SENATE BILL NO. 112

INTRODUCED BY T. MCGILLVRAY

A BILL FOR AN ACT ENTITLED: “AN ACT REVISING PHARMACIST PRESCRIBING AUTHORITY TO ALLOW THE PRESCRIBING OF CERTAIN DRUGS OR DEVICES UNDER LIMITED CIRCUMSTANCES; PROVIDING DEFINITIONS; AMENDING SECTIONS 37-2-101, 37-2-102, 37-2-103, 37-2-104, 37-2-108, 37-7-101, AND 37-7-103, MCA.”

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

NEW SECTION. **Section 1. Pharmacist prescribing authority -- exception.** (1) A pharmacist may prescribe a drug or device for a legitimate medical purpose as allowed under this section for a person with whom the pharmacist has a patient-prescriber relationship.

(2) A pharmacist shall establish the patient-prescriber relationship through a documented patient evaluation that is adequate to:

(a) establish diagnoses, if the drug or device is being prescribed pursuant to subsection (3)(b); and

(b) identify underlying conditions and contraindications to the treatment.

(3) A pharmacist's prescribing authority is limited to drugs and devices that are prescribed for conditions that:

(a) do not require a new diagnosis; or

(b) (i) are minor and generally self-limiting;

(ii) are diagnosed by or for which clinical decisions are made using a test that is waived under the federal clinical laboratory improvement amendments of 1988; or

(iii) are patient emergencies.

(4) A pharmacist may prescribe only the drugs or devices for which the pharmacist is educationally prepared and for which competency has been achieved and maintained.

(5) A pharmacist may not prescribe a controlled substance.

(6) A pharmacist prescribing a drug or device pursuant to this section shall:

(a) recognize the limits of the pharmacist's knowledge and experience and consult with and refer to other health care providers as appropriate; and

(b) maintain documentation sufficient to justify the care provided, including but not limited to the:

(i) information collected as part of the patient record;

(ii) prescription record;

(iii) provider notification; and

(iv) follow-up care plan.

(7) This section does not apply to a pharmacist who is operating within a collaborative pharmacy practice agreement.

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) "Collaborative pharmacy practice agreement" has the meaning provided in 37-7-101.

~~(1)~~(2) "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)~~(3) "Controlled substance" has the meaning provided in 37-7-101.

~~(3)~~(4) "Device" means any instrument, apparatus, or contrivance intended:

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

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

~~(4)~~(5) "Dispense" has the meaning provided in 37-7-101.

~~(5)~~(6) "Drug" has the meaning provided in 37-7-101.

~~(6)~~(7) "Drug company" means any person engaged in the manufacturing, processing, packaging, or distribution of drugs. The term does not include a pharmacy.

~~(7)~~(8) "Medical practitioner" means any person licensed by the state of Montana to engage in:

(a) the practice of medicine, dentistry, osteopathy, podiatry, or optometry;

(b) the practice of pharmacy and authorized to:

(i) prescribe immunizations pursuant to 37-7-105; or

(ii) prescribe drugs pursuant to [section 1] or in accordance with a collaborative pharmacy practice agreement;~~,~~ or

(c) a nursing specialty as described in 37-8-202 and in the licensed practice to administer or prescribe drugs.

~~(8)~~(9) "Naturopathic physician" means a person licensed under Title 37, chapter 26, to practice naturopathic health care.

~~(9)~~(10) "Opioid" has the meaning of "opiate" provided in 50-32-101.

~~(10)~~(11)~~–~~ "Opioid-naive patient" means a patient who has not been prescribed a drug containing an opioid in the 90 days prior to the acute event or surgery for which an opioid is prescribed.

~~(11)~~(12)~~–~~ "Person" means any individual and any partnership, firm, corporation, association, or other business entity.

~~(12)~~(13)~~–~~ "Pharmacy" has the meaning provided in 37-7-101.

~~(13)~~(14)~~–~~ "State" means the state of Montana or any political subdivision of the state."

