MONTANA
ADMINISTRATIVE
REGISTER

DEPARTMENT OF PUBLIC HEALTH AND HUMAN SERVICES

NOTICE OF ADOPTION

MAR NOTICE NO. 2026-427.2

Summary

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

Previous Notice(s) and Hearing Information

On April 10, 2026, the Department of Public Health and Human Services published MAR Notice No. 2026-427.1 pertaining to the public hearing on the proposed adoption of the above-stated rules in the 2026 Montana Administrative Register, Issue Number 7.

A public hearing was held April 30, 2026.

Final Rulemaking Action – Effective July 25, 2026

ADOPT AS PROPOSED

The agency has adopted the following rules as proposed:

NEW RULE 1 (37.106.3301) PURPOSE

NEW RULE 2 (37.106.3302) SCOPE

NEW RULE 3 (37.106.3303) APPLICATION OF OTHER RULES

NEW RULE 6 (37.106.3306) POLICIES AND PROCEDURES

NEW RULE 9 (37.106.3309) STAFF REQUIREMENTS

NEW RULE 10 (37.106.3310) STAFF FILES

NEW RULE 14 (37.106.3314) EMERGENCY PROCEDURES

NEW RULE 15 (37.106.3315) QUALITY ASSURANCE AND PERFORMANCE IMPROVEMENT PROGRAM

NEW RULE 18 (37.106.3318) INFECTION PREVENTION AND CONTROL

NEW RULE 19 (37.106.3319) SAFETY PROGRAM

NEW RULE 20 (37.106.3320) ANESTHESIA RISK AND EVALUATION

NEW RULE 25 (37.106.3325) AGREEMENT WITH OUTSIDE ENTITIES

ADOPT WITH CHANGES

The agency has adopted the following rules with changes from the original proposal, stricken matter interlined, new matter underlined:

NEW RULE 4 (37.106.3304) 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 ARM 37.106.3316.

(5) An “inpatient experimental treatment center” offers experimental treatment services to patients who ~~will reside there~~ are admitted to or reside at the facility 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 has the responsibilities outlined in ARM 37.106.3308 and who~~:~~

~~(a) had a three-year residency in internal medicine;~~ is the head of the experimental treatment center's Quality Assurance and Performance Improvement (QAPI) and infection control programs.

~~(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~~ 1 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 (37.106.3305) 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, including demonstrating accountability and reliably fulfilling commitments, 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 7 (37.106.3307) 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) is responsible for regulatory compliance for the licensure of the experimental treatment center;

(h) promotes and protects the health, safety, and welfare of patients; and

~~(g)~~(i) 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 (37.106.3308) 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~~ The 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.

(8) The medical director has the responsibility of the infection control officer, ensuring that the infection control program meets all requirements of ARM 37.106.3318.

(a) The medical director may delegate this responsibility to another practitioner who, given the clinical risks and oversight demands, is qualified to serve as the infection control officer.

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

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

NEW RULE 11 (37.106.3311) 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~~ patient 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 (37.106.3312) 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~~30 days of the visit to the experimental treatment center;

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

(d) admitting diagnosis ~~or~~ and desired health outcomes;

(i) desired health outcomes must be specific to the patient's condition for which experimental treatment is being provided;

(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 ARM 37.106.3311;

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

(j) pre-treatment screening for contraindications, concomitant medications, and lifestyle risk factors;

~~(j)~~(k) interdisciplinary progress notes;

~~(k)~~(l) treatment plans and outcomes; and

~~(l)~~(m) 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 (37.106.3313) 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, including the source used to determine these 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 16 (37.106.3316) 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~~ five 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~~ aggregate treatment outcome data;

(iv) ~~recommended system-wide quality improvements~~ general approval or review time frames; and

(v) 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 ARM 37.106.3317; 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).

(8) The experimental treatment review board must meet at least monthly.

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

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

NEW RULE 17 (37.106.3317) ADVERSE EVENT REPORTING

(1) Experimental treatment centers must report any serious 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) All ~~Adverse~~ adverse event data collected and reported ~~under this rule~~ must be reported to the experimental treatment review board and to the QAPI program pursuant to ARM 37.106.3315.

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

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

NEW RULE 21 (37.106.3321) 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 ARM 37.106.3307.

(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 and procedures to address device malfunction, emergency removal, ~~and~~ reporting of adverse events, and device or device part recalls.

(7) Device performance and safety must be reviewed regularly as part of the center's QAPI program in accordance with ARM 37.106.3315.

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

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

NEW RULE 22 (37.106.3322) 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~~ February 1 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.

(3) All identifying patient information must be redacted for standard reporting purposes.

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

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

NEW RULE 23 (37.106.3323) 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~~ patients 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 (37.106.3324) 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~~ patient 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~~ patients 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

Statement of Reasons

The agency has considered the comments and testimony received. A summary of the comments received, and the agency's responses are as follows:

Comment #1: Multiple written comments were received expressing general support of SB 535.

Response #1: The Office of Inspector General (OIG) thanks the commenters for their comments on the legislation.

Comment #2: Two written comments were received requesting clarification of the terms "inpatient experimental treatment center," "qualified medical institution," and "qualifications" under NEW RULE 4.

Response #2: The OIG has revised the definition of "inpatient experimental treatment center" to include: "services to patients who are admitted to or reside at the facility for 24 hours or more."

In response to the requests for additional protocols for the qualified medical institution, the OIG does not agree with the suggested language. Experimental Treatment Centers (ETCs) do not administer clinical trials and as such they should not be required to participate in an IRB review. The ETC review board requirement to obtain evidence of pre-regulatory efficacy and the required documentation of informed consent ensure adequate oversight while minimizing administrative burden.

The OIG declines to define "qualifications" as ETCs may offer a wide range of services, and the qualifications needed will differ from provider to provider, depending on the particular services and treatments offered. ETCs are responsible for ensuring they have adequate staff with appropriate qualifications to provide treatment and services with minimal risk to patients.

Comment #3: A written comment was received recommending that the administrator and medical director roles under NEW RULE 4 be separated.

Response #3: The OIG thanks the commenter for this suggestion. NEW RULE 7 addresses the roles and responsibilities of administrators. NEW RULE 8 addresses the roles and responsibilities of medical directors.

Comment #4: A written comment was received indicating that the definition of “administrator” under NEW RULE 4 should be revised to provider greater detail on the requirements for administrators.

Response #4: The OIG thanks the commenter for this suggestion. The roles and responsibilities of administrators are addressed in greater detail in NEW RULE 7.

Comment #5: A written comment was received suggesting that NEW RULE 7 be revised to require the administrator to be on-site and on call.

Response #5: The OIG thanks the commenter for this suggestion but believes such a requirement is already addressed in NEW RULE 7. Specifically, NEW RULE 7(3) provides: “The administrator or their designee must be in charge, on call, and available (physically or remotely) daily as needed.”

Comment #6: Multiple written comments were received suggesting the qualifications for the physician medical director under NEW RULE 8 should be broadened beyond doctors of internal medicine, allowing for medical degrees in other fields of medicine.

Response #6: The OIG thanks the commenters for this suggestion. NEW RULE 8 does not specify that the medical director must have a three-year residency in internal medicine. However, such a requirement is found under NEW RULE 4. The OIG has revised the definition of “medical director” in NEW RULE 4 to allow treatments and services by those with a specialty or license to provide them.

Comment #7: A written comment was received requesting that NEW RULE 8 be revised to prohibit a single medical director from overseeing multiple facilities.

