

1 HOUSE BILL NO. 279

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5
6 A BILL FOR AN ACT ENTITLED: "AN ACT GENERALLY REVISING THE PRACTICE OF PHARMACY;
7 CLARIFYING THE NUMBER OF TERMS A MEMBER OF THE BOARD OF PHARMACY MAY SERVE;
8 PROVIDING THAT A BOARD MEMBER'S REFUSAL OR INABILITY TO PERFORM DUTIES IS GROUNDS FOR
9 REMOVAL FROM THE BOARD; ADDING AND CLARIFYING DEFINITIONS; CLARIFYING THE DUTIES OF
10 THE BOARD OF PHARMACY; PROVIDING FOR REGISTRATION TO PRACTICE TELEPHARMACY;
11 PROVIDING FOR REGISTRATION FOR PHARMACY TECHNICIANS; PROVIDING FOR LICENSURE OF
12 PHARMACY INTERNS; AND AMENDING SECTIONS 2-15-1843, 37-2-101, 37-7-101, 37-7-201,
13 37-7-301, 37-7-303, 37-7-321, 37-7-322, 37-7-323, 37-7-401, 37-7-406, 37-7-502, 37-7-505,
14 37-7-602, ~~37-7-703~~, AND 50-32-101, MCA; ~~AND REPEALING SECTIONS 37-7-307, 37-7-308, AND~~
15 ~~37-7-309, MCA.~~"

16
17 BE IT ENACTED BY THE LEGISLATURE OF THE STATE OF MONTANA:

18
19 **Section 1.** Section 2-15-1843, MCA, is amended to read:

20 **"2-15-1843. Board of pharmacy.** (1) There is a board of pharmacy.

21 (2) The board consists of five members appointed by the governor with the consent of the senate.

22 Three members must be licensed pharmacists, and two members must be from the general public.

23 (a) Each licensed member must have graduated and received the first professional undergraduate
24 degree from the school of pharmacy of the university of Montana-Missoula or from an accredited pharmacy
25 degree program that has been approved by the board. Each licensed member ~~shall~~ must have at least 5
26 consecutive years of practical experience as a pharmacist immediately before ~~his~~ his appointment to the
27 board. A licensed member who, during ~~his~~ the member's term of office, ceases to be actively engaged in
28 the practice of pharmacy in this state ~~shall~~ must be automatically disqualified from membership on the
29 board.

30 (b) Each public member of the board must be a resident of the state and may not be or ever have

1 been:

2 (i) a member of the profession of pharmacy or the spouse of a member of the profession of
3 pharmacy;

4 (ii) a person having any material financial interest in the providing of pharmacy services; or

5 (iii) a person who has engaged in any activity directly related to the practice of pharmacy.

6 (3) Members shall serve staggered 5-year terms. A member may not serve ~~consecutive 5-year~~
7 ~~terms on the board~~ more than two consecutive full terms. For the purposes of this section, an
8 appointment to fill an unexpired term does not constitute a full term.

9 (4) A member ~~shall~~ must be removed from office by the governor;

10 (a) ~~on~~ upon proof of malfeasance or misfeasance in office, after reasonable notice of charges
11 against ~~him~~ the member and after a hearing; or

12 (b) upon refusal or inability to perform the duties of a board member in an efficient, responsible,
13 and professional manner.

14 (4)(5) The board is allocated to the department for administrative purposes only as prescribed in
15 2-15-121."

16

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

18 **"37-2-101. Definitions.** As used in this part, the following definitions apply:

19 (1) "Community pharmacy", when used in relation to a medical practitioner, means a pharmacy
20 situated within 10 miles of any place at which the medical practitioner maintains an office for professional
21 practice.

22 (2) "Device" means any instrument, apparatus, or contrivance intended:

23 (a) for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in ~~man~~ humans;

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

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

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

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

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

30 ~~— (d) intended for use as a component of any article described in subsection (a), (b), or (c) of this~~

1 subsection (3), but the term does not include any device or any components of a device has the same
 2 meaning as provided in 37-7-101.

3 (4) "Drug company" means any person engaged in the manufacturing, processing, packaging, or
 4 distribution of drugs; but the term does not include a pharmacy.

5 (5) "Medical practitioner" means any person licensed by the state of Montana to engage in the
 6 practice of medicine, dentistry, osteopathy, podiatry, optometry, or a nursing specialty as described in
 7 37-8-202(5) and in the licensed practice to administer or prescribe drugs.

8 (6) "Person" means any individual and any partnership, firm, corporation, association, or other
 9 business entity.

10 (7) "Pharmacy" ~~means an establishment which engages in the sale of drugs requiring a~~
 11 ~~prescription~~ has the same meaning as provided in 37-7-101.

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

13

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

15 **"37-7-101. Definitions.** ~~Unless the context requires otherwise, As used~~ in parts 1 through 3 7 of
 16 this chapter, the following definitions apply:

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

19 (b) The term does not include immunization by injection for children under 18 years of age.

20 ~~(1)(2)~~ "Board" means the board of pharmacy provided for in 2-15-1843.

