

RULES AND REGULATIONS
FOR LICENSURE OF CRITICAL ACCESS HOSPITALS

Chapter 17

Section 1. Authority. These rules are promulgated by the Department of Health pursuant to the Health Facilities Act at W.S. 35-2-901 et seq. and the Wyoming Administrative Procedures Act at W.S. 16-3-101 et seq.

Section 2. Purpose and Applicability.

(a) These rules have been adopted to protect the health, safety and welfare of patients and employees in Critical Access Hospitals.

(b) The Office of Health Facilities may issue manuals, bulletins, or both, to interpret the provisions of these rules and regulations. Such manuals and bulletins shall be consistent with and reflect the policies contained in these rules and regulations. The provisions contained in manuals or bulletins shall be subordinate to the provisions of these rules and regulations.

(c) The incorporation by reference of any external standard is intended to be the incorporation of that standard as it is in effect on the effective date of these rules and regulations.

Section 3. Severability. If any portion of these rules is found to be invalid or unenforceable, the remainder shall continue in effect.

Section 4. Definitions.

The following definitions shall apply in the interpretation and enforcement of these rules. Where the context in which words are used in these rules indicates that such is the intent, words in the singular number shall include the plural and *visa versa*. Throughout these rules gender pronouns are used interchangeably. The drafters have attempted to utilize each gender pronoun in equal numbers, in random distribution. Words in each gender include individuals of the other gender.

For the purpose of these rules, the following shall apply:

(a) "Acceptable Plan of Correction" means the Licensing Division approved the Critical Access Hospital's plan to correct the deficiencies identified during an on-site survey conducted by the Survey Division or its designated representative. The plan of correction shall be a written document and shall provide, but not be limited to, the following information:

- (i) Who is responsible for the correction;
- (ii) What was done to correct the problem;
- (iii) Who will monitor to ensure that the situation does not develop again; and

(iv) An appropriate date, not to exceed sixty (60) days after the last day of survey, for the correction of deficiencies.

(b) "Administrator" is the person in charge of the facility twenty-four (24) hours per day and is:

(i) A physician;

(ii) A mid-level practitioner;

(iii) A registered nurse; or

(iv) An individual with training and experience in health service administration.

(c) "Advanced Practitioner of Nursing" means a person who is licensed by the Wyoming Board of Nursing to practice as an advanced practitioner of nursing.

(d) "Central Registry" means the registry operated by the Wyoming Department of Family Services pursuant to W.S.14-3-213, which indexes perpetrators of child abuse or neglect and abuse, neglect, exploitation or abandonment of disabled adults. The registry information is available by calling 307-777-5366, such number may be subject to change.

(e) "Clinical Laboratory Improvement Act (CLIA)" means the clinical laboratories approved by the U.S. Department of Health and Human Services, Health Care Financing Administration as required by 42 CFR Part 493, Section 1861 (e) and (j), the sentence following section 1861 (s)(13), and 1902(a)(9) of the Social Security Act and Section 353 of the Public Health Service Act.

(f) "Collaborative Practice" means the implementation of a formal written agreement that outlines procedures for consultation and collaboration with other health care professionals, e.g., licensed physicians and mid-level practitioners.

(g) "Complaint Investigations" means those facility investigations required to be performed by the Licensing Division.

(h) "Critical Access Hospital" means a hospital which meets the criteria required by the Wyoming State Rural Health Plan and rules for designation of critical access hospitals.

(i) "Designation" means an official finding and recognition by the Director, Department of Health that a health clinic or health center meets Wyoming State Rural Health Care Plan requirements to be a Critical Access Hospital.

(j) "Dietitian" means a person who is registered by the American Dietetic Association and provides nutritional dietary services.

(k) "Facility" means a Critical Access Hospital.

(l) "Governing Body" means the individual(s), group or corporation that is legally responsible for the Critical Access Hospital.

(m) "Hospital" means an institution licensed pursuant to W.S. 35-2-901 et seq.

(n) "License" means the authority granted by the Licensing Division to operate a Critical Access Hospital.

