MONTANA
ADMINISTRATIVE
REGISTER

DEPARTMENT OF PUBLIC HEALTH AND HUMAN SERVICES

NOTICE OF PROPOSED RULEMAKING

MAR NOTICE NO. 2026-427.1

Summary

Adoption of NEW RULES 1 through 25 pertaining to Experimental Treatment Centers

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Hearing Date and Time

Thursday, April 30, 2026, at 3:00 p.m.

Virtual Hearing Information

Join Zoom Meeting: https://mt-gov.zoom.us/j/87431979739?pwd=uHweijbyTmrf58HZPwEqZzXTi5JEMe.1

Meeting ID: 874 3197 9739 and Password: 826127

Dial by Telephone: +1 646 558 8656

Meeting ID: 874 3197 9739 and Password: 826127

Find your local number: https://mt-gov.zoom.us/u/k32k42Lzx

Comments

Comments may be submitted using the contact information below. Comments must be received by Friday, May 8, 2026, at 5:00 p.m.

Accommodations

The agency will make reasonable accommodations for persons with disabilities who wish to participate in this rulemaking process or need an alternative accessible format of this notice. Requests must be made by Thursday, April 16, 2026, at 5:00 p.m.

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Rulemaking Actions

ADOPT

The rules proposed to be adopted are as follows:

NEW RULE 1 PURPOSE

(1) The purpose of these rules is to establish the minimum licensing requirements for the licensure of experimental treatment centers, pursuant to Title 50, chapter 5, part 2, MCA.

Authorizing statute(s): 50-5-250, MCA

Implementing statute(s): 50-5-250, MCA

NEW RULE 2 SCOPE

(1) For purposes of this subchapter, experimental treatment centers include the facilities described at 50-5-101(17), MCA.

Authorizing statute(s): 50-5-250, MCA

Implementing statute(s): 50-5-250, MCA

NEW RULE 3 APPLICATION OF OTHER RULES

(1) To the extent that other licensure rules in ARM Title 37, chapter 106, subchapter 3 conflict with the terms of ARM Title 37, chapter 106, subchapter [33], the terms of subchapter [33] will apply to experimental treatment centers.

Authorizing statute(s): 50-5-250, MCA

Implementing statute(s): 50-5-250, MCA

NEW RULE 4 DEFINITIONS

(1) "Administrator" means the person designated on the center application or by written notice to the department as the person responsible for the daily operation of the center and for the daily patient care provided in the center.

(2) "Change of ownership" means the transfer of ownership of an experimental treatment center to any person or entity other than the person or entity to whom the experimental treatment center's license was issued, including the transfer of ownership to an entity that is wholly owned by the person or entity to whom the experimental treatment center's license was issued.

(3) "Department" means the Department of Public Health and Human Services.

(4) “Experimental treatment review board” means a board that examines and evaluates patient safety and treatment results pursuant to [NEW RULE 16].

(5) An “inpatient experimental treatment center” offers experimental treatment services to patients who will reside there for 24 hours or more.

(6) “Investigational medical device” means any device, including devices with health-tracking or data monitoring functions, falling under the definition of “experimental treatment” as defined in 50-12-102(1), MCA.

(7) "License" means the document issued by the department that authorizes a person or entity to provide experimental treatments in the center in which the license is issued.

(8) "Licensed health care professional" means a licensed physician, physician assistant-certified, advanced practice registered nurse, or registered nurse who is practicing within the scope of the license issued by the appropriate licensing board at the Montana Department of Labor and Industry.

(9) "Medical director" means a physician licensed by the Montana Board of Medical Examiners, who:

(a) had a three-year residency in internal medicine;

(b) has been licensed in the state of Montana for at least one year; and

(c) is the head of the experimental treatment center's Quality Assurance and Performance Improvement (QAPI) program.

(10) An "outpatient experimental treatment center" offers experimental treatment services to patients who reside there for 23 hours and 59 minutes or less per day.

(11) "Practitioner" means an individual licensed by the Montana Department of Labor and Industry who has assessment, admission, and prescription authority.

(12) "Qualified medical institution" means an institution that has generated documented clinical evidence supporting the safety of a medical intervention equivalent to that required for successful completion of a phase I clinical trial, and operates under one of the following frameworks:

(a) oversight by a regulatory authority recognized by international standards; or

(b) oversight by a regulatory authority that demonstrates substantially equivalent standards for data quality, monitoring, and patient protection.

(13) "Treatment" means a medication, modality, product, device, or dietary supplement used to maintain well-being or to diagnose, assess, alleviate, or prevent a disability, injury, illness, disease, or other similar condition.

Authorizing statute(s): 50-5-250, MCA

Implementing statute(s): 50-5-250, MCA

NEW RULE 5 APPLICATION AND LICENSING

(1) In addition to the requirements set forth in 50-5-203, MCA, each application for an experimental treatment center must include:

(a) the name of the medical director of the experimental treatment center;

(b) the qualifications of the administrator, medical director, and all professional staff;

(c) the disclosures regarding:

(i) whether the applicant, owner, or affiliate has operated a health care facility that was closed as a direct result of issues of patient health and safety;

(ii) whether the owner or any clinic staff has been convicted of a felony offense; and

(iii) whether the owner or any clinic staff was ever employed by a facility owned or operated by the applicant that was closed because of administrative or legal action;

(d) the general types of experimental treatments the center intends to perform or provide;

(e) an attestation that the applicant is of reputable and responsible character and is able to comply with all rules applicable to experimental treatment centers; and

(f) an explanation of how the experimental treatment center will fulfill the health freedom and access requirement pursuant to 50-5-251, MCA.

(2) Pursuant to 50-5-201(2), MCA, upon a change of ownership, a new owner must apply for a new license.

Authorizing statute(s): 50-5-250, 50-5-251, MCA

Implementing statute(s): 50-5-250, 50-5-251, MCA

NEW RULE 6 POLICIES AND PROCEDURES

(1) An experimental treatment center must maintain a policies and procedures manual that is available to all patients, visitors, and members of the public.

