HOUSE BILL NO. 409

INTRODUCED BY J. POMNICHOWSKI

A BILL FOR AN ACT ENTITLED: "AN ACT ESTABLISHING A CANCER DRUG REPOSITORY PROGRAM AND PARTICIPANT REGISTRY; PROVIDING DEFINITIONS; PROVIDING IMMUNITY; AND AMENDING SECTIONS 37-7-101, 37-7-1401, 37-7-1402, AND 37-7-1408, MCA."

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

NEW SECTION. **Section 1. Cancer drug repository program -- donations -- registry.** (1) The board shall establish a cancer drug repository program for accepting donated cancer drugs and devices and dispensing the drugs and devices to qualified patients. Participation in the program is voluntary.

(2) Any person or entity, including but not limited to a health care facility or the manufacturer of a cancer drug or device, may donate cancer drugs or devices to a participant pursuant to the provisions of [sections 1 through 3].

(3) The board shall establish and maintain a registry of participants in the cancer drug repository program. The participant registry must:

(a) include the participant's name, address, and telephone number; and

(b) identify whether the participant is a physician's office, pharmacy, hospital, or health clinic.

(4) The board shall make the participant registry available to a person or entity wishing to donate a cancer drug or device to the cancer drug repository program.

NEW SECTION. **Section 2. Cancer drugs accepted or dispensed -- conditions.** (1) (a) Unless otherwise prohibited by law, a cancer drug or device may be accepted or dispensed under the cancer drug repository program established under [section 1] if the drug or device is in its original, unopened, sealed, and tamper-evident unit dose packaging.

(b) A cancer drug packaged in single-unit doses may be accepted and dispensed if the outside packaging is opened but the single-unit dose packaging is unopened.

(2) A cancer drug may not be accepted or dispensed under this section if the drug:

(a) bears an expiration date that is earlier than 6 months after the date the drug was donated; or

(b) is considered adulterated or misbranded under the provisions of Title 50, chapter 31, part 3.

(3) Subject to the limitations provided in this section, an unused cancer drug or device dispensed under the medicaid program provided for in Title 53, chapter 6, may be accepted and dispensed under the cancer drug repository program.

(4) A cancer drug or device donated under this program must be stored:

(a) separately from other prescription drugs or stock;

(b) according to the manufacturer's recommended storage conditions; and

(c) in the compounding or dispensing area if stored in a pharmacy.

(5) In dispensing a donated cancer drug or device, a participant shall give first priority to a qualified patient in the participant's service area. Other cancer patients may receive donated cancer drugs or devices if a qualified patient is not available.

(6) A participant shall notify a patient if the patient is receiving a cancer drug or device that has been donated.

NEW SECTION. **Section 3. Participants -- duties -- fee authorized.** (1) A participant shall comply with all applicable provisions of state and federal law relating to the storage, distribution, and dispensing of a donated cancer drug or device and shall inspect all donated drugs and devices before dispensing them to determine if they are adulterated or misbranded.

(2) A cancer drug or device may be:

(a) dispensed only pursuant to a prescription issued by a prescriber authorized to prescribe cancer drugs or devices; or

(b) distributed to another participant for dispensing.

(3) A cancer drug or device donated to the cancer drug repository program may not be resold.

(4) A participant may charge a handling fee for distributing or dispensing a cancer drug or device.

(5) A participant shall maintain records of donated drugs and devices and the distribution of the drugs and devices.

(6) (a) For cancer drugs or devices that are donated to the participant, records maintained pursuant to subsection (5) must include but are not limited to the following information:

(i) the date the participant received the cancer drug or device;

(ii) the drug name, strength, and amount;

(iii) the prescription number;

(iv) the expiration date of the drug;

(v) the manufacturer's name and lot number; and

(vi) the name and address of the person or entity donating the drug.

(b) For cancer drugs or devices that are distributed or dispensed by the participant, records maintained pursuant to subsection (5) must include but are not limited to the following information:

(i) the name and address of the receiving person or entity;

(ii) the name, strength, and quantity of the drug;

(iii) the dosage form, if applicable;

(iv) the name and address of the participant who distributed or dispensed the drug or device;

(v) the date the participant distributed or dispensed the drug or device;

(vi) the manufacturer's name and lot number; and

(vii) the expiration date of the drug.

Section 4. Section 37-7-101, MCA, is amended to read:

"37-7-101. Definitions. As used in ~~parts 1 through 7 of~~ 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) 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.

~~(3)~~(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.

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

~~(5)~~(6) "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.

~~(6)~~(7) "Commercial purposes" means the ordinary purposes of trade, agriculture, industry, and

commerce, exclusive of the practices of medicine and pharmacy.

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

(a) a practitioner's prescription drug order;

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

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

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

~~(8)~~(9) "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.

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

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

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

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

~~(13)~~(14) "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 ~~(13)(a)~~ (14)(a), ~~(13)(b)~~ (14)(b), or ~~(13)(c)~~ (14)(c).

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

(a) known allergies;

(b) rational therapy contraindications;

(c) reasonable dose and route administration;

(d) reasonable directions for use;

(e) drug-drug interactions;

(f) drug-food interactions;

(g) drug-disease interactions; and

(h) adverse drug reactions.

~~(15)~~(16) "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.

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

(18) (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.

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

~~(16)~~(20) "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.

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

~~(17)~~(22) (a) "Manufacturing" means the production, preparation, ~~propogation~~ 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.

(b) Manufacturing includes:

(i) any packaging or repackaging;

(ii) labeling or relabeling;

(iii) promoting or marketing; and

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

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

(24) "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 [section 1] and that accepts donated cancer drugs or devices under rules adopted by the board.

~~(19)~~(25) "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.

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

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

~~(22)~~(28) "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.".

