

ADMINISTRATIVE RULE OF MONTANA

HEALTHCARE FACILITIES

37.106 Subchapter 500

Outpatient Centers for Surgical Services

RULE

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37.106.501 Purpose (1) The purpose of these rules is to establish the minimum licensing requirements for the licensure of outpatient centers for surgical services. Authorizing statute(s): 50-5-103, MCA Implementing statute(s): 50-5-103, MCA History: NEW, 2013 MAR p. 1626, Eff. 9/6/13.

37.106.502 Scope (1) For purposes of this subchapter, outpatient centers for surgical services include facilities described at 50-5-101(42), MCA. Authorizing statute(s): 50-5-103, MCA Implementing statute(s): 50-5-103, MCA History: NEW, 2013 MAR p. 1626, Eff. 9/6/13.

37.106.503 Definitions (1) "Medical director" means a physician licensed under Title 37, chapter 3 MCA, who oversees the services provided in an outpatient center for surgical services. The medical director may also serve in the outpatient center as a licensed health care professional. The medical director can also serve as the outpatient center administrator. (2) "Outpatient center" for purposes of this subchapter, refers to an outpatient center for surgical services. Outpatient centers are limited to provide care for periods of less than 24 hours. (3) "Safe manner" means that physicians and other clinical staff must follow acceptable surgical standards of practice in all phases of a surgical procedure, beginning with the preoperative preparation of the patient, through to the postoperative recovery and discharge. Authorizing statute(s): 50-5-103, MCA Implementing statute(s): 50-5-103, MCA History: NEW, 2013 MAR p. 1626, Eff. 9/6/13; AMD, 2024 MAR p. 334, Eff. 2/24/24.

37.106.506 Standards for Outpatient Centers for Surgical Services (1) An outpatient center must: (a) meet the requirements of ARM Title 37, chapter 106, subchapter 3 relating to the minimum standards for all health care facilities; (b) to the extent that other licensure rules in ARM Title 37, chapter 106, subchapter 3 conflict with the terms of this subchapter, the rules in this subchapter will apply; (c) have a written policy and procedure manual as described in ARM 37.106.507 available to, and followed by, all personnel; (d) establish a coordinated transfer of care for patients who require services longer than 24 hours or for patients requiring care beyond the capabilities of the outpatient center. This coordinated transfer of care must include one of the following: (i) a written transfer agreement with the receiving hospital; (ii) one or more physicians with surgical privileges in the outpatient center must have admitting privileges at the receiving hospital and are present in the outpatient center during any surgical procedure; or (iii) the receiving hospital writes a coordinated transfer policy and specifies the respective roles and responsibilities of the outpatient center upon arrival at the receiving hospital; and (e) in transferring patients, the outpatient center must: (i) coordinate and provide notice to the receiving hospital, including the reason for the transfer prior to the patient's transfer; and (ii) provide the patient's medical records to the receiving hospital during the transfer. (2) An outpatient center may: (a) show written evidence of current accreditation by an accreditation entity approved by the U.S. Centers for Medicare & Medicaid Services including recommendations for future compliance as a condition of licensure; or (b) meet the standards as specified in ARM 37.106.507 through 37.106.515. Authorizing statute(s): 50-5-103, MCA Implementing statute(s): 50-5-103, MCA History: NEW, 2013 MAR p. 1626, Eff. 9/6/13; AMD, 2024 MAR p. 334, Eff. 2/24/24.

37.106.507 Policies and Procedures (1) Each outpatient center must maintain a policy and procedure manual. The policy and procedure manual must be reviewed by the medical director or administrator and updated as necessary, but at least annually. The manual must contain policies and procedures for: (a) preadmission; (b) patient education; (c) preoperative assessment; (d) postoperative assessment; (e) observation and recovery; (f) discharge planning; (g) emergency procedures of the outpatient center to include information on the transfer agreement with the receiving hospital; (h) anesthesia policies as described in ARM 37.106.514; (i) business practices; and (j) patient and staff security. (2) The policy and procedure manual must include a current organizational chart delineating the lines of authority, responsibility, and accountability for the administration and provision of all outpatient center patient services. (3) Each outpatient center must have policies and procedures that address the criteria for clinical staff privileges and the process the governing body uses when reviewing physician credentials and determining whether to grant privileges. (4) The outpatient center must implement a policy and a process which addresses the Food and Drug Administration (FDA) or manufacturer recall of drugs, vaccines, blood and blood products, medical devices, equipment, and supplies. The policy must address: (a) the sources of information; (b) methods for notifying staff; (c) methods to determine if the recalled product is present at the facility; (d) documentation of response to the recalled product; (e) disposition or return of the recalled product; and (f) patient notification as appropriate. Authorizing statute(s): 50-5-103, MCA Implementing statute(s): 50-5-103, MCA History: NEW, 2013 MAR p. 1626, Eff. 9/6/13.