Response #7: The OIG thanks the commenter for this suggestion, but disagrees that a medical director should be categorially precluded from serving in the position for multiple facilities. NEW RULE 8 allows for serving as a medical director for multiple facilities if the facilities are owned and operated by the same entity and the medical director can demonstrate adequate availability and oversight capacity for each facility. The OIG believes these limitations will safely allow a medical director to serve multiple facilities.

Comment #8: A written comment was received requesting clarification of the requirement under NEW RULE 9 for a qualified practitioner to be present during patient intake or patient services that require assessment or intervention.

Response #8: NEW RULE 9 requires that at least one of the types of health care professionals enumerated under the rule be on-site when patients are admitted or present. An ETC may choose to have a policy that is more stringent than the requirements of the rule by requiring a practitioner on site for these situations if it chooses.

Comment #9: A written comment was received suggesting NEW RULE 9 be revised so that responsibility for medical care remains with a Montana-licensed practitioner and is not outsourced.

Response #9: The OIG thanks the commenter for this suggestion but believes revision of NEW RULE 9 is unwarranted. Disallowing health care providers licensed in other states to collaborate and consult with ETCs could hinder a patient from receiving appropriate and effective treatment and services. Additionally, due to Montana's limited availability of specialty health services, such a limitation in rule could result in Montana patients needing to travel to other states, potentially across the country, to receive appropriate treatment and services.

Comment #10: A written comment was received requesting NEW RULE 9 be revised to explicitly require that a Montana-licensed practitioner and the medical director retain responsibility for patient care and be available as needed to assess, admit, treat, or transfer patients.

Response #10: The OIG thanks the commenter for the suggestion, but believes the suggested revision is unnecessary. NEW RULE 9 requires that ETC health care professionals be licensed under their respective Montana licensing board. NEW RULE 8 provides that the medical director is responsible for overseeing all treatment provided.

Comment #11: A written comment was received recommending that NEW RULE 11 be revised to remove the word "resident" and replace it with "patient" to ensure consistency with the other rules.

Response #11: The OIG thanks the commenter for this suggestion and has revised the rule accordingly.

Comment #12: Two written comments were received suggesting that the patient agreement requirements under NEW RULE 11 be revised to incorporate informed-consent requirements from 50-12-105, MCA, and include information about relevant phase 1 trials to support meaningful consent.

Response #12: The OIG thanks the commenters for their suggestions but declines to revise the rule. The informed-consent requirements of 50-12-105, MCA, are addressed in NEW RULE 12. The patient agreement requirements under NEW RULE 11 are intended as a separate stand-alone requirement.

In response to including relevant phase 1 trial information as part of the informed consent, the OIG declines to include this as part of the informed-consent requirements. ETCs may add additional language to their informed consent as long as the informed consent meets the minimum requirements of 50-12-105, MCA. The OIG's stand-alone informed consent complies with 50-12-105, MCA.

Comment #13: A written comment was received suggesting that the time frame for completing a patient's full history and physical under NEW RULE 12 be changed to 30 days before or 24 hours after admission/registration to align with the Centers for Medicare & Medicaid Services (CMS) hospital standards under 42 CFR 482.24.

Response #13: The OIG thanks the commenter for this suggestion. The intent under NEW RULE 12 is for a patient's full history and physical (H&P) to have been completed prior to the initiation of treatment/services by the facility. The OIG has revised the H&P time frame to "within 30 days" to better capture the patient's current health status.

Comment #14: A written comment was received suggesting that "and" under NEW RULE 12(2)(d) be revised to "or."

Response #14: The OIG agrees with the commenter's suggestion and has revised the rule accordingly.

Comment #15: A written comment was received suggesting that NEW RULE 13 be revised to require that transfer agreements be signed by a physician, consistent with the federal Emergency Medical Treatment and Labor Act requirements for hospital-level transfers.

Response #15: The OIG thanks the commenter for this suggestion but declines to make the suggested change. It is unnecessary to mandate that a physician sign the transfer agreement. The administrator or medical director is responsible for the transfer agreement under NEW RULE 13.

Comment #16: A written comment was received recommending that the requirements regarding emergency procedures under NEW RULE 14 be revised to align with nationally accepted accreditation processes used in comparable care settings.

Response #16: The OIG thanks the commenter for this suggestion but declines to make the suggested change. The requirements in NEW RULE 14 align with minimum standards for all health care facilities. Not all health care facilities are accredited. Requiring accreditation standards for all ETCs would be unduly burdensome for those facilities that plan to provide only minimal experimental services. Additionally, it is anticipated that some ETCs will neither fit within a "comparable setting" nor have an accreditation emergency procedure standard.

Comment #17: A written comment was received objecting to language under NEW RULE 14 addressing the performance of surgery in ETCs.

Response #17: The OIG disagrees with the commenter. Under 50-12-102, MCA, experimental treatment includes, "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…." The definition does not exclude medical

interventions applied or administered via a surgical procedure. NEW RULE 14 is necessary to ensure adequate protocols, safety measures, and staff are in place for potential experimental treatments requiring a surgical procedure.

Comment #18: A written comment was received objecting to the language in NEW RULE 14 addressing performance of surgery under anesthesia. The commenter indicated these types of procedures exceed the scope of this regulatory structure.

Response #18: Please see the response to comment #17.

Comment #19: A written comment was received indicating the surgical procedures described under NEW RULE 14 should either be excluded or made subject to the full set of requirements applicable to licensed facilities that perform surgery (e.g., hospitals, ASCs, and/or outpatient surgical centers).

Response #19: Please see the response to comment #17. Additionally, the OIG considered the Outpatient for Surgical Services licensing requirements when drafting the surgical rules.

Comment #20: A written comment was received suggesting that NEW RULE 18 be revised to require the infection control program to be led by the medical director, or another qualified practitioner designated by the medical director, who is qualified to serve as the infection control officer, given clinical risks and oversight demands.

Response #20: The OIG thanks the commenter for the suggestion and agrees with the suggested change. NEW RULE 8 has been revised to provide that the medical director is responsible for infection control program requirements of NEW RULE 18 and to allow for delegation of this responsibility to another licensed and qualified practitioner.

Comment #21: A written comment was received suggesting that NEW RULES 23 and 24 be revised for consistency to use the term “patient” instead of “resident.”

Response #21: The OIG thanks the commenter for this suggestion and has revised the rules accordingly.

Comment #22: A written comment was received indicating that the standards for inpatient services under NEW RULE 24 appear to be minimally more restrictive as compared to outpatient services.

Response #22: The OIG thanks the commenter for this comment. The OIG believes that NEW RULE 24 as proposed provides for appropriate standards for both inpatient and outpatient services.

Comment #23: A written comment was received recommending that NEW RULE 24 be revised to impose limits and standards on length of stay that are at least as protective as the CMS Conditions of Participation for critical access hospitals.

Response #23: The OIG thanks the commenter for this suggestion but believes that the standards suggested by the commenter are not appropriate for ETCs given the different type of care these centers are intended to provide compared to critical access hospitals. Critical access hospitals are required to maintain an average length of stay of 96 hours or less. Critical access hospitals provide standard, approved medical care. ETCs are intended to provide a range of non-standard therapies.

Comment #24: A written comment was received suggesting that NEW RULE 24 be revised to address a concern that inpatient-level care without hospital-equivalent safeguards may pose a risk to patients.

Response #24: The OIG thanks the commenter for this suggestion. Due to the wide range of potential services and treatments that ETCs may provide, requiring all ETCs to meet hospital-like standards is unnecessary and would pose an undue regulatory burden. The OIG believes the regulatory requirements under these proposed rules, in conjunction with the Right to Try Act, will ensure patient safety and appropriate treatment and care.