Section 3. Section 37-2-102, MCA, is amended to read:

"**37-2-102. Practices declared unlawful between drug companies and medical practitioners -- exception.** (1) ~~It~~ Except as provided in subsection (2), it is unlawful:

~~(1)~~(a) for a drug company to give or sell to a medical practitioner any legal or beneficial interest in the company or in the income of the company with the intent or for the purpose of inducing the medical practitioner to prescribe to patients the drugs of the company. The giving or selling of an interest by the company to a medical practitioner without the interest first having been publicly offered to the general public is prima facie evidence of the intent or purpose.

~~(2)~~(b) for a medical practitioner to acquire or own a legal or beneficial interest in any drug company, provided it is not unlawful for a medical practitioner to acquire or own an interest solely for investment, and the acquisition of an interest that is publicly offered to the general public is prima facie evidence of its acquisition solely for investment; or

~~(3)~~(c) for a medical practitioner to solicit or to knowingly receive from a drug company or for a drug company to pay or to promise to pay to a medical practitioner any rebate, refund, discount, commission, or

other valuable consideration for, on account of, or based upon the volume of wholesale or retail sales, at any place, of drugs manufactured, processed, packaged, or distributed by the company.

(2) Subsection (1)(c) does not prohibit a pharmacy licensed under Title 37, chapter 7, from undertaking activities allowed under Title 37, chapter 7."

Section 4. Section 37-2-103, MCA, is amended to read:

"**37-2-103. Practices declared unlawful between medical practitioners and pharmacies -- exceptions.** (1) It is unlawful for a medical practitioner other than a pharmacist to own, directly or indirectly, a community pharmacy. This subsection does not prohibit a medical practitioner from dispensing a drug that the medical practitioner is permitted to dispense under 37-2-104.

(2) It is unlawful for a medical practitioner, directly or indirectly, to solicit or to knowingly receive from a community pharmacy or for a community pharmacy knowingly to pay or promise to pay to a medical practitioner any rebate, refund, discount, commission, or other valuable consideration for, on account of, or based upon income received or resulting from the sale or furnishing by the community pharmacy of drugs to patients of a medical practitioner.

(3) Subsection (2) does not prohibit a pharmacy licensed under Title 37, chapter 7, from undertaking activities allowed under Title 37, chapter 7."

Section 5. Section 37-2-104, MCA, is amended to read:

"**37-2-104. Dispensing of drugs by medical practitioners -- registration -- exceptions.** (1) Subject to subsection (7), a medical practitioner may dispense drugs if the practitioner:

(a) registers with the board of pharmacy provided for in 2-15-1733; and

(b) complies with the requirements of this section.

(2) Drugs dispensed by a medical practitioner must be:

(a) dispensed directly by the practitioner at the practitioner's office or place of practice;

(b) dispensed only to the practitioner's own patients; and

(c) necessary in the treatment of the condition for which the practitioner is attending the patient.

(3) Before dispensing a drug, a medical practitioner shall offer to give a patient the prescription in a

written, electronic, or facsimile form that the patient may choose to have filled by the practitioner or any pharmacy.

(4) Except as otherwise provided in this section, a medical practitioner:

(a) may dispense only those drugs that the practitioner is allowed to prescribe under the practitioner's scope of practice unless the practitioner is engaged in the practice of pharmacy and dispensing a drug pursuant to Title 37, chapter 7; and

(b) may not dispense a controlled substance unless the practitioner is engaged in the practice of pharmacy and is dispensing a controlled substance pursuant to Title 37, chapter 7.

(5) A medical practitioner dispensing drugs shall comply with and is subject to the provisions of this part and the provisions of:

(a) Title 37, chapter 7, parts 4, 5, and 15;

(b) Title 50, chapter 31, parts 3 and 5;

(c) the labeling, storage, inspection, and recordkeeping requirements established by the board of pharmacy; and

(d) all applicable federal laws and regulations.

(6) A medical practitioner registering with the board of pharmacy shall pay a fee established by the board by rule. The fee must be paid at the time of registration and on each renewal of the practitioner's license.

