitoring drug therapy and use;

(f) initiating or modifying drug therapy in accordance with collaborative pharmacy practice agreements established and approved by health care facilities or voluntary agreements with prescribers;

(g) participating in quality assurance and performance improvement activities;

(h) providing information on drugs, dietary supplements, and devices to patients, the public, and other health care providers; and

(i) participating in scientific or clinical research as an investigator or in collaboration with other investigators.

(39) "Practice pharmacy by means of telehealth" means to provide pharmaceutical care through the

use of information technology to patients at a distance.

(40) "Preceptor" means an individual who is registered by the board and participates in the instructional training of a pharmacy intern.

(41) "Prescriber" has the same meaning as provided in 37-7-502.

(42) "Prescription drug" means any drug that is required by federal law or regulation to be dispensed only by a prescription subject to section 353(b) of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. 301 et seq.

(43) "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.

(44) "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.

(45) "Qualified patient" means a person who is uninsured, indigent, or has insufficient funds to obtain needed prescription drugs or cancer drugs.

(46) "Registry" means the prescription drug registry provided for in 37-7-1502.

~~(47) "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.~~

~~(48)~~ (47) "Wholesale" means a sale for the purpose of resale."

Section 3. Section 37-7-105, MCA, is amended to read:

"**37-7-105. Administration of immunizations.** (1) An immunization-certified pharmacist may:

(a) prescribe and administer the following immunizations without a collaborative practice agreement in place:

(i) influenza to individuals who are 12 years of age or older;

(ii) pneumococcal, tetanus, ~~diptheria~~ diphtheria, and pertussis to individuals who are 18 years of age or older; and

(iii) herpes zoster to those individuals identified in the guidelines published by the United States centers for disease control and prevention's advisory committee on immunization practices; and

(b) administer immunizations to individuals 7 years of age or older as provided by the most recent guidelines by vaccine and age group published by the United States centers for disease control and prevention and as determined within a collaborative practice agreement.

(2) In the event of an adverse reaction, a pharmacist may administer epinephrine or diphenhydramine to:

(a) an individual who is 12 years of age or older; and

(b) a child who is 7 years of age or older and under 12 years of age within a collaborative practice agreement.

(3) If a pharmacist provides an immunization that is part of a series requiring multiple doses over time, the pharmacist shall notify the individual or the individual's legal representative at the time the next immunization in the series is due to be administered by sending a notice to the individual or representative that the followup immunization is needed to fulfill the series requirement.

(4) A pharmacist who administers an immunization pursuant to this section shall:

(a) ensure that the individual who is being immunized is assessed for contraindications to immunization;

(b) ensure that the individual who is being immunized or the individual's legal representative receives a copy of the appropriate vaccine information statement;

(c) if the pharmacist is notified of an adverse reaction, report the reaction to:

(i) the patient's primary health care provider, if the patient identifies one;

(ii) the medical provider or providers with whom the pharmacist has a collaborative practice agreement; and

(iii) the vaccine adverse event reporting system established under the United States department of health and human services;

(d) provide a signed certificate of immunization to the primary health care provider, if known, of each individual who is immunized and to the individual who is immunized that includes the individual's name, date of immunization, address of immunization, administering pharmacist, immunization agent, manufacturer, and lot number;

(e) create a record for each immunization, in which the individual's name, date, address of immunization, administering pharmacist, immunization agent, manufacturer, and lot number are included, and maintain the record for 7 years from the date the immunization was administered or until 7 years after the individual reaches 18 years of age, whichever is later; and

(f) offer the patient the opportunity to have the immunization information reported to the state immunization information system.

(5) (a) A pharmacist may delegate the administration of immunizations authorized under this section only to the following persons who meet the requirements of subsection (5)(b):

(i) a licensed intern who is under the supervision of the pharmacist; or

(ii) a pharmacy technician who is ~~acting under a technician utilization plan and~~ under the supervision of the pharmacist.

(b) A licensed intern or a pharmacy technician administering immunizations must hold a current certification to provide basic cardiac life support and must have completed a practical training program that is:

(i) accredited by the accreditation council for pharmacy education or a similar health authority or professional body approved by the board; and

(ii) at a minimum, includes instruction in hands-on injection technique and recognizing and treating emergency reactions to vaccines.