(2) The manual must contain policies and procedures for:

(a) preadmission screening and admitting patients;

(b) obtaining informed consent pursuant to 50-12-105, MCA;

(c) obtaining documentation of the patient requirements in 50-12-104, MCA;

(d) staff screening and hiring;

(e) maintaining and securing medical records, including:

(i) retention of active records;

(ii) retirement of inactive records;

(iii) timely entry of data in records; and

(iv) release of information contained in records;

(f) patient files;

(g) patient progress notes, including frequency and responsible party;

(h) observation and recovery;

(i) discharging patients;

(j) follow-up care;

(k) patient grievances;

(l) patient education;

(m) emergency procedures;

(n) medically necessary transfers;

(o) infection control;

(p) investigational medical device procedures, if applicable;

(q) the types of anesthesia to be used, the conduct of anesthesia assessments, and the criteria to be used in conducting anesthesia assessments, if applicable;

(r) disaster planning and training;

(s) staff training on emergency and disaster protocols; and

(t) fulfilling the health freedom and access requirement, pursuant to 50-5-251, MCA.

(3) The policies and procedures manual must include a current organizational chart.

(4) The policies and procedures manual must have a documented review at least biennially. The manual should be kept current and updated as needed, with documentation of amendments or updates.

Authorizing statute(s): 50-5-250, MCA

Implementing statute(s): 50-5-250, MCA

NEW RULE 7 ADMINISTRATOR

(1) An experimental treatment center must have an administrator who:

(a) maintains daily overall responsibility for the center operations;

(b) develops and oversees the implementation of all policies and procedures pertaining to the operation of the experimental treatment center;

(c) establishes written policies and procedures for all human resource services;

(d) establishes a process for patient complaints and grievances;

(e) establishes a patient incident report file on all patient incidents or allegations of abuse;

(f) develops and maintains an organizational chart that delineates the current lines of authority, responsibility, and accountability for the administration and provision of all center patient treatment programs and services; and

(g) develops and implements written orientation and training procedures on all center policies and procedures for all employees or contractors, relief workers, temporary employees, students, interns, volunteers, and trainees to include, but not limited to:

(i) defining responsibilities, limitations, and supervision of students, interns, and volunteers working for the experimental treatment center; and

(ii) verifying each professional staff member's credentials, when hired, and annually thereafter, to ensure the continued credentialing of required licenses.

(2) The administrator must develop policies and procedures for screening, hiring, and assessing staff, which include practices that assist the employer in identifying employees that may pose a risk or threat to the health, safety, or welfare of any patient, and provide written documentation of findings and the outcome in the employee’s file.

(3) In the administrator's absence, a staff member must be designated to oversee the operation of the center. The administrator or their designee must be in charge, on call, and available (physically or remotely) daily as needed. They must also ensure that there are sufficient, qualified staff on site to meet the care, health, safety, and welfare needs of patients at all times.

(4) If the administrator is absent for more than 30 calendar days, the department must be given written notice of the individual who has been appointed as the designee.

(5) An administrator may serve multiple experimental treatment centers, provided that:

(a) each center is owned and operated by the same legal entity;

(b) each center maintains a written agreement with the administrator defining specific responsibilities;

(c) the administrator can demonstrate adequate availability and oversight capacity for each center; and

(d) each center meets all applicable standards under these rules.

Authorizing statute(s): 50-5-250, MCA

Implementing statute(s): 50-5-250, MCA

NEW RULE 8 MEDICAL DIRECTOR

(1) An experimental treatment center must have a medical director who has a current physician license in good standing with the Montana Board of Medical Examiners. A medical director may serve multiple experimental treatment centers, provided that each center is owned and operated by the same legal entity, and that the medical director can effectively fulfill all responsibilities at each location.

(2) The medical director is responsible for:

(a) overseeing treatment delivered in the center;

(b) developing and maintaining a comprehensive system that tracks all experimental treatments conducted at the center, including patient outcomes for each treatment and the current Food and Drug Administration (FDA) approval status of each; and

(c) overseeing the performance of the medical staff.

(3) The medical director must participate in establishing competency criteria for medical personnel, including training in procedures performed at the center.

(4) The medical director must ensure that treatments are compliant with 50-12-102(1), MCA.

(5) The medical director may also serve as the experimental treatment center administrator.

(6) A medical director may provide oversight to multiple experimental treatment centers, provided that:

(a) each center is owned and operated by the same legal entity;

(b) each center maintains a written agreement with the medical director defining specific responsibilities;

(c) the medical director can demonstrate adequate availability and oversight capacity for each center; and

(d) each center meets all applicable standards under these rules.

(7) The medical director serves as the center's safety officer and is responsible for overseeing the center's safety program.

Authorizing statute(s): 50-5-250, MCA

Implementing statute(s): 50-5-250, MCA

NEW RULE 9 STAFF REQUIREMENTS

(1) A physician, an advanced practice registered nurse authorized by the Montana Board of Nursing to have prescription authority, a physician assistant, or a nurse practitioner must be physically present on site whenever there are patients admitted to or present in the experimental treatment center.

(2) All licensed health care professional staff must have current licenses that are in good standing with the respective Montana licensing board.

(3) Licensed health care professionals licensed in states other than Montana may collaborate or consult with center licensed health care professional staff on treatments, treatment options, adverse side effects, and patient outcomes.

Authorizing statute(s): 50-5-250, MCA

Implementing statute(s): 50-5-250, MCA

NEW RULE 10 STAFF FILES

(1) An experimental treatment center must keep a file for all staff employed and contracted by an experimental treatment center.

(2) Each staff file must contain:

(a) the most recent copy of the staff's license or certification;

(b) documented orientation, including orientation to policies and procedures and emergency and disaster protocols;

(c) a signed job description for their current position;

(d) evaluations as applicable; and

(e) ongoing training.

