

NEBRASKA HEALTH AND HUMAN SERVICES  
REGULATION AND LICENSURE

175 NAC 9

TITLE 175 HEALTH CARE FACILITIES AND SERVICES LICENSURE

CHAPTER 9 HOSPITALS

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9-001 SCOPE AND AUTHORITY: These regulations govern licensure of hospitals. The regulations are authorized by and implement the Health Care Facility Licensure Act, Neb. Rev. Stat. §§ 71-401 to 71-459.

9-001.01 These regulations apply to hospitals. A hospital is a health care facility where diagnosis, treatment, medical care, obstetrical care, nursing care or related services are provided on an outpatient basis or on an inpatient basis for a period of more than 24 consecutive hours to persons who have an illness, injury or deformity or to aged or infirm persons requiring or receiving convalescent care.

9-001.02 Hospital includes a health care facility or part of a health care facility which provides space for a general acute hospital, a rehabilitation hospital, a long-term care hospital, a critical access hospital or a psychiatric or mental hospital.

9-001.03 Hospital does not include a health care practitioner facility in which persons do not receive care or treatment for a period of more than 24 consecutive hours.

9-002 DEFINITIONS

Abuse means any knowing, intentional or negligent act or omission on the part of a person which results in physical, sexual, verbal or mental abuse, unreasonable confinement, cruel punishment, exploitation, or denial of essential care, treatment, and services to a patient.

Activities of daily living (See definition of "Care.")

Adjoining means located to allow access without having to enter a general corridor area used or observed by other facility occupants.

Administrator means the operating officer for a hospital and may include such titles as administrator, chief executive officer, manager, superintendent, director, or similar designation.

Applicant means the individual, government, corporation, partnership, limited liability company, or other form of business organization who applies for a license.

prescribed by a medical practitioner and dispensed by a pharmacist or other person authorized by law to do so.

Direction and monitoring means, for the purpose of medication administration, the acceptance of responsibility for observing and taking appropriate action regarding any desired effects, side effects, interactions and contraindications associated with the medication. Direction and monitoring can be done by a:

1. Competent individual for himself or herself;
2. Caretaker; or
3. Licensed health care professional.

Director means the Director of Regulation and Licensure.

Drug means substances as defined in Neb. Rev. Stat. § 71-1,142.

Existing facility means a licensed health care facility or a facility whose construction or remodeling plans were approved by the Department prior to the effective date of 175 NAC 9.

Exploitation means the taking of property of a patient by means of undue influence, breach of a fiduciary relationship, deception, extortion or by any unlawful means.

Facility means the building or buildings constituting the hospital.

Five rights means getting the right drug to the right recipient in the right dosage by the right route at the right time.

Food code means the Nebraska Food Code as defined in Neb. Rev. Stat. § 81-2,244.01 and as published by the Nebraska Department of Agriculture, except for compliance and enforcement provisions.

Foreign when applied to corporations means all those created by authority other than that of the State of Nebraska.

General acute hospital means a hospital with a duly constituted governing authority where medical, nursing, surgical, anesthesia, laboratory, diagnostic radiology, pharmacy and dietary services are provided on an inpatient or outpatient basis by the organized medical staff of such hospital.

Governing authority means, depending on the organizational structure, an owner or owners, a board of directors or other governing members of the licensee, or state, city, or county officials appointed by the licensee.

Grievance means a written expression of dissatisfaction which may or may not be the result of an unresolved complaint.

Health care facility means an ambulatory surgical center, an assisted-living facility, a center or group home for the developmentally disabled, a critical access hospital, a general acute

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2. Recording medication provision; and
3. Observing, monitoring, reporting and otherwise taking appropriate actions regarding desired effects, side effects, interactions, and contraindications associated with the medication.

Medication aide means an individual who is listed on the medication aide registry operated by the Department as provided in 172 NAC 95 and 172 NAC 96.

Medication provision means the component of the administration of medication that includes giving or applying a dose of medication to an individual and includes helping an individual in giving or applying such medication to himself or herself.

Mental abuse means humiliation, harassment, threats of punishment, deprivation, or other actions causing mental anguish.

NAC means Nebraska Administrative Code.

Neglect means a failure to provide care, treatment, or services necessary to avoid physical harm or mental anguish of a patient.

New construction means a facility or a distinct part of a facility in which care and treatment is to be provided and which is enlarged, remodeled or altered in any fashion or is built from the ground up on or after the effective date of 175 NAC 9.

New facility means a facility or a distinct part of a facility in which care and treatment is to be provided and which is not currently licensed as a health care facility. New facility also includes those facilities which were previously licensed for care and treatment in another licensure category that now intends to seek licensure in a different category.

Outpatient means a person who receives care for less than 24 hours by or under the supervision of a medical practitioner in the emergency service department, outpatient department or elsewhere in the hospital, but who is not admitted to the hospital as an inpatient.

Patient means a person who receives care and treatment as recommended by a medical practitioner at a hospital and includes inpatients and outpatients.

Personal care (See definition of "Care.")

Physical abuse means hitting, slapping, pinching, kicking, or other actions causing injury to the body.

Physical restraint means any manual method or physical or mechanical device, material, or equipment attached or adjacent to the patient's body that he or she cannot remove easily and that restricts freedom of movement or normal access to his or her own body.

Physician means any person authorized to practice medicine in this state as provided in Neb. Rev. Stat. §§ 71-102 to 71-110.

9-003.01 Initial License: The initial license process occurs in two stages. The first stage consists of the applicant's submission of affirmative evidence of the ability to comply with the operational and physical plant standards contained in 175 NAC 9-006 and 175 NAC 9-007. The application is not complete until the Department receives documents specified in 175 NAC 9-003.01.

The second stage consists of the Department's review of the completed application together with an inspection of the hospital. The Department determines whether the applicant meets the standards contained in 175 NAC 9 and the Health Care Facility Licensure Act.

9-003.01A Applicant Responsibilities: An applicant for an initial hospital license must:

1. Intend to provide hospital services as defined;
2. Comply with the applicable codes, guidelines, and standards specified in 175 NAC 9-007;
3. Submit a written application to the Department as provided in 175 NAC 9-003.01B;
4. Receive approval in writing, from the Department, of schematic plan and, if new construction, of construction plans; and
5. Notify the Department at least 30 working days prior to planned patient occupancy.

9-003.01B Application Requirements: The applicant may construct an application or obtain an application form from the Department. The application must include:

1. Full name of the hospital to be licensed, street and mailing address, telephone number and facsimile number, if any;
2. Type of hospital to be licensed;
3. Name of the administrator;
4. Name and address(es) of the hospital owner(s);
5. Ownership type;
6. Mailing address(es) for the owner(s);
7. Preferred mailing address for receipt of official notices from the Department;
8. List of names and addresses of all persons in control of the hospital. The list must include all individual owners, partners, limited liability company members, parent companies, if any, and members of boards of directors owning or managing the operations and any other persons with financial interests or investments in the hospital. In the case of publicly held corporations, the individual owners listed must include any stockholders who own 5% or more of the company's stock;
9. Legal name of the individual or business organization (government, corporation, partnership, limited liability company or other type) to whom the license should be issued and a statement that the individual or organization accepts the legal responsibility for compliance with 175 NAC 9;
10. Applicant's federal employer identification number, if not an individual;
11. Applicant's social security number, if the applicant is an individual. To ensure social security numbers are not part of public records and are used only for

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3. Confirm, either by Department review or by accepting certification from an architect or engineer, that the schematic plans and, if new construction, the construction plans meet the standards of 175 NAC 9-007;
4. Upon receipt of the requested information, conduct an on-site inspection in accordance with 175 NAC 9-005 prior to the issuance of a hospital license; and
5. Issue or deny a license based on the results of the initial inspection.

9-003.01D Denial of License: See 175 NAC 9-008.01 and 9-008.02 for grounds and procedures for the Department's denial of an initial license.

9-003.02 Renewal Licenses

9-003.02A Licensee Responsibilities: The licensee must submit a written application to the Department. The licensee may construct an application, or obtain an application form from the Department. The application must include:

1. Full name of the hospital to be licensed, street and mailing address, telephone number, and facsimile number, if any;
2. Type of hospital to be licensed;
3. Name of the administrator;
4. Name and address(es) of the hospital or service owner(s);
5. Ownership type;
6. Mailing address(es) for the owner(s);
7. Preferred mailing address for receipt of official notices from the Department;
8. List of names and addresses of all persons in control of the hospital. The list must include all individual owners, partners, limited liability company members, parent companies, if any, and members of boards of directors owning or managing the operations and any other persons with financial interests or investments in the hospital. In the case of publicly held corporations, the individual owners listed must include any stockholders who own 5% or more of the company's stock;
9. Legal name of the individual or business organization (government, corporation, partnership, limited liability company or other type) to whom the license should be issued and a statement that the individual or organization accepts the legal responsibility for compliance with 175 NAC 9;
10. Applicant's federal employer identification number, if an individual;
11. Applicant's social security number if the applicant is an individual. To ensure social security numbers are not part of public records and are used only for administrative purposes, applicants may submit social security numbers in a separate document;
12. Number of beds;
13. Signature(s) of:
  - a. The owner, if the applicant is an individual or partnership;
  - b. Two of its members, if the applicant is a limited liability company;
  - c. Two of its officers, if the applicant is a corporation; or

treatment, and physical plant requirements of 175 NAC 9-006 and 9-007. The decision is based on the following factors:

1. The length of time that has transpired from the date the license was placed on lapsed status to the date of the reinstatement application; and
2. Whether the hospital has provided care or treatment from the site under a license that is different from the lapsed license.

9-003.03B When the Department decides that a reinstatement inspection is warranted, it will conduct the inspection in accordance with 175 NAC 9-005.

9-003.03C When the Department decides that a reinstatement inspection is not warranted, it will reinstate the license.

9-003.03D Refusal to Reinstate: See 175 NAC 9-008.01 and 9-008.02 for grounds and procedures for the Department's refusal to reinstate a lapsed license.

#### 9-004 GENERAL REQUIREMENTS

9-004.01 Separate License: An applicant must obtain a separate license for each type of health care facility or health care service that the applicant seeks to operate. All buildings in which care and treatment are provided must comply with 175 NAC 9-006 and if applicable, 175 NAC 9-007. A single license may be issued for:

1. A hospital or service operating in separate buildings or structures on the same premises under one management;
2. An inpatient hospital that provides services on an outpatient basis at multiple locations; or
3. A health clinic operating satellite clinics on an intermittent basis within a portion of the total geographic area served by the health clinic and sharing administration with the clinics.

9-004.02 Single License Document: The Department may issue one license document that indicates the various types of health care facilities or health care services for which the entity is licensed.

9-004.03 Effective Date and Term of License: A hospital license expires on December 31 of each year.

