

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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ATTACHMENTS

42 CFR 485.601 to 485.641
(Critical Access Hospitals)

and

42 CFR 482.60 to 482.62
(Psychiatric 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.

Bed capacity means the total number of adult and pediatric beds which can be set up in a hospital for use by patients. The term "bed capacity" excludes beds intended for ancillary usage such as emergency room beds, labor beds, recovery room beds, or stretchers, and excludes bassinets for newborn infants.

Biological means any virus, therapeutic serum, toxin, antitoxin or analogous product applicable to the prevention, treatment or cure of disease or injuries of humans.

Care means the exercise of concern or responsibility for the comfort, welfare, and habilitation of persons, including a minimum amount of supervision and assistance with or provision of personal care, activities of daily living, health maintenance activities, or other supportive services. For purposes of this chapter:

1. Activities of daily living means transfer, ambulation, exercise, toileting, eating, self-administered medication and similar activities;
2. Health maintenance activities means noncomplex interventions which can safely be performed according to exact directions, which do not require alteration of the standard procedure, and for which the results and patient responses are predictable; and
3. Personal care means bathing, hair care, nail care, shaving, dressing, oral care, and similar activities.

Chemical restraint means a psychopharmacologic drug that is used for discipline or convenience and is not required to treat medical symptoms.

Complaint means an expression of a concern or dissatisfaction.

Completed application means an application that contains all the information specified in 175 NAC 9-003 and includes all required attachments and documentation and the licensure fee.

Critical access hospital means a facility (1) with acute care inpatient beds where care or treatment is provided on an outpatient basis or on an inpatient basis to persons for an average period of not more than 96 hours and emergency services are provided on a 24 hour basis and (2) which has formal agreements with at least one hospital and other appropriate providers for services such as patient referral and transfer, communications systems, provision of emergency and nonemergency transportation, and backup medical and emergency services. A facility licensed as a critical access hospital must have no more than 25 acute care inpatient beds.

Department means the Department of Health and Human Services Regulation and Licensure.

Designee means a person who is authorized by law or the patient to act on his or her behalf, for example, a parent of a minor child, a legal guardian, a conservator, and an attorney in fact named in a durable power of attorney for health care.

Device means an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including any component, part, or accessory, which is

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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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hospital, a health clinic, a hospital, an intermediate care facility, an intermediate care facility for the mentally retarded, a long-term care hospital, a mental health center, a nursing facility, a pharmacy, a psychiatric or mental hospital, a public health clinic, a rehabilitation hospital, a skilled nursing facility, or a substance abuse treatment center.

Health care practitioner means any individual credentialed under the Uniform Licensing Law or other laws of the State of Nebraska.

Health care practitioner facility means the residence, office or clinic of a practitioner or group of practitioners credentialed under the Uniform Licensing Law or any distinct part of the residence, office, or clinic.

Health care service means an adult day service, a home health agency, a hospice or hospice service, or a respite care service.

Health maintenance activities (See definition of "Care.")

Hospital means a 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.

Inpatient means a person who receives 24-hour care and treatment or is to receive care and treatment and is admitted to the hospital by a medical practitioner.

Licensed health care professional means an individual for whom administration of medication is included in the scope of practice.

Licensee means the individual, government, corporation, partnership, limited liability company or other form of business organization legally responsible for the operation of the hospital and to whom the Department has issued a license.

Long-term care hospital means a hospital or any distinct part of a hospital that provides the care and services of an intermediate care facility, a nursing facility, or a skilled nursing facility.

Medical practitioner means any licensed physician, osteopathic physician, dentist, podiatrist, optometrist, chiropractor, physician assistant, certified registered nurse anesthetist, advanced practice registered nurse, or certified nurse midwife.

Medical staff bylaws means a set of rules adopted by the medical staff which governs its activities and includes any related rules and regulations.

Medication means any prescription or nonprescription drug intended for treatment or prevention of disease or to affect body functions in humans.

Medication administration includes, but is not limited to:

1. Providing medications for another person according to the five rights;

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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.

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Premises means a facility, the facility's grounds and each building or grounds on contiguous property used for administering and operating a facility.

PRN means an administration scheme in which a medication is not routine, is taken as needed, and requires assessment for need and effectiveness.

Psychiatric or mental hospital means a hospital that provides psychiatric services on an inpatient or outpatient basis to persons who have a mental disease, disorder, or disability.

Qualified inspector means a professional architect or engineer licensed to practice in Nebraska, an official or employee of a local jurisdiction authorized by that jurisdiction to make inspections of particular building equipment or systems, or an individual certified by a nationally recognized organization to make such inspections.

Rehabilitation hospital means a hospital that provides an integrated program of medical and other services for the rehabilitation of disabled persons.

Schematic plans means a diagram of the facility or service which describes the number and location of beds; the location of care and treatment rooms, Life Safety Code construction and occupancy classifications locations, fire compartments, and Fire Marshal approved points of safety.

Sexual abuse means sexual harassment, sexual coercion, or sexual assault.

Treatment means a therapy, modality, product, device or other intervention used to maintain well being or to diagnose, assess, alleviate or prevent a disability, injury, illness, disease or other similar condition.

Unlicensed direct care staff means personnel who are not licensed or certified under the Uniform Licensing Law or other state laws governing the practice of health care and whose primary responsibility is to manage, supervise, and/or provide direct care to patients. Unlicensed direct care staff includes nursing assistants, medication aides, and other personnel with this responsibility and with job titles designated by the facility.

Utilization review committee means a committee established by the hospital to review the effective use of hospital resources and to ensure care is consistent with recognized professional standards, delivered in a cost effective manner and provided in a safe environment. This committee may be titled something other than utilization review.

Verbal abuse means the use of oral, written, or gestured language including disparaging and derogatory terms to patients or within their hearing distance.

9-003 LICENSING REQUIREMENTS AND PROCEDURES: Any person intending to establish, operate, or maintain a hospital must first obtain a license from the Department. A facility must not hold itself out as a hospital or as providing health care services unless licensed under the Health Care Facility Licensure Act. An applicant for an initial or renewal license must demonstrate that the hospital meets the care, treatment, operational, and physical plant standards contained in 175 NAC 9.

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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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
 - d. The head of the governmental unit having jurisdiction over the hospital to be licensed, if the applicant is a governmental unit;
14. Copy of the registration as a foreign corporation filed with the Nebraska Secretary of State, if applicant is a foreign corporation;
15. Schematic plans;
16. For new construction, construction plans completed in accordance with the Engineers and Architects Regulation Act, Neb. Rev. Stat. §§ 81-3401 to 81-3455. An applicant may construct a project description and/or certification document, or obtain a form from the Department. Construction plans must include the following:
 - a. Project name, description of the project with quantity and floor area information on bed, care, treatment, bathing, toileting, dining, and activity locations, building systems, medical equipment, street address, and contact person;
 - b. Site plan, floor plans, elevations, wall, and building sections, construction details, plumbing and electrical diagrams, and construction component schedules;
 - c. Complete list of names, titles, and telephone numbers of other authorities reviewing or inspecting the construction;
 - d. Upon Department request, any additional information that may be required for review, such as structural and mechanical calculations, electrical system calculations, and product and equipment information; and
 - e. Certification, if any, from a licensed architect or engineer that the schematic plans, construction plans, and any revisions thereof meet the requirements of 175 NAC 9-007;
17. Planned occupancy date;
18. Copies of zoning approval from the relevant jurisdiction;
19. Occupancy certificates issued by the State Fire Marshal or delegated authority; and
20. Required licensure fee specified in 175 NAC 9-004.10.

9-003.01C Department Responsibilities: The Department will:

1. Review the application for completeness;
2. Provide notification to the applicant of any information needed to complete the application;

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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

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- d. The head of the governmental unit having jurisdiction over the hospital to be licensed, if the applicant is a governmental unit;
14. Occupancy certificates issued by the State Fire Marshal or delegated authority dated within the 18 months prior to the license expiration date; and
15. Required licensure fee as specified in 175 NAC 9-004.10.

9-003.02B Department Responsibilities: The Department will:

1. Send a notice of expiration and an application for renewal to the licensee's preferred mailing address not later than 30 days prior to the expiration date. The licensure renewal notice specifies:
 - a. Date of expiration;
 - b. Fee for renewal;
 - c. License number; and
 - d. Name and address of the hospital.
2. Issue a renewal when it determines that the licensee has submitted a completed application;
3. Send to each licensee that fails to renew its license a second notice, which is the final notice and specifies that:
 - a. The licensee failed to pay the renewal fee or submit an application or both;
 - b. The license has expired;
 - c. The Department will suspend action for 30 days following the date of expiration;
 - d. Upon receipt of the renewal fee and completed renewal application, the Department will issue the renewal license; and
 - e. That upon failure to receive the renewal fee and completed renewal application, the license will be lapsed.
4. Place the hospital license on lapsed status for nonpayment of fees if the licensee fails to renew the license. During this time, the hospital may not operate. The license remains in lapsed status until it is reinstated.

9-003.02C Refusal to Renew: See 175 NAC 9-008.01 and 9-008.02 for grounds and procedures for the Department's refusal to renew a license.

9-003.03 Reinstatement from Lapsed Status: A hospital requesting reinstatement of its lapsed license must submit to the Department an application for reinstatement and pay the required licensure fee specified in 175 NAC 9-004.10. The application must conform to the requirements specified in 175 NAC 9-003.02.

9-003.03A The Department will review the application for completeness and will decide if an onsite inspection is needed to determine compliance with the operation, care,

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 Reinstatement: 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

location of beds may occur at any time without prior Departmental approval for licensure purposes. A licensee must not locate more patients in a patient room than the capacity for which the room was originally approved.

9-004.06 Change of Ownership or Premises: The licensee must notify the Department in writing ten days before a hospital is sold, leased, discontinued, or moved to new premises.

