## ADMINISTRATIVE RULE OF MONTANA

## HEALTHCARE FACILITIES

## 37.106 Subchapter 400

## Hospital

**RULE** 

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37.106.401 General Requirements (1) A hospital shall comply with the Conditions of Participation for Hospitals in 42 CFR subchapter G part 482. (2) If a hospital provides skilled nursing care or intermediate nursing care, as those levels of care are defined in 50-5-101, MCA, the hospital shall comply with the skilled nursing facility requirements listed in 42 CFR subchapter G part 483. (3) The department adopts and incorporates by reference 42 CFR subchapter G part 482 and 42 CFR subchapter G part 483. 42 CFR subchapter G part 482 sets forth the conditions of participation a hospital must meet to participate in the Medicare program. 42 CFR subchapter G part 483 sets forth the skilled nursing facility requirements a hospital provider of long term care services must meet to participate in the Medicare program. A copy of the regulations may be obtained from the Department of Public Health and Human Services, Office of Inspector General, 2401 Colonial Drive, P.O. Box 202953, Helena, MT 59620-2953. Authorizing statute(s): 50-5-103, 50-5-404, MCA Implementing statute(s): 50-5-103, 50-5-204, 50-5-404, MCA History: NEW, 1980 MAR p. 1587, Eff. 6/13/80; AMD, 1996 MAR p. 3216, Eff. 12/20/96; AMD, 1999 MAR p. 146, Eff. 1/15/99; TRANS, from DHES, 2002 MAR p. 185; AMD, 2003 MAR p. 1321, Eff. 7/1/03; AMD, 2022 MAR p. 1876, Eff. 9/24/22.

37.16.402 Medical Records Medical records shall comply with the following requirements: (1) A patient's entire medical record must be maintained, in either its original form or that allowed by ARM 37.106.314(3), for not less than 10 years following the date of a patient's discharge or death, or, in the case of a patient who is a minor, for not less than 10 years following the date the patient either attains the age of majority or dies, if earlier. (2) An obstetrical record shall be developed for each maternity patient and must include the prenatal record, labor notes, obstetrical anesthesia notes and delivery record. (3) A record must be developed for each newborn, and shall include, in addition to the information in (2), the following information: (a) observations of newborn after birth; (b) delivery room care of newborn; (c) physical examinations performed on newborn; (d) temperature of newborn; (e) weight of newborn; (f) time of newborn's first urination; (g) number, character and consistency of newborn's stool; (h) type of feeding administered to newborn; (i) phenylketonuria report for newborn; (j) name of person to whom newborn is released. (4) A patient's entire medical record may be abridged following the dates established in (1) to form a core medical record of the patient's medical record. The core medical record or the microfilmed medical record should be maintained permanently but must be maintained not less than 10 years beyond the periods provided in (1). A core record shall contain at a minimum the following information: (a) identification of patient data which includes name, maiden name if relevant, address, date of birth, sex, and, if available, social security number; (b) medical history; (c) physical examination report; (d) consultation reports; (e) report of operation; (f) pathology report; (g) discharge summary, except that for newborns and others for whom no discharge summary is available, the final progress note must be retained; (h) autopsy findings; (i) for each maternity patient, the information required by (2); and (j) for each newborn, the information required by (3). (5) Nothing in this rule may be construed to prohibit retention of hospital medical records beyond the period described herein or to prohibit the retention of the entire medical record. (6) Diagnostic imaging film and electrodiagnostic tracings must be retained for a period of five years; their interpretations must be retained for the same periods required for the medical record in (1), but need not be retained beyond those periods. Authorizing statute(s): Sec. 50-5-103 and 50-5-404, MCA Implementing statute(s): Sec. 50-5-103, 50-5-106 and 50-5-404,

MCA History: NEW, 1980 MAR p. 1587, Eff. 6/13/80; AMD, 1986 MAR p. 1583, Eff. 9/26/86; AMD, 1990 MAR p. 1259, Eff. 6/29/90; TRANS, from DHES, 2002 MAR p. 185.

<u>37.106.403 Hospital Records</u> (1) Hospital records must be maintained. Authorizing statute(s): Sec. 50-5-103 and 50-5-404, MCA Implementing statute(s): Sec. 50-5-103, 50-5-106 and 50-5-404, MCA History: NEW, 1980 MAR p. 1587, Eff. 6/13/80; TRANS, from DHES, 2002 MAR p. 185.