9-004.04 License Not Transferable: A license is issued only for the premises and persons named in the application and is not transferable or assignable. Change of ownership (sale, whether of stock, title, or assets, lease, discontinuance of operations) or change of premises terminates the license. If there is a change of ownership and the hospital remains on the same premises, the inspection in 175 NAC 9-005 is not required. If there is a change of premises, the hospital must pass the inspection specified in 175 NAC 9-005.

9-004.05 Bed Capacity, Usage, and Location: The licensee must not put into use more beds than the total number of beds for which the hospital is licensed. Changes in the use or

9-004.09A1 The applicant or licensee must request the Department to deem its facility in compliance with 175 NAC 9-006 based on accreditation or certification. The request must be:

1. Made in writing;
2. Submitted within 30 days of receipt of a report granting accreditation or certification; and
3. Accompanied by a copy of the accreditation or certification report.

9-004.09A2 Upon receipt of the request, the Department will deem the facility in compliance with 175 NAC 9-006 and will provide written notification of the decision to the facility within ten working days of receipt of the request.

9-004.09A3 The Department will exclude a facility that has been deemed in compliance with 175 NAC 9-006 from the random selection of up to 25% of facilities for compliance inspections under 175 NAC 9-005.04A. The facility may be selected for a compliance inspection under 175 NAC 9-005.04B.

9-004.09A4 To maintain deemed compliance, the licensee must maintain the accreditation or certification on which the license was issued. If the accreditation or certification has been sanctioned, modified, terminated, or withdrawn, the licensee must notify the Department within 15 days of receipt of notification of the action. After notifying the Department, the hospital may continue to operate unless the Department determines that the hospital no longer meets the requirements for licensure under the Health Care Facilities Licensure Act. If the Department determines the facility no longer qualifies for deemed compliance, the facility is subject to inspections under 175 NAC 9-005.

9-004.10 Fees: The licensee must pay fees for licensure as set forth below:

1. Initial and Renewal Licensure fees:
  - a. 1 to 50 Beds \$1,750
  - b. 51 to 100 Beds \$1,850
  - c. 101 or more Beds \$1,950
  - d. All hospitals must also pay with their renewal licensure fee an additional fee under the Outpatient Surgical Procedures Data Act, Neb. Rev. Stat. §§ 81-6,111 to 81-6,119, as follows:

(1) 500 or fewer outpatient surgeries per year	\$275
(2) 501 to 2,000 outpatient surgeries per year	\$350
(3) More than 2,000 outpatient surgeries per year	\$425
2. Duplicate license: \$10
3. Refunds for denied applications:



2. If the hospital fails to submit and implement a statement of compliance that indicates a good faith effort to correct the violations, the Department may deny the license.

9-005.02E When the Department finds the applicant fails to meet the requirements of 175 NAC 9-006 and 9-007 and the failure(s) would create an imminent danger of death or serious physical harm, the Department will deny the license.

9-005.03 Physical Plant Inspections: The Department will conduct inspections for conformity with construction plans and compliance with 175 NAC 9-007 at new facilities or new construction prior to use or occupancy.

9-005.03A On-site progress inspections of the physical plant by qualified inspectors for conformity to construction documents and compliance with code requirements may occur at any time after construction has begun and prior to the concealment of essential components.

9-005.03B The Department will conduct an on-site final inspection of the physical plant prior to use or occupancy. In lieu of an on-site final inspection by the Department, the Department may accept a certification from a licensed architect or engineer that the physical plant meets the requirements of the Health Care Facility Licensure Act and 175 NAC 9, and that the hospital is complete and ready for occupancy in accordance with Department-approved plans. The architect or engineer may construct a certification form or obtain a certification form from the Department.

9-005.03B1 The certification must state:

1. Name of the architect or engineer;
2. Name of the professional entity with which he or she is affiliated, if any;
3. Address and telephone number;
4. Type of license held, the state in which it is held, and the license number;
5. Name and location of the facility;
6. Name(s) of the owner(s) of the facility;
7. New construction had the building structure and plumbing rough-in inspected by a qualified inspector prior to the time these would be concealed and preclude observation;
8. All new construction, care and treatment room sizes, bedroom sizes, handrails, grab bars, hardware, building systems, protective shielding, privacy curtains, appropriate room finishes, and other safety equipment are completed in accordance with approved construction plans; and
9. The facility is furnished, cleaned, and equipped for the care and treatment to be performed in compliance with 175 NAC 9-007, and approved for use and occupancy.

9-005.03B2 The certification must have attached to it:

9-005.05B When the inspection reveals one or more violations that create no imminent danger of death or serious physical harm and no direct or immediate adverse effect on the health, safety, or security of hospital patients, the Department may request a statement of compliance from the hospital. The statement of compliance must indicate any steps that have been or will be taken to correct each violation and the estimated time to correct each violation. Based on the statement of compliance, the Department will take one of the following actions:

1. If the hospital submits and implements a statement of compliance that indicates a good faith effort to correct the violations, the Department will not take any disciplinary action against the license; or
2. If the hospital fails to submit and implement a statement of compliance, the Department will initiate disciplinary action against the hospital license, in accordance with 175 NAC 9-008.

9-005.06 Re-Inspections

9-005.06A The Department may conduct re-inspections to determine if a hospital fully complies with the requirements of 175 NAC 9-006 and 9-007. Re-inspection occurs:

1. After the Department has issued a provisional license;
2. Before a provisional license is converted to a regular license;
3. Before a disciplinary action is modified or terminated; or
4. After the Department receives a statement of compliance for cited violations.

9-005.06B Following a re-inspection, the Department may:

1. Convert a provisional license to a regular license;
2. Affirm that the provisional license is to remain effective;
3. Modify a disciplinary action in accordance with 175 NAC 9-008.02; or
4. Grant full reinstatement of the license.

9-006 STANDARDS OF OPERATION, CARE AND TREATMENT: 175 NAC 9-006.01 through 006.08 and 9-006.14 apply to the following hospitals: general acute, critical access, long-term care, psychiatric or mental and rehabilitation unless specified otherwise. Each hospital must organize, manage and administer resources to promote the attainment of its objectives and purposes, and in a manner consistent with its size, resources, and particular needs to ensure each patient receives the necessary service, care, and treatment. The major organizational divisions in each hospital must include a governing authority, an administration and a medical staff. In addition, the basic organization, responsibility and operation of each hospital must be described in a set of governing instruments which will vary with the form of organization but which must include a constitution or articles of incorporation, bylaws and medical staff bylaws. The governing instruments must describe the makeup of the governing authority, the terms of office and method of election or appointment and removal of governing authority members and officers, and the responsibilities of governing authority members, officers and standing committees.

There must be a mechanism provided in the medical staff bylaws, rules and regulations for review of decisions, including the right to be heard when requested by the practitioner;

13. Ensuring the medical staff is accountable to the governing authority for the quality of medical care and treatment;
14. Ensuring a medical staff committee and a utilization review committee are formed and operated for the purpose of reviewing the medical and hospital care provided and the use of hospital resources to assist individual physicians, administrators and nurses in maintaining and providing a high standard of medical and hospital care and promoting the efficient use of the hospital;
15. Ensuring that any person engaged in work in or about the hospital and having any information or knowledge relating to the medical and hospital care provided or the efficient use of the hospital facilities, provides all related facts and information to the hospital medical staff committee or utilization review committee upon request by the committee(s). Such facts and information include, for example, medical records, quality assurance records, pharmacy records, observations or personal knowledge, and other similar information and documents related to the care and treatment provided by the hospital and the efficient use of its facilities.
16. Periodically reviewing reports and recommendations regarding all Quality Assurance/Performance Improvement activities and Medical Staff and Utilization Review Committee reports. Reports must be utilized to implement programs and policies to maintain and improve the quality of patient care and treatment;
17. Establishing a means for liaison and communication between the governing authority, the medical staff and administration and promote effective communication and coordination of services among the various hospital departments, administration and the medical staff;
18. Approving the organization, bylaws, rules and regulations, and policies and procedures of the medical staff and the departments in the hospital;
19. Establishing visitation policies which are in the best interest of patients, including, but not limited to, protection from communicable diseases, protection from exposure to deleterious substances and hazardous equipment and assurance of health and safety of patients; and
20. Determining if emergency medical technician-intermediates or emergency medical technician-paramedics may perform activities within their scope of practice as either an employee or volunteer within the hospital.

9-006.01B Administration: The administrator is responsible for planning, organizing, and directing the day to day operation of the hospital. The administrator must report and

1. Initially review the background, experience, training and credentials of applicants for medical staff membership;
2. Make recommendations to the governing authority with regard to membership and category of memberships; and
3. Make recommendations to the governing authority regarding reappointment to the medical staff.

9-006.02C Clinical Privileges: The medical staff must establish a written process for the delineation of clinical privileges. The scope of privileges to be delineated must be stated with sufficient clarity to indicate the nature and extent of privileges. The process must include, but is not limited to:

1. The disciplines and the procedures/tasks for which medical staff must be privileged to perform;
2. The process by which application for clinical privileges is made and reviewed;
3. The process for notification of clinical privilege decisions; and
4. The process for appealing decisions to deny, limit, or otherwise modify privileges.

9-006.02D Medical Staff Bylaws: The medical staff must recommend and adhere to bylaws to carry out its responsibilities, subject to adoption by the governing authority. Medical staff bylaws must include, but are not limited to, the following:

1. A description of how the medical staff is organized;
2. The time frame for medical staff meetings and the rules for conducting business;
3. Methods for evaluating clinical practice in the hospital;
4. Criteria and procedures for membership and clinical privileges;
5. The procedure for medical staff adoption and amendment of medical staff bylaws; and
6. Provision for establishing a utilization review committee.

9-006.03 Staff Requirements: Each hospital must maintain a sufficient number of staff with the qualifications, training and skills necessary to meet patient needs. The hospital must be staffed 24 hours per day. The rotation of staff and the determination of when specifically licensed, registered or certified staff must be present in the hospital must be determined according to operational and patient care needs.

9-006.03A Employment Eligibility: Each hospital must ensure and maintain evidence of the following:

9-006.03A1 Staff Credentials: Each hospital must verify:

1. The current active licensure, registration, certification or other credentials in accordance with applicable state law, prior to staff assuming job responsibilities and must have procedures for verifying that the current status is maintained; and

9-006.03B Training: Each hospital must ensure staff receive training in order to perform assigned job responsibilities.

9-006.03B1 Orientation: Each hospital must provide and maintain evidence of an orientation program for all new staff and, as needed, for existing staff who are given new assignments. The orientation program must include an explanation of the:

1. Job duties and responsibilities;
2. Hospital's sanitation and infection control programs;
3. Organizational structure within the hospital;
4. Patient rights;
5. Patient care policies and procedures;
6. Personnel policies and procedures;
7. Emergency procedures;
8. Disaster preparedness plan; and
9. Reporting requirements for abuse, neglect or exploitation in accordance with the Adult Protective Service Act, Neb. Rev. Stat. § 28-372, or in the case of a child in accordance with Neb. Rev. Stat. § 28-711, and with hospital policies and procedures.