37.106.508 Operational Standards for Outpatient Centers for Surgical Services 1) An outpatient center is organized under a governing body that sets policy and is responsible for the organization. This governing body must meet regularly, but at least quarterly. (2) The outpatient center administration must: (a) operate under clearly defined mission, goals, and objectives for the organization; (b) employ qualified personnel, both medical and managerial; (c) adopt policies and procedures necessary for the orderly conduct of the organization, including the scope of clinical and surgical activities; (d) ensure that the quality of care is evaluated and that identified problems are appropriately addressed; (e) maintain effective communication throughout the organization, including ensuring a correlation between quality management and improvement activities and other management functions of the organization; and (f) follow generally accepted accounting principles. (3) Facility requirements for an outpatient center include: (a) compliance with regulations established in the local jurisdiction, including applicable local and state codes for construction, fire prevention, public safety and access, and annual inspections by the fire department; and (b) an emergency plan for use in the event of fire or natural disaster and documents exercise of the plan on an annual basis. The "exercise" may involve a functional review of the process. That review must be documented accordingly. (4) Each outpatient center for surgical services will have a quality management and improvement plan which must include: (a) a peer review process that includes: (i) at least two licensed health care professionals one of whom is a physician, and operating within their scope of practice; and (ii) that the results of the peer review are reported to the governing body. (b) a credentialing process that provides a monitoring function to ensure the continued maintenance of licensure and certification, or both, of professional personnel who provide health care services at the outpatient center; (c) a quality improvement program that: (i) is ongoing; (ii) is data-driven; (iii) is broad in scope; (iv) addresses clinical and administrative issues as well as actual patient outcomes; (v) has a defined set of

quality improvement goals and objectives; (vi) actively seeks patient feedback, evaluates complaints and suggestions, and works to improve patient satisfaction; (vii) includes the active participation of the medical staff; (viii) respects the health care rights of all patients, including the right to privacy; (ix) at least annually conducts evaluation of outpatient center effectiveness; (x) describes to the outpatient center's governing board the reports, findings, and activities relating to quality improvement; and (xi) analyzes ongoing comprehensive self-assessment of the quality of care, including medical necessity of care or procedures performed and appropriateness of care. The findings from this process should be used to update facility policies and procedures. (d) a risk management plan that: (i) has a designated individual or committee that is responsible for the risk management program; and (ii) addresses safety of patients and other important issues including: (A) consistent application of the risk management program throughout the organization; (B) review of all deaths, trauma, or other adverse incidents including reactions to drugs and materials; (C) review and analysis of all actual and potential infection control occurrences and breaches, surgical site infections, and other health care acquired infections; (D) review of patient complaints; (E) impaired health care professionals; (F) establishment and documentation of coverage after normal working hours; (G) methods for prevention of unauthorized prescribing; and (H) periodic review of clinical records and clinical record policies. Authorizing statute(s): 50-5-103, MCA Implementing statute(s): 50-5-103, MCA History: NEW, 2013 MAR p. 1626, Eff. 9/6/13

37.106.511 Staffing and Personal Requirements (1) Staffing and personnel requirements for an outpatient center for surgical services include: (a) professional staff who are licensed under Title 37, MCA, to practice in their profession and have the knowledge and skills required to provide the services offered by the outpatient center; (b) all personnel assisting in the provision of health care services are appropriately trained, qualified, and supervised according to the policies and procedures of the outpatient center; and (c) the outpatient center must keep a schedule for clinical staff, to make sure all shifts are adequately covered. Authorizing statute(s): 50-5-103, MCA Implementing statute(s): 50-5-103, MCA History: NEW, 2013 MAR p. 1626, Eff. 9/6/13.