21 ~~(2)(3)~~ "Chemical" means medicinal or industrial substances, whether simple, compound, or
 22 obtained through the process of the science and art of chemistry, whether of organic or inorganic origin.

23 (4) "Collaborative pharmacy practice" means the practice of pharmacy by a pharmacist who has
 24 agreed to work in conjunction with one or more prescribers, on a voluntary basis and under protocol, and
 25 who may perform certain patient care functions under certain specified conditions or limitations authorized
 26 by the prescriber.

27 (5) "Collaborative pharmacy practice agreement" means a written and signed agreement between
 28 one or more pharmacists and one or more prescribers that provides for collaborative pharmacy practice
 29 for the purpose of drug therapy management of patients.

30 ~~(3)(6)~~ "Commercial purposes" means the ordinary purposes of trade, agriculture, industry, and

1 commerce, exclusive of the practices of medicine and pharmacy.

2 (7) "Compounding" means the preparation, mixing, assembling, packaging, or labeling of a drug
3 or device based on:

4 (a) a practitioner's prescription drug order;

5 (b) a professional practice relationship between a practitioner, pharmacist, and patient;

6 (c) research, instruction, or chemical analysis, but not for sale or dispensing; or

7 (d) the preparation of drugs or devices based on routine, regularly observed prescribing patterns.

8 (8) "Confidential patient information" means privileged information accessed by, maintained by,
9 or transmitted to a pharmacist in patient records or that is communicated to the patient as part of patient
10 counseling.

11 ~~(4)(9)~~ "Department" means the department of commerce provided for in Title 2, chapter 15, part
12 18.

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

14 (11) "Dispense" or "dispensing" means the interpretation, evaluation, and implementation of a
15 prescription drug order, including the preparation and delivery of a drug or device to a patient or patient's
16 agent in a suitable container appropriately labeled for administration to or use by a patient.

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

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

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

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

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

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

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

29 (14) "Drug utilization review" means an evaluation of a prescription drug order and patient records
30 for duplication of therapy, interactions, proper utilization, and optimum therapeutic outcomes. The term

1 includes but is not limited to the following evaluations:

2 (a) known allergies;

3 (b) rational therapy contraindications;

4 (c) reasonable dose and route administration;

5 (d) reasonable directions for use;

6 (e) drug-drug interactions;

7 (f) drug-food interactions;

8 (g) drug-disease interactions; and

9 (h) adverse drug reactions.

10 (15) "Equivalent drug product" means a drug product that has the same established name, active
11 ingredient or ingredients, strength or concentration, dosage form, and route of administration and meets
12 the same standards as another drug product as determined by any official compendium or supplement.
13 Equivalent drug products may differ in shape, scoring, configuration, packaging, excipients, and expiration
14 time.

15 ~~(6)(16) "Intern" means a natural person licensed by the department to prepare, compound,~~
16 ~~dispense, and sell drugs, medicines, chemicals, and poisons under the supervision of a registered and~~
17 ~~licensed pharmacist;~~

18 (a) a person who is licensed by the state to engage in the practice of pharmacy while under the
19 personal supervision of a preceptor and who is satisfactorily progressing toward meeting the requirements
20 for licensure as a pharmacist;

21 (b) a graduate of an accredited college of pharmacy who is licensed by the state for the purpose
22 of obtaining practical experience as a requirement for licensure as a pharmacist;

23 (c) a qualified applicant awaiting examination for licensure; or

24 (d) a person participating in a residency or fellowship program.

25 (17) (a) "Manufacturing" means the production, preparation, propogation, conversion, or processing
26 of a drug or device, either directly or indirectly, by extraction from substances of natural origin or
27 independently by means of chemical or biological synthesis.

28 (b) Manufacturing includes:

29 (i) any packaging or repackaging;

30 (ii) labeling or relabeling;

1 (iii) promoting or marketing; and

2 (iv) preparing and promoting commercially available products from bulk compounds for resale by
3 pharmacies, practitioners, or other persons.

4 ~~(7)~~(18) "Medicine" means a remedial agent which has the property of curing, preventing, treating,
5 or mitigating diseases or which is used for this purpose.

6 (19) "Patient counseling" means the verbal communication by the pharmacist of information, as
7 defined by the rules of the board, to the patient or caregiver in order to ensure the proper use of drugs or
8 devices.

9 ~~(8)~~(20) "Person" includes an individual, partnership, corporation, ~~or~~ association, or other legal
10 entity.

11 (21) "Pharmaceutical care" means the provision of drug therapy and other patient care services
12 intended to achieve outcomes related to the cure or prevention of a disease, elimination or reduction of
13 a patient's symptoms, or arresting or slowing of disease process.

14 ~~(9)~~(22) "Pharmacist" means a ~~natural~~ person licensed by the ~~department~~ state to ~~prepare,~~
15 ~~compound, dispense, and sell drugs, medicines, chemicals, and poisons~~ engage in the practice of pharmacy
16 and who may affix to the person's name the term "R.Ph.".

