_____ BILL NO. _____

INTRODUCED BY _____
(Primary Sponsor)

BY REQUEST OF THE DEPARTMENT OF COMMERCE

A BILL FOR AN ACT ENTITLED: "AN ACT GENERALLY REVISING THE PRACTICE OF PHARMACY; CLARIFYING THE NUMBER OF TERMS A MEMBER OF THE BOARD OF PHARMACY MAY SERVE; PROVIDING THAT A BOARD MEMBER'S REFUSAL OR INABILITY TO PERFORM DUTIES IS GROUNDS FOR REMOVAL FROM THE BOARD; ADDING AND CLARIFYING DEFINITIONS; CLARIFYING THE DUTIES OF THE BOARD OF PHARMACY; PROVIDING FOR REGISTRATION TO PRACTICE TELEPHARMACY; PROVIDING FOR REGISTRATION FOR PHARMACY TECHNICIANS; PROVIDING FOR LICENSURE OF PHARMACY INTERNS; AND AMENDING SECTIONS 2-15-1843, 37-2-101, 37-7-101, 37-7-201, 37-7-301, 37-7-303, 37-7-307, 37-7-308, 37-7-309, 37-7-321, 37-7-322, 37-7-323, 37-7-401, 37-7-406, 37-7-502, 37-7-505, 37-7-602, AND 50-32-101, MCA."

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

Section 1. Section 2-15-1843, MCA, is amended to read:

"2-15-1843. Board of pharmacy. (1) There is a board of pharmacy.

(2) The board consists of five members appointed by the governor with the consent of the senate. Three members must be licensed pharmacists, and two members must be from the general public.

(a) Each licensed 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 member ~~shall~~ must have at least 5 consecutive years of practical experience as a pharmacist immediately before ~~his~~ appointment to the board. A licensed member who, during ~~his~~ the member's term of office, ceases to be actively engaged in the practice of pharmacy in this state ~~shall~~ must be automatically disqualified from membership on the board.

(b) 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 ~~consecutive 5-year terms on the board~~ 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 ~~shall~~ must be removed from office by the governor:

(a) ~~on~~ upon proof of malfeasance or misfeasance in office, after reasonable notice of charges against ~~him~~ 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.

~~(4)~~(5) The board is allocated to the department for administrative purposes only as prescribed in 2-15-121."

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

"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 ~~man~~ humans;

(b) to affect the structure or any function of the body of ~~man~~ humans.

(3) "Drug" ~~means any article:~~

~~(a) recognized in the official United States Pharmacopoeia/National Formulary or in any supplement to the pharmacopoeia/formulary;~~

~~(b) intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man;~~

~~(c) intended to affect the structure or any function of the body of man;~~

~~(d) intended for use as a component of any article described in subsection (a), (b), or (c) of this subsection (3), but the term does not include any device or any components of a device~~ 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; but 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(5) 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" ~~means an establishment which engages in the sale of drugs requiring a prescription~~ has the same meaning as provided in 37-7-101.

(8) "State" means the state of Montana or any political subdivision ~~thereof~~ of the state."

Section 3. Section 37-7-101, MCA, is amended to read:

"37-7-101. Definitions. ~~Unless the context requires otherwise,~~ As used in parts 1 through ~~3~~ 7 of this chapter, the following definitions apply:

(1) "Administer" means the direct application of a drug to the body of a patient by injection, inhalation, ingestion, or any other means.

~~(1)~~(2) "Board" means the board of pharmacy provided for in 2-15-1843.

~~(2)~~(3) "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.

(4) "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.

(5) "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.

~~(3)~~(6) "Commercial purposes" means the ordinary purposes of trade, agriculture, industry, and commerce, exclusive of the practices of medicine and pharmacy.

(7) "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.

(8) "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.

~~(4)~~(9) "Department" means the department of commerce provided for in Title 2, chapter 15, part 18.