(o) "Licensed Practical Nurse (LPN)" means a person who is licensed to practice as a licensed practical nurse by the Wyoming Board of Nursing pursuant to W.S. 33-21-120.

(p) "Licensee" means any person, association, partnership, or corporation holding a Critical Access Hospital license.

(q) "Licensing Division" means the Department of Health, Office of Health Facilities.

(r) "LSC" means NFPA 101 Life Safety Code cited in the Department of Health, Chapter III Construction Rules for Health Facilities.

(s) "Mid-level Practitioner" means either an advanced practitioner of nursing or a physician assistant.

(t) "NFPA" means the National Fire Protection Association.

(u) "Registered Nurse" means a person who is a graduate of an approved school of professional nursing and is currently licensed to practice as a registered nurse by the Wyoming Board of Nursing pursuant to W.S. 33-21-120.

(v) "Physician" means a person licensed to practice medicine in Wyoming by the Wyoming Board of Medicine.

(w) "Physician Assistant" means a person who is licensed by the Wyoming Board of Medicine to practice as a physician assistant.

(x) "Practitioner" means a person licensed in Wyoming as a physician, advanced practitioner of nursing, or physician assistant.

(y) "Survey" means a periodic on-site evaluation conducted by the Survey Division or its designated representative to determine compliance with State rules and regulations for licensure of Critical Access Hospitals.

(z) "Survey Division" means the Department of Health, Office of Health Facilities.

Section 5. Licensure.

(a) Licensing Procedure.

(i) For an initial license to be issued, the Licensing Division shall receive:

(A) A completed application form as supplied by the Licensing Division;

(B) A copy of the Director, Department of Health's written notice of designation to become a Critical Access Hospital;

(C) The required licensure fee identified in Chapter 1, Rules and Regulations for Health Care Facilities Licensure Fees. The check or money order shall be made payable to the Treasurer, State of Wyoming.

(D) Applicant shall demonstrate full compliance with the licensure requirements in paragraph (b) of this section.

(ii) For renewal of a full license for one (1) year beginning July 1st, and unless suspended or revoked, expiring on June 30th of the following year, the Licensing Division shall receive:

(A) A completed application form by the date stated in the application cover letter supplied by the Licensing Division; and

(B) The license fee as required in paragraph (a)(i)(C) of this section.

(C) Demonstration of compliance with the requirements for licensure as required in paragraph (b) of this section.

(b) Requirements for Licensure.

(i) Meet the criteria required by the Wyoming State Rural Health Plan for designation as a Critical Access Hospital by the Director, Department of Health.

(ii) The Critical Access Hospital shall be in compliance with all laws and standards relating to communicable and reportable diseases as required by the Department of Health, State Health Officer and Public Health Division.

(iii) Cited survey and complaint investigation deficiencies shall not create a hazard to the health, safety or welfare of the patients.

(iv) The Critical Access Hospital shall make a positive effort to correct all survey and complaint investigation deficiencies.

(v) Policies and procedures shall be in place to guide operations.

(vi) An adequate number of appropriately trained staff shall be maintained.

(vii) An organized quality improvement plan shall be in place and implemented.

(viii) There shall be an approved plan of correction for all survey and complaint investigation deficiencies.

(c) Issuance of License.

(i) For initial licensure, the date of license shall be:

(A) The date of the survey, if there are no deficiencies; or

(B) If deficiencies exist, the date that an acceptable plan of correction is developed.

(C) The period of license shall be one year beginning on July 1st, and unless suspended or revoked, shall expire on June 30th of the following year.

(d) Transfer of License.

(i) A license shall apply only to the geographical location described in the license application.

(A) Whenever ownership of a Critical Access Hospital is transferred from the individual or entity named in the license application to any other individual or entity, written notification of change of ownership shall be made to the Licensing Division. The transferee shall notify the Licensing Division of the transfer and apply for a new license.

(l) Any license granted to the transferee shall be subject to the plan of correction submitted by the previous owner as approved by the Survey Division.

