SENATE BILL NO. 535

INTRODUCED BY K. BOGNER

A BILL FOR AN ACT ENTITLED: "AN ACT REVISING LAWS RELATED TO EXPERIMENTAL TREATMENTS; PROVIDING FOR LICENSING OF EXPERIMENTAL TREATMENT CENTERS; AMENDING THE RIGHT TO TRY ACT; PROVIDING DEFINITIONS; PROVIDING RULEMAKING AUTHORITY; AMENDING DEFINITIONS; AMENDING SECTIONS 33-1-102, 37-3-103, 50-5-101, 50-12-102, 50-12-103, 50-12-104, 50-12-105, 50-12-106, 50-12-107, 50-12-108, 50-12-109, AND 50-12-110, MCA; AND PROVIDING AN IMMEDIATE EFFECTIVE DATE."

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

NEW SECTION. **Section 1. Licensure of experimental treatment centers -- fees -- rulemaking.** (1) (a) The department shall adopt procedures for licensing experimental treatment centers. A person may not operate an experimental treatment center without a license. The application for a license must include:

(i) the name and address of the applicant;

(ii) the location of the experimental treatment center;

(iii) the name of the person or persons who will manage or supervise the experimental treatment center; and

(iv) other information required by the department by rule.

(b) The department shall approve or deny the application within 90 calendar days after receiving a complete application.

(2) The department shall adopt administrative rules for licensure, including but not limited to rules establishing:

(a) minimum operational standards;

(b) the creation of written policies and procedures;

(c) oversight mechanisms;

applications, charge membership fees, and provide air ambulance services to subscription members and designated members of their households.

(14) This code does not apply to guaranteed asset protection waivers that are governed by Title 30, chapter 14, part 22, or to vehicle theft protection products or vehicle theft protection product warranties that are governed by Title 30, chapter 14, part 13.

(15) This code does not apply to direct patient care agreements established pursuant to 50-4-107.

(16) This code does not apply to a health care sharing ministry that meets the requirements of 50-4-111.

(17) This code does not apply to a regulatory sandbox waiver, except as otherwise specified by the commissioner or as provided in 33-2-2501. (Subsection (17) terminates July 30, 2029--sec. 5, Ch. 546, L. 2023.)"

Section 3. Section 37-3-103, MCA, is amended to read:

"**37-3-103. Exemptions from licensing requirements.** (1) This chapter does not prohibit or require a license with respect to any of the following acts:

(a) the gratuitous rendering of services in cases of emergency or catastrophe;

(b) the rendering of services in this state by a physician lawfully practicing medicine in another state or territory. However, if the physician does not limit the services to an occasional case or if the physician has any established or regularly used hospital connections in this state or maintains or is provided with, for the physician's regular use, an office or other place for rendering the services, the physician must possess a license to practice medicine in this state.

(c) the practice of dentistry under the conditions and limitations defined by the laws of this state;

(d) the practice of podiatry under the conditions and limitations defined by the laws of this state;

(e) the practice of optometry under the conditions and limitations defined by the laws of this state;

(f) the practice of chiropractic under the conditions and limitations defined by the laws of this state;

(g) the practice of Christian Science, with or without compensation, and ritual circumcisions by rabbis;

(h) the practice of medicine by a physician licensed in another state and employed by the federal government;

(i) the rendering of nursing services by registered or other nurses in the lawful discharge of their duties as nurses or of midwife services by registered nurse-midwives under the conditions and limitations defined by law;

(j) the rendering of services by interns or resident physicians in a hospital or clinic in which they are training, subject to the conditions and limitations of this chapter;

(k) the rendering of services by a surgical or medical technician or medical assistant, as provided in 37-3-104, under the appropriate amount and type of supervision of a person licensed under the laws of this state to practice medicine, but this exemption does not extend the scope of the individuals listed in this subsection (1)(k);

(l) the rendering of services by a physician assistant in accordance with Title 37, chapter 20;

(m) the practice by persons licensed under the laws of this state to practice a limited field of the healing arts, including physical therapists and other licensees not specifically designated, under the conditions and limitations defined by law;

(n) the execution of a death sentence pursuant to 46-19-103;

(o) the practice of direct-entry midwifery. For the purpose of this section, the practice of direct-entry midwifery means the advising, attending, or assisting of a woman during pregnancy, labor, natural childbirth, or the postpartum period. Except as authorized in 37-27-302, a direct-entry midwife may not dispense or administer a prescription drug, as those terms are defined in 37-7-101.