(7) Except as provided in subsection (8), a medical practitioner registered with the board of pharmacy may not dispense drugs to an injured worker being treated pursuant to Title 39, chapter 71.

(8) This section does not prohibit any of the following when a medical practitioner has not registered to dispense drugs or when a practitioner registered to dispense drugs is treating an injured worker pursuant to Title 39, chapter 71:

(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 to a patient by a medical practitioner whenever there is no community pharmacy available to the patient;

(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 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:

(i) a physician's written protocol specifying the circumstances under which dispensing is appropriate; and

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

(g) a contract physician at an urban Indian clinic from dispensing drugs to qualified patients of the clinic. The clinic may not stock or dispense any dangerous drug, as defined in 50-32-101, or any controlled substance. The contract physician may not delegate the authority to dispense any drug for which a prescription is required under 21 U.S.C. 353(b).

(h) a medical practitioner from dispensing a drug if the medical practitioner has prescribed the drug and verified that the drug is not otherwise available from a community pharmacy. A drug dispensed pursuant to this subsection (8)(h) must meet the labeling, storage, and recordkeeping requirements of the board of pharmacy.

(i) a medical practitioner from dispensing an opioid antagonist as provided in 50-32-605."

Section 6. Section 37-2-108, MCA, is amended to read:

"**37-2-108. (Temporary) Restriction on prescriptions for opioid-naive patients -- exceptions.** (1) Except as provided in subsection (2), when a medical practitioner or a naturopathic physician <u>authorized to prescribe an opioid</u> prescribes an opioid to an opioid-naive patient on an outpatient basis, the prescription may not be for more than a 7-day supply.

(2) The restriction imposed under subsection (1) does not apply if:

(a) in the professional medical judgment of the medical practitioner or naturopathic physician, a prescription for more than a 7-day supply is necessary to treat chronic pain, pain associated with cancer, or pain experienced while the patient is in palliative care; or

(b) the opioid being prescribed is designed for the treatment of opioid abuse or dependence,

including but not limited to opioid agonists and opioid antagonists. (Terminates June 30, 2025--sec. 8, Ch. 89, L. 2019.)"

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

"**37-7-101. Definitions.** As used in this chapter, the following definitions apply:

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

(b) Except as provided in 37-7-105, the term does not include immunization by injection for children under 18 years of age.

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

(3) "Cancer drug" means a prescription drug used to treat:

(a) cancer or its side effects; or

(b) the side effects of a prescription drug used to treat cancer or its side effects.

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

(5) "Clinical pharmacist practitioner" means a licensed pharmacist in good standing who meets the requirements specified in 37-7-306.

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

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

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

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

(a) a practitioner's prescription drug order;

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

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

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

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

(11) "Controlled substance" means a substance designated in Schedules II through V of Title 50, chapter 32, part 2.

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

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

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

(15) "Distribute" or "distribution" means the sale, purchase, trade, delivery, handling, storage, or receipt of a drug or device and does not include administering or dispensing a prescription drug, pursuant to section 353(b)(1), or a new animal drug, pursuant to section 360b(b) of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. 301, et seq.

(16) "Drug" means a substance:

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

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

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

(d) intended for use as a component of a substance specified in subsection (16)(a), (16)(b), or (16)(c).

(17) "Drug utilization review" means an evaluation of a prescription drug order and patient records

for duplication of therapy, interactions, proper utilization, and optimum therapeutic outcomes. The term includes but is not limited to the following evaluations:

(a) known allergies;

(b) rational therapy contraindications;

(c) reasonable dose and route administration;

(d) reasonable directions for use;

(e) drug-drug interactions;

(f) drug-food interactions;

(g) drug-disease interactions; and

(h) adverse drug reactions.

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

(19) "FDA" means the United States food and drug administration.

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

(21) (a) "Health clinic" means a facility in which advice, counseling, diagnosis, treatment, surgery, care, or services relating to preserving or maintaining health are provided on an outpatient basis for a period of less than 24 consecutive hours to a person not residing at or confined to the facility.

(b) The term includes an outpatient center for primary care and an outpatient center for surgical services, as those terms are defined in 50-5-101, and a local public health agency as defined in 50-1-101.