17 ~~(10)~~(23) "Pharmacy" means an established ~~place registered by the department of commerce in~~
18 ~~which prescriptions, board where drugs or devices requiring a prescription, medicines, chemicals, and~~
19 ~~poisons are compounded, dispensed, vended, or sold and pharmaceutical care is provided. The term~~
20 ~~includes an established place outside of this state where drugs or devices are dispensed and~~
21 ~~pharmaceutical care is provided to residents of this state~~ LOCATION, EITHER PHYSICAL OR ELECTRONIC,
22 REGISTERED BY THE BOARD WHERE DRUGS OR DEVICES ARE DISPENSED WITH PHARMACEUTICAL CARE OR WHERE
23 PHARMACEUTICAL CARE IS PROVIDED.

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

26 ~~(12)~~(25) "Poison" means a substance which, when introduced into the system, either directly or
27 by absorption, produces violent, morbid, or fatal changes or which destroys living tissue with which it
28 comes in contact.

29 (26) "Practice of pharmacy" means:

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

1 (b) ~~compounding, labeling, dispensing, administering,~~ DRUGS AND DEVICES PURSUANT TO A
 2 COLLABORATIVE PRACTICE AGREEMENT AND COMPOUNDING, LABELING, DISPENSING, and distributing drugs and
 3 devices, including patient counseling;

4 (c) properly and safely procuring, storing, distributing, and disposing of drugs and devices and
 5 maintaining proper records;

6 (d) monitoring drug therapy and use;

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

9 (f) participating in quality assurance and performance improvement activities;

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

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

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

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

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

19 (30) "Prescription drug" means any drug that is required by federal law or regulation to be
 20 dispensed only by a prescription subject to section 503(b) of the Federal Food, Drug, and Cosmetic Act
 21 (21 U.S.C. 353).

22 ~~(13)~~(31) "Prescription drug order" means an order given individually for the person for whom
 23 prescribed, directly from the prescriber to the furnisher or indirectly to the furnisher, from a prescriber for
 24 a drug or device that is communicated directly or indirectly by the prescriber to the furnisher by means of
 25 an order signed by the prescriber and bearing a signed order, by electronic transmission, in person, or by
 26 telephone. The order must include the name and address of the prescriber, the prescriber's license
 27 classification, the name and address of the patient, the name, strength, and the quantity of the drug or,
 28 drugs, or device prescribed, the directions for use, and the date of its issue. These stipulations apply to
 29 both written, oral, ELECTRONICALLY TRANSMITTED, and telephoned prescriptions and orders derived from
 30 collaborative pharmacy practice.

1 ~~(14) "Utilization plan" means a plan under which a pharmacist may use the services of a pharmacy~~
 2 ~~technician or auxiliary in the practice of pharmacy to perform tasks that:~~

3 ~~—— (a) do not require the exercise of the pharmacist's independent professional judgment; and~~

4 ~~—— (b) are verified by the pharmacist.~~

5 (32) "UTILIZATION PLAN" MEANS A PLAN UNDER WHICH A PHARMACIST MAY USE THE SERVICES OF A PHARMACY
 6 TECHNICIAN IN THE PRACTICE OF PHARMACY TO PERFORM TASKS THAT:

7 (A) DO NOT REQUIRE THE EXERCISE OF THE PHARMACIST'S INDEPENDENT PROFESSIONAL JUDGMENT; AND

8 (B) ARE VERIFIED BY THE PHARMACIST.

9 ~~(15)(32)(33) "Wholesale" means a sale for the purpose of resale."~~

10

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

12 **"37-7-201. Organization -- powers and duties.** (1) The board shall meet at least once a year to
 13 transact its business. The board shall annually elect from its members a president, ~~vice-president~~ vice
 14 president, and secretary.

15 (2) The board shall:

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

18 ~~(b)(a) determine the minimum~~ establishing minimum standards for:

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

20 (ii) the purity and quality of drugs, devices, and other materials dispensed within the state through
 21 the practice of pharmacy, using the United States Pharmacopoeia/National Formulary AN OFFICIAL
 22 COMPENDIUM RECOGNIZED BY THE BOARD or current practical standards;

23 (iii) specifications for the facilities, environment, supplies, technical equipment, personnel, and
 24 procedures for the storage, compounding, or dispensing of drugs and devices;

25 (iv) monitoring drug therapy; and

26 (v) maintaining the integrity and confidentiality of prescription information and other confidential
 27 patient information;

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

30 ~~—— (d) regulate the quality of drugs and medicines dispensed in this state, using the United States~~

1 ~~Pharmacopoeia/National Formulary or revisions thereof as the standards;~~
2 ~~——(e)(b) request requesting~~ the department to ~~enter and~~ inspect, at reasonable times;
3 (i) places where drugs, medicines, chemicals, or poisons are sold, vended, given away,
4 compounded, dispensed, or manufactured; and
5 (ii) the appropriate records and the license of any person engaged in the practice of pharmacy for
6 the purpose of determining whether any laws governing the legal distribution of drugs or devices or the
7 practice of pharmacy are being violated. The board shall cooperate with all agencies charged with the
8 enforcement of the laws of the United States, other states, or this state relating to drugs, devices, and
9 the practice of pharmacy. It is a misdemeanor for a person to refuse to permit or otherwise prevent the
10 department from entering these places and making an inspection.

