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:

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.

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.

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.

(3) This code applies to health service corporations as prescribed in 33-30-102. The existence of the corporations is governed by Title 35, chapter 2, and related sections of the Montana Code Annotated.

(4) This code does not apply to health maintenance organizations to the extent that the existence and operations of those organizations are governed by chapter 31.

(5) This code does not apply to workers' compensation insurance programs provided for in Title 39, chapter 71, part 21, and related sections.

(6) The department of public health and human services may limit the amount, scope, and duration of services for programs established under Title 53 that are provided under contract by entities subject to this title. The department of public health and human services may establish more restrictive eligibility requirements and fewer services than may be required by this title.

(7) This code does not apply to the state employee group insurance program established in Title 2, chapter 18, part 8, or the Montana university system group benefits plans established in Title 20, chapter 25, part 13.

(8) This code does not apply to insurance funded through the state self-insurance reserve fund provided for in 2-9-202.

(9) (a) Except as otherwise provided in Title 33, chapters 22 and 28, this code does not apply to any arrangement, plan, or interlocal agreement between political subdivisions of this state in which the political subdivisions undertake to separately or jointly indemnify one another by way of a pooling, joint retention, deductible, or self-insurance plan.

(b) Except as otherwise provided in Title 33, chapter 22, this code does not apply to any arrangement, plan, or interlocal agreement between political subdivisions of this state or any arrangement, plan, or program of a single political subdivision of this state in which the political subdivision provides to its officers, elected officials, or employees disability insurance or life insurance through a self-funded program.

(10) This code does not apply to the marketing of, sale of, offering for sale of, issuance of, making of, proposal to make, and administration of a service contract governed by Title 30, chapter 14, part 13.

(11) (a) Subject to 33-18-201 and 33-18-242, this code does not apply to insurance for ambulance services sold by a county, city, or town or to insurance sold by a third party if the county, city, or town is liable

for the financial risk under the contract with the third party as provided in 7-34-103.

(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.)"

~~"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~~

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~~(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.

(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.

(iii) "Disabled adult" means a person who is 18 years of age or older and who is defined by department rule as disabled.

(iv) (A) "Light personal care" means assisting the aged person or disabled adult in accomplishing

such personal hygiene tasks as bathing, dressing, and hair grooming and supervision of prescriptive medicine administration.

(B) The term does not include the administration of prescriptive medications.

(5) "Affected person" means an applicant for a certificate of need, a long-term care facility located in the geographic area affected by the application, an agency that establishes rates for long-term care facilities, or a third-party payer who reimburses long-term care facilities in the area affected by the proposal.

(6) "Assisted living facility" means a congregate residential setting that provides or coordinates personal care, 24-hour supervision and assistance, both scheduled and unscheduled, and activities and health-related services.

(7) "Capital expenditure" means:

(a) an expenditure made by or on behalf of a long-term care facility that, under generally accepted accounting principles, is not properly chargeable as an expense of operation and maintenance; or

(b) a lease, donation, or comparable arrangement that would be a capital expenditure if money or any other property of value had changed hands.

(8) "Certificate of need" means a written authorization by the department for a person to proceed with a proposal subject to 50-5-301.

(9) "Chemical dependency facility" means a facility whose function is the treatment, rehabilitation, and prevention of the use of any chemical substance, including alcohol, that creates behavioral or health problems and endangers the health, interpersonal relationships, or economic function of an individual or the public health, welfare, or safety.

(10) "Clinical laboratory" means a facility for the microbiological, serological, chemical, hematological, radiobioassay, cytological, immunohematological, pathological, or other examination of materials derived from the human body for the purpose of providing information for the diagnosis, prevention, or treatment of a disease or assessment of a medical condition.

(11) "Comparative review" means a joint review of two or more certificate of need applications that are determined by the department to be competitive in that the granting of a certificate of need to one of the applicants would substantially prejudice the department's review of the other applications.

(12) "Congregate" means the provision of group services designed especially for elderly or disabled

persons who require supportive services and housing.