(3) A staff file meeting these requirements must be maintained onsite at the center for all out-of-state professionals providing collaboration and consultation for an experimental treatment center.

Authorizing statute(s): 50-5-250, MCA

Implementing statute(s): 50-5-250, MCA

NEW RULE 11 PATIENT AGREEMENT

(1) An experimental treatment center must enter into a written patient agreement with each prospective patient prior to admission.

(2) The patient agreement must include:

(a) documentation that the patient, or their legal representative, agrees to the treatment;

(b) the criteria for admitting and discharging from the center;

(c) the treatment name, form, and what phase in the clinical trials the treatment the resident is to be receiving;

(d) the full text of the provisions contained in 50-12-110, MCA (Immunity From Suit);

(e) a detailed description of all the anticipated costs to the patients, if any, and how the center intends to bill or receive payments;

(f) the acknowledgment related to the patient's health insurance as stated in 50-12-105(2)(e), MCA; and

(g) the center's patient grievance policy.

(3) The patient agreement must be signed and dated by both the patient or the patient's legal representative and a licensed health care professional of the center prior to the initiation of any treatment.

Authorizing statute(s): 50-5-250, MCA

Implementing statute(s): 50-5-250, MCA

NEW RULE 12 PATIENT FILES

(1) An experimental treatment center must keep a separate, secured file for each patient treated at the center.

(2) The patient file must include, at a minimum:

(a) patient identification, including the patient's full name, sex, address, date of birth, and next of kin or emergency contact;

(b) a full history and physical (H&P) by a treating practitioner;

(i) documentation from the patient's treating practitioner that the patient meets the criteria for experimental treatments;

(ii) the recommendation from the patient's treating practitioner for an experimental treatment;

(iii) the H&P must have been completed within 12 months of the visit to the experimental treatment center;

(c) relevant procedure, laboratory, and pathology reports;

(d) admitting diagnosis or desired health outcomes;

(e) allergies or known abnormal drug reactions;

(f) documentation to support that the patient evaluated and attempted other treatment options currently approved by the United States Food and Drug Administration;

(g) informed consent pursuant to and in alignment with 50-12-105, MCA;

(h) a copy of the patient agreement required by [NEW RULE 11];

(i) documentation and results of all tests, reports, procedures, and labs obtained at the center;

(j) interdisciplinary progress notes;

(k) treatment plans and outcomes; and

(l) discharge note, discharge diagnosis, and discharge instructions.

(3) If the center performs procedures requiring anesthesia, each patient who receives anesthesia must also have in their chart:

(a) anesthesia reports;

(b) nurses' notes on preoperative and recovery conditions; and

(c) preoperative and postoperative orders.

(4) Patient files must include the date and circumstances of discharge. Discharged patient files must be kept for a minimum of five years after the date of discharge.

Authorizing statute(s): 50-5-250, 50-12-105, MCA

Implementing statute(s): 50-5-250, 50-12-105, MCA

NEW RULE 13 TREATMENT DOCUMENTATION

(1) An experimental treatment center must keep documentation for all experimental treatments provided for each patient. The documentation must include:

(a) the treatment being provided;

(b) expected outcomes;

(c) adverse side effects, if applicable;

(d) remedy for adverse side effects and outcome; and

(e) patient response to treatment, adverse side effects, and remedies.

(2) An experimental treatment center must obtain and retain a transfer agreement with a local hospital.

(3) Before transferring a patient from an experimental treatment center, the experimental treatment center must:

(a) notify the receiving hospital before the patient is transferred, and receive confirmation from the receiving hospital that the services necessary to treat the patient are available;

(b) use medically appropriate life support measures to stabilize the patient before the transfer and to sustain the patient during the transfer;

(c) transfer all necessary records for continuing the care for the patient; and

(d) in cases of non-emergency care services, ensure that the patient or legally responsible person acting on the patient's behalf is informed of the risks and benefits of transfer.

(4) The transfer agreement must be renewed annually.

Authorizing statute(s): 50-5-250, MCA

Implementing statute(s): 50-5-250, MCA

NEW RULE 14 EMERGENCY PROCEDURES

(1) Staff trained in the use of emergency equipment and cardiopulmonary resuscitation must be available whenever a patient is in the experimental treatment center.

(2) If the experimental treatment center performs surgical or anesthetic procedures, the following equipment shall be available to the operating room:

(a) emergency call system;

(b) oxygen;

(c) assistance equipment, including airways and manual breathing bag;

(d) sonography; and

(e) emergency drugs and supplies specified by the medical staff.

(3) The experimental treatment center must have policies and procedures in the event of an emergency with documented staff training in:

(a) hemorrhage;

(b) perforation;

(c) respiratory distress/arrest;

(d) anaphylaxis; and

(e) emergency transfer to the facility with which the experimental treatment center has a written transfer agreement.

Authorizing statute(s): 50-5-250, MCA

Implementing statute(s): 50-5-250, MCA

NEW RULE 15 QUALITY ASSURANCE AND PERFORMANCE IMPROVEMENT PROGRAM

(1) An experimental treatment center must have a quality assurance and performance improvement (QAPI) program that:

(a) is ongoing;

(b) is data-driven; and

(c) is broad in scope.

(2) The QAPI program must be led by a medical director who meets the definition of [NEW RULE 4(9)].

(3) In addition to the medical director, the QAPI program must also include at least one member from each department within the experimental treatment center.

(4) The QAPI program will meet at least quarterly and maintain a written record of key information discussed, decisions made, and action items assigned during each meeting.

(5) The center will retain QAPI program meeting documentation onsite for a minimum of three years.

