

CHAPTER 33-07-01.1 HOSPITALS

Section

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33-07-01.1-01. General provisions - Definitions.

1. Institutions covered by medical hospital licensure laws. The following types of institutions are covered by North Dakota Century Code chapter 23-16 for the purpose of rules and are deemed to come within the provisions of North Dakota Century Code section 23-16-01 which provides for licensure of any institution that maintains and operates organized facilities for the diagnosis, treatment, or care of two or more nonrelated persons suffering from illness, injury, or deformity or where obstetrical or other care is rendered over a period exceeding twenty-four hours:
 - a. General acute, primary care, and specialized hospitals, including rehabilitation, psychiatric, and outpatient birth hospitals.

- b. Skilled nursing facilities and nursing facilities.
 - c. Outpatient facilities, including surgical centers and trauma centers, excluding physicians' clinics.
 - d. Maternity homes that receive more than one patient in six months.
2. Institutions not covered by medical hospital licensure laws. The following types of institutions that provide some medical or nursing service are deemed not to come within the provisions of North Dakota Century Code chapter 23-16:
- a. Any institutions that are regularly licensed by the social service board of North Dakota, such as homes for unmarried mothers.
 - b. Federal and state institutions. For state institutions, the primary purpose of which is the provision of medical care, the department has the responsibility for inspection on the same basis as those institutions that are covered by North Dakota Century Code chapter 23-16. Upon the findings of such inspections, recommendations will be formulated by the department.
 - c. Chiropractic hospitals licensed under North Dakota Century Code chapter 23-17.
 - d. Homes in which the only persons receiving nursing care are those related to the householder by blood or marriage.
 - e. Homes in which only one person receives care at any one time.
3. An institution shall hold licensure in the same category for which it seeks federal certification.
4. The following terms are defined for purposes of this chapter and North Dakota Century Code chapter 23-16:
- a. "Abuse" includes mental, physical, sexual, and verbal abuse which would result in temporary or permanent mental or physical injury, harm, or ultimately death. Mental abuse includes humiliation, harassment, threats of punishment, or deprivation. Physical abuse includes hitting, slapping, pinching, and kicking. It also includes controlling behavior through corporal punishment. Sexual abuse includes sexual harassment, sexual coercion, sexual contact, or sexual assault. Verbal abuse includes any use of oral, written, or gestured language that includes disparaging and derogatory terms to patients or their families used within their hearing distance to describe the patients, regardless of their age, ability to comprehend, or disability.
 - b. "Acute care" means care for an episode of illness, injury, deformity, or pregnancy which may have a rapid onset or be severe in nature or have a short duration which requires medical treatment and continuous nursing care in a hospital setting.
 - c. "Authentication" means identification of the individual who made the medical record entry by that individual in writing, and verification that the contents are what the individual intended.
 - d. "Bed capacity" is bed space designed for inpatient care.
 - (1) Areas to be included:
 - (a) Bed space in all nursing units, including:
 - [1] Intensive care or cardiac care units.

- [2] Minimal or self-care units.
- (b) Isolation units.
- (c) Pediatrics units, including:
 - [1] Pediatric bassinets.
 - [2] Incubators located in the pediatrics department.
- (2) Areas to be excluded:
 - (a) Newborn nurseries in the obstetrical department.
 - (b) Labor and delivery rooms.
 - (c) Recovery rooms.
 - (d) Emergency units.
 - (e) Preparation or anesthesia induction rooms.
 - (f) Rooms designed for diagnostic or treatment procedures.
 - (g) Hospital staff sleeping quarters, including accommodations for oncall staff.
- e. "Department" means the North Dakota state department of health.
- f. "Governing body" means the individual or group in whom the ultimate authority and legal responsibility is vested for the conduct of the institution.
- g. "Hospital" means a facility that provides continuous nursing services, the principal activity or business of which is the reception of a person for diagnosis, medical care, and treatment of human illness to meet the needs of the patient served.
 - (1) "General acute hospital" means a facility with physician services available, permanent facilities that include inpatient beds, and continuous registered nurse staffing on a twenty-four-hour basis for treatment or care for illness, injury, deformity, abnormality, or pregnancy.
 - (a) In addition to medical staff and nursing services, the hospital shall regularly maintain either directly or through agreement the following services to meet the needs of the patients served:
 - [1] Dietary services.
 - [2] Medical records services.
 - [3] Pharmaceutical services.
 - [4] Laboratory services.
 - [5] Radiology services.
 - [6] Emergency services.
 - [7] Social services.
 - [8] Basic rehabilitation services.

[9] Housekeeping and related services including laundry.

[10] Central services.

(b) Complementary services are optional services that the hospital may provide and include:

[1] Nuclear medicine services.

[2] Surgical services.

[3] Recovery services.

[4] Anesthesia services.

[5] Respiratory care services.

[6] Obstetrical services.

[7] Specialized rehabilitation services.

[8] Psychiatric services.

[9] Outpatient birth services.

(2) "Primary care hospital" means a facility that has available twenty-four-hour licensed health care practitioner and nursing services, provides inpatient care to ill or injured persons prior to their transportation to a general acute hospital, or provides inpatient care to persons needing acute-type care for a period of no longer than an average of ninety-six hours, excluding persons participating in a federal swing-bed program.

(a) In addition to medical staff and nursing services, the hospital shall regularly maintain either directly or through agreement the following services to meet the needs of the patients served:

[1] Dietary services.

[2] Medical records services.

[3] Pharmaceutical services.

[4] Laboratory services.

[5] Radiology services.

[6] Emergency services.

[7] Social services.

[8] Basic rehabilitation services.

[9] Housekeeping and related services including laundry.

[10] Central services.

(b) Complementary services are optional services which the hospital may provide and include:

[1] Nuclear medicine services.

- [2] Surgical services.
 - [3] Recovery services.
 - [4] Anesthesia services.
 - [5] Respiratory care services.
 - [6] Obstetrical services.
- (3) "Specialized hospital" means a facility with hospital characteristics which provides medical care for persons with a categorical illness or condition.
- (a) In addition to medical staff and nursing services, the hospital shall regularly provide directly or through agreement the following services to meet the needs of the patients served:
- [1] Dietary services.
 - [2] Medical records services.
 - [3] Pharmaceutical services.
 - [4] Laboratory services.
 - [5] Radiology services.
 - [6] Emergency services.
 - [7] Social services.
 - [8] Basic rehabilitation services.
 - [9] Housekeeping and related services including laundry.
 - [10] Central services.
- (b) Complementary services are optional services which the hospital may provide and include:
- [1] Nuclear medicine services.
 - [2] Surgical services.
 - [3] Recovery services.
 - [4] Anesthesia services.
 - [5] Respiratory care services.
 - [6] Obstetrical services.
- (c) Hospitals meeting the definition of a specialized hospital shall be licensed as such and may include the following:
- [1] "Psychiatric hospital" means a facility or unit providing psychiatric services to patients with a diagnosis of mental illness. A psychiatric hospital is a hospital licensed to provide only psychiatric services or is a distinct unit providing only psychiatric services located in a general acute

hospital. Psychiatric hospitals must provide services consistent with section 33-07-01-36.

[2] "Rehabilitation hospital" means a facility or unit providing specialized rehabilitation services to patients for the alleviation or amelioration of the disabling effects of illness or injury. Specialized rehabilitation services are characterized by the coordinated delivery of interdisciplinary care intended to achieve the goals of maximizing the self-sufficiency of the patient. A rehabilitation hospital is a facility licensed to provide only specialized rehabilitation services or is a distinct unit providing only specialized rehabilitation services located in a general acute hospital. A rehabilitation hospital must arrange to provide the services identified in section 33-07-01-35.

[3] "Outpatient birth hospital" means a facility, separate from acute obstetric and newborn care, providing outpatient obstetrical, birthing, and neonatal services to patients. Outpatient birth services are organized to provide maternity care in which births are planned to occur in a setting away from the mother's usual residence following a low-risk pregnancy with anticipation of a low-risk birth. Low-risk pregnancy and birth means a normal uncomplicated birth as defined by generally accepted criteria of maternal and fetal health. A low-risk pregnancy and birth must be full term, singleton, and multipara, with vertex presentation.

- h. "Level I nursery" means a well newborn nursery, consistent with American academy of pediatrics standards, providing a basic level of care to neonates who are low risk.
- i. "Level II nursery" means a special care nursery, consistent with American academy of pediatrics standards, for stable or moderately ill newborn infants who are born at greater than or equal to thirty-two weeks gestation or who weigh greater than or equal to one thousand five hundred grams at birth with problems that are expected to resolve rapidly and who would not be anticipated to need subspecialty-level services on an urgent basis.
- j. "Level III nursery" means a neonatal intensive care unit, consistent with American academy of pediatrics standards, for infants who are born at less than thirty-two weeks gestation, weigh less than one thousand five hundred grams at birth, or have medical or surgical conditions.
- k. "Licensed health care practitioner" means an individual who is licensed or certified to provide medical, medically related, or advanced registered nursing care to individuals in North Dakota.
- l. "Licensee" means an individual, officer, or member of the governing body of a hospital or related institution.
- m. "Medical staff" in general acute and specialized hospitals means a formal organization of physicians (and dentists) and may include other licensed health care practitioners with the delegated authority and responsibility to maintain proper standards of patient care and to plan for continued improvement of that care. Medical staff in primary care hospitals means one or more licensed health care practitioners with the delegated authority and responsibility to maintain proper standards of medical care and to plan for continued improvement of that care.
- n. "Misappropriation of patient property" means the deliberate misplacement, exploitation, or wrongful temporary or permanent taking or use of a patient's belongings or money, or both.

- o. "Neglect" includes one severe incident or a pattern of incidents of willful failure to carry out patient services as directed or ordered by the licensed health care practitioner, willful failure to give proper attention to patients, or failure to carry out patient services through careless oversight.
- p. "Nursing facilities" are the following:
 - (1) "Basic care facility" means a facility consistent with North Dakota Century Code chapter 23-09.3 and North Dakota Administrative Code chapter 33-03-24.
 - (2) "Nursing facility" means a facility consistent with North Dakota Century Code chapter 23-16 and North Dakota Administrative Code chapters 33-07-03.1 and 33-07-04.1.
- q. "Outpatient facility" (including ambulatory surgical centers and trauma centers - excluding physicians' clinic) means a facility, located in or apart from a hospital; providing community service for the diagnosis or diagnosis and treatment of ambulatory patients (including ambulatory inpatients) in need of physical or mental care:
 - (1) Which is operated in connection with a hospital; or
 - (2) Which offers to patients not requiring hospitalization the services of licensed health care practitioners in various medical specialties, and which makes provision for its patients to receive a reasonably full range of diagnostic and treatment services.
- r. "Qualified activities coordinator" means a qualified therapeutic recreation specialist who is eligible for registration as a therapeutic recreation specialist by the national therapeutic recreation society (branch of national recreation and park association) under its requirements; is a qualified occupational therapist as defined in North Dakota Century Code chapter 43-40; is certified as an occupational therapist assistant; or has two years of experience in a social or recreational program within the last five years, one year of which was as a full-time employee in a patient activities program in a health care setting; or has completed a training course approved by the department.
- s. "Separate license for building on separate premises" means, in the case of a hospital or related institution where two or more buildings are used in the housing of patients, a separate license is required for each building. Separate licenses are required even though the buildings may be operated under the same management.
- t. "Signature" means the name of the individual written by the individual or an otherwise approved identification mechanism used by the individual which may include the approved use of a rubber stamp or an electronic signature.
- u. "Writing" means the use of any tangible medium for entries into the medical record, including ink or electronic or computer coding, unless otherwise specifically required.

History: Effective April 1, 1994; amended effective August 1, 1999; May 1, 2001; July 1, 2017.

General Authority: NDCC 23-01-03(3), 28-32-02

Law Implemented: NDCC 23-16-06, 31-08-01.2, 31-08-01.3

33-07-01.1-02. Issuance of license.

The department shall issue licenses to hospitals that meet the licensing requirements. The license must reflect the annual or provisional status of the hospital. The license applies only to the hospital designated on the license.

1. The department shall issue an annual license to a hospital when that hospital is in full compliance with the provisions of these licensing requirements, as determined by periodic onsite surveys conducted by the department, submission of the survey reports and other information from the accrediting agency, or both. Each license is valid only in the hands of the entity to whom it is issued and is not subject to sale, assignment, or other transfer, voluntary or involuntary, nor is a license valid for any premises other than those for which originally issued.
2. The department may issue a provisional license, valid for a specified period of time not to exceed ninety days, when there are numerous deficiencies or a serious specific deficiency in relationship to compliance with these licensing requirements.
 - a. A provisional license may be renewed at the discretion of the department provided the licensee demonstrates to the department that it has made substantial progress towards compliance and can effect compliance within the next ninety days. A provisional license may be renewed no more than twice.
 - b. Whenever any hospital that has been out of compliance, as determined by the department, notifies the department that it has completed a plan of correction and corrected its deficiencies, the department will review the plan and may conduct an onsite survey to ascertain completion of the plan of correction. Upon finding compliance, the department may issue an annual license.

History: Effective April 1, 1994.

General Authority: NDCC 23-01-03(3), 28-32-02

Law Implemented: NDCC 23-16-06

33-07-01.1-03. Waiver provision.

Rules adopted under North Dakota Century Code chapter 23-16 may be waived by the department for a specified period in specific instances, provided such a waiver does not adversely affect the health and safety of the patients and if compliance with the requirement would result in unreasonable hardship upon the hospital.

History: Effective April 1, 1994; amended effective May 1, 1998.

General Authority: NDCC 23-01-03(3), 28-32-02

Law Implemented: NDCC 23-16-06

33-07-01.1-04. Access by the department.

Upon presenting identification to the hospital's chief executive officer or designee, authorized agents of the department shall have access to the hospital to determine compliance with licensure requirements. Such access includes:

1. Entry to all hospital premises.
2. Inspection and examination of all of the hospital's records and documents as required by this chapter.
3. Interviewing of any hospital staff, medical staff, or members of the governing body with their consent.
4. Examination of any patient and interview of any patient or the person with legal authority to act on behalf of the patient if this person is available at the facility at the time of the visit, with his or her consent.