(6) For the purposes of this section, "vaccine information statement" means an information sheet that is produced by the United States centers for disease control and prevention that explains the benefits and risks associated with a vaccine to a vaccine recipient or the legal representative of the vaccine recipient."

Section 4. Section 37-7-201, MCA, is amended to read:

"**37-7-201. ~~Organization -- powers~~ Powers and duties -- rulemaking authority.** (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~~ establish minimum standards for:

~~(i)~~ (a) ~~equipment necessary in and for a pharmacy~~ necessary pharmacy equipment;

~~(ii)~~ (b) 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)~~ (c) ~~specifications for the~~ facilities, including outsourcing facilities, ~~as well as for~~ and the environment, supplies, technical equipment, personnel, and procedures for the storage, compounding, distribution, or dispensing of drugs and devices;

~~(iv)~~ (d) monitoring drug therapy; and

~~(v)~~ (e) maintaining the integrity and confidentiality of prescription information and other confidential patient information~~;~~.

~~(b)~~ (2) ~~requesting the department to~~ The department shall inspect, at reasonable times:

~~(i)~~ (a) places where drugs, medicines, chemicals, or poisons are sold, vended, given away, compounded, dispensed, distributed, or manufactured; and

~~(ii)~~ (b) the appropriate records and the license of any person engaged in the practice of pharmacy ~~for the purpose of determining whether any~~ to determine compliance with laws governing the legal dispensing, distribution, or manufacture of drugs or devices or the practice of pharmacy ~~are being violated~~.

(3) The department and 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:~~

(4) The board shall adopt rules concerning:

~~(i)~~ (a) the training, qualifications, employment, licensure, and practice of pharmacists and interns;

~~(ii)~~ (b) the training, qualifications, employment, and ~~registration~~ licensure of pharmacy technicians;

~~and~~

~~(iii)~~ (c) under therapeutic classification, the dispensing, distribution, 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 distributors;

(iv) third-party logistics providers as defined in 37-7-602; ~~and~~

(v) persons engaged in the ~~manufacture and~~ manufacturing, dispensing, or distribution of drugs or devices regarding the practice of pharmacy and authorized under Title 37, chapter 2, Title 50, chapter 31, part 3, Title 50, chapter 32, and this chapter; and

(vi) persons engaged in the dispensing of animal prescription drugs as authorized in Title 37, chapter 18;

(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)~~ (f) 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)~~ (g) establishing a medical assistance program to assist and rehabilitate licensees who are subject to the jurisdiction of the board and who are 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 illness or chronic physical illness. The board shall ensure that a licensee who is required or volunteers to participate in the medical assistance program as a condition of continued licensure or reinstatement of licensure must be allowed to enroll in a qualified medical assistance program within this state and may not require a licensee to enroll in a qualified treatment program outside the state unless the board finds that there is

no qualified treatment program in this state.

~~(j) making rules for the conduct of its business;~~

~~(k) performing other duties and exercising other powers as this chapter requires; and~~

~~(l) 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)~~ (h) requirements and procedures necessary to allow a pharmacy licensed in another jurisdiction to be registered to practice pharmacy by means of telehealth across state lines.

~~(3)~~ (5) 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)~~ (a) establish standards of care for patients concerning health care services that a patient may expect with regard to pharmaceutical care; and

(b) approve pharmacy practice initiatives that improve the quality of or access to pharmaceutical care, but that fall outside the scope of this chapter. This subsection (5)(b) may not be construed to expand on the definition of the practice of pharmacy."

Section 5. Section 37-7-301, MCA, is amended to read:

"**37-7-301. Unlawful practice.** ~~Except as provided in 37-7-307 through 37-7-309, it~~ 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."

Section 6. Section 37-7-306, MCA, is amended to read:

"**37-7-306. Clinical pharmacist practitioner endorsement required -- qualifications -- scope of practice.** (1) A pharmacist may not practice as a clinical pharmacist practitioner ~~is a licensed pharmacist in good standing who:~~ without an endorsement issued under Title 37, chapter 1, and this chapter.

