**REQUIRED POLICIES FOR MONTANA CRITICAL ACCESS HOSPITALS**

A CAH’s governing body or legally responsible individual is responsible for monitoring and administering the policies to ensure that quality health care is provided in a safe environment.[[1]](#footnote-1) This document sets forth a list of policies that Montana Critical Access Hospitals (“CAHs”) are required to maintain under both the federal conditions of participation (“CoPs”) for CAHs set forth by the Center for Medicare and Medicaid Services (“CMS”) and Montana state licensure requirements specific to CAHs.

This document sets forth the following information for each policy: (1) Policy Name; (2) Description of the Policy; and (3) the related legal citation. As applicable, the description of the policy may include comments on review requirements, such as the timing of policy reviews and which professional must be involved in the development or review of certain policies. Where not otherwise specified, biennial review (every two years) by applicable stakeholders is recommended.

Note that this list only sets forth the policies specifically required as a function of the facility’s CAH status. Other policies not listed here may be required, encouraged, or desirable such as those relating to patient confidentiality, information security, fraud and abuse practices, or general compliance. Additionally, please note that Montana state licensure requirements for CAHs require compliance with the federal CoPs ***effective as of 2005***, [[2]](#footnote-2) which differ slightly from the most current CoPs effective as of 2019. When the current, cited regulation differs from the 2005 regulation, these differences are described in accompanying footnotes. There are minimal substantive differences between the current CoPs and the 2005 CoPs and the differences mostly reflect recently updated infection control standards related to COVID-19.

**REQUIRED POLICIES**

| **Policy** | **Description** | **Citation** |
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| Emergency Preparedness Plan and Policies/Disaster Planning[[3]](#footnote-3) | CAHs must develop and maintain an integrated emergency preparedness plan, emergency preparedness policies and procedures, and a communication plan, each of which must include specific requirements and is addressed separately in the rows immediately following.Under state licensure requirements, CAHs must develop a written disaster plan in conjunction with other emergency services in the community. These procedures must be developed such that they can be followed in the event of a natural or man-caused disaster. *Review Comment*: Annual review of each emergency preparedness/disaster plan or policy is recommended.[[4]](#footnote-4) | 42 C.F.R. § 485.625 (2019)[[5]](#footnote-5)Mont. Admin. R. 37.106.322(1) (2020) |
| Emergency Preparedness Plan | CAHs must develop and maintain an integrated emergency preparedness plan that: (1) Is based on and includes a documented, facility-based and community-based risk assessment, utilizing an all-hazards approach.(2) Includes strategies for addressing emergency events identified by the risk assessment.(3) Addresses patient population, including, but not limited to, persons at-risk; the type of services the CAH has the ability to provide in an emergency; and continuity of operations, including delegations of authority and succession plans.(4) Includes a process for cooperation and collaboration with local, tribal, regional, State, and Federal emergency preparedness officials' efforts to maintain an integrated response during a disaster or emergency situation.*Review Comment*: Annual review of each emergency preparedness/disaster plan or policy is recommended. | 42 C.F.R. § 485.625(a) (2019) |
| Emergency Preparedness: Subsistence Needs Policy | The CAH must develop and implement the subsistence needs policy based on the emergency plan and the communication plan. At a minimum, the policy must address the provision of subsistence needs for staff and patients, whether they evacuate or shelter in place, including, but not limited to: 1. Food, water, medical, and pharmaceutical supplies; and
2. Alternate energy sources to maintain temperatures to protect patient health and safety and for the safe and sanitary storage of provisions, emergency lighting, fire detection, extinguishing, alarm systems, and sewage and waste disposal.