(13) "Construction" means the physical erection of a new health care facility and any stage of the physical erection, including groundbreaking, or remodeling, replacement, or renovation of:

(a) an existing health care facility; or

(b) a long-term care facility as defined in 50-5-301.

(14) "Critical access hospital" means a facility that is located in a rural area, as defined in 42 U.S.C. 1395ww(d)(2)(D), and that has been designated by the department as a critical access hospital pursuant to 50-5-233.

(15) "Department" means the department of public health and human services provided for in 2-15-2201.

(16) "Eating disorder center" means a facility that specializes in the treatment of eating disorders.

(17) "End-stage renal dialysis facility" means a facility that specializes in the treatment of kidney diseases and includes freestanding hemodialysis units.

(18) "Experimental treatment center" means a facility that specializes in providing experimental treatments pursuant to Title 50, chapter 12, part 1.

~~(18)~~(19)"Federal acts" means federal statutes for the construction of health care facilities.

~~(19)~~(20)"Governmental unit" means the state, a state agency, a county, municipality, or political subdivision of the state, or an agency of a political subdivision.

~~(20)~~(21)(a) "Health care facility" or "facility" means all or a portion of an institution, building, or agency, private or public, excluding federal facilities, whether organized for profit or not, that is used, operated, or designed to provide health services, medical treatment, or nursing, rehabilitative, or preventive care to any individual. The term includes abortion clinics as defined in 50-20-901, chemical dependency facilities, critical access hospitals, eating disorder centers, end-stage renal dialysis facilities, experimental treatment centers, home health agencies, home infusion therapy agencies, hospices, hospitals, infirmaries, long-term care facilities, intermediate care facilities for the developmentally disabled, medical assistance facilities, mental health centers, outpatient centers for primary care, outpatient centers for surgical services, rehabilitation facilities, residential care facilities, residential treatment facilities, and rural emergency hospitals.

(b) The term does not include offices of private physicians, dentists, or other physical or mental

health care workers regulated under Title 37, including licensed addiction counselors.

~~(21)~~(22)"Home health agency" means a public agency or private organization or subdivision of the agency or organization that is engaged in providing home health services to individuals in the places where they live. Home health services must include the services of a licensed registered nurse and at least one other therapeutic service and may include additional support services.

~~(22)~~(23)"Home infusion therapy agency" means a health care facility that provides home infusion therapy services.

~~(23)~~(24)"Home infusion therapy services" means the preparation, administration, or furnishing of parenteral medications or parenteral or enteral nutritional services to an individual in that individual's residence. The services include an educational component for the patient, the patient's caregiver, or the patient's family member.

~~(24)~~(25)"Hospice" means a coordinated program of home and inpatient health care that provides or coordinates palliative and supportive care to meet the needs of a terminally ill patient and the patient's family arising out of physical, psychological, spiritual, social, and economic stresses experienced during the final stages of illness and dying and that includes formal bereavement programs as an essential component. The term includes:

(a) an inpatient hospice facility, which is a facility managed directly by a medicare-certified hospice that meets all medicare certification regulations for freestanding inpatient hospice facilities; and

(b) a residential hospice facility, which is a facility managed directly by a licensed hospice program that can house three or more hospice patients.

~~(25)~~(26)(a) "Hospital" means a facility providing, by or under the supervision of licensed physicians, services for medical diagnosis, treatment, rehabilitation, and care of injured, disabled, or sick individuals. Except as otherwise provided by law, services provided must include medical personnel available to provide emergency care onsite 24 hours a day and may include any other service allowed by state licensing authority. A hospital has an organized medical staff that is on call and available within 20 minutes, 24 hours a day, 7 days a week, and provides 24-hour nursing care by licensed registered nurses. The term includes:

(i) hospitals specializing in providing health services for psychiatric, developmentally disabled, and tubercular patients; and

(ii) specialty hospitals.

(b) The term does not include critical access hospitals.

