

ADMINISTRATIVE RULE OF MONTANA

HEALTHCARE FACILITIES

37.106 Subchapter 10

Outpatient for Primary Care

RULE

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37.106.1002 Purpose (1) The purpose of these rules is to establish the licensing requirements for the licensure of outpatient centers for primary care. Authorizing statute(s): 50-5-103, 53-6-106, MCA Implementing statute(s): 50-5-103, 50-5-106, 50-5-114, 50-5-116, 50-5-201, 50-5-204, 50-5-207, MCA History: NEW, 2011 MAR p. 578, Eff. 4/15/11.

37.06.1004 Scope (1) For purposes of this subchapter, outpatient centers for primary care include the facilities described at 50-5-101(41), MCA, outpatient birth centers and radiological imaging facilities. Authorizing statute(s): 50-5-103, 53-6-106, MCA Implementing statute(s): 50-5-103, 50-5-106, 50-5-114, 50-5-116, 50-5-201, 50-5-204, 50-5-207, MCA History: NEW, 2011 MAR p. 578, Eff. 4/15/11.

37.106.1006 Definitions (1) "Low risk patient" means a pregnant woman with a normal, uncomplicated prenatal course as determined by adequate prenatal care and prospects for a normal, uncomplicated birth as defined by reasonable and generally accepted criteria of maternal and fetal health. (2) "Medical director" means a physician licensed under Title 37, MCA, who oversees the services provided in an outpatient center for primary care. The medical director may also serve in the outpatient center for primary care as a licensed health care professional. (3) "Outpatient birth center" means a facility that provides comprehensive prenatal, delivery, and newborn care to ambulatory, low risk patients under the direction of a health care provider who is licensed under Title 37, MCA, and is operating within the scope of practice allowed by the health care provider's license. Outpatient birthing services are provided on an outpatient basis for a period of generally less than 24 consecutive hours, unless requiring transfer to another level of care if medically indicated. (4) "Outpatient center for primary care" means a facility that provides, under the direction of a licensed physician, either diagnosis or treatment, or both, to ambulatory patients and that is not an outpatient center for surgical services. Authorizing statute(s): 50-5-103, 53-6-106, MCA Implementing statute(s): 50-5-103, 50-5-106, 50-5-114, 50-5-116, 50-5-201, 50-5-204, 50-5-207, MCA History: NEW, 2011 MAR p. 578, Eff. 4/15/11; AMD, 2024 MAR p. 334, Eff. 2/24/24.

37.106.1008 Minimum Standards for Outpatient Centers for Primary Care (1) An outpatient center for primary care must meet the requirements of ARM Title 37, chapter 106, subchapter 3 relating to minimum standards for all health care facilities. (2) An outpatient center for primary care shall have a written policy and procedure manual as described in 37.106.1010 available to and followed by all personnel. (3) Each outpatient center for primary care shall employ, or contract with, a medical director who shall: (a) coordinate with and advise the staff of the center on clinical matters; (b) provide direction, consultation, and training regarding the center operations as needed; (c) act as a liaison for the center with community physicians, hospital staff, and other professionals and agencies; and (d) ensure the quality of treatment and related services through participation in the center's quality assurance process as outlined in the center's policies and procedures. (4) Nursing services must be provided by or under the supervision of a licensed registered nurse. (5) Standing orders utilized for emergency or post-operative care shall be recorded in each patient's medical record and dated and signed by the patient's licensed health care professional. (6) An outpatient center for primary care shall maintain a medical record for each patient that includes the following information: (a) identification data; (b) chief complaint; (c) present illness; (d) medical history; (e) physical examination; (f) laboratory and imaging reports; (g) treatment administered; (h) tissue report; (i) progress reports; and (j) discharge summary. Authorizing statute(s): 50-5-103, 53-6-106, MCA Implementing statute(s): 50-5-103, 50-5-106, 50-5-114, 50-5-116, 50-5-201, 50-5-204, 50-5-207, MCA History: NEW, 2011 MAR p. 578, Eff. 4/15/11.

37.106.1010 Written Policies and Procedures (1) Each outpatient center for primary care shall maintain a policy and procedure manual. The policy and procedure manual shall be reviewed and updated as necessary, but at least annually. The manual shall contain policies and procedures for: (a) notifying staff of all changes in policies and procedures; (b) addressing patient rights, including a procedure for informing patients of their rights; (c) informing patients of the policy and procedures for patient complaints and grievances; (d) addressing and reviewing ethical issues faced by staff and reporting allegations of ethics violations to the applicable professional licensing authority; (e) emergency procedures of the birth center; (f) establishing fiscal policies governing the management of organization; and (g) developing and implementing policy(s) for security. (2) The policy and procedures manual must include a current organizational chart delineating the lines of authority, responsibility, and accountability for the administration and provision of all facility patient services. Authorizing statute(s): 50-5-103, 53-6-106, MCA Implementing statute(s): 50-5-103, 50-5-106, MCA, NEW, 2011 MAR p. 578, Eff. 4/15/11. History:

37.106.1012 Birth Centers (1) If an outpatient center for primary care operates a birth center, the birth center shall: (a) comply with the requirements of ARM 37.106.1008; (b) 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 or meet the standards as outlined in ARM 37.106.1014; and (c) establish a coordinated transfer of care through a mutually established agreement to the nearest hospital or critical access hospital that provides obstetrical and surgical services as required by the patient's acuity or the outpatient birth center 24 hour length of stay limitation. (d) A transfer of care agreement must show that a physician who has admitting privileges at the hospital or critical access hospital that provides obstetrical and surgical services has agreed to admit and treat patients of the birthing center should the need arise. In transferring patients, the birth center shall: (i) before transfer, coordinate and provide notice to the hospital, including the reason for the transfer; and (ii) during transfer, provide the medical records related to the patient's current condition. Authorizing statute(s): 50-5-

103, 53-6-106, MCA Implementing statute(s): 50-5-103, 50-5-106, MCA History: NEW, 2011 MAR p. 578, Eff. 4/15/11; AMD, 2024 MAR p. 334, Eff. 2/24/24.