37.106.404 Laboratories (1) A hospital laboratory shall comply with the Conditions for Coverage of Services of Independent Laboratories as set forth in 42 CFR 405.1310, 405.1311, 405.1314, 405.1316, and 405.1317. A copy of the cited rules is available at the Department of Public Health and Human Services, Quality Assurance Division, 2401 Colonial Drive, P.O. Box 202953, Helena, MT 59620-2953. Authorizing statute(s): Sec. 50-5-103 and 50-5-404, MCA Implementing statute(s): Sec. 50-5-103, 50-5-204 and 50-5-404, MCA History: NEW, 1980 MAR p. 1587, Eff. 6/13/80; TRANS, from DHES, 2002 MAR p. 185.

37.106.405 Organ Donation Requests and Protocols (1) This rule is adopted to implement Chapter 219, Laws of 1987, which amended both the Uniform Anatomical Gift Act, Title 72, chapter 17, MCA, and the Montana Health Care Facility Licensing Act, Title 50, chapter 5, part 2, MCA. Sections (2) through (5) of this rule paraphrase 72-17-211, MCA of the Uniform Anatomical Gift Act and are included here to clarify the requirements for hospitals in cases of patients who are suitable organ donors. For a full text of the Uniform Anatomical Gift Act, reference should be made to Title 72, chapter 17, MCA. (2) When, according to generally accepted medical standards, a patient is a suitable candidate for donation of body parts as defined in 72-17-102 (8), MCA, the hospital administrator or his/her designated representative shall communicate to the next-of-kin (as defined in (3) below) the option of donating all or any part of the patient's body and of the next-of-kin's option to decline. In addition to communicating such options, the hospital administrator or his/her designee must also request the next-of-kin to consent to an anatomical gift. The foregoing obligations of the administrator must be carried out unless the administrator or his/her designee: (a) has actual notice of opposition to the gift by the decedent or the next-ofkin as defined in (3) below; or (b) has reason to believe that an anatomical gift is contrary to the decedent's religious beliefs; or (c) is aware of medical or emotional conditions under which the request would contribute to severe emotional distress. (3) "Next-of-kin" as provided in 72-17-201 (2), MCA, means one of the following persons in order of priority listed: (a) the spouse; (b) an adult son or daughter; (c) either parent; (d) an adult brother or sister; and (e) a guardian of the person of the decedent at the time of death. (4) The medical record of each patient who dies in a hospital and who is determined (under the hospital's protocol established under (6) below) to be a suitable candidate for donation of body parts must contain an entry setting forth the following: (a) the name and affiliation of the individual who communicated the option to donate to the nextofkin and who made the request for anatomical gift under (1) above; (b) the name, relationship to the patient, and response of the individual to whom the option to donate was communicated and of whom the request for anatomical gift was made; and (c) if no communication of an option or if no request for anatomical gift was made, the reason why no such request was made. (5) An anatomical gift by a next-of-kin may be made in writing or by telegraphic, recorded telephonic, or other recorded message. (6) By November 1, 1987, every hospital shall establish and have on file a written protocol that: (a) assures identification of potential organ and tissue donors; (b) assures that next-of-kin of patients who are suitable candidates for donation of body parts are made

