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; ESTABLISHING A HEALTH FREEDOM AND ACCESS REQUIREMENT FOR EXPERIMENTAL TREATMENT CENTERS; ESTABLISHING THE INSURANCE PREMIUM SUPPORT ACCOUNT AND RELATED STRUCTURE; 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, AND 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;

(iv) how the experimental treatment center will fulfill the health freedom and access requirement provided in [section 2]; 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;

(d) facility inspections;

(e) facility safety standards; and

(f) data collection and quality assurance systems, including outcome monitoring and adverse event reporting.

(3) (a) The fee to process an application for an experimental treatment center is $10,000 to assist with administrative processing costs.

(b) The annual renewal fee is $5,000.

NEW SECTION. **Section 2. Health freedom and access requirement.** (1) A licensed experimental treatment center shall allocate 2% of its net annual profits to support access to experimental treatments and health care for qualifying Montana residents. This allocation must be documented on a form provided by the department and submitted by February 1 of each year.

(2) The health freedom and access requirement prescribed in subsection (1) may be fulfilled by:

(a) providing free experimental treatment, as that term is defined in 50-12-102, to qualifying Montana residents in an amount that is equal to at least 2% of the center's net annual profits; or

(b) contributing 2% of the center's net annual profits into the insurance premium support account established in [section 3].

(3) The department shall develop policies and procedures, including application and reimbursement processes, to:

(a) determine who are qualifying Montana residents for the purpose of implementing this section; and

(b) support requests by Montana residents for the provision of experimental treatments at experimental treatment centers under this section.

NEW SECTION. **Section 3. Insurance premium support account -- contributions --**

nonsupplantation of funds -- reporting. (1) There is an insurance premium support account in the state special revenue fund in the state treasury. The money in the account is allocated to the department of public health and human services to fund health insurance premiums for Montana residents who:

(a) purchase health insurance on the federal health insurance marketplace; and

(b) have an income between 139% and 400% of the federal poverty level.

(2) The department of public health and human services may accept contributions from experimental treatment centers as provided for in [section 2]. Contributions must be deposited into the insurance premium support account.

(3) Funds deposited in the insurance premium support account may be used only for the purpose authorized in subsection (1) and may not be used to pay the expenses of any other program or service administered in whole or in part by the department of public health and human services or any other state government entity.

(4) By September 1 of each year, the department of public health and human services shall provide a written report detailing the use of funds in the insurance premium support account to the children, families, health, and human services interim committee in accordance with 5-11-210.

Section 4. Section 33-1-102, MCA, is amended to read:

"**33-1-102. Compliance required -- exceptions -- health service corporations -- health maintenance organizations -- governmental insurance programs -- service contracts.** (1) A person may not transact a business of insurance in Montana or a business relative to a subject resident, located, or to be performed in Montana without complying with the applicable provisions of this code.

(2) The provisions of this code do not apply with respect to:

(a) domestic farm mutual insurers as identified in chapter 4, except as stated in chapter 4;

(b) domestic benevolent associations as identified in chapter 6, except as stated in chapter 6; ~~and~~

(c) fraternal benefit societies, except as stated in chapter 7; and

(d) direct agreements between a health care provider or health care facility as defined in 50-12-102 and a patient for the provision of an experimental treatment or services related to the provision of an experimental treatment.

(b) If the financial risk for ambulance service insurance is with an entity other than the county, city, or town, the entity is subject to the provisions of this code.

(12) This code does not apply to the self-insured student health plan established in Title 20, chapter 25, part 14.

(13) Except as provided in 33-2-2212, this code does not apply to private air ambulance services that are in compliance with 50-6-320 and that solicit membership subscriptions, accept membership 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 5.** 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 an y 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 5. 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.

(iv) long-term care hospitals; or

(v) critical access hospitals.

~~(53)~~(54)"State long-term care facilities plan" means the plan prepared by the department to project the need for long-term care facilities within Montana and approved by the governor and a statewide health coordinating council appointed by the director of the department.

~~(54)~~(55)"Swing bed" means a bed approved pursuant to 42 U.S.C. 1395tt to be used to provide either acute care or extended skilled nursing care to a patient."