(2) An applicant for a clinical pharmacist practitioner endorsement must have:

(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~~ a pharmacist license issued under Title 37, chapter 1, and this chapter;

(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 current collaborative pharmacy practice agreement.

~~(2)~~ (3) ~~Only a pharmacist certified by the board may legally be identified as a clinical pharmacist practitioner~~. The requirements in subsections (2)(a) through (2)(c) must be maintained for active licensure and are subject to audit as provided in 37-1-306.

(4) For the purposes of this section, a clinical pharmacist practitioner provides 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 provided through a collaborative pharmacy practice agreement as defined in this chapter."

Section 7. Section 37-7-502, MCA, is amended to read:

"**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 that, when administered to the same individual in the same dosage regimen, will result in comparable bioavailability.

(3) "Biological product" has the meaning provided in 42 U.S.C. 262.

(4) "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.

(5) "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.

(6) "Drug product" means a dosage form containing one or more active therapeutic ingredients along with other substances included during the manufacturing process.

(7) "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.

(8) "Interchangeable biological product" means a biological product that the federal food and drug administration has:

(a) licensed; and

(b) (i) determined meets the standards for interchangeability pursuant to 42 U.S.C. 262(k)(4); or

(ii) determined is therapeutically equivalent as set forth in the latest edition of or supplement to the federal food and drug administration's approved drug products with therapeutic equivalence evaluations.

(9) "Person" has the meaning provided in 37-7-101.

(10) "Prescriber" means a medical practitioner, as defined in 37-2-101, licensed under the professional laws of the state to purchase, administer, and prescribe medicine and drugs. For the purposes of this chapter, the term includes a naturopathic physician and a physician assistant.

(11) "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.

(12) "Product selection" means to dispense without the prescriber's express authorization a different drug product in place of the drug product prescribed.

(13) "Therapeutically equivalent" means those chemical equivalents that, 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."

Section 8. Section 37-7-505, MCA, is amended to read:

"**37-7-505. Product selection permitted -- limitation -- notice to purchaser.** (1) Except as limited by subsection (2) and unless instructed otherwise by the purchaser:

(a) a 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; and

(b) a pharmacist who receives a prescription for a specific biological product may select a less expensive interchangeable biological product.

(2) If, in the professional opinion of the prescriber, it is medically necessary that an equivalent drug product or interchangeable biological product not be selected, the prescriber may so indicate by certifying that the specific brand-name drug product prescribed or the specific brand-name biological product prescribed 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 specific brand-name drug product prescribed or the specific biological product prescribed is medically necessary.

~~(3) (a) Within 5 business days following the dispensing of a biological product, the dispensing pharmacist or the pharmacist's designee shall communicate the specific product provided to the patient, including the name of the product and the manufacturer, to the prescriber through any of the following electric records systems:~~

~~(i) an interoperable electronic medical records system;~~

~~(ii) an electronic prescribing technology;~~

~~(iii) a pharmacy benefit management system; or~~

~~(iv) a pharmacy record.~~

~~(b) Communication through an electronic records system as described in subsection (3)(a) is presumed to provide notice to the prescriber.~~

~~(c) If the pharmacist is unable to communicate pursuant to an electronic records system as provided in subsection (3)(a), the pharmacist shall communicate to the prescriber which biological product was dispensed to the patient using facsimile, telephone, electronic transmission, or other prevailing means.~~

~~(d) Communication is not required under this subsection (3) when:~~

~~(i) there is no federal food and drug administration approved interchangeable biological product for the product prescribed; or~~

~~(ii) a refill prescription is not changed from the product dispensed on the prior filling of the prescription.~~

~~(4) The pharmacist shall maintain a record of the biological product dispensed for at least 2 years.~~

(3) A pharmacist who selects a drug product, as provided in this section, shall notify the person presenting the prescription that the person may refuse the product selection."