37.106.1014 Operation Standards for Birth Centers (1) A birth center organization: (a) maintains a governing body that meets regularly; and (b) actively seeks and takes appropriate action on feedback from its consumers. (2) A birth center administration shall: (a) operate under a clearly defined mission, philosophy, and goals; (b) follow generally accepted accounting principles and take measures to make sure it is fiscally responsible, including a plan to cover shortfalls; and (c) ensure continuity of leadership and quality of care. (3) Facility requirements for a birth 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, annual inspections by the fire department, building inspector, and other officials concerned with public safety as determined by the local jurisdiction; and (b) an emergency plan in the event of fire and natural disasters and documents practice of the plan on an annual basis. (4) Equipment requirements for a birth center include: (a) a readily available emergency cart or tray for the mother and newborn that is equipped to carry out the written emergency procedures of the birth center and securely placed with a written log of routine maintenance; and (b) regular inspections of all medical equipment and documents accordingly. (5) A birth center shall maintain sufficient supplies, including basic medical supplies for both mothers and babies, on hand, for the number of childbearing families served at the birth center. (6) Quality of service requirements for a birth center include: (a) respect for health care rights of all clients, including privacy; (b) standard HIPAA practices; and (c) providers who practice midwifery and support the normal birth process including: (i) careful screening for potential complications; (ii) honoring the mother's needs and desires throughout labor; (iii) assisting the mother in managing pain; and (iv) paying close attention to the mother and baby's status in labor. (d) limits its services to normal labor, therefore it does not utilize interventions such as: (i) vacuum extraction; (ii) medications to speed up labor; (iii) continuous electronic monitoring; and (iv) epidural nerve block. (7) The birth center has a specific plan for transferring to a hospital if complications arise before, during labor, or after birth and interventions are required. (8) Staffing and personnel requirements for a birth center include: (a) professional staff and consulting specialists licensed to practice their profession and having the knowledge and skills required to provide the services offered by the birth center; (b) at least two staff members attending every birth who are trained and certified in CPR and newborn resuscitation; (c) staff members who are trained according to the policies and procedures of the birth center; (d) the birth center must keep a schedule for clinical staff on call, to make sure all shifts are covered, day and night, seven days a week; and (e) the birth center must conduct regular emergency drills to make sure staff members are prepared to manage unexpected situations with laboring mothers and newborns. (9) Health record requirements for a birth center include: (a) forms appropriate for use in a birth center, and clinicians document patient care accordingly; (b) use of the chart supports a full prenatal exam to ensure that all clients are low risk; (c) educates clients on self-care in pregnancy, including: (i) nutritional counseling; (ii) informed decision-making about pain relief in labor; and (iii) newborn care. (10) The birth center maintains a plan for coordinating the transfer of the patient chart to another facility if the mother or newborn needs to be transferred and clearly communicates this plan to the mother. (11) Quality assessment and improvement activity requirements for a birth center include: (a) a well defined quality improvement program; (b) reviews of its practices and clinical outcomes on a regular basis to ensure that it follows its own policies; (c) procedures to actively seek client feedback, and then evaluate complaints and suggestions and work to improve client satisfaction

on a regular basis; and (d) staff must be evaluated on a regular basis to ensure competency and alignment with birth center policies. Authorizing statute(s): 50-5-103, 53-6-106, MCA
Implementing statute(s): 50-5-103, 50-5-201, MCA History: NEW, 2011 MAR p. 578, Eff. 4/15/11.

37.106.1016 Imaging Services (1) If an outpatient center for primary care provides diagnostic imaging services, the center must meet the following standards: (a) a qualified full-time, part-time, or consulting radiologist must be utilized to interpret radiographic tests that are determined by the medical staff to require a radiologist's specialized knowledge; (b) only personnel designated as qualified by the medical staff, and meeting requirements of state law, may use the radiographic equipment and administer procedures; (c) each report that contains interpretations must be signed by the radiologist or other practitioner who provided the radiological services; and (d) the facility must maintain diagnostic imaging film and electrodiagnostic tracings: (i) for at least five years; and (ii) interpretations must be retained for the same periods required for the medical records provided by ARM 37.106.402. Authorizing statute(s): 50-5-103, 53-6-106, MCA
Implementing statute(s): 50-5-103, 50-5-106, 50-5-201, MCA History: NEW, 2011 MAR p. 578, Eff. 4/15/11.

37.106.1018 Facility Inspections (1) Outpatient centers for primary care are subject to inspection requirements provided in 50-5-116 and 50-5-204, MCA. Authorizing statute(s): 50-5-103, 53-6-106, MCA
Implementing statute(s): 50-5-103, 50-5-106, MCA History: NEW, 2011 MAR p. 578, Eff. 4/15/11.