(6) At each QAPI program meeting, the following must be reviewed and discussed, with documentation of discussion:

(a) any patient or staff incidents that occurred since either the initial center licensing or the last QAPI meeting;

(b) all treatments provided since the later of the initial center licensing or the last QAPI meeting, that had adverse side effects;

(c) all patient grievances that have been received since the later of the initial center licensing or the last QAPI meeting;

(i) the QAPI program will ensure that the center's policy is followed in response to the grievance;

(d) address clinical and administrative issues as well as patient outcomes;

(e) any unresolved matters that were discussed or reviewed at the previous QAPI meeting; and

(f) a review of adverse event data as reported under [NEW RULE 17].

Authorizing statute(s): 50-5-250, MCA

Implementing statute(s): 50-5-250, MCA

NEW RULE 16 EXPERIMENTAL TREATMENT REVIEW BOARD

(1) An experimental treatment center must establish or contract with an experimental treatment review board.

(2) The review board may be:

(a) independently contracted through competitive selection; or

(b) shared among multiple experimental treatment centers.

(3) The review board must be comprised only of members who have no personal, financial, employment, or ownership interest, or any other conflict of interest in the experimental treatment center or centers for which it is contracted.

(a) Each experimental treatment center must maintain a list of all board members and documentation supporting that each member declares no interest in the experimental treatment center as described in (3).

(b) The declaration must align with the requirements set forth in 1-6-105, MCA.

(4) An experimental treatment review board may serve multiple experimental treatment centers, provided that:

(a) adequate capacity exists to review all assigned protocols within competitive time frames;

(b) each center designates the board through a written agreement;

(c) consolidated quarterly safety outcome reports are prepared by the review board and must clearly identify outcomes by center. These reports shall be maintained for internal quality assurance and made available to:

(i) the department during survey or upon request; and

(ii) the QAPI program;

(d) all board members meet the requirements of (3) for each center to which the board provides review services.

(5) The experimental treatment review board shall consist of at least four members. It shall include at least one Montana-licensed physician, at least one researcher with expertise in clinical outcome data, and at least one ethicist.

(a) The credentials of each board member shall be provided to the department.

(b) Members of the board shall adhere to professional standards regarding disclosure and management of financial conflicts of interest.

(6) The experimental treatment review board shall:

(a) review and approve treatment protocols to be offered at an experimental treatment center that meet the standards of 50-12-102(1), MCA, documenting that:

(i) safety standards equivalent to or higher than those of recognized regulatory authorities are met;

(ii) informed consent procedures are comprehensive and understandable;

(iii) risk-benefit analysis demonstrates a reasonable safety profile; and

(iv) alternative treatments have been appropriately evaluated;

(b) evaluate quality and safety outcomes using recognized metrics;

(c) prepare, at least annually, a public summary report to be published on the center's website or otherwise made accessible for public review. The report must include:

(i) aggregate numbers and types of experimental treatments reviewed and approved;

(ii) aggregate safety outcome data (including number and general categories of serious adverse events, with a patient's personal identifiable information removed);

(iii) general approval or review time frames; and

(iv) recommended system-wide quality improvements;

(d) preserve all records related to protocol review, approvals, safety evaluations, and reports for at least five years, and make such records available to the department upon request;

(e) review adverse event data as reported under [NEW RULE 17]; and

(f) evaluate each experimental treatment and medical device to determine the level of risk to patients, and whether the treatment or device is safe for administration outside of an experimental treatment center.

(i) An experimental treatment center is responsible for formulating an evaluation assessment and standard to determine the level of risk to patients and guidelines for determining whether the treatment or device is safe for delivery outside of the center.

(7) An experimental treatment center may be licensed provisionally without the establishment of an experimental treatment review board, but may not provide any treatments or devices until a review board is established and provides the evaluation requirements in (6)(f).

Authorizing statute(s): 50-5-250, MCA

Implementing statute(s): 50-5-250, MCA

NEW RULE 17 ADVERSE EVENT REPORTING

(1) Experimental treatment centers must report any adverse events to the department within five days.

(2) An adverse event or suspected adverse reaction is considered "serious" if, in the view of the medical director, it results in any of the following outcomes: death, a life-threatening adverse event, inpatient hospitalization or prolongation of existing hospitalization, a persistent or significant incapacity or substantial disruption of the ability to conduct normal life functions, or a congenital anomaly/birth defect. Important medical events that may not result in death, be life-threatening, or require hospitalization may be considered serious when, based upon appropriate medical judgment, they may jeopardize the patient and may require medical or surgical intervention to prevent one of the outcomes listed in this definition.

(3) Each report must include, at a minimum:

(a) the type of experimental treatment involved;

(b) the nature and severity of the adverse event;

(c) the date of occurrence;

(d) any corrective actions taken; and

(e) information about the patient's medical condition.

(4) Adverse event data collected and reported under this rule must be reported to the QAPI program pursuant to [NEW RULE 15].

Authorizing statute(s): 50-5-250, MCA

Implementing statute(s): 50-5-250, MCA

NEW RULE 18 INFECTION PREVENTION AND CONTROL

(1) An experimental treatment center must maintain an infection prevention and control program that seeks to minimize infections and communicable diseases. An experimental treatment center is responsible for developing a plan of action to prevent, identify, and manage infections and communicable diseases, and for promptly implementing corrective and preventive measures that lead to improvement.

(a) The infection prevention and control program must include documentation that the experimental treatment center has considered, selected, and implemented nationally recognized infection control guidelines.

(b) The infection prevention and control program is under the direction of a designated and qualified infection control officer who is a licensed health care professional and has training in infection control.

(2) An experimental treatment center must have written policies that also address the cleaning of patient treatment areas and care areas, to include:

(a) cleaning before use; and

(b) cleaning between patients.

(3) An experimental treatment center must have policies and processes in place for:

(a) the monitoring and documentation of the cleaning, high-level disinfection, and sterilization of medical equipment, accessories, instruments, and implants; and

(b) minimizing the sources and transmission of infections, including the use of adequate surveillance techniques.