9-006.03B1a Each hospital that approves emergency medical technician-intermediates and emergency medical technician-paramedics to provide service as either an employee or a volunteer must provide orientation to registered nurses, physicians, and physician assistants involved in the supervision of emergency medical technician-intermediates and emergency medical technician-paramedics. The orientation must include:

1. Information regarding the scope of practice of an emergency medical technician-intermediate or emergency medical technician-paramedic; and
2. Supervision requirements, as determined by the medical staff of the hospital, for emergency medical technician-intermediates and emergency medical technician-paramedics, to perform activities within their scope of practice as defined in 172 NAC 11, Regulations Governing Out-of-Hospital Emergency Care Providers, Section 11-006.

9-006.03B2 Ongoing Training: Each hospital must provide and maintain evidence of ongoing/continuous inservices or continuing education for staff. A record must be maintained including date, topics and participants.

9-006.03C Employment Record: Each hospital must maintain a current employment record for each staff person. The record must contain, at a minimum, information on orientation, inservices, credentialing and health history screening.

9-006.04 Patient Rights: Each hospital must protect and promote each patient's rights. This includes the establishment and implementation of written policies and procedures, which include, but are not limited to, the following rights. Each patient or designee, when appropriate, must have the right to:

4. The tracking of outpatient surgical procedures that result in unplanned patient admissions to a hospital within 72 hours of a procedure, due to post surgical complications;
5. Evaluation of care and treatment provided both by staff and through contract;
6. Appropriate action to address problems found through the program;
7. Evaluation of the outcome for any action taken; and
8. Reporting to the governing authority.

**9-006.06 Patient Care and Treatment:** Each hospital must provide the necessary care and treatment within the hospital's ability to meet the needs of patients. Care and treatment provided must meet prevailing professional standards and scope of practice requirements. Each hospital must establish and implement written policies and procedures that encompass care and treatment provided to patients.

**9-006.06A Plan of Care:** A plan of care must be established, implemented and kept current to meet the identified needs for each inpatient. The plan of care must be interdisciplinary when appropriate to meet individual needs of patients.

**9-006.06B Administration of Medications:** Each hospital must establish and implement policies and procedures to ensure patients receive medications only as legally prescribed by a medical practitioner in accordance with the Five Rights and prevailing professional standards.

**9-006.06B1 Methods of Administration of Medications:** When the hospital is responsible for the administration of medications, it must be accomplished by the following methods:

**9-006.06B1a Self-Administration:** The hospital must allow patients to self-administer medications, with or without supervision, when assessment determines patient is capable of doing so.

**9-006.06B1b Licensed Health Care Professional:** When the hospital utilizes licensed health care professionals for whom medication administration is included in the scope of practice, the hospital must ensure the medications are properly administered in accordance with prevailing professional standards.

**9-006.06B1c Provision of Medication by a Person Other Than a Licensed Health Care Professional:** When the hospital utilizes persons other than a licensed health care professional in the provision of medications, the hospital must follow 172 NAC 95 Regulations Governing the Provision of Medications by Medication Aides and Other Unlicensed Persons and 172 NAC 96 Regulations Governing the Medication Aide Registry. Each hospital must establish and implement policies and procedures:

1. To ensure that medication aides who provide medications are trained and have demonstrated the minimum competency standards specified in 172 NAC 95-004;

prescriber in a timely manner upon discovery and a written report of the error prepared.

9-006.06B3 Each hospital must establish and implement policies and procedures for reporting any adverse reaction to a medication in a timely manner upon discovery to the prescriber and for documenting the event in the patient's medical record.

9-006.06B4 Handling of Medications: Each hospital must establish and implement procedures to ensure that patients receive medications as prescribed by a medical practitioner. At a minimum, the following must be evident:

1. A current policy and procedure manual regarding the handling of drugs in the hospital;
2. A shift count of all controlled substances at each nursing unit which have been dispensed as multiple-dose floor stock or individual patient prescriptions. Unit-dose systems which do not exceed 24 hours duration may be exempt from this requirement; and
3. Only authorized personnel designated by hospital policy are allowed access to medications.

9-006.06B5 Medication Record: Each hospital must maintain records in sufficient detail to assure that patients receive the medications prescribed by a medical practitioner and maintain records to protect medications against theft and loss. Each inpatient must have an individual medication administration record which includes, but is not limited to:

1. The identification of the patient;
2. The name of the medication given;
3. The date, time, dosage, method of administration or provision for each medication, identification of the person who administered or provided the medication and any refusal by the patient; and
4. The patient's medication allergies and sensitivities.

9-006.06C Nutrition: Each hospital must provide for the daily nutritional needs of all patients, including the provision of any diets ordered by a medical practitioner.

9-006.06C1 A current diet manual acceptable to dietary, nursing and medical staff must be maintained and available for reference.

9-006.06C2 Education on matters of diet and nutrition must be available to patients when appropriate.

9-006.06C3 Assessments of the nutritional status of patients must be conducted by a licensed medical nutrition therapist as required by Neb. Rev. Stat. §§ 71-1,286 to 71-1,287 and 172 NAC 61 Regulations Governing the Practice of Medical Nutrition Therapy.

9-006.07A2 Medical records must contain entries which are dated, legible, and indelible. The author of each entry must be identified and authenticated. Authentication must include signature, written initials, or computer entry.

9-006.07A3 Telephone or verbal orders of authorized individuals are accepted and transcribed by qualified personnel who are identified by title or category in the medical staff bylaws or rules and regulations. Telephone or verbal orders must be authenticated as soon as is practical by the medical practitioner who is responsible for ordering, providing or evaluating the service furnished.

9-006.07A4 The hospital must monitor and require medical records be completed within 30 days of discharge of the patient.

9-006.07A5 Retention: The medical record of each patient must be maintained and preserved, in original, microfilm, electronic or other similar form, for a period of at least ten years following discharge or in the case of minors, the records must be kept until three years after the age of majority has been attained. In cases in which a hospital ceases operation, all medical records of patients must be transferred as directed by the patient or authorized representative to the hospital or other health care facility or health care service to which the patient is transferred. All other medical records that have not reached the required time for destruction must be stored to assure confidentiality and the Department must be notified of the address where stored.

9-006.07A6 Confidentiality: Medical records must be kept confidential, available only for use by authorized persons or as otherwise permitted by law. Records must be available for examination by authorized representatives of the Department.

9-006.07A7 Access: Patient information and/or records will be released only with consent of the patient or designee or as permitted by law. When a patient is transferred to another health care facility or service, appropriate information for continuity of care must be sent to the receiving health care facility or service.

9-006.07A8 Destruction: Medical records may be destroyed only when they are in excess of the retention requirements specified in 175 NAC 9-006.07A5. In order to ensure the patient's right of confidentiality, medical records are destroyed or disposed of by shredding, incineration, electronic deletion, or another equally effective protective measure.

9-006.07B Other Records/Reports: In addition to patient medical records, each hospital must maintain, when applicable, the following:

9-006.07B1 A permanent patient index that includes, but is not limited to:

1. Name and identification numbers of each patient;
2. Dates of admission and discharge;
3. Name of admitting physician; and
4. Disposition or place to which patient was discharged/transferred.



9-006.09B1 Each hospital must have a registered nurse on duty 24 hours a day, seven days a week and registered nursing service available for all patients at all times.

9-006.09B2 Each hospital must have a person designated as fulltime Director of Nursing, Chief Nursing Executive or other similar title who is a registered nurse having a current license in the State of Nebraska. The Director of Nursing may serve as charge nurse in hospitals of 25 beds or less. A registered nurse must be designated to act as director in the director's absence.

9-006.09B3 A registered nurse must assign the nursing care of each patient to other nursing personnel in accordance with the patient's needs and the specialized qualifications and competence of the nursing staff available.

9-006.09B4 A registered nurse must be responsible for supervision and direction of nursing care.

9-006.09B5 Registered nurses on duty must be sufficient to provide nursing care and supervision in the patient areas.

9-006.09B6 Nursing care policies and procedures must be in writing and consistent with generally accepted practice.

9-006.09B7 There must be a continuing planned staff development program for all nursing department personnel. A record must be maintained including date, topic and participants. Specialized training of personnel to permit them to perform particular procedures or render specialized care, whether as part of a training program or as individualized instruction must be documented.

9-006.09B8 A schedule of nursing department personnel must be maintained for each area, including first initial and last name of staff member, title, and hours of duty. Nursing schedules must be maintained for not less than three years.

9-006.09B9 Each hospital must establish appropriate policies and procedures for those personnel authorized to receive telephone and verbal diagnostic and therapeutic orders.

9-006.09B10 There must be sufficient staff by qualifications and numbers on each shift to assist directly and indirectly in the provision of care or treatment to meet patient needs.

9-006.09C Surgical Services: Each hospital must provide surgical services in a manner sufficient to meet the needs of patients. Surgical services must be under the direction of a qualified physician member of the medical staff who must be responsible for the quality and scope of surgical services. Surgical services must be provided by medical practitioners who are authorized by their scope of practice and who have received privileges that define and describe the scope and conduct of surgical services that can be performed at the hospital.

9-006.09D Anesthesia Services: Each hospital must provide anesthesia services in a manner sufficient to meet the needs of patients. Anesthesia is provided only by qualified individuals who are allowed to administer anesthesia under their scope of practice. This does not prohibit administration of anesthesia by medical or nurse anesthetist students under the supervision of a qualified individual.

9-006.09D1 Written policies and procedures must be established and implemented to ensure safe and competent delivery of anesthesia services to patients. These policies and procedures must be approved by the medical staff and include, but are not limited to:

1. Equipment maintenance;
2. Safety measures to guard against hazards;
3. Infection control measures; and
4. Pre and post anesthesia evaluations for inpatients and outpatients.

9-006.09E Laboratory Services: Each hospital must provide clinical laboratory services and these services may be available on the premises or through written agreement to meet the needs of patients. All laboratory testing, whether provided directly by the hospital or through agreement, must comply with the Clinical Laboratory Improvement Amendments of 1988 as amended (CLIA). Laboratory services must be under the direction of a physician, preferably a pathologist.

9-006.09E1 Each hospital provides or has available necessary laboratory services as determined by the medical staff.

9-006.09E2 The hospital must have accessible emergency laboratory services including urinalysis, complete blood counts, blood typing and cross matching and other necessary emergency laboratory work as determined by the medical staff.

9-006.09E3 Provision must be made for proper receipt and reporting of tissue specimens.

9-006.09E4 The medical staff must determine which tissue specimens require a macroscopic examination and which require both macroscopic and microscopic examinations.

9-006.09F Radiology Services: Each hospital must provide radiology services and these services may be available on the premises or through written agreement to meet the needs of patients.