Section 9. Section 37-7-601, MCA, is amended to read:

"**37-7-601. Scope and purpose.** This part applies to the wholesale distribution, third-party logistics, manufacturing, or repackaging of prescription drugs or devices in this state. The purpose of this part is to implement the federal Prescription Drug Marketing Act of 1987 and the Drug Quality and Security Act of 2013, which includes but is not limited to the Drug Supply Chain Security Act, by providing minimum standards, terms, and conditions for licensing by the department of persons or entities engaged in the wholesale distribution, third-party logistics, manufacturing, or repackaging of prescription drugs or devices."

Section 10. Section 37-7-602, MCA, is amended to read:

"**37-7-602. Definitions.** As used in this part, the following definitions apply:

(1) (a) "Dispenser" means a retail pharmacy, a hospital pharmacy, a group of chain pharmacies under common ownership and control that do not act as a wholesale distributor, or any other person authorized by law to dispense or administer prescription drugs, and the affiliated warehouses or distribution centers of the entities listed in this subsection (1)(a), if they are under common ownership and control and do not act as a wholesale distributor.

(b) The term does not include a person who dispenses only products used in animals in accordance with FDA laws and regulations, except for persons engaged in animal prescription drug dispensing authorized in Title 37, chapter 18.

(2) "Manufacturer" means:

(a) a person approved by application to the FDA to manufacture a product as defined in section 360eee of the Drug Supply Chain Security Act, 21 U.S.C. 301, et seq., or a biologic pursuant to 42 U.S.C. 262;

(b) a person who manufactures a product as defined in section 360eee of the Drug Supply Chain

Security Act, 21 U.S.C. 301, et seq., or a biologic pursuant to 42 U.S.C. 262 that is not the subject of an approved application or license by the FDA;

(c) a colicensed partner of a person described in subsection (2)(a) or (2)(b) that obtains the product directly from a person described in subsection (2)(a), (2)(b), or (2)(d); or

(d) an affiliate of a person described in subsection (2)(a), (2)(b), or (2)(c) that receives the product directly from a person described in subsection (2)(a), (2)(b), or (2)(c).

(3) "Prescription drug" has the same meaning as provided in 37-7-101.

(4) "Repackager" means a person who owns or operates an establishment that repacks and relabels a product or a package in accordance with the requirements of the FDA for:

(a) further sale; or

(b) distribution without a further transaction.

(5) "Third-party logistics provider" or "3PL" means an entity that provides or coordinates warehousing or other logistics services of a product in interstate commerce on behalf of a manufacturer, wholesale distributor, or dispenser of a product but does not take ownership of the product or have responsibility to direct the sale or disposition of the product.

(6) "Transaction" has the same meaning as provided in section 360eee of the Drug Supply Chain Security Act, 21 U.S.C. 301, et seq.

(7) (a) "Wholesale distribution" means distribution of prescription drugs or devices to persons other than a consumer or patient, including the distribution of prescription drugs or devices to persons or entities authorized to purchase, administer, or dispense prescription drugs or devices.

(b) The term does not include the exclusions listed in section 353(e)(4) of the Drug Supply Chain Security Act, 21 U.S.C. 301, et seq.

(8) "Wholesale distributor" means a person or entity, other than a manufacturer, a manufacturer's colicensed partner, a third-party logistics provider, or a repackager, who is engaged in wholesale distribution of prescription drugs or devices, including entities registered with the FDA."

Section 11. Section 37-7-603, MCA, is amended to read:

"**37-7-603. Prohibited purchase or receipt of drugs or devices -- dispensing and distribution**

restrictions -- penalty. (1) Except as otherwise provided, it is unlawful for a person to knowingly purchase or receive a prescription drug or device from a source other than a person or entity ~~licensed under this part~~ engaged in wholesale distribution.

(2) Licensed wholesale distributors, third-party logistics providers, manufacturers, and repackagers may not dispense or distribute prescription drugs or devices directly to patients, except when the licensed wholesale distributor is also ~~a licensed pharmacy~~ licensed by the board to dispense prescription drugs or devices.

(3) A person who violates the provisions of this section is guilty of a misdemeanor."

Section 12. Section 37-7-604, MCA, is amended to read:

"**37-7-604. Wholesale distributor, third-party logistics provider, manufacturer, and repackager ~~licensing requirements~~ license required -- ~~fee~~ qualifications -- federal compliance.** (1) A person or distribution outlet may not act as a wholesale distributor, third-party logistics provider, manufacturer, or repackager ~~without first obtaining a license from the board and paying the license fee~~ unless licensed under Title 37, chapter 1, and this chapter.