9-004.07 Notification: An applicant or licensee must notify the Department in writing by electronic mail, facsimile, or postal service:

1. At the time of license renewal, of any change in the use or location of beds;
2. At least 30 working days prior to the date it wishes to increase the number of beds for which the hospital is licensed;
3. To request a single license document;
4. To request simultaneous facility or service licensure inspections for all types of licensure held or sought;
5. If new construction is planned, submit construction plans for Department approval prior to any new construction affecting patient care and treatment areas of the hospital. The Department may accept certification from an architect or engineer in lieu of Department review;
6. Within 24 hours of any patient death that occurred due to suicide, a violent act, or the patient's leaving the facility without staff knowledge when departure presented a threat to the safety of the patient or others;
7. Within 24 hours if a facility has reason to believe that a patient death was due to abuse or neglect by staff;
8. Within 24 hours of any facility fire requiring fire department response; or
9. Within 24 hours of an accident or natural disaster resulting in damage to the physical plant and having a direct or immediate adverse effect on the health, safety, and security of patients. This must include a description of the well-being of the facility's patients and the steps being taken to assure patient safety, well-being, and continuity of care and treatment. The notification may be made by telephone if the accident or natural disaster has affected the facility's capacity to communicate.

9-004.08 Information Available to Public: The licensee must make available for public inspection upon request licenses, license record information, and inspection reports. This information may be displayed on the licensed premises.

9-004.09 Deemed Compliance

9-004.09A Accreditation or Certification: The Department may deem an applicant or licensee in compliance with 175 NAC 9-006 based on its accreditation or certification as a hospital by the:

1. Joint Commission on Accreditation of Healthcare Organizations;
2. American Osteopathic Association;
3. Commission on Accreditation of Rehabilitation Facilities; or
4. Medicare or Medicaid certification program.

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:

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- a. If the Department did not perform an inspection, the license fee is refunded except for an administrative fee of \$25;
- b. If the Department performed an inspection, the fee is not refunded.

9-005 INSPECTIONS: To determine compliance with operational, care, treatment, and physical plant standards, the Department inspects the hospital prior to and following licensure. The Department determines compliance through on-site inspections, review of schematic and construction plans, and reports of qualified inspectors.

9-005.01 Initial Inspection: The Department will conduct an announced initial on-site inspection to determine compliance with 175 NAC 9-006 and 9-007. The inspection will occur within 30 working days, or later if requested by the applicant, of receipt of a completed application for an initial license. The Department will provide a copy of the inspection report to the hospital within ten working days after completion of an inspection.

9-005.02 Results of Initial Inspection

9-005.02A When the Department finds that the applicant fully complies with the requirements of 175 NAC 9-006 and 9-007, the Department will issue a license.

9-005.02B When the Department finds that the applicant had complied substantially but has failed to comply fully with the requirements of 175 NAC 9-006 and 9-007 and the failure(s) would not pose an imminent danger of death or physical harm to hospital patients, the Department may issue a provisional license. The provisional license:

1. Is valid for up to one year; and
2. Is not renewable.

9-005.02C When the Department finds the applicant has one or more violations that create no imminent danger of death or serious physical harm and no direct or immediate adverse relationship to the health, safety, or security of the hospital patients, the Department may send a letter to the hospital requesting a statement of compliance. The letter will include:

1. A description of each violation;
2. A request that the hospital submit a statement of compliance within ten working days; and
3. A notice that the Department may take further steps if the statement of compliance is not submitted.

9-005.02D 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 issue either a regular license or a provisional license; or

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:

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1. Copies of documents from other authorities having jurisdiction verifying that the facility meets the codes specified in 175 NAC 9-007.03A, and is approved for use and occupancy;
2. Copies of certifications and documentation from equipment and building system installers verifying that all equipment and systems installed are operating and approved for use and occupancy; and
3. Schematic floor plans documenting actual room numbers and titles, bed locations, capacity, and life safety information.

9-005.04 Compliance Inspections: The Department may, following the initial licensure of a hospital, conduct an unannounced onsite inspection at any time as it deems necessary to determine compliance with 175 NAC 9-006 and 9-007. The inspection may occur based on random selection or focused selection.

9-005.04A Random Selection: Each year the Department may inspect up to 25% of the hospitals based on a random selection of licensed hospitals.

9-005.04B Focused Selection: The Department may inspect a hospital when the Department is informed of one or more of the following:

1. An occurrence resulting in patient death or serious physical harm;
2. An occurrence resulting in imminent danger to or the possibility of death or serious physical harm to patients;
3. An accident or natural disaster resulting in damage to the physical plant and having a direct or immediate adverse effect on the health, safety, and security of patients;
4. The passage of five years without an inspection;
5. A complaint alleging violation of the Health Care Facility Licensure Act or 175 NAC 9;
6. Complaints that, because of their number, frequency, or type, raise concerns about the maintenance, operation, or management of the hospital;
7. Financial instability of the licensee or of the licensee's parent company;
8. Outbreaks or recurrent incidents of physical health problems such as dehydration, pressure sores, or other illnesses;
9. Change of services, management or ownership;
10. Change of status of accreditation or certification on which licensure is based as provided in 175 NAC 9-004.09; or
11. Any other event that raises concerns about the maintenance, operation, or management of the hospital.

9-005.05 Results of Compliance Inspections

9-005.05A When the inspection reveals violations that create imminent danger of death or serious physical harm or have a direct or immediate adverse effect on the health, safety, or security of hospital patients, the Department will review the inspection findings within 20 working days after the inspection. If the evidence from the inspection supports the findings, the Department will impose discipline in accordance with 175 NAC 9-008.03.

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.

9-006.01 Governing Authority: Each hospital must have a governing authority that oversees and establishes the policy direction for the hospital. The governing authority meets at regular, stated intervals and at other times necessary for proper operation of the hospital and keeps written minutes of its meetings and actions.

9-006.01A The governing authority responsibilities include:

1. Monitoring policies to assure appropriate administration and management of the facility;
2. Maintaining the hospital's compliance with all applicable state statutes and relevant rules and regulations;
3. Ensuring the quality of all services, care and treatment provided to patients whether those services, care or treatment are furnished by hospital staff or through contract with the hospital;
4. Designating an administrator who is responsible for the day to day management of the hospital;
5. Defining the duties and responsibilities of the administrator in writing;
6. Notifying the Department in writing within five working days when a vacancy in the administrator position occurs, including who will be responsible for the position until another administrator is appointed;
7. Notifying the Department in writing within five working days when the administrator vacancy is filled indicating effective date and name of person appointed administrator;
8. Determining which categories of practitioners are eligible candidates for appointment to the medical staff;
9. Ensuring that under no circumstances is the accordance of medical staff membership or clinical privileges in the hospital dependent solely upon certification, fellowship or membership in a specialty body or society although Board certification can be one permissible criterion;
10. Appointment and reappointment of medical staff members and delineating their clinical privileges, according to the procedures for credentials review established by the medical staff and approved by the governing authority;
11. In collaboration with the medical staff, establishing criteria for membership on the medical staff or clinical privileges;
12. Rendering within a fixed period of time the final decision regarding medical staff recommendations for denial of staff appointments and reappointments, as well as for the denial, limitation, suspension or revocation of privileges.

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

be directly responsible to the governing authority in all matters related to the maintenance, operation, and management of the hospital. The administrator's responsibilities include:

1. Being on the premises a sufficient number of hours to permit adequate attention to the management of the hospital;
2. Providing for the protection of patients' health, safety, and well-being;
3. Maintaining staff appropriate to meet patient needs;
4. Designating a substitute, who is responsible and accountable for management of the facility, to act in the absence of the administrator;
5. Developing procedures which require the reporting of any evidence of abuse, neglect, or exploitation of any patient served by the hospital in accordance with Neb. Rev. Stat. § 28-732 of the Adult Protective Services Act or in the case of a child, in accordance with Neb. Rev. Stat. § 28-711; and
6. Ensuring an investigation is completed on suspected abuse, neglect or exploitation and that steps are taken to prevent and protect patients.

9-006.02 Medical Staff: Each hospital must have a medical staff that operates under medical staff bylaws approved by the governing authority. Two or more hospitals may share a single medical staff, provided that all medical staff functions are completed for each hospital. The medical staff must be organized in a manner and must function in a manner consistent with the size, needs and resources of the hospital and of the medical staff.

9-006.02A Medical Staff Responsibilities: The medical staff must be responsible to the governing authority for the quality of medical care and treatment provided in the hospital and must:

1. Participate in a Quality Assurance/Performance Improvement program to determine the status of patient care and treatment;
2. Abide by hospital and medical staff policies;
3. Establish a disciplinary process for infraction of the policies;
4. Recommend criteria and procedures for appointment and reappointment to the medical staff and for delineating clinical privileging to facilitate the provision of quality patient care and treatment; and
5. Determine the supervision of and training for emergency medical technician-intermediates or emergency medical technician-paramedics.

9-006.02B Medical Staff Appointment: Membership on the medical staff must be limited to those disciplines specified in the medical staff bylaws, rules and regulations or other similar governance document. Criteria for appointment and reappointment must include, at a minimum, continuing licensure or authority to practice in Nebraska. The medical staff must:

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

2. That an emergency medical technician-intermediate or an emergency medical technician-paramedic providing service in the hospital is employed by or serving as a volunteer member of an emergency medical service licensed by the Department.

9-006.03A2 Health Status: Each hospital must establish and implement policies and procedures related to the health status of staff to prevent the transmission of disease to patients.

9-006.03A2a Each hospital must ensure a health history screening is completed for each staff prior to assuming job responsibilities and must require staff to have a physical examination when the results of the health history screening indicate the examination is necessary.

9-006.03A3 Criminal Background and Registry Checks: Each hospital must complete and maintain documentation of pre-employment criminal background and registry checks on each unlicensed direct care staff member.

9-006.03A3a Criminal Background Checks: The hospital must complete a criminal background check through a governmental law enforcement agency or a private entity that maintains criminal background information.