History: Effective April 1, 1994.

General Authority: NDCC 23-01-03(3), 28-32-02

Law Implemented: NDCC 23-16-06

33-07-01.1-05. Continuing surveillance.

At any time, the department may evaluate a hospital's compliance with these licensure requirements through an announced or unannounced onsite review scheduled at the discretion of the department.

History: Effective April 1, 1994.

General Authority: NDCC 23-01-03(3), 28-32-02

Law Implemented: NDCC 23-16-06

33-07-01.1-06. Hospitals accredited by nationally recognized accrediting agencies.

1. A hospital may request that the department consider it in compliance with this chapter if it is in compliance with the standards of a nationally recognized accrediting agency.
2. Hospitals requesting to be licensed through an accrediting agency shall initially submit to the department a copy of the entire accrediting agency survey report. Subsequent accreditation survey or revisit documentation must be submitted prior to licensure renewal. If an accreditation survey or revisit has not occurred since the prior licensure renewal, the hospital shall include notice of prior submission of required accreditation information at the time of annual licensure renewal.
3. Hospitals requesting licensure in accordance with national accreditation status shall comply with all requirements of this section. Licensure requirements not covered by the standard survey of an accrediting agency may be monitored by the department.
4. Hospitals that receive a denial of accreditation from the accrediting agency are subject to an onsite survey by the department to determine compliance with the licensure requirements.
5. For hospitals that choose not to apply for a license through the accrediting procedure even though qualified to do so under this section, an onsite survey will be conducted by the department to determine compliance with the licensure requirements.
6. For those portions of the accrediting agency survey report which the department accepts, the hospital will be considered to be in compliance with the corresponding licensure requirements.

History: Effective April 1, 1994.

General Authority: NDCC 23-01-03(3), 28-32-02

Law Implemented: NDCC 23-16-06

33-07-01.1-07. Plans of correction.

1. Hospitals shall submit to the department plans of correction addressing the areas of noncompliance with the licensure requirements in this chapter.
2. Plans of correction are required within ten calendar days of receipt of the deficiency statement and are subject to acceptance, acceptance with revisions, or rejection by the department.
3. The department may require a directed plan of correction. A directed plan of correction is a plan of correction, submitted by a hospital in response to cited deficiencies, which has been developed in coordination with the department and has been accepted by the department.
4. Plans of correction must be completed within sixty days of the survey completion date, unless an alternative schedule of correction has been approved by the department.

History: Effective April 1, 1994.

General Authority: NDCC 23-01-03(3), 28-32-02

Law Implemented: NDCC 23-15-06

33-07-01.1-08. Enforcement.

1. Hospitals are subject to one or more enforcement actions, which may include a ban or limitation on admissions, suspension or revocation of a license, or a denial to license for the following reasons:
 - a. Noncompliance to the licensure requirements in this chapter have been identified which:
 - (1) Present imminent danger to patients;
 - (2) Have a direct or immediate relationship to the health, safety, or security of the hospital's patients;
 - (3) If left uncorrected, have a potential for jeopardizing patient health or safety if left uncorrected; or
 - (4) Is a recurrence of the same or substantially same violation in a twenty-four-month period.
 - b. Failure to correct any deficiency pursuant to a plan of correction, unless the department approves in writing an extension or modification of the plan of correction.
 - c. Gross incompetence, negligence, or misconduct in operating the hospital as determined through department investigation or through a court of law.
 - d. Fraud, deceit, misrepresentation, or bribery in obtaining or attempting to obtain a license.
 - e. Lending, borrowing, or using the license of another hospital.
 - f. Knowingly aiding or abetting in any way the improper granting of a license.
2. Conditions or practices which the department has determined to present an imminent danger to patients in the hospital must be abated or eliminated immediately or within a fixed period of time as specified by the department.
3. The department shall notify the hospital in writing when a decision is made to initiate a ban or limitation on admissions, a suspension or revocation of a license, or a denial to license. The notice must include the basis of the department's decision and must advise the hospital of the right to:
 - a. Request a review by the department.
 - (1) The hospital's request for a review shall be made to the department in writing within thirty days from the date the department determined the hospital to be noncompliant with the licensure requirements as identified in subsection 1 unless imminent danger to the patients in the hospital has been identified. The request for a review must include documentation that assures the areas of noncompliance have been corrected and the dates this was achieved. Compliance must be achieved prior to the forty-fifth day to allow for completion of a revisit by the department by that date.
 - (2) If a request for an onsite review is made, the department shall review all material relating to the deficiencies specific to the basis on which the enforcement action has been made. The department shall determine, based on review of the material and an onsite revisit if necessary, whether or not to sustain the enforcement action.

- b. Request a hearing before the health council on the department's decision to initiate a ban or limitation on admissions, a suspension or revocation of a license, or denial to license.
 - (1) The request for a hearing must be filed with the department in writing within sixty days from the date the department notified the hospital of the decision to initiate the enforcement action. A request for a review under subdivision a does not extend the time period in which the hospital must request a hearing before the health council under this subsection.
 - (2) The request for a hearing under this section must be accompanied by written documents including all of the following information:
 - (a) A copy of the notice received from the department.
 - (b) The reason or basis for the requested hearing.
 - (c) The statute or rule related to each disputed issue.
 - (d) The name, address, and telephone number of the person to whom all notices must be mailed or delivered regarding the requested hearing.
 - (3) Within ten days of receipt of the request for a hearing, the department shall request a hearing officer from the office of administrative hearings as provided in North Dakota Century Code chapter 54-57.
 - (4) The hearing officer must make written findings of fact and conclusions of law, and must recommend a decision to the health council. The recommended decision must set forth the reasons for the decision and the evidence upon which the decision is based.
 - (5) The health council may accept, modify, or reject the recommended decision. If the health council rejects the recommended decision, it may remand the matter to the office of administrative hearings with directions. The health council, through its directions, may require the receipt of additional evidence, and submission of amended findings of fact, conclusions of law, and recommended decision which reflects consideration of additional evidence. The health council, through its directions, may require that the matter be referred to the same or a different hearing officer, and the office of administrative hearings shall comply with that direction unless compliance is impossible.
4. All enforcement determinations by the department to limit or ban admissions, revoke or suspend a license, or to deny a license become final within sixty days unless a request for a hearing before the health council has been filed by the hospital with the department. The enforcement action takes effect ninety days from the date on which the department notified the hospital of the decision to implement an enforcement action unless the hospital has requested a hearing.
5. The department may place a public notice in the newspapers in the area in which the hospital is located to notify the public of the enforcement action that is to be imposed and the effective dates. The department shall notify the hospital in writing of the impending public notice fifteen days prior to the publication of the notice.

History: Effective April 1, 1994.

General Authority: NDCC 23-01-03(3), 28-32-02

Law Implemented: NDCC 23-16-06

33-07-01.1-09. Governing body.

The governing body is legally responsible for the quality of patient care services, for patient safety and security, for the conduct, operation, and obligations of the hospital as an institution, and for ensuring compliance with all federal, state, and local laws.

1. General acute hospital. The hospital must have a governing body legally responsible for directing the operation of the hospital in accordance with its mission. Hospitals operated by governmental organizations, with the exception of those sponsored by the federal government, shall provide written notification to the department of their designated governing bodies and the legal authority establishing these designations. No contracts, arrangements, or other agreements may limit or diminish the responsibility of the governing body in any way.
 - a. The governing body, in order to achieve and maintain generally accepted standards of professional practice and patient care services in the hospital, shall establish, cause to implement, maintain, and, as necessary, revise its practices, policies, and procedures for the ongoing evaluation of the services operated or delivered by the hospital and for the identification, assessment, and resolution of problems that may develop in the conduct of the hospital.
 - b. The governing body shall receive orientation and continuing education addressing the mission of the hospital, their roles and responsibilities, patients' rights, and the organization, goals, and operation of the hospital.
 - c. The governing body shall adopt written bylaws reflecting its legal responsibility and accountability to the patients and its obligation to the community. The bylaws must specify at least the following:
 - (1) The role and purpose of the hospital.
 - (2) The duties and responsibilities of the governing body.
 - (3) The responsibilities of any governing body committees, including the requirement that minutes reflect all business conducted, including findings, conclusions, and recommendations.
 - (4) The relationships and responsibilities of the governing body, hospital administration, and medical staff, and the mechanism established by the governing body for holding such parties accountable.
 - (5) The mechanisms for adopting, reviewing, and revising governing body bylaws.
 - (6) The mechanisms for formal adoption of the organization, bylaws, rules, and regulations of the medical staff.
 - d. Meetings of the governing body must be held in order for the governing body to evaluate the conduct of the hospital, including the care and treatment of patients as well as its own performance. Based on these evaluations, the governing body shall take necessary actions sufficient to correct noted problems. A record of all governing body proceedings which reflects all business conducted, including findings, conclusions, and recommendations, must be maintained for review.
 - e. The governing body shall ensure the establishment and maintenance of a coordinated quality improvement program that integrates the review activities of all hospital services for the purpose of enhancing the quality of patient care.

- f. The governing body shall ensure that policies and procedures are reviewed at a minimum of every three years and when changes in standards of practice occur and shall at a minimum include:
- (1) Personnel records including application forms and verification of credentials where applicable.
 - (2) Periodic performance appraisals.
 - (3) Patient care needs and services as determined by the hospital.
 - (4) Patient rights to include at least the following and require that each patient admitted be notified of these rights.
 - (a) The right to considerate and respectful care.
 - (b) The right to treatment and services consistent with acceptable professional standards of practice.
 - (c) The right to make informed decisions involving care in collaboration with the licensed health care practitioner.
 - (d) The right to personal privacy and confidentiality of information.
 - (e) The right to review the patient's own medical record and to have information explained.
 - (f) The right to formulate advanced directives consistent with the federal Self Determination Act.
 - (g) The right to consent or decline to participate in proposed research studies.
 - (h) The right to expect reasonable continuity of care at the time when hospital care is no longer needed.
 - (i) The right to be informed of hospital policies and practices that relate to patient care, treatment, and responsibilities.
 - (j) The right to be free from abuse, neglect, and misappropriation of patient property.
 - (5) The orientation program for all new employees.
 - (6) The governing body shall ensure the establishment and maintenance of a risk management plan that includes a mechanism for reporting, investigating, acting on, and documenting incidents and identified risks.
 - (7) The transfer and discharge of patients, including discharge planning to meet the patients' needs.
 - (8) An effective procedure for reporting transfusion reactions and adverse drug reactions to the licensed health care practitioner. The governing body shall ensure that blood transfusions and intravenous medications are administered in accordance with state law.
 - (9) An effective disaster plan.
- g. The governing body shall develop a procedure to ensure that all personnel for whom licensure or certification is required have a valid and current license or certificate.

- h. The governing body shall take all appropriate and necessary actions to monitor and restore compliance when deficiencies with statutory or regulatory requirements are identified.
- i. The governing body shall appoint a chief executive officer who is responsible to the governing body for the management of the hospital. The governing body shall assure the chief executive officer's effective performance through ongoing documented monitoring and evaluation of that performance against written criteria developed for the position. Criteria must include, at a minimum, the hospital's compliance with statutory and regulatory requirements, the corrective actions required and taken to achieve such compliance, and the maintenance of corrective actions to achieve continued compliance in previously deficient areas.
- j. The governing body shall ensure that the medical staff comply with the following:
 - (1) Determine in accordance with state law which categories of licensed health care practitioners are eligible candidates for appointment to the medical staff.
 - (2) Appoint a physician as chief of staff who has been approved by the medical staff and is qualified for membership on the medical staff. The chief of staff is responsible for directing the medical staff organization and shall report to the governing body.
 - (3) Ensure the implementation of written criteria for selection, appointment, and reappointment of medical staff members and for the delineation of their medical privileges.
 - (4) Ensure that staff membership or professional privileges in the hospital are not dependent solely upon certification, fellowship, or membership in a specialty body or society.
 - (5) Appoint members of the medical staff after considering the recommendations of the existing members of the medical staff in accordance with written procedures.
 - (6) Ensure that actions taken on applications for medical staff appointments and reappointments including the delineation of privileges are put in writing.
 - (7) Approve and ensure that the medical staff has written bylaws, rules, and regulations.
 - (8) Require that members of the medical staff abide by the medical staff bylaws, rules, and regulations.
 - (9) Ensure that the medical staff is accountable to the governing body for the quality of care provided to patients.
 - (10) Require that members of the medical staff practice only within the scope of privileges granted by the governing body.
- k. The governing body shall ensure that the following patient care practices are implemented and monitored and take corrective action as necessary to attain compliance:
 - (1) Every patient of the hospital, whether an inpatient, emergency service patient, or outpatient, must be provided care that meets generally acceptable standards of professional practice.

- (2) Every patient must be under the care of a licensed health care practitioner who is credentialed by the medical staff.
 - (3) Patients must be admitted to the hospital only by a licensed health care practitioner with admitting privileges.
 - (4) Staff must be available at all times, sufficient to meet the patient care needs.
 - (5) A patient's licensed health care practitioner shall arrange for the care of the patient by an alternate licensed health care practitioner during his or her unavailability.
 - (6) One or more licensed health care practitioners must be on duty or call at all times and available to the hospital within thirty minutes to give necessary orders or medical care to patients in case of emergency.
 - (7) Every patient must receive effective discharge planning consistent with identified patient and family needs from the hospital. Discharge planning must be initiated in a timely manner. Patients, along with necessary medical information, must be transferred or referred to appropriate facilities, agencies, or outpatient services, as needed, for followup or ancillary care.
 - (8) That all medical orders must be in writing and signed and dated by a licensed health care practitioner.
- I. The governing body is responsible for providing a physical plant equipped with the needed facilities and services for the care of patients in compliance with construction standards contained in chapter 33-07-02.1.
 - m. The governing body is responsible for services furnished in the hospital whether or not they are furnished by outside entities under contracts. The governing body shall ensure that a contractor of services (including one for shared services and joint ventures) furnishes services that permit the hospital to comply with all applicable laws, codes, rules, and regulations.
 - (1) The governing body shall ensure that the services performed under a contract are provided in a safe and effective manner.
 - (2) The hospital shall maintain a list of all contracted services, including the scope and nature of the services provided.
2. A primary care hospital shall have a governing body that is legally responsible for the conduct of the hospital and shall at least:
 - a. Adopt written bylaws reflecting its legal responsibility and accountability to the patients and its obligation to the community. The bylaws must specify at least the following:
 - (1) The role and purpose of the hospital.
 - (2) The duties and responsibilities of the governing body.
 - (3) The responsibilities of any governing body committees, including the requirement that minutes reflect all business conducted, including findings, conclusions, and recommendations.
 - (4) The relationships and responsibilities of the governing body, hospital administration, and medical staff, and the mechanism established by the governing body for holding such parties accountable.