(c) The emergency care requirement for a hospital that specializes in providing health services for psychiatric, developmentally disabled, or tubercular patients is satisfied if the emergency care is provided within the scope of the specialized services provided by the hospital and by providing 24-hour nursing care by licensed registered nurses.

~~(26)~~(27)"Infirmary" means a facility located in a university, college, government institution, or industry for the treatment of the sick or injured, with the following subdefinitions:

(a) an "infirmary--A" provides outpatient and inpatient care;

(b) an "infirmary--B" provides outpatient care only.

~~(27)~~(28)(a) "Intermediate care facility for the developmentally disabled" means a facility or part of a facility that provides intermediate developmental disability care for two or more persons.

(b) The term does not include community homes for persons with developmental disabilities that are licensed under 53-20-305 or community homes for persons with severe disabilities that are licensed under 52-4-203.

~~(28)~~(29)"Intermediate developmental disability care" means the provision of intermediate nursing care services, health-related services, and social services for persons with a developmental disability, as defined in 53-20-102, or for persons with related problems.

~~(29)~~(30)"Intermediate nursing care" means the provision of nursing care services, health-related services, and social services under the supervision of a licensed nurse to patients not requiring 24-hour nursing care.

~~(30)~~(31)"Licensed health care professional" means a licensed physician, physician assistant, advanced practice registered nurse, or registered nurse who is practicing within the scope of the license issued by the department of labor and industry.

~~(31)~~(32)(a) "Long-term care facility" means a facility or part of a facility that provides skilled nursing care, residential care, intermediate nursing care, or intermediate developmental disability care to a total of two or more individuals or that provides personal care.

(b) The term does not include community homes for persons with developmental disabilities

licensed under 53-20-305; community homes for persons with severe disabilities, licensed under 52-4-203; youth care facilities, licensed under 52-2-622; hotels, motels, boardinghouses, roominghouses, or similar accommodations providing for transients, students, or individuals who do not require institutional health care; or correctional facilities operating under the authority of the department of corrections.

~~(32)~~(33)"Medical assistance facility" means a facility that meets both of the following:

(a) provides inpatient care to ill or injured individuals before their transportation to a hospital or that provides inpatient medical care to individuals needing that care for a period of no longer than 96 hours unless a longer period is required because transfer to a hospital is precluded because of inclement weather or emergency conditions. The department or its designee may, upon request, waive the 96-hour restriction retroactively and on a case-by-case basis if the individual's attending physician, physician assistant, or nurse practitioner determines that the transfer is medically inappropriate and would jeopardize the health and safety of the individual.

(b) either is located in a county with fewer than six residents a square mile or is located more than 35 road miles from the nearest hospital.

~~(33)~~(34)"Mental health center" means a facility providing services for the prevention or diagnosis of mental illness, the care and treatment of mentally ill patients, the rehabilitation of mentally ill individuals, or any combination of these services.

~~(34)~~(35)"Nonprofit health care facility" means a health care facility owned or operated by one or more nonprofit corporations or associations.

~~(35)~~(36)"Offer" means the representation by a health care facility that it can provide specific health services.

~~(36)~~(37)(a) "Outdoor behavioral program" means a program that provides treatment, rehabilitation, and prevention for behavioral problems that endanger the health, interpersonal relationships, or educational functions of a youth and that:

(i) serves either adjudicated or nonadjudicated youth;

(ii) charges a fee for its services; and

(iii) provides all or part of its services in the outdoors.

(b) "Outdoor behavioral program" does not include recreational programs such as boy scouts, girl

scouts, 4-H clubs, or other similar organizations.

~~(37)~~(38)"Outpatient center for primary care" means a facility that provides, under the direction of a licensed physician, either diagnosis or treatment, or both, to ambulatory patients and that is not an outpatient center for surgical services.

~~(38)~~(39)"Outpatient center for surgical services" means a clinic, infirmary, or other institution or organization that is specifically designed and operated to provide surgical services to patients not requiring hospitalization and that may include recovery care beds.