(10) "Device" has the same meaning as defined in 37-2-101.

(11) "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.

(12) "Distribute" means the delivery of a drug or device by means other than administering or dispensing.

~~(5) (a)~~(13) "Drug" means a substance:

~~(i)~~(a) ~~articles~~ recognized as a drug in ~~the~~ any official ~~United States Pharmacopoeia/National Formulary~~ compendium or ~~a~~ supplement;

~~(ii)~~(b) ~~articles~~ intended for use in diagnosis, cure, mitigation, treatment, or prevention of disease in ~~people~~ humans or ~~other~~ animals;

~~(iii)~~(c) ~~articles,~~ other than food, intended to affect the structure or function of the body of ~~an individual~~ humans or ~~other animal~~ animals; and

~~(iv)~~(d) ~~articles~~ intended for use as a component of ~~an article~~ a substance specified in subsection ~~(5)(a)(i), (5)(a)(ii), or (5)(a)(iii)~~ (13)(a), (13)(b), or (13)(c).

~~(b) Drug does not include devices or their components, parts, or accessories.~~

(14) "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.

(15) "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.

~~(6)~~(16) "Intern" means ~~a natural person licensed by the department to prepare, compound, dispense, and sell drugs, medicines, chemicals, and poisons under the supervision of a registered and licensed pharmacist~~:

(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.

(17) (a) "Manufacturing" means the production, preparation, propogation, 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.

~~(7)~~(18) "Medicine" means a remedial agent which has the property of curing, preventing, treating, or mitigating diseases or which is used for this purpose.

(19) "Patient counseling" means the verbal 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.

~~(8)~~(20) "Person" includes an individual, partnership, corporation, ~~or~~ association, or other legal entity.

(21) "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.

~~(9)~~(22) "Pharmacist" means a ~~natural~~ person licensed by the ~~department~~ state to ~~prepare, compound, dispense, and sell drugs, medicines, chemicals, and poisons~~ engage in the practice of pharmacy and who may affix to the person's name the term "R.Ph.".

~~(10)~~(23) "Pharmacy" means an established place registered by the ~~department of commerce in which prescriptions,~~ board where drugs or devices ~~requiring a prescription, medicines, chemicals, and poisons~~ are ~~compounded,~~ dispensed~~, vended, or sold~~ and pharmaceutical care is provided. The term includes an established place outside of this state where drugs or devices are dispensed and pharmaceutical care is provided to residents of this state.

~~(11)~~(24) "Pharmacy ~~technician or auxiliary"~~ technician" means an individual who assists a pharmacist in the practice of pharmacy pursuant to an approved utilization plan.

~~(12)~~(25) "Poison" means a substance which, when introduced into the system, either directly or by absorption, produces violent, morbid, or fatal changes or which destroys living tissue with which it comes in contact.

(26) "Practice of pharmacy" means:

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

(b) compounding, labeling, dispensing, administering, 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.

(27) "Practice telepharmacy" means to provide pharmaceutical care through the use of information technology to patients at a distance.

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

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

(30) "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).

~~(13)~~(31) "Prescription drug order" means an order ~~given individually for the person for whom prescribed, directly from the prescriber to the furnisher or indirectly to the furnisher,~~ from a prescriber for a drug or device that is communicated directly or indirectly by the prescriber to the furnisher by means of ~~an order signed by the prescriber and bearing~~ 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 ~~the~~ quantity of the drug ~~or~~, drugs, or device prescribed, the directions for use, and the date of its issue. These stipulations apply to ~~both~~ written, oral, and telephoned prescriptions and orders derived from collaborative pharmacy practice.

~~(14) "Utilization plan" means a plan under which a pharmacist may use the services of a pharmacy technician or auxiliary 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.~~

~~(15)~~(32) "Wholesale" means a sale for the purpose of resale."

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

"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~~ vice president, and secretary.