9-006.09F1 Radiology services must be under the direction of a physician, preferably a radiologist, and must comply with the provisions of Neb. Rev. Stat. §§ 71-3501 to 71-3520, the Radiation Control Act, and the regulations promulgated thereunder.

9-006.09H Dietary Services: Dietary services must be provided directly or through written agreement to meet the general nutritional needs of patients and must be supervised by a registered dietitian. If there is not a full-time registered dietitian, a person must be designated as full-time director of dietary services and is responsible for the daily management of dietary services.

9-006.09H1 There must be written policies and procedures established and implemented that provide dietary services to meet patient needs.

9-006.09H2 There must be a sufficient number of trained staff to provide dietary services.

9-006.09H3 Menus must be planned, written and followed to meet the nutritional needs of patients.

9-006.09H4 Meals must be served to patients at appropriate intervals.

9-006.09H5 Each hospital stores, prepares, protects, serves and disposes of food in a safe and sanitary manner and in accordance with the Food Code.

9-006.09I Emergency Services: Critical Access Hospitals must provide emergency services on a 24-hour basis. General Acute, Long-Term Care, Psychiatric or Mental and Rehabilitation Hospitals are not required to provide emergency services. However, if provided, there must be an easily accessible emergency area which must be equipped and staffed to ensure that ill or injured persons can be promptly assessed and treated or transferred to a hospital capable of providing needed specialized services. Emergency services must be under the direction of a physician member of the medical staff who must be responsible for the quality and scope of emergency services.

9-006.09I1 Each hospital that provides emergency services must establish and implement written policies and procedures which include, but are not limited to:

1. Provision for 24 hour per day medical and nursing services by medical staff and registered nurses on duty or on call;
2. Medical and nursing personnel must be qualified in emergency care to carry out the written emergency procedures and needs anticipated by the hospital;
3. Emergency drugs, devices, biologicals, equipment and supplies must be available for immediate use in the emergency area for treating life-threatening conditions;
4. A medical record must be kept for each patient receiving emergency services and must be integrated into the patient's medical record;
5. An emergency room log that documents:
  - a. Patient name;
  - b. Date, time and method of arrival;
  - c. Physical findings;
  - d. Care and treatment provided;

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7. Care and staff responsibilities during induction or augmentation of labor;
8. The presence of fathers or other support persons during labor and delivery;
9. The method for correct identification of the newborn and mother; and
10. Immediate care of a newborn.

9-006.09L Pediatric Services: Pediatric services, if provided, must be under the direction of a physician member of the medical staff, qualified to direct the services, and who must be responsible for the quality and scope of services.

9-006.09L1 Each hospital that provides care and treatment to pediatric patients in a distinct unit must establish and implement written policies and procedures which include, but are not limited to:

1. The scope of and care for pediatric patients;
2. Supervision by a qualified registered nurse;
3. Location of pediatric patients apart from adult patients and newborn infants;
4. Drugs, devices, biologicals, equipment and supplies suitable for use with pediatric patients; and
5. Policies defining conditions under which parents or support persons may stay or "room in" with pediatric patients.

9-006.09M Rehabilitation Services: Rehabilitation services, if provided, must be under the direction of a qualified individual(s), as determined by the hospital. This individual is responsible for the quality and scope of rehabilitation services.

9-006.09M1 Each hospital that provides rehabilitation services must establish and implement written policies and procedures which include, but are not limited to:

1. The scope and care of patients receiving rehabilitation services;
2. Supervision by a qualified therapist;
3. Provision of rehabilitation services by qualified personnel who are credentialed in Nebraska, if required, and who act within their scope of practice;
4. Provision of therapy in accordance with medical practitioner orders;
5. Coordination with other services in the hospital;
6. Treatment plan documentation and record keeping requirements; and
7. Equipment maintenance to ensure patient safety.

9-006.09N Respiratory Care Services: Respiratory care services, if provided, are under the direction of a physician member of the medical staff who is responsible for the quality and scope of respiratory care services.

9-006.09N1 Each hospital that provides respiratory care services must establish and implement written policies and procedures which include, but are not limited to:

1. The scope and care of patients receiving respiratory care services;

qualify for a written agreement with the Centers for Medicare and Medicaid Services of the United States Department of Health and Human Services or its successor to participate in Medicare as a critical access hospital as defined in 42 CFR 485.601 to 485.641 attached to 175 NAC 9 and incorporated by this reference. In addition to those requirements, each critical access hospital must meet the following:

1. Governing Authority regulations specified in 175 NAC 9-006.01;
2. Medical Staff regulations specified in 175 NAC 9-006.02;
3. Staff Requirement regulations specified in 175 NAC 9-006.03, except that staff are not required to be present in the hospital when there are no patients in the hospital;
4. Patient Rights regulations specified in 175 NAC 9-006.04;
5. Patient Care and Treatment regulations specified in 175 NAC 9-006.06;
6. Record Keeping Requirements specified in 175 NAC 9-006.07;
7. Nursing Services regulations specified in 175 NAC 9-006.09B except that a registered nurse is not required to be on duty 24 hours a day, 7 days a week, if there are no acute patients in the hospital;
8. Emergency services are provided on a 24-hour basis and meet the requirements specified in 175 NAC 9-006.09I;
9. Environmental Services specified in 175 NAC 9-006.14; and
10. Physical Plant requirements specified in 175 NAC 9-007.

9-006.11 Long-Term Care Hospital: Each long-term care hospital or distinct part of a hospital that provides the care and services of an intermediate care facility, a nursing facility or a skilled nursing facility must meet all requirements specified in 175 NAC 12 except the administrator is not required to hold a current nursing home administrator's license issued by the State of Nebraska.

9-006.12 Psychiatric or Mental Hospital: Each psychiatric or mental hospital must meet all requirements specified in 175 NAC 9-006.01 to 9-006.08, 9-006.14 and 9-007. If any of the services in 175 NAC 9-006.09A to 9-006.09P are provided, each hospital must meet the requirements specified in those sections. In addition, each psychiatric or mental hospital must meet the requirements of 42 CFR 482.60 to 482.62 attached to 175 NAC 9 and incorporated by this reference.

9-006.13 Rehabilitation Hospital: Each rehabilitation hospital must meet all requirements specified in 175 NAC 9-006.01 to 9-006.08, 9-006.14 and 9-007. If any of the services in 175 NAC 9-006.09A to 9-006.09P are provided, each hospital must meet the requirements specified in those sections. In addition, each rehabilitation hospital must meet the following:

1. Direction and supervision of all rehabilitation services by a fulltime physician who is a member of the medical staff and is trained in rehabilitation medicine;
2. Provision of physical therapy, occupational therapy, speech pathology and audiology, social work, psychological and vocational services. These services must be organized and supervised by qualified professional personnel credentialed in Nebraska when required and who have been approved by the Governing Authority;
3. All care and treatment must be provided by qualified staff for the type of services performed in accordance with state law and prevailing professional standards;

9-006.14B3 The hospital must establish and implement a process designed for routine and preventative maintenance of equipment and furnishings to ensure that the equipment and furnishings are safe and function to meet the intended use.

9-006.14C Linens: The hospital must provide each patient with an adequate supply of clean bed, bath and other linens necessary for care and treatment. Linens must be in good repair.

9-006.14C1 The hospital must establish and implement procedures for the storage and handling of soiled and clean linens.

9-006.14C2 When the hospital provides laundry services, water temperatures to laundry equipment must exceed 160 degrees Fahrenheit or the laundry may be appropriately sanitized or disinfected by another acceptable method in accordance with manufacturer's instructions.

9-006.14D Pets: The hospital must assure any facility owned pet does not negatively affect patients. The hospital must have policies and procedures regarding pets that include:

1. An annual examination by a licensed veterinarian;
2. Vaccinations as recommended by the licensed veterinarian that include, at a minimum, current vaccination for rabies for dogs, cats and ferrets;
3. Provision of pet care necessary to prevent the acquisition and spread of fleas, ticks and other parasites; and
4. Responsibility for care and supervision of the pet by facility staff.

9-006.14E Environmental Safety: The hospital must be responsible for maintaining the environment in a manner that minimizes accidents.

9-006.14E1 The hospital must maintain the environment to protect the health and safety of patients by keeping surfaces smooth and free of sharp edges, mold or dirt; keeping floors free of objects and slippery or uneven surfaces and keeping the environment free of other conditions which may pose a potential risk.

9-006.14E2 The hospital must maintain all doors, stairways, passageways, aisles, or other means of exit in a manner that provides safe and adequate access for care and treatment.

9-006.14E3 The hospital must provide water for bathing and handwashing at safe and comfortable temperatures to protect patients from potential for burns or scalds.

9-006.14E3a The hospital must establish and implement policies and procedures to monitor and maintain water temperatures that accommodate patient comfort and preferences, but not to exceed the following temperatures:

1. Water temperature at patient handwashing fixtures must not exceed 120 degrees Fahrenheit.

9-007.01A Dietary: If food preparation is provided on site, the hospital must dedicate space and equipment for the preparation of meals. Food service physical environment and equipment must comply with the Food Code, except when used only for training or activity purposes.

9-007.01B Laundry: If the hospital provides laundry services, the services may be provided by contract or on-site by the hospital.

9-007.01B1 Contract: If contractual services are used, the hospital must have areas for soiled linen awaiting pickup and separate areas for storage and distribution of clean linen.

9-007.01B2 On-Site: If on-site services are provided, the hospital must have areas dedicated to laundry.

9-007.01B2a If personal laundry areas are provided, the areas must be equipped with a washer and dryer for use by patients. In new construction, the hospital must provide a conveniently located sink for soaking and hand washing of laundry.

9-007.01B2b Hospital laundry area for hospital processed bulk laundry must be divided into separate soiled (sort and washer areas) and clean (drying, folding, and mending areas) rooms. In new facilities a separate soaking and hand washing sink and housekeeping room must be provided in the laundry area.

9-007.01B2c Separate clean linen supply storage facilities must be conveniently located in each care and treatment location.

9-007.01C Diagnostic: If the hospital provides radiology or laboratory services, the services must comply with the following:

9-007.01C1 Imaging rooms must accommodate the operational and shielding requirements of the equipment installed, condition of the patient, and provide clear floor area adequate for the safety of staff and patients.

9-007.01C2 Laboratory areas must provide for sample collection and protection, analyzing, testing, and storage. The hospital must handle all potentially contagious and hazardous samples in a manner as to minimize transmission of infectious diseases.

9-007.01D Waste Processing: The hospital must provide areas to collect, contain, process, and dispose of medical and general waste produced within the hospital in such a manner as to prevent the attraction of rodents, flies, and all other insects and vermin, and to minimize the transmission of infectious diseases.

9-007.01E Cosmetology and Barber: When provided, cosmetology and barber services must be in conformance with the Nebraska Cosmetology Act, Neb. Rev. Stat. §§ 71-340 to 71-3,248 and the Barber Act, Neb. Rev. Stat. §§ 71-201 to 71-248.