(p) the use of an automated external defibrillator pursuant to Title 50, chapter 6, part 5; or

(q) the rendering of experimental treatment services by a ~~health care provider~~ physician exclusively through a licensed experimental treatment center pursuant to Title 50, chapter 12, part 1, provided that:

(i) the ~~health care provider~~ physician holds a valid license in ~~any~~ good standing in another state, territory, or jurisdiction, registers with the department of labor and industry, and has appropriate qualifications as determined by the center; and

(ii) delivers services under the supervision of a medical director licensed to practice medicine in the state.

(2) Licensees referred to in subsection (1) who are licensed to practice a limited field of healing arts shall confine themselves to the field for which they are licensed or registered and to the scope of their respective licenses and, with the exception of those licensees who hold a medical degree, may not use the title "M.D.", "D.O.", or any word or abbreviation to indicate or to induce others to believe that they are engaged in the diagnosis or treatment of persons afflicted with disease, injury, or defect of body or disorder of mind except to the extent and under the conditions expressly provided by the law under which they are licensed."

Section 4. Section 50-5-101, MCA, is amended to read:

"**50-5-101. Definitions.** As used in parts 1 through 3 of this chapter, unless the context clearly indicates otherwise, the following definitions apply:

(1) "Accreditation" means a designation of approval.

(2) "Activities of daily living" means tasks usually performed in the course of a normal day in a resident's life that include eating, walking, mobility, dressing, grooming, bathing, toileting, and transferring.

(3) "Adult day-care center" means a facility, freestanding or connected to another health care facility, that provides adults, on a regularly scheduled basis, with the care necessary to meet the needs of daily living but that does not provide overnight care.

(4) (a) "Adult foster care home" means a private home or other facility that offers, except as provided in 50-5-216, only light personal care or custodial care to four or fewer disabled adults or aged persons who are not related to the owner or manager of the home by blood, marriage, or adoption or who are not under the full guardianship of the owner or manager.

(b) As used in this subsection (4), the following definitions apply:

(i) "Aged person" means a person as defined by department rule as aged.

(ii) "Custodial care" means providing a sheltered, family-type setting for an aged person or disabled adult so as to provide for the person's basic needs of food and shelter and to ensure that a specific person is available to meet those basic needs.

experimental treatment.

(3) A manufacturer, health care provider, or health care facility is not required to make an ~~investigational drug, biological product, or device~~ experimental treatment available to a patient."

Section 7. Section 50-12-104, MCA, is amended to read:

"**50-12-104. Patient requirements.** A patient is eligible for an experimental treatment ~~with an investigational drug, biological product, or device~~ if the patient has:

(1) ~~considered all~~ evaluated other treatment options currently approved by the United States food and drug administration;

(2) received a recommendation from the patient's treating health care provider for an ~~investigational drug, biological product, or device~~ experimental treatment;

(3) given ~~written~~ informed consent for the use of the ~~investigational drug, biological product, or device~~ experimental treatment; and

(4) received documentation from the treating health care provider that the patient meets the requirements of this section."

Section 8. Section 50-12-105, MCA, is amended to read:

"**50-12-105. ~~Written informed~~ Informed consent required.** (1) A patient or a patient's legal guardian ~~must~~ shall provide ~~written~~ informed consent ~~for~~ to receive an experimental treatment ~~with an investigational drug, biological product, or device~~.

(2) At a minimum, the ~~written~~ informed consent must include:

(a) an explanation of the currently approved products, ~~and~~ treatments, and services relevant to the patient's ~~for the~~ disease, ~~or~~ condition, or desired health outcomes ~~from which the patient suffers~~;

(b) an attestation that the patient concurs with the treating health care provider in believing that ~~all~~ currently approved and conventionally recognized treatments are either unlikely to ~~improve the patient's condition~~ achieve the patient's desired health outcomes or are otherwise impractically available ~~to achieve the patient's desired health outcomes~~;

(c) clear identification of the specific ~~investigational drug, biological product, or device~~ experimental treatment that the patient is seeking to use;

(d) a description of the potentially best and worst outcomes of ~~using the investigational drug, biological product, or device~~ receiving the experimental treatment and a realistic description of the most likely outcome;

(e) a statement that the patient's health plan or third-party administrator and provider are not obligated to pay for any care or treatments consequent to the use of the ~~investigational drug, biological product, or device~~ experimental treatment unless they are specifically required to do so by law or contract;

(f) as applied to patients potentially eligible for hospice care, a statement that the patient's eligibility for hospice care may be withdrawn if the patient begins curative treatment with the ~~investigational drug, biological product, or device~~ experimental treatment and that hospice care may be reinstated if the treatment ends and the patient meets hospice eligibility requirements; ~~and~~

(g) a statement that the patient understands that the patient is liable for all expenses related to the use of the ~~investigational drug, biological product, or device~~ experimental treatment and that the liability for expenses extends to the patient's estate, unless a contract between the patient and the manufacturer, ~~of the drug, biological product, or device~~ health care provider, or health care facility providing the experimental treatment states otherwise; and

(h) a statement that the patient acknowledges that the experimental treatment cannot be used to assist with ending the patient's natural life.