11 ~~(f)(c) regulate~~ regulating:
12 (i) the training, qualifications, employment, licensure, and the practice of interns under national
13 standards;
14 (ii) the training, qualifications, employment, and registration of pharmacy technicians; and
15 (iii) under therapeutic classification, the sale and labeling of drugs, devices, medicines, chemicals,
16 and poisons;
17 (d) examining applicants and issuing and renewing licenses of:
18 (i) applicants whom the board considers qualified under this chapter to practice pharmacy;
19 (ii) pharmacies and certain stores under this chapter;
20 (iii) wholesale drug distributors; and
21 (iv) persons engaged in the manufacture and distribution of drugs or devices;
22 (e) issuing certificates of "certified pharmacy" under this chapter;
23 (f) establishing and collecting license and registration fees;
24 (g) approving pharmacy practice initiatives that improve the quality of, or access to,
25 pharmaceutical care but that fall outside the scope of this chapter. This subsection (2)(g) may not be
26 construed to expand on the definition of the practice of pharmacy as defined in 37-7-101;
27 ~~(g)(h) make~~ making rules for the conduct of its business;
28 ~~(h)(i) perform~~ performing other duties and ~~exercise~~ exercising other powers as this chapter
29 requires;
30 ~~(i)(j) adopt~~ adopting and ~~authorize~~ authorizing the department to publish rules for carrying out and

1 enforcing parts 1 through ~~3~~ 7 of this chapter, including but not limited to:

2 (i) requirements and qualifications for the transfer of board-issued licenses;

3 (ii) minimum standards for pharmacy internship programs and qualifications for licensing pharmacy

4 interns;

5 (iii) qualifications and procedures for registering pharmacy technicians; and

6 (iv) requirements and procedures necessary to allow ~~pharmacists~~ A PHARMACY licensed in another
7 jurisdiction to be registered to practice telepharmacy across state lines.

8 ~~—— (3) The department shall:~~

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

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

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

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

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

15 (3) The board may:

16 (a) join professional organizations and associations organized exclusively to promote the
17 improvement of standards of the practice of pharmacy for the protection of the health and welfare of the
18 public and whose activities assist and facilitate the work of the board; and

19 (b) establish a bill of rights STANDARDS OF CARE for patients concerning health care services that
20 a patient may expect with regard to pharmaceutical care."

21

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

23 ~~"37-7-301. Sale of drugs or medicines unlawful except as provided~~ **Unlawful practice.** ~~Except as~~
24 ~~provided in 37-7-307 through 37-7-309, it is~~ EXCEPT AS PROVIDED IN 37-7-307 THROUGH 37-7-309, IT IS
25 unlawful for a person to:

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

29 (2) proprietor, owner, or manager of a pharmacy or any other person to permit the compounding
30 or dispensing of prescriptions or the vending or selling at retail of drugs, medicines, chemicals, or poisons

1 ~~in any pharmacy except by a registered and licensed pharmacist or by an intern registered and licensed~~
 2 ~~by the department and under the supervision of a registered and licensed pharmacist;~~
 3 ~~———(3) person to assume or pretend to the title of pharmacist or intern unless the person has a license~~
 4 ~~as such, issued and in force pursuant to parts 1 through 3 of this chapter;~~
 5 ~~———(4) person other than a licensed and registered pharmacist or a licensed and registered intern under~~
 6 ~~the supervision of a licensed and registered pharmacist to compound, dispense, vend, or sell at retail~~
 7 ~~drugs, medicines, chemicals, or poisons except as provided in parts 1 through 3~~ assist in the practice of
 8 pharmacy unless registered by the board as a pharmacy technician."

9

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

11 **"37-7-303. Renewal fee.** A person licensed and registered by the ~~department~~ board shall pay to
 12 the ~~department~~ board on or before the license expiration date set by ~~department~~ board rule a renewal of
 13 registration fee prescribed by the board. A default in the payment of a renewal fee after the date it is due
 14 increases the renewal fee as prescribed by the board. It is unlawful for a person who refuses or fails to
 15 pay the renewal fee to practice pharmacy in this state. A certificate and renewal expires at the time
 16 prescribed by ~~department~~ board rule. A defaulter in a renewal fee may be reinstated within 1 year of the
 17 default without examination on payment of the arrears and compliance with other requirements prescribed
 18 by law."

19

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

21 **"37-7-321. Certified pharmacy license.** (1) The board shall provide for the original certification and
 22 renewal by the ~~department~~ board of every pharmacy doing business in this state. On presentation of
 23 evidence satisfactory to the board and on application on a form prescribed by the board and on the
 24 payment of an original certification fee prescribed by the board, the ~~department~~ board shall issue a license
 25 to a pharmacy as a certified pharmacy. However, the license may be granted only to pharmacies operated
 26 by registered pharmacists qualified under this chapter. The renewal fee for a pharmacy must be set by the
 27 board. Any default in the payment of the renewal fee after the date the fee is due increases the renewal
 28 fee as prescribed by the board. The license must be displayed in a conspicuous place in the pharmacy for
 29 which it is issued and expires on the date set by ~~department~~ board rule. It is unlawful for a person to
 30 conduct a pharmacy, use the word "pharmacy" to identify the business, or use the word "pharmacy" in

1 advertising unless a license has been issued and is in effect.