Authorizing statute(s): 50-5-250, MCA

Implementing statute(s): 50-5-250, MCA

NEW RULE 19 SAFETY PROGRAM

(1) An experimental treatment center must have a safety program that addresses the organization's environment of care and safety for all patients, staff, and visitors. The elements of the safety program must include:

(a) a process for identifying hazards, potential threats, near misses, and other safety concerns;

(b) a process for reporting known adverse incidents to proper authorities;

(c) a process for reducing and avoiding medication errors; and

(d) prevention of falls or physical injuries involving patients, staff, and visitors.

(2) Products that carry an expiration date, including medications, reagents, and solutions, must be monitored and disposed of accordingly.

Authorizing statute(s): 50-5-250, MCA

Implementing statute(s): 50-5-250, MCA

NEW RULE 20 ANESTHESIA RISK AND EVALUATION

(1) An experimental treatment center that performs procedures requiring anesthesia must:

(a) prohibit the use of flammable anesthesia;

(b) have a policy that defines the types of anesthesia that will be used within the center. Similarly, the experimental treatment center must address in this policy the American Society of Anesthesiologists (ASA) Physical Status Classification System level appropriate to receive surgical services in these types of facilities;

(c) conduct an assessment prior to the patient's admission as well as prior to surgery to evaluate the risk of anesthesia and of the procedure to be performed; and

(d) have policies that address the basis or criteria used in conducting the assessments.

(2) Supplies and exhaust systems for windowless anesthetizing locations must be arranged to automatically vent smoke and products of combustion.

(a) Ventilating systems for anesthetizing locations using general anesthesia must be provided that automatically:

(i) prevent recirculation of smoke originating within the surgical suite; and

(ii) prevent the circulation of smoke entering the system intake, without, in either case, interfering with the exhaust function of the system.

(3) Anesthesia must be administered only by:

(a) a qualified anesthesiologist;

(b) a physician qualified to administer anesthesia; or

(c) a certified registered nurse anesthetist (CRNA).

(4) Before discharge, each patient must be evaluated by a physician or by a person authorized to administer anesthesia in accordance with applicable state health and safety laws, standards of practice, and center policy. This post-anesthesia assessment must include evaluation of:

(a) respiratory function, including respiratory rate, airway patency, and oxygen saturation;

(b) cardiovascular function, including pulse rate and blood pressure;

(c) mental status and level of consciousness, or both;

(d) temperature;

(e) pain;

(f) nausea and vomiting; and

(g) postoperative hydration.

Authorizing statute(s): 50-5-250, MCA

Implementing statute(s): 50-5-250, MCA

NEW RULE 21 INVESTIGATIONAL MEDICAL DEVICES

(1) An experimental treatment center that provides investigational medical devices must:

(a) maintain specialized equipment and facilities appropriate for device implantation, monitoring, or administration;

(b) establish device-specific informed consent procedures in addition to those required under 50-12-105, MCA. These procedures must address:

(i) risks associated with device implantation and removal;

(ii) long-term monitoring requirements;

(iii) compatibility with other medical devices or treatments; and

(iv) data collection, cybersecurity, and transmission capabilities of smart devices.

(2) Experimental treatment centers administering investigational devices must have procedures in place for the following:

(a) pre-procedure device inspection and calibration protocols;

(b) device implementation;

(c) post-procedure device monitoring and maintenance;

(d) device malfunction reporting and response procedures; and

(e) patient device registry and maintenance for long-term tracking.

(3) Health care providers who administer investigational medical devices to patients must have documented training and demonstrated competency for device-specific procedures. Records must be maintained by the center's administrator pursuant to [NEW RULE 7].

(4) The center must maintain a registry of all investigational medical devices administered to patients for a minimum of five years. The registry must include:

(a) purpose of the treatment;

(b) device identifiers;

(c) patient outcomes; and

(d) any adverse events.

(5) For smart or internet-connected devices, the center must have policies and procedures addressing:

(a) cybersecurity;

(b) patient data privacy; and

(c) patient access to device-generated data.

(6) The center must have policies to address device malfunction, emergency removal, and reporting of adverse events.

(7) Device performance and safety must be reviewed regularly as part of the center's QAPI program in accordance with [NEW RULE 15].

Authorizing statute(s): 50-5-250, MCA

Implementing statute(s): 50-5-250, MCA

NEW RULE 22 REPORTS TO THE DEPARTMENT

(1) The Department of Public Health and Human Services, Office of Inspector General, will develop a reporting form that facilitates data collection and review of quality assurance systems, pursuant to 50-5-250(2)(f), MCA. The department will make the form available through the electronic licensing system.

(2) An experimental treatment center must complete the form with information from the full calendar year.

(a) The report is due to the department by January 31 of the next calendar year and submitted through the electronic licensing system.

(b) The department may reduce the license of an experimental treatment center to a provisional license if the report is not received by the date it is due.

(c) Further licensing action may be taken if there is continued noncompliance with this rule.

Authorizing statute(s): 50-5-250, MCA

Implementing statute(s): 50-5-250, MCA

NEW RULE 23 PHYSICAL PLANT REQUIREMENTS FOR AN OUTPATIENT CENTER

(1) An outpatient experimental treatment center must have the local building authority inspect and approve the center prior to initial licensing. The department must receive a copy of the signed approval.

(2) The local or state fire marshal must inspect the center prior to licensing and annually thereafter.

(3) Each center must be equipped with a fire alarm system that is tested and inspected annually.

(a) Inspection results must be maintained at the center for three years.

(4) All patient rooms must be a minimum of ten feet by ten feet in size.

(5) All corridors within a center must be at a minimum of six feet wide.

(6) There must be illuminated exit signs on all exit doors.

(7) The department may waive any provision of this rule if construction factors would make compliance extremely difficult or impossible and if the department determines that the level of safety to residents and staff is not diminished.