Comment #25: A written comment was received in opposition to NEW RULE 25, that allows under certain conditions for treatments to occur outside the licensed treatment center.

Response #25: The OIG declines to revise the rule to categorically prohibit treatment from occurring outside of a licensed ETC. Much of Montana is occupied by rural communities. Individuals in these communities cannot always travel to a larger city where an ETC might be located to receive treatment, especially for outpatient treatment. The conditions under which treatment may be provided outside of an ETC include safeguards designed to ensure patient safety.

Comment #26: A written comment was received indicating that the allowance for off-site treatments under NEW RULE 25 undermines oversight, documentation, and patient safety mechanisms that the licensure framework is designed to ensure.

Response #26: Please see the response to comment #25.

Comment #27: A written comment was received requesting that the provisions of NEW RULE 25 be removed from the proposed rules.

Response #27: Please see the response to comment #25.

Comment #28: Two written comments were received praising the potential for telemedicine under NEW RULE 25.

Response #28: The OIG thanks the commenters for the comments. No further response is necessary, as there are no questions or suggestions made by the commenters.

Comment #29: Two written comments were received praising the potential for experimental treatment devices.

Response #29: The OIG thanks the commenters for this comment. No further response is necessary, as there are no questions or suggestions made by the commenters.

Comment #30: An oral and written comment was received suggesting that in-vitro diagnostics should not be subject to the full ETC licensing framework.

Response #30: The OIG thanks the commenter for this suggestion. These rules apply only to facilities that meet the definition of an experimental treatment center under 50-5-101, MCA. The OIG does not believe that diagnostic-only entities constitute an ETC. Laboratories operating under the Clinical Laboratory Improvement Amendments (CLIA) of 1988, 42 CFR Part 493 (Standards and Certification: Laboratory Requirements), are not intended to fall under these ETC rules.

Comment #31: A written comment was received suggesting the creation of a streamlined pathway for facilities that conduct specimen analysis with no therapeutic intervention, no medication, and no patient hospitalization.

Response #31: Please see the response to comment #30.

Comment #32: An oral and written comment was received suggesting the creation of a review board waiver for CLIA-Certified diagnostics.

Response #32: The OIG thanks the commenter for the suggestion. Please see the response to comment #30.

Comment #33: An oral and written comment was received suggesting technical clarifications to NEW RULES 11 and 12 that reflect the diagnostic paradigm without reducing consent quality or record integrity.

Response #33: Please see the response to comment #30.

Comment #34: An oral and written comment was received regarding NEW RULE 25(1), requesting specificity for the time of review, what “safe administration outside of an experimental treatment center” means for diagnosing, and whether the facility can begin delivery while awaiting approval under NEW RULE 25.

Response #34: There is no specific time frame under NEW RULE 25 for which an experimental treatment review board is required to complete its evaluation of a medical device to determine if it can be safely administered outside of the ETC. ETCs are anticipated to provide a wide range of services, treatments, and devices. Some treatments and devices may require longer review than others. The intent of the rule is for a service, treatment, or device to be administered outside of an ETC only after the review board has completed its evaluation and the service, treatment, or device has been deemed safe to administer outside the ETC. These rules concern treatment in ETCs and purely diagnosing patients outside of an experimental treatment center is not covered under NEW RULE 25.

Comment #35: A written comment was received stating that the non-practicing restriction under NEW RULE 8 should be removed.

Response #35: The OIG thanks the commenter for this comment. NEW RULE 8 does not contain a non-practicing restriction.

Comment #36: A written comment was received requesting that NEW RULE 7 be revised to add minimum administrator qualifications commensurate with the role's operational and compliance responsibilities.

Response #36: The OIG thanks the commenter for the suggestion. The rule, as currently written, places responsibility for policy and procedures, staff training protocols, and oversight of the facility's daily operations with the administrator. The OIG agrees to the additional requirement of adding compliance with licensing regulations and the health, safety, and welfare of the patients within the ETC as a responsibility of the administrator and has revised the rule accordingly.

Comment #37: A written comment was received requesting that NEW RULE 7(5) be revised to permit co-contracting with a qualified professional administrator across ETCs owned by different entities or people — not just commonly owned ones — subject to the same written agreement, availability, and compliance conditions already specified in the proposed rule, mirroring the portable competency model recommended for review boards.

Response #37: The OIG thanks the commenter for this suggestion. The OIG does not agree with the suggestion, and declines to revise the rule as the OIG believes allowing such an arrangement may result in conflicts of interest.

Comment #38: A written comment was received requesting that NEW RULE 16(4) be revised to permit shared review boards across unaffiliated ETCs — not only commonly owned ones — subject to independent conflict-of-interest compliance for each center.

Response #38: The OIG thanks the commenter for this suggestion. NEW RULE 16(4), as written, does not preclude a review board from serving multiple unaffiliated ETCs.

Comment #39: Two written comments were received suggesting that NEW RULE 16 be revised to: (1) increase the minimum number of review board members from four to five in order to prevent potential deadlock; and (2) clarify that arm's-length professional compensation for board service does not constitute a disqualifying financial interest.

Response #39: The OIG thanks the commenters for these suggestions. The OIG agrees to increasing to five the minimum number of review board members and has revised the rule accordingly. The OIG does not believe that specifying the second part of the commenters' suggestion in rule is necessary. A bona-fide arm's length professional compensation arrangement is a common practice and would not be considered a disqualifying financial interest by the OIG under the rule.

Comment #40: A written comment was received requesting NEW RULE 16 be revised to establish a minimum monthly review board meeting frequency for active ETCs, with an expedited review pathway for time-sensitive safety questions.

Response #40: The OIG thanks the commenter for this suggestion. The OIG agrees to adding requirements for the experimental treatment review board to regularly meet and has revised NEW RULE 16 to establish a monthly meeting requirement. The OIG does not agree to requiring an expedited review process for time-sensitive safety questions. Treatments should not be administered prior to the review board's approval, and all safety evaluations must be conducted prior to approval under these proposed rules. Additionally, the OIG does not believe there should be facilitation to speed up or rush the approval process. The intent is to ensure that these experimental treatments are safe for delivery following thorough evaluation and consideration by a review board.

Comment #41: A written comment was received requesting the proposed rules be revised to mandate for therapy-level review board approval for each intervention offered, rather than only facility-level oversight, with a structured evaluation framework addressing evidence maturity, supply pathway context, clinical leadership competency, and financial interest disclosure.

Response #41: The OIG thanks the commenter for this suggestion, but does not believe a change to the rules is necessary as this function can be adequately handled by the experimental treatment review board.

Comment #42: A written comment was received requesting that NEW RULE 17 be revised to require that serious adverse event reports be transmitted simultaneously to the review board and the department.

Response #42: The OIG thanks the commenter for this suggestion. The OIG agrees with the commenter and has revised the rule accordingly.

Comment #43: A written comment was received requesting that the proposed rules be revised to require coordination with active IND sponsors for therapies operating in parallel with U.S. Food and Drug Administration (FDA) trials.

Response #43: The OIG thanks the commenter for this request. The OIG does not agree with the commenter's suggestion. ETCs are not intended to be directly tied to FDA trials and associated regulatory requirements.

Comment #44: A written comment was received requesting clarification that internationally licensed clinicians may participate in a defined consultative capacity under the supervision of the ETC's Montana-licensed medical director, supporting the Port of Entry supply pathway.

Response #44: NEW RULE 10 indicates that "out-of-state professionals" may collaborate and consult for an ETC. The OIG clarifies that this does not restrict international professionals, as they are out-of-state.