(B) The transferor shall notify the Licensing Division at least thirty (30) days before the transfer.

(ii) If the Critical Access Hospital's name is changed, the Licensing Division shall be advised in writing and a new license shall be issued upon receipt of the licensure fee and application.

(e) Conditions for Denying, Revoking, or Suspending a License.

(i) Denial, revocation, or suspension of a license may occur for noncompliance with any provisions of these licensure rules.

(f) Suspension of Admissions.

(i) The Licensing Division may suspend new admissions or re-admissions to a Critical Access Hospital when conditions are such that patient needs cannot be met. Conditions in a Critical Access Hospital shall not jeopardize the patient's health and/or safety.

(g) Monitor.

(i) When conditions are such that patient needs are not being met, the Licensing Division shall install a Department of Health approved monitor at the expense of the Critical Access Hospital.

(h) Hearings.

(i) Any Critical Access Hospital aggrieved by a decision of the Licensing Division may request a hearing by submitting a written request within ten (10) days of the date of receipt of the notice of adverse action.

(ii) Except in matters concerned with the spread of communicable disease, the Licensing Division shall present the preliminary decisions and reasons for the decision to the parties concerned and shall provide an opportunity for a hearing. Any request for a hearing shall adhere to the time frame of (i) above.

(iii) In matters concerned with the spread of communicable disease, the Wyoming State Health Officer or designated representative shall present the preliminary decisions and reasons for the decision to the parties concerned and shall provide an opportunity for a hearing. Any request for a hearing shall adhere to the time frame in (i) above.

(iv) Hearings requested under the terms of these licensure rules shall be held in accordance with the provisions of the Wyoming Administrative Procedures Act.

(i) Posting of License.

(i) The current license issued by the Licensing Division shall be displayed in a public area within the Critical Access Hospital.

(j) Surveys for Licensure.

(i) The Survey Division or designed representative shall perform initial and periodic surveys for the renewal of licensure.

(A) These surveys shall be based on the current Licensure Rules and Regulations for Critical Access Hospitals as promulgated by the Wyoming Department of Health.

(B) The Survey Division shall provide, within ten (10) working days after the last day of survey, copies of the cited deficiencies to the Critical Access Hospital.

(C) The Critical Access Hospital shall provide an acceptable plan of correction for all cited deficiencies, within ten (10) working days after receipt of the deficiencies to the Survey Division.

(ii) At the time of survey, all records, including patient medical records, pertaining to matters involved in the survey shall be made available to members of the survey team in their assigned disciplines.

(k) Voluntary Closure.

(i) If a Critical Access Hospital voluntarily ceases to operate, it shall notify the Licensing Division in writing at least fifteen (15) working days prior to closure.

(ii) The first working day after closure, the Critical Access Hospital's license shall be hand carried to or sent by certified mail to the Office of Health Facilities; 2020 Carey Avenue, Eighth Floor; Cheyenne, WY 82002.

Section 6. Organization and Management.

(a) Governing Body. The Critical Access Hospital shall have a governing body which:

- (i) Has the legal authority and responsibility to operate the facility.
- (ii) Appoints an administrator who is responsible for managing the facility.
- (iii) Provides verification of a central registry information check on all employees hired at the time of or after the filing of these rules. The individual agencies or corporations are responsible to initiate and follow this process to completion.

Central registry information can be obtained by contacting the Department of Family Services at 307-777-5366. (This number is subject to change.)

- (iv) Adopts, revises, and approves personnel policies, including; but not limited to:

- (A) Frequency of evaluations;

- (B) Insuring confidentiality of central registry information checks.

- (v) Prepare an organizational chart that reflects the administrative control and lines of authority for the delegation of responsibility from management down to the client care level.

- (vi) The governing body shall ensure that all services provided are consistent with accepted standards of practice.

- (vii) The governing body shall be accountable for the quality of care provided to the patient.

- (viii) There shall be policies and procedures for services offered, which shall be reviewed annually by the governing body. Policies required, but not limited to:

- (A) Every patient shall be under the care of a physician or under the care of a mid-level practitioner supervised by a physician.