- (5) The mechanisms for adopting, reviewing, and revising governing body bylaws.
 - (6) The mechanisms for formal adoption of the organization, bylaws, rules, and regulations of the medical staff.
- b. Ensure that the medical staff:
- (1) Are approved by the governing body after considering the recommendations of the existing members of the medical staff.
 - (2) Have current bylaws and written policies that are approved by the governing body.
 - (3) Are accountable to the governing body for the quality of care provided to patients.
 - (4) Are selected on the basis of individual character, competence, training, experience, and judgment.
- c. Approve a chief executive officer who is responsible for managing the hospital.
- d. In accordance with a written policy, ensure that:
- (1) Every patient is under the care of a licensed health care practitioner who is a member of the medical staff.
 - (2) Whenever a patient is admitted to the hospital by a physician assistant, the physician assistant's supervising physician must be notified of that fact, by phone or otherwise, within four hours after the admission and a written notation of that consultation and of the physician's approval or disapproval must be placed in the patient's medical record.
 - (3) A licensed health care practitioner must be on duty or on call at all times and available to the hospital to give necessary orders and medical care in the case of emergency.
 - (4) Sufficient staff must be available at all times to meet patient care needs.
 - (5) That all medical orders must be in writing and signed and dated by a licensed health care practitioner.
- e. Maintain a list of all contracted services, including the scope and nature of the services provided, and ensure that a contractor providing services to the hospital:
- (1) Furnishes services that permit the hospital, including the contracted services, to comply with all applicable laws, codes, rules, and regulations.
 - (2) Provides the services in a safe and effective manner.
- f. Ensure that the medical and nursing staff of the hospital are licensed, certified, or registered in accordance with state statutes and rules and that each such staff member provides health services within the scope of his or her license, certification, or registration.
- g. Ensure that all drugs and biologicals are administered by, or under the supervision of, personnel in accordance with federal and state laws and rules and in accordance with medical staff policies and procedures which have been approved by the facility's governing body.

- h. Ensure that each order for drugs and biologicals is consistent with federal and state law and is in writing and signed by the licensed health care practitioner who is both responsible for the care of the patient and legally authorized to prescribe.
 - i. Ensure that blood transfusions and intravenous medications are administered in accordance with state law.
 - j. Establish a quality improvement committee, at least one member to be an appropriately licensed health care practitioner.
 - k. Provide a physical plant equipped with the needed facilities and services for patients in compliance with construction standards contained in chapter 33-07-02.1.
 - l. Have written contracts for referral purposes. The hospital shall have agreements with at least the following:
 - (1) A general acute hospital.
 - (2) A provider of specialized diagnostic imaging or laboratory services that are not available at the facility.
3. Specialized hospitals are subject to the governing body requirements for general acute hospitals in this section.

History: Effective April 1, 1994.

General Authority: NDCC 23-01-03(3), 28-32-02

Law Implemented: NDCC 23-16-06

33-07-01.1-10. Physical environment.

- 1. The general acute hospital must be constructed, arranged, and maintained to ensure the safety and well-being of the patients and must provide facilities for diagnosis and treatment and for special services appropriate to the hospital.
 - a. The physical plant must comply with the construction standards of chapter 33-07-02.1.
 - b. In addition to the construction standards, all hospitals shall provide an environment that appropriately responds to the physical, functional, and psychosocial needs of the patients. The hospital shall provide adequate space, lighting levels, ventilation, and safety measures consistent with the services being offered and the patients being served.
- 2. Primary care hospitals are subject to the physical environment requirements for general acute hospitals in this section.
- 3. Specialized hospitals are subject to the physical environment requirements for general acute hospitals in this section.

History: Effective April 1, 1994.

General Authority: NDCC 23-01-03(3), 28-32-02

Law Implemented: NDCC 23-16-06

33-07-01.1-11. Fire control.

- 1. General acute hospitals shall comply with the fire code standards. This compliance is subject to review and approval by the state fire marshal's office.

2. Primary care hospitals are subject to the fire control requirements for general acute hospitals in this section.
3. Specialized hospitals are subject to the fire control requirements for general acute hospitals in this section.

History: Effective April 1, 1994.

General Authority: NDCC 23-01-03(3), 28-32-02

Law Implemented: NDCC 23-16-06

33-07-01.1-12. Disaster plan.

1. The general acute hospital shall have a written procedure to be followed in case of fire, explosion, or other emergency. It shall specify persons to be notified, locations of alarm signals and extinguishers, evacuation routes, procedures for evacuating helpless patients, frequency of fire drills at not less than four fire drills per year per shift, and assignment of specific tasks and responsibilities to the personnel of each shift. The plan should be developed with the assistance of qualified fire and safety experts.
2. Primary care hospitals are subject to the disaster plan requirements for general acute hospitals in this section.
3. Specialized hospitals are subject to the disaster plan requirements for general acute hospitals in this section.

History: Effective April 1, 1994.

General Authority: NDCC 23-01-03(3), 28-32-02

Law Implemented: NDCC 23-16-06

33-07-01.1-13. Quality improvement.

The hospital shall have an ongoing, facilitywide, written quality improvement program and risk management program approved by the governing body with implementation plans that evaluate and improve the quality of patient care, governance, and managerial and support activities.

1. The general acute hospital shall develop and implement a quality improvement program for assessing and improving quality which describes objectives, organization, scope, and mechanisms for overseeing the effectiveness of monitoring, evaluation, and improvement activities.
 - a. The quality improvement program must include a written plan for all services including indicators of care which are important to the health and safety of the patients.
 - b. The indicators of the written quality improvement plan must relate to the quality of care and must be objective, measurable, and based on current knowledge and clinical experience.
 - c. Written documentation of the quality improvement activities and risk management activities must be prepared and reported through established channels to the governing body at least four times a year.
2. Primary care hospitals are subject to the quality improvement requirements for general acute hospitals in this section.
3. Specialized hospitals are subject to the quality improvement requirements for general acute hospitals in this section.

History: Effective April 1, 1994.

General Authority: NDCC 23-01-03(3), 28-32-02

Law Implemented: NDCC 23-16-06

33-07-01.1-14. Infection control.

The hospital shall have a hospitalwide program for the surveillance, prevention, and control of infections consistent with the occupational safety and health administration and centers for disease control standards regulations specific to infection control.

1. The general acute hospital shall establish and implement an infection control program that is responsible for the infection surveillance, prevention, and control in the hospital.
 - a. The responsibilities of the program include:
 - (1) The establishment of a written infection control plan that includes the use of aseptic techniques, universal precautions, and appropriate procedures for each department or service.
 - (2) The establishment of policies and procedures for reporting, surveillance, monitoring, and documentation of infections and the development and implementation of systems used to collect and analyze data and activities to prevent and control infections.
 - (3) Ensuring the assignment of the responsibility for the management of infection surveillance, prevention, and control to a qualified person or persons.
 - b. Written documentation of the activities of the infection control program must be prepared and reported through established channels.
 - c. There must be procedures available for the immediate isolation of all patients in whom infectious conditions or other conditions that jeopardize the safety of the patient or other patients are thought to exist.
 - d. There must be inspections and cleaning of air-intake sources, screens, and filters at a frequency consistent with manufacturer's recommendations and hospital policies.
 - e. Proper facilities must be maintained and appropriate procedures used for disposal of all infectious and other wastes.
2. A primary care hospital is subject to the infection control requirements for general acute hospitals in this section.
3. Specialized hospitals are subject to the infection control requirements for general acute hospitals in this section.

History: Effective April 1, 1994.

General Authority: NDCC 23-01-03(3), 28-32-02

Law Implemented: NDCC 23-16-06

33-07-01.1-15. Medical staff.

1. The general acute hospital shall have an organized medical staff that is accountable to the governing body in accordance with written bylaws, rules, and regulations approved by the governing body. The medical staff shall adopt and enforce bylaws, rules, and regulations to carry out its responsibilities which specifically provide, but are not limited to, the following:
 - a. Describe the organization, composition, and accountability of the medical staff.

- b. The mechanism for appointment, reappointment, and renewal of medical staff membership, and the granting of clinical privileges initially and at least every twenty-four months as a part of an evaluation of staff membership. Medical staff membership and clinical privileges shall be granted by the governing body based on medical staff recommendations in accordance with the bylaws, rules, regulations, and policies of the medical staff and the hospital.
- c. The acceptance and processing of initial applications for medical staff membership, granting and denying of medical staff reappointment, and medical staff membership or disciplinary matters related to clinical privileges.
- d. The equal application of procedures for evaluating eligible licensed health care practitioners for staff membership, including procedures for determination of qualifications, credentials, and privileges; criteria for evaluation of qualifications; procedures requiring information about current mental and physical health status; current license status in this state; procedures to address the issue of staff members who are reportedly impaired by substance abuse; and current competence in delivering health care services.
 - (1) The following information must be collected from a licensed health care practitioner prior to appointment or reappointment to the medical staff and the granting or renewing of clinical privileges or association in any capacity with the hospital:
 - (a) The name of any hospital or facility with which the licensed health care practitioner has had any association, employment, privileges, or practice and, if such association, employment, privileges, or practice have been suspended, restricted, terminated, curtailed or not renewed, the reasons for such.
 - (b) The substance of any pending professional liability actions or other professional misconduct proceedings in this or any other state.
 - (c) Any judgment or settlement of any professional liability action and any finding of professional misconduct in this or any other state.
 - (d) Any information relative to findings pertinent to violations of patients' rights.
 - (e) A waiver by the licensed health care practitioner of any confidentiality provisions concerning the information.
 - (2) Prior to granting or renewing privileges or association to any licensed health care practitioner, the hospital shall query the national practitioner data bank regarding physicians and request all previous hospital or clinical practice information.
 - (3) A file must be maintained on each licensed health care practitioner granted privileges or otherwise associated with the hospital which must contain the information collected. This file must be updated at least every twenty-four months and contain all relevant information gathered in accordance with this section.
 - (4) A physician assistant and advanced registered nurse practitioner shall keep on file at the hospital and available for review by the department, upon request, documents that are required to be filed with the board of medical examiners or the board of nursing as appropriate.
- f. A statement of the duties, privileges, and responsibilities of each category of medical staff.

- (1) Regardless of any other categories having privileges in the hospital, there must be an active staff that includes physicians and may also include other licensed health care practitioners which is organized and which performs all the duties pertaining to medical staff, including the maintenance of the proper quality of all medical care and treatment of inpatients and outpatients in the hospital.
 - (2) Active medical staff meetings must be held regularly and written minutes of all meetings must be kept. Documentation on meetings must be prepared and reported through established channels.
- g. Additional privileges may be granted a staff member for the use of their employed allied health personnel in the hospital in accordance with policies and procedures recommended by the medical staff and approved by the governing body. The staff member requesting this additional privilege shall submit for review and approval by the medical staff and the governing body:
- (1) The curriculum vitae of the identified allied health personnel.
 - (2) Written protocol with a description of duties, assignments, and functions including a description of the manner of performance within the hospital by the allied health personnel in relationship with other hospital staff.
- h. The responsibility for such quality improvement activities as pharmacy and therapeutics, surgical case and tissue review, infection control, utilization review, patient care evaluation, use of blood and blood components, review of unexpected mortalities, review of morbidities in circumstances other than those related to the natural course of disease or illness, and the maintenance of complete medical records.
- i. That the findings of tissue removed at operation which is examined by a pathologist be made a part of the patient's medical record.
- j. The maintenance and continuous collection of information concerning the hospital's experience with negative health care outcomes and incidents injurious to patients; patient grievances; professional liability insurance premiums, settlements, awards, and costs incurred by the hospital for patient injury prevention; and safety improvement activities.
- k. The identification of clinical conditions and procedures requiring consultation.
- l. The provision for the exchange of information between medical, administrative, and nursing staffs.
- m. The procedure for submitting recommendations to the governing body regarding matters within the purview of the medical staff.
- n. The procedures to be used to grant to current medical staff members formal professional review for actions involving credentialing, competence, or professional conduct concerning hospital privileges. The formal professional review must be conducted in accordance with a fair hearing and appeal process identified in the medical staff bylaws, substantially in the following manner:
- (1) The medical staff member must be given a notice stating:
 - (a) That a professional review action has been proposed to be taken against the medical staff member.
 - (b) The reasons for the proposed action.

- (c) That the medical staff member has the right to request a hearing on the proposed action.
 - (d) Any time limit, which may not be less than thirty days, within which to request such a hearing.
 - (e) A summary of the medical staff member's rights in a hearing.
- (2) If a hearing is requested, the medical staff member involved must be given notice of the hearing on a timely basis.
- (3) Any action relating to professional incompetence or professional conduct adversely affecting the clinical privileges of the medical staff member must be reported by the governing body of the hospital, within fifteen days, to the state board charged with responsibility for licensure of the professional practice and any disciplinary action affecting practice longer than thirty days must be reported to the national data bank.
2. The primary care hospital shall have a medical staff that includes at least one or more physician, physician assistant, or advanced registered nurse practitioner which does the following:
- a. Adopts bylaws, rules, and regulations for self-governance of medical staff activities and enforces the bylaws, rules, and regulations after their approval by the governing body. The bylaws, rules, and regulations must at least contain the following:
 - (1) A description of the qualifications a medical staff candidate must meet in order to be recommended to the governing body for appointment.
 - (2) A statement of the duties and privileges of each category of medical staff.
 - (3) The requirement for a physical examination to be made and the medical history taken of a patient by a member of the medical staff no more than fourteen days before or twenty-four hours after the patient's admission to the primary care hospital.
 - b. Responsible for quality improvement activities including pharmacy and therapeutics, infection control, utilization review, patient care evaluation, use of blood and blood components, review of unexpected mortalities, review of morbidities in circumstances other than those related to the natural course of the disease or illness, and maintenance of complete medical records.
 - c. A licensed health care practitioner on staff must:
 - (1) Provide health care services to the patients in the hospital whenever needed and requested.
 - (2) Prepare guidelines for the medical management of health problems, including conditions requiring medical consultation and patient referral.
 - (3) Provide medical direction for the hospital's health care activities.
 - (4) Participate in developing, executing, and periodically reviewing the hospital's written policies and the services provided to patients.
 - (5) Review and sign the records of each patient admitted and treated no later than one month after that patient's discharge from the hospital.