Comment #45: A written comment was received requesting NEW RULE 11(2)(c) be revised to permit a description of prior development history and regulatory status in lieu of a phase designation where a formal phase classification does not apply.

Response #45: The OIG does not agree with the commenter's suggested amendment to this rule. Montana law defines experimental treatment in 50-12-102(1), MCA, as: "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.…" A treatment or device must have undergone phase 1 clinical trials to be considered for administration at an ETC.

Comment #46: A written comment was received requesting a risk-stratification for the H&P currency requirement under NEW RULE 12(2)(b). The commenter suggests 12 months for stable conditions and 3 to 6 months for progressive disease, with medical director discretion to require a more current assessment.

Response #46: Please see the response to comment #13.

Comment #47: A written comment was received requesting that NEW RULE 13 be revised to require that treatment documentation cite to the source of evidence underlying expected outcomes and not merely state the expected outcomes.

Response #47: The OIG agrees with the commenter's suggestion and has revised the rule accordingly.

Comment #48: A written comment was received requesting that NEW RULE 21 be revised to include a device safety alert and recall response protocol covering monitoring, patient notification, treatment suspension criteria, and clinical management.

Response #48: The OIG thanks the commenter for this suggestion. The rule, as currently written, requires the facility to have protocols in place for monitoring and assisting with device malfunctions and for safety. Due to the wide range of devices anticipated to be used at ETCs, it is not feasible to require all devices to have device safety alert capabilities. The OIG has revised the rule to require ETCs to have procedures in place for recalls.

Comment #49: A written comment was received requesting NEW RULE 22 be revised to include a notice-and-cure period prior to any action being taken to reduce licensure to provisional status when a facility fails to timely file an annual report.

Response #49: The OIG thanks the commenter for the suggestion, but disagrees with the suggested change. The report is statutorily required and must be submitted by February 1 of each year. 50-5-221, MCA. The OIG has revised NEW RULE 22 to update the submittal date to February 1 of each year to align with the statute.

Comment #50: A written comment was received requesting revision of NEW RULES 23(9)(e) and 24(12)(e) to permit dual staff roles in co-located settings, provided written policies clearly delineate ETC and non-ETC activities.

Response #50: The OIG thanks the commenter for this suggestion, but declines to revise the rule. Federal requirements exist for staff working in a federally certified health care facility. The OIG does not have authority to waive these federal requirements. The intent of the rule is to ensure that the certification or licensure status of another health care facility is not jeopardized when an ETC operates within the facility.

Comment #51: Two written comments were received requesting that NEW RULE 23 be revised to establish a mobile service delivery process to permit ETCs to extend services to rural and frontier communities through units operating under the supervision of the medical director of the primary ETC, consistent with the access mandate of 50-5-251, MCA.

Response #51: The OIG disagrees with the suggested change. The addition of mobile services would remove the ability to render additional services to the patient and for the patient to be seen by a practitioner in an emergency. The intent of NEW RULE 25 is to facilitate the offering of experimental treatments in rural communities. In addition, the OIG will consider approving branch locations for an ETC under the center's main license, as is done for other types of health care facilities. However, each branch location would be required to meet all requirements as the main location would for approval.

Comment #52: Two written comments were received requesting clarification if open floor plan treatment zones satisfy the patient room requirements under NEW RULE 23(4), provided that

patient privacy and infection control standards are met, applying the clearance-and-visibility design standards already contemplated in NEW RULE 24(4) and (10) for inpatient facilities.

Response #52: The intent of NEW RULE 23 is to require enclosed patient rooms, but the OIG would consider waivers to this requirement on an individualized, as-needed basis.

Comment #53: A written comment was received requesting the proposed rules be revised to define the term “net annual profits” for 2% the calculation.

Response #53: This term is not used in the proposed new rules, and therefore it is unnecessary to define the term within the rules.

Comment #54: A written comment was received requesting confirmation of no obligation in loss years.

Response #54: This comment is outside the scope of the rulemaking.

Comment #55: A written comment was received requesting permission of carry-forward of excess contributions.

Response #55: This comment is outside the scope of the rulemaking.

Comment #56: A written comment was received requesting recognition of donor-advised funds and qualified nonprofits as a third fulfillment pathway.

Response #56: This comment is outside the scope of the rulemaking.

Comment #57: A written comment was received requesting consolidation of the 2% reporting under 50-5-251, MCA, into the annual report required under NEW RULE 22.

Response #57: The OIG declines to make this rule change and believes the report statutorily required under 50-5-251, MCA, should remain separate from the report required under the administrative rule because each report addresses different subject matter and legal requirements.

Comment #58: A written comment was received requesting the proposed rules be revised to address authentication standards for digitally recorded informed consent, given the legal significance of what patients waive under 50-12-110, MCA.

Response #58: The OIG thanks the commenter for this suggestion. Informed-consent requirements are addressed in 50-12-105, MCA. Section 50-12-105(4), MCA, recommends that health care providers and facilities utilize enhanced informed consent processes. Each facility will need to determine how to authenticate digital consent, if used.

Comment #59: A written comment was received requesting that NEW RULE 11 be revised to reference the alternative currency payment option under 50-12-106(4), MCA. The commenter also suggests NEW RULES 1 and 2 be revised to reference the prohibition against the state restricting access to ETCs under 50-12-109, MCA.

Response #59: The OIG thanks the commenter for these suggestions. Responding to the comment regarding 50-12-106(4), MCA, and NEW RULE 11, the statute allows providers to enter into provider agreements and establish payment arrangements. NEW RULE 11 requires that the patient agreement include a detailed description of all the anticipated costs to the patients, if any, and how the center intends to bill or receive payments. The OIG believes the rule as written is consistent with the statute. Responding to the comment regarding 50-12-109, MCA and NEW RULES 1 and 2, there is no conflict between the statute and these rules. ETCs are statutorily required to be licensed under 50-5-250, MCA.

Comment #60: A written comment was received requesting the definition of "treatment" under NEW RULE 4(13) be amended to exclude dietary supplements and wellness products that have no credible on-ramp to the FDA approval pathway. The commenter indicates these interventions cannot, in principle, qualify as experimental treatment under SB 535.

Response #60: The OIG thanks the commenter for this suggestion, but declines to make the suggested change. Treatments that have not successfully completed a phase 1 trial are already statutorily excluded from being administered by ETCs because such treatments do not meet the definition of an "experimental treatment." 50-12-102(1), MCA.

Comment #61: A written comment was received requesting that NEW RULES 11 and 12 be revised to include language under 50-12-105(2)(h), MCA, that provides that informed consent must include patient acknowledgment that experimental treatment cannot be used to assist with ending the patient's natural life.

Response #61: The OIG thanks the commenter for this suggestion. NEW RULE 12 already requires that the patient file must include "informed consent pursuant to and in alignment with 50-12-105, MCA." The OIG believes repeating the statutory language referenced by the commenter in rule would be redundant and is unnecessary. Additionally, the Montana Administrative Procedure Act provides that rules must not unnecessarily repeat statutory language. 2-4-305(2), MCA.

Comment #62: Two written comments were received requesting expansion of the 50-12-105(2)(e) and (g) financial disclosure in NEW RULE 11 to explicitly address the downstream insurance coverage cascade: that complications from the experimental treatment — including emergency care, hospitalization, and follow-on adverse event management — may be denied coverage by the patient's insurer as causally related to the experimental treatment, and that the patient may bear the full cost of that consequent care personally; encourage patients to verify their policy's experimental treatment exclusions with their insurer before proceeding.

Response #62: The OIG believes the commenter's suggestion is already covered under 50-12-105(2)(e), MCA, and the statutory language does not need to be repeated in the rule.