- (B) Whenever a patient is admitted to the facility by a mid-level practitioner, the facility's sponsoring physician shall be notified of that fact, by phone or otherwise, within twenty-four (24) hours, and a written notation of the consultation and of the physician's approval or disapproval shall be maintained in the patient's record;

- (C) A physician, a mid-level practitioner or a registered nurse shall be on duty and physically available in the facility when there are inpatients;

(D) When there are no inpatients, the facility may close (i.e. be unstaffed) provided an effective system is in place to ensure that a practitioner with training and experience in emergency care is on call and available by telephone or radio twenty-four (24) hours a day; and

(E) Patient care shall meet the provisions in Section 4.(h).

(ix) Personnel Records.

(A) There shall be one person designated responsible for maintaining confidentiality.

(x) Employee Health.

(A) Policies and procedures shall be developed for employee health, including a policy identifying communicable diseases that could put the patient population at risk.

(xi) Services.

(A) Furnished services, including contracted services, shall comply with all applicable licensure standards;

(B) Medical and nursing staff shall be licensed, certified, or registered according to Wyoming laws and rules; and

(C) Staff members shall provide health services only within the scope of his or her license, certification or registration.

Section 7. Medical Staff.

(a) The facility shall have a medical staff that includes at least one (1) physician, and may also include one (1) or more mid-level practitioners, who:

(i) Examines the credentials of candidates for medical staff membership and makes recommendations to the governing body on the appointment of candidates; and

(ii) Adopts a collaborative plan containing the following, and enforces the collaborative plan after approval by the governing body:

(A) A statement of the duties and privileges of each category of medical staff (e.g., physician and mid-level practitioner); and

(B) A requirement that a physical examination be made and medical history taken of a patient by a member of the medical staff no more than twenty-four (24) hours after the patient's admission to the facility.

(b) A physician on staff shall:

(i) Provide medical direction to the facility's health care activities and consultation for non-physician health care providers;

(ii) In conjunction with the mid-level practitioner staff members, participate in developing, executing, and periodically reviewing the facility's written policies and the services provided to patients.

(iii) Review and sign the records of each patient admitted and treated by a mid-level practitioner no later than fifteen (15) days after the patient's discharge from the facility;

(iv) Provide health care services to the patients in the facility, whenever needed and requested;

(v) Prepare guidelines for the medical management of health problems, including conditions requiring medical consultation and/or patient referral; and

(vi) At intervals no more than two (2) weeks apart, be physically present in the facility for a sufficient time to provide medical direction, medical care services, and staff consultation required by the collaborative agreement;

(A) When not present, either be available through direct telecommunication for consultation and assistance with medical emergencies, and patient referral, or ensure that another physician is available for this purpose.

(B) However, the physical site visit for a given two (2) week period is not required if, during that period, no inpatients have been treated in the facility.

(c) A mid-level practitioner on staff shall:

(i) Participate in the development, execution, and periodic review of the guidelines and written policies governing the services furnished by the facility;

(ii) Participate with a physician in a review of each patient's health records;

- (iii) Provide health care services to patients according to the facility's policies;
- (iv) Arrange for, or refer patients to needed services that are not provided at the facility; and
- (v) Assure that adequate patient health records are maintained and transferred as necessary.

Section 8. Emergency Services.

(a) The Critical Access Hospital shall meet the emergency needs of patients in accordance with acceptable standards of practice.

(i) Diagnostic and treatment equipment, drugs, supplies, and space, including space for a sufficient number of treatment rooms, shall be adequate in terms of the size and scope of service.

(ii) The following equipment shall be available to the emergency suites: cardiac monitor, resuscitator, defibrillator, aspirator, thoracotomy set and tracheotomy set.

(iii) Service shall be available twenty-four (24) hours a day, and emergency room staff shall be adequate to ensure that an applicant for treatment will be seen within a reasonable length of time relative to his/her illness.

