

HOUSE BILL NO. 257

INTRODUCED BY R. DRISCOLL

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A BILL FOR AN ACT ENTITLED: "AN ACT ALLOWING A MEDICAL PRACTITIONER TO DISPENSE A DRUG OR DEVICE NOT AVAILABLE AT A COMMUNITY PHARMACY; PROVIDING FOR A NONPHARMACIST AUXILIARY OF A LICENSED PHARMACIST WHO CAN DISPENSE CERTAIN DRUGS OR DEVICES; REQUIRING THE BOARD OF PHARMACY TO DETERMINE REQUIREMENTS AND PROCEDURES NECESSARY FOR LICENSING OR REGISTRATION OF NONPHARMACIST AUXILIARIES; AND AMENDING SECTIONS 37-2-104, 37-7-101, AND 37-7-201, MCA."

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

**Section 1.** Section 37-2-104, MCA, is amended to read:

**"37-2-104. Dispensing of drugs or devices by medical practitioners unlawful -- exceptions.** (1)

Except as otherwise provided by this section, it is unlawful for a medical practitioner to engage, directly or indirectly, in the dispensing of drugs.

(2) This section does not prohibit:

- (a) a medical practitioner from furnishing a patient any drug in an emergency;
- (b) the administration of a unit dose of a drug to a patient by or under the supervision of a medical practitioner;
- (c) dispensing a drug or device to a patient by a medical practitioner whenever there is no community pharmacy available to the patient or the pharmacy does not stock or dispense the prescribed drug or device;
- (d) the dispensing of drugs occasionally, but not as a usual course of doing business, by a medical practitioner;
- (e) a medical practitioner from dispensing drug samples;
- (f) the dispensing of factory prepackaged contraceptives, other than mifepristone, by:
- (i) a registered nurse employed by a family planning clinic under contract with the department of public health and human services if the dispensing is in accordance with:
  - (A) a physician's written protocol specifying the circumstances under which dispensing is appropriate;

and

1           ~~(ii)~~(B) the drug labeling, storage, and recordkeeping requirements of the board of pharmacy;

2           (ii) an auxiliary of a licensed pharmacist if the dispensing is in accordance with 37-7-307;

3           (g) a contract physician at an urban Indian clinic from dispensing drugs to qualified patients of the clinic.

4 The clinic may not stock or dispense any dangerous drug, as defined in 50-32-101, or any controlled substance.

5 The contract physician may not delegate the authority to dispense any drug for which a prescription is required  
6 under 21 U.S.C. 353(b)."

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

9           **"37-7-101. Definitions.** As used in parts 1 through 7 of this chapter, the following definitions apply:

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

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

13           (2) "Auxiliary" means a nonpharmacist adult employed by a licensed pharmacy who assists a licensed  
14 pharmacist in the practice of pharmacy or telepharmacy.

15           ~~(2)~~(3) "Board" means the board of pharmacy provided for in 2-15-1733.

16           ~~(3)~~(4) "Chemical" means medicinal or industrial substances, whether simple, compound, or obtained  
17 through the process of the science and art of chemistry, whether of organic or inorganic origin.

18           ~~(4)~~(5) "Collaborative pharmacy practice" means the practice of pharmacy by a pharmacist who has  
19 agreed to work in conjunction with one or more prescribers, on a voluntary basis and under protocol, and who  
20 may perform certain patient care functions under certain specified conditions or limitations authorized by the  
21 prescriber.

22           ~~(5)~~(6) "Collaborative pharmacy practice agreement" means a written and signed agreement between  
23 one or more pharmacists and one or more prescribers that provides for collaborative pharmacy practice for the  
24 purpose of drug therapy management of patients.

25           ~~(6)~~(7) "Commercial purposes" means the ordinary purposes of trade, agriculture, industry, and  
26 commerce, exclusive of the practices of medicine and pharmacy.

27           ~~(7)~~(8) "Compounding" means the preparation, mixing, assembling, packaging, or labeling of a drug or  
28 device based on:

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

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

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

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

3 ~~(8)(9)~~ "Confidential patient information" means privileged information accessed by, maintained by, or  
4 transmitted to a pharmacist in patient records or that is communicated to the patient as part of patient counseling.