*Review Comment*: Annual review of each emergency preparedness/disaster plan or policy is recommended. | 42 C.F.R. § 485.625(b)(1) (2019) |
| Emergency Preparedness: Location Tracking Policy | The CAH must develop and implement the Location Tracking policy based on the emergency plan and the communication plan. At a minimum, the policy must address a system to track the location of on-duty staff and sheltered patients in the CAH's care during an emergency. If on-duty staff and sheltered patients are relocated during the emergency, the CAH must document the specific name and location of the receiving facility or other location.*Review Comment*: Annual review of each emergency preparedness/disaster plan or policy is recommended. | 42 C.F.R. § 485.625(b)(2) (2019) |
| Emergency Preparedness: Safe Evacuation Policy | The CAH must develop and implement the Safe Evacuation policy based on the emergency plan and the communication plan. At a minimum, the policy must address the safe evacuation from the CAH, which includes consideration of care and treatment needs of evacuees; staff responsibilities; transportation; identification of evacuation location(s); and primary and alternate means of communication with external sources of assistance.*Review Comment*: Annual review of each emergency preparedness/disaster plan or policy is recommended. | 42 C.F.R. § 485.625(b)(3) (2019) |
| Emergency Preparedness: Shelter Policy | The CAH must develop and implement the Shelter policy based on the emergency plan and the communication plan. At a minimum, the policy must address a means to shelter in place for patients, staff, and volunteers who remain in the facility.*Review Comment*: Annual review of each emergency preparedness/disaster plan or policy is recommended. | 42 C.F.R. § 485.625(b)(4) (2019) |
| Emergency Preparedness: Medical Documentation Policy | The CAH must develop and implement the Medical Documentation policy based on the emergency plan and the communication plan (referenced elsewhere). At a minimum, the policy must address a system of medical documentation that preserves patient information, protects confidentiality of patient information, and secures and maintains the availability of records.*Review Comment*: Annual review of each emergency preparedness/disaster plan or policy is recommended. | 42 C.F.R. § 485.625(b)(5) (2019) |
| Emergency Preparedness: Volunteer Policy | The CAH must develop and implement the Volunteer policy based on the emergency plan and the communication plan. At a minimum, the policy must address the use of volunteers in an emergency or other emergency staffing strategies, including the process and role for integration of State or Federally designated health care professionals to address surge needs during an emergency.*Review Comment*: Annual review of each emergency preparedness/disaster plan or policy is recommended. | 42 C.F.R. § 485.625(b)(6) (2019) |
| Emergency Preparedness: Provider Arrangements Policy | The CAH must develop and implement the Provider Arrangements policy based on the emergency plan and the communication plan. At a minimum, the policy must address the development of arrangements with other CAHs or other providers to receive patients in the event of limitations or cessation of operations to maintain the continuity of services to CAH patients.*Review Comment*: Annual review of each emergency preparedness/disaster plan or policy is recommended. | 42 C.F.R. § 485.625(b)(7) (2019) |
| Emergency Preparedness: Alternate Care Site Policy | The CAH must develop and implement the subsistence needs policy based on the emergency plan and the communication plan. At a minimum, the policy must address the role of the CAH under a waiver declared by the Secretary, in accordance with section 1135 of the Act, in the provision of care and treatment at an alternate care site identified by emergency management officials.*Review Comment*: Annual review of each emergency preparedness/disaster plan or policy is recommended. | 42 C.F.R. § 485.625(b)(8) (2019) |
| Emergency Preparedness: Communication Plan | The CAH must develop and maintain an emergency preparedness communication plan that complies with Federal, State, and local laws. The communication plan must include all of the following:(1) Names and contact information for the Staff; Entities providing services under arrangement; Patients' physicians; Other CAHs and hospitals; and Volunteers.(2) Contact information for the Federal, State, tribal, regional, and local emergency preparedness staff and other sources of assistance.(3) Primary and alternate means for communicating with the CAH's staff; Federal, State, tribal, regional, and local emergency management agencies.(4) A method for sharing information and medical documentation for patients under the CAH's care, as necessary, with other health care providers to maintain the continuity of care.(5) A means, in the event of an evacuation, to release patient information as permitted under 45 CFR 164.510(b)(1)(ii).(6) A means of providing information about the general condition and location of patients under the facility's care as permitted under 45 CFR 164.510(b)(4).(7) A means of providing information about the CAH's occupancy, needs, and its ability to provide assistance, to the authority having jurisdiction or the Incident Command Center, or designee.*Review Comment*: Annual review of each emergency preparedness/disaster plan or policy is recommended. | 42 C.F.R. § 485.625(c) (2019) |
| Patient Care: Provision of Services Policy | A CAH must have a policy setting forth a description of the services the CAH furnishes, including those furnished through arrangement or agreement. *Review Comment*: At least one active physician and at least one active advanced practice provider must advise the CAH on developing patient care policies and must review these policies at least every other year. | 42 C.F.R. § 485.635(a)(3)(i) (2019) [[6]](#footnote-6) |