(8) A licensed outpatient experimental treatment center may apply to the department to transfer its primary location, provided that:

(a) there is no change in legal ownership, administrative structure, or core staff as relevant for compliance;

(b) the department receives at minimum 30 days' prior notice, updated address, floor plans, and an attestation of ongoing compliance;

(c) the new site is approved by the department's licensing construction consultant prior to treating patients; and

(d) a copy of the continuity of care plan covering patient notification, handling of ongoing treatments, and medical record access or transfer shall be provided to the department with the relocation notice and must be available for review.

(9) If an outpatient experimental treatment center operates within another health care facility, the center must:

(a) be operated in a distinct and separate unit of the facility;

(b) have two-hour fire barriers separating the experimental treatment center from the other health care facility;

(c) store all experimental treatment medications, treatments, or devices in such a manner that they are inaccessible to any staff other than those who work for the experimental treatment center;

(d) separately store and maintain all equipment pertinent to the care and treatment of patients within the experimental treatment center; and

(e) maintain a separate staff from that of the other health care facility.

Authorizing statute(s): 50-5-250, MCA

Implementing statute(s): 50-5-250, MCA

NEW RULE 24 PHYSICAL PLANT REQUIREMENTS FOR AN INPATIENT CENTER

(1) An inpatient experimental treatment center must have the local building authority inspect and approve the center prior to initial licensing. The department must receive a copy of the signed approval.

(2) The local or state fire marshal must inspect the center prior to licensing and annually thereafter.

(3) Each center must be fully suppressed. The suppression system must be tested and inspected annually.

(a) Inspection results must be maintained at the center for three years.

(4) All patient rooms must have three feet of clearance to the foot and each side of the bed.

(5) All corridors within the center must be at a minimum of eight feet wide.

(6) There must be illuminated exit signs on all exit doors.

(7) There must be at least one toilet for every four patients.

(8) There must be at least one shower for every 12 patients.

(9) Each resident room must be equipped with a call system that meets the standard in the American Institute of Architects (AIA) Guidelines chapter 4.1-8.3.7.4 (2).

(10) There must be a nurses' station for each wing of the center. The nurses' station should provide a clear line of sight to each patient room and the room’s light for the call system.

(11) Every patient room must have generator-backup electrical for provisions of oxygen and medical gas to be rolled in and utilized whenever necessary.

(12) If an inpatient experimental treatment center operates within another health care facility, the center must:

(a) be operated in a distinct and separate unit of the facility;

(b) have two-hour fire barriers separating the experimental treatment center from the other health care facility;

(c) store all experimental treatment medications, treatments, or devices in such a manner that they are inaccessible to any staff other than those who work for the experimental treatment center;

(d) separately store and maintain all equipment pertinent to the care and treatment of patients within the experimental treatment center; and

(e) maintain a separate staff from that of the other health care facility.

(13) The department may waive any provision of this rule if construction factors would make compliance extremely difficult or impossible and if the department determines that the level of safety to residents and staff is not diminished.

(14) A licensed inpatient experimental treatment center may apply to the department to transfer its primary location, provided that:

(a) there is no change in legal ownership, administrative structure, or core staff as relevant for compliance;

(b) the department receives 30 days' prior notice, updated address, floor plans, and an attestation of ongoing compliance;

(c) the new site is approved by the department's licensing construction consultant prior to treating patients;

(d) a copy of the continuity of care plan covering patient notification, handling of ongoing treatments, and medical record access or transfer shall be provided to the department with the relocation notice and must be available for review.

Authorizing statute(s): 50-5-250, MCA

Implementing statute(s): 50-5-250, MCA

NEW RULE 25 AGREEMENT WITH OUTSIDE ENTITIES

(1) When an experimental treatment or medical device has been evaluated by the experimental treatment review board and deemed to have minimal potential risk to a patient and determined to be safe to administer outside of the experimental treatment center, the center may make the treatment or device available for administration to private practicing physicians if there is a signed written agreement between the experimental treatment center and the physician that includes at a minimum:

(a) the name of the disease or health condition that the treatment is approved to treat;

(b) the requirement that the physician document the treatment outcomes;

(c) the requirement that the physician report any adverse side effects to the experimental treatment center within 24 hours;

(d) that the physician provides all patients with the name, number, and address of the experimental treatment center that the physician is contracting with for the treatment; and

(e) that the physician agrees to share all treatment documentation, laboratory, and other test results of a patient receiving experimental treatments or devices with the contracted experimental treatment center.

(2) There must be a written and signed agreement for each treatment or device that is approved for administration or delivery.

(3) The agreement must have a documented renewal annually by both parties.

(4) If a treatment or device is discontinued from use outside of the experimental treatment center or when a treatment or device clears Food and Drug Administration (FDA) approval and no longer meets experimental treatment criteria, there must be a documented termination of the agreement.

Authorizing statute(s): 50-5-250, MCA

Implementing statute(s): 50-5-250, MCA

General Reasonable Necessity Statement

The Department of Public Health and Human Services (department) is proposing to adopt NEW RULES 1 through 25.

The 2025 legislature enacted Senate Bill No. 535, an act revising laws related to experimental treatments. The bill was signed by the Governor on May 13, 2025. The department proposes adopting NEW RULES 1 through 25. Adoption of these new rules is necessary to provide for the creation and licensing of experimental treatment centers, as described in this bill. The initiation and application of new rules for this new designation of a health care facility are necessary to ensure that there are qualified, oriented, and continually trained staff and that patients receiving services through these facilities are provided with a safe environment and safe, appropriate treatment and care. The implementation of these rules ensures that documentation of a facility's policies and procedures, an overview of the experimental treatment review board's involvement, and required reports are submitted to the department.

NEW RULE 1

Implementing this rule is necessary to clarify the purpose of the rules, ensuring that constituents or other entities researching or looking up rules understand what this new subchapter of rules entails.

NEW RULE 2

It is necessary to adopt this new rule to define the scope of this subchapter, which applies only to experimental treatment centers as defined in 50-5-101, MCA.