(2) ~~A license may not be issued or renewed for~~ An applicant for initial licensure or license renewal as a wholesale distributor, third-party logistics provider, manufacturer, or repackager ~~to operate in this state unless the applicant~~ must:

(a) ~~agrees~~ agree to abide by federal and state law and to comply with the rules adopted by the FDA and the board; and

(b) ~~pays~~ pay the license fee set by the board.

(3) The board in its discretion may require that a separate license be obtained for:

(a) each facility directly or indirectly owned or operated by the same business entity within the state; or

(b) a parent entity with divisions, subsidiaries, or affiliates within the state if operations are conducted at more than one location and joint ownership and control exists among all entities.

(4) An applicant ~~for a license~~ under this section ~~or for a license renewal~~ shall provide written documentation to the board attesting that the applicant has maintained and will continue to maintain:

(a) adequate storage conditions and facilities;

(b) minimum liability and other insurance that may be required by applicable federal or state law;

(c) a functioning security system that includes:

(i) an after hours central alarm or comparable entry detection system;

(ii) restricted access to the premises;

(iii) comprehensive employee applicant screening; and

(iv) safeguards against employee theft;

(d) a system of records setting forth all activities of wholesale distribution, third-party logistics, manufacturing, or repackaging for at least a period of the 2 previous years. The system of records must be accessible, as defined by board regulations, for inspections authorized by the board.

(e) a list of active business entity principals, including officers, directors, primary shareholders, and management executives, who shall ~~at all times~~ demonstrate and maintain their responsibility for conducting the business in conformity with sound financial practices ~~as well as~~ and state and federal law;

(f) complete, updated information, to be provided to the board as a condition for obtaining and renewing a license, pertaining to each wholesale distributor, third-party logistics provider, manufacturer, or repackager to be licensed, including but not limited to:

(i) all pertinent corporate license information, if applicable; and

(ii) other information regarding ownership, principals, key personnel, and facilities;

(g) a written protocol of procedures and policies that ensures preparation by the applicant or licensee under this section for the handling of security or operational problems, including but not limited to those caused by:

(i) natural disaster or government emergency;

(ii) inventory inaccuracies or product shipping and receiving;

(iii) insufficient inspections for all incoming and outgoing product shipments;

(iv) lack of control of outdated or other unauthorized products;

(v) inappropriate disposition of returned goods; and

(vi) failure to promptly comply with product recalls; and

(h) operations in compliance with all federal requirements applicable to a wholesale distributor,

third-party logistics provider, manufacturer, or repackager.

(5) An agent or employee of a licensed wholesale distributor, third-party logistics provider, manufacturer, or repackager need not be licensed as a wholesale distributor, third-party logistics provider, manufacturer, or repackager.

(6) ~~For purposes of this section, all~~ All rules ~~and regulations~~ promulgated by the board pertaining to this section must conform to the wholesale distributor, third-party logistics provider, manufacturer, and repackager licensing guidelines and rules formally adopted by the FDA. If a conflict arises between an FDA guideline or rule and a rule or regulation of the board, the former controls.

(7) Wholesale distributors, third-party logistics providers, manufacturers, and repackagers licensed by the board shall comply with the applicable tracing requirements defined in sections 353 and 360eee of the Drug Supply Chain Security Act, 21 U.S.C. 301, et seq., and all corresponding guidelines and rules."

Section 13. Section 37-7-701, MCA, is amended to read:

"**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~~ order 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~~ order 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."

Section 14. Section 37-7-702, MCA, is amended to read:

"**37-7-702. Out-of-state mail ~~service~~ order pharmacy defined.** "Out-of-state mail ~~service~~ order 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."