(iv) Medical records for patients receiving emergency services shall be in accordance with Section 15.

(v) Critical Access Hospitals must receive, and maintain, formal designation through the Department of Health's trauma system enhancement program W.S. 35-1-801). The level of designation shall be at the discretion of the hospital.

Section 9. Nursing Services.

(a) A Critical Access Hospital shall have a nursing service program that provides twenty-four (24) hour services, whenever a patient is in the facility, and meets the following requirements:

(i) The director of nursing services shall:

- (A) Be a Wyoming licensed registered nurse;
 - (B) Determine the type and number of nursing personnel and staff necessary to provide nursing care; and
 - (C) Schedule adequate numbers of licensed registered nurses, licensed practical nurses, certified nursing assistants and other personnel to provide nursing care as needed.
- (ii) A registered nurse shall be on duty at least eight (8) hours per day, and the director of nursing or another registered nurse designated as the director's alternate shall be on call and available within twenty (20) minutes at all times.
 - (iii) All drugs and biologicals shall be administered by a nurse, a physician, or a mid-level practitioner according to Federal and state laws and regulations, including applicable licensing requirements.

Section 10. Pharmaceutical Services.

- (a) The facility shall have pharmaceutical services that meet the needs of the patients and comply with the following:
 - (i) A drug storage area under the supervision of the Director of Nursing who shall develop, supervise, and coordinate all of the pharmacy services;
 - (ii) The pharmacy or drug storage area shall be administered according to accepted professional standards;
 - (iii) All compounding, packaging, and dispensing of drugs and biologicals shall be consistent with federal and state laws;
 - (iv) Drugs and biologicals shall be kept in a locked storage area;
 - (v) Outdated, mislabeled, or otherwise unusable drugs and biologicals shall be destroyed by grinding in a garbage disposal or incineration; and
 - (vi) Drug administration errors, adverse drug reactions, and incompatibilities shall be immediately reported to the attending practitioner.

Section 11. Radiologic Services.

(a) The facility shall maintain, or have available, diagnostic radiologic services, which shall meet the following:

(i) The radiologic services shall be free from radiation hazards for patients and personnel;

(ii) Annual inspection of equipment shall be made and hazards identified are promptly corrected;

(iii) Radiation workers shall continuously wear monitoring badges that are to be checked quarterly to determine the amount of radiation to which they are routinely exposed;

(iv) A qualified full-time, part-time, or consulting radiologist shall be utilized to interpret those radiographic tests that are determined by the medical staff to require a radiologist's specialized knowledge;

(A) The radiologist or other practitioner who provides radiology services shall sign each report containing his/her interpretations.

(v) Only personnel designated as qualified by the medical staff, and meeting the requirements of state law, may use the radiographic equipment and administer procedures; and

(vi) The facility shall maintain any radiographic studies and their interpretations for at least six (6) years.

Section 12. Laboratory Services.

(a) The facility shall maintain, or have available, clinical laboratory services adequate to fulfill the needs of its patients and meets the following:

(i) The facility, at a minimum, shall provide basic laboratory services essential to the immediate diagnosis and treatment of patients, including:

(A) Chemical examinations of urine by stick or tablet methods, or both (including urine ketones);

(B) Microscopic examinations of urine sediment;

- (C) Hemoglobin and hematocrit;
- (D) Blood sugar;
- (E) Gram stain;
- (F) Examination of stool specimens for occult blood;
- (G) Pregnancy test;
- (H) Primary culturing for transmittal to a CLIA certified laboratory;
- (I) Sediment rate;
- (J) CBC; and
- (K) Chemistry Panel.

(ii) The facility shall have a contractual agreement with a CLIA approved hospital or independent laboratory for any additional laboratory services that are needed by a patient.

(iii) Emergency provision of basic laboratory services shall be available twenty-four (24) hours a day.

(iv) Only personnel designated as qualified by the medical staff by virtue of education, experience, and training may perform and report laboratory results.

(v) The laboratory shall be a CLIA certified laboratory.

Section 13. Dietary Services.