aware of their option to make an anatomical gift and are requested to consent to an anatomical gift of all or any part of the patient's body, unless one of the exceptions in (2) (a), (2) (b) or (2) (c) applies; (c) encourages discretion and sensitivity with respect to the circumstances, views, and beliefs of families of potential organ donors; and (d) provides for notification of an appropriate federally approved organ procurement organization when potential organ donors are identified in the hospital. (7) Upon request, every hospital must make its adopted written protocol available to department personnel for their review. (8) The protocol must, at a minimum, in addition to the items in (6) above, address and provide for the following aspects of an organ donation notification/request/referral program: (a) method(s) by which the public is notified that the hospital has an organ procurement program; (b) determination of medical suitability of potential donors of body parts, including consideration of factors such as donor age, previous disease history, and presence of infection; and documentation of non-suitability of patients initially identified as potential donors; (c) a training and educational program conducted on a yearly basis in conjunction with a procurement organization (or the equivalent) to instruct appropriate hospital staff or others to convey organ donation information to next-of-kin and to make requests from next-of-kin, which program consists of formal training, seminars, in-service workshops, or other training (or a combination thereof) leading to a knowledge of and familiarity with the following: (i) general historical, medical, legal and social concepts involved in organ donation and transplantation; (ii) psychological and emotional considerations when dealing with bereaved families; (iii) religious, cultural, and ethical considerations associated with organ donation; and (iv) procedures for approaching donors and/or donors' next-of-kin, including physician notification, timing and location of contact, content(s) of communication concerning donor cards, consent forms, donation costs (if any), and actual requests for donation; (d) orientation and instruction on a yearly basis in conjunction with a procurement organization (or the equivalent) in the respective disciplines of hospital staff and/or other personnel who will or may be participating in the hospital's organ procurement program, such as chief of staff, attending physicians, nursing staff, social workers, clergy, or a team combining any of such persons; and (e) the following forms to be used by the hospital to document that next-of-kin of medically suitable patients have been notified of the option to consent to an anatomical gift and have been requested to authorize such donation(s) as required in (2) above (and, if any such contact has not been made, the reason(s) why not): (i) patient authorization; (ii) consent of next-of-kin; and (iii) notification of organ procurement organization(s). (9) The hospital administrator shall designate a person or persons to represent him/her for the purpose of communicating to the next-of-kin the option of an anatomical gift and to make requests for anatomical gifts, in cases where the administrator is unable or will not be making such requests personally. Such persons shall receive the training specified in (8) above, and a list of such person(s) must be made available upon request to department personnel. (10) A person who acts in good faith in accordance with the terms of (2) of this rule is not liable for damages in any civil proceeding or subject to prosecution in any criminal proceeding that might result from this action. Authorizing statute(s): Sec. 50-5-103 and 50-5-404, MCA Implementing statute(s): Sec. 50-5-103, 50-5-204 and 50-5-404, MCA History: NEW, 1987 MAR p. 1786, Eff. 10/16/87; TRANS, from DHES, 2002 MAR p. 185.

<u>37.106.410 Coronary Care Unit</u> If a hospital provides a coronary care unit, the unit shall comply with the following requirements: (1) When a patient is cared for in a coronary care unit, a licensed registered nurse shall be on duty. (2) At a minimum, the following equipment and supplies must

be available in a coronary care unit: (a) oxygen, oxygen and suction apparatus; (b) defibrillator, resuscitator and respirator; (c) emergency drugs; (d) oscilloscope; (e) heart-rate meter with an alarm system; (f) an electrocardiograph which is activated simultaneously with the alarm system and which may also be activated manually or at predetermined intervals; (g) external pacemaker. Authorizing statute(s): Sec. 50-5-103 and 50-5-404, MCA Implementing statute(s): Sec. 50-5-103, 50-5-204 and 50-5-404, MCA History: NEW, 1980 MAR p. 1587, Eff. 6/13/80; TRANS, from DHES, 2002 MAR p. 185.

37.106.411 Intensive Care Unit If a hospital provides an intensive care unit, the unit shall comply with the following requirements: (1) When a patient is cared for in an intensive care unit, a licensed registered nurse shall be on duty. (2) At a minimum, the following equipment and supplies must be available in an intensive care unit: (a) oxygen, oxygen and suction apparatus; (b) defibrillator, resuscitator and respirator; (c) emergency drugs. Authorizing statute(s): Sec. 50-5-103 and 50-5-404, MCA Implementing statute(s): Sec. 50-5-103, 50-5-204 and 50-5-404, MCA History: NEW, 1980 MAR p. 1587, Eff. 6/13/80; TRANS, from DHES, 2002 MAR p. 185.