Comment #63: A written comment was received requesting the establishment of ETC-specific marketing and advertising standards that cross-reference Montana's existing consumer protection framework (30-14-103, MCA), physician advertising rules (37-3-323, MCA), and FTC health care advertising guidance.

Response #63: The OIG thanks the commenter for this suggestion. These proposed rules address ETC licensing requirements and the care and services provided within these centers to ensure patients receive adequate and safe care, including informed consent requirements under 50-12-105, MCA. The OIG believes that regulating ETC marketing and promotion is outside the scope of this rulemaking.

Comment #64: A written comment was received requesting all ETC marketing accurately identify treatments as experimental and investigational, that outcome representations not exceed what the review board's therapy approval documents support, and that all materials include a plain-language experimental treatment disclaimer.

Response #64: The OIG thanks the commenter for their suggestion. Please see the response to comment #63.

Comment #65: A written comment was received requesting routing of complaints through DPHHS licensing compliance with referral authority to the Montana DOJ Consumer Protection Office and the Board of Medical Examiners for serious violations.

Response #65: The OIG thanks the commenter for this suggestion. As a standard practice, the OIG refers complaints to other state entities as appropriate.

Comment #66: Two written comments were received requesting that all patient-facing consent and agreement documents be written at a sixth grade reading comprehension level.

Response #66: The OIG thanks the commenters for this suggestion. It is the responsibility of the patient or legal representative to have a clear understanding of the consent form before signing it, and to ask clarifying questions as needed. Additionally, the OIG does not dictate as a condition of licensing the reading comprehension levels of other health care facilities' consent and agreement documents. It would be inconsistent to do so here. Accordingly, the OIG declines to make this requested change.

Comment #67: A written comment was received requesting qualified third-party interpreter services for patients whose primary language is not English.

Response #67: The OIG thanks the commenter for this suggestion. A prospective patient of an ETC has the right to request a third-party interpreter to assist with understanding informed

consent, treatment, and services, and to assist before signing any document or receiving services. It would be needlessly burdensome to condition licensing on this suggested amendment.

Comment #68: A written comment was received requesting clarification that the "desired health outcomes" eligibility standard operates within the scope of the experimental treatment definition — it governs who may receive qualifying treatments, not what qualifies as a treatment.

Response #68: The OIG thanks the commenter for this request. The OIG agrees and has updated NEW RULE 12(2)(d) to require that the desired outcomes be specific to recipients who have the condition for which the experimental treatment is intended.

Comment #69: A written comment was received requesting expansion of NEW RULE 11(2)(d)'s immunity from suit provision to require a plain-language explanation of what patients are waiving, not merely verbatim statutory text.

Response #69: The OIG thanks this commenter for this suggestion. These rules are intended to set forth the requirements for licensure. NEW RULE 11(2)(d) requires that an ETC include as part of its patient agreement the full text of 50-12-110, MCA. It is up to the patient to seek clarifying information as needed for better comprehension. An ETC may also choose to elaborate upon the Immunity From Suit statute during patient counseling in addition to providing the law as written, but such a requirement is not needed in the licensing regulations. As such, the OIG declines to make this suggested change.

Comment #70: A written comment was received requesting that differential inpatient clinical standards be aligned with NEW RULE 24, cross-referencing Montana's existing inpatient facility definitions and standards in ARM Title 37, chapter 106, rather than creating new parallel definitions.

Response #70: The OIG thanks the commenter for this request. NEW RULE 24 was written in conjunction with the Licensure Bureau's construction consultant. Because ETCs do not have current chapters within the National Fire Protection Association (NFPA) or Facilities Guidelines Institute (FGI) editions, or are a subject matter within the Americans with Disabilities Act (ADA), the OIG used portions of the rules for other inpatient facilities to generate the requirements found in NEW RULE 24 to ensure patient safety and the facilitation of treatments in an inpatient setting.

Comment #71: A written comment was received requesting a maximum 180-day provisional licensing period to NEW RULE 16(7), after which the license lapses if the review board has not been constituted.

Response #71: The OIG thanks the commenter for this request. Provisional licenses for health care facilities may be issued for up to one year per 50-5-207(3), MCA.

Comment #72: A written comment was received requesting a definition for “reputable and responsible character” in NEW RULE 5(1)(e) with objective criteria or to remove the attestation as redundant to NEW RULE 5(1)(c)'s specific disclosure requirements.

Response #72: The OIG thanks the commenter for this suggestion. The OIG agrees and has revised NEW RULE 5 to provide parameters around what would constitute “reputable and responsible character.”

Comment #73: A written comment was received requesting a cross-reference to 33-1-102(d), MCA's direct agreement insurance exemption in NEW RULE 11 or NEW RULE 6.

Response #73: The OIG thanks the commenter for this request. The new rules are intended to provide ETCs with the requirements they must meet to achieve and retain licensure as an ETC. It is unnecessary to include references to laws that set exemption allowances in licensing regulations.

Comment #74: A written comment was received requesting a mandatory three-year program review and legislative reporting requirement so that aggregate outcomes, adverse event patterns, and access data inform future rule revisions.

Response #74: The OIG thanks the commenter for this suggestion. Experimental treatment centers have been placed under the health care facility definition under 50-5-101(26), MCA. This facilitates the application of 50-5-201(2), MCA, to ETCs. These facilities will receive a one-, two-, or three-year license based on the results of their previous survey. A license cannot be renewed/administered without a full inspection for compliance monitoring. Therefore, ETCs will be reviewed for compliance, at a minimum, every three years.

Comment #75: A written comment was received requesting a systematic review of ARM Title 37, chapter 106, subchapter 3 to identify general facility provisions that will apply to ETCs by default, cross-referencing existing Montana definitions where applicable, rather than creating new parallel standards.

Response #75: The OIG thanks the commenter for its request. Please see the response to comment #70.

Comment #76: A written comment was received requesting the narrowing of NEW RULE 5(1)(c)'s felony disclosure requirement to owners, operators, administrators, medical directors, and licensed clinical staff.

Response #76: The OIG thanks the commenter for this request. This rule applies only to an ETC application. Requiring full attestation of this for all professional and administrative staff may not be feasible when a facility is first applying, as those positions are often not fully staffed/determined at that time. This would also not necessarily prevent someone with a

felony conviction from being hired after the initial application is completed. NEW RULE 9 requires all professional staff to have licenses in good standing. It is the OIG's understanding that if an individual with a professional license has been convicted of a felony, that individual would have to face the board under which they are licensed and that the board would then impose appropriate sanctions or restrictions on that license.

Comment #77: A written comment was received requesting codification of the 90-day application review timeline in NEW RULE 5 and adding a 90-day transition provision to NEW RULE 25(4) for patients mid-treatment when a therapy receives FDA approval.

Response #77: The OIG thanks the commenter for these suggestions. The OIG does not understand where the commenter is reviewing documentation of a 90-day application review timeline and, therefore, is unable to respond to that specific request. A 90-day transition period for a treatment that has received FDA approval is unnecessary, as a patient can continue treatment outside the experimental treatment center once FDA approval is granted. For these reasons, the OIG declines to make the requested amendments.

Comment #78: A written comment was received requesting all ETC staff — clinical and administrative — to obtain and maintain training in Good Clinical Practice consistent with ICH E6(R2) prior to initiation of patient care, with renewal on a defined cycle.

Response #78: The OIG thanks the commenter for this request. The OIG does not believe these requirements are necessary, since staff at ETCs are neither generating clinical trial data nor participating in a trial. The OIG's focus for ETC licensing is licensed personnel under Montana statute, the collection of outcome data, both positive and negative, and adverse event reporting.