Section 6. Section 50-12-102, MCA, is amended to read:

"**50-12-102. Definitions.** As used in this part, the following definitions apply:

(1) "Experimental treatment" means the provision of a medical intervention by a health care provider involving an investigational drug, biological product, device, or other treatment that has successfully completed phase 1 of a clinical trial but has not yet been approved for general use by the United States food and drug administration and either:

(a) remains under investigation in a clinical trial approved by the United States food and drug administration; or

(b) has a demonstrated safety record through documented clinical evidence from a qualified medical institution as defined by department rule.

(2) "Experimental treatment center" has the same meaning as provided in 50-5-101.

~~(1)~~(3) "Health care facility" has the same meaning as provided in 50-5-101. The term includes an experimental treatment center.

~~(2)~~(4) "Health care provider" means any of the following individuals licensed pursuant to Title 37 ~~or otherwise exempted pursuant to 37-3-103~~:

(a) a physician;

(b) an advanced practice registered nurse authorized by the board of nursing to prescribe medicine; ~~and~~

(c) a physician assistant; and

(d) a registered nurse performing services at an experimental treatment center.

~~(3) "Investigational drug, biological product, or device" means a drug, biological product, or device that:~~

~~(a) has successfully completed phase 1 of a clinical trial but has not yet been approved for general use by the United States food and drug administration; and~~

~~(b) remains under investigation in a United States food and drug administration-approved clinical trial.~~

~~(4)~~(5) ~~"Written informed~~ "Informed consent" means ~~a written document~~ written documentation or digital recordation that meets the requirements of 50-12-105.

(6) "Provider agreement" means a contract authorizing a health care provider to deliver an experimental treatment, or services related to the provision of an experimental treatment, under the supervision of an experimental treatment center's medical director."

Section 7. Section 50-12-103, MCA, is amended to read:

"**50-12-103. Availability of experimental ~~drugs~~ treatments.** (1) A manufacturer, ~~of an investigational drug, biological product, or device~~ health care provider, or health care facility may make ~~the drug, product, or device~~ an experimental treatment available ~~to a patient who has requested the drug, product, or device pursuant to this part~~ upon a patient's request.

(2) The manufacturer, health care provider, or health care facility may:

(a) provide an ~~investigational drug, biological product, or device~~ experimental treatment to a patient without receiving compensation; or

(b) ~~require a patient to pay the costs of or the costs associated with the manufacture of the investigational drug, biological product, or device~~ establish payment arrangements with a patient for an 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 8. 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 9. 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 10. 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 11. 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 12. 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 13. 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 treatment; or

(b) a health care facility's recommendation that a patient have access to, or the health care facility's provision of, an experimental treatment.

(2) ~~Counseling~~ A health care provider's counseling, advice, or ~~a~~ recommendation ~~consistent with medical standards of care from a licensed health care provider~~ about treatment options, including experimental treatments, is not a violation of this section."

~~**Section 13.** Section 50-12-110, MCA, is amended to read:~~

~~"**50-12-110. Immunity from suit.** A manufacturer of an investigational drug, biological product, or device experimental treatment, a pharmacist, a health care facility, a health care provider, or a person or entity~~

~~involved in the care of a patient using an investigational drug, biological product, or device experimental treatment is immune from suit for any harm done to the patient resulting from the investigational drug, biological product, or device experimental treatment if:~~

~~(1) the manufacturer, pharmacist, health care facility, health care provider, or other person or entity is complying in good faith with the terms of this part act and has exercised reasonable care ;~~

~~(2) the harm was not the result of gross negligence or willful or wanton acts or omissions by the manufacturer, pharmacist, health care facility, health care provider, or other person or entity involved in the care of the patient; and~~

~~(3) established experimental treatment center protocols and safety standards, as applicable, were followed.~~"

NEW SECTION. **Section 14. Codification instruction.** ~~[Section 1] is~~ [Sections 1 through 3] are intended to be codified as an integral part of Title 50, chapter 5, part 2, and the provisions of Title 50, chapter 5, part 2, apply to ~~[section 1]~~ [sections 1 through 3].

NEW SECTION. **Section 15. Effective date.** [This act] is effective on passage and approval.

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