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

4

5 **Section 8.** Section 37-7-322, MCA, is amended to read:

6 **"37-7-322. Use of words pharmacy, apothecary, drug store, or chemist shop for advertising.** It
7 is unlawful for a person to carry on, conduct, or transact a retail business under a name which contains
8 as a part ~~thereof~~ of the business the words "pharmacy", "apothecary", "drug store", or "chemist shop"
9 or any abbreviation, translation, extension, or variation ~~thereof~~ of those terms or in any manner by
10 advertisement circular or poster, sign, or otherwise to describe or refer to the place of business conducted
11 by that person by ~~such~~ the term, abbreviation, translation, extension, or variation unless the ~~place so~~
12 business conducted is a pharmacy within the meaning of this chapter and ~~duly~~ licensed ~~as such~~ and in the
13 charge of a ~~registered~~ licensed pharmacist."

14

15 **Section 9.** Section 37-7-323, MCA, is amended to read:

16 **"37-7-323. Penalty -- enforcement.** ~~(1)~~(1) A person, firm, partnership, or corporation violating any
17 of the provisions of parts 1 through 3 of this chapter is guilty of a misdemeanor and upon conviction for
18 each violation shall ~~be punished accordingly and shall~~ automatically lose any license issued by the board.

19 ~~(2) In addition to the penalty provided in subsection (1), the board may withdraw its approval of~~
20 ~~a utilization plan previously approved for a supervising pharmacist who:~~

21 ~~—— (a) violates any provision of 37-7-307 through 37-7-309 or rules adopted under those sections;~~

22 ~~—— (b) obtained the approval of the utilization plan through fraud; or~~

23 ~~—— (c) acts in a manner contrary to the terms of the utilization plan.~~

24 ~~—— (3) The board may seek an injunction to enforce the provisions of subsection (2).~~

25 (2) IN ADDITION TO THE PENALTY PROVIDED IN SUBSECTION (1), THE BOARD MAY WITHDRAW ITS APPROVAL OF

26 A UTILIZATION PLAN PREVIOUSLY APPROVED FOR A SUPERVISING PHARMACIST WHO:

27 (A) VIOLATES ANY PROVISION OF 37-7-307 THROUGH 37-7-309 OR RULES ADOPTED UNDER THOSE SECTIONS;

28 (B) OBTAINED THE APPROVAL OF THE UTILIZATION PLAN THROUGH FRAUD; OR

29 (C) ACTS IN A MANNER CONTRARY TO THE TERMS OF THE UTILIZATION PLAN.

30 (3) THE BOARD MAY SEEK AN INJUNCTION TO ENFORCE THE PROVISIONS OF SUBSECTION (2)."

1

2 **Section 10.** Section 37-7-401, MCA, is amended to read:

3 "**37-7-401. Restrictions ~~upon sale or prescription of opiates -- coding prohibited -- refilling on~~**
4 **prescriptions.** (1) It is unlawful for any ~~physician, physician assistant-certified, or nurse specialist~~
5 authorized prescriber to sell ~~or~~ give to, or prescribe for any person any opium, morphine, alkaloid-cocaine,
6 ~~or~~ alpha or beta eucaine, ~~or~~ codeine, ~~or~~ heroin, or any derivative, mixture, or preparation of any of them,
7 except to a patient believed in good faith to require ~~the same~~ opium, morphine, alkaloid-cocaine, alpha or
8 beta eucaine, codeine, heroin, or any derivative, mixture, or preparation of the enumerated substances for
9 medical use and in quantities proportioned to the needs of the patient.

10 (2) A prescription must be written so that it can be compounded by any registered pharmacist.
11 The coding of any prescription is a violation of this section.

12 (3) A prescription marked "non repetatur", "non rep", or "N.R." cannot be refilled. A prescription
13 marked to be refilled by a specified amount may be filled by any registered pharmacist the number of times
14 marked on the prescription. A prescription not bearing any refill instructions may not be refilled without
15 first obtaining permission from the prescriber. A prescription may not be refilled for more than ~~3 years~~ 1
16 year from the date it was originally filled. A ~~narcotic~~ Schedule II prescription may not be refilled."