9-006.03A3b Registry Checks: The hospital must check for adverse findings with each of the following registries:

1. Nurse Aide Registry;
2. Adult Protective Services Central Registry;
3. Central Register of Child Protection Cases; and
4. Nebraska State Patrol Sex Offender Registry.

9-006.03A3c The hospital must:

1. Determine how to use the criminal background and registry information, except for the Nurse Aide Registry, in making hiring decisions;
2. Decide whether employment can begin prior to receiving the criminal background and registry information; and
3. Document any decision to hire a person with a criminal background or adverse registry findings, except for the Nurse Aide Registry. The documentation must include the basis for the decision and how it will not pose a threat to patient safety or patient property.

9-006.03A3d The hospital must not employ a person with an adverse finding on the Nurse Aide Registry regarding patient abuse, neglect, or misappropriation of patient property.

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:

1. Respectful and safe care given by competent personnel;
2. Be informed of patient rights during the admission process;
3. Be informed in advance about care and treatment and of any change;
4. Participate in the development and implementation of a plan of care and any changes;
5. Make informed decisions regarding care and to receive information necessary to make decisions;
6. Refuse treatment and to be informed of the medical consequences of refusing treatment;
7. Formulate advance directives and to have the hospital comply with the directives unless the hospital notifies the patient of the inability to do so;
8. Personal privacy and confidentiality of medical records;
9. Be free from abuse, neglect, and exploitation;
10. Access information contained in his/her medical record within a reasonable time frame when requested, subject to limited circumstances where the attending physician determines it would be harmful to disclose the information to the patient for therapeutic reasons;
11. Be free from chemical and physical restraints that are not medically necessary;
12. Receive hospital services without discrimination based upon race, color, religion, gender, national origin, or payer. Hospitals are not required to provide uncompensated or free care and treatment unless otherwise required by law; and
13. Voice complaints and file grievances without discrimination or reprisal and have those complaints and grievances addressed.

9-006.04A Grievances: Each hospital must establish and implement a written process that promptly addresses grievances filed by patients or their representatives. The process includes, but is not limited to:

1. A procedure for submission of grievances which is made available to patients or representatives;
2. Time frames and procedures for review of grievances and provision of a response; and
3. How information from grievances and responses are utilized to improve the quality of patient care and treatment.

9-006.05 Quality Assurance/Performance Improvement: Each hospital must have an effective, hospital-wide quality assurance/performance improvement program to evaluate care and treatment provided to patients. The program, must include, but is not limited to:

1. Establishment of appropriate committees such as a medical staff and utilization review committee for the purpose of reviewing the medical and hospital care as required under Neb. Rev. Stat. § 71-2046 with the power and authority provided under Neb. Rev. Stat. § 71-2047;
2. A written plan of implementation;
3. All services provided including contracted services;

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;

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2. To ensure that competency assessments and/or courses for medication aides have been completed in accordance with the provisions of 172 NAC 96-005;
3. That specify how direction and monitoring will occur when the hospital allows medication aides to perform the routine/acceptable activities authorized by 172 NAC 95-005 and as follows:
 - a. Provide routine medication; and
 - b. Provision of medications by the following routes:
 - (1) Oral, which includes any medication given by mouth including sublingual (placing under the tongue) and buccal (placing between the cheek and gum) routes and oral sprays;
 - (2) Inhalation, which includes inhalers and nebulizers, including oxygen given by inhalation;
 - (3) Topical application of sprays, creams, ointments, and lotions and transdermal patches; and
 - (4) Instillation by drops, ointments and sprays into the eyes, ears and nose;
4. That specify how direction and monitoring will occur when the hospital allows medication aides to perform the additional activities authorized by 172 NAC 95-009, which include, but are not limited to:
 - a. Provision of PRN medications;
 - b. Provision of medications by additional routes, including, but not limited to, gastrostomy tube, rectal and vaginal; and/or
 - c. Participation in monitoring;
5. That specify how competency determinations will be made for medication aides to perform routine and additional activities pertaining to medication provision;
6. That specify how written direction will be provided for medication aides to perform the additional activities authorized by 172 NAC 95-009;
7. That specify how records of medication provision by medication aides will be recorded and maintained; and
8. That specify how medication errors made by medication aides and adverse reactions to medications will be reported. The reporting must be:
 - a. Made to the identified person responsible for direction and monitoring;
 - b. Made immediately upon discovery; and
 - c. Documented in patient medical records.

9-006.06B2 Each hospital must establish and implement policies and procedures for reporting any errors in administration or provision of prescribed medications to the

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.

9-006.06D Patient Education: Each hospital must establish and implement a process to provide patients and/or their designee appropriate education to assist in understanding the identified condition and the necessary care and treatment.

9-006.06E Discharge Planning: Each hospital must provide discharge planning to patients who request information or who are identified as likely to suffer adverse health consequences upon discharge if there is not adequate discharge planning. The discharge planning program includes, but is not limited to:

1. A system for timely evaluation of any discharge planning needs of patients;
2. Identification of staff responsible for the program;
3. Development of a discharge plan with the patient or representative when need is identified;
4. Maintenance of a complete and accurate list of community-based services, resources and facilities to which patients can be referred; and
5. Arrangement for the initial implementation of a discharge plan including transfer of necessary medical information.

9-006.07 Record Keeping Requirements: Each hospital must maintain records and reports in a manner to ensure accuracy and easy retrieval.

9-006.07A Medical Records: A medical record must be maintained for every patient, including newborn infants, admitted for care in the hospital or treated in the emergency or outpatient service. Medical records may be created and maintained in written or electronic form, or a combination of both, provided the record meets 175 NAC 9. Medical records must contain sufficient information to clearly identify the patient, to justify the diagnosis and treatment and to document the results accurately.

9-006.07A1 Content: Each medical record must contain, when applicable, the following information:

1. Identification data;
2. Chief complaint;
3. Present illness;
4. History and physical examination;
5. Admitting diagnosis;
6. All pathology/laboratory and radiology reports;
7. Properly executed informed consent forms;
8. Consultation reports;
9. Medical practitioner orders;
10. Documentation of all care and treatment, medical and surgical;
11. Tissue report;
12. Progress notes of all disciplines;
13. Discharge summary and final diagnosis;
14. Autopsy findings; and
15. Advance directives, if available.

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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.

9-006.07B2 Administrative records and reports including governing authority and departmental meeting minutes, staff orientation and inservice records and staff schedules as worked for a minimum of three years, unless longer is required by law.

9-006.07B3 Records of all reports made regarding abuse, neglect or exploitation as required by Neb. Rev. Stat. §§ 28-372 and 28-711.

9-006.08 Infection Control: Each hospital must provide a sanitary environment to avoid sources and transmission of infections and communicable diseases. There must be an active program for the prevention, control and investigation of infections and communicable diseases.

9-006.08A The infection control program must include, but is not limited to:

1. All departments/services of the hospital;
2. The responsible person(s) for the program;
3. A system for identifying, reporting, investigating and controlling infections, communicable diseases, and nosocomial infections of patients and staff;
4. A definition of nosocomial infection;
5. A system for the early detection of infectious outbreaks to contain and prevent further spread of infection;
6. A method of monitoring treatment of infection for appropriateness and for alteration of treatment when necessary;
7. Implementation of corrective action plans; and
8. Mechanism for evaluation of the program.

9-006.09 General Acute Hospital Requirements: Each general acute hospital must have a duly constituted governing authority and organized medical staff and must provide medical, nursing, surgical, anesthesia, laboratory, diagnostic radiology, pharmacy and dietary services on an inpatient or outpatient basis.

9-006.09A Medical Services: Medical services must be provided in a manner sufficient to meet the medical needs of patients. Medical services must be given under the direction and supervision of a physician member of the medical staff.

9-006.09A1 There must be written policies and procedures that govern medical services approved by the medical staff.

9-006.09A2 There must be a mechanism for a sample review of medical services provided to evaluate the quality of services furnished to both inpatients and outpatients.

9-006.09B Nursing Services: Each hospital must have an organized nursing department, including a departmental plan of administrative authority with written delineation of responsibilities and duties of each category of nursing personnel in the form of written job descriptions.

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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.

9-006.09C1 Written policies and procedures must be established and implemented that define and describe the scope and conduct of surgical services and ensure safe and competent delivery of surgical services to patients. These policies and procedures are approved by the medical staff and include, but are not limited to:

1. Restrictions on access to the surgical suite and recovery room areas;
2. Proper attire in the surgical suite and recovery room areas;
3. Sterilization and disinfection of equipment and supplies;
4. Aseptic surveillance and practice;
5. Maintenance of a roster in the surgical suite which delineates the surgical privileges granted to each medical practitioner;
6. Maintenance of an operating room record log that includes, but is not limited to:
 - a. Name and identification number of each patient;
 - b. Date and inclusive time of surgical procedure;
 - c. Surgical procedure(s) performed;
 - d. Name(s) of surgeons and any assistants;
 - e. Name of nursing personnel (scrub and circulating);
 - f. Type of anesthesia; and
 - g. Name and title of person administering anesthesia.
7. Responsibility for the supervision of the surgical suite and recovery room;
8. Immediate availability of an emergency call system, cardiac monitor, defibrillator, suction and emergency airway supplies;
9. Availability of blood and blood products;
10. Requirement for patient history and physical examination;
11. Requirements for testing and disposal of surgical specimens;
12. Circumstances that require the presence of an assistant during surgery;
13. Procedures for handling infectious cases;
14. Immediate post-surgical care; and
15. Operative report requirements.

9-006.09C2 Each hospital must, at least annually, provide surgeons performing surgery at the hospital a report as to the number and rates of surgical infections in surgical patients of the surgeons as required by Neb. Rev. Stat. § 71-2083.

9-006.09C3 Each hospital that provides outpatient surgical services must evaluate patients for proper recovery before discharge. Qualified personnel must remain with the patient until the patient's status is stable and protective reflexes have returned to normal. A patient may be discharged only when a medical practitioner and hospital policies determine it is safe and appropriate to discharge. The hospital must establish medical criteria for discharge which are consistent with prevailing professional standards.