- (6) Arrange for, or refer patients to, needed services that are not provided at the hospital.
 - (7) Assure that adequate patient medical records are maintained and transferred as necessary when a patient is referred.
- d. A physician assistant or advanced registered nurse practitioner must keep on file at the primary care hospital and available for review by the department, upon request, documents that are required to be filed with the board of medical examiners or the board of nursing as appropriate.
3. Specialized hospitals are subject to the medical staff requirements for general acute hospitals in this section.

History: Effective April 1, 1994.

General Authority: NDCC 23-01-03(3), 28-32-02

Law Implemented: NDCC 23-16-06

33-07-01.1-16. Nursing services.

1. The general acute hospital shall have a plan of administrative authority with delineation of responsibilities and duties for nursing personnel, including written job descriptions.
 - a. Nursing services must be under the direction of a nurse executive (director of nursing) who is a registered nurse licensed to practice in North Dakota. The nurse executive must have written administrative authority, responsibility, and accountability for the integration and coordination of nursing services consistent with the overall hospital plan and philosophy of patient care. The nurse executive shall retain overall responsibility for:
 - (1) Development, maintenance, and periodic review of a nursing service philosophy, objectives, standards of practice, policies and procedures, and job descriptions for each level of nursing service personnel.
 - (2) Whenever the nurse executive is not available in person or by phone, the nurse executive shall designate in writing a specific registered nurse to be available in person or by phone to direct nursing services.
 - b. There must be sufficient qualified nursing personnel to meet the nursing care needs of the patients.
 - (1) At least one registered nurse must be on duty per shift twenty-four hours per day seven days per week when a patient is present. The nurse executive or other registered nurse designated as the nurse executive's alternate must be on call and available within twenty minutes at all times.
 - (2) In hospitals providing obstetrical or surgical services, additional nursing staff must be available to care for these patients as determined necessary dependent on facility policy and patient needs.
2. Primary care hospitals shall provide twenty-four-hour licensed nursing services whenever a patient is in the hospital and meet the following standards:
 - a. Nursing services must be under the direction of a nurse executive (director of nursing) who is a registered nurse licensed to practice in North Dakota. The nurse executive must have written administrative authority, responsibility, and accountability for the integration and coordination of nursing services consistent with the overall hospital plan and philosophy of patient care. The nurse executive shall retain overall responsibility for:

- (1) Development, maintenance, and periodic review of nursing service philosophy, objectives, standards of practice, policies and procedures, and job descriptions for each level of nursing service personnel.
 - (2) Determine and schedule adequate numbers of licensed registered nurses, licensed practical nurses, and other personnel to provide nursing care as needed.
 - b. A registered nurse must provide or assign to other personnel the nursing care of each patient, including patients at a skilled nursing facility level of care in a swingbed. The care must be provided in accordance with the patient's needs and the specialized qualifications and competence of the staff available. When a registered nurse is not on duty, the nurse executive or another registered nurse designated as the nurse executive's alternate must be on call and available within twenty minutes at all times.
 - c. When no patients are in the facility, staffing must include at least a licensed nurse with a registered nurse on call and available within twenty minutes to respond immediately to patient needs.
3. Specialized hospitals are subject to the nursing services requirements for general acute hospitals in this section.

History: Effective April 1, 1994; amended effective August 1, 1999.

General Authority: NDCC 23-01-03(3), 28-32-02

Law Implemented: NDCC 23-16-06

33-07-01.1-17. Patient care plan.

1. The general acute hospital shall ensure that a patient care plan is developed for each patient in coordination with the patient and appropriate health care personnel consistent with the licensed health care practitioner's orders.
 - a. Initial assessment must begin upon admission and the patient care plan must be developed and implemented consistent with patient needs. The initial written patient care plan must be completed within twenty-four hours of admission and updated as needed.
 - (1) Patient care plans must be kept current. Plans must address patient needs, including the methods and approaches to be implemented and modifications necessary to ensure that the patient attains or maintains the highest practicable level of functioning.
 - (2) Patient care plan goals must be identified, measurable, and made known to all appropriate personnel.
 - b. Progress notes must be reflective of the patient care plan and be informative and descriptive of the care given. The progress notes must include information and observations of significance which contribute to the continuity of patient care.
 - c. Discharge planning must be initiated upon admission and kept current.
 - (1) Appropriate discharge instructions must be provided to patients and family members dependent upon the patient's identified needs.
 - (2) Patients, along with necessary medical information, must be transferred or referred to appropriate facilities, agencies, or outpatient services for followup or ancillary care as needed.

2. Primary care hospitals are subject to the patient care plan requirements for general acute hospitals in this section.
3. Specialized hospitals are subject to the patient care plan requirements for general acute hospitals in this section.

History: Effective April 1, 1994.

General Authority: NDCC 23-01-03(3), 28-32-02

Law Implemented: NDCC 23-16-06

33-07-01.1-18. Education programs.

1. The general acute hospital shall design, implement, and document educational programs to orient new employees and to keep all staff current on new and expanding programs, techniques, equipment, and concepts of quality care. The following topics must be covered annually:
 - a. Infection control measures, including blood-borne pathogens.
 - b. Safety and emergency procedures, including procedures for fire and other disasters.
 - c. Procedures for life-threatening situations, including cardiopulmonary resuscitation and the lifesaving techniques for choking victims.
 - d. Patient rights.
2. Primary care hospitals are subject to the education programs requirements for general acute hospitals in this section.
3. Specialized hospitals are subject to the education programs requirements for general acute hospitals in this section.

History: Effective April 1, 1994.

General Authority: NDCC 23-01-03(3), 28-32-02

Law Implemented: NDCC 23-16-06

33-07-01.1-19. Dietary services.

1. The general acute hospital shall provide dietary service to meet the needs of the patients served and shall ensure the following:
 - a. The hospital shall designate an employee to be responsible for the total food service of the facility. If this employee is not a licensed registered dietitian, the employee must have at least completed a food service course approved by the academy of nutrition and dietetics or its predecessor or successor organization and receive at least monthly consultation from a licensed registered dietitian consultant.
 - b. There must be current written policies and procedures for the dietary department.
 - c. The number of employees must be adequate to effectively perform all functions necessary to meet the dietary needs of the patients.
 - d. A person must be designated to be in charge of the dietary service when the department head is not present.
 - e. Dietary personnel must practice recognized hygienic techniques in accordance with the food service sanitation manual issued by the North Dakota state department of health, division of food and lodging.

- f. The dietitian must have available a diet manual of regimens for all therapeutic diets, approved jointly by the dietitian and medical staff. Copies must be available in the dietary service area.
- g. At least three meals or their equivalent must be served daily, at regular times, with not more than a fourteen-hour span between a substantial evening meal and breakfast.
- h. Regular and therapeutic diets must be prescribed in writing by the licensed health care practitioner. Regular and therapeutic menus must be planned in writing and served as ordered, with supervision or consultation from the dietitian.
- i. Facilities must be provided for the general dietary needs of the hospital patients and staff, and for maintenance of sanitary conditions in the storage, preparation, service, and distribution of food.
 - (1) Appropriate lighting and ventilation must be maintained.
 - (2) Facilities for storage of personal effects outside of food preparation area must be provided for food service personnel.
 - (3) Lavatories, specifically for handwashing, with hot and cold running water, soap dispenser, and disposable towels, must be conveniently located.
 - (4) Dry or staple food items must be stored off the floor in a ventilated room that is free of sewage or wastewater backflow or contamination by condensation, leakage, rodents, or vermin, and separate from cleaning supplies.
 - (5) Effective procedures for cleaning all equipment and work areas must be developed and consistently followed.
 - (6) Dishwashing procedures and techniques must be carried out in compliance with state and local health codes.
 - (7) Waste that is not disposed of by mechanical means must be kept in leakproof nonabsorbent containers with closefitting covers and must be disposed of daily in a manner that will prevent transmission of disease, a nuisance, a breeding place for flies, or a feeding place for rodents. Containers must be thoroughly cleaned inside and outside each time they are emptied.
- 2. Primary care hospitals are subject to the dietary services requirements for general acute hospitals in this section.
- 3. Specialized hospitals are subject to the dietary services requirements for general acute hospitals in this section.

History: Effective April 1, 1994; amended effective April 1, 2013.

General Authority: NDCC 23-01-03(3), 28-32-02

Law Implemented: NDCC 23-16-06

33-07-01.1-20. Medical records services.

- 1. The general acute hospital shall establish and implement procedures to ensure that the hospital has a medical records service with administrative responsibility for medical records.
 - a. A medical record must be maintained and kept confidential, in accordance with accepted medical record principles, for every patient admitted for care in the hospital.
 - (1) Only authorized personnel may have access to the record.

- (2) Written consent of the patient must be presented as authority for release of medical information.
 - (3) Medical records may not be removed from the hospital environment except upon subpoena or court order.
 - (4) If a hospital discontinues operation, it shall make known to the department where its records are stored. Records are to be stored in a facility offering retrieval services for at least ten years after the closure date. Prior to destruction, public notice must be made to permit former patients or their representatives to claim their own records. Public notice must be in at least two forms, legal notice and display advertisement in a newspaper of general circulation.
- b. Records must be preserved in original or any other method of preservation, such as by microfilm, for a period of at least the tenth anniversary of the date on which the patient who is the subject of the record was last treated in the hospital.
 - (1) If a patient was less than eighteen years of age at the time of last treatment, the hospital may authorize the disposal of medical records relating to the patient on or after the date of the patient's twenty-first birthday or on or after the tenth anniversary of the date on which the patient was last treated, whichever is later.
 - (2) The hospital may not destroy medical records that relate to any matter that is involved in litigation if the hospital knows the litigation has not been finally resolved.
 - (3) It is the governing body's responsibility to determine which records have research, legal, or medical value and to preserve such records beyond the above-identified timeframes until such time in the governing body's determination the record no longer has a research, legal, or medical value.
 - c. If a registered record administrator or accredited record technician is not in charge of medical records, a consultant registered record administrator or accredited record technician shall organize the service, coordinate the training of the personnel, and make at least quarterly visits to the hospital to evaluate the records and the operation of the service.
 - d. Personnel must be available so that medical records services may be provided as needed.
 - e. A system of identification and filing to ensure the prompt location of a patient's medical record must be maintained.
 - f. Upon discharge, all clinical information pertaining to a patient's hospitalization must be centralized in the patient's medical record. The original of all reports must be filed in the medical record.
 - g. Records must be retrievable by disease, operation, and licensed health care practitioner and must be kept up to date. For abstracting, any recognized system may be used. Indexing must be current within six months following discharge of the patient.
 - h. The medical records must contain sufficient information to justify the diagnosis and warrant the treatment and end results. The medical records must contain the following information: identification data, chief complaint, present illness, past history, family history, physical examination, provisional diagnosis, treatment, progress notes, final diagnosis, discharge summary, nurses' notes, clinical laboratory reports, x-ray reports, consultation reports, surgical and tissue reports and applicable autopsy findings. Progress notes must be informative and descriptive of the care given and must include

information and observations of significance so that they contribute to continuity of patient care.

- (1) The chief complaint must include a concise statement of complaints that led the patient to consult the patient's licensed health care practitioner and the date of onset and duration of each.
 - (2) The physical examination statement must include all findings resulting from an inventory of systems.
 - (3) The provisional diagnosis must be an impression (diagnosis) reflecting the examining licensed health care practitioner's evaluation of the patient's condition based mainly on physical findings and history.
 - (4) Progress notes must give a chronological picture of the patient's progress and must be sufficient to delineate the course and results of treatment. The condition of the patient determines the frequency with which they are made.
 - (5) A definitive final diagnosis must be expressed in terminology of a recognized system of disease nomenclature.
 - (6) The discharge summary must be a recapitulation of the significant findings and events of the patient's hospitalization and the patient's condition on discharge.
 - (7) The consultation report must be a written opinion signed by the consultant including the consultant's findings.
 - (8) All diagnostic and treatment procedures must be recorded in the medical record.
 - (9) Tissue reports must include a report of microscopic findings if hospital regulations require that microscopic examination be done. If only gross examination is warranted, a statement that the tissue has been received and a gross description must be made by the laboratory and filed in the medical record.
 - (10) When an autopsy is performed, findings in a complete protocol must be filed in the record.
 - (11) Complete records, both medical and dental, of each dental patient must be a part of the hospital record.
- i. All entries into the medical record must be authenticated by the individual who made the written entry.
- (1) All entries that the licensed health care practitioner personally makes in writing must be signed and dated by that licensed health care practitioner.
 - (2) Telephone and verbal orders may be used provided they are given only to qualified licensed personnel and reduced to writing and dated, timed, and signed or initialed by a licensed health care practitioner responsible for the care of the patient within forty-eight hours unless the hospital policies and procedures for verbal orders and telephone orders include a process by which the reviewer of the order reads the order back to the ordering practitioner to verify its accuracy. For verbal orders and telephone orders using the read-back and verify process, the verbal orders and telephone orders must be authenticated within thirty days of discharge or within thirty days of the date the order was given if the length of stay is longer than thirty days.