17

18 **Section 11.** Section 37-7-406, MCA, is amended to read:

19 "**37-7-406. Standards for prospective drug utilization review and patient counseling.** (1) The board
20 may by rule set standards for the provision of prospective drug utilization review information from a
21 pharmacist to a patient before a prescription is dispensed to the patient or ~~his~~ the patient's representative.
22 The review may include, when applicable, an appropriate level of screening for potential drug therapy
23 problems due to therapeutic duplication, drug disease contraindications, drug interactions, incorrect drug
24 dosage or duration of drug treatment, drug-allergy interactions, and clinical abuse or misuse. ~~The sources~~
25 ~~for the standards must be nationally recognized compendia as the board may designate.~~

26 (2) Under the standards provided for in this section, the pharmacist should offer to discuss those
27 matters that, in ~~his~~ the pharmacist's professional judgment, ~~he~~ the pharmacist considers significant to the
28 patient's safe and proper use of the prescribed drug. The patient counseling should encompass the topics
29 set forth in 42 U.S.C. 1396r-8 of the Social Security Act and administrative rules established by the board.

30 (3) Communications between a pharmacist and a patient pursuant to the standards provided for

1 in this section constitute health care information for the purposes of Title 50, chapter 16, part 5.

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

6

7 **Section 12.** Section 37-7-502, MCA, is amended to read:

8 **"37-7-502. Definitions.** As used in this part, the following definitions apply:

9 (1) "Bioavailability" means the extent and rate of absorption from a dosage form as reflected by
10 the time-concentration curve of the administered drug in the systemic circulation.

11 (2) "Bioequivalent" means a chemical equivalent which, when administered to the same individual
12 in the same dosage regimen, will result in comparable bioavailability.

13 (3) "Brand name" means the proprietary or the registered trademark name given to a drug product
14 by its manufacturer, labeler, or distributor and placed upon the drug, its container, label, or wrapping at
15 the time of packaging.

16 (4) "Chemical equivalent" means drug products that contain the same amounts of the same
17 therapeutically active ingredients in the same dosage forms and that meet present compendium standards.

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

20 (6) "Generic name" means the chemical or established name of a drug product or drug ingredient
21 published in the latest edition of ~~the official United States Pharmacopoeia/National Formulary~~ AN OFFICIAL
22 COMPENDIUM RECOGNIZED BY THE BOARD.

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

25 (8) "Prescriber" means a MEDICAL practitioner, AS DEFINED IN 37-2-101, licensed under the
26 professional laws of the state to administer AND PRESCRIBE medicine and drugs.

27 (9) "Present compendium standard" means the official standard for drug excipients and drug
28 products listed in the latest revision of ~~the United States Pharmacopoeia/National Formulary~~ AN OFFICIAL
29 COMPENDIUM RECOGNIZED BY THE BOARD.

30 (10) "Product selection" means to dispense without the prescriber's express authorization a

1 different drug product in place of the drug product prescribed.

2 (11) "Therapeutically equivalent" means those chemical equivalents which, when administered in
3 the same dosage regimen, will provide essentially the same therapeutic effect as measured by the control
4 of a symptom or a disease and/or toxicity."

5

6 **Section 13.** Section 37-7-505, MCA, is amended to read:

7 **"37-7-505. Product selection permitted -- limitation.** (1) Except as limited by subsection (2) ~~of this~~
8 ~~section~~ and unless instructed otherwise by the purchaser, the pharmacist who receives a ~~written or oral~~
9 prescription for a specific drug product by brand or proprietary name may select a less expensive drug
10 product with the same generic name, ~~the same~~ strength, quantity, dose, and dosage form as the
11 prescribed drug ~~which~~ that is, in the pharmacist's professional opinion, therapeutically equivalent,
12 bioequivalent, and bioavailable.

13 (2) If, in the professional opinion of the prescriber, it is medically necessary ~~for his patient~~ that
14 an equivalent drug product not be selected, the prescriber may so indicate by certifying that ~~in his~~
15 ~~professional judgment~~ the specific brand-name drug product is medically necessary for that particular
16 patient. In the case of a prescription transmitted orally, the prescriber must expressly indicate to the
17 pharmacist that the brand-name drug product prescribed is medically necessary."

18

19 **Section 14.** Section 37-7-602, MCA, is amended to read:

20 **"37-7-602. Definitions.** As used in this part, the following definitions apply:

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

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

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

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

29 (5) "Prescription drug" ~~means any drug for humans that is required by federal law or regulation~~
30 ~~to be dispensed only by a prescription, including finished dosage forms and active ingredients subject to~~

1 ~~section 503(b) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C.S. 353)~~ has the same meaning as
 2 provided in 37-7-101.

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

5 (b) The term does not include:

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

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

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

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

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

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

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

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

27 (7) "Wholesale drug distributor" means a person or entity engaged in wholesale distribution of
 28 prescription drugs, including but not limited to manufacturers, repackers, own-label distributors,
 29 private-label distributors, jobbers, brokers, warehouses (including manufacturers' and distributors'
 30 warehouses, chain drug warehouses, and wholesale drug warehouses), independent wholesale drug

1 traders, and retail pharmacies that conduct wholesale distributions."