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.

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9-006.09F2 Personnel performing medical radiography procedures must be licensed in accordance with Neb. Rev. Stat. §§ 71-3515.01 to 71-3515.02 and the regulations promulgated thereunder.

9-006.09F3 Each hospital must have available emergency radiology services.

9-006.09F4 All x-ray films must be reviewed and interpreted by a physician. Complete reports of the results of x-ray examinations must be kept on file for not less than five years and a copy must be filed in the patient's medical record.

9-006.09G Pharmacy Services: Pharmacy services must be provided to meet the needs of patients directly or through written agreement, and must be under the supervision of a pharmacist licensed in Nebraska. The storage, control, handling, compounding and dispensing of drugs, devices and biologicals must be in accordance with Neb. Rev. Stat. §§ 71-1,142 to 71-1,147.59 and the regulations promulgated thereunder.

9-006.09G1 Emergency drugs, devices and biologicals as determined by the medical staff must be readily available for use at designated locations when an emergency occurs.

9-006.09G2 Current and accurate records must be kept on the receipt and disposition of all controlled substances.

9-006.09G3 The supply of drugs, devices and biologicals and controlled substances must be protected and restricted to use for legally authorized purposes.

9-006.09G4 Abuses and losses of controlled substances must be reported in accordance with Neb. Rev. Stat. §§ 28-401 to 28-445, the Uniform Controlled Substances Act, and the regulations promulgated thereunder.

9-006.09G5 Drugs, devices and biologicals must be stored in locked areas in accordance with the manufacturer's instructions for temperature, light, humidity or other storage instructions.

9-006.09G6 Drugs, devices and biologicals must be removed from the pharmacy or storage area only by personnel designated in hospital policies and in accordance with state and federal law.

9-006.09G7 The supply of drugs, devices and biologicals must be checked on a regular basis to ensure expired, mislabeled, unlabeled or unusable products are not available for patient use and are disposed of in accordance with hospital policies and state and federal law.

9-006.09G8 Information relating to interactions, contraindications, side effects, toxicology, dosage, indications for use, and routes of administration for drugs, devices and biologicals must be available to staff.

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;

- e. Name of treating medical practitioner; and
 - f. Disposition including time; and
6. Provision of written instructions to patients for care and an oral explanation of those instructions.

9-006.09I2 Any hospital that ceases to provide emergency services must notify the Department as soon as possible prior to the action.

9-006.09J Critical Care Unit Services: If a hospital provides critical care unit services, e.g., an intensive care, coronary care, intensive newborn nursery, burn unit, or transplant unit, the unit must be under the direction of a physician member of the medical staff, qualified to direct such services, and who must be responsible for the quality and scope of services.

9-006.09J1 Each hospital that provides special care unit services must establish and implement written policies and procedures which include, but are not limited to:

- 1. The scope and care for patients in each special care unit service;
- 2. Supervision by a qualified registered nurse;
- 3. The special equipment, medications and supplies that are to be immediately available in the unit for provision of care and treatment and to carry out the functions of the unit;
- 4. Qualifications of personnel assigned to provide care in the unit;
- 5. Medical and nursing staff coverage for the unit; and
- 6. Admission and discharge criteria.

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

9-006.09K1 Each hospital that provides obstetrical and newborn services must establish and implement written policies and procedures which include, but are not limited to:

- 1. The scope of and care for patients receiving obstetrical and newborn services;
- 2. Supervision of nursing care including labor, delivery, and nursery by a qualified registered nurse;
- 3. The drugs, devices, biologicals, equipment and supplies that are to be immediately available for provision of care;
- 4. Appropriate attire to be worn during labor and delivery and in the nursery;
- 5. The flow of hospital staff between the obstetric and newborn units and other patient care areas;
- 6. The use of oxytocic drugs and administration of anesthetics, sedatives, analgesics and other drugs, devices and biologicals;

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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;

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2. Supervision by a qualified respiratory care practitioner;
3. Provision of respiratory care services by qualified personnel as allowed by their scope of practice;
4. Provision of therapy must be provided 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.

9-006.09O Social Work Services: Social work services, if provided, must be under the direction of a certified social worker who must be responsible for the quality and scope of social work services.

9-006.09O1 Each hospital that provides social work services must establish and implement written policies and procedures which include, but are not limited to:

1. The scope and care of patients receiving social work services;
2. The assessment of personal and social functioning of patients;
3. Coordination with other services in the hospital;
4. Role in intervention, discharge planning and referral of patients; and
5. Documentation and record keeping requirements.

9-006.09P Outpatient Services: Outpatient services, if provided, must be under the direction of a qualified individual(s), as determined by the hospital, who must be responsible for the quality and scope of outpatient services.

9-006.09P1 Each hospital that provides outpatient services in a distinct area on the hospital premises or at another location must establish and implement written policies and procedures which include, but are not limited to:

1. The scope and care of outpatient services;
2. Provision of outpatient services in accordance with medical practitioner orders;
3. The numbers and qualifications of staff necessary to meet patient needs based on the type and volume of services provided;
4. Documentation and record keeping requirements and procedures to integrate the outpatient medical record with existing inpatient records; and
5. Equipment and allocation of space for the provision of outpatient services to ensure safety and privacy to patients.

9-006.10 Critical Access Hospital: Each critical access hospital must have no more than 25 acute care inpatient beds. The average length of stay for acute care inpatients must not be more than 96 hours, and emergency services must be provided on a 24-hour basis. Critical access hospitals must have formal agreements with at least one hospital and other appropriate providers for services such as patient referral and transfer, communication systems, provision of emergency and nonemergency transportation and backup medical and emergency services. Each critical access hospital must meet the requirements to

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;

4. There must be written policies and procedures established and implemented that govern care and treatment provided to patients to ensure health and safety needs of patients are met;
5. A preadmission screening procedure must be established and implemented to review each prospective patient's condition and medical history to determine whether the patient is likely to benefit significantly from an intensive inpatient hospital program or assessment;
6. There must be a plan of treatment for each inpatient established, implemented, reviewed and revised as needed by a physician in consultation with other professional personnel who provide services to the patient; and
7. There must be a multidisciplinary team approach in the rehabilitation of each inpatient, as documented by periodic clinical entries made in the patient's medical record to note the patient's status in relationship to goal attainment. Team conferences must be held at least every two weeks to determine the appropriateness of treatment.

9-006.14 Environmental Services: Each hospital must provide a safe, clean and comfortable environment for patients. Every detached building on the same premises used for care and treatment must comply with 175 NAC 9.

9-006.14A Housekeeping and Maintenance: The hospital must provide the necessary housekeeping and maintenance to protect the health and safety of patients.

9-006.14A1 The hospital's buildings and grounds must be kept clean, safe and in good repair.

9-006.14A2 All garbage and rubbish must be disposed of in such a manner as to prevent the attraction of rodents, flies and all other insects and vermin. Garbage must be disposed of in such a manner as to minimize the transmission of infectious diseases and minimize odor.

9-006.14A3 The hospital must provide and maintain adequate lighting, environmental temperatures and sound levels in all areas that are conducive to the care and treatment provided.

9-006.14A4 The hospital must maintain and equip the premises to prevent the entrance, harborage or breeding of rodents, flies and all other insects and vermin.

9-006.14B Equipment, Fixtures and Furnishings: The hospital must provide and maintain all equipment, fixtures and furnishings clean, safe and in good repair.

9-006.14B1 Common areas and patient areas must be furnished with beds, chairs, sofas, tables and storage that is comfortable and reflective of patient needs.

9-006.14B2 The hospital must provide equipment adequate to meet the care and treatment needs of patients.

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.

2. Water temperatures at patient bathing and therapy fixtures must not exceed 110 degrees Fahrenheit.

9-006.14E4 The hospital must establish and implement policies and procedures to ensure hazardous/poisonous materials are properly handled and stored to prevent accidental ingestion, inhalation, or consumption of the hazardous/poisonous materials by patients.

9-006.14E5 The hospital must restrict access to mechanical equipment which may pose a danger to patients.

9-006.14F Disaster Preparedness and Management: The hospital must establish and implement disaster preparedness plans and procedures to ensure that patient care and treatment, safety, and well-being are provided and maintained during and following instances of natural (tornado, flood, etc.) or other disasters, disease outbreaks, or other similar situations. Such plans and procedures must address and delineate:

1. How the hospital will maintain the proper identification of each patient to ensure that care and treatment coincide with the patient's needs;
2. How the hospital will move patients to points of safety or provide other means of protection when all or part of the building is damaged or uninhabitable due to natural or other disaster.
3. How the hospital will protect patients during the threat of exposure to the ingestion, absorption, or inhalation of hazardous substances or materials;
4. How the hospital will provide food, water, medicine, medical supplies, and other necessary items for care and treatment in the event of a natural or other disaster; and
5. How the hospital will provide for the comfort, safety, and well-being of patients in the event of 24 or more consecutive hours of:
 - a. Electrical or gas outage;
 - b. Heating, cooling, or sewer system failure; or
 - c. Loss or contamination of water supply.

9-007 PHYSICAL PLANT 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 physical plant standards for facilities, which include support services, care and treatment areas, construction standards, building systems and waivers, are set forth below.

9-007.01 Support Areas: The hospital may share the following support service areas among detached structures, care and treatment areas, or with other licensed health care facilities.

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.

9-007.01F Housekeeping Room: The hospital must have a room with a service sink and space for storage of supplies and housekeeping equipment.

9-007.02 Care and Treatment Areas: The hospital must not share the following care and treatment areas among detached structures or with other facilities operated by another licensee:

9-007.02A Staff Areas: Facilities that provide nursing services must provide the following support areas for each distinct group of care and treatment patient rooms.

9-007.02A1 Control Point: The hospital must have an area or areas for charting, and patient records, and call and alarm annunciation systems.