- (3) In hospitals with medical students and unlicensed residents, the attending licensed health care practitioner shall countersign at least the history and physical examination and summary written by the medical students and unlicensed residents.
- (4) Signature stamps may be utilized consistent with hospital policies as long as the signature stamp is utilized only by the licensed health care practitioner whose signature the signature stamp represents. Written assurance must be on file from the licensed health care practitioner to indicate that the practitioner is the sole user of the signature stamp.
- (5) Electronic signatures may be utilized if the hospital's medical staff and governing body adopt a policy that permits authentication by electronic signature. The policy must include:
 - (a) The categories of medical staff and other staff within the hospital who are authorized to authenticate patients' medical records using electronic signatures.
 - (b) The safeguards to ensure confidentiality, including:
 - [1] Each user must be assigned a unique identifier that is generated through a confidential access code.
 - [2] The hospital shall certify in writing that each identifier is kept strictly confidential. This certification must include a commitment to terminate the user's use of that particular identifier if it is found that the identifier has been misused. Misused means that the user has allowed another individual to use the user's personally assigned identifier, or that the identifier has otherwise been inappropriately used.
 - [3] The user must certify in writing that the user is the only individual with user access to the identifier and the only individual authorized to use the signature code.
 - [4] The hospital shall monitor the use of the identifiers periodically and take corrective action as needed. The process by which the hospital will conduct the monitoring must be described in the policy.
 - (c) A process to verify the accuracy of the content of the authenticated entries, including:
 - [1] A system that requires completion of certain designated fields for each type of document before the document may be authenticated, with no blanks, gaps, or obvious contradictory statements appearing within those designated fields. The system must require that correction or supplementation of previously authenticated entries must be made by additional entries, separately authenticated and made subsequent in time to the original entry.
 - [2] The system must make an opportunity available to the user to verify that the document is accurate and that the signature has been properly recorded.
 - [3] As a part of the quality improvement activities, the hospital shall periodically sample records generated by the system to verify the accuracy and integrity of the system.

- (d) A user may terminate authorization for use of an electronic signature upon written notice to the staff member in charge of medical records or other person designated by the hospital's policy.
 - (e) Each report generated by the user must be separately authenticated.
 - (f) A list of these codes must be maintained under adequate safeguards by hospital administration.
- j. Current records and those on discharged patients must be completed promptly.
- (1) Past history and physical examination information must be completed within twenty-four hours following admission.
 - (2) All reports or records must be completed and filed within a period consistent with current medical practice and not longer than thirty days following discharge.
 - (3) If a patient is readmitted within a month's time for the same conditions, reference to the previous history with an interval note and physical examination suffices.
- 2. Primary care hospitals are subject to the medical records services requirements for general acute hospitals in this section.
 - 3. Specialized hospitals are subject to the medical records services requirements for general acute hospitals in this section.

History: Effective April 1, 1994; amended effective July 1, 2004; July 1, 2009.

General Authority: NDCC 23-01-03(3), 28-32-02

Law Implemented: NDCC 23-16-06, 31-08-01.2, 31-08-01.3

33-07-01.1-21. Pharmaceutical services.

- 1. General acute hospitals shall provide pharmaceutical services consistent with chapter 61-07-01. The hospital, upon receipt, shall submit to the department a copy of the annual board of pharmacy hospital inspection report under subsection 2 of section 61-07-01-13 and plans of correction to the department.
- 2. Primary care hospitals are subject to the pharmaceutical services requirements for general acute hospitals in this section.
- 3. Specialized hospitals are subject to the pharmaceutical services requirements for general acute hospitals in this section.

History: Effective April 1, 1994.

General Authority: NDCC 23-01-03(3), 28-32-02

Law Implemented: NDCC 23-16-06

33-07-01.1-22. Laboratory services.

- 1. General acute hospitals shall have a well-organized, adequately supervised, clinical laboratory service available with the necessary space, facilities, and equipment and qualified, licensed staffing to perform these services commensurate with the hospital's needs for its patients. At a minimum, the hospital must adhere to the following:
 - a. The medical director of laboratory service must be a physician who is a member of the medical staff with delineated clinical privileges for interpretation of diagnostic studies.

- b. The medical director of the laboratory service shall assure procedures and tests are within the scope of education, training, and experience of the individuals employed to perform technical procedures in the laboratory.
 - c. Provisions must be made to assure twenty-four-hour availability of emergency laboratory services either directly or through contract.
 - d. Examination in the fields of hematology, chemistry, microbiology, sero-immunology, clinical microscopy, and other services necessary to meet patient care needs must be provided within the hospital or by contractual agreement.
 - e. All surgically removed tissues must be examined by a pathologist and signed reports must be included in the patient's medical record. If the hospital provides anatomical pathology services, such may be provided either by the hospital directly or per contractual arrangement with a certified laboratory. Written policies and procedures must be established through the medical staff and pathologist governing prompt transportation of specimens and submission of reports.
 - f. There must be a quality control program designed to ensure reliability of the laboratory data and which includes written provisions for no less than:
 - (1) The method of quantitative and qualitative testing and the frequency of control performance, including control data and evaluation criteria.
 - (2) The frequency and method of quality control testing and calibration of instruments, equipment, and commercially prepared testing kits.
 - (3) A preventive and corrective maintenance program for instruments and equipment involved in laboratory testing.
 - (4) Participation in an approved external proficiency testing program if one is available.
 - (5) Maintenance of records documenting all quality control and related activities.
 - g. An autopsy service must be provided either directly by the hospital or by contractual arrangement with another institution having an approved laboratory. Hospitals providing the service directly must have adequate space, equipment, and personnel for services provided.
 - h. Each hospital shall provide appropriate facilities and equipment for the procurement, storage, safekeeping, and administration of whole blood and blood products either directly or through participation in a multifacility community blood collection, storage, and processing system. Written policies and procedures for all phases of operation of blood banks and transfusion services must be established and revised as needed.
 - i. Reports indicating the name and address of the testing laboratory must be authenticated, dated, and clearly indicate the results of all pathological and clinical laboratory examinations, including autopsies, and made part of the patient's medical record.
2. The primary care hospital shall maintain, or have available through contract, clinical laboratory services adequate to fulfill the needs of its patients and meeting the following:
- a. The hospital, at a minimum, shall provide basic laboratory services essential to immediate diagnosis and treatment, including:
 - (1) Chemical examinations of urine by stick or tablet methods, or both (including urine ketones).

- (2) Hemoglobin or spun hematocrit.
 - (3) Blood sugar by whole blood testing device.
 - (4) Examination of stool specimens for occult blood.
 - (5) Primary culturing for transmittal to a certified laboratory.
- b. The hospital shall provide, or have a contractual agreement with a certified laboratory for, any additional laboratory services that are needed by a patient.
 - c. Emergency provision of basic laboratory services must be available twenty-four hours a day.
 - d. The hospital shall assign personnel to direct and conduct the laboratory services.
 - e. Only personnel designated as qualified by the medical staff by virtue of education, experience, and training may perform and report laboratory test results.
 - f. Each hospital shall provide appropriate facilities and equipment for the procurement, storage, safekeeping, and administration of whole blood and blood products either directly or through participation in a multifacility community blood collection, storage, and processing system. Written policies and procedures for all phases of operation of blood banks and transfusion services must be established and periodically revised.
3. Specialized hospitals shall provide laboratory services to meet the needs of patients served consistent with the laboratory services requirements for general acute hospitals in this section. If onsite laboratory services are not necessary to meet the needs of patients served, such as in hospitals serving only psychiatric or substance abuse patients, the laboratory services may be provided through a contractual agreement with a certified laboratory.

History: Effective April 1, 1994.

General Authority: NDCC 23-01-03(3), 28-32-02

Law Implemented: NDCC 23-16-06

33-07-01.1-23. Radiology services.

- 1. The general acute hospital shall provide and maintain radiology services sufficient to perform and interpret the radiological examinations necessary for the diagnosis and treatment of patients, to the extent that the complexity of services are commensurate with the size, scope, and nature of the hospital. Additional required services must be provided by shared services or referral of patients.
 - a. The physician responsible for the direction and supervision of radiology services must be board certified or eligible for certification by the American board of radiology or equivalent. The physician responsible for radiology services must be a member of the medical staff. This individual's responsibilities must be identified in the policy and procedure manual or other document.
 - b. Technicians and technologists employed in the radiology services must have had sufficient training and experience to carry out the procedures safely and efficiently commensurate with the size, scope, and nature of the service. A means for evaluating qualifications must be established and used. The physician responsible for radiology services shall document as to the acceptability of the qualifications specific to each radiology technician or technologist.
 - c. The hospital shall provide for emergency radiology services at all times.

- d. Complete signed reports of the radiological examinations must be made part of the patient's record and duplicate copies, as well as the films, must be kept in the hospital for a period of five years.
 - e. Written reports of each radiological interpretation, consultation, and treatment must be signed by the physician responsible for conducting the radiological examination and must be a part of the patient's medical record.
 - f. Radiation workers must be checked by film dosimeter to determine the amount of radiation to which they are routinely exposed. Records must be maintained to reflect each individual's exposure level. These checks must be conducted on a monthly basis until the radiation exposure history for the radiation worker indicates levels below maximum permissible dose for a period of one year. When radiation dose levels have remained below the maximum permissible dose for a year, radiation doses may be monitored on a quarterly basis as long as the exposure remains below the maximum permissible dose.
2. Primary care hospitals are subject to the radiology services requirements for general acute hospitals in this section.
 3. Specialized hospitals shall provide radiology services to meet the needs of patients served consistent with the radiology services requirements for general acute hospitals in this section. If onsite radiology services are not necessary, such as in hospitals serving only psychiatric or substance abuse patients, the radiology services may be provided through a contractual agreement with an institution providing radiology services.

History: Effective April 1, 1994.

General Authority: NDCC 23-01-03(3), 28-32-02

Law Implemented: NDCC 23-16-06

33-07-01.1-24. Nuclear medicine services.

1. If the acute hospital provides nuclear medicine services, the services must be provided to meet the needs of the patients and in a safe and effective manner.
 - a. The hospital shall have available written verification of compliance with article 33-10.
 - b. The hospital shall have evidence of licensure to handle radioactive materials.
 - c. The physician responsible for the direction of the nuclear medicine services must be a physician who is qualified to provide nuclear medicine services and who is a member of the medical staff.
 - d. Nuclear medicine services may be ordered only by a licensed health care practitioner whose qualifications and medical staff privileges allow such referrals.
 - e. Personnel employed in nuclear medicine services must meet the qualification and training requirements, perform the functions, and carry out the responsibilities specified by the director and approved by the medical staff.
 - f. The diagnostic procedures must be interpreted by a licensed health care practitioner who has been approved by the medical staff to do so. The licensed health care practitioner shall document, sign, and date reports of procedures, interpretations of procedures, and consultations.
 - g. The hospital shall retain copies of nuclear medicine reports consistent with current standards of practice.

- h. The nuclear medicine services shall develop and implement policies in accordance with standards of practice specific for the services provided, and consistent with chapter 61-05-01, including:
 - (1) Handling, maintenance, and inspection of equipment.
 - (2) Protection of patients and personnel from radiation hazards.
 - (3) Testing of equipment for radiation hazards.
 - (4) Maintenance of personnel radiation monitoring devices.
 - (5) Preparation and administration of radio-pharmaceutical.
 - (6) Documentation of receipt, storage, use, and disposal of radioactive materials.
2. If the primary care hospital provides nuclear medicine services, the hospital shall comply with nuclear medicine services requirements for general acute hospitals in this section.
3. Specialized hospitals providing nuclear medicine services are subject to the nuclear medicine services requirements for general acute hospitals in this section.

History: Effective April 1, 1994; amended effective August 1, 1999.

General Authority: NDCC 23-01-03(3), 28-32-02

Law Implemented: NDCC 23-16-06

33-07-01.1-25. Emergency services.

1. Each general acute hospital shall provide emergency services to its inpatients. If the hospital does not provide emergency services to the public, it shall be prepared to provide immediate lifesaving measures to persons who may appear for emergency care and arrange for their transfer to another hospital that does provide a public emergency service.
 - a. Each hospital shall have a well-defined plan for emergency care service based on the capability of the hospital and its specialized supportive services.
 - (1) The hospital plan for emergency care services must be developed to coordinate with representatives of community emergency medical services agencies or groups.
 - (2) Hospitals without emergency service for the public shall have written policies and procedures governing the handling of emergencies.
 - b. Every hospital with an emergency service shall provide treatment to every person in an emergency without discrimination on account of economic status or source of payment.
 - c. Every emergency service shall have a qualified licensed health care practitioner designated in charge of the emergency medical services to ensure that emergency patient care services meet the standards herein and for the coordination of professional coverage according to a plan established by the medical staff and approved by the governing body.
 - d. A hospital must have one or more licensed health care practitioners qualified by training and experience in care of emergency patients on duty or call at all times and available to respond to emergencies within thirty minutes. The licensed health care practitioner shall determine the nature, level, and urgency of care required of all persons seeking treatment and categorize them accordingly, assuring that serious cases are accorded priority treatment.

- e. The staffing pattern of nursing or allied health personnel must be consistent with the scope and complexity of the emergency services provided. At least one licensed person who is qualified by training and experience in emergency care must be assigned to the emergency services at all times.
- f. A current roster of licensed health care practitioners, medical specialists, or consultants on emergency call, including alternates, must be kept posted at all times in the emergency service area.
- g. There must be current written policies governing emergency services. The policies and procedures must pertain to at least the following:
 - (1) Medical staff and obligation for emergency patient care.
 - (2) Circumstances under which definitive care will not be provided and procedures to be followed in referrals.
 - (3) Procedures that may or may not be performed in the emergency service area.
 - (4) Handling of persons who are emotionally ill, under the influence of drugs or alcohol, dead on arrival, or other categories of special cases as determined necessary.
 - (5) Procedures for early transfer of severely ill or injured to special in-house treatment areas or to other facilities.
 - (6) Written instructions to be given for followup care and disposition of all cases.
 - (7) Notification of patient's personal licensed health care practitioner and transmission of relevant reports.
 - (8) Disclosure of patient information in accordance with federal and state law.
 - (9) Communication with police, health authorities, and emergency vehicle operators.
 - (10) Appropriate utilization of observation beds.
 - (11) Procurement of equipment and drugs.
 - (12) Location and storage of medications, supplies, and special equipment.
 - (13) Operation of the emergency service in times of disaster.
- h. A list of poison antidotes and the telephone number of the poison control center must be posted in a prominent place in the emergency service area.
- i. The emergency service shall have necessary supportive services available on a twenty-four-hour basis. These services must include onsite clinical laboratory service plasma expanders, provision for blood or blood products; pharmaceutical service; onsite radiology service including protocol to govern the interpretation by a radiologist of diagnostic images produced by x-ray, or other modalities if provided, including a procedure for the prompt communication of the radiologist's interpretation; and surgical and anesthesia service or referral process for surgical and anesthesia service.
- j. At a minimum, the following special supplies and equipment must be available in a complete set of adult and pediatric sizes for the provision of emergency services:
 - (1) Oxygen.
 - (2) Pulse oximeter.