9-007.02B3 Equipment Storage: The hospital must have space to store equipment, stretchers, wheelchairs, supplies, and linen out of the path of normal traffic.

9-007.02C Surgery: A hospital providing surgical services must have at least one operating or procedure room and the following support areas. In new construction and hospitals with more than two operating rooms, the following support areas and central processing areas must be located in restricted access areas:

1. Preoperative Patient Area: Preoperative patient area(s) must have sufficient space and equipment to accommodate both ambulatory and non-ambulatory patients. These areas must be under the direct visual control of the nursing staff.
2. Recovery Area: Recovery area(s) must contain a medication station, handwashing sink, charting area, provisions for bedpan cleaning; and equipment and supply storage space.
3. Dressing Area: A hospital providing outpatient surgery must have patient dressing and toilet rooms separate from staff gowning areas.
4. Housekeeping Room: The hospital must have soiled utility and housekeeping areas exclusively for the surgical suite.

9-007.02D Emergency Care: A hospital providing emergency services must have at least one procedure or treatment room. To support the provision of emergency care, the hospital must have the following:

1. Entrance: A well marked, illuminated covered entrance at grade level for emergency vehicle and pedestrian access;
2. Waiting Area: Patient and visitor waiting area(s) that are in direct observation of the reception, triage, or control station, with access to a public phone and drinking fountain;
3. Storage: Storage areas for general medical/surgical emergency supplies, medications and equipment under staff control and out of the path of normal traffic; and
4. Toilet Room: A patient toilet room with handwashing sink convenient to the procedure or treatment room(s).

9-007.02E Rehabilitation: A hospital providing rehabilitation services in a distinct unit must have at least one treatment room or cubicle, an area for specialized treatment and care, handwashing sink(s), storage for equipment and supplies, call system, medication storage and distribution, and areas to allow for patient toileting, dressing, and consultation.



9-007.03 Construction Standards: All hospitals must be designed, constructed, and maintained in a manner that is safe, clean, and functional for the type of care and treatment to be provided. The standards for the facilities are set forth below.

9-007.03A Codes and Guidelines

9-007.03A1 New Construction: New construction must comply with the following codes and guidelines to provide a safe and accessible environment that is conducive to the care and treatment to be provided:

1. Building: Building Construction Act, Neb. Rev. Stat. §§ 71-6401 to 71-6407;
2. Plumbing: Plumbing Ordinance or Code, Neb. Rev. Stat. § 18-1915;
3. Electrical: State Electrical Act, Neb. Rev. Stat. §§ 81-2101 to 81-2143;
4. Elevators: Nebraska Elevator Code, Neb. Rev. Stat. § 48-418.12 and Department of Labor Regulations, 230 NAC 1;
5. Boiler: Boiler Inspection Act, Neb. Rev. Stat. §§ 48-719 to 48-743;
6. Accessibility: Nebraska Accessibility Requirements, State Fire Marshal Regulations, 156 NAC 1 to 12;
7. Design: Guidelines for Design and Construction of Hospitals and Health Care Facilities, 2001 edition, published by the American Institute of Architects, applicable chapters as follow:
  - a. Chapter 7 General Hospital;
  - b. Chapter 10 Rehabilitation Facilities; and
  - c. Chapter 11 Psychiatric Hospital.
8. Energy: Nebraska Energy Code, Neb. Rev. Stat. §§ 81-1608 to 81-1626, for construction initiated on or after July 1, 2005.

9-007.03A2 All Facilities: All facilities must comply with the following applicable codes and standards to provide a safe environment:

1. Fire Codes: Nebraska State Fire Code Regulations, State Fire Marshal, 153 NAC 1; and
2. The Food Code, Neb. Rev. Stat. § 81-2,244.01, as published by the Nebraska Department of Agriculture, except for compliance and enforcement provisions.

9-007.03A3 Existing and New Facilities: Existing and new facilities must comply with the physical plant standards contained in 175 NAC 9-007. The hospital must maintain all building materials and structural components so that total loads imposed do not stress materials and components more than one and one-half times the working stresses allowed in the building code for new buildings of similar structure, purpose, or location.

9-007.03G1 In new construction a central bathing room must open off the corridor and contain a toilet and sink or have an adjoining toilet room, and not open directly in food preparation or dining area.

9-007.03G2 Bathing Fixtures: Existing and new facilities must have at least one bathing fixture per 20 licensed beds. New construction must have at least one bathing fixture per 12 licensed beds.

9-007.03H Toilet Rooms: The hospital must provide toilet rooms with handwashing sinks for patient use.

9-007.03H1 Existing facilities must have a toilet and sink adjoining each bedroom or shared toilet rooms may provide one fixture per four licensed beds.

9-007.03H2 New construction and new facilities must have a toilet and sink fixture provided adjoining each patient room.

9-007.03I Patient Rooms: The hospital must provide patient rooms which allow for sleeping, afford privacy, provide access to furniture and belongings, and accommodate inpatient care and treatment.

9-007.03I1 Patient Rooms:

1. Must not be located in any garage, storage area, shed or similar detached buildings;
2. Must be a single room located within an apartment, dwelling, or dormitory-like structure;
3. Must not be accessed through a bathroom, food preparation area, laundry or another bedroom;
4. Must be located on an outside wall or atrium with a window with a minimum glass size of 8 square feet per patient. The window must provide an unobstructed view of at least 10 feet;
5. Must contain at least 25 cubic feet of storage volume per patient in dressers, closets or wardrobes; and
6. Which contain multiple beds must allow for an accessible arrangement of furniture, which provides a minimum of three feet between beds.

9-007.03I2 Existing or New Facility: Patient rooms in existing and new facilities must have at least the following floor areas:

1. Floor areas for single patient rooms must be 100 square feet.
2. Floor areas for multiple bed patient rooms must be 80 square feet per bed with a maximum of 4 beds.

9-007.03I3 New Construction: Patient rooms in new construction must have at least the following floor areas.

1. Floor areas for single patient rooms must be 120 square feet.

9-007.03P Treatment Rooms: Treatment room for procedures performed under topical, local, or regional anesthesia without pre-operative sedation must have a minimum floor area of 120 square feet and a minimum of 10 feet clear dimension.

9-007.03Q Procedure Rooms: Procedure rooms for invasive and minor surgical procedures performed in conjunction with oral, parenteral, or intravenous sedation or under analgesic or dissociative drugs must have a minimum floor area of 200 square feet and a minimum of 14 feet clear dimension.

9-007.03R Operating Rooms: Operating rooms for major surgical procedures that require general or regional block anesthesia and support of vital bodily functions must have a minimum floor area of 300 square feet and a minimum of 16 feet clear dimension.

9-007.03S Corridors: The hospital corridors must be wide enough to allow passage and be equipped as needed by the patient with safety and assistive devices to minimize injury. All stairways and ramps must have handrails.

9-007.03T Doors: The hospital doors must be wide enough to allow passage and be equipped for privacy, safety, and with assistive devices to minimize patient injury.

9-007.03T1 All patient room, toilet, and bathing room doors must provide privacy yet not create seclusion or prohibit staff access for routine or emergency care.

9-007.03T2 In new construction all toilet and bathing rooms used by patients with less than 50 square feet of clear floor area must not have doors that solely swing inward.

9-007.03T3 Doors may prevent escape and create seclusion where therapeutically required, such as emergency protective custody, detoxification and psychiatric locations.

9-007.03U Outdoor Areas: Any outdoor area for patient usage provided by the hospital must be equipped and situated to allow for patient safety and abilities.

9-007.03V Handwashing Sinks: The hospital must provide a handwashing sink equipped with towels and soap dispenser in all examination, treatment, isolation, and procedure rooms; available to every four care and treatment cubicle locations; and two scrub sinks near the entrance of each operating room.

9-007.03W Privacy: In multiple bed patient rooms, visual privacy, and window curtains must be provided for each patient. In new facilities and new construction the curtain layout must totally surround each care and treatment location which will not restrict access to the entrance to the room, lavatory, toilet, or enclosed storage facilities.

9-007.03X Finishes: A hospital must provide the following special room finishes:

9-007.04C1 In existing and new facilities the systems must be capable of producing a temperature of at least 70 degrees Fahrenheit during heating conditions and a temperature that does not exceed 85 degrees Fahrenheit during cooling conditions.

9-007.04C2 In new construction the systems must be capable of producing a temperature of at least 75 degrees Fahrenheit during heating conditions and a temperature that does not exceed 80 degrees Fahrenheit during cooling conditions.

9-007.04C3 In new construction and new facilities, central air distribution and return systems must have the following percent dust spot rated filters:

1. General areas: 30 +%; and
2. Care, treatment, and treatment processing areas: 90 +%.

9-007.04C4 Surgical areas must have heating and cooling systems that are capable of producing room temperatures at a range between 68 and 73 degrees Fahrenheit and humidity at a range between 30 and 60% relative humidity.

9-007.04C5 Airflow must move from clean to soiled locations. In new construction, air movement must be designed to reduce the potential of contamination of clean areas.

9-007.04C6 Floors in operating, procedure, and other locations subject to wet cleaning methods or body fluids must not have openings to the heating and cooling system.

9 007.04D Ventilation System: All hospitals must provide exhaust and clean air to prevent the concentrations of contaminants which impair health or cause discomfort to patient and employees.

9-007.04D1 Existing facilities must have adequate ventilation.

9-007.04D2 New construction and new facilities must provide a mechanical exhaust ventilation system for windowless toilets, baths, laundry rooms, housekeeping rooms, kitchens and similar rooms at ten air changes per hour.

9-007.04D3 New construction must provide mechanical ventilation system(s) capable of providing air changes per hour (hereafter ACH) as follows:

1. Care and treatment areas: 5 ACH;
2. Procedure and respiratory isolation areas: 15 ACH; and
3. Operating rooms: 20 ACH.

9-007.04D4 Hospitals must provide an emergency backup ventilation system(s) or procedures for all patient rooms without operable windows.

9-007.04G1 In new construction the call system must have a dedicated emergency call device which allows activation by a patient from treatment rooms and cubicles, and toilet and bathing fixtures.

9-007.04G2 In locations where patients are unable to activate the call, a dedicated staff assist or code call device must promptly summon other staff for assistance.

9-007.04H Medical Gas System: The hospital must safely provide medical gas and vacuum by means of portable equipment or building systems as required by patient receiving care and treatment.

9-007.04H1 The installation, testing, and certification of nonflammable medical gas, clinical vacuum, and air systems must comply with the requirements of 153 NAC 1, Nebraska State Fire Code Regulations.

9-007.04H2 The hospital must identify portable and system components, and periodically test and approve all medical gas piping, alarms, valves, and equipment for patient care and treatment. The hospital must document such approvals for review and reference.