Comment #79: A written comment was received requesting each ETC to submit a documented investigational product management plan covering temperature-controlled storage with continuous monitoring and excursion management, chain-of-custody from receipt through administration or disposal, preparation and assembly procedures under appropriate aseptic technique, and administration standards.

Response #79: The OIG thanks the commenter for this suggestion. The OIG declines to make this change as it is unnecessary given the protocols, reviews, and expectations required of the experimental treatment review board. Many of the suggestions above will be achieved through the careful processing and review of these treatments by the ETRB; acquisition and submission of this documentation is redundant.

Comment #80: A written comment was received requesting that structured pre-treatment screening for contraindications, concomitant medications, and lifestyle risk factors be established as a defined operational standard.

Response #80: The OIG thanks the commenter for this suggestion. The OIG agrees and has added these requirements to the required documentation within a patient file in NEW RULE 12.

Comment #81: A written comment was received requesting explicit post-treatment monitoring obligations scaled to therapeutic risk and evidence maturity.

Response #81: The OIG thanks the commenter for this suggestion; however, it does not agree with the requested changes. ETCs will be able to offer a wide range of services, making it difficult for licensing to define what each center must provide to demonstrate explicit post-treatment monitoring and how to quantify it.

Comment #82: A written comment was received requesting event attribution documentation distinguishing treatment-attributable adverse events from expected clinical outcomes of the underlying disease.

Response #82: The OIG thanks the commenter for this suggestion. NEW RULE 13 covers adverse side effects and is distinct from the requirement to document patient outcomes. The suggestion in the comment is relevant to clinical trials, not licensed ETCs.

Comment #83: A written comment was received requesting interpretive guidance on NEW RULE 4(12)'s qualified medical institution standard — including a recognized authority list, qualifying non-trial evidence sources, and a consistent equivalency review template.

Response #83: The OIG thanks the commenter for this comment. The OIG's definition of a qualified medical institution provides provisions that an institute must meet to be deemed as such. The OIG does not believe an administrative rule is an appropriate place to list professional entities that may be considered. This information can be requested and facilitated, as able, by the OIG upon request.

Comment #84: A written comment was received requesting adoption of an explicit proprietary information protection process modeled on Montana's Uniform Trade Secrets Act framework and State Procurement Bureau affidavit procedure.

Response #84: The OIG thanks the commenter for this suggestion. The OIG does not request or expect ETCs to provide us with proprietary information as part of the licensing process, and therefore OIG declines to make the requested change as it is unnecessary.

Comment #85: A written comment was received requesting the establishment of patient privacy as an explicit rule requirement, mandating de-identification as the default for all board and department reporting, consistent with HIPAA and 50-16-501, MCA, et seq.

Response #85: The OIG thanks the commenter for this request. The OIG agrees to include the requirement that all identifying patient information be redacted for standard reporting purposes. The OIG requires access to patient charts and information for renewal surveys and

complaint investigations under ARM 37.106.310, and may refer to certain patients in reports, but that information is never made available on a public-facing platform. The extent to which patient information between an ETC and a review board may be shared is addressed under existing health privacy laws, including HIPAA and Montana's Uniform Health Care Information Act.

Comment #86: Two written comments were received requesting reconsideration of the one-year Montana licensure requirement of NEW RULES 4 and 8.

Response #86: The OIG thanks the commenter for this suggestion. The OIG agrees to remove the requirement that a physician must be licensed in the State of Montana for one year to qualify as a medical director in NEW RULE 4. There is no such requirement in NEW RULE 8.

Comment #87: A written comment was received requesting alternatives to the hospital transfer agreement when hospital partners are limited.

Response #87: The OIG thanks the commenter for the suggestion. A patient can be transferred to other health care facilities for non-emergent situations without a transfer agreement, but when a patient needs to be seen and treated at a hospital for an emergency, a transfer agreement must be in place with a hospital that will accept the patient. For this reason, the OIG declines to make any changes to this requirement.

Comment #88: A written comment was received requesting a rule addressing physician supervision via telehealth or standing order for defined low-acuity contexts.

Response #88: The OIG thanks the commenter for this suggestion. The OIG declines to make these changes. NEW RULE 10 allows for out-of-state providers to collaborate and provide consultation to professionals within the ETC, and it is assumed that those collaborations and consultations can occur via telehealth, but direct care should be provided in-person by licensed professionals who are physically available to the patient. Additionally, the purpose of ETCs is to provide experimental treatments with unstable, unknown, or unpredictable outcomes. Standing orders are meant for predictable, routine situations, which are not realistic for experimental treatments.

Comment #89: Multiple written comments were received requesting a narrowly tailored provisional licensure pathway, available during the period when applications are pending immediately following rule adoption, for patients whose treating practitioners document time-sensitive medical urgency.

Response #89: The OIG thanks the commenters for this suggestion. The OIG declines to make this change. Medical urgency is vague and not specific, leaving it open to interpretation whether it is truly a medical urgency. It is the intent of the OIG to assist with licensing ETCs as quickly as possible when an application is initiated, but it is important that the OIG do so in a

manner that protects patient health and safety. Speeding up the process through shortcuts and exemptions could have detrimental effects on patients.

Comment #90: A written comment was received requesting clarification that electronic signatures are permitted for patient agreements and informed consent, with minimum authentication standards to address emerging fraud risks.

Response #90: The OIG thanks the commenter for this question. Please see the response to comment #58.

Comment #91: A written comment was received requesting recognition of donor-advised fund and qualified-nonprofit pathways for fulfilling the 2% obligation, alongside direct-care provision and the Insurance Premium Support Account.

Response #91: The purpose of this rulemaking is to establish the licensing requirements for ETCs. This comment is outside the scope of this rulemaking.

Comment #92: A written comment was received requesting clarification that the patient agreement required by NEW RULE 11 may identify a treatment's regulatory or clinical development status, including completed Phase 1 status not currently in active trial enrollment.

Response #92: The OIG thanks the commenter for this suggestion. It is the expectation of the OIG that all experimental treatments meet the definition provided in 50-12-102(1), MCA. The OIG does not find it necessary to require this information in the patient agreement, but a patient may request more information about the treatment they are seeking.

Comment #93: A written comment was received requesting clarification on which drugs can be provided under the ETC program, their cost to the patient, and manufacturing requirements.

Response #93: The OIG thanks the commenter for this request. The purpose of this rulemaking is to establish the licensing requirements for ETCs. Manufacturing requirements and costs to patients for some experimental treatments are issues outside the scope of this rulemaking.

Comment #94: A written comment was received requesting the department utilize different terminology for experimental treatment centers, such as “investigational medical product” or “investigational experimental treatment device.”

Response #94: The OIG thanks the commenter for this suggestion. “Experimental treatment” and “experimental treatment center” are statutory definitions (see 50-12-102, MCA). Accordingly, the OIG does not have the authority to change these definitions in regulation.

Comment #95: A written comment was received requesting inclusion of a Montana state registry for the use of experimental treatments, mirroring the clinicaltrials.gov registry.

Response #95: The OIG thanks the commenter for this suggestion. All facilities licensed by the OIG are on a public database found at: https://mt-reports.com/portal/SearchFacility.aspx. The search feature lets you find facilities and review their licensing information, past inspections, and services.

Comment #96: A written comment was received praising the clearly defined parameters of SB 535 language requiring that an experimental treatment "has a demonstrated safety record through documented clinical evidence from a qualified medical institution as defined by department rule."

Response #96: The OIG thanks the commenter for the comment.