5 ~~(9)(10)~~ "Department" means the department of labor and industry provided for in Title 2, chapter 15, part  
6 17.

7 ~~(10)(11)~~ "Device" has the same meaning as defined in 37-2-101.

8 ~~(11)(12)~~ "Dispense" or "dispensing" means the interpretation, evaluation, and implementation of a  
9 prescription drug order, including the preparation and delivery of a drug or device to a patient or patient's agent  
10 in a suitable container appropriately labeled for administration to or use by a patient.

11 ~~(12)(13)~~ "Distribute" means the delivery of a drug or device by means other than administering or  
12 dispensing.

13 ~~(13)(14)~~ "Drug" means a substance:

14 (a) recognized as a drug in any official compendium or supplement;

15 (b) intended for use in diagnosis, cure, mitigation, treatment, or prevention of disease in humans or  
16 animals;

17 (c) other than food, intended to affect the structure or function of the body of humans or animals; and

18 (d) intended for use as a component of a substance specified in subsection ~~(13)(a)~~ (14)(a), ~~(13)(b)~~  
19 (14)(b), or ~~(13)(c)~~ (14)(c).

20 ~~(14)(15)~~ "Drug utilization review" means an evaluation of a prescription drug order and patient records  
21 for duplication of therapy, interactions, proper utilization, and optimum therapeutic outcomes. The term includes  
22 but is not limited to the following evaluations:

23 (a) known allergies;

24 (b) rational therapy contraindications;

25 (c) reasonable dose and route administration;

26 (d) reasonable directions for use;

27 (e) drug-drug interactions;

28 (f) drug-food interactions;

29 (g) drug-disease interactions; and

30 (h) adverse drug reactions.

1           ~~(15)~~(16) "Equivalent drug product" means a drug product that has the same established name, active  
2 ingredient or ingredients, strength or concentration, dosage form, and route of administration and meets the same  
3 standards as another drug product as determined by any official compendium or supplement. Equivalent drug  
4 products may differ in shape, scoring, configuration, packaging, excipients, and expiration time.

5           ~~(16)~~(17) "Intern" means:

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

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

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

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

13           ~~(17)~~(18) (a) "Manufacturing" means the production, preparation, propagation, conversion, or processing  
14 of a drug or device, either directly or indirectly, by extraction from substances of natural origin or independently  
15 by means of chemical or biological synthesis.

16           (b) Manufacturing includes:

17           (i) any packaging or repackaging;

18           (ii) labeling or relabeling;

19           (iii) promoting or marketing; and

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

22           ~~(18)~~(19) "Medicine" means a remedial agent that has the property of curing, preventing, treating, or  
23 mitigating diseases or which is used for this purpose.

24           ~~(19)~~(20) "Patient counseling" means the communication by the pharmacist of information, as defined by  
25 the rules of the board, to the patient or caregiver in order to ensure the proper use of drugs or devices.

26           ~~(20)~~(21) "Person" includes an individual, partnership, corporation, association, or other legal entity.

27           ~~(21)~~(22) "Pharmaceutical care" means the provision of drug therapy and other patient care services  
28 intended to achieve outcomes related to the cure or prevention of a disease, elimination or reduction of a patient's  
29 symptoms, or arresting or slowing of disease process.

30           ~~(22)~~(23) "Pharmacist" means a person licensed by the state to engage in the practice of pharmacy and

1 who may affix to the person's name the term "R.Ph."

2 ~~(23)~~(24) "Pharmacy" means an established location, either physical or electronic, registered by the board  
3 where drugs or devices are dispensed with pharmaceutical care or where pharmaceutical care is provided.

4 ~~(24)~~(25) "Pharmacy technician" means an individual who assists a pharmacist in the practice of  
5 pharmacy.

6 ~~(25)~~(26) "Poison" means a substance that, when introduced into the system, either directly or by  
7 absorption, produces violent, morbid, or fatal changes or that destroys living tissue with which it comes in contact.

8 ~~(26)~~(27) "Practice of pharmacy" means:

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

10 (b) administering drugs and devices pursuant to a collaborative practice agreement and compounding,  
11 labeling, dispensing, and distributing drugs and devices, including patient counseling;

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

14 (d) monitoring drug therapy and use;

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

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

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

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

22 ~~(27)~~(28) "Practice telepharmacy" means to provide pharmaceutical care through the use of information  
23 technology to patients at a distance.