- (3) Complete set of bag/valve/mask ventilation devices.
 - (4) Complete set of oral and nasal airways.
 - (5) Suction equipment.
 - (6) Endotracheal intubation, pericardiocentesis thoracotomy, and cricotracheotomy trays.
 - (7) Electrocardiograph.
 - (8) Cardiac monitor and defibrillator with battery pack.
 - (9) Moveable equipment cart for use as a crash cart.
 - (10) American heart association advanced cardiac life support recommended drug inventory.
 - (11) Intravenous fluids including lactated ringers solution and dextrose five percent in water.
 - (12) Infusion pump.
 - (13) Pressure infuser.
 - (14) Gastric lavage equipment.
 - (15) Urinary catheter kits.
 - (16) Emergency obstetrical pack.
 - (17) Spine board.
 - (18) Rigid cervical collars.
 - (19) Fracture splints.
 - (20) Sterile dressings and bandages.
 - (21) Sterile burn sheets.
 - (22) Gurney or exam table.
- k. Facilities must be provided to assure prompt diagnosis and emergency treatment.
- (1) Facilities must be separate from, and independent of, the operating rooms.
 - (2) The location of the emergency services must be easily accessible from an exterior entrance of the hospital.
- l. Adequate emergency room medical records on every patient must be kept and must include:
- (1) Patient identification and history of disease or injury.
 - (2) Physical findings and laboratory and x-ray reports, if any.
 - (3) Time of arrival, time of treatment, major diagnosis, treatment provided, and disposition including discharge instructions.

2. Primary care hospitals are subject to the emergency services requirements for general acute hospitals in this section. Primary care hospitals providing emergency services to the public may provide low intensity outpatient services consistent with those services commonly provided in a physician's office and consistent with the privileges granted to the licensed health care practitioner rendering the service.
3. Specialized hospitals are subject to the emergency services requirements for general acute hospitals in this section.

History: Effective April 1, 1994.

General Authority: NDCC 23-01-03(3), 28-32-02

Law Implemented: NDCC 23-16-06

33-07-01.1-26. Social services.

1. Social services must be provided in all general acute hospitals by a qualified social worker or a social services designee to meet the needs of the patients. Hospitals utilizing social services designees must have quarterly consultation by a qualified social worker.
 - a. Records of social service activity related to individual patient's needs must be kept, and must be available to the professional personnel concerned. Functions and activities recorded must include, as appropriate:
 - (1) Assessment, planning, implementation, and evaluation of psychosocial and rehabilitation needs of patients.
 - (2) Evaluation of financial status of patients.
 - (3) Referrals to community agencies.
 - b. The hospital shall provide facilities that will serve the personnel of the service. The services must be easily accessible to patients and to the medical staff, and must assure privacy for interviews.
2. Primary care hospitals are subject to the social services requirements for general acute hospitals in this section.
3. Specialized hospitals are subject to the social services requirements for general acute hospitals in this section.

History: Effective April 1, 1994.

General Authority: NDCC 23-01-03(3), 28-32-02

Law Implemented: NDCC 23-16-06

33-07-01.1-27. Basic rehabilitation services.

1. General acute hospitals shall provide basic rehabilitation services, including physical, occupational, and speech pathology and audiology to meet the needs of the patients served.
 - a. Basic rehabilitation services must be provided by qualified staff licensed or certified consistent with state law either directly or through contract or referral to an appropriate facility.
 - b. Basic rehabilitation services must be provided consistent with a written plan of treatment and based on the orders of the licensed health care practitioner who is authorized by the medical staff to order such services. The licensed health care practitioner's orders must be incorporated into the patient's medical record.

- c. Sufficient qualified staff must be available to ensure the following services are provided:
 - (1) Evaluate the patient.
 - (2) Initiate the plan of treatment.
 - (3) Instruct and supervise supportive personnel when they are used to provide services.
 - (4) Provide education as needed to the patient and significant others.
 - d. Documentation of basic rehabilitation services provided must be placed in the patient's medical record, including the nature, duration, frequency, and complexity of the treatment and the results.
 - e. If basic rehabilitation services are offered on an outpatient basis, the quality of the service must be consistent with the inpatient basic rehabilitation services in accordance with the complexity of the services provided.
 - f. Specialized rehabilitation services must be provided in a distinct, clearly defined, special unit of a general acute hospital, or in a rehabilitation hospital. Hospitals holding themselves out to the public as providing specialized rehabilitation services are subject to licensure as a specialized rehabilitation hospital as described in section 33-07-01-35.
- 2. Primary care hospitals are subject to the basic rehabilitative services requirements for general acute hospitals in this section.
 - 3. Specialized hospitals are subject to the basic rehabilitative services requirements for general acute hospitals in this section.

History: Effective April 1, 1994.

General Authority: NDCC 23-01-03(3), 28-32-02

Law Implemented: NDCC 23-16-06

33-07-01.1-28. Housekeeping and related services including laundry.

- 1. The general acute hospital shall provide the housekeeping and related services necessary to maintain a sanitary and comfortable environment.
 - a. The hospital shall provide personnel to maintain the interior and exterior of the facility in a safe, clean, orderly, and attractive manner. The hospital shall establish, implement, and update consistent with current standards of practice procedures whereby:
 - (1) Housekeeping personnel use accepted practices and procedures to keep the facility free from offensive odors; accumulations of dirt, rubbish, and dust; and safety hazards.
 - (2) Floors are cleaned regularly. Polishes on floors provide a nonslip finish. Throw or scatter rugs are not used, except for nonslip entrance mats.
 - (3) Walls and ceilings are maintained free from cracks and are cleaned and painted as needed.
 - (4) Grounds are kept free from refuse and litter.
 - b. The hospital must be maintained free from insects and rodents.
 - (1) A pest control program must be operated in the hospital. Pest control services must be provided by maintenance personnel of the hospital or by contract with a pest

control company. Care must be taken to use the least toxic and least flammable effective insecticides and rodenticides. These compounds must be stored in nonpatient areas and in nonfood preparation and storage areas. Poisons must be locked in cabinets provided for this purpose.

- (2) Windows and doors, if appropriate, must be screened during the insect breeding season.
 - (3) Harborages and entrances for insects and rodents must be eliminated.
 - (4) Garbage and trash must be stored in appropriately covered containers in areas separate from those used for the preparation and storage of food and must be removed from the premises in a timely manner to avoid infection control problems.
- c. The hospital shall establish and implement procedures whereby the hospital has available at all times a quantity of linen essential for the proper care and comfort of patients and that linens are handled, stored, and processed so as to control the spread of infection.
- (1) Clean linen and clothing must be stored in clean, dry, and dust-free areas easily accessible to the patient rooms.
 - (2) Soiled linen must be sorted and stored in well-ventilated areas, separate from other laundry spaces, and may not be permitted to accumulate. Soiled linen and clothing must be stored separately in suitable bags or covered containers. Contaminated and potentially infectious soiled linen must be handled with particular attention to avoid contamination of clean linen.
 - (3) Soiled linen may not be sorted, laundered, rinsed, or stored in bathrooms, patient rooms, kitchens, or food storage areas.
 - (4) When linen is sent to an outside laundry, it must be the responsibility of the hospital to determine that work is done in accordance with approved standards.
2. Primary care hospitals are subject to the housekeeping and related services including laundry requirements for general acute hospitals in this section.
 3. Specialized hospitals are subject to the housekeeping and related services including laundry requirements for general acute hospitals in this section.

History: Effective April 1, 1994.

General Authority: NDCC 23-01-03(3), 28-32-02

Law Implemented: NDCC 23-16-06

33-07-01.1-29. Surgical services.

1. The general acute hospital that provides surgical services shall have effective policies and procedures regarding surgical privileges, maintenance of the operating rooms, and evaluation of the surgical patient.
 - a. Surgical services must be provided in a manner sufficient to meet the surgical needs of the patients. The surgical service must have a defined organization, must be integrated with other departments and services of the hospital, and must be governed by current written policies and procedures.
 - b. Surgical services must be directed by a physician who is qualified by training and experience and approved by the medical staff and governing body.

- c. A roster of physicians, specifying the surgical privileges of each, must be maintained and available to staff in the surgical services area and in the files of the hospital administration.
 - d. The operating rooms must be supervised by a qualified registered nurse.
 - (1) A licensed practical nurse or a surgical technician may be used as "scrub nurse" under the supervision of the registered nurse.
 - (2) A registered nurse may perform circulating duties in the operating room in accordance with applicable state law. Licensed practical nurses and surgical technicians may assist in circulating duties under the supervision of a registered nurse who is immediately available to respond to emergencies.
 - e. The following equipment must be available for use in the surgical services area: call-in system, cardiac monitor, resuscitator, defibrillator, aspirator, tracheotomy tray, and such other instruments or equipment available for lifesaving measures.
 - f. The surgical services area must be located so that traffic in and out can be and is controlled and there is no through traffic.
 - g. All infections of clean surgical cases must be recorded and reported to administration and medical staff. A written procedure must be established for the investigation of such cases.
 - h. The operating room register must be maintained as identified by hospital policy and procedure.
 - i. There must be a complete history and physical examination, including any indicated laboratory and x-ray examination reports, in the medical record of every patient prior to surgery, except in life-threatening emergencies. If this has been transcribed, but not yet recorded in the patient's record, there must be a statement to that effect, an admission note identifying any abnormal findings, and the preoperative diagnosis in writing by the physician in the patient's medical record.
 - j. An operative report describing techniques, findings, and tissue removed or altered must be dictated or written immediately after the surgery and signed by the surgeon.
 - k. There must be a properly executed informed consent form consistent with hospital policies for operation in the patient's medical record prior to surgery, except in life-threatening emergencies.
 - l. If outpatient surgical services are offered by a hospital, the quality of the services must be consistent with the inpatient surgical services in accordance with the complexity of the services.
2. If the primary care hospital provides surgical services, the hospital shall comply with surgical services requirements for general acute hospitals in this section.
 3. If a specialized hospital provides surgical services, the specialized hospital is subject to the surgical services requirements for general acute hospitals in this section.

History: Effective April 1, 1994; amended effective August 1, 1999.

General Authority: NDCC 23-01-03(3), 28-32-02

Law Implemented: NDCC 23-16-06

33-07-01.1-30. Recovery services.

1. Postoperative recovery services must be provided by all general acute hospitals in which surgery is performed.
 - a. Recovery services must be provided in a room where patients who have undergone surgical procedures can be immediately observed, receive specialized care by selected and trained personnel, and when necessary, prompt emergency care can be initiated.
 - b. The services of the postoperative recovery room may be utilized for postpartum if the delivery room or place of delivery is in close proximity to the postoperative recovery room. Postpartum patients, after appropriate observation, must be returned to the obstetrical service area.
 - c. A physician shall be responsible for the conduct of the recovery services and for the establishment of admission and discharge policies and procedures.
 - d. A registered nurse who has education and experience in postoperative recovery services shall supervise all personnel performing nursing service functions.
 - (1) A licensed nurse shall be in attendance at all times when patients are in the recovery room.
 - (2) There must be sufficient nursing personnel to provide the specialized care required for the postsurgical patient.
 - e. Known contaminated cases must be returned to the isolation room or a private room.
 - f. A member of the medical staff shall provide initial orders for the care of each patient upon admission to the recovery services.
 - (1) A member of the medical staff shall be responsible for the patient's discharge from the recovery services.
 - (2) Patients under or recovering from anesthesia, and those who have received sedatives or analgesics, must remain under continuous, direct nursing supervision until vital signs have stabilized. Any nurse performing this duty must have been instructed in the management of postanesthetic patients, must have no other clinical duties while supervising such patients, and must have immediate recourse to the attending surgeon or anesthesiologist, or certified registered nurse anesthetist, present in the hospital.
 - (3) Side rails must be attached to movable carts and beds and raised above mattress level when occupied by anesthetized patients. Cribs must be provided for the anesthetized or postsurgical child.
 - g. Personnel with communicable diseases must be excluded from the recovery services.
 - h. Drugs, supplies, and equipment must be immediately and continually accessible in the unit during postoperative care, including emergencies. These include cardiac-respiratory resuscitation materials.
2. If the primary care hospital provides recovery services, the hospital shall comply with recovery services requirements for general acute hospitals in this section.
3. If a specialized hospital provides surgical services, the hospital is required to provide recovery services consistent with the recovery services requirements for general acute hospitals in this section.

History: Effective April 1, 1994; amended effective August 1, 1999.

General Authority: NDCC 23-01-03(3), 28-32-02

Law Implemented: NDCC 23-16-06

33-07-01.1-31. Central services.

1. General acute hospitals shall provide central services consistent with at least the following:
 - a. The central services must be provided with adequate direction, staffing, and facilities to provide service to all services in the hospital.
 - b. Policies and procedures must be developed, implemented, and updated as needed for all decontamination and sterilization services provided and at a minimum must include:
 - (1) Sterilization of equipment and supplies.
 - (2) Shelf life of stored sterile items.
 - (3) Reuse of disposable items.
 - (4) Reprocessing of disposable items to be reused.
 - (5) Proper handling of linen.
2. Primary care hospitals are subject to the central service requirements for general acute hospitals in this section.
3. Specialized hospitals are subject to the central services requirements for general acute hospitals in this section.

History: Effective April 1, 1994.

General Authority: NDCC 23-01-03(3), 28-32-02

Law Implemented: NDCC 23-16-06

33-07-01.1-32. Anesthesia services.