Section 15. Section 37-7-703, MCA, is amended to read:

"**37-7-703. ~~Registration requirements~~ Out-of-state mail order pharmacy -- registration requirements.** (1) Each out-of-state mail ~~service~~ order pharmacy must be registered ~~with the board of pharmacy~~ under Title 37, chapter 1, and this chapter. ~~In order to be registered with the board to do business in this state and for the renewal of its~~ To register or to renew its registration, an out-of-state mail ~~service~~ order pharmacy shall:

~~(1)~~ (a) ~~(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)~~ (c) ~~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~~ order 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~~ order pharmacy; and

~~(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)~~ (d) ~~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)~~ (1)(c) 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)~~ (2) 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."

Section 16. Section 37-7-703, MCA, is amended to read:

"**37-7-703. Registration requirements.** Each out-of-state mail ~~service~~ order 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~~ order 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~~ order 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~~ order pharmacy;

(3) shall submit a utilization plan for the employment of pharmacy technicians if allowed by the state where the mail ~~service~~ order 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~~ order 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."

Section 17. Section 37-7-704, MCA, is amended to read:

"**37-7-704. Inspections.** If the licensing or regulatory agency of the state in which an out-of-state mail ~~service~~ order pharmacy is domiciled fails or refuses to inspect the out-of-state mail ~~service~~ order 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."

Section 18. Section 37-7-705, MCA, is amended to read:

"**37-7-705. Product selection of prescribed drugs -- notification.** (1) An out-of-state mail ~~service~~ order 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~~ order 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."

Section 19. Section 37-7-706, MCA, is amended to read:

"**37-7-706. Patient communication -- telephone service.** Every out-of-state mail ~~service~~ order 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~~ order pharmacy. The toll-free telephone number must be affixed to all drug product containers dispensed to patients in this state."

Section 20. Section 39-71-727, MCA, is amended to read:

"**39-71-727. Payment for prescription drugs -- limitations.** (1) For payment of prescription drugs, an insurer is liable only for the purchase of generic-name drugs if the generic-name product is the therapeutic

equivalent of the brand-name drug prescribed by the physician, unless the generic-name drug is unavailable.

(2) If an injured worker prefers a brand-name drug, the worker may pay directly to the pharmacist the difference in the reimbursement rate between the brand-name drug and the generic-name product, and the pharmacist may bill the insurer only for the reimbursement rate of the generic-name drug.

(3) The pharmacist may bill only for the cost of the generic-name product on a signed itemized billing, except if purchase of the brand-name drug is allowed as provided in subsection (1).

(4) When billing for a brand-name drug, the pharmacist shall certify that the generic-name drug was unavailable.

(5) The department shall establish a schedule of fees for prescription drugs.

(6) Except as provided in subsection (8), a pharmacist may not dispense more than a 30-day supply at any one time.

(7) For purposes of this section, the terms "brand name" and "generic name" have the meanings provided in 37-7-502.

(8) An insurer may not require a worker receiving benefits under this chapter to obtain medications from an out-of-state mail ~~service~~ order pharmacy. ~~H~~However, an insurer may authorize up to a 90-day supply of medications from an in-state mail ~~service~~ order pharmacy.

(9) The provisions of this section do not apply to an agreement between a preferred provider organization and an insurer."

Section 21. Section 53-6-1002, MCA, is amended to read:

"**53-6-1002. Prescription drug plus discount program -- rules.** (1) The department may provide for a prescription drug plus discount program offering prescription drugs at a discounted price to qualified individuals whose income is at a level set by the department at or below 250% of the federal poverty level and who meet the requirements in 53-6-1003.

(2) There is a prescription drug plus discount program rebate account in the state special revenue fund to the credit of the department. All money received by the state as rebates from pharmaceutical manufacturers for the program must be deposited in the account. The money in the account, which is administered by the department, must be used to expand prescription drug benefits to qualified individuals.

Interest on account balances accrues to the account. The purpose of the account is to:

(a) reimburse participating retail pharmacies for the secondary discounted price; and

(b) reimburse the department for contracted services, administrative costs, associated computer costs, professional fees paid to participating retail pharmacies, pharmacy benefit administrators, and other reasonable program costs.