24 ~~(28)~~(29) "Preceptor" means an individual who is registered by the board and participates in the  
25 instructional training of a pharmacy intern.

26 ~~(29)~~(30) "Prescriber" has the same meaning as provided in 37-7-502.

27 ~~(30)~~(31) "Prescription drug" means any drug that is required by federal law or regulation to be dispensed  
28 only by a prescription subject to section 503(b) of the Federal Food, Drug, and Cosmetic Act, ~~{21 U.S.C. 353}~~.

29 ~~(31)~~(32) "Prescription drug order" means an order from a prescriber for a drug or device that is  
30 communicated directly or indirectly by the prescriber to the furnisher by means of a signed order, by electronic

1 transmission, in person, or by telephone. The order must include the name and address of the prescriber, the  
 2 prescriber's license classification, the name and address of the patient, the name, strength, and quantity of the  
 3 drug, drugs, or device prescribed, the directions for use, and the date of its issue. These stipulations apply to  
 4 written, oral, electronically transmitted, and telephoned prescriptions and orders derived from collaborative  
 5 pharmacy practice.

6 ~~(32)~~(33) "Utilization plan" means a plan under which a pharmacist may use the services of a pharmacy  
 7 technician or auxiliary in the practice of pharmacy or telepharmacy to perform tasks that:

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

9 (b) are verified by the pharmacist.

10 ~~(33)~~(34) "Wholesale" means a sale for the purpose of resale."  
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12 **Section 3.** Section 37-7-201, MCA, is amended to read:

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

15 (2) The board shall regulate the practice of pharmacy in this state, including but not limited to:

16 (a) establishing minimum standards for:

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

18 (ii) the purity and quality of drugs, devices, and other materials dispensed within the state through the  
 19 practice of pharmacy, using an official compendium recognized by the board or current practical standards;

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

22 (iv) monitoring drug therapy; and

23 (v) maintaining the integrity and confidentiality of prescription information and other confidential patient  
 24 information;

25 (b) requesting the department to inspect, at reasonable times:

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

28 (ii) the appropriate records and the license of any person engaged in the practice of pharmacy for the  
 29 purpose of determining whether any laws governing the legal distribution of drugs or devices or the practice of  
 30 pharmacy are being violated. The board shall cooperate with all agencies charged with the enforcement of the

1 laws of the United States, other states, or this state relating to drugs, devices, and the practice of pharmacy. It  
2 is a misdemeanor for a person to refuse to permit or otherwise prevent the department from entering these places  
3 and making an inspection.

4 (c) regulating:

5 (i) the training, qualifications, employment, licensure, and practice of interns;

6 (ii) the training, qualifications, employment, and registration of pharmacy technicians; and

7 (iii) under therapeutic classification, the sale and labeling of drugs, devices, medicines, chemicals, and  
8 poisons;

9 (d) examining applicants and issuing and renewing licenses of:

10 (i) applicants whom the board considers qualified under this chapter to practice pharmacy;

11 (ii) pharmacies and certain stores under this chapter;

12 (iii) wholesale drug distributors; and

13 (iv) persons engaged in the manufacture and distribution of drugs or devices;

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

15 (f) establishing and collecting license and registration fees;

16 (g) approving pharmacy practice initiatives that improve the quality of, or access to, pharmaceutical care  
17 but that fall outside the scope of this chapter. This subsection (2)(g) may not be construed to expand on the  
18 definition of the practice of pharmacy as defined in 37-7-101.

19 (h) making rules for the conduct of its business;

20 (i) performing other duties and exercising other powers as this chapter requires;

21 (j) adopting and authorizing the department to publish rules for carrying out and enforcing parts 1 through  
22 7 of this chapter, including but not limited to:

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

24 (ii) minimum standards for pharmacy internship programs and qualifications for licensing pharmacy  
25 interns;

26 (iii) qualifications and procedures for registering pharmacy technicians; ~~and~~

27 (iv) requirements and procedures necessary to allow a pharmacy licensed in another jurisdiction to be  
28 registered to practice telepharmacy across state lines; and

29 (v) requirements and procedures necessary for licensing or registration of nonpharmacist auxiliaries for  
30 the purpose of dispensing prepackaged contraceptives.