1. General acute hospitals providing surgical services shall provide anesthesia services to meet the needs of the patients served and shall ensure the following:
 - a. The anesthesia service must be under the direction of a qualified physician who is a member of the medical staff.
 - b. The anesthesia service must be organized under current written policies and procedures regarding staff qualifications, the administration of anesthetics, the maintenance of safety controls, and required electronic monitoring of patient vital signs and oxygen levels during the anesthetic procedures consistent with current standards of practice. The anesthesia service is responsible for all anesthetics administered in the hospital.
 - c. The patient must receive a preoperative visit from the anesthesiologist or the certified registered nurse anesthetist involved in the case.
 - d. The anesthesia service shall establish policies, procedures, rules, and regulations for the control, storage, and safe use of combustible anesthetics, oxygen, and other medicinal gases in accordance with national fire protection association standards; types of anesthesia to be administered and procedures for each; personnel permitted to administer anesthesia; infection control; safety regulations to be followed; and responsibility for regular inspection, maintenance, and repair of anesthesia equipment and supplies.

- e. Anesthesia services may be initiated only when ordered by a member of the medical staff and must be administered only by persons qualified and licensed in the management of such materials.
 - f. An intraoperative anesthetic record must be made a part of the patient's medical record. Drugs used, vital signs, and other relevant information must be recorded at regular intervals during anesthesia.
 - (1) There must be a preanesthesia evaluation by an individual qualified and licensed to administer anesthesia, performed within forty-eight hours prior to the surgery, with findings recorded in the patient's medical record.
 - (2) Except in emergency, anesthetic may not be administered until the patient has had a history and physical examination, and a record made of the findings.
 - g. Postanesthetic followup visits must be made within forty-eight hours after the procedure by the anesthesiologist, certified registered nurse anesthetist, or responsible physician who shall note and record any postoperative abnormalities or complications from anesthesia.
2. If the primary care hospital provides anesthesia services, the hospital shall comply with anesthesia services requirements for general acute hospitals in this section.
 3. Specialized hospitals providing surgical services shall comply with the anesthesia services requirements for general acute hospitals in this section.

History: Effective April 1, 1994; amended effective August 1, 1999.

General Authority: NDCC 23-01-03(3), 28-32-02

Law Implemented: NDCC 23-16-06

33-07-01.1-33. Respiratory care services.

1. If the general acute hospital provides respiratory care services, the services must be under the supervision of a licensed health care practitioner, organized and integrated with other services of the hospital.
 - a. Respiratory care policies and procedures must be developed, implemented, and updated as needed for at least the following:
 - (1) Responsibility of the service to the medical staff.
 - (2) Clear protocol as to who can perform specific procedures.
 - (3) Written procedures for each type of therapeutic or diagnostic procedure.
 - (4) Written procedures for the cleaning, disinfection, or sterilization of all equipment that is not disposable.
 - (5) Written procedures for infection control.
 - (6) Written procedures for the control of all water used for respiratory therapy, if applicable.
 - (7) Protocol that establishes calibration and operation of equipment consistent with manufacturer's specifications and ensures that all equipment is maintained according to an established schedule.

- b. All treatments involving respiratory care must be recorded in the patient's medical record by the person rendering the service, and must include type of therapy, date and time of treatments, any adverse reactions to treatments, and records of periodic evaluations by the licensed health care practitioner.
 - c. All treatments must be administered by respiratory therapists or other qualified staff in compliance with state law.
2. If the primary care hospital provides respiratory care services, the hospital shall comply with the respiratory care services requirements for general acute hospitals in this section.
 3. If the specialized hospital provides respiratory care services, the hospital shall comply with the respiratory care services requirements for general acute hospitals in this section.

History: Effective April 1, 1994.

General Authority: NDCC 23-01-03(3), 28-32-02

Law Implemented: NDCC 23-16-06

33-07-01.1-34. Obstetrical services.

1. All general acute hospitals providing obstetrical services shall provide for the admission, medical care, transfer, or discharge of obstetric and neonatal patients. Obstetrical services must include the following:
 - a. The obstetrical services must have an organized obstetric staff with a chief of obstetrical services who is either certified or qualified in obstetrics or a physician who regularly practices obstetrics as head of the obstetrical service. The level of qualification and expertise of the chief of the obstetrical services must be appropriate to the level of care rendered in the hospital. Responsibilities of the chief of the obstetrical service include:
 - (1) The general supervision of the care of obstetrical patients.
 - (2) The arrangement of conferences held at regular intervals to review surgical procedures and operations, complications, and mortality.
 - (3) The provision for exchange of information between medical, administrative, and nursing staffs.
 - b. Only members of the medical staff with appropriate privileges may admit and care for patients in the obstetrical services areas. A roster of licensed health care practitioners, specifying the obstetrical privileges of each, must be maintained and available to staff in the obstetrical services area and in the files of the hospital administration.
 - c. Obstetrical patients under the effect of an analgesic or an anesthetic, in active labor or delivery, must be monitored and attended in accordance with the current standards of practice for obstetric-gynecologic services as identified by the association of women's health, obstetric and neonatal nursing and defined by hospital policies and procedures.
 - d. Fetal maturity must be established and documented prior to elective inductions and Caesarean sections.
 - e. There must be a written policy and procedure established in accordance with the current standards of practice as identified by the association of women's health, obstetric, and neonatal nursing concerning the administration and documentation of oxytocic drugs and their effects. Oxytocin may be used for medical induction or stimulation of labor only when qualified personnel, determined by the medical staff, can attend the patient closely. If electronic fetal monitoring is not available, the patient must be monitored on a

one-to-one basis during the administration of the oxytocic drugs. The following areas must be included in the written policy and procedure for administration and documentation of oxytocic medications:

- (1) The licensed health care practitioner shall evaluate the patient for induction or stimulation, especially with regard to indications for use of oxytocic medications.
 - (2) The licensed health care practitioner or other individuals starting the oxytocin shall be familiar with its effects and complications and be qualified to identify both maternal and fetal complications.
 - (3) A qualified licensed health care practitioner shall be immediately available as necessary to manage complications effectively.
- f. Birthing and delivery rooms must be equipped and staffed to provide emergency resuscitation for infants in accordance with the current association of women's health, obstetric, and neonatal nursing standards of practice. Only personnel qualified and trained to do so may use infant emergency resuscitation equipment.
- g. Equipment and personnel trained to use the equipment to maintain a neutral thermal environment for the neonate must be available and utilized as needed.
- h. Nursing staff for obstetrical services must include:
- (1) Nursing supervision by a registered nurse must be provided for the entire twenty-four-hour period the obstetrical services is occupied.
 - (2) At least one nurse trained in obstetrical and nursery care must be assigned to the care of mothers and infants at all times. Infants must be visually or electronically monitored at all times.
 - (3) A registered nurse must be in attendance at all deliveries, and must be available to monitor the mother's general condition and that of the fetus during labor.
- i. A clean nursery must be provided near the mothers' rooms with adequate lighting and ventilation and must include the following:
- (1) Bassinets equipped to provide for the medical examination of the newborn and for the storage of necessary supplies and equipment.
 - (2) A glass observation window through which infants may be viewed.
 - (3) Each nursery must have immediately on hand equipment necessary to stabilize the sick infant in accordance with current standards of practice established by the association of women's health, obstetric, and neonatal nursing and defined in hospital policies.
- j. The hospital shall identify specific rooms and beds to be used exclusively for obstetrical patients, obstetrical and gynecological patients, and nursery patients as provided in a plan specifically approved by the department.
- (1) Obstetrical services must be located and arranged to provide maximum protection for obstetrical and neonatal patients from infection and cross-infection from patients in other services of the hospital.
 - (2) Obstetrical services must be located in the hospital so as to prevent through traffic to any other part of the hospital.

2. If the primary care hospital provides obstetrical services, the hospital shall comply with obstetrical services requirements for general acute hospitals in this section.
3. If a specialized hospital provides obstetrical services, the specialized hospital is subject to the obstetrical services requirements for general acute hospitals.

History: Effective April 1, 1994; amended effective May 1, 1998; August 1, 1999.

General Authority: NDCC 23-01-03(3), 28-32-02

Law Implemented: NDCC 23-16-06

33-07-01.1-34.1. Outpatient birth services in hospitals.

1. General acute hospitals providing outpatient birth services in hospitals are subject to the outpatient birth services requirements for specialized hospitals in this section.
2. Primary care hospitals may not provide outpatient birth services.
3. Any facility that provides outpatient birth services shall comply with this section. A facility may not hold itself out to the public as providing outpatient birth services unless such outpatient birth service has been licensed by the department and meets the requirements for outpatient birth services in this section.
 - a. The facility provides peripartum care of low-risk women for whom prenatal and intrapartum history, physical examination, and laboratory screening procedures have demonstrated normal, uncomplicated singleton term (thirty-seven to forty-one and six-sevenths weeks), multipara pregnancies with a spontaneous labor, and vertex presentation that are expected to have an uncomplicated birth. The policy and procedures must specify medical and social criterion to determine risk status at admission and during labor.
 - b. Patients who are not considered low risk, patients who experience no cervical dilation in over three hours who are considered in active labor according to the American college of obstetricians and gynecologists standards, and patients who develop a high-risk condition based on standards of practice shall be transferred as described in subsection 6.
 - c. Patients shall be fully informed on and provide written consent to the benefits and risks of the services available and alternatives if more advanced services are required.
 - d. Surgical procedures must be limited to those procedures normally encountered during uncomplicated childbirth, such as episiotomy and repair, and must not include operative obstetrics or cesarean section. Circumcisions of newborns are allowed.
 - e. Labor may not be inhibited, stimulated, or augmented with chemical agents during the first or second stage of labor nor may labor be induced by artificial rupture of membranes.
 - f. Vacuum extractors, forceps, and recorded electronic fetal monitors are not appropriate for use after admittance in active labor in outpatient birth services. Patients requiring these interventions shall be transferred as described in subsection 6.
 - g. General and conduction anesthesia may not be administered. Local anesthesia and pudendal block may be administered if procedures are established and approved by medical staff.
 - h. Emergency medications, equipment, and supplies must be available, including tocolytics and uterotonic medications. Nothing in the foregoing should be construed to prohibit

exercise of medical skills or the use of emergency medications to benefit the mother or the baby in case of emergency. Patients requiring these interventions shall be transferred as described in subsection 6.

- i. Mothers and infants must be discharged within twenty-six hours after birth in accordance with standards set by the medical staff and specified in the policies and procedures. A program for prompt followup care and postpartum evaluation after discharge must be ensured and outlined in the policies and procedures. This program must include assessment of infant health, including physical examination, laboratory and screening tests required by state law at the appropriate times, maternal postpartum status, instruction in child care including immunization, referral to sources of pediatric care, provision of family planning services, and assessment of mother-child relationship including breastfeeding.
4. The outpatient birth services shall ensure care is provided by licensed health care practitioners and nursing staff with access to and availability of consulting clinical specialists as follows:
 - a. Every birth must be attended by at least two health care professionals, licensed or certified consistent with state laws, with relevant experience, training, and demonstrated competence and who have maintained competence in basic life support, including fluid resuscitation and a neonatal resuscitation program to respond to patient needs.
 - b. The primary maternity care licensed health care practitioner who attends each birth shall be educated, licensed, and have approved clinical privileges to provide birthing services.
 - c. A licensed health care practitioner with relevant experience, training, and demonstrated competence shall be on call and readily available within a reasonable time of birth for resuscitation if needed.
 - d. A licensed health care practitioner with relevant experience, training, and demonstrated competence shall assess the neonate within twenty-four hours of delivery.
 - e. There must be adequate numbers of nursing staff who have completed orientation and demonstrated competence in the care of uncomplicated pregnancies with the ability to detect, stabilize, and initiate management of unanticipated maternal-fetal or neonatal problems which occur during the antepartum, intrapartum, or postpartum period until the patient can be discharged or transferred to a facility at which specialty maternal care is available.
 5. An appropriately staffed level I nursery must be available on the premises.
 6. There must be criteria and a written agreement for transfer of patients to an acute care hospital capable of providing inpatient obstetrical and neonatal services with a level II or level III nursery. The outpatient birth services must be located within thirty minutes of this hospital.
 7. There must be provisions in place either directly or by agreement for transport services, obstetric consultation services, pediatric consultation services, and childbirth and parent education support services.
 8. The outpatient birth service shall develop and implement policies and procedures to ensure physical security of mothers and newborns.

History: Effective July 1, 2017.

General Authority: NDCC 23-01-03(3), 28-32-02

Law Implemented: NDCC 23-16-06

33-07-01.1-35. Specialized rehabilitation services in hospitals.

1. Specialized rehabilitation services in a general acute hospital must be provided in a distinct, clearly defined, special unit and are subject to the specialized rehabilitation services in hospitals requirements for specialized hospitals in this section. If in the course of the inspection of a general acute hospital, the department finds from a review of the rehabilitation services rendered and the adequacy of the consultation and referral resources that the hospital practice and staffing warrants the establishment of a specialized rehabilitation service, the department shall recommend the establishment of such service.
2. Primary care hospitals may not provide specialized rehabilitation services.
3. The specialized rehabilitation hospital shall provide preventive, diagnostic, therapeutic, and rehabilitative services to patients in accordance with the licensure requirements in this chapter.
 - a. The rehabilitation hospital shall provide for services to inpatients and outpatients by a core group of professionals, who are licensed or certified consistent with state laws, which must include, dependent on the patient's needs, the following:
 - (1) Occupational therapist.
 - (2) Physical therapist.
 - (3) Physician.
 - (4) Psychologist.
 - (5) Rehabilitation nurse.
 - (6) Social worker.
 - (7) Speech and language pathologist.
 - (8) Therapeutic recreation specialist.
 - b. Additional services that must be provided to inpatients and outpatients, either directly by the rehabilitation hospital or by arrangement, dependent upon the identified needs and program goals, include:
 - (1) Audiology.
 - (2) Chaplaincy.
 - (3) Chemical dependency counseling.
 - (4) Dental services.
 - (5) Dietary services and nutritional counseling.
 - (6) Driver evaluation and education.
 - (7) Environmental modification.
 - (8) Laboratory services.
 - (9) Licensed health care practitioner services.
 - (10) Orthotics and prosthetics.