(2) The board shall~~:~~

~~(a)~~ regulate the practice of pharmacy in this state ~~subject to this chapter;~~, including but not limited to:

~~(b)~~(a) ~~determine the minimum~~ 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 the United States Pharmacopoeia/National Formulary 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;

~~(c) regulate, under therapeutic classification, the sale of drugs, medicines, chemicals, and poisons and their labeling;~~

~~(d) regulate the quality of drugs and medicines dispensed in this state, using the United States Pharmacopoeia/National Formulary or revisions thereof as the standards;~~

~~(e)~~(b) ~~request~~ requesting the department to ~~enter and~~ 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.

~~(f)~~(c) ~~regulate~~ regulating:

(i) the training, qualifications, employment, licensure, and ~~the~~ practice of interns ~~under national standards~~;

(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) issuing certificates of "certified pharmacy" under this chapter;

(f) establishing and collecting license and registration fees;

(g) 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)(g) may not be construed to expand on the definition of the practice of pharmacy as defined in 37-7-101;

~~(g)~~(h) ~~make~~ making rules for the conduct of its business;

~~(h)~~(i) ~~perform~~ performing other duties and ~~exercise~~ exercising other powers as this chapter requires;

~~(i)~~(j) ~~adopt~~ adopting and ~~authorize~~ authorizing the department to publish rules for carrying out and enforcing parts 1 through ~~3~~ 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 pharmacists licensed in another jurisdiction to be registered to practice telepharmacy across state lines.

~~(3) The department shall:~~

~~(a) license, register, and examine, subject to 37-1-101, applicants whom the board considers qualified under this chapter;~~

~~(b) license pharmacies and certain stores under this chapter;~~

~~(c) license wholesale drug distributors;~~

~~(d) issue certificates of "certified pharmacy" under this chapter; and~~

~~(e) establish and collect license fees.~~

(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 a bill of rights for patients concerning health care services that a patient may expect with regard to pharmaceutical care."

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

"37-7-301. ~~Sale of drugs or medicines unlawful except as provided~~ Unlawful practice. Except as provided in 37-7-307 through 37-7-309, it is unlawful for a person to:

(1) ~~person to compound, dispense, vend, or sell at retail drugs, medicines, chemicals, or poisons in any place other than a pharmacy, except as hereinafter provided~~ engage in the practice of pharmacy unless licensed by the board; or

(2) ~~proprietor, owner, or manager of a pharmacy or any other person to permit the compounding or dispensing of prescriptions or the vending or selling at retail of drugs, medicines, chemicals, or poisons in any pharmacy except by a registered and licensed pharmacist or by an intern registered and licensed by the department and under the supervision of a registered and licensed pharmacist;~~

~~(3) person to assume or pretend to the title of pharmacist or intern unless the person has a license as such, issued and in force pursuant to parts 1 through 3 of this chapter;~~

~~(4) person other than a licensed and registered pharmacist or a licensed and registered intern under the supervision of a licensed and registered pharmacist to compound, dispense, vend, or sell at retail drugs, medicines, chemicals, or poisons except as provided in parts 1 through 3~~ assist in the practice of pharmacy unless registered by the board as a pharmacy technician according to the provisions of 37-7-307 through 37-7-309."

Section 6. Section 37-7-303, MCA, is amended to read:

"37-7-303. Renewal fee. A person licensed and registered by the ~~department~~ board shall pay to the ~~department~~ board on or before the license expiration date set by ~~department~~ board rule a renewal of registration fee prescribed by the board. A default in the payment of a renewal fee after the date it is due increases the renewal fee as prescribed by the board. It is unlawful for a person who refuses or fails to pay the renewal fee to practice pharmacy in this state. A certificate and renewal expires at the time prescribed by ~~department~~ board rule. A defaulter in a renewal fee may be reinstated within 1 year of the default without examination on payment of the arrears and compliance with other requirements prescribed by law."

Section 7. Section 37-7-307, MCA, is amended to read:

"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."