9-007.02A2 Medication Station: The hospital must have a medication station for storage and distribution of drugs and routine medications. Distribution may be done from a medicine preparation room or unit, from a self-contained medicine-dispensing unit, or by another system. If used, a medicine preparation room or unit must be under visual control of nursing staff and must contain a work counter, sink, refrigerator, and double-locked storage for controlled substances.

9-007.02A3 Utility Areas: The hospital must have a work area where clean materials are assembled. The work area must contain a work counter, a handwashing fixture, and storage facilities for clean and sterile supplies. If the area is used only for storage and holding as part of a system for distribution of clean and sterile supply materials, the work counter and handwashing fixtures may be omitted. A hospital must have separate work rooms or holding rooms for soiled materials. A work room for soiled materials must contain a fixture for disposing wastes and a handwashing sink.

9-007.02B Equipment and Supplies: The hospital must have services and space to distribute, maintain, clean and sanitize durable medical instruments, equipment, and supplies required for the care and treatment performed in the hospital.

9-007.02B1 Durable Medical: The hospital must ensure that the durable medical equipment is tested and calibrated in accordance with the manufacturer's recommendations.

9-007.02B2 Sterile Processing: The hospital must have areas for decontamination and sterilizing of durable medical instruments and equipment.

9-007.02B2a The hospital must provide separate central sterile processing and waste processing areas.

9-007.02B2b In new construction and where provided, central processing areas must have separate soiled (sorting and decontamination) and clean (sterilizing and processing) rooms. The hospital must have handwashing sinks in both clean and soiled rooms.

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.

9-007.02F Obstetrics: A hospital providing obstetric services in a distinct unit must have at least one patient room, nursery with work area, space and equipment to allow for care and treatment of both mother and infant, handwashing sink, storage for equipment and supplies, call and alarm annunciation systems, medication storage and distribution, and convenient accommodations for patient toileting, dressing, and consultation.

9-007.02G Psychiatric or Mental Health: A hospital providing psychiatric or mental health services in a distinct unit must provide space and equipment that allows for patient and staff safety. The hospital must provide at least one observation room, separate quiet and noisy activity areas, dining areas, private and group areas for specialized treatment and care, a handwashing sink, storage for equipment and supplies, security systems, and an area for medication storage and distribution. Patient toileting, dressing, holding, and consultation rooms must have durable finishes. In rooms where care and treatment is provided to patients exhibiting violent, aggressive or suicidal behavior, the rooms must have:

1. Tamper-resistant air distribution devices, lighting fixtures, sprinkler heads, and safety devices;
2. Ventilation, exhaust, heating and cooling components that are inaccessible to patients;
3. Bedroom, toilet, and bathing room doors that are not lockable or capable of being obstructed from within; and
4. Electrical outlets protected by ground fault interrupting devices.

9-007.02H In-Patient Hospice Care: A hospital providing in-patient hospice services in a distinct unit must have private patient bedrooms, over-night and dining accommodations for family members, private family visiting areas, areas that allow for toileting, bathing, dressing and handwashing, storage for equipment and supplies, call system, medication storage and distribution.

9-007.02I Alzheimer's, Dementia, and Related Conditions: A hospital providing in-patient services for Alzheimer's, dementia, and related conditions in a distinct unit must have personalized patient bedrooms, activity areas, separate dining areas, features that support patient orientation to their surroundings, areas for specialized treatment and care, handwashing sinks, secured storage for equipment and supplies, call and security systems, and an area for medication storage and distribution.

9-007.02J Outpatient Areas: Areas for the care and treatment of patients not residing in the hospital must comply with the following:

1. Areas must not interfere with inpatients being served;
2. Furniture and equipment must meet care and treatment needs of outpatients;
3. Toilets, which are easily accessible from all program areas must be provided; and
4. Sufficient inside and outside space to accommodate the full range of program activities and services must be provided.

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.

9-007.03B Conflicts in Standards: In situations where the referenced codes and guidelines conflict with 175 NAC 9, the adopted rules and regulations of the Department and the Nebraska State Fire Marshal will prevail.

9-007.03C Interpretations: All dimension, sizes, and quantities noted herein will be determined by rounding fractions to the nearest whole number.

9-007.03D Floor Area: Floor area is the space with ceilings at least seven feet in height and does not include areas such as enclosed storage, toilets, and bathing rooms, corridors and halls. The space beyond the first two feet of vestibules and alcoves less than five feet in width will not be included in the required floor area. In rooms with sloped ceilings, at least half of the ceiling must be at least seven feet in height with areas less than five feet in height not included in the required floor area.

9-007.03E Dining Areas: If provided, dining areas for patients must have an outside wall with windows for natural light and ventilation.

9-007.03E1 Dining areas must be furnished with tables and chairs that accommodate or conform to patient needs.

9-007.03E2 Dining areas must have a floor area of 15 square feet per patient in existing facilities and 20 square feet per patient in new construction.

9-007.03E3 Dining areas must allow for group dining at the same time in either separate dining areas or a single dining area, or dining in two shifts, or dining during open dining hours.

9-007.03E4 Dining areas must not be used for sleeping, offices or corridors.

9-007.03F Activity Areas: If provided, activity areas must have space for patient socialization and leisure time activities.

9-007.03F1 Activity areas must have furnishings to accommodate group and individual activities.

9-007.03F2 Activity areas must have a floor area of at least 15 square feet per patient residing in bedrooms and may be combined with dining areas.

9-007.03F3 Activity areas must not be used for sleeping, offices, or as a corridor.

9-007.03F4 The hospital must make activity areas available to all patients.

9-007.03G Bathing Rooms: A hospital must provide a bathing room consisting of a tub and/or shower adjacent to each bedroom or provide a central bathing room on each floor with patient rooms. Tubs and showers regardless of location must be equipped with hand grips or other assistive devices as needed or desired by the bathing patient.

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.

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

9-007.03J Isolation Rooms: The number and type of isolation rooms in a hospital must be determined by the hospital and based upon an infection control risk assessment.

9-007.03J1 Facilities must make provisions for isolating patients with infectious diseases.

9-007.03J2 A hospital must have a minimum of one isolation room with an adjoining toilet room.

9-007.03J3 In new construction, facilities must equip isolation rooms with hand washing and gown changing facilities at the entrance of the room.

9-007.03K Observation Areas: If the hospital provides medical observation, extended recovery or behavior intervention methods, the hospital must provide one or more appropriately equipped rooms for patients needing close supervision. Each room must:

1. Have appropriate temperature control, ventilation and lighting;
2. Be void of unsafe wall or ceiling fixtures and sharp edges;
3. Have a way to observe the patient, such as an observation window or if necessary, flat wall mirrors so that all areas of the room are observable by staff from outside of the room;
4. Have a way to assure that the door cannot be held closed by the patient in the room which could deny staff immediate access to the room; and
5. Be equipped to minimize the potential of the patient's escape, injury, suicide or hiding of restricted substances.

9-007.03L Critical Care Rooms: If monitored complex nursing care is provided, the hospital must provide one or more rooms for patients needing the care. Each room must be appropriately located and equipped to promote staff observation of patients. Rooms with a single occupant must have a minimum floor area of no less than 130 square feet. Multiple bed locations must contain at least 110 square feet per bed with a minimum of 4 feet between beds. The room must include provision for life support, medical gas, sleeping, and convenient bathing and toileting facilities.

9-007.03M Bassinets: Each bassinet must have a minimum floor area of 40 square feet with at least 3 feet between bassinets.

9-007.03N Cubicles: Patient care and treatment cubicles must have a minimum floor area of 60 square feet with at least 3 feet between bedsides and adjacent side walls.

9-007.03O Examination Rooms: Each examination room must have a minimum floor area of 80 square feet and a minimum of 3 feet clear dimension around 3 sides of the examination table or chair.

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:

1. Washable room finishes provided in procedure rooms, existing isolation rooms, sterile processing rooms, workroom, laundry, and food-preparation areas must have smooth, non-absorptive surfaces which are not physically affected by routine housekeeping cleaning solutions and methods. Acoustic and lay-in ceilings, if used, must not interfere with infection control. Perforated, tegular, serrated cut, or highly textured tiles are not acceptable.
2. Scrubbable room finishes provided in operating rooms and new isolation rooms must have smooth, non-absorptive, non-perforated surfaces that are not physically affected by harsh germicidal cleaning solutions and methods.

9-007.04 Building Systems: Hospitals must have building systems that are designed, installed and operated in such a manner as to provide for the safety, comfort, and well being of the patient.

9-007.04A Water and Sewer Systems: The hospital must have and maintain an accessible, adequate, safe and potable supply of water. Where an authorized public water supply of satisfactory quantity, quality, and pressure is available, the hospital must be connected to it and its supply used exclusively.

9-007.04A1 The collection, treatment, storage, and distribution potable water system of a hospital that regularly serves 25 or more individuals must be constructed, maintained, and operated in accordance with all provisions of the Nebraska Safe Drinking Water Act and Title 179, Regulations Governing Public Water Systems.

9-007.04A2 The collection, treatment, storage and distribution potable water system of a hospital that serves less than 25 individuals on a regular basis must be maintained and operated as if it were a public water system in accordance with the Regulations Governing Public Water Systems, 179 NAC 2-002, 2-003, and 2-004. The facilities must report to the Department the result of all tests that indicate the water is in violation of the standards set out in 179 NAC 2-002 or 2-003. The facilities must construct all water wells in accordance with 178 NAC 12, Water Well Construction, Pump Installation, and Water Well Decommissioning.

9-007.04A3 The water distribution system must be protected with anti-siphon devices, and air-gaps to prevent potable water system and equipment contamination.

9-007.04A4 Continuously circulated filtered and treated water systems must be provided as required for the care and treatment equipment used in the hospital.

9-007.04A5 The hospital must maintain a sanitary and functioning sewage system.

9-007.04B Hot Water System: The hot water system must have the capacity to provide continuous hot water at temperatures as required by these regulations.