(3) The department shall provide for sufficient personnel to ensure efficient administration of the program. The extent and the magnitude of the program must be determined by the department on the basis of the calculated need of the recipient population and available funds. The department may not spend more on this program than is available through appropriations, federal or other grants, and other established and committed funding sources. The department may accept, for the purposes of carrying out this program, federal funds appropriated under any federal law relating to the furnishing of free or low-cost drugs to disadvantaged, elderly, and disabled individuals, may take action that is necessary for the purposes of carrying out that federal law, and may accept from any other agency of government, individual, group, or corporation funds that may be available to carry out this part.

(4) The department may adopt rules relating to the conduct of this program.

(5) The department shall, if the department determines that sufficient funds are available, adopt rules to establish the secondary discounted price to be charged to participants in the program. The department may establish a secondary discounted price to encourage the use of generic drugs over higher-cost brand-name drugs.

(6) The department shall establish by rule eligibility based upon the applicant's family income as provided in 53-6-1003. The total income may not exceed 250% of the federal poverty level. The department may adopt rules defining income. In establishing eligibility based upon income, the department shall take into account the amount of funding available for the program. The department shall issue enrollment materials to eligible individuals.

(7) Establishment of the program is contingent upon compliance with all applicable federal laws. The department may adopt rules necessary to implement conditions required by federal law.

(8) If program costs are expected to exceed the legislative authorization for the program, the department shall adjust discounted prices or eligibility standards to maintain the program within the available

funding.

(9) Participation in the program by a pharmacy or a pharmaceutical manufacturer is voluntary.

(10) (a) The department may not contract with either an in-state or out-of-state mail ~~service~~ order pharmacy, as defined in 37-7-702, for the purposes of the program for at least 1 year after persons eligible for the program have begun to purchase drugs through the program. At that time, the department shall evaluate the number of pharmacies within the state providing prescription drugs as part of the program.

(b) If the department determines that there are insufficient pharmacies participating in the program to allow reasonable access to persons qualified to purchase prescription drugs through the program, it may, after the evaluation provided for in subsection (10)(a), use one or more in-state or out-of-state mail ~~service~~ order pharmacies, or both, for the purposes of the program."

Section 22. Repealer. The following sections of the Montana Code Annotated are repealed:

37-7-307. Utilization plan -- contents -- responsibility of pharmacist.

37-7-308. Preparation and approval of utilization plan -- revocation of or refusal to renew plan -- contested case hearing.

37-7-309. Utilization plan approval fee -- renewal of approval -- renewal fee.

37-7-506. Notice to purchaser.

- END -

I hereby certify that the within bill,

HB 794, originated in the House.

_____

Chief Clerk of the House

_____

Speaker of the House

Signed this _____day

of_____, 2025.

_____

President of the Senate

Signed this _____day
of_____, 2025.

HOUSE BILL NO. 794

INTRODUCED BY C. SCHOMER, J. ETCHART

AN ACT GENERALLY REVISING PHARMACY LAWS; UPDATING AND CLARIFYING DEFINITIONS; REVISING THE DEFINITION OF A PHARMACY TECHNICIAN; REMOVING THE UTILIZATION PLAN REQUIREMENT FOR IN-STATE PHARMACIES AND OUT-OF-STATE MAIL ORDER PHARMACIES; CLARIFYING THE POWERS AND DUTIES OF THE BOARD OF PHARMACY; PROVIDING RULEMAKING AUTHORITY; REQUIRING AN ENDORSEMENT TO PRACTICE AS A CLINICAL PHARMACIST PRACTITIONER; REMOVING OUTDATED NOTIFICATION PRACTICES REGARDING BIOSIMILAR PRODUCT SELECTION; REMOVING OUTDATED GENERIC DRUG SIGNAGE REQUIREMENTS; CLARIFYING PHARMACY WHOLESALE DISTRIBUTION LICENSES; AMENDING SECTIONS 2-18-704, 37-7-101, 37-7-105, 37-7-201, 37-7-301, 37-7-306, 37-7-502, 37-7-505, 37-7-601, 37-7-602, 37-7-603, 37-7-604, 37-7-701, 37-7-702, 37-7-703, 37-7-704, 37-7-705, 37-7-706, 39-71-727, AND 53-6-1002, MCA; AND REPEALING SECTIONS 37-7-307, 37-7-308, 37-7-309 AND 37-7-506, MCA."