NEW RULE 3

The department proposes adopting this rule to identify other areas within the Administrative Rules of Montana that apply to this type of facility. This is necessary because experimental treatment centers are classified as health care facilities under SB 535, and there is a subchapter of regulations specific to all health care facilities. Specific requirements not addressed in the new rules for experimental treatment center may be addressed in the minimum standards for all health care facilities regulations and must therefore also be adhered to.

NEW RULE 4

The department has determined that there is a reasonable necessity to adopt this rule, which provides definitions for the terminology used in this subchapter. This is necessary so that both providers and constituents understand the terminology used and the qualifications of defined entities.

NEW RULE 5

The department proposes adopting this new rule to inform applicants and constituents of the requirements for applying to an experimental treatment center. This is necessary to ensure

prospective providers know what is required to apply for this type of facility, and how the facility will receive and maintain licensure.

NEW RULE 6

The department proposes adopting this rule to specify the requirements for experimental treatment centers (ETCs) regarding written policies and procedures. This is necessary to ensure that the facilities have policies and procedures in place to guide their operations and serve as a reference for staff and patients to complete and follow through on these operations. It is essential for a facility to have clear policies and procedures for hiring and training staff to ensure that staff members are properly hired and receive adequate training to perform their duties and services effectively. Policies and procedures are required for all services provided by the ETC to facilitate consistent, appropriate, and safe care and treatment for patients. Lastly, disaster and emergency policies and procedures are required to ensure that staff are knowledgeable and capable of responding quickly and appropriately in the event of a disaster or emergency, thereby ensuring patient safety and facilitating evacuation, if necessary. An updated, accurate organizational chart is necessary to ensure that all staff, visitors, and patients understand the ETC's organizational structure and who to contact in an emergency. The requirement to update and review the policy and procedure manual biennially is standard practice for all health care facilities, ensuring that the policy manual is maintained and accurately conveys the facility's current staff and operations.

NEW RULE 7

The department proposes adopting this rule, which designates an administrator and outlines the responsibilities of that position. This is necessary to ensure that a qualified and dedicated person is responsible for overseeing the facility's operations and for the health, safety, and welfare of patients receiving care in the ETC. It is necessary to require the facility to designate an administrator designee if the center's true administrator will be gone for more than 30 days, and to notify the department, as this ensures the department has the appropriate point of contact in the event of needing to contact the facility.

NEW RULE 8

The department proposes adopting this rule, which designates a medical director and outlines the responsibilities of that position. This rule is necessary to ensure that the individual in this position has specific qualifications to oversee the treatment delivered in the center and to verify that it meets requirements and is provided in a safe manner. The requirement that the medical director must not be a practicing physician within the facility removes the potential for discrimination amongst practitioners and ensures that the medical director can fulfill their duties and responsibilities in that capacity. The allowance for the medical director to also serve as the administrator is necessary, as an individual qualified and capable of fulfilling both roles should be given the opportunity to do so.

NEW RULE 9

The department proposes adopting this new rule to establish specific requirements for staff. This is necessary to ensure that appropriately licensed and trained staff are present and on-site during the operation of the experimental treatment center, and that individuals holding positions that require licensure hold a good-standing license issued by the State of Montana.

NEW RULE 10

The department proposes adopting this new rule to ensure that the experimental treatment centers maintain a file for all staff who work at the centers. This is necessary to provide evidentiary documentation of staff qualifications, the training provided to staff, and that each position requiring licensure has a valid, good-standing license to practice in the state of Montana. The requirement to maintain a staff file for individuals who provide collaboration and consultation from out of state is necessary to ensure that these individuals are trained and appropriately licensed to provide services to patients in Montana.

NEW RULE 11

The department proposes adopting this new rule to ensure that experimental treatment centers enter into a written patient agreement with each patient requesting treatment at their center. This is necessary to ensure there is documented evidence that both parties – the center and the patient – are aware of the other party's expectations and responsibilities, and that each party agrees to adhere to their respective responsibilities.

NEW RULE 12

The department proposes to adopt a new rule requiring experimental treatment centers to maintain a file for all patients who are or have received treatment at the center. This is necessary to ensure that there is a centralized place where all patient information is stored and kept current, and that all required documentation has been obtained or completed. The requirement to maintain anesthesia records when a center performs anesthesia is necessary to ensure that proper protocols are followed before, during, and after anesthesia administration in the event of an adverse reaction. The requirement to document and maintain discharge files is necessary to ensure there is documented evidence of discharge from treatment and to ensure that patient files are accessible after discharge if an authorized outside entity needs to review or obtain information about their stay or treatment at the center.

NEW RULE 13

The department proposes to adopt this new rule to ensure consistent and appropriate documentation of treatment provided by the experimental treatment center (ETC). This is necessary to ensure that the center provides the services it indicates in its policy and procedures, through patient agreements, and to enable the center to review documentation to

ensure that treatment was given safely and appropriately. It is necessary for an experimental treatment center to obtain and maintain a transfer agreement with a hospital in the event that a patient receiving services at an ETC requires emergent, acute medical attention outside the scope of an ETC, a receiving hospital should be aware of the potential for a patient to be coming in from an ETC and have a good line of communication and documentation between the two entities. The requirement that the transfer agreement be updated annually ensures that it is discussed, reviewed, and agreed upon by current administrative staff at each facility.

NEW RULE 14

The adoption of NEW RULE 14 requires staff to be trained in the use of emergency equipment and procedures. This is necessary to ensure the best possible outcome for patients in the event of an emergency while receiving treatment at an experimental treatment center. The requirement for specific emergency procedures for anesthesia in facilities that plan to use it is necessary to ensure a swift and appropriate response if a patient has an emergency while receiving or after receiving anesthesia.

NEW RULE 15

The department proposes to adopt this new rule requiring a quality assurance and performance improvement program to ensure that services rendered at experimental treatment centers are reviewed and assessed to provide quality and appropriate treatment. It is necessary to establish rules on who serves on the board and the board's responsibilities to ensure that qualified individuals discuss patient treatments, grievances, and clinical and administrative issues to develop solutions and resolutions.