9-007.04C Heating and Cooling Systems: The hospital must provide a heating and air conditioning system for the comfort of the patient and capable of maintaining the temperature in patient care and treatment areas as follows:

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.

9-007.04E Electrical System: The hospital must have an electrical system that has sufficient capacity to maintain the care and treatment services that are provided and that properly grounds care and treatment areas.

9-007.04E1 New construction and new facilities must have ground fault circuit interrupters protected outlets in wet areas and within 6 feet of sinks.

9-007.04E2 All facilities must provide minimum illumination levels as follows:

1. General purpose areas: 5 foot candles;
2. General corridors: 10 foot candles;
3. Personal care and dining areas: 20 foot candles;
4. Reading and activity areas: 30 foot candles;
5. Food preparation areas: 40 foot candles;
6. Hazardous work surfaces: 50 foot candles;
7. Care and treatment locations: 70 foot candles;
8. Examination task lighting: 100 foot candles;
9. Procedure task lighting: 200 foot candles;
10. Surgery task lighting: 1000 foot candles; and
11. Reduced night lighting in patient rooms and corridors.

Light levels are measured at 30 inches above the floor in multiple areas in the room being evaluated and the readings are averaged.

9-007.04F Essential Power System: Facilities must have an emergency power generator for all care and treatment locations which involve general anesthetics or electrical life support equipment, and in emergency procedure and treatment rooms.

9-007.04F1 Existing and new facilities must maintain emergency power for essential care and treatment equipment and lighting, medical gas systems, and nurse call systems.

9-007.04F2 New construction must maintain emergency power for essential care and treatment equipment and lighting, medical gas systems, ventilation and heating systems, and nurse call systems.

9-007.04F3 Facilities with electrical life support equipment must maintain essential power systems with an on-site fuel source. The minimum fuel source capacity must allow for non-interrupted system operation.

9-007.04G Call Systems: Call systems must be operable from patient beds (except at psychiatric or mental hospital beds), procedure and operating rooms, and recovery bed and toilet locations. The system must transmit a receivable (visual, audible, tactile, or other) signal to on-duty staff which readily notifies and directs the staff to the location where the call was activated.

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;

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2. Waivers may be granted for a period of time that ends at the time the conditions of approval no longer exist;
3. Waivers may be granted to permit a hospital time to come into compliance with the physical plan standards for a period of one year. Upon submission of proof of ongoing progress, the waiver may be continued for an additional year; and
4. An applicant or licensee must submit a request for waiver of any construction or physical plant requirements set forth in 175 NAC 9. An applicant for a waiver may construct a request for waiver form or obtain a form from the Department.

9-007.05C Denial of Waiver: If the Department denies a hospital's request for waiver, the facility may request an administrative hearing as provided in the Administrative Procedure Act (APA) and the Department's rules and regulations adopted and promulgated under the APA.

9-008 DENIAL, REFUSAL TO RENEW, OR DISCIPLINARY ACTION

9-008.01 Grounds for Denial, Refusal to Renew, or Disciplinary Action

9-008.01A The Department may deny or refuse to renew a hospital license for failure to meet the requirements for licensure, including:

1. Failing an inspection specified in 175 NAC 9-005;
2. Having had a license revoked within the two-year period preceding an application; or
3. Any of the grounds specified in 175 NAC 9-008.01B.

9-008.01B The Department may take disciplinary action against a hospital license for any of the following grounds:

1. Violation of any of the provisions of the Health Care Facility Licensure Act or 175 NAC 9;
2. Committing, permitting, aiding, or abetting the commission of any unlawful act;
3. Conduct or practices detrimental to the health or safety of a hospital patient or employee;
4. A report from an accreditation body or public agency sanctioning, modifying, terminating, or withdrawing the accreditation or certification of the hospital;
5. Failure to allow an agent or employee of 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 access to the hospital for the purposes of inspection, investigation, or other information collection activities necessary to carry out the duties of the Departments;

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.

9-008.02C2 Within 20 working days of the conference, the Department representative will state in writing the specific reasons for affirming, modifying, or dismissing the notice. The representative will send a copy of the statement to the applicant or licensee by certified mail to the last address shown in the Department's records and a copy to the Director.

9-008.02C3 If the applicant or licensee successfully demonstrates at the informal conference that the deficiencies should not have been cited in the notice, the Department will remove the deficiencies from the notice and rescind any sanction imposed solely as a result of those cited deficiencies.

9-008.02C4 If the applicant or licensee contests the affirmed or modified notice, the applicant or licensee must submit a request for hearing in writing to the Director within five working days after receipt of the statement.

9-008.02D Administrative Hearing

9-008.02D1 When an applicant or a licensee contests the notice and request a hearing, the Department will hold a 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.

9-008.02D2 On the basis of evidence presented at the hearing, the Director will affirm, modify, or set aside the determination. The Director's decision will:

1. Be in writing;
2. Be sent by registered or certified mail to the applicant or licensee; and
3. Become final 30 days after mailing unless the applicant or licensee, within the 30-day period, appeals the decision.

9-008.02D3 An applicant or a licensee's appeal of the Director's decision must be in accordance with the APA.

9-008.03 Types of Disciplinary Action

9-008.03A The Department may impose any one or a combination of the following types of disciplinary action against the license :

1. A fine not to exceed \$10,000 per violation;
2. A prohibition on admissions or re-admissions, a limitation on enrollment, or a prohibition or limitation on the provision of care or treatment;
3. A period of probation not to exceed two years during which the hospital may continue to operate under terms and conditions fixed by the order of probation;
4. A period of suspension not to exceed three years during which the hospital may not operate; and

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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:

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1. Order the revocation, suspension, or limitation of the license, or
2. Set aside the temporary suspension or temporary limitation.

If the Director does not reach a decision within 90 days of the date of the temporary suspension or temporary limitation, the temporary suspension or temporary limitation will expire.

9-008.03D4 Any appeal of the Department's decision after hearing must be in accordance with the APA.

9-008.04 Reinstatement from Disciplinary Probation or Suspension, and Re-Licensure After Revocation

9-008.04A Reinstatement at the End of Probation or Suspension

9-008.04A1 Reinstatement at the End of Probation: A license may be reinstated at the end of probation after the successful completion of an inspection, if the Department determines an inspection is warranted.

9-008.04A2 Reinstatement at the End of Suspension: A license may be reinstated at the end of suspension following:

1. Submission of an application to the Department for renewal that conforms to the requirements of 175 NAC 9-003.02;
2. Payment of the renewal fee as specified in 175 NAC 9-004.10; and
3. Successful completion of an inspection.

The Department will reinstate the license when it finds, based on an inspection as provided for in 175 NAC 9-005, that the hospital is in compliance with the operation, care, treatment, and physical plant requirements of 175 NAC 9-006 and 9-007.

9-008.04B Reinstatement Prior to Completion of Probation or Suspension

9-008.04B1 Reinstatement Prior to the Completion of Probation: A licensee may request reinstatement prior to the completion of probation 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 probation completion date; and
 - b. The corrective action taken to prevent recurrence of the violation(s) that served as the basis of the probation; and
2. Successfully complete any inspection the Department determines necessary.

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.

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ATTACHMENTS

42 CFR 485.601 to 485.641
(Critical Access Hospitals)

and

42 CFR 482.60 to 482.62
(Psychiatric Hospitals)

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(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 CORF.

[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]

§ 485.604

§ 485.604 Personnel qualifications.

Staff that furnish services in a CAH must meet the applicable requirements of this section.

(a) *Clinical nurse specialist.* A clinical nurse specialist must be a person who performs the services of a clinical nurse specialist as authorized by the State, in accordance with State law or the State regulatory mechanism provided by State law.

(b) *Nurse practitioner.* A nurse practitioner must be a registered professional nurse who is currently licensed to practice in the State, who meets the State's requirements governing the qualification of nurse practitioners, and who meets one of the following conditions:

(1) Is currently certified as a primary care nurse practitioner by the American Nurses' Association or by the National Board of Pediatric Nurse Practitioners and Associates.

(2) Has successfully completed a 1 academic year program that—

(i) Prepares registered nurses to perform an expanded role in the delivery of primary care;

(ii) Includes at least 4 months (in the aggregate) of classroom instruction and a component of supervised clinical practice; and

(iii) Awards a degree, diploma, or certificate to persons who successfully complete the program.

(3) Has successfully completed a formal educational program (for preparing registered nurses to perform an expanded role in the delivery of primary care) that does not meet the requirements of paragraph (a)(2) of this section, and has been performing an expanded role in the delivery of primary care for a total of 12 months during the 18-month period immediately preceding June 25, 1993.

(c) *Physician assistant.* A physician assistant must be a person who meets the applicable State requirements governing the qualifications for assistants to primary care physicians, and who meets at least one of the following conditions:

(1) Is currently certified by the National Commission on Certification of Physician Assistants to assist primary care physicians.

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(2) Has satisfactorily completed a program for preparing physician assistants that—

(i) Was at least one academic year in length;

(ii) Consisted of supervised clinical practice and at least 4 months (in the aggregate) of classroom instruction directed toward preparing students to deliver health care; and

(iii) Was accredited by the American Medical Association's Committee on Allied Health Education and Accreditation.

(3) Has satisfactorily completed a formal educational program (for preparing physician assistants) that does not meet the requirements of paragraph (c)(2) of this section and has been assisting primary care physicians for a total of 12 months during the 18-month period immediately preceding June 25, 1993.

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

§ 485.606 Designation and certification of CAHs.

(a) *Criteria for State designation.* (1) A State that has established a Medicare rural hospital flexibility program described in section 1820(c) of the Act may designate one or more facilities as CAHs if each facility meets the CAH conditions of participation in this subpart F.

(2) The State must not deny any hospital that is otherwise eligible for designation as a CAH under this paragraph (a) solely because the hospital has entered into an agreement under which the hospital may provide posthospital SNF care as described in § 482.66 of this chapter.