| Patient Care: Emergency Services Policy | The CAH medical staff must establish policies and procedures governing emergency medical services. Policies must include the following provisions: (1) emergency services must be organized under a member of the medical staff who is a physician or an advance practice practitioner; (2) the practitioner on duty or on-all must by physically available in one hour unless the facility meets exemptions under rule 37.106.810(4)(e).*Review Comment*: At least one active physician and at least one active advanced practice provider must advise the CAH on developing patient care policies and must review these policies at least every other year. | 42 C.F.R. § 485.635(a)(3)(ii) (2019); Mont. Admin. R. 37.106.810 (2020) |
| Patient Care: Medical Management Policy | A CAH must have a policy setting forth guidelines for the medical management of health problems that include the conditions requiring medical consultation and/or patient referral, the maintenance of health care records, and procedures for the periodic review and evaluation of provided services.*Review Comment*: At least one active physician and at least one active advanced practice provider must advise the CAH on developing patient care policies and must review these policies at least every other year. | 42 C.F.R. § 485.635(a)(3)(iii) (2019) |
| Patient Care: Drugs and Biologicals Policy | A CAH must have a policy setting forth rules for the storage, handling, dispensation, and administration of drugs and biologicals specifying drug storage and disposition. These rules must provide that there is a drug storage area that is administered in accordance with accepted professional principles, that current and accurate records are kept of the receipt and disposition of all scheduled drugs, and that outdated, mislabeled, or otherwise unusable drugs are not available for patient use.*Review Comment*: At least one active physician and at least one active advanced practice provider must advise the CAH on developing patient care policies and must review these policies at least every other year. | 42 C.F.R. § 485.635(a)(3)(iv) (2019) |
| Patient Care: Adverse Drug Reactions and Drug Administration Errors Policy | A CAH must have policies and procedures for reporting adverse drug reactions and drug administration errors.*Review Comment*: At least one active physician and at least one active advanced practice provider must advise the CAH on developing patient care policies and must review these policies at least every other year.  | 42 C.F.R. § 485.635(a)(3)(v) (2019) |
| Patient Care: Nutritional and Dietary Needs of Inpatients Policy | A CAH must have policies and procedures that ensure that the nutritional needs of inpatients are met in accordance with recognized dietary practices. The policy should ensure that all patient diets, including therapeutic diets, must be ordered by the practitioner responsible for the care of the patients or by a qualified dietitian or qualified nutrition professional as authorized by the medical staff in accordance with State law governing dietitians and nutrition professionals.Note that there are additional requirements for those inpatients who will be receiving SNF care following their CAH inpatient stay.[[7]](#footnote-7)*Review Comment*: At least one active physician and at least one active advanced practice provider must advise the CAH on developing patient care policies and must review these policies at least every other year. | 42 C.F.R. § 485.635(a)(3)(vi) (2019) |
| Patient Care: Post-Acute Care Needs Policy | A CAH must have policies and procedures that address the post-acute care needs of patients receiving CAH services.*Review Comment*: At least one active physician and at least one active advanced practice provider must advise the CAH on developing patient care policies and must review these policies at least every other year.  | 42 C.F.R. § 485.635(a)(3)(viii) (2019) |
| Patient Visitation Rights  | A CAH must have written policies and procedures regarding the visitation rights of patients, including those setting forth any clinically necessary or reasonable restriction or limitation that the CAH may need to place on such rights and the reasons for the clinical restriction or limitation. The policy should ideally address the following patient visitation requirements:(1) Inform each patient (or support person, where appropriate) of his or her visitation rights, including any clinical restriction or limitation on such rights, in advance of furnishing patient care whenever possible.(2) Inform each patient (or support person, where appropriate) of the right, subject to his or her consent, to receive the visitors whom he or she designates, including, but not limited to, a spouse, a domestic partner (including a same-sex domestic partner), another family member, or a friend, and his or her right to withdraw or deny such consent at any time.(3) Not restrict, limit, or otherwise deny visitation privileges on the basis of race, color, national origin, religion, sex, gender identity, sexual orientation, or disability.(4) Ensure that all visitors enjoy full and equal visitation privileges consistent with patient preferences. | 42 C.F.R. § 485.635(f) |
| Clinical Records | CAHs must have written policies addressing maintenance of the clinical patient records system, conditions for the release of information, and governing the use and removal of records from the CAH. The policy should ensure that the other requirements for a clinical records system set forth in 42 C.F.R. § 485.638 are met. | 42 C.F.R. § 485.638(a), (b)(2) (2019) |
| Infections Prevention and Control | CAHs are required to implement policies to administer an infection prevention and control program. The policies should ensure that the program:1. Employs methods for preventing and controlling the transmission of infections within the CAH and between the CAH and other healthcare settings;
2. Includes surveillance, prevention, and control of healthcare-associated infections (“HAIs”), including maintaining a clean and sanitary environment to avoid sources and transmission of infection, and that the program also addresses any infection control issues identified by public health authorities; and
3. Reflects the scope and complexity of services offered at the CAH.