9-007.05 Waivers: The Department may waive any provision of 175 NAC 9 relating to construction or physical plant requirements of a hospital upon proof by the licensee satisfactory to the Department (a) that the waiver would not unduly jeopardize the health, safety, or welfare of the persons residing in or served by the hospital or service, (b) that the provision would create an unreasonable hardship for the hospital or service, and (c) that the waiver would not cause the State of Nebraska to fail to comply with any applicable requirements of Medicare or Medicaid so as to make the state ineligible for the receipt of all funds to which it might otherwise be entitled.

9-007.05A Unreasonable Hardship: In evaluating the issue of unreasonable hardship, the Department will consider the following:

1. The estimated cost of the modification or installation;
2. The extent and duration of the disruption of the normal use of areas used by persons residing in or served by the hospital or service resulting from construction work;
3. The estimated period over which the cost would be recovered through reduced insurance premiums and increase reimbursement related to costs;
4. The availability of financing; and
5. The remaining useful life of the building.

9-007.05B Waiver Terms and Conditions: Any waiver may be granted under the terms and conditions and for such period of time as are applicable and appropriate to the waiver. Terms and conditions and period of waiver include but are not limited to:

1. Waivers that are granted to meet the special needs of a patient remain in effect as long as required by the patient;

6. Discrimination or retaliation against a hospital patient or employee who has submitted a complaint or information to the Department of Health and Human Services, the Department of Health and Human Services Finance and Support, or the Department of Health and Human Services Regulation and Licensure;
7. Discrimination or retaliation against a hospital patient or employee who has presented a grievance or information to the office of the state long-term care ombudsman;
8. Failure to allow a state long-term care ombudsman or an ombudsman advocate access to the hospital for the purposes of investigation necessary to carry out the duties of the office of the state long-term care ombudsman as specified in 15 NAC 3;
9. Violation of the Emergency Box Drug Act;
10. Failure to file a report of payment or action taken due to a liability claim or an alleged violation, as required by Neb. Rev. Stat. § 71-168.02;
11. Violation of the Medication Aide Act; or
12. Failure to file a report of suspected abuse or neglect as required by Neb. Rev. Stat. §§ 28-372 and 28-711.

9-008.02 Procedures for Denial, Refusal to Renew, or Disciplinary Action

9-008.02A If the Department determines to deny, refuse renewal of, or take disciplinary action against a license, the Department will send a notice to the applicant or licensee, by certified mail to the last address shown on its records. The notice will state the determination, including a specific description of the nature of the violation and the statute or regulation violated, and the type of disciplinary action pending.

9-008.02B The denial, refusal to renew, or disciplinary action will become final 15 days after the mailing of the notice unless the applicant or licensee, within the 15-day period, makes a written request to the Director for an informal conference or an administrative hearing.

9-008.02C Informal Conference

9-008.02C1 At the request of the applicant or licensee, the Department will hold an informal conference within 30 days of the receipt of the request. The conference will be held in person or by other means, at the request of the applicant or licensee.

If the pending action is based on an inspection, the Department's representative at the conference will not be the individual who did the inspection.

5. Revocation, which is a permanent termination of the license. The licensee may not apply for a license for a minimum of two years after the effective date of the revocation.

9-008.03B In determining the type of disciplinary action to impose, the Department will consider:

1. The gravity of the violation, including the probability that death or serious physical or mental harm will result;
2. The severity of the actual or potential harm;
3. The extent to which the provisions of applicable statutes, rules, and regulations were violated;
4. The reasonableness of the diligence exercised by the hospital in identifying or correcting the violation;
5. Any previous violations committed by the hospital; and
6. The financial benefit to the hospital of committing or continuing the violation.

9-008.03C If the licensee fails to correct a violation or to comply with a particular type of disciplinary action, the Department may take additional disciplinary action as described in 175 NAC 9-008.03A.

9-008.03D Temporary Suspension or Temporary Limitation: If the Department determines that patients of the hospital are in imminent danger of death or serious physical harm, the Director may:

1. Temporarily suspend or temporarily limit the hospital license, effective when the order is served upon the hospital. If the licensee is not involved in the daily operation of the hospital, the Department will mail a copy of the order to the licensee, or if the licensee is a corporation, to the corporation's registered agent;
2. Order the immediate removal of patients; or
3. Order the temporary closure of the hospital pending further action by the Department.

The Department will simultaneously institute proceedings for revocation, suspension, or limitation of the license, and will conduct an administrative hearing no later than ten days after the date of the temporary suspension or temporary limitation.

9-008.03D1 The Department will conduct the hearing in accordance with the Administrative Procedure Act (APA) and the Department's rules and regulations adopted and promulgated under the APA. Either party may subpoena witnesses, who must be allowed fees at the rate prescribed by Neb. Rev. Stat. §§ 33-139 and 33-139.01.

9-008.03D2 If a written request for continuance of the hearing is made by the licensee, the Department will grant a continuance, which may not exceed 30 days.

9-008.03D3 On the basis of evidence presented at the hearing, the Director will:

9-008.04B2 Reinstatement Prior to Completion of Suspension: A licensee may request reinstatement prior to the completion of suspension and must meet the following conditions:

1. Submit a petition to the Department stating:
  - a. The reasons why the license should be reinstated prior to the suspension completion date; and
  - b. The corrective action taken to prevent recurrence of the violation(s) that served as the basis of the suspension;
2. Submit a written renewal application to the Department as specified in 175 NAC 9-003.02;
3. Pay the renewal fee as specified in 175 NAC 9-004.10; and
4. Successfully complete an inspection.

9-008.04B3 The Director will consider the petition submitted and the results of any inspection or investigation conducted by the Department and:

1. Grant full reinstatement of the license;
2. Modify the probation or suspension; or
3. Deny the petition for reinstatement.

9-008.04B4 The Director's decision is final 30 days after mailing the decision to the licensee unless the licensee requests a hearing within the 30-day period. The requested hearing will be held according to rules and regulations of the Department for administrative hearings in contested cases.

9-008.04C Re-Licensure After Revocation: A hospital license that has been revoked is not eligible for re-licensure until two years after the date of revocation.

9-008.04C1 A hospital seeking re-licensure must apply for an initial license and meet the requirements for initial licensure in 175 NAC 9-003.01.

9-008.04C2 The Department will process the application for re-licensure in the same manner as specified in 175 NAC 9-003.01.



(ii) Have equivalent training and experience as determined by the National Board for Respiratory Therapy, Inc.

(k) A *respiratory therapy technician* must—

(1) Be licensed by the State in which practicing, if applicable;

(2) Have successfully completed a training program accredited by the Committees on Allied Health Education and Accreditation (CAHEA) in collaboration with the Joint Review Committee for Respiratory Therapy Education; and

(3) Either—

(i) Be eligible to take the certification examination for respiratory therapy technicians administered by the National Board for Respiratory Therapy, Inc.; or

(ii) Have equivalent training and experience as determined by the National Board for Respiratory Therapy, Inc.

(l) A *social worker* must—

(1) Be licensed by the State in which practicing, if applicable;

(2) Hold at least a bachelor's degree from a school accredited or approved by the Council on Social Work Education; and

(3) Have 1 year of social work experience in a health care setting.

(m) A *speech-language pathologist* must meet the qualifications set forth in § 485.705(f) of this chapter.

[48 FR 56293, Dec. 15, 1982, Redesignated and amended at 50 FR 33034, Aug. 16, 1985; 51 FR 41352, Nov. 14, 1986; 60 FR 2327, Jan. 9, 1995]

#### § 485.74 Appeal rights.

The appeal provisions set forth in part 498 of this chapter, for providers, are applicable to any entity that is participating or seeks to participate in the Medicare program as a CORP.

[48 FR 56293, Dec. 15, 1982, as amended at 52 FR 22454, June 12, 1987]

### Subparts C-E [Reserved]

### Subpart F—Conditions of Participation: Critical Access Hospitals (CAHs)

SOURCE: 58 FR 30671, May 26, 1993, unless otherwise noted.

#### § 485.601 Basis and scope.

(a) *Statutory basis.* This subpart is based on section 1820 of the Act which sets forth the conditions for designating certain hospitals as CAHs.

(b) *Scope.* This subpart sets forth the conditions that a hospital must meet to be designated as a CAH.

[58 FR 30671, May 26, 1993, as amended at 62 FR 46037, Aug. 29, 1997]

#### § 485.602 Definitions.

As used in this subpart, unless the context indicates otherwise:

*Direct services* means services provided by employed staff of the CAH, not services provided through arrangements or agreements.

[59 FR 45403, Sept. 1, 1994, as amended at 62 FR 46037, Aug. 29, 1997]

#### § 485.603 Rural health network.

A rural health network is an organization that meets the following specifications:

(a) It includes—

(1) At least one hospital that the State has designated or plans to designate as a CAH; and

(2) At least one hospital that furnishes acute care services.

(b) The members of the organization have entered into agreements regarding—

(1) Patient referral and transfer;

(2) The development and use of communications systems, including, where feasible, telemetry systems and systems for electronic sharing of patient data; and

(3) The provision of emergency and nonemergency transportation among members.

(c) Each CAH has an agreement with respect to credentialing and quality assurance with at least—

(1) One hospital that is a member of the network when applicable;

(2) One QIO or equivalent entity; or

(3) One other appropriate and qualified entity identified in the State rural health care plan.

[58 FR 30671, May 26, 1993, as amended at 62 FR 46035, Aug. 29, 1997; 63 FR 26359, May 12, 1998]

CAH by the State under the rules in this subpart.

[62 FR 46036, Aug. 29, 1997, as amended at 63 FR 26359, May 12, 1998]

**§ 485.608 Condition of participation: Compliance with Federal, State, and local laws and regulations.**

The CAH and its staff are in compliance with applicable Federal, State and local laws and regulations.

(a) *Standard: Compliance with Federal laws and regulations.* The CAH is in compliance with applicable Federal laws and regulations related to the health and safety of patients.

(b) *Standard: Compliance with State and local laws and regulations.* All patient care services are furnished in accordance with applicable State and local laws and regulations.

(c) *Standard: Licensure of CAH.* The CAH is licensed in accordance with applicable Federal, State and local laws and regulations.

(d) *Standard: Licensure, certification or registration of personnel.* Staff of the CAH are licensed, certified, or registered in accordance with applicable Federal, State, and local laws and regulations.

[58 FR 30671, May 26, 1993, as amended at 62 FR 46037, Aug. 29, 1997]

**§ 485.610 Condition of participation: Status and location.**

(a) *Standard: Status.* The facility is—

(1) A currently participating hospital that meets all conditions of participation set forth in this subpart;

(2) A recently closed facility, provided that the facility—

(i) Was a hospital that ceased operations on or after the date that is 10 years before November 29, 1999; and

(ii) Meets the criteria for designation under this subpart as of the effective date of its designation; or

(3) A health clinic or a health center (as defined by the State) that—

(i) Is licensed by the State as a health clinic or a health center;

(ii) Was a hospital that was downsized to a health clinic or a health center; and

(iii) As of the effective date of its designation, meets the criteria for designation set forth in this subpart.