Section 8. Section 37-7-308, MCA, is amended to read:

"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~~ may refuse to approve or ~~shall~~ may 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."

Section 9. Section 37-7-309, MCA, is amended to read:

"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)."

Section 10. Section 37-7-321, MCA, is amended to read:

"37-7-321. Certified pharmacy license. (1) The board shall provide for the original certification and renewal by the ~~department~~ board of every pharmacy doing business in this state. On presentation of evidence satisfactory to the board and on application on a form prescribed by the board and on the payment of an original certification fee prescribed by the board, the ~~department~~ 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 renewal fee for a pharmacy must be set by the board. Any default in the payment of the renewal fee after the date the fee is due increases the renewal fee as prescribed by the board. The license must be displayed in a conspicuous place in the pharmacy for which it is issued and expires on the date set by ~~department~~ board rule. It is unlawful for a person to conduct 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.

(2) The board may impose discipline or deny or refuse to renew a pharmacy license for reasons specified in and subject to conditions specified in Title 37, chapter 1."

Section 11. Section 37-7-322, MCA, is amended to read:

"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 ~~thereof~~ of the business the words "pharmacy", "apothecary", "drug store", or "chemist shop" or any abbreviation, translation, extension, or variation ~~thereof~~ 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 ~~such~~ the term, abbreviation, translation, extension, or variation unless the ~~place so~~ business conducted is a pharmacy within the meaning of this chapter and ~~duly~~ licensed ~~as such~~ and in the charge of a ~~registered~~ licensed pharmacist."

Section 12. Section 37-7-323, MCA, is amended to read:

"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 ~~be punished accordingly and 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)."

Section 13. Section 37-7-401, MCA, is amended to read:

"37-7-401. Restrictions ~~upon sale or prescription of opiates -- coding prohibited -- refilling~~ on prescriptions. (1) It is unlawful for any ~~physician, physician assistant-certified, or nurse specialist~~ authorized prescriber to sell ~~or~~, give to, or prescribe for any person any opium, morphine, alkaloid-cocaine, ~~or~~ alpha or beta eucaine, ~~or~~ codeine, ~~or~~ heroin, or any derivative, mixture, or preparation of any of them, except to a patient believed in good faith to require ~~the same~~ 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 it 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 by a specified amount 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 ~~3 years~~ 1 year from the date it was originally filled. A ~~narcotic~~ Schedule II prescription may not be refilled."

Section 14. Section 37-7-406, MCA, is amended to read:

"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 ~~his~~ 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. ~~The sources for the standards must be nationally recognized compendia as the board may designate.~~

(2) Under the standards provided for in this section, the pharmacist should offer to discuss those

matters that, in ~~his~~ the pharmacist's professional judgment, ~~he~~ 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."

Section 15. 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 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 the official United States Pharmacopoeia/National Formulary.

(7) "Person" ~~means an individual, firm, partnership, association, corporation, or any other entity, whether organized for profit or not~~ has the same meaning as provided in 37-7-101.

(8) "Prescriber" means a practitioner licensed under the professional laws of the state to administer medicine and drugs.

(9) "Present compendium standard" means the official standard for drug excipients and drug

products listed in the latest revision of the United States Pharmacopoeia/National Formulary.

(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."

Section 16. Section 37-7-505, MCA, is amended to read:

"37-7-505. Product selection permitted -- limitation. (1) Except as limited by subsection (2) ~~of this section~~ and unless instructed otherwise by the purchaser, the pharmacist who receives a ~~written or oral~~ prescription for a specific drug product by brand or proprietary name may select a less expensive drug product with the same generic name, ~~the same~~ strength, quantity, dose, and dosage form as the prescribed drug ~~which~~ 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 ~~for his patient~~ that an equivalent drug product not be selected, the prescriber may so indicate by certifying that ~~in his professional judgment~~ 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."