2

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

4 ~~"37-7-703. Registration requirements.~~ Each out-of-state mail service pharmacy must be registered
5 with the board of pharmacy. In order to be registered with the board to do business in this state and for
6 the renewal of its registration, an out-of-state mail service pharmacy:

7 ~~(1) (a) shall submit a certificate from the appropriate licensing authority with which it is currently
8 licensed and in good standing in the state in which its dispensing facilities are located; and~~

9 ~~(b) shall comply with all applicable laws, regulations, and standards of that state and the United
10 States and, if requested by the board, provide evidence that it has complied;~~

11 ~~(2) shall register with the board and provide information on ownership and location, including the
12 names and titles of the corporate officers, of the out-of-state mail service pharmacy and the identity of
13 a pharmacist licensed in the state in which the pharmacy is located who is in charge of dispensing
14 prescriptions for shipment to Montana from the out-of-state mail service pharmacy;~~

15 ~~(3) shall submit a utilization plan for the employment of pharmacy technicians if allowed by the
16 state where the mail service pharmacy is located. If the state in which the pharmacy is located does not
17 establish a ratio of technicians to pharmacists for determining the number of pharmacy technicians or
18 otherwise define the role of the pharmacist in compounding or dispensing drugs at the pharmacy, then the
19 out-of-state mail service pharmacy may not allow a pharmacist to supervise more than one supportive
20 person at any one time in the compounding or dispensing of prescription drugs, unless approved by the
21 board as provided in 37-7-307 through 37-7-309.~~

22 ~~(3) SHALL SUBMIT A UTILIZATION PLAN FOR THE EMPLOYMENT OF PHARMACY TECHNICIANS IF ALLOWED BY THE
23 STATE WHERE THE MAIL SERVICE PHARMACY IS LOCATED. IF THE STATE IN WHICH THE PHARMACY IS LOCATED DOES NOT
24 ESTABLISH A RATIO OF TECHNICIANS TO PHARMACISTS FOR DETERMINING THE NUMBER OF PHARMACY TECHNICIANS OR
25 OTHERWISE DEFINE THE ROLE OF THE PHARMACIST IN COMPOUNDING OR DISPENSING DRUGS AT THE PHARMACY, THEN THE
26 OUT-OF-STATE MAIL SERVICE PHARMACY MAY NOT ALLOW A PHARMACIST TO SUPERVISE MORE THAN ONE SUPPORTIVE
27 PERSON AT ANY ONE TIME IN THE COMPOUNDING OR DISPENSING OF PRESCRIPTION DRUGS, UNLESS APPROVED BY THE
28 BOARD AS PROVIDED IN 37-7-307 THROUGH 37-7-309.~~

29 ~~(4)(3)(4) shall submit to the board proof of the pharmacist's good standing with the licensing
30 authority in the state where the pharmacist is employed and the pharmacist's written commitment to~~

1 ~~comply with the utilization plan, if any, for each pharmacist identified under subsection (2) UTILIZATION PLAN,~~
 2 ~~IF ANY, FOR EACH PHARMACIST IDENTIFIED UNDER SUBSECTION (2) AND board rules governing the practice of~~
 3 ~~pharmacy in this state and shall provide to the board the same toll-free telephone service referenced in~~
 4 ~~37-7-706 in order to comply with all information requests by the board; and~~
 5 ~~———— (5)(4)(5) shall pay an initial registration fee and a periodic renewal fee in an amount to be~~
 6 ~~determined by the board and at a time established by the department by rule."~~

7

8 **Section 15.** Section 50-32-101, MCA, is amended to read:

9 **"50-32-101. Definitions.** As used in this chapter, the following definitions apply:

10 (1) "Administer" means the direct application of a dangerous drug, whether by injection,
 11 inhalation, ingestion, or other means, to the body of a patient or research subject by:

12 (a) a practitioner or by the practitioner's authorized agent; or

13 (b) the patient or research subject at the direction and in the presence of the practitioner.

14 (2) "Agent" means an authorized person who acts on behalf of or at the direction of a
 15 manufacturer, distributor, or dispenser. The term does not include a common or contract carrier, public
 16 warehouse operator, or employee of the carrier or warehouse operator.

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

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

20 (5) "Counterfeit substance" means a dangerous drug ~~that~~ or the container or labeling of a
 21 dangerous drug without authorization that bears the trademark, trade name, or other identifying mark,
 22 imprint, number, or device or a likeness of an identifying mark, imprint, number, or device of a
 23 manufacturer, distributor, or dispenser other than the person who in fact manufactured, distributed, or
 24 dispensed the drug.

25 (6) "Dangerous drug" means a drug, substance, or immediate precursor in Schedules I through
 26 V set forth in part 2.

27 (7) "Deliver" or "delivery" means the actual, constructive, or attempted transfer from one person
 28 to another of a dangerous drug, whether or not there is an agency relationship.

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

30 (9) "Dispense" means to deliver a dangerous drug to an ultimate user or research subject by or

1 pursuant to the lawful order of a practitioner, including the prescribing, administering, packaging, labeling,
2 or compounding necessary to prepare the drug for that delivery.

3 (10) "Dispenser" means a practitioner who dispenses.

4 (11) "Distribute" means to deliver other than by administering or dispensing a dangerous drug.

5 (12) "Distributor" means a person who distributes.