NEW RULE 16

The department proposes adopting a new rule requiring experimental treatment centers to establish or contract with an experimental treatment review board. This is necessary to establish regulations on which positions or professions comprise the board and what the board's duties are, to ensure that experimental treatments and outcomes are reviewed by those qualified to do so in a timely manner, and that documentation and reporting are completed and accurate. The requirement to allow an experimental treatment center to be licensed provisionally without establishing an experimental treatment review board is necessary so that treatments can be provided for review by the board.

NEW RULE 17

The department proposes adopting this new rule to require experimental treatment centers to report adverse events. This is necessary to ensure that adverse events are promptly documented, reviewed, and reported, with the intended outcome of determining whether they can be minimized or eliminated in the future. This is also necessary for collecting data on indications and descriptions of possible side effects of experimental treatments.

NEW RULE 18

The department proposes adopting this new rule to require all experimental treatment centers to maintain infection control programs and policies. This is necessary to ensure that the experimental treatment centers maintain clean, sanitary spaces and equipment for patient care and treatment.

NEW RULE 19

The department proposes adopting this new rule requiring experimental treatment centers to establish a safety program to ensure that environmental and equipment-related materials are kept safe and up to date. This is necessary for patient health and safety during treatment at a center.

NEW RULE 20

The department proposes adopting this rule regarding anesthesia risk and evaluation to ensure that experimental treatment centers (ETCs) that provide anesthesia services have safeguards in place to minimize patient risk. This is necessary as anesthesia has significant risks to individuals, is highly flammable, and requires specialized supervision, assessment, and equipment. Maintaining patient health and safety must be a primary focus of ETCs when providing anesthesia.

NEW RULE 21

This proposed new rule is necessary to require experimental treatment centers that provide investigational medical devices to have procedures for implementing and training on these devices. Proper training, implementation, and documentation of investigational medical devices increase the likelihood of successful outcomes. It is also necessary for the oversight and evaluation by the quality assurance and program improvement program and the experimental treatment review board. This requirement enhances patient safety.

NEW RULE 22

This proposed new rule is necessary to ensure that the Office of Inspector General develops and maintains reporting forms for facilities data collection and review. This is necessary not only to meet legal requirements, but also to provide a streamlined, consistent reporting tool to gather data on treatments provided and the quantity and significance of adverse side effects.

NEW RULE 23

This proposed new rule is necessary to ensure compliance with certain physical plant requirements for outpatient experimental treatment centers. This is necessary to align the

physical and fire-life safety requirements with those of other healthcare facilities that provide similar services. These requirements were formulated in conjunction with the Office of Inspector General's (OIG) construction consultant and in accordance with National Fire Protection Association (NFPA) and Facility Guidelines Institute (FGI) guidelines. These facility types are not specifically identified in these manuals, but the OIG compared similar facility types to develop these guidelines, with the intent to guide best practices for safe and effective outpatient treatment for patients. It is necessary to identify specific requirements if an outpatient experimental treatment center wants to operate within another licensed healthcare facility that is certified and regulated by the Centers for Medicare and Medicaid (CMS). This ensures that the CMS-regulated health care facility remains compliant with the federal requirements when a non-certified experimental treatment center is to operate on the same premises.

NEW RULE 24

This proposed new rule is necessary to ensure compliance with certain physical plant requirements for inpatient experimental treatment centers. This is necessary to align the physical and fire-life safety requirements with those of other health care facilities that provide similar services on an inpatient basis. These requirements were formulated in conjunction with the Office of Inspector General's (OIG) construction consultant and in accordance with National Fire Protection Association (NFPA) and Facility Guidelines Institute (FGI) guidelines. These facility types are not specifically identified in these manuals, but the OIG compared similar facility types to develop these guidelines, with the intent to guide best practices for safe and effective inpatient treatment for patients. It is necessary to identify specific requirements if an inpatient experimental treatment center wants to operate within another licensed healthcare facility that is certified and regulated by the Centers for Medicare and Medicaid (CMS). This ensures that the CMS-regulated health care facility remains compliant with the federal requirements when a non-certified experimental treatment center is to operate on the same premises.

NEW RULE 25

The department proposes to adopt this new rule to provide guidance on when an experimental treatment center may contract with an outside entity to provide pre-approved experimental treatments or medical devices outside the experimental treatment center. This is necessary to allow a wider clientele to receive treatments and devices that have been reviewed and determined by the experimental treatment review board to have minimal adverse side effects for patients and therefore do not require immediate oversight by the experimental treatment center. It is necessary to ensure that these approved treatments or devices are reviewed and approved before agreeing to have outside entities provide them to minimize the risk that individuals receiving these treatments or devices will have a reaction or complication and need to seek care from a medical facility not familiar with or qualified to evaluate and treatment of the experimental treatment. It is necessary that the experimental treatment centers and the

outside entity agree on reporting requirements to ensure that the experimental treatment centers can maintain their reporting obligations to the department and their associated experimental treatment review board.

Small Business Impact

Pursuant to 2-4-111, MCA, the department has determined that the new rules proposed in this notice will not create a significant and direct impact upon small businesses. The application for and operation of these facilities are voluntary and are specific to experimental treatment centers.

Bill Sponsor Notification

The bill sponsor contact requirements apply and have been fulfilled. The primary bill sponsor of SB 535 was notified by electronic mail on January 21, 2026.

Interested Persons

The department maintains a list of interested persons who wish to receive notices of rulemaking actions proposed by the department. Persons who wish to have their name added to the list shall make a written request that includes the name, e-mail, and mailing address of the person to receive notices and specifies for which program the person wishes to receive notices. Notices will be sent by e-mail unless a mailing preference is noted in the request. Such written request may be emailed, mailed or otherwise delivered to the contact person above.

Rule Reviewer

Gregory Henderson

Approval

Charles T. Brereton, Director
Department of Public Health and Human Services