~~(3) The description of potential outcomes required under subsection (2)(d) must:~~

~~(a) include the possibility that new, unanticipated, different, or worse symptoms might result; and~~

~~(b) be based on the treating health care provider's knowledge of the proposed treatment in conjunction with an awareness of the patient's condition.~~

~~(4)~~(3) The ~~written~~ informed consent must ~~be~~:

(a) (i) be signed by:

~~(i)~~(A) the patient;

~~(ii)~~(B) a parent or legal guardian, if the patient is a minor; or

~~(iii)~~(C) a legal guardian, if a guardian has been appointed pursuant to Title 72, chapter 5; and

~~(b)~~(ii) be attested to by the patient's treating health care provider and a witness; or

(b) include verified comprehension and consent through interactive discussions with the individuals set forth in subsection (3)(a) that have been recorded using audio, video, or any other digital platform.

(4) For transparency and quality purposes~~,~~:

(a) it is recommended that health care providers and health care facilities utilize the enhanced informed consent process set forth in subsection (3)(b); and

(b) a physician providing services at an experimental treatment center shall notify the patient regarding where the physician is licensed to practice medicine."

Section 9. Section 50-12-106, MCA, is amended to read:

"**50-12-106. Effect on insurance coverage and health care services.** (1) This part does not:

(a) expand the coverage required of an insurer under Title 33 or of the state or a local government under Title 2 or Title 53;

(b) affect the requirements for insurance coverage of routine patient costs for patients involved in approved cancer clinical trials pursuant to 2-18-704, 33-22-101, 33-22-153, 33-31-111, 33-35-306, 53-4-1005, or 53-6-101;

(c) require a health plan, third-party administrator, or governmental agency to pay costs associated with the use, care, or treatment of a patient with an ~~investigational drug, biological product, or device; or~~ experimental treatment;

(d) require a health care facility to provide new or additional services; or

(e) prevent health care facilities or health care providers from establishing payment requirements for experimental treatments and other services related to the provision of experimental treatments.

(2) A health plan, third-party administrator, or governmental agency may provide coverage for the cost of an ~~investigational drug, biological product, or device~~ experimental treatment or the cost of services related to the ~~use~~ provision of an ~~investigational drug, biological product, or device~~ experimental treatment under this part.

(3) A health care facility may approve the ~~use~~ provision of an ~~investigational drug, biological product, or device~~ experimental treatment in the health care facility.

(4) An experimental treatment ~~facility~~ center may enter into provider agreements and establish any payment arrangement, including digital and alternative currencies, with patients, providers, or third-party payers."

Section 10. Section 50-12-107, MCA, is amended to read:

"**50-12-107. Heirs not liable for payments.** If a patient dies while being treated with an ~~investigational drug, biological product, or device~~ experimental treatment, the patient's heirs are not liable for any outstanding debt related to the treatment or to a lack of insurance as a result of the treatment."

Section 11. Section 50-12-108, MCA, is amended to read:

"**50-12-108. Disciplinary action prohibited.** (1) A licensing board may not revoke, fail to renew, suspend, or take any action against a license issued under Title 37 to a health care provider based solely on the health care provider's recommendations to a patient regarding access to or provision of an experimental treatment ~~with an investigational drug, biological product, or device~~.

(2) The department of public health and human services may not take action against:

(a) a health care provider's medicare certification based solely on the health care provider's recommendation that a patient have access to an ~~investigational drug, biological product, or device~~ experimental treatment; or

(b) a health care facility's license based solely on the facility's recommendation to a patient regarding access to or the provision of an experimental treatment in accordance with this part."

Section 12. Section 50-12-109, MCA, is amended to read:

"**50-12-109. State action prohibited.** (1) An official, employee, or agent of the state ~~of Montana~~ may not block or attempt to block:

(a) a patient's access to an ~~investigational drug, biological product, or device~~ experimental