(b) *Standard: Location in a rural area or treatment as rural.* The CAH meets the requirements of either paragraph (b)(1) or (b)(2) or (b)(3) of this section.

(1) The CAH meets the following requirements:

(i) The CAH is located outside any area that is a Metropolitan Statistical Area, as defined by the Office of Management and Budget, or that has been recognized as urban under § 412.64(b), excluding paragraph (b)(3) of this chapter;

(ii) The CAH has not been classified as an urban hospital for purposes of the standardized payment amount by CMS or the Medicare Geographic Classification Review Board under § 412.230(e) of this chapter, and is not among a group of hospitals that have been redesignated to an adjacent urban area under § 412.232 of this chapter.

(2) The CAH is located within a Metropolitan Statistical Area, as defined by the Office of Management and Budget, but is being treated as being located in a rural area in accordance with § 412.103 of this chapter.

(3) Effective only for October 1, 2004 through September 30, 2006, the CAH does not meet the location requirements in either paragraph (b)(1) or (b)(2) of this section and is located in a county that, in FY 2004, was not part of a Metropolitan Statistical Area as defined by the Office of Management and Budget, but as of FY 2005 was included as part of such an MSA as a result of the most recent census data and implementation of the new MSA definitions announced by OMB on June 6, 2003.

(c) *Standard: Location relative to other facilities or necessary provider certification.* The CAH is located more than a 35-mile drive (or, in the case of mountainous terrain or in areas with only secondary roads available, a 15-mile drive) from a hospital or another CAH, or before January 1, 2006, the CAH is certified by the State as being a necessary provider of health care services to residents in the area. A CAH that is designated as a necessary provider as of October 1, 2006, will maintain its necessary provider designation after January 1, 2006.

(d) *Standard: Relocation of CAHs with a necessary provider designation.* A CAH

monitor, chest tubes, and indwelling urinary catheters.

(c) *Standard: Blood and blood products.* The facility provides, either directly or under arrangements, the following:

(1) Services for the procurement, safekeeping, and transfusion of blood, including the availability of blood products needed for emergencies on a 24-hours a day basis.

(2) Blood storage facilities that meet the requirements of 42 CFR part 493, subpart K, and are under the control and supervision of a pathologist or other qualified doctor of medicine or osteopathy. If blood banking services are provided under an arrangement, the arrangement is approved by the facility's medical staff and by the persons directly responsible for the operation of the facility.

(d) *Standard: Personnel.* (1) Except as specified in paragraph (d)(2) of this section, there must be a doctor of medicine or osteopathy, a physician assistant, a nurse practitioner, or a clinical nurse specialist, with training or experience in emergency care on call and immediately available by telephone or radio contact, and available onsite within the following timeframes:

(i) Within 30 minutes, on a 24-hour a day basis, if the CAH is located in an area other than an area described in paragraph (d)(1)(ii) of this section; or

(ii) Within 60 minutes, on a 24-hour a day basis, if all of the following requirements are met:

(A) The CAH is located in an area designated as a frontier area (that is, an area with fewer than six residents per square mile based on the latest population data published by the Bureau of the Census) or in an area that meets the criteria for a remote location adopted by the State in its rural health care plan, and approved by CMS, under section 1820(b) of the Act.

(B) The State has determined, under criteria in its rural health care plan, that allowing an emergency response time longer than 30 minutes is the only feasible method of providing emergency care to residents of the area served by the CAH.

(C) The State maintains documentation showing that the response time of up to 60 minutes at a particular CAH it designates is justified because other

available alternatives would increase the time needed to stabilize a patient in an emergency.

(2) A registered nurse satisfies the personnel requirement specified in paragraph (d)(1) of this section for a temporary period if—

(i) The CAH has no greater than 10 beds;

(ii) The CAH is located in an area designated as a frontier area or remote location as described in paragraph (d)(1)(ii)(A) of this section;

(iii) The State in which the CAH is located submits a letter to CMS signed by the Governor, following consultation on the issue of using RNs on a temporary basis as part of their State rural healthcare plan with the State Boards of Medicine and Nursing, and in accordance with State law, requesting that a registered nurse with training and experience in emergency care be included in the list of personnel specified in paragraph (d)(1) of this section. The letter from the Governor must attest that he or she has consulted with State Boards of Medicine and Nursing about issues related to access to and the quality of emergency services in the States. The letter from the Governor must also describe the circumstances and duration of the temporary request to include the registered nurses on the list of personnel specified in paragraph (d)(1) of this section;

(iv) Once a Governor submits a letter, as specified in paragraph (d)(2)(iii) of this section, a CAH must submit documentation to the State survey agency demonstrating that it has been unable, due to the shortage of such personnel in the area, to provide adequate coverage as specified in this paragraph (d).

(3) The request, as specified in paragraph (d)(2)(iii) of this section, and the withdrawal of the request, may be submitted to us at any time, and are effective upon submission.

(e) *Standard: Coordination with emergency response systems.* The CAH must, in coordination with emergency response systems in the area, establish procedures under which a doctor of medicine or osteopathy is immediately available by telephone or radio contact on a 24-hours a day basis to receive

(4) The CAH maintains written evidence of regular inspection and approval by State or local fire control agencies.

(5) Beginning March 13, 2006, a critical access hospital must be in compliance with Chapter 9.2.9, Emergency Lighting.

(6) Beginning March 13, 2006, Chapter 19.3.6.3.2, exception number 2 does not apply to critical access hospitals.

(7) Notwithstanding any provisions of the 2000 edition of the Life Safety Code to the contrary, a critical access hospital may install alcohol-based hand rub dispensers in its facility if—

(i) Use of alcohol-based hand rub dispensers does not conflict with any State or local codes that prohibit or otherwise restrict the placement of alcohol-based hand rub dispensers in health care facilities;

(ii) The dispensers are installed in a manner that minimizes leaks and spills that could lead to falls;

(iii) The dispensers are installed in a manner that adequately protects against access by vulnerable populations; and

(iv) The dispensers are installed in accordance with chapter 18.3.2.7 or chapter 19.3.2.7 of the 2000 edition of the Life Safety Code, as amended by NFPA Temporary Interim Amendment 00-1(101), issued by the Standards Council of the National Fire Protection Association on April 15, 2004. The Director of the Office of the Federal Register has approved NFPA Temporary Interim Amendment 00-1(101) for incorporation by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. A copy of the amendment is available for inspection at the CMS Information Resource Center, 7500 Security Boulevard, Baltimore, MD and at the Office of the Federal Register, 800 North Capitol Street NW., Suite 700, Washington, DC. Copies may be obtained from the National Fire Protection Association, 1 Batterymarch Park, Quincy, MA 02269. If any additional changes are made to this amendment, CMS will publish notice in the FEDERAL REGISTER to announce the change.

[58 FR 30671, May 26, 1993, as amended at 62 FR 46036, 46037, Aug. 29, 1997; 68 FR 1387, Jan. 10, 2003; 69 FR 49271, Aug. 11, 2004; 70 FR 15239, Mar. 25, 2005]

#### § 485.627 Condition of participation: Organizational structure.

(a) *Standard: Governing body or responsible individual.* The CAH has a governing body or an individual that assumes full legal responsibility for determining, implementing and monitoring policies governing the CAH's total operation and for ensuring that those policies are administered so as to provide quality health care in a safe environment.

(b) *Standard: Disclosure.* The CAH discloses the names and addresses of—

(1) Its owners, or those with a controlling interest in the CAH or in any subcontractor in which the CAH directly or indirectly has a 5 percent or more ownership interest, in accordance with subpart C of part 420 of this chapter;

(2) The person principally responsible for the operation of the CAH; and

(3) The person responsible for medical direction.

[58 FR 30671, May 26, 1993, as amended at 62 FR 46037, Aug. 29, 1997]

#### § 485.631 Condition of participation: Staffing and staff responsibilities.

(a) *Standard: Staffing.*—(1) The CAH has a professional health care staff that includes one or more doctors of medicine or osteopathy, and may include one or more physician assistants, nurse practitioners, or clinical nurse specialists.

(2) Any ancillary personnel are supervised by the professional staff.

(3) The staff is sufficient to provide the services essential to the operation of the CAH.

(4) A doctor of medicine or osteopathy, nurse practitioner, clinical nurse specialist, or physician assistant is available to furnish patient care services at all times the CAH operates.

(5) A registered nurse, clinical nurse specialist, or licensed practical nurse is on duty whenever the CAH has one or more inpatients.

(b) *Standard: Responsibilities of the doctor of medicine or osteopathy.* (1) The doctor of medicine or osteopathy—

(i) Provides medical direction for the CAH's health care activities and consultation for, and medical supervision of, the health care staff;

(vi) A system for identifying, reporting, investigating and controlling infections and communicable diseases of patients and personnel.

(vii) If the CAH furnishes inpatient services, procedures that ensure that the nutritional needs of inpatients are met in accordance with recognized dietary practices and the orders of the practitioner responsible for the care of the patients, and that the requirement of § 483.25(i) is met with respect to inpatients receiving posthospital SNF care.

(4) These policies are reviewed at least annually by the group of professional personnel required under paragraph (a)(2) of this section, and reviewed as necessary by the CAH.

(b) *Standard: Direct services*—(1) *General*. The CAH staff furnishes, as direct services, those diagnostic and therapeutic services and supplies that are commonly furnished in a physician's office or at another entry point into the health care delivery system, such as a low intensity hospital outpatient department or emergency department. These direct services include medical history, physical examination, specimen collection, assessment of health status, and treatment for a variety of medical conditions.

(2) *Laboratory services*. The CAH provides, as direct services, basic laboratory services essential to the immediate diagnosis and treatment of the patient that meet the standards imposed under section 353 of the Public Health Service Act (42 U.S.C. 236a). (See the laboratory requirements specified in part 493 of this chapter.) The services provided include:

- (i) Chemical examination of urine by stick or tablet method or both (including urine ketones);
- (ii) Hemoglobin or hematocrit;
- (iii) Blood glucose;
- (iv) Examination of stool specimens for occult blood;
- (v) Pregnancy tests; and
- (vi) Primary culturing for transmittal to a certified laboratory.

(3) *Radiology services*. Radiology services furnished at the CAH are provided as direct services by staff qualified under State law, and do not expose CAH patients or staff to radiation hazards.

(4) *Emergency procedures*. In accordance with the requirements of § 485.618, the CAH provides as direct services medical emergency procedures as a first response to common life-threatening injuries and acute illness.

(c) *Standard: Services provided through agreements or arrangements*. (1) The CAH has agreements or arrangements (as appropriate) with one or more providers or suppliers participating under Medicare to furnish other services to its patients, including—

- (i) Inpatient hospital care;
  - (ii) Services of doctors of medicine or osteopathy; and
  - (iii) Additional or specialized diagnostic and clinical laboratory services that are not available at the CAH.
- (iv) Food and other services to meet inpatients' nutritional needs to the extent these services are not provided directly by the CAH.