~~(23)~~(29) "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.

~~(24)~~(30) "Pharmacy technician" means an individual who assists a pharmacist in the practice of pharmacy.

~~(25)~~(31) "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.

~~(26)~~(32) "Practice of pharmacy" means:

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

(b) administering drugs and devices pursuant to a collaborative practice agreement 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) monitoring drug therapy and use;

(e) initiating or modifying drug therapy in accordance with collaborative pharmacy practice agreements

established and approved by health care facilities or voluntary agreements with prescribers;

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

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

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

~~(27)~~(33) "Practice telepharmacy" means to provide pharmaceutical care through the use of information technology to patients at a distance.

~~(28)~~(34) "Preceptor" means an individual who is registered by the board and participates in the instructional training of a pharmacy intern.

~~(29)~~(35) "Prescriber" has the same meaning as provided in 37-7-502.

~~(30)~~(36) "Prescription drug" means any drug that is required by federal law or regulation to be dispensed only by a prescription subject to section 503(b) of the Federal Food, Drug, and Cosmetic Act, ~~(~~21 U.S.C. 353~~)~~.

~~(31)~~(37) "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.

(38) "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.

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

~~(32)~~(40) "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.

~~(33)~~(41) "Wholesale" means a sale for the purpose of resale."

Section 5. Section 37-7-1401, MCA, is amended to read:

"37-7-1401. ~~Department of public health and human services and board of pharmacy to create program~~ Programs for donation of unused prescription drugs, cancer drugs, and devices -- rulemaking required. (1) The board of pharmacy shall, in consultation and cooperation with the department of public health and human services, create a program for the donation of prescription drugs collected from long-term care facilities to qualified patients.

(2) For the purposes of the program created pursuant to subsection (1), prescription drugs, except those drugs defined as a dangerous drug in 50-32-101 or a drug designated as a precursor to a controlled substance in 50-32-401, unneeded by a resident or former resident of a long-term care facility may be donated by the long-term care facility to a provisional community pharmacy that provides or may provide prescription drugs to individuals who are qualified patients for transfer free of charge or at a reduced charge to those individuals.

(3) This section does not amend or otherwise change the law applicable to the prescribing of prescription drugs, the sale of those drugs, or the licensing of long-term care facilities or pharmacies.

(4) The board of pharmacy shall adopt rules to implement this part. The rules must address ~~the subjects of~~:

(a) the collection, ~~and~~ receipt, and storage of donated ~~prescription~~ drugs and devices ~~from residents of long-term care facilities, keeping of those drugs within the long-term care facility,~~;

(b) the transfer of ~~the drugs~~ prescription drugs donated by a long-term care facility to provisional community pharmacies~~,~~;

(c) which pharmacies may be considered provisional community pharmacies that may sell or give the prescription drugs donated by long-term care facilities to others~~, and~~;

(d) eligibility criteria and other standards and procedures for participants that accept and distribute or dispense donated cancer drugs or devices;

(e) the forms needed for the administration of the donated drug programs;

(f) categories of cancer drugs and devices that the cancer drug repository program will accept for dispensing and categories it will not accept, including the reason that a cancer drug or device will not be accepted;

(g) the price for which the prescription drugs donated by a long-term care facility may be sold; and

(h) the maximum handling fee that may be charged by participants that accept and distribute or dispense a cancer drug or device.

(5) In adopting the rules, the board of pharmacy shall consider the ability of persons to pay for the drugs

and the existence and operation of similar programs in other states.

~~(5) As used in this part, the following definitions apply:~~

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

~~(b) "Provisional community pharmacy" means the practice of pharmacy at a site 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.~~

~~(c) "Qualified patients" mean persons who are uninsured, indigent, or have insufficient funds to obtain needed prescription drugs.~~"

Section 6. Section 37-7-1402, MCA, is amended to read:

"37-7-1402. ~~Long-term care facilities to delete identifying~~ Identifying information to be deleted from donated ~~prescription~~ drugs or devices. ~~A long-term care facility~~ A person or entity donating a prescription drug, a cancer drug, or a device pursuant to the ~~program~~ programs created under this part shall delete from the container in which ~~that~~ the drug or device is held any information by which the ~~long-term care facility resident or former resident~~ person for whom the ~~drugs were~~ drug or device was prescribed may be identified."

Section 7. Section 37-7-1408, MCA, is amended to read:

"37-7-1408. ~~Immunity~~ Donated drugs and devices -- immunities ~~for long-term care patients and facilities donating prescription drugs~~. (1) A resident or former resident of a long-term care facility and the long-term care facility donating a prescription drug, a cancer drug, or a device as part of the ~~program~~ programs created pursuant to this part are not liable for simple negligence in the donation of a drug or device if the requirements of this part and the rules implementing this part have been complied with.

(2) Except as provided in subsection (3), a person or entity, including the manufacturer of a cancer drug or device that exercises reasonable care in donating, accepting, distributing, or dispensing a cancer drug or device under the provisions of [sections 1 through 3] and rules adopted by the board is immune from civil or criminal liability or professional disciplinary action of any kind for an injury, death, or loss to a person or property relating to the accepting, distributing, or dispensing of the cancer drug or device.

(3) (a) The donation of a cancer drug or device by the manufacturer of the drug or device does not absolve the manufacturer from criminal or civil liability or increase a liability that would have existed had the drug or device not been donated.

(b) The civil immunity provisions of subsection (2) do not apply to a person employed by or an entity

operated by the state or a political subdivision of the state."

NEW SECTION. **Section 8. Codification instruction.** [Sections 1 through 3] are intended to be codified as an integral part of Title 37, chapter 7, part 14, and the provisions of Title 37, chapter 7, part 14, apply to [sections 1 through 3].

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