37.106.512 Medical, Clinical, and Health Record Information (1) An individual clinical record must be established for each person receiving care. Each record must be accurate, legible, and promptly completed. The record must include at least the following: (a) patient identification; (b) significant medical history and results of physical examination; (c) preoperative diagnostic studies, if performed; (d) findings and techniques of the operation including a pathologist's report on all tissues removed during surgery, except those exempted by the governing body; (e) any allergies and abnormal drug reactions; (f) entries related to anesthesia administration; (g) documentation of properly executed informed patient consent which includes notice of transfer when deemed appropriate; (h) discharge diagnosis; and (i) discharge recommendations and instructions given to the patient. (2) To ensure confidentiality, security, and physical safety of a patient's medical record, the outpatient center must designate a person to oversee and manage the clinical records. (3) The outpatient center must have policies concerning clinical records. The policies must include: (a) the retention of active records; (b) the retirement of inactive records; (c) the timely entry of data in records; and (d) the release of information contained in records. Authorizing statute(s): 50-5-103, MCA Implementing statute(s): 50-5-103, MCA History: NEW, 2013 MAR p. 1626, Eff. 9/6/13.

37.106.513 Infection Prevention, Control, and Safety (1) The outpatient center must maintain an infection control program that seeks to minimize infections and communicable diseases. The outpatient center is responsible for providing a plan of action for preventing, identifying, and managing infections and communicable diseases, and for immediately implementing corrective and preventive measures that result in improvement. (a) The infection prevention and control program must include documentation that the outpatient center has considered, selected, and implemented nationally recognized infection control guidelines. (b) The infection prevention and control program is under the direction of a designated and qualified infection control officer who is a licensed health care professional and has training in infection control. (2) The outpatient center must have written policies that also address cleaning of patient treatment and care areas to include: (a) cleaning before use; and (b) cleaning between patients. (3) The outpatient center will have policies and processes in place for: (a) the monitoring and documentation of the cleaning, high level disinfection, and sterilization of medical equipment, accessories, instruments, and implants; and (b) minimizing the sources and transmission of infections, including adequate surveillance techniques. (4) The outpatient center must designate a safety officer who is responsible for the facility's safety plan. (5) The outpatient center must have a safety program which addresses the organization's environment of care and safety for all patients, staff, and others. The elements of the safety program include: (a) a process for identifying hazards, potential threats, near misses, and other safety concerns; (b) a process for reporting known adverse incidents to proper authorities; (c) a process for reducing and avoiding medication errors; and (d) prevention of falls or physical injuries involving patients, staff, and others. (6) The outpatient center must have a written emergency and disaster preparedness plan. The plan must address both internal and external emergencies and must also address provision for the safe evacuation of individuals during an emergency, especially for individuals who are at greater risk. (a) The outpatient center must complete a written evaluation of each drill and promptly implement any corrections identified during the drill. This documentation must be on site at the facility for the period of licensure. (7) The outpatient center must have a policy concerning the training of outpatient center staff in terms of the emergency and disaster plan. (8) Products, including medications, reagents, and solutions that carry an expiration date are monitored and disposed of accordingly. (9) Prior to use, appropriate education is provided to intended operators of newly acquired devices or products to be used in the care of patients. (10) A system must exist for the proper identification, management, handling, transport, storage, and disposal of biohazardous materials and wastes, whether solid, liquid, or gas. Authorizing statute(s): 50-5-103, MCA Implementing statute(s): 50-5-103, MCA History: NEW, 2013 MAR p. 1626, Eff. 9/6/13.