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

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

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

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

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

15 ~~—— (b) Drug does not include a device or its components, parts, or accessories has the same meaning~~
16 ~~as provided in 37-7-101.~~

17 (14) "Hashish", as distinguished from marijuana, means the mechanically processed or extracted
18 plant material that contains tetrahydrocannabinol (THC) and is composed of resin from the cannabis plant.

19 (15) "Immediate precursor" means a substance that the board finds to be and by rule designates
20 as being the principal compound commonly used or produced primarily for use and that is an immediate
21 chemical intermediary used or likely to be used in the manufacture of a dangerous drug, the control of
22 which is necessary to prevent, curtail, or limit manufacture.

23 (16) (a) "Manufacture" means the production, preparation, propagation, compounding, conversion,
24 or processing of a dangerous drug either directly or indirectly by extraction from substances of natural
25 origin, independently by means of chemical synthesis, or by a combination of extraction and chemical
26 synthesis and includes the packaging or repackaging of the drug or labeling or relabeling of its container.

27 (b) Manufacture does not include the preparation or compounding of a dangerous drug by an
28 individual for personal use or the preparation, compounding, packaging, or labeling of a dangerous drug:

29 (i) by a practitioner as an incident to the administering or dispensing of a dangerous drug in the
30 course of a professional practice; or

1 (ii) by a practitioner or the practitioner's authorized agent under the practitioner's supervision for
2 the purpose of or as an incident to research, teaching, or chemical analysis and not for sale.

3 (17) "Marijuana (marihuana)" means all plant material from the genus cannabis containing
4 tetrahydrocannabinol (THC) or seeds of the genus capable of germination.

5 (18) "Narcotic drug" means any of the following, whether produced directly or indirectly by
6 extraction from substances of vegetable origin, independently by means of chemical synthesis, or by a
7 combination of extraction and chemical synthesis:

8 (a) opium and opiate and a salt, compound, derivative, or preparation of opium or opiate;

9 (b) a salt, compound, isomer, derivative, or preparation of a salt, compound, isomer, or derivative
10 that is chemically equivalent or identical with any of the drugs referred to in subsection (18)(a), but not
11 including the isoquinoline alkaloids of opium;

12 (c) opium poppy and poppy straw; or

13 (d) coca leaves and a salt, compound, derivative, or preparation of coca leaves and a salt,
14 compound, isomer, derivative, or preparation of a salt, compound, isomer, or derivative that is chemically
15 equivalent or identical with any of these drugs, but not including decocainized coca leaves or extractions
16 of coca leaves that do not contain cocaine or ecgonine.

17 (19) "Opiate" means a drug having an addiction-forming or addiction-sustaining liability similar to
18 morphine or being capable of conversion into a drug having addiction-forming or addiction-sustaining
19 liability. The term does not include, unless specifically designated as a dangerous drug under 50-32-202,
20 the dextrorotatory isomer of 3-methoxy-n-methylmorphinan and its salts (dextromethorphan). The term
21 does include its racemic and levorotatory forms.

22 (20) "Opium poppy" means the plant of the species *papaver somniferum* L., except its seeds.

23 (21) "Person" means an individual, corporation, government or governmental subdivision or agency,
24 business trust, estate, trust, partnership, association, or any other legal entity.

25 (22) "Poppy straw" means all parts, except the seeds, of the opium poppy after mowing.

26 (23) "Practitioner" means:

27 (a) a physician, dentist, veterinarian, scientific investigator, or other person licensed, registered,
28 or otherwise permitted to distribute, dispense, or conduct research with respect to or to administer a
29 dangerous drug in the course of professional practice or research in this state;

30 (b) a pharmacy or other institution licensed, registered, or otherwise permitted to distribute,

1 dispense, or conduct research with respect to or to administer a dangerous drug in the course of
2 professional practice or research in this state; and

3 (c) a physician licensed to practice medicine or a dentist licensed to practice dentistry in another
4 state.

5 (24) "Prescription" ~~has the meaning that it has in 37-7-101~~ means an order given individually for
6 the person for whom prescribed, directly from the prescriber to the furnisher or indirectly to the furnisher,
7 by means of an order signed by the prescriber and bearing the name and address of the prescriber, the
8 prescriber's license classification, the name of the patient, the name and quantity of the drug or drugs
9 prescribed, the directions for use, and the date of its issue. These stipulations apply to both written,
10 ELECTRONICALLY TRANSMITTED, and telephoned prescriptions.

11 (25) "Production" includes the manufacture, planting, cultivation, growing, or harvesting of a
12 substance or drug regulated under the provisions of this chapter.

13 (26) "State", when applied to a part of the United States, includes a state, district, commonwealth,
14 territory, insular possession of the United States, and any area subject to the legal authority of the United
15 States of America.

16 (27) "Ultimate user" means a person who lawfully possesses a dangerous drug for personal use
17 or for the use of a member of the person's household or for administering to an animal owned by the
18 person or by a member of the person's household."

19

20 ~~NEW SECTION. Section 17. Repealer. Sections 37-7-307, 37-7-308, and 37-7-309, MCA, are~~
21 ~~repealed.~~

22

- END -