(b) *Criteria for CMS certification.* CMS certifies a facility as a CAH if—

(1) The facility is designated as a CAH by the State in which it is located and has been surveyed by the State survey agency or by CMS and found to meet all conditions of participation in this Part and all other applicable requirements for participation in Part 489 of this chapter.

(2) The facility is a medical assistance facility operating in Montana or a rural primary care hospital designated by CMS before August 5, 1997, and is otherwise eligible to be designated as a

CAH by the State under the rules in this subpart.

[62 FR 46036, Aug. 29, 1997, as amended at 63 FR 26350, 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, 1990; 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

that has a necessary provider designation from the State that was in effect prior to January 1, 2006, and relocates its facility after January 1, 2006, can continue to meet the location requirement of paragraph (c) of this section based on the necessary provider designation only if the relocated facility meets the requirements as specified in paragraph (d)(1) of this section.

(1) If a necessary provider CAH relocates its facility and begins providing services in a new location, the CAH can continue to meet the location requirement of paragraph (c) of this section based on the necessary provider designation only if the CAH in its new location—

(i) Serves at least 75 percent of the same service area that it served prior to its relocation;

(ii) Provides at least 75 percent of the same services that it provided prior to the relocation; and

(iii) Is staffed by 75 percent of the same staff (including medical staff, contracted staff, and employees) that were on staff at the original location.

(2) If a CAH that has been designated as a necessary provider by the State begins providing services at another location after January 1, 2006, and does not meet the requirements in paragraph (d)(1) of this section, the action will be considered a cessation of business as described in § 489.52(b)(3).

[62 FR 46036, Aug. 29, 1997, as amended at 65 FR 47052, Aug. 1, 2000; 66 FR 39938, Aug. 1, 2001; 69 FR 49271, Aug. 11, 2004; 69 FR 60252, Oct. 7, 2004; 70 FR 47490, Aug. 12, 2005]

§ 485.612 Condition of participation: Compliance with hospital requirements at the time of application.

Except for recently closed facilities as described in § 485.610(a)(2), or health clinics or health centers as described in § 485.610(a)(3), the facility is a hospital that has a provider agreement to participate in the Medicare program as a hospital at the time the hospital applies for designation as a CAH.

[66 FR 32196, June 13, 2001]

§ 485.616 Condition of participation: Agreements.

(a) *Standard: Agreements with network hospitals.* In the case of a CAH that is a member of a rural health network as

defined in § 485.603 of this chapter, the CAH has in effect an agreement with at least one hospital that is a member of the network for—

(1) Patient referral and transfer;

(2) The development and use of communications systems of the network, including the network's system for the electronic sharing of patient data, and telemetry and medical records, if the network has in operation such a system; and

(3) The provision of emergency and nonemergency transportation between the facility and the hospital.

(b) *Standard: Agreements for credentialing and quality assurance.* Each CAH that is a member of a rural health network shall have an agreement with respect to credentialing and quality assurance with at least—

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

(2) One QIO or equivalent entity; or

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

[62 FR 46036, Aug. 29, 1997]

§ 485.618 Condition of participation: Emergency services.

The CAH provides emergency care necessary to meet the needs of its inpatients and outpatients.

(a) *Standard: Availability.* Emergency services are available on a 24-hours a day basis.

(b) *Standard: Equipment, supplies, and medication.* Equipment, supplies, and medication used in treating emergency cases are kept at the CAH and are readily available for treating emergency cases. The items available must include the following:

(1) *Drugs and biologicals* commonly used in life-saving procedures, including analgesics, local anesthetics, antibiotics, anticonvulsants, antidotes and emetics, serums and toxoids, antiarrhythmics, cardiac glycosides, antihypertensives, diuretics, and electrolytes and replacement solutions.

(2) *Equipment and supplies* commonly used in life-saving procedures, including airways, endotracheal tubes, ambu bag/valve/mask, oxygen, tourniquets, immobilization devices, nasogastric tubes, splints, IV therapy supplies, suction machine, defibrillator, cardiac

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

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emergency calls, provide information on treatment of emergency patients, and refer patients to the CAH or other appropriate locations for treatment.

[58 FR 30671, May 26, 1993, as amended at 62 FR 46037, Aug. 29, 1997; 64 FR 41544, July 30, 1999; 67 FR 80041, Dec. 31, 2002; 69 FR 49271, Aug. 11, 2004]

§ 485.620 Condition of participation: Number of beds and length of stay.

(a) *Standard: Number of beds.* Except as permitted for CAHs having distinct part units under § 485.647, the CAH maintains no more than 25 inpatient beds after January 1, 2004, that can be used for either inpatient or swing-bed services.

(b) *Standard: Length of stay.* The CAH provides acute inpatient care for a period that does not exceed, on an annual average basis, 96 hours per patient.

[62 FR 46036, Aug. 29, 1997, as amended at 65 FR 47052, Aug. 1, 2000; 69 FR 49271, Aug. 11, 2004; 69 FR 60252, Oct. 7, 2004]

§ 485.623 Condition of participation: Physical plant and environment.

(a) *Standard: Construction.* The CAH is constructed, arranged, and maintained to ensure access to and safety of patients, and provides adequate space for the provision of direct services.

(b) *Standard: Maintenance.* The CAH has housekeeping and preventive maintenance programs to ensure that—

(1) All essential mechanical, electrical, and patient-care equipment is maintained in safe operating condition;

(2) There is proper routine storage and prompt disposal of trash;

(3) Drugs and biologicals are appropriately stored;

(4) The premises are clean and orderly; and

(5) There is proper ventilation, lighting, and temperature control in all pharmaceutical, patient care, and food preparation areas.

(c) *Standard: Emergency procedures.* The CAH assures the safety of patients in non-medical emergencies by—

(1) Training staff in handling emergencies, including prompt reporting of fires, extinguishing of fires, protection and, where necessary, evacuation of patients, personnel, and guests, and cooperation with fire fighting and disaster authorities;

(2) Providing for emergency power and lighting in the emergency room and for battery lamps and flashlights in other areas;

(3) Providing for an emergency fuel and water supply; and

(4) Taking other appropriate measures that are consistent with the particular conditions of the area in which the CAH is located.

(d) *Standard: Life safety from fire.* (1) Except as otherwise provided in this section—

(i) The CAH must meet the applicable provisions of the 2000 edition of the Life Safety Code of the National Fire Protection Association. The Director of the Office of the Federal Register has approved the NFPA 101® 2000 edition of the Life Safety Code, issued January 14, 2000, for incorporation by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. A copy of the Code is available for inspection at the CMS Information Resource Center, 7500 Security Boulevard, Baltimore, MD or at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202-741-6030, or go to: http://www.archives.gov/federal_registered_code_of_federal_regulations/1br_locations.html. Copies may be obtained from the National Fire Protection Association, 1 Batterymarch Park, Quincy, MA 02260. If any changes in this edition of the Code are incorporated by reference, CMS will publish notice in the FEDERAL REGISTER to announce the changes.

(ii) Chapter 10.3.6.3.2, exception number 2 of the adopted edition of the Life Safety Code does not apply to a CAH.

(2) If CMS finds that the State has a fire and safety code imposed by State law that adequately protects patients, CMS may allow the State survey agency to apply the State's fire and safety code instead of the LSC.

(3) After consideration of State survey agency findings, CMS may waive specific provisions of the Life Safety Code that, if rigidly applied, would result in unreasonable hardship on the CAH, but only if the waiver does not adversely affect the health and safety of patients.

(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 02260. 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;

(ii) In conjunction with the physician assistant and/or nurse practitioner member(s), participates in developing, executing, and periodically reviewing the CAH's written policies governing the services it furnishes.

(iii) In conjunction with the physician assistant and/or nurse practitioner members, periodically reviews the CAH's patient records, provides medical orders, and provides medical care services to the patients of the CAH; and

(iv) Periodically reviews and signs the records of patients cared for by nurse practitioners, clinical nurse specialists, or physician assistants.

(2) A doctor of medicine or osteopathy is present for sufficient periods of time, at least once in every 2 week period (except in extraordinary circumstances) to provide the medical direction, medical care services, consultation, and supervision described in this paragraph, and is available through direct radio or telephone communication for consultation, assistance with medical emergencies, or patient referral. The extraordinary circumstances are documented in the records of the CAH. A site visit is not required if no patients have been treated since the latest site visit.

(c) *Standard: Physician assistant, nurse practitioner, and clinical nurse specialist responsibilities.* (1) The physician assistant, the nurse practitioner, or clinical nurse specialist members of the CAH's staff—

(i) Participate in the development, execution and periodic review of the written policies governing the services the CAH furnishes; and

(ii) Participate with a doctor of medicine or osteopathy in a periodic review of the patients' health records.

(2) The physician assistant, nurse practitioner, or clinical nurse specialist performs the following functions to the extent they are not being performed by a doctor of medicine or osteopathy:

(i) Provides services in accordance with the CAH's policies.

(ii) Arranges for, or refers patients to, needed services that cannot be furnished at the CAH, and assures that adequate patient health records are

maintained and transferred as required when patients are referred.

(3) Whenever a patient is admitted to the CAH by a nurse practitioner, physician assistant, or clinical nurse specialist, a doctor of medicine or osteopathy on the staff of the CAH is notified of the admission.

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

§ 485.635 Condition of participation: Provision of services.

(a) *Standard: Patient care policies.* (1) The CAH's health care services are furnished in accordance with appropriate written policies that are consistent with applicable State law.

(2) The policies are developed with the advice of a group of professional personnel that includes one or more doctors of medicine or osteopathy and one or more physician assistants, nurse practitioners, or clinical nurse specialists, if they are on staff under the provisions of § 485.631(a)(1): at least one member is not a member of the CAH staff.

(3) The policies include the following: (1) A description of the services the CAH furnishes directly and those furnished through agreement or arrangement.

(ii) Policies and procedures for emergency medical services.

(iii) Guidelines for the medical management of health problems that include the conditions requiring medical consultation and/or patient referral, the maintenance of health care records, and procedures for the periodic review and evaluation of the services furnished by the CAH.