37.106.514 Anesthesia Risk and Evaluation (1) The outpatient center must: (a) prohibit the use of flammable anesthesia; (b) have a policy which defines the types of anesthesia that will be used within the facility. Similarly, the outpatient center must address in this policy the level of American Society of Anesthesiologists (ASA) Physical Status Classification System level appropriate to receive surgical services in these types of facilities; (c) conduct an assessment prior to the patient's admission as well as prior to surgery to evaluate the risk of anesthesia and of the procedure to be performed; and (d) have policies that address the basis or criteria used in conducting the assessments. (2) Supplies and exhaust systems for windowless anesthetizing locations must be arranged to automatically vent smoke and products of combustion. (a) Ventilating systems for anesthetizing locations using general anesthesia must be provided that automatically: (i) prevent recirculation of smoke originating within the surgical suite; and (ii) prevent the circulation of smoke entering the system intake, without, in either case, interfering with the exhaust function of the system. (3) Anesthesia must be administered only by: (a) a qualified anesthesiologist; (b) a physician qualified to administer anesthesia; or (c) a certified registered nurse anesthetist (CRNA). (4) Before discharge, each patient must be evaluated by a physician or by an anesthetist in accordance with applicable state health and safety laws, standards of practice, and facility policy. This postanesthesia assessment must include evaluation of: (a) respiratory function, including respiratory rate, airway patency, and oxygen saturation; (b) cardiovascular function, including pulse rate and blood pressure; (c) mental status and level of consciousness, or both; (d) temperature; (e) pain; (f) nausea and vomiting; and (g) postoperative hydration. Authorizing statute(s): 50-5-103, MCA Implementing statute(s): 50-5-103, MCA History: NEW, 2013 MAR p. 1626, Eff. 9/6/13; AMD, 2014 MAR p. 2974, Eff. 12/12/14.

37.106.515 Surgical and Related Services (1) Surgical procedures must be performed in a safe manner by qualified physicians functioning within their scope of practice and who limit the surgical procedures to those that are approved by the governing body in accordance to the facility policies and procedures. (2) The outpatient center uses acceptable standards of practice to ensure proper identification of the patient and the surgical site in order to avoid wrong site/wrong person/wrong procedure errors. Generally accepted procedures to avoid such errors include: (a) a preprocedure verification process to make sure all relevant documents and related information are available, are correctly identified, match the patient, and are consistent with the procedure the patient and the surgical staff are expecting to perform; (b) marking of the intended procedure site by the physician who will be performing the procedure so that it is clear where the procedure is to be performed on the patient's body; (c) verification that a current health history is complete which includes a list of current prescription and nonprescription medications and dosages, physical examination, and pertinent preoperative diagnostic studies have been completed; and (d) a recheck of the procedures listed in (a) through (c). (3) Each operating or procedure room is designed and equipped so that the types of surgery conducted can be performed in a manner that protects the lives and ensures the physical safety of all persons in the area. Only nonflammable agents are to be present in the operating or procedure room. (4) All personnel with direct patient contact will maintain skills in basic cardiac life support and are available whenever there is a patient in the facility. (5) A safe environment for treating surgical patients, including adequate safeguards to protect the patient from cross-infection, is ensured through the provision of adequate space, equipment, supplies, and personnel including: (a) all persons entering the

operating or procedure room are properly attired as defined by the governing body; (b) acceptable aseptic techniques are used by all persons in the surgical area; (c) only authorized persons are allowed in the surgical or treatment areas; and (d) measures are implemented to prevent skin and tissue injury from chemicals, cleaning solutions, and other hazardous exposure. (6) The outpatient center has established protocols for instructing patients in self-care following surgery. (7) The outpatient center has a procedure to address when sponge, sharps, and instrument counts will occur. (8) Suitable equipment for rapid and routine sterilization is available to ensure the operating room materials are sterile. Sterilized materials are packaged, labeled, and stored in a manner to maintain sterility and identify sterility dates. Sterility requirements also include: (a) processes for cleaning and sterilization of supplies and equipment must comply with manufacturer's instructions and recommendations; and (b) internal and external indicators are used to demonstrate the safe processing of items undergoing high level disinfection and sterilization. (9) Periodic calibration and preventive maintenance, or both of equipment is provided. (10) An alternate source of power must be available in the event of power shortages, surges, or loss of utility. (a) In accordance to National Fire Protection Association (NFPA) 110 Standard the outpatient center must have a generator which automatically starts within 10 seconds of loss of the utility. An Uninterrupted Power Supply (UPS) system is not acceptable as a substitute in any location using general anesthesia. (b) UPS systems are permitted in settings where a patient is not under general anesthesia. Authorizing statute(s): 50-5-103, MCA Implementing statute(s): 50-5-103, MCA History: NEW, 2013 MAR p. 1626, Eff. 9/6/13.