Comment #97: A written comment was received suggesting the department utilize the language of "serious adverse events" to better align with industry terminology.

Response #97: The OIG thanks the commenter for this suggestion. NEW RULE 17 has been revised to clarify adverse event and serious adverse event reporting.

Comment #98: A written comment was received suggesting additional language to ensure that the experimental treatment centers have oversight over all "satellite" sites.

Response #98: The OIG thanks the commenter for this suggestion. The OIG believes the current rules and proposed rules already address this suggestion; it is a standard occurrence within the licensure bureau for health care facilities, as satellite facilities are currently allowed under existing health care facility rules.

Comment #99: Two written comments were received suggesting the department strike "and attempted" from NEW RULE 12(2)(f) so the rule mirrors the statutory requirements and does not create new requirements.

Response #99: The OIG thanks the commenter for this suggestion. The OIG agrees and has removed "and attempted" from NEW RULE 12(2)(f) to facilitate consistency with the law.

Comment #100: A written comment was received suggesting deleting the second sentence of NEW RULE 8(1) as more detailed information is contained within (6). Section (6) further aligns with NEW RULE 7(5).

Response #100: The OIG thanks the commenter for this suggestion and agrees with it. NEW RULE 8(1) has been revised accordingly.

Comment #101: A written comment was received suggesting the department clarify that separate staff does not mean a staff of entirely different people, but rather people clearly working under an ETC license versus another health care facility license.

Response #101: The OIG thanks the commenter for this suggestion. The OIG's review of the rule, as written, states that staff working in the health care facility and in the ETC must be kept separate. Staff cannot work in both facilities at the same time. The OIG does not think further reiteration is required.

Comment #102: A written comment was received suggesting less restrictive requirements for outpatient ETCs that do not offer invasive treatments, such as an infusion center which is designed much differently than individual hospital rooms, or for diagnostic tests like treatments that use simple blood tests.

Response #102: The OIG thanks the commenter for this suggestion. The intent of the ETC rules is to designate centers where experimental treatments and devices are administered to patients, on either an inpatient or outpatient basis. ETCs are not intended to solely provide diagnostic or sample analysis services. It is understood that providers who do not offer experimental treatments pursuant to 50-12-102(1), MCA, would not be required to meet the ETC licensing requirement.

Comment #103: A written comment was received requesting clarification whether members serving on an experimental treatment review board may be compensated if they have no other employment/ownership interest in the entities for which they are reviewing proposed treatments.

Response #103: The proposed rules do not address provisions for or restrictions on ETRB members' compensation for their participation on the review board.

Comment #104: A written comment was received suggesting the role of ethicist should be construed more broadly to include those with a patient advocate background.

Response #104: The OIG thanks the commenter for this suggestion. This requirement was the state medical director's request to ensure ethical practices are part of the review of the ETRB. Patient advocacy is a separate service and is not of a parallel nature to what an ethicist can provide.

Comment #105: A written comment was received requesting modification of 50-12-105, MCA, to reflect that other treatments may also improve the condition, but not to the same degree, or be cost-prohibitive or have blocked access.

Response #105: The OIG thanks the commenter for their request. The intent of this comment period is to comment on the proposed new rules. Changes to the MCA require legislative involvement and are not subject to consideration through this rulemaking process.

Comment #106: A written comment was received requesting elaboration on the definition of "ethicist."

Response #106: The OIG thanks the commenter for this suggestion. An ethicist is defined in the standard dictionary as "a specialist in ethics." Repetitive definition within administrative rules is not required.

Comment #107: A written comment was received proposing that if the experimental treatment center is for-profit, it should be clarified if the 2% of net profits are a tax-deductible donation.

Response #107: The OIG thanks the commenter for this proposal. This rulemaking is limited to the licensing requirements for ETCs.

Comment #108: A written comment was received requesting a description of what constitutes an inpatient treatment, as the normal CMS requirements for inpatient versus outpatient do not necessarily apply.

Response #108: The OIG thanks the commenter for this question. In this proposed rulemaking, inpatient and outpatient refer to the type of center, not the specific treatment. It is understood that the administering practitioner, the recommendations of the phase 1 trials, and the recommendations of the experimental treatment review board will determine whether a treatment or device is administered on an inpatient or outpatient basis. It is important to note that the ETCs are not recognized by CMS, and therefore, CMS standards do not apply.

Comment #109: A written comment was received requesting clarification that staff may have dual employment.

Response #109: The OIG thanks the commenter for this question. The OIG does not regulate an individual's employment capabilities, and cannot comment on dual employment. The administrative rules require staff to be kept separate between an ETC and another health care facility when operating in the same structure.

Comment #110: A written comment was received suggesting strengthening the provisions of ETC licensure, particularly by requiring demonstration of clinical governance infrastructure, including medical director oversight, peer review processes, policies regarding patient privacy and data protection, and policies for escalation of adverse events; establishing a graduated or provisional licensure pathway for new centers, with enhanced monitoring during initial operations; and conditioning license renewal on demonstrated compliance with reporting, safety, and inspection requirements.

Response #110: ETCs have been placed within the health care facility definition. This requires the OIG to follow the licensing requirements common to all health care facilities, which allow regular one-, two-, or three-year licenses, and allows provisional licenses to be issued as needed. These requirements put into action the suggestion above that the facilities be licensed based on the results of their services. Additionally, as standard process, a provisional license is issued to each new health care facility after the application is completed and approved. This

requires OIG staff to conduct the first compliance review within the first six months of operations to ensure the facility meets licensing standards and poses no safety risks to patients.

Comment #111: A written comment was received recommending the development of specific provisions pertaining to minors, pregnant women, and low-income patients, as groups particularly vulnerable to long-term impacts of experimental treatments.

Response #111: The OIG thanks the commenter for this recommendation. The proposed rules require an ETC to obtain informed consent, pursuant to 50-12-105, MCA, for each patient treated at the center. This requirement sufficiently addresses potential issues across all populations.

Comment #112: A written comment was received recommending that the rules explicitly state that any physician or licensed clinician involved in recommending, administering, or managing experimental treatments must both hold an active, unrestricted Montana license, and operate within the scope of practice, training, and board certification relevant to the condition being treated.

Response #112: The OIG thanks the commenter for this suggestion. The OIG does not agree with this suggestion, as it removes the ability of a physician or clinician who holds an internal medicine or general practitioner role to make any recommendations or refer a patient for treatment. This would then require that the general practitioner refer to a specialist, who would need to see the patient and potentially provide treatment before referring to an ETC, which could be cost-prohibitive for many individuals. This may also deter people in rural communities from considering experimental treatments if they know they must travel extensively – first to see a specialist in their condition, and perhaps several times – and then to an ETC.

Comment #113: A written comment was received requesting details on privacy protections and how a patient's data will be used and protected in the future.

Response #113: The OIG thanks the commenter for this question. Please see the response to comment #85. It is the interpretation of the OIG that ETCs, as health care facilities, would be required to uphold and adhere to applicable state and federal laws.

Comment #114: A written comment was received requesting explicit discussion of alternative standard-of-care options, including palliative and supportive care.

Response #114: The OIG thanks the commenter for this request. This comment is outside the scope of this rulemaking.

Comment #115: A written comment was received requesting a cooling-off period between education and consent for non-emergent treatments.

Response #115: The OIG thanks the commenter for this suggestion. Given the wide range of services, treatments, and devices ETCs may offer, the OIG does not believe such a requirement is necessary. The rules as proposed consider patient autonomy, provider judgment, and necessary regulatory oversight. It is OIG's position that the current rules balance these interests.