(c) The term does not include a facility that provides routine health screenings, health education, or immunizations.

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

(a) an electronic health record system;

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

(c) a pharmacy dispensing system; or

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

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

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

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

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

(25) "Intern" means:

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

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

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

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

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

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

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

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

(a) engages in compounding of sterile drugs;

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

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

(30) "Participant" means a physician's office, pharmacy, hospital, or health clinic that has elected to voluntarily participate in the cancer drug repository program provided for in 37-7-1403 and that accepts donated cancer drugs or devices under rules adopted by the board.

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

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

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

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

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

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

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

(38) "Practice of pharmacy" means:

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

(b) administering drugs and devices pursuant to a collaborative practice agreement, except as provided in 37-7-105, and compounding, labeling, dispensing, and distributing drugs and devices, including patient counseling;

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

(d) prescribing drugs and devices in accordance with [section 1];

~~(d)~~(e) monitoring drug therapy and use;

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

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

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

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

(39) "Practice pharmacy by means of telehealth" means to provide pharmaceutical care through the use of information technology to patients at a distance.

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

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

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

(43) "Prescription drug order" means an order from a prescriber for a drug or device that is communicated directly or indirectly by the prescriber to the furnisher by means of a signed order, by electronic transmission, in person, or by telephone. The order must include the name and address of the prescriber, the prescriber's license classification, the name and address of the patient, the name, strength, and quantity of the drug, drugs, or device prescribed, the directions for use, and the date of its issue. These stipulations apply to written, oral, electronically transmitted, and telephoned prescriptions and orders derived from collaborative pharmacy practice.

(44) "Provisional community pharmacy" means a pharmacy that has been approved by the board, including but not limited to federally qualified health centers, as defined in 42 CFR 405.2401, where prescription drugs are dispensed to appropriately screened, qualified patients.

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

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

(47) "Utilization plan" means a plan under which a pharmacist may use the services of a pharmacy technician in the practice of pharmacy to perform tasks that:

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

(b) are verified by the pharmacist.

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

Section 8. Section 37-7-103, MCA, is amended to read:

"**37-7-103. Exemptions.** Subject only to 37-2-104, 37-7-401, and 37-7-402, this chapter does not:

(1) subject a medical practitioner, as defined in 37-2-101, who is not a pharmacist or a person who is licensed in this state to practice veterinary medicine to inspection by the board, prevent the person from compounding or using drugs, medicines, chemicals, or poisons in the person's practice, or prevent a medical practitioner from furnishing to a patient drugs, medicines, chemicals, or poisons that the person considers proper in the treatment of the patient;

(2) prevent the sale of drugs, medicines, chemicals, or poisons at wholesale;

(3) prevent the sale of drugs, chemicals, or poisons at either wholesale or retail for use for commercial purposes or in the arts;

(4) change any of the provisions of this code relating to the sale of insecticides and fungicides;

(5) prevent the sale of common household preparations and other drugs if the stores selling them are licensed under the terms of this chapter;

(6) apply to or interfere with manufacture, wholesaling, vending, or retailing of flavoring extracts, toilet articles, cosmetics, perfumes, spices, and other commonly used household articles of a chemical nature for use for nonmedicinal purposes;

(7) prevent a registered nurse employed by a family planning clinic under contract with the department of public health and human services from dispensing factory prepackaged contraceptives, other than mifepristone, if the dispensing is in accordance with a physician's written protocol specifying the circumstances under which dispensing is appropriate and is in accordance with the board's requirements for labeling, storage, and recordkeeping of drugs; or

(8) prevent a certified agency from possessing, or a certified euthanasia technician or support personnel under the supervision of the employing veterinarian from administering, any controlled substance authorized by the board of veterinary medicine for the purpose of euthanasia pursuant to Title 37, chapter 18, part 6."

NEW SECTION. **Section 9. Codification instruction.** [Section 1] is intended to be codified as an integral part of Title 37, chapter 7, part 1, and the provisions of Title 37, chapter 7, apply to [section 1].

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