37.106.420 Obstetrical Services If a hospital provides obstetrical services, the hospital shall comply with the following requirements: (1) Obstetrical services must be under the supervision of a licensed registered nurse on a 24-hour basis. (2) A maternity patient shall only be placed in a room with other maternity patients. The use of maternity rooms for other than maternity patients shall be restricted to noninfected gynecological and surgical patients. A maternity patient with infection shall be isolated in a separate room outside of the obstetrical service. (3) An equipped room must be provided for each patient in labor. (4) At least one delivery room must be provided. (5) A delivery record shall be made for a maternity patient delivering and include, but not be limited to, the following information: (a) starting time of patient's labor; (b) time of birth of patient's newborn; (c) anesthesia used on patient; (d) whether an episiotomy was performed on patient; (e) whether forceps were used in delivery; (f) names of attending physicians; (g) names of attending nurses; (h) names of all other persons attending delivery; (i) sex of the newborn; (j) time of eye prophylactic treatment and name of drug used. (6) A newborn must be marked for identification before removal from the delivery area. Authorizing statute(s): Sec. 50-5-103 and 50-5-404, MCA Implementing statute(s): Sec. 50-5-103, 50-5-204 and 50-5-404, MCA History: NEW, 1980 MAR p. 1587, Eff. 6/13/80; TRANS, from DHES, 2002 MAR p. 185.

37.106.421 Newborn Nursery If a hospital provides a newborn nursery, the nursery shall comply with the following requirements: (1) The newborn nursery must be under the supervision of a licensed registered nurse on a 24-hour basis. (2) An individual bassinet must be provided for each newborn. (3) Each newborn must have separate equipment and supplies for bathing, dressing and other handling. (4) At least one incubator must be provided in the nursery. (5) Oxygen, oxygen and suction equipment must be available and adapted to the size of newborns. When oxygen is administered, the concentration within the incubatory and near the newborn's head shall be determined by means of a reliable oxygen analyzer. These measurements shall be recorded on the newborn's chart. (6) Formula prepared in the hospital shall be prepared by terminal heat method using separate equipment furnished for formula preparation. Authorizing statute(s): Sec. 50-5-103 and 50-5-404, MCA Implementing statute(s): Sec. 50-5-103, 50-5-204 and 50-5-404, MCA History: NEW, 1980 MAR p. 1587, Eff. 6/13/80; TRANS, from DHES, 2002 MAR p. 185.

<u>37.106.422 Pediatric and Adolescent Services If</u> a hospital provides pediatric and adolescent services, the hospital shall comply with the following requirements: (1) Pediatric and adolescent services must be under the supervision of a licensed registered nurse. (2) At a minimum pediatric and adolescent services shall provide the following: (a) an examination and treatment room with equipment and supplies designed for the care of children; (b) oxygen and suction equipment designed for children. Authorizing statute(s): Sec. 50-5-103 and 50-5-404, MCA Implementing statute(s): Sec. 50-5-103, 50-5-204 and 50-5-404, MCA History: NEW, 1980 MAR p. 1587, Eff. 6/13/80; TRANS, from DHES, 2002 MAR p. 185.

<u>37.106.430 Psychiatric Services</u> If a hospital provides psychiatric services, the hospital shall comply with the following requirements: (1) Psychiatric services must be under the supervision of a licensed psychiatrist on a 24-hour basis. (2) Psychiatric service staff must include a sufficient number of adjunctive therapists to provide restorative and rehabilitation services for the number of patients accommodated. (3) A licensed registered nurse or a licensed practical nurse under the supervision of a registered nurse shall be in charge 24 hours a day. Authorizing statute(s): Sec. 50-5-103 and 50-5-404, MCA Implementing statute(s): Sec. 50-5-103, 50-5-204 and 50-5-404, MCA History: NEW, 1980 MAR p. 1587, Eff. 6/13/80; TRANS, from DHES, 2002 MAR p. 185.

37.106.440 Respiratory Therapy If a hospital provides respiratory therapy, the hospital shall comply with the following requirements: (1) Respiratory therapy services must be under the supervision of a licensed physician appointed from the active medical staff. (2) An internal and external quality control program must be provided for all parameters of acid-base testing. (3) Written policies and procedures must be developed describing the control measures to be followed in order to eliminate the transfer of infection from the use of respiratory equipment. Authorizing statute(s): Sec. 50-5-103 and 50-5-404, MCA Implementing statute(s): Sec. 50-5-103, 50-5-204 and 50-5-404, MCA History: NEW, 1980 MAR p. 1587, Eff. 6/13/80; TRANS, from DHES, 2002 MAR p. 185.