

HOUSE BILL NO. 284

INTRODUCED BY S. DICKENSON

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A BILL FOR AN ACT ENTITLED: "AN ACT CREATING THE MONTANA PHARMACY PATIENT PROTECTION ACT; ESTABLISHING REQUIREMENTS FOR PHARMACIES AND PHARMACISTS UNDER THIS ACT; PROVIDING FOR RULEMAKING AUTHORITY; AND AMENDING SECTION 37-7-101, MCA."

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

NEW SECTION. **Section 1. Short title.** [Sections 1 through 4] may be cited as the "Montana Pharmacy Patient Protection Act".

NEW SECTION. **Section 2. Requirements of pharmacy.** (1) (a) A pharmacy has a duty to properly fill prescription drug orders for drugs or devices that it carries for customers without undue delay.

(b) As used in this section, "undue delay" means an extension of the normal delivery cycle sufficient to jeopardize or alter the patient treatment plan.

(2) If a pharmacy does not have a prescription drug or device that it carries in stock, the pharmacy shall offer to:

- (a) obtain the drug or device under its standard expedited ordering procedures; or
- (b) locate a pharmacy of the patient's choice that is reasonably accessible to the patient and that has the drug or device in stock and transfer the prescription drug order there in accordance with the pharmacy's standard procedure.

(3) If a pharmacy does not carry a prescription drug or device and a patient presents a prescription drug order for that drug or device, the pharmacy shall offer to locate a pharmacy that is reasonably accessible to the patient and that has the drug or device in stock.

NEW SECTION. **Section 3. Requirements for pharmacists.** (1) The board shall establish ethical conduct standards for pharmacists under [sections 1 through 4]. A pharmacist:

(a) shall provide written notice to the pharmacist's employer 90 days prior to refusing services to patients on personal grounds;



- 1 (b) may not destroy unfilled prescription drug orders;
2 (c) may not refuse to return unfilled prescription drug orders;
3 (d) may not violate a patient's privacy; and
4 (e) may not discriminate against a patient or a patient's agent in a manner prohibited by state or federal
5 law.

6 (2) Violations of these standards constitutes grounds for discipline or other enforcement actions
7 considered appropriate by the board.

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9 **NEW SECTION. Section 4. Rulemaking.** The board may adopt, amend, or repeal rules necessary for
10 the implementation, continuation, and enforcement of [sections 1 through 4] in accordance with the Montana
11 Administrative Procedure Act.

12
13 **Section 5.** Section 37-7-101, MCA, is amended to read:
14 **"37-7-101. Definitions.** As used in parts 1 through 7 of this chapter and [sections 1 through 4], the
15 following definitions apply:

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

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

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

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

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

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

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

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

- 3 (a) a practitioner's prescription drug order;
4 (b) a professional practice relationship between a practitioner, pharmacist, and patient;
5 (c) research, instruction, or chemical analysis, but not for sale or dispensing; or
6 (d) the preparation of drugs or devices based on routine, regularly observed prescribing patterns.

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

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

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

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

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

15 (13) "Drug" means a substance:

- 16 (a) recognized as a drug in any official compendium or supplement;
17 (b) intended for use in diagnosis, cure, mitigation, treatment, or prevention of disease in humans or
18 animals;
19 (c) other than food, intended to affect the structure or function of the body of humans or animals; and
20 (d) intended for use as a component of a substance specified in subsection (13)(a), (13)(b), or (13)(c).

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

- 24 (a) known allergies;
25 (b) rational therapy contraindications;
26 (c) reasonable dose and route administration;
27 (d) reasonable directions for use;
28 (e) drug-drug interactions;
29 (f) drug-food interactions;
30 (g) drug-disease interactions; and

1 (h) adverse drug reactions.

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

6 (16) "Intern" means:

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

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

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

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

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

17 (b) Manufacturing includes:

18 (i) any packaging or repackaging;

19 (ii) labeling or relabeling;

20 (iii) promoting or marketing; and

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

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

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

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

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

1 (22) "Pharmacist" means a person licensed by the state to engage in the practice of pharmacy and who
2 may affix to the person's name the term "R.Ph."

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

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

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

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

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

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

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

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

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

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 (33) "Wholesale" means a sale for the purpose of resale."
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11 **NEW SECTION. Section 6. Codification instruction.** [Sections 1 through 4] are intended to be codified
12 as an integral part of Title 37, chapter 7, and the provisions of Title 37, chapter 7, apply to [sections 1 through 4].

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