(a) The facility shall provide dietary services that are directed and staffed by adequate personnel and meet the following:

(i) The facility shall assign an employee, or contract with a consultant, to direct dietetic services and be responsible for the daily management of dietary services. The individual shall be qualified by experience and training as a food service supervisor.

(ii) The facility shall utilize a qualified dietitian, full-time, part-time, or on a consultant basis; and

(iii) The facility shall provide dietetic services that meet the nutritional needs of patients according to the science of nutrition:

(A) The dietetic service must operate from receipt through production and service with safe food handling practices in accordance with the most current edition of FOOD CODE from the U.S. Public Health Service, Food and Drug Administration; and

(B) Therapeutic diets shall be prescribed by the practitioner responsible for the care of the patients.

Section 14. Required Contracted Services.

(a) The facility shall enter into agreements with one or more hospitals participating in the Medicare/Medicaid programs to provide services which the Critical Access Hospital is unable to provide.

Section 15. Medical Records.

(a) The facility shall maintain a medical records system in accordance with written policies and procedures.

(i) Professional standards of practice for medical records shall be met.

(ii) A medical record shall be created and maintained for each patient receiving health care services that includes, if applicable:

(A) Identification and social data;

(B) Admitting diagnosis;

(C) Pertinent medical history;

(D) Properly executed consent forms;

(E) Reports of physical examinations, diagnostic and laboratory test results, and consultation findings;

(F) All physicians' orders, nurses' notes, and reports of treatment and medications;

(G) Final diagnosis;

(H) Discharge summary; and

(I) Any other pertinent information necessary to monitor the patient's prognosis.

(iii) Each record shall include the signatures of the physician and the health care professional's documentation.

(iv) Records of a discharged patient shall be completed within fifteen (15) days of the discharge date.

(v) The facility shall have written policies and procedures ensuring the confidentiality of patient records, safeguards against loss, destruction, or unauthorized use, in accordance with applicable state and federal laws. These policies and procedures shall:

(A) Govern the use and removal of records from the record storage area;

(B) Specify the conditions under which record information may be released and to whom; and

(C) Specify when the patient's written consent is required for release of information.

Section 16. Quality Improvement.

(a) The governing body, in accordance with W.S. 35-2-910, shall ensure there is an effective, on-going, facility-wide, written quality improvement program which ensures and evaluates the quality of patient care provided and includes an annual review of the following:

(i) The utilization of facility services, including at least the number of patients served and volume of services; and

(ii) The facility's health care policies.

(b) The initiation and documentation of appropriate remedial action to address deficiencies found through the quality improvement program, as well as documentation of the outcome of remedial action.

Section 17. Infection Control.

(a) The facility shall:

(i) Maintain a sanitary environment which prevents the transmission and sources of infections and communicable diseases;

(ii) Develop and implement policies governing control of infections and communicable diseases; and

(iii) Maintain a log of incidents related to infections and communicable diseases.

Section 18. Disaster Plan.

(a) All Critical Access Hospitals shall develop and adopt a written disaster preparedness plan in accordance with the Health Care Emergency Preparedness chapter of the applicable Life Safety Code (Ref: Page 17, Section 21(a)(i)).

Section 19. Physical Environment.

(a) The Critical Access Hospital building(s) shall be designed, constructed, arranged, equipped and maintained to ensure the safety of patients, personnel and visitors and to provide adequate and efficient care and treatment of patients.

Fire safety shall be in accordance with the requirements of the applicable NFPA Life Safety Code 101 (Ref: Page 17, Section 21(a)(i)).

Section 20. Construction/Remodeling/Changes in Space Use.

(a) Department of Health Chapter III, Construction Rules for Health Facilities apply.

Section 21. Life Safety and Electrical Safety.

(a) Department of Health Chapter III, Construction Rules for Health Facilities apply.

(i) Designated Critical Access Hospitals shall meet the Life Safety Code of the National Fire Protection Association that was in effect at the time the facility was licensed as a hospital, health clinic or health center.