*Review Comment*: These policies must be developed, implemented, and administered by a qualified infection prevention and control professional who is appointed by the governing body based on the recommendations of the medical staff and nursing leadership.  | 42 C.F.R. § 485.640(a) (2020)[[8]](#footnote-8) |
| Antibiotic Stewardship Programs | CAHs are required to implement policies to administer a facility-wide antibiotic stewardship program. The policies should ensure that the program: 1. Adheres to nationally recognized guidelines and best practices;
2. Reflects the scope and complexity of services offered at the CAH;
3. Demonstrates coordination among all components of the CAH responsible for antibiotic use and resistance, including, but not limited to, the infection prevention and control program, the QAPI program, the medical staff, nursing services, and pharmacy services;
4. Documents the evidence-based use of antibiotics in all departments and services of the CAH; and
5. Documents any improvements, including sustained improvements, in proper antibiotic use.

*Review Comment*: These policies must be developed, implemented, and administered by an individual qualified by education, training, or experience in infectious diseases and/or antibiotic stewardship who is appointed by the governing body based on the recommendations of the medical staff and pharmacy leadership. | 42 C.F.R. § 485.640 (b) (2020) |
| General Policy Requirements for Healthcare Facilities[[9]](#footnote-9) | All facilities must have the following policies as applicable to the hospital and the services it performs:(1) Elective delivery policy in accordance with the American College of Obstetricians and Gynecologists; (2) Policies for outpatient surgical services; (3) Manual of policies for outpatient primary care; (4) Policies and procedures for a birthing center; (5) Policies for hospice care; and (6) Policies and procedures for operating a mental health center and providing mental health services.  | Mont. Admin. R. 37.106.2902(8) (2020)Mont. Admin. R. 37.106.506 (2020)Mont. Admin. R. 37.106.1006 (2020)Mont. Admin. R. 37.106.1014 (2020) Mont. Admin. R. 37.106.2301 (2020)Mont. Admin. R. 37.106.1907 (2020) |

1. 42 C.F.R. § 485.627 (2019) [↑](#footnote-ref-1)
2. Mont. Admin. R. 37.106.704(1) (2020) [↑](#footnote-ref-2)
3. While technically these are distinct CoP and state policy requirements, the substantive content overlaps and both requirements can be fulfilled by adhering to the current CoP emergency preparedness requirements. Additionally, each of the separately required emergency preparedness policies and plans may be addressed jointly or in separate documents. [↑](#footnote-ref-3)
4. Although the CoPs only require emergency preparedness plans and policies to be updated and reviewed every two years, the state licensure requirements require annual review. Given the shorter state requirement, annual review of any emergency preparedness or disaster planning policy is recommended. [↑](#footnote-ref-4)
5. The 2005 CoPs do not include an Emergency Preparedness Policy requirement. [↑](#footnote-ref-5)
6. The 2005 regulation included infection control policies and procedures in this requirement and did not include post-acute care needs and patient visitation requirements. 42 C.F.R. § 485.635(a)(2005). The current regulations require a separate infection control policy (listed below) that encompass the requirements previously set forth in the 2005 regulation. *See* 42 C.F.R. § 485.640 (2020). [↑](#footnote-ref-6)
7. 42 C.F.R. § 485.25 [↑](#footnote-ref-7)
8. Since 2005 this has become a separately governed policy requirement. [↑](#footnote-ref-8)
9. Mont. Admin. R. 37.106.704(5) (2020). Policies required for chemical dependency facilities are not listed here but are captured in Mont. Admin. R. 37.106.1440 (2020) as applicable. [↑](#footnote-ref-9)