- (11) Pharmaceutical services.
 - (12) Psychiatry.
 - (13) Radiology services.
 - (14) Rehabilitation engineering.
 - (15) Respiratory care services.
 - (16) Sexual counseling.
 - (17) Vocational testing and rehabilitation.
- c. For inpatients, unless contraindicated in writing by the qualified psychiatrist, the rehabilitation hospital shall provide at a minimum three hours of services per patient per day, which must include one or a combination of the following: physical therapy, occupational therapy, speech-language pathology, prosthetics and orthotics services, or therapeutic recreational therapy.
 - d. Rehabilitation hospitals must be accredited by the commission on accreditation of rehabilitation facilities in the category of comprehensive inpatient rehabilitation prior to licensure as a rehabilitation hospital by the department.
 - e. If a hospital licensed by the department provides specialized rehabilitation services in addition to other hospital services, the hospital shall adhere to the rules of this section in addition to the rules for other hospital services.
 - f. Submission of documents and onsite review must be as follows:
 - (1) The rehabilitation hospital, upon receipt, shall submit all commission on accreditation of rehabilitation facilities survey results, recommendations, and plans of correction to the department.
 - (2) Based on the commission on accreditation of rehabilitation facilities survey results, the department may require changes or additions to the recommendations or plans of corrections if endangerment to the health, well-being, or safety of patients is involved.
 - (3) Onsite review must be conducted by the department to assess compliance with licensure requirements not included in the commission on accreditation of rehabilitation facilities standards.

History: Effective April 1, 1994.

General Authority: NDCC 23-01-03(3), 28-32-02

Law Implemented: NDCC 23-16-06

33-07-01.1-36. Psychiatric services in hospitals.

- 1. General acute hospitals providing psychiatric services are subject to the psychiatric services in hospitals requirements for specialized hospitals in this section. If, in the course of the inspection of a general acute hospital, the department finds from a review of the psychiatric treatment rendered and the adequacy of the consultation and referral resources that the hospital practice and staffing warrants the establishment of a psychiatric service, the department shall notify the hospital of the need to establish the service in a manner that complies with this section.
- 2. Primary care hospitals may not provide psychiatric services.

3. Any facility that provides or purports to provide psychiatric inpatient or inpatient and outpatient diagnosis or treatment on other than an emergency basis shall comply with this section. A hospital may not hold itself out to the public as providing psychiatric services unless such psychiatric service has been licensed by the department and meets the requirements for a psychiatric hospital in this section.
 - a. Hospitals accredited by a national accrediting entity in the category of psychiatric services shall submit, upon receipt, all accreditation survey results, recommendations, and plans of correction to the department.
 - b. In hospitals without an approved psychiatric service, psychiatric care to patients with a primary diagnosis of a psychiatric disorder may be rendered on an emergency basis by appropriate members of the medical staff as determined by the hospital. Psychiatric consultation must be available and utilized appropriately as determined by the hospital.
 - c. The organization and responsibilities of the medical staff for psychiatric services must be in accordance with licensure requirements, except as amended and modified:
 - (1) The physician in charge of the psychiatric services must be a psychiatrist who is licensed to practice medicine in North Dakota.
 - (2) The psychiatrists on the staff of the psychiatric hospital or psychiatric services of a general acute hospital must have as minimum qualifications at least three years' approved residency training in psychiatry or equivalent training and experience. If physicians other than psychiatrists are authorized to treat patients in a psychiatric hospital or in a psychiatric service there must be timely evidence of psychiatric consultation after the patient is admitted, and ongoing consultation with a psychiatrist who is a member of the psychiatric staff, as needed.
 - (3) There must be other medical staff in appropriate specialties, available at all times to the psychiatric staff.
 - d. The organization and staffing of the nursing service must be in accordance with the licensure requirements, except as amended and modified:
 - (1) The registered nurse supervising the nursing services of the psychiatric services must have experience and demonstrated competency in psychiatric nursing.
 - (2) The nursing personnel of the psychiatric services in a general acute hospital must be a separate staff who are assigned to the psychiatric services.
 - (3) There must be at least one registered nurse with experience in psychiatric nursing on duty at all times on each psychiatric nursing unit. The number of registered nurses and other nursing personnel must be adequate to provide the individual patient care required to carry out the patient care plan for each patient.
 - e. The following services or consultative resources are required: clinical psychological services, social work services, and occupation and recreational therapy services. These services must be under the direction of a psychiatrist in charge of the psychiatric services in a general acute hospital or the psychiatric diagnosis or treatment units in a psychiatric hospital. The staff used to support these services must be adequate in number and be qualified by professional education, experience, and demonstrated ability. If registration or licensing of personnel is required by statute or regulation, the registration number must be on file and available upon request.
 - f. Personnel development and training for psychiatric services staff must include the following:

- (1) There must be written evidence of orientation training for all staff and ongoing, planned, and scheduled inservice training for all staff.
 - (2) Ongoing interdisciplinary staff conferences must be held to ensure communication, coordination, and participation of all professional staff and personnel involved in the care of patients.
- g. Specialized procedures for psychiatric services must be provided for and implemented as follows:
- (1) A patient may not be subject to the withholding of privileges or to any system of rewards, except as part of a treatment plan.
 - (2) Electroconvulsive therapy, experimental treatments involving any risk to the patient, or aversion therapy may not be prescribed, unless:
 - (a) The patient's treatment team has documented in the patient's record that all reasonable and less intensive treatment modalities have been considered, the treatment represents the most effective therapy for the patient at that time, the patient has been given a full explanation of the nature and duration of the proposed treatment and why the treatment team is recommending the treatment, and the patient has been informed of the right to accept or refuse the proposed treatment and, if the patient consents, has the right to revoke the consent for any reason at any time prior to or between treatments.
 - (b) The treatment was recommended by qualified staff members trained and experienced in the treatment procedure and has been approved by the psychiatrist.
 - (c) The patient has given written informed consent to the specific proposed treatment. In the alternative, oral informed consent is sufficient if that consent is witnessed by two persons not part of the patient's treatment team. In either case, such consent must be limited to a specified number of maximum treatments over a period of time and must be revocable at any time before or between treatments. Such withdrawal of consent is immediately effective.
 - (d) If a patient's treatment team determines that the patient could benefit from one of those specified treatments but also believes that the patient does not have the capacity to give informed consent to the treatment, appropriate consent consistent with applicable state laws must be obtained before such treatment may be administered to the patient.
 - (3) A patient may not be subject to chemical, physical, or psychological restraints, including seclusion, other than in accordance with the policy and procedures for seclusion and restraint approved by the medical staff and governing body. A copy of the applicable regulations must be made available to patients upon request.
 - (4) A patient may not be the subject of any research, unless conducted in strict compliance with federal regulations on the protection of human subjects. Patients considered for research approved by the hospital must receive and understand a full explanation of the nature of the research, the expected benefit, and the potential risk involved. Copies of the federal regulations must be made available to patients or their advocates involved in, or considering becoming involved in, research.
- h. If the treatment team determines that continued voluntary inpatient treatment is not indicated, the treatment team shall discharge the patient with an appropriate postdischarge plan. The postdischarge plan must address followup needs, future

consultative needs, or in the event of patient regression or deterioration, treatment or admission needs.

- i. Care of patients for psychiatric services must include the following:
 - (1) Each psychiatric unit shall have available recreational and occupational therapy and other appropriate facilities adequate in size in relation to patient population, number of beds, and program.
 - (2) Restraints and seclusion facilities must be available, and written policies must be established for their use. Mechanical restraints or seclusion may be used only on the written order of a physician. This written order must be valid for specific periods of time. In an emergency, the licensed professional in charge may order restraints. Confirmation of the order by a physician must be secured. Policies and procedures regarding use of restraints and seclusion must be reviewed annually. The patient medical record must indicate justification for the restraint, time applied and released, and other pertinent information.
 - (3) A current policy and procedure manual must be maintained for the psychiatric service. The manual must include procedures for the care and treatment of patients including the care of suicidal and assaultive patients, and the elopement of patients. The manual must identify the relationship with state agencies and community organizations providing psychiatric services. It must also describe plans for the evaluation and disposition of psychiatric emergencies.
 - (4) The design of facilities and the selection of equipment and furnishings must be conducive to the psychiatric program and must minimize hazards to psychiatric patients.
- j. The psychiatric services shall develop an interdisciplinary team composed of mental health professionals, health professionals, and other persons who may be relevant to the patient's treatment. At least one member of the team must be a psychiatrist. The team and patient or advocate shall formulate and evaluate an appropriate treatment plan for the patient.
 - (1) The director of the interdisciplinary team shall assure that staff trained and experienced in the use of modalities proposed in the treatment plan participate in its development, implementation, and review.
 - (2) The director of the interdisciplinary team is responsible for:
 - (a) Ensuring that the person in treatment is encouraged to become increasingly involved in the treatment planning process.
 - (b) Implementing and reviewing the individualized treatment plan and participating in the coordination of service delivery with other service providers.
 - (c) Ensuring that the unique skills and knowledge of each team member are utilized and that specialty consultants are utilized when needed.
 - (3) Although an interdisciplinary team must be under the direction of a psychiatrist, specific treatment modalities may be under the direction of other mental health professionals when they are specifically trained to administer or direct such modalities.
- k. A comprehensive individualized treatment plan must:

- (1) Be formulated to the extent feasible with the consultation of the patient. When appropriate to the patient's age, or with the patient's consent, the patient's family, personal guardian, or appropriate other persons should be consulted about the plan.
 - (2) Be based upon diagnostic evaluation that includes examination of medical, psychological, social, cultural, behavioral, familial, educational, vocational, and developmental aspects of the patient's situation.
 - (3) Set forth treatment objectives and prescribe an integrated program of therapies, activities, experiences, and appropriate education designed to meet these objectives.
 - (4) Result from the collaborative recommendation of the patient's interdisciplinary team.
 - (5) Be maintained and updated with progress notes, and be retained in the patient's medical record.
 - (6) State the basis for the restraints if the plan provides for restraints. The patient medical record must indicate what less restrictive alternatives were considered and why they were not utilized.
 - (7) Be written in terms easily explainable to the lay person. A copy of the current treatment plan must be available for review by the person in treatment.
 - (8) Note when the most appropriate form of treatment for the individual is not available or is too expensive to be feasible.
- I. At least once every seven days every person in treatment must be plan reviewed. A report of the review and findings must be summarized in the patient's medical record and the treatment plan must be updated as necessary.
- m. Subject to certain limitations authorized by a parent, legal guardian, legal custodian, or a court of law concerning a minor or guardian of an incapacitated person or restrictions by the treating physician or psychiatrist, which in their professional judgment is in the best interest of the patient, each patient has the right to:
- (1) Receive or refuse treatment for mental and physical ailments and for the prevention of illness or disability.
 - (2) The least restrictive conditions necessary to achieve the purposes of the treatment plan.
 - (3) Be treated with dignity and respect.
 - (4) Be free from unnecessary restraint and isolation.
 - (5) Visitation and telephone communications.
 - (6) Send and receive mail.
 - (7) Keep personal clothing and possessions.
 - (8) Regular opportunities for outdoor physical exercise.
 - (9) Participate in religious worship of choice.
 - (10) Be free from unnecessary medication.
 - (11) Exercise all civil rights, including the right to habeas corpus.

- (12) Not be subjected to experimental research without the express written consent of the patient or of the patient's guardian.
- (13) Not be subjected to psychosurgery, electroconvulsive treatment, or aversive reinforcement conditioning, without the express and informed written consent of the patient or the patient's guardian.
- n. Each hospital must have a clearly defined appeal system through which any patient who wishes to voice objections concerning the patient's treatment must be heard and have objections determined.
 - (1) Each hospital shall monitor the appeal system to see that it works properly and records must be maintained for review by the department in order to investigate any complaint.
 - (2) All patients must be advised of such system and be encouraged to use it when they believe their treatment plan is not necessary or appropriate to their needs.
- o. Medical record requirements for psychiatric hospitals and psychiatric services of general acute hospitals must include the following:
 - (1) Medical records must stress the psychiatric components of the patient's condition and care including history of findings and treatment rendered for the psychiatric condition for which the patient is hospitalized.
 - (2) A provisional or admitting diagnosis must be made on every patient at the time of admission and include the diagnoses of current diseases as well as the psychiatric diagnoses.
 - (3) Data from all pertinent sources must be included, in addition to data obtained from the patient.
 - (4) A psychiatric evaluation must be performed within forty-eight hours of admission, include a medical history, contain a record of mental status, and note the onset of illness, the circumstances leading to admission, attitudes, behavior, estimate of intellectual functions, memory functioning, orientation, and an inventory of the patient's assets in descriptive, not interpretive, fashion.
 - (5) A complete neurological examination must be recorded at the time of the admission physical examination, when indicated.
 - (6) Social service records, including reports of interviews with patients, family members, and others must provide an assessment of home plans, family attitudes, and community resource contacts, with appropriate recommendations for family or community resource involvement, as well as a social history.
 - (7) Reports of consultations, reports of electroencephalograms, and other pertinent reports of special studies.
 - (8) The patient's comprehensive treatment plan must be recorded, must be based on an inventory of the patient's strengths as well as disabilities, and must include a substantiated diagnosis in the terminology of the most current edition of the American psychiatric association's diagnostic and statistical manual, short-term and long-range goals, and the specific treatment modalities utilized as well as the responsibilities of each member of the treatment team in such a manner that it provides adequate justification and documentation for the diagnoses and for the treatment and rehabilitation activities carried out.

- (9) The treatment received by the patient must be documented to assure that all active therapeutic efforts such as individual and group psychotherapy, drug therapy, milieu therapy, occupational therapy, recreational therapy, industrial or work therapy, nursing care, and other therapeutic interventions are included.
- (10) The discharge summary must include a recapitulation of the patient's hospitalization and recommendations from appropriate services concerning followup or aftercare as well as a brief summary of the patient's condition on discharge.
- (11) Confidentiality of the psychiatric record must be recognized and safeguarded in medical records services of the hospital.

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