HOUSE BILL NO. 231

INTRODUCED BY C. KNUDSEN, Z. PERRY

A BILL FOR AN ACT ENTITLED: "AN ACT GENERALLY REVISING THE SCOPE OF PRACTICE FOR PHARMACISTS ALLOWED TO ADMINISTER VACCINES; EXPANDING RULEMAKING AUTHORITY; AMENDING SECTIONS 37-7-101 AND 37-7-105, MCA; AND PROVIDING AN EFFECTIVE DATE."

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

Section 1. 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~~ For ~~children under 18 years of age, an immunization by injection is subject to rules adopted under 37-7-105.~~

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

(23) "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.

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

(25) "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.

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

(27) "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.

(28) "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.

(29) "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.

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

(31) "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.

(32) "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.".

(33) "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.

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

(35) "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.

(36) "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) 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.

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

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

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

(40) "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.

(41) "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.

(42) "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.

(43) "Qualified patient" means a person who is uninsured, indigent, or has insufficient funds to obtain

needed prescription drugs or cancer drugs.

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

(45) "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.

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

Section 2. Section 37-7-105, MCA, is amended to read:

"37-7-105. Administration of immunizations. (1) An immunization-certified pharmacist may prescribe and administer ~~the following~~ immunizations without a collaborative practice agreement in place TO INDIVIDUALS 7 YEARS OF AGE OR OLDER as provided by board rule and based on the board's adoption by rule of the most recent guidelines by vaccine and age group published by the United States centers for disease control and prevention.~~:~~

~~(a) influenza to individuals who are 12 years of age or older;~~

~~(b) pneumococcal, tetanus, and diphtheria to individuals who are 18 years of age or older;~~

~~(c) herpes zoster to those individuals identified in the guidelines published by the United States centers for disease control and prevention's advisory committee on immunization practices; or~~

~~(d)~~(2) ~~in~~ In the event of an adverse reaction, a pharmacist may administer epinephrine or diphenhydramine ~~to individuals who are 12 years of age or older~~.

(3) IF A PHARMACIST PROVIDES AN IMMUNIZATION THAT IS PART OF A SERIES REQUIRING MULTIPLE DOSES OVER TIME, THE PHARMACIST SHALL NOTIFY THE INDIVIDUAL OR THE INDIVIDUAL'S LEGAL REPRESENTATIVE AT THE TIME THE NEXT IMMUNIZATION IN THE SERIES IS DUE TO BE ADMINISTERED BY SENDING A NOTICE TO THE INDIVIDUAL OR REPRESENTATIVE THAT THE FOLLOWUP IMMUNIZATION IS NEEDED TO FULFILL THE SERIES REQUIREMENT.

~~(2)~~(3)(4) A pharmacist who administers an immunization pursuant to this section shall:

(a) ensure that the individual who is being immunized is assessed for contraindications to immunization;

(b) ensure that the individual who is being immunized or the individual's legal representative receives a copy of the appropriate vaccine information statement;

(c) ~~report an adverse reaction~~ if the pharmacist is notified of ~~the~~ an adverse reaction, report the reaction to:

(i) the patient's primary health care provider, if the patient identifies one; and

(ii) to the vaccine adverse event reporting system established under the United States department of health and human services;

(d) provide a signed certificate of immunization to the ~~primary health care provider of each~~ PRIMARY HEALTH CARE PROVIDER, IF KNOWN, OF EACH individual who is immunized ~~and to the individual who is immunized~~ AND TO THE INDIVIDUAL WHO IS IMMUNIZED that includes the individual's name, date of immunization, address of immunization, administering pharmacist, immunization agent, manufacturer, and lot number; ~~and~~

(e) create a record for each immunization, in which the individual's name, date, address of immunization, administering pharmacist, immunization agent, manufacturer, and lot number are included, and maintain the record for 7 years from the date the immunization was administered; AND

(F) OFFER THE PATIENT THE OPPORTUNITY TO HAVE THE IMMUNIZATION INFORMATION REPORTED TO THE STATE IMMUNIZATION INFORMATION SYSTEM.

~~(3)~~(4)(5) For the purposes of this section, the following definitions apply:

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

(i) has successfully completed a vaccine course of training that is approved by the United States centers for disease control and prevention, by a provider accredited by the accreditation counsel for pharmacy education, or by an authority approved by the board and that, at a minimum, includes instruction on a hands-on injection technique, clinical evaluation of indications and contraindications of vaccines, storage and handling, and documentation and reporting; and ~~and who~~

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

(b) "Vaccine information statement" means an information sheet that is produced by the United States centers for disease control and prevention that explains the benefits and risks associated with a vaccine to a vaccine recipient or the legal representative of the vaccine recipient."

NEW SECTION. **Section 3. Effective date.** [This act] is effective July 1, 2019.

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