Comment #116: A written comment was received recommending the department set limits on the number of experimental treatment centers per region based on population, workforce availability, and inspection capacity.

Response #116: The OIG thanks the commenter for this request. The OIG does not have the authority to do what the requester recommends. ETCs are not subject to Certificate of Need requirements, and the OIG does not have the authority to apply those standards.

Comment #117: A written comment was received recommending periodically reassessing the limits on the number of ETCs based on demonstrated outcomes and compliance history.

Response #117: The OIG thanks the commenter for this request. The OIG does not have the statutory authority to limit the number of ETC licenses issued statewide.

Comment #118: A written comment was received requesting that the department should also aggregate and publish de-identified, statewide safety summaries to promote transparency and continuous improvement.

Response #118: The OIG thanks the commenter for this request. Since this comment did not request edits of the proposed rules, the OIG declines to make any. However, for instructions on how to view publicly available information about facilities licensed by the OIG, please see the response to comment #95.

Comment #119: A written comment was received suggesting rules should incorporate periodic independent audits or inspections for high-risk therapies or noncompliant centers.

Response #119: The OIG thanks the commenter for this suggestion. The OIG cannot mandate another agency to audit or inspect the ETCs.

Comment #120: A written comment was received requesting that the review board have the authority not only to review proposed experimental treatments but also to issue approval before treatments could begin.

Response #120: The OIG thanks the commenter for this request. This is already covered by NEW RULE 16(6).

Comment #121: A written comment was received requesting a language cleanup in NEW RULE 8; specifically, the statement of reasonable necessity (SORN) in the proposal notice appears to

contain language justifying a proposed rule that prohibited an ETC medical director from also practicing medicine at the same ETC, but that the proposed rule text did not contain such a prohibition.

Response #121: The OIG thanks the commenter for this request. The OIG recognizes that the draft provision was ultimately not included in the proposed rule, but the corresponding SORN was not updated. The current version of the rule is the intended version.

Comment #122: A written comment was received regarding NEW RULE 16(6)(c), suggesting that the annual summary's value to patients, providers, and the broader research community would be substantially enhanced by the addition of aggregate treatment outcome data.

Response #122: The OIG thanks the commenter for this suggestion. The OIG agrees with the suggestion and has added this requirement as part of NEW RULE 16(6)(c).

Comment #123: A written comment was received suggesting adding to NEW RULE 13(1) a requirement that experimental treatment centers define prospective outcome measures for each treatment protocol at the point of protocol adoption, ensuring that efficacy data collection is integrated into the treatment process from the outset.

Response #123: The OIG thanks the commenter for this suggestion. However, the OIG declines to make this change. ETCs are distinct from clinical trials, and this suggestion appears to conflate the two. The desired outcome will be defined by the underlying condition being treated, the type of treatment, and the desired result; these criteria must be reviewed by the experimental treatment review board pursuant to NEW RULE 16.

Comment #124: A written comment was received requesting the department to apply a "least burdensome" standard across all 25 rules and eliminate any reporting or administrative requirement that is not strictly necessary to protect patient safety. Specific requirements that should be reconsidered include quarterly QAPI meetings (NEW RULE 15), annual reports (NEW RULE 22), biennial policy reviews (NEW RULE 6), five-day adverse event reporting (NEW RULE 17), and annual renewal of transfer and outside-entity agreements (NEW RULES 13 and 25).

Response #124: The OIG thanks the commenter for these suggestions; however, OIG declines to make any changes based on this comment. It is the position of the OIG that the proposed rules, as written, appropriately monitor patient safety without needless regulatory burden.

Comment #125: A written comment was received suggesting amendments to NEW RULES 4(9) and 8 to allow nurse practitioners, physician assistants (PAs), and other advanced practice registered nurses (APRNs) licensed in Montana to serve as a medical director.

Response #125: The OIG thanks the commenter for this suggestion. However, the OIG declines to make this change. The treatments to be provided in ETCs are not routine, and therefore

require a high level of oversight and medical understanding. The OIG believes the regulations as written best address the unique oversight needs of ETCs.

Comment #126: A written comment was received suggesting an amendment to NEW RULE 8 to explicitly state that the medical director may fulfill oversight and administrative responsibilities remotely via telehealth.

Response #126: The OIG thanks the commenter for this suggestion. Please see the response to comment #88. It is not the intent of the OIG that practitioners and medical directors provide their services via telehealth.

Comment #127: A written comment was received suggesting an amendment to NEW RULE 12(2)(b) to explicitly permit the required history and physical examination (H&P) to be conducted via a synchronous telehealth visit.

Response #127: The OIG thanks the commenter for this suggestion. Please see the response to comment #126.

Comment #128: A commenter suggested reducing the application, license, and renewal fees, or adopting a sliding-scale fee structure that provides meaningful relief for non-profit and mission-driven organizations applying to operate ETCs.

Response #128: The OIG thanks the commenter for this suggestion. The licensing fees are specified by law (50-5-250(3)(a) and(b), MCA), and therefore the OIG must decline to make this change.

Comment #129: A written comment was received suggesting clarification that the immunity protections available under 50-12-110, MCA, extend to all providers involved in recommending or facilitating an experimental treatment.

Response #129: The OIG thanks the commenter for the suggestion. These rules relate specifically to establishing the minimum licensing requirements for ETCs. Immunity from suit protections are outside the scope of this rulemaking.

Comment #130: A written comment was received suggesting the department should consider tracking the broad liability protection framework in the federal Right to Try Act, 21 U.S.C. § 360bbb-3e.

Response #130: The OIG thanks the commenter for the suggestion. The OIG is authorized by statute to write licensing rules for ETCs. Liability waivers/exemptions are outside the scope of this rulemaking.

Comment #131: A written comment was received suggesting a revision to NEW RULE 17(2) to exclude expected, protocol-anticipated effects.

Response #131: The OIG thanks the commenter for this suggestion. However, the OIG declines to make the suggested change. As written, the rule defines the parameters for what constitutes an adverse side effect, and anything that meets those specifications must be reported. The OIG believes this requirement will help ensure adequate information is available to the department and QAPIs to properly monitor ETC performance.

Comment #132: A written comment was received suggesting the removal or significant narrowing of the open-ended catch-all language that allows any event to be deemed "serious" based solely on the medical director's judgment if they are expected events for a given experimental treatment.

Response #132: The OIG thanks the commenter for this suggestion. Please see the response to comment #131. Additionally, this requirement relies on the clinical judgment of the provider who is responsible for the facility. The OIG believes these requirements properly balance program safety with clinical judgement.

Comment #133: A written comment was received suggesting amendments to NEW RULES 4 and 9 to explicitly recognize psychologists, licensed professional counselors (LPCs), licensed clinical social workers (LCSWs), and licensed therapists as qualified ETC staff.

Response #133: The OIG thanks the commenter for this suggestion. The intent of the rule specifying staff is specific to the individuals who may prescribe, administer, or provide intervention to an individual receiving experimental treatments, and who must be physically present in an ETC when patients are admitted. These rules are not intended to be an exhaustive list of all the professionals who are qualified to be staff members at ETCs.

Comment #134: A written comment was received suggesting creation of a supervised practice pathway or reciprocity provision that allows out-of-state facilitators, including those licensed as psilocybin facilitators under Oregon's or Colorado's regulatory frameworks, to provide facilitation services at Montana ETCs offering psychedelic-assisted therapies.

Response #134: The OIG thanks the commenter for this suggestion. This rulemaking is specific to the licensing of experimental treatment centers, not to the creation of practice pathways for individuals to practice in Montana. The rules, as currently proposed, allow for collaboration and consultation with out-of-state providers.

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Approval

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