(iv) Rules for the storage, handling, dispensation, and administration of drugs and biologicals. These rules must provide that there is a drug storage area that is administered in accordance with accepted professional principles, that current and accurate records are kept of the receipt and disposition of all scheduled drugs, and that outdated, mislabeled, or otherwise unusable drugs are not available for patient use.

(v) Procedures for reporting adverse drug reactions and errors in the administration of drugs.

(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(l) 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.

(2) A registered nurse or, where permitted by State law, a physician assistant, must supervise and evaluate the nursing care for each patient, including patients at a SNF level of care in a swing-bed CAH.

(3) All drugs, biologicals, and intravenous medications must be administered by or under the supervision of a registered nurse, a doctor of medicine or osteopathy, or, where permitted by State law, a physician assistant, in accordance with written and signed orders, accepted standards of practice, and Federal and State laws.

(4) A nursing care plan must be developed and kept current for each inpatient.

[58 FR 30671, May 26, 1993; 58 FR 40935, Sept. 24, 1993, as amended at 59 FR 45403, Sept. 1, 1994; 62 FR 46037, Aug. 29, 1997]

§ 485.638 Conditions of participation: Clinical records.

(a) *Standard: Records system.*—(1) The CAH maintains a clinical records system in accordance with written policies and procedures.

(2) The records are legible, complete, accurately documented, readily accessible, and systematically organized.

(3) A designated member of the professional staff is responsible for maintaining the records and for ensuring that they are completely and accurately documented, readily accessible, and systematically organized.

(4) For each patient receiving health care services, the CAH maintains a record that includes, as applicable—

(i) Identification and social data, evidence of properly executed informed consent forms, pertinent medical history, assessment of the health status and health care needs of the patient, and a brief summary of the episode, disposition, and instructions to the patient;

(ii) Reports of physical examinations, diagnostic and laboratory test results, including clinical laboratory services, and consultative findings;

(iii) All orders of doctors of medicine or osteopathy or other practitioners, reports of treatments and medications, nursing notes and documentation of complications, and other pertinent information necessary to monitor the patient's progress, such as temperature

graphics, progress notes describing the patient's response to treatment; and

(iv) Dated signatures of the doctor of medicine or osteopathy or other health care professional.

(b) *Standard: Protection of record information.*—(1) The CAH maintains the confidentiality of record information and provides safeguards against loss, destruction, or unauthorized use.

(2) Written policies and procedures govern the use and removal of records from the CAH and the conditions for the release of information.

(3) The patient's written consent is required for release of information not required by law.

(c) *Standard: Retention of records.* The records are retained for at least 6 years from date of last entry, and longer if required by State statute, or if the records may be needed in any pending proceeding.

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

§ 485.639 Condition of participation: Surgical services.

Surgical procedures must be performed in a safe manner by qualified practitioners who have been granted clinical privileges by the governing body of the CAH in accordance with the designation requirements under paragraph (a) of this section.

(a) *Designation of qualified practitioners.* The CAH designates the practitioners who are allowed to perform surgery for CAH patients, in accordance with its approved policies and procedures, and with State scope of practice laws. Surgery is performed only by—

(1) A doctor of medicine or osteopathy, including an osteopathic practitioner recognized under section 1101(a)(7) of the Act;

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

(3) A doctor of podiatric medicine.

(b) *Anesthetic risk and evaluation.* (1) A qualified practitioner, as specified in paragraph (a) of this section, must examine the patient immediately before surgery to evaluate the risk of the procedure to be performed.

(2) A qualified practitioner, as specified in paragraph (c) of this section, must examine each patient before surgery to evaluate the risk of anesthesia.

(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 39038, Aug. 1, 2001; 66 FR 56760, 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;

(4) The quality and appropriateness of the diagnosis and treatment furnished by doctors of medicine or osteopathy at the CAH are evaluated by—

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

(ii) One QIO or equivalent entity; or

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

(5)(i) The CAH staff considers the findings of the evaluations, including any findings or recommendations of the QIO, and takes corrective action if necessary.

(ii) The CAH also takes appropriate remedial action to address deficiencies found through the quality assurance program.

(iii) The CAH documents the outcome of all remedial action.

[58 FR 30671, May 26, 1993, as amended at 62 FR 46037, Aug. 29, 1997; 63 FR 26359, May 12, 1998]

§ 485.643 Condition of participation: Organ, tissue, and eye procurement.

The CAH must have and implement written protocols that:

(a) Incorporate an agreement with an OPO designated under part 486 of this chapter, under which it must notify, in a timely manner, the OPO or a third party designated by the OPO of individuals whose death is imminent or who have died in the CAH. The OPO determines medical suitability for organ donation and, in the absence of alternative arrangements by the CAH, the OPO determines medical suitability for tissue and eye donation, using the definition of potential tissue and eye donor and the notification protocol developed in consultation with the tissue and eye banks identified by the CAH for this purpose;

(b) Incorporate an agreement with at least one tissue bank and at least one eye bank to cooperate in the retrieval, processing, preservation, storage and distribution of tissues and eyes, as may be appropriate to assure that all usable tissues and eyes are obtained from potential donors, insofar as such an agreement does not interfere with organ procurement;

(c) Ensure, in collaboration with the designated OPO, that the family of each potential donor is informed of its

option to either donate or not donate organs, tissues, or eyes. The individual designated by the CAH to initiate the request to the family must be a designated requestor. A designated requestor is an individual who has completed a course offered or approved by the OPO and designed in conjunction with the tissue and eye bank community in the methodology for approaching potential donor families and requesting organ or tissue donation;

(d) Encourage discretion and sensitivity with respect to the circumstances, views, and beliefs of the families of potential donors;

(e) Ensure that the CAH works cooperatively with the designated OPO, tissue bank and eye bank in educating staff on donation issues, reviewing death records to improve identification of potential donors, and maintaining potential donors while necessary testing and placement of potential donated organs, tissues, and eyes take place.

(f) For purposes of these standards, the term "organ" means a human kidney, liver, heart, lung, pancreas, or intestines (or multivisceral organs).

[65 FR 47110, Aug. 1, 2000, as amended at 66 FR 30938, Aug. 1, 2001]

§ 485.645 Special requirements for CAH providers of long-term care services ("swing-beds")

A CAH must meet the following requirements in order to be granted an approval from CMS to provide post-hospital SNF care, as specified in § 409.30 of this chapter, and to be paid for SNF-level services, in accordance with paragraph (c) of this section.

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

(1) The facility has been certified as a CAH by CMS under § 485.606(b) of this subpart; and

(2) The facility provides not more than 25 inpatient beds. Any bed of a unit of the facility that is licensed as a distinct-part SNF at the time the facility applies to the State for designation as a CAH is not counted under paragraph (a) of this section.

(b) *Facilities participating as rural primary care hospitals (RPCHs) on September 30, 1997.* These facilities must meet the following requirements:

(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;

(iv) The responsibilities of each member of the treatment team; and

(v) Adequate documentation to justify the diagnosis and the treatment and rehabilitation activities carried out.

(2) The treatment received by the patient must be documented in such a way to assure that all active therapeutic efforts are included.

(d) *Standard: Recording progress.* Progress notes must be recorded by the doctor of medicine or osteopathy responsible for the care of the patient as specified in § 482.12(c), nurse, social worker and, when appropriate, others significantly involved in active treatment modalities. The frequency of progress notes is determined by the condition of the patient but must be recorded at least weekly for the first 2 months and at least once a month thereafter and must contain recommendations for revisions in the treatment plan as indicated as well as precise assessment of the patient's progress in accordance with the original or revised treatment plan.

(e) *Standard: Discharge planning and discharge summary.* The record of each patient who has been discharged must have a discharge summary that includes a recapitulation of the patient's hospitalization and recommendations from appropriate services concerning follow-up or aftercare as well as a brief summary of the patient's condition on discharge.

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

§ 482.62 Condition of participation: Special staff requirements for psychiatric hospitals.

The hospital must have adequate numbers of qualified professional and supportive staff to evaluate patients, formulate written, individualized comprehensive treatment plans, provide active treatment measures, and engage in discharge planning.

(a) *Standard: Personnel.* The hospital must employ or undertake to provide adequate numbers of qualified professional, technical, and consultative personnel to:

- (1) Evaluate patients;
- (2) Formulate written individualized, comprehensive treatment plans;

(3) Provide active treatment measures; and

(4) Engage in discharge planning.

(b) *Standard: Director of inpatient psychiatric services; medical staff.* Inpatient psychiatric services must be under the supervision of a clinical director, service chief, or equivalent who is qualified to provide the leadership required for an intensive treatment program. The number and qualifications of doctors of medicine and osteopathy must be adequate to provide essential psychiatric services.

(1) The clinical director, service chief, or equivalent must meet the training and experience requirements for examination by the American Board of Psychiatry and Neurology or the American Osteopathic Board of Neurology and Psychiatry.

(2) The director must monitor and evaluate the quality and appropriateness of services and treatment provided by the medical staff.

(c) *Standard: Availability of medical personnel.* Doctors of medicine or osteopathy and other appropriate professional personnel must be available to provide necessary medical and surgical diagnostic and treatment services. If medical and surgical diagnostic and treatment services are not available within the institution, the institution must have an agreement with an outside source of these services to ensure that they are immediately available or a satisfactory agreement must be established for transferring patients to a general hospital that participates in the Medicare program.

(d) *Standard: Nursing services.* The hospital must have a qualified director of psychiatric nursing services. In addition to the director of nursing, there must be adequate numbers of registered nurses, licensed practical nurses, and mental health workers to provide nursing care necessary under each patient's active treatment program and to maintain progress notes on each patient.

(1) The director of psychiatric nursing services must be a registered nurse who has a master's degree in psychiatric or mental health nursing, or its equivalent from a school of nursing accredited by the National League for Nursing, or be qualified by education

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-

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).