Section 17. Section 37-7-602, MCA, is amended to read:

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

(1) "Blood" means whole blood collected from a single donor and processed either for transfusion or for further manufacturing.

(2) "Blood component" means that part of blood separated by physical or mechanical means.

(3) "Drug sample" means a unit of a prescription drug that is not intended to be sold and is intended to promote the sale of the drug.

(4) "Manufacturer" means a person or entity engaged in the manufacturing, preparing, propagating, compounding, processing, packaging, repackaging, or labeling of a prescription drug or device.

(5) "Prescription drug" ~~means any drug for humans that is required by federal law or regulation to be dispensed only by a prescription, including finished dosage forms and active ingredients subject to section 503(b) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C.S. 353)~~ has the same meaning as provided in 37-7-101.

(6) (a) "Wholesale drug distribution" means distribution of prescription drugs to persons other than a consumer or patient.

(b) The term does not include:

~~(a)~~(i) intracompany sales;

~~(b)~~(ii) the purchase or other acquisition, by a hospital or other health care entity that is a member of a group purchasing organization, of a drug for its own use from the group purchasing organization or from other hospitals or health care entities that are members of group purchasing organizations;

~~(c)~~(iii) the sale, purchase, or trade of a drug or an offer to sell, purchase, or trade a drug by a charitable organization described in section 501(c)(3) of the Internal Revenue Code of 1954 to a nonprofit affiliate of the organization to the extent otherwise permitted by law;

~~(d)~~(iv) the sale, purchase, or trade of a drug or an offer to sell, purchase, or trade a drug among hospitals or other health care entities that are under common control. For purposes of this subsection ~~(d)~~ (6)(b)(iv), "common control" means the power to direct or cause the direction of the management and policies of a person or an organization, whether by ownership of stock, voting rights, contract, or otherwise.

~~(e)~~(v) the sale, purchase, or trade of a drug or an offer to sell, purchase, or trade a drug for emergency medical reasons. For the purposes of this subsection ~~(e)~~ (6)(b)(v), "emergency medical reasons" includes transfers of prescription drugs by a retail pharmacy to another retail pharmacy to alleviate a temporary shortage.

~~(f)~~(vi) the sale, purchase, or trade of a drug or an offer to sell, purchase, or trade a drug, or the dispensing of a drug pursuant to a prescription;

~~(g)~~(vii) the distribution of drug samples by manufacturers' representatives or distributors' representatives; or

~~(h)~~(viii) the sale, purchase, or trade of blood and blood components intended for transfusion.

(7) "Wholesale drug distributor" means a person or entity engaged in wholesale distribution of prescription drugs, including but not limited to manufacturers, repackers, own-label distributors,

private-label distributors, jobbers, brokers, warehouses (including manufacturers' and distributors' warehouses, chain drug warehouses, and wholesale drug warehouses), independent wholesale drug traders, and retail pharmacies that conduct wholesale distributions."

Section 18. Section 50-32-101, MCA, is amended to read:

"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) "Agent" means an authorized person who acts on behalf of or at the direction of a manufacturer, distributor, or dispenser. 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 2-15-1843.

(4) "Bureau" means the drug enforcement administration, United States department of justice, or its successor agency.

(5) "Counterfeit substance" means a dangerous drug ~~that~~ 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 commerce provided for in Title 2, chapter 15, part 18.

(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) ~~(a)~~ "Drug" ~~means:~~

~~(i) a substance recognized as a drug in the official United States Pharmacopoeia/National Formulary or any supplement to it;~~

~~(ii) a substance intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in humans or animals;~~

~~(iii) a substance, other than food, intended to affect the structure or a function of the body of humans or animals; and~~

~~(iv) a substance intended for use as a component of an article specified in subsection (13)(a)(i), (13)(a)(ii), or (13)(a)(iii).~~

~~(b) Drug does not include a device or its components, parts, or accessories~~ 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" ~~has the meaning that it has in 37-7-101~~ 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 both written 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."

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