(2) If the agreements or arrangements are not in writing, the CAH is able to present evidence that patients referred by the CAH are being accepted and treated.

(3) The CAH maintains a list of all services furnished under arrangements or agreements. The list describes the nature and scope of the services provided.

(4) The person principally responsible for the operation of the CAH under § 485.627(b)(2) of this chapter is also responsible for the following:

(i) Services furnished in the CAH whether or not they are furnished under arrangements or agreements.

(ii) Ensuring that a contractor of services (including one for shared services and joint ventures) furnishes services that enable the CAH to comply with all applicable conditions of participation and standards for the contracted services.

(d) *Standard: Nursing services*. Nursing services must meet the needs of patients.

(1) A registered nurse must provide (or assign to other personnel) the nursing care of each patient, including patients at a SNF level of care in a swing-bed CAH. The care must be provided in accordance with the patient's needs and the specialized qualifications and competence of the staff available.

(3) Before discharge from the CAH, each patient must be evaluated for proper anesthesia recovery by a qualified practitioner, as specified in paragraph (c) of this section.

(c) *Administration of anesthesia.* The CAH designates the person who is allowed to administer anesthesia to CAH patients in accordance with its approved policies and procedures and with State scope-of-practice laws.

(1) Anesthesia must be administered by only—

(i) A qualified anesthesiologist;

(ii) A doctor of medicine or osteopathy other than an anesthesiologist; including an osteopathic practitioner recognized under section 1101(a)(7) of the Act;

(iii) A doctor of dental surgery or dental medicine;

(iv) A doctor of podiatric medicine;

(v) A certified registered nurse anesthetist (CRNA), as defined in § 410.69(b) of this chapter;

(vi) An anesthesiologist's assistant, as defined in § 410.69(b) of this chapter; or

(vii) A supervised trainee in an approved educational program, as described in §§ 413.85 or 413.86 of this chapter.

(2) In those cases in which a CRNA administers the anesthesia, the anesthesiologist must be under the supervision of the operating practitioner except as provided in paragraph (e) of this section. An anesthesiologist's assistant who administers anesthesia must be under the supervision of an anesthesiologist.

(d) *Discharge.* All patients are discharged in the company of a responsible adult, except those exempted by the practitioner who performed the surgical procedure.

(e) *Standard: State exemption.* (1) A CAH may be exempted from the requirement for physician supervision of CRNAs as described in paragraph (c)(2) of this section, if the State in which the CAH is located submits a letter to CMS signed by the Governor, following consultation with the State's Boards of Medicine and Nursing, requesting exemption from physician supervision for CRNAs. The letter from the Governor must attest that he or she has consulted with the State Boards of Medi-

cine and Nursing about issues related to access to and the quality of anesthesia services in the State and has concluded that it is in the best interests of the State's citizens to opt-out of the current physician supervision requirement, and that the opt-out is consistent with State law.

(2) The request for exemption and recognition of State laws and the withdrawal of the request may be submitted at any time, and are effective upon submission.

[60 FR 45851, Sept. 1, 1995, as amended at 62 FR 46037, Aug. 29, 1997; 66 FR 39938, Aug. 1, 2001; 66 FR 56769, Nov. 13, 2001]

**§ 485.641 Condition of participation: Periodic evaluation and quality assurance review.**

(a) *Standard: Periodic evaluation.*—(1) The CAH carries out or arranges for a periodic evaluation of its total program. The evaluation is done at least once a year and includes review of—

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

(ii) A representative sample of both active and closed clinical records; and

(iii) The CAH's health care policies.

(2) The purpose of the evaluation is to determine whether the utilization of services was appropriate, the established policies were followed, and any changes are needed.

(b) *Standard: Quality assurance.* The CAH has an effective quality assurance program to evaluate the quality and appropriateness of the diagnosis and treatment furnished in the CAH and of the treatment outcomes. The program requires that—

(1) All patient care services and other services affecting patient health and safety, are evaluated;

(2) Nosocomial infections and medication therapy are evaluated;

(3) The quality and appropriateness of the diagnosis and treatment furnished by nurse practitioners, clinical nurse specialists, and physician assistants at the CAH are evaluated by a member of the CAH staff who is a doctor of medicine or osteopathy or by another doctor of medicine or osteopathy under contract with the CAH;

(2) There must be adequate numbers of respiratory therapists, respiratory therapy technicians, and other personnel who meet the qualifications specified by the medical staff, consistent with State law.

(b) *Standard: Delivery of Services.* Services must be delivered in accordance with medical staff directives.

(1) Personnel qualified to perform specific procedures and the amount of supervision required for personnel to carry out specific procedures must be designated in writing.

(2) If blood gases or other laboratory tests are performed in the respiratory care unit, the unit must meet the applicable requirements for laboratory services specified in § 482.27.

(3) Services must be provided only on, and in accordance with, the orders of a doctor of medicine or osteopathy.

[51 FR 22042, June 17, 1986; 51 FR 27848, Aug. 4, 1986, as amended at 57 FR 7136, Feb. 28, 1992]

### Subpart E—Requirements for Specialty Hospitals

#### § 482.60 Special provisions applying to psychiatric hospitals.

Psychiatric hospital must—

(a) Be primarily engaged in providing, by or under the supervision of a doctor of medicine or osteopathy, psychiatric services for the diagnosis and treatment of mentally ill persons;

(b) Meet the conditions of participation specified in §§ 482.1 through 482.23 and §§ 482.25 through 482.57;

(c) Maintain clinical records on all patients, including records sufficient to permit CMS to determine the degree and intensity of treatment furnished to Medicare beneficiaries, as specified in § 482.61; and

(d) Meet the staffing requirements specified in § 482.62.

[51 FR 22042, June 17, 1986; 51 FR 27848, Aug. 4, 1986]

#### § 482.61 Condition of participation: Special medical record requirements for psychiatric hospitals.

The medical records maintained by a psychiatric hospital must permit determination of the degree and intensity of the treatment provided to individuals

who are furnished services in the institution.

(a) *Standard: Development of assessment/diagnostic data.* Medical records must stress the psychiatric components of the record, including history of findings and treatment provided for the psychiatric condition for which the patient is hospitalized.

(1) The identification data must include the patient's legal status.

(2) A provisional or admitting diagnosis must be made on every patient at the time of admission, and must include the diagnoses of intercurrent diseases as well as the psychiatric diagnoses.

(3) The reasons for admission must be clearly documented as stated by the patient and/or others significantly involved.

(4) The social service records, including reports of interviews with patients, family members, and others, must provide an assessment of home plans and family attitudes, and community resource contacts as well as a social history.

(5) When indicated, a complete neurological examination must be recorded at the time of the admission physical examination.

(b) *Standard: Psychiatric evaluation.* Each patient must receive a psychiatric evaluation that must—

(1) Be completed within 60 hours of admission;

(2) Include a medical history;

(3) Contain a record of mental status;

(4) Note the onset of illness and the circumstances leading to admission;

(5) Describe attitudes and behavior;

(6) Estimate intellectual functioning, memory functioning, and orientation; and

(7) Include an inventory of the patient's assets in descriptive, not interpretative, fashion.

(c) *Standard: Treatment plan.* (1) Each patient must have an individual comprehensive treatment plan that must be based on an inventory of the patient's strengths and disabilities. The written plan must include—

(i) A substantiated diagnosis;

(ii) Short-term and long-range goals;

(iii) The specific treatment modalities utilized;

## § 482.66

and experience in the care of the mentally ill. The director must demonstrate competence to participate in interdisciplinary formulation of individual treatment plans: to give skilled nursing care and therapy; and to direct, monitor, and evaluate the nursing care furnished.

(2) The staffing pattern must insure the availability of a registered professional nurse 24 hours each day. There must be adequate numbers of registered nurses, licensed practical nurses, and mental health workers to provide the nursing care necessary under each patient's active treatment program.

(e) *Standard: Psychological services.* The hospital must provide or have available psychological services to meet the needs of the patients.

(f) *Standard: Social services.* There must be a director of social services who monitors and evaluates the quality and appropriateness of social services furnished. The services must be furnished in accordance with accepted standards of practice and established policies and procedures.

(1) The director of the social work department or service must have a master's degree from an accredited school of social work or must be qualified by education and experience in the social services needs of the mentally ill. If the director does not hold a masters degree in social work, at least one staff member must have this qualification.

(2) Social service staff responsibilities must include, but are not limited to, participating in discharge planning, arranging for follow-up care, and developing mechanisms for exchange of appropriate information with sources outside the hospital.

(g) *Standard: Therapeutic activities.* The hospital must provide a therapeutic activities program.

(1) The program must be appropriate to the needs and interests of patients and be directed toward restoring and maintaining optimal levels of physical and psychosocial functioning.

(2) The number of qualified therapists, support personnel, and consultants must be adequate to provide comprehensive therapeutic activities con-

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sistent with each patient's active treatment program.

[51 FR 22042, June 17, 1986; 51 FR 27848, Aug. 4, 1986]

### § 482.66 Special requirements for hospital providers of long-term care services ("swing-beds").

A hospital that has a Medicare provider agreement must meet the following requirements in order to be granted an approval from CMS to provide post-hospital extended care services, as specified in § 409.30 of this chapter, and be reimbursed as a swing-bed hospital, as specified in § 413.114 of this chapter:

(a) *Eligibility.* A hospital must meet the following eligibility requirements:

(1) The facility has fewer than 100 hospital beds, excluding beds for newborns and beds in intensive care type inpatient units (for eligibility of hospitals with distinct parts electing the optional reimbursement method, see § 413.24(d)(5) of this chapter).

(2) The hospital is located in a rural area. This includes all areas not delineated as "urbanized" areas by the Census Bureau, based on the most recent census.

(3) The hospital does not have in effect a 24-hour nursing waiver granted under § 488.54(c) of this chapter.

(4) The hospital has not had a swing-bed approval terminated within the two years previous to application.

(b) *Skilled nursing facility services.* The facility is substantially in compliance with the following skilled nursing facility requirements contained in subpart B of part 483 of this chapter.

(1) Resident rights (§ 483.10 (b)(3), (b)(4), (b)(5), (b)(6), (d), (e), (h), (i), (j)(1)(vii), (j)(1)(viii), (l), and (m)).

(2) Admission, transfer, and discharge rights (§ 483.12 (a)(1), (a)(2), (a)(3), (a)(4), (a)(5), (a)(6), and (a)(7)).

(3) Resident behavior and facility practices (§ 483.13).

(4) Patient activities (§ 483.15(f)).

(5) Social services (§ 483.15(g)).

(6) Discharge planning (§ 483.20(e)).

(7) Specialized rehabilitative services (§ 483.45).