~~(39)~~(40)"Patient" means an individual obtaining services, including skilled nursing care, from a health care facility.

~~(40)~~(41)"Person" means an individual, firm, partnership, association, organization, agency, institution, corporation, trust, estate, or governmental unit, whether organized for profit or not.

~~(41)~~(42)"Personal care" means the provision of services and care for residents who need some assistance in performing the activities of daily living.

~~(42)~~(43)"Practitioner" means an individual licensed by the department of labor and industry who has assessment, admission, and prescription authority.

~~(43)~~(44)"Recovery care bed" means, except as provided in 50-5-235, a bed occupied for less than 24 hours by a patient recovering from surgery or other treatment.

~~(44)~~(45)"Rehabilitation facility" means a facility that is operated for the primary purpose of assisting in the rehabilitation of disabled individuals by providing comprehensive medical evaluations and services, psychological and social services, or vocational evaluation and training or any combination of these services and in which the major portion of the services is furnished within the facility.

~~(45)~~(46)"Resident" means an individual who is in a long-term care facility or in a residential care facility.

~~(46)~~(47)"Residential care facility" means an adult day-care center, an adult foster care home, an assisted living facility, or a retirement home.

~~(47)~~(48)"Residential psychiatric care" means active psychiatric treatment provided in a residential treatment facility to psychiatrically impaired individuals with persistent patterns of emotional, psychological, or behavioral dysfunction of such severity as to require 24-hour supervised care to adequately treat or remedy the individual's condition. Residential psychiatric care must be individualized and designed to achieve the patient's

discharge to less restrictive levels of care at the earliest possible time.

~~(48)~~(49)"Residential treatment facility" means a facility operated for the primary purpose of providing residential psychiatric care to individuals under 21 years of age.

~~(49)~~(50)"Retirement home" means a building or buildings in which separate living accommodations are rented or leased to individuals who use those accommodations as their primary residence.

~~(50)~~(51)"Rural emergency hospital" means a facility defined in 42 U.S.C. 1395x(kkk)(2) that is designated by the department as a rural emergency hospital in accordance with 50-5-234.

~~(51)~~(52)"Skilled nursing care" means the provision of nursing care services, health-related services, and social services under the supervision of a licensed registered nurse on a 24-hour basis.

~~(52)~~(53)(a) "Specialty hospital" means a subclass of hospital that is exclusively engaged in the diagnosis, care, or treatment of one or more of the following categories:

(i) patients with a cardiac condition;

(ii) patients with an orthopedic condition;

(iii) patients undergoing a surgical procedure; or

(iv) patients treated for cancer-related diseases and receiving oncology services.

(b) For purposes of this subsection ~~(52)~~ (53), a specialty hospital may provide other services for medical diagnosis, treatment, rehabilitation, and care of injured, disabled, or sick individuals as otherwise provided by law if the care encompasses 35% or less of the hospital services.

(c) The term "specialty hospital" does not include:

(i) psychiatric hospitals;

(ii) rehabilitation hospitals;

(iii) children's hospitals;

(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 :

(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 ;

(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 purposesit is recommended that health care providers and health care facilities utilize the enhanced informed consent process set forth in subsection (3)(b)."

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 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."

~~"50-12-110. **Immunity from suit.** A manufacturer of an investigational drug, biological product, or device, 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 is immune from suit for any harm done to the patient resulting from the investigational drug, biological product, or device if~~

~~the manufacturer, pharmacist, health care facility, health care provider, or other person or entity is complying in good faith with the terms of this act and has exercised reasonable care. "~~

Section 14. Codification instruction. [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 [sections 1 through 3].

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

- END -

I hereby certify that the within bill,

SB 535, originated in the Senate.

_____

Secretary of the Senate

_____

President of the Senate

Signed this _____day

of_____, 2025.

_____

Speaker of the House

Signed this _____day
of_____, 2025.

SENATE BILL NO. 535

INTRODUCED BY K. BOGNER

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."