SUBCHAPTER 13B – LICENSING OF HOSPITALS

10A NCAC 13B .0100 RESERVED FOR FUTURE CODIFICATION

SECTION .0200 – RESERVED FOR FUTURE CODIFICATION

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SECTION .1800 – RESERVED FOR FUTURE CODIFICATION

10A NCAC 13B .1800 RESERVED FOR FUTURE CODIFICATION

SECTION .1900 - SUPPLEMENTAL RULES FOR THE LICENSURE OF THE SKILLED: INTERMEDIATE: ADULT CARE HOME BEDS IN A HOSPITAL

10A NCAC 13B .1901 SUPPLEMENTAL RULES

When a hospital offers nursing facility or adult care home long-term care services, the services shall be included under one hospital license as provided in Rule .0201(c). The general requirements included in this Subchapter shall apply when applicable but in addition the nursing facility care and adult care home care unit must meet the supplemental requirements of this Section.

History Note: *Authority G.S. 131E-79; 42 U.S.C. 1396 r (a);*
Eff. February 1, 1986;
Temporary Amendment Eff. October 1, 1990 For a Period of 142 Days to Expire on February 28, 1991;
Amended Eff. March 1, 1991;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. July 22, 2017.

10A NCAC 13B .1902 DEFINITIONS

The following definitions shall apply throughout this Section, unless text otherwise indicates to the contrary:

(1) "Accident" means something occurring by chance or without intention that has caused physical or mental harm to a patient, resident, or employee.
(2) "Administer" means as defined in G.S. 90-87.
(3) "Administrator" means the person who has authority for and is responsible to the governing board for the overall operation of a facility.
(4) "Brain injury long-term care" is defined as an interdisciplinary, intensive maintenance program for patients who have incurred brain damage caused by external physical trauma and who have completed a primary course of rehabilitative treatment and have reached a point of no gain or progress for more than three consecutive months. Services are provided through a medically supervised interdisciplinary process and are directed toward maintaining the individual at the optimal level of physical, cognitive, and behavioral functioning.
(5) "Combination Facility" means any hospital with nursing home beds that is licensed to provide more than one level of care such as a combination of intermediate care and skilled nursing care and adult care home care.
(6) "Department" means the North Carolina Department of Health and Human Services.
(7) "Director of Nursing" means the nurse who has authority and responsibility for all nursing services and nursing care.
(8) "Dispense" means as defined in G.S. 90-87.
(9) "Drug" means as defined in G.S. 90-87.

(10) "Duly Licensed" means holding a current and valid license as required under the General Statues of North Carolina.
(11) "Incident" means an intentional or unintentional action, occurrence or happening that is likely to cause or lead to physical or mental harm to a patient, resident, or employee.
(12) "Licensed Practical Nurse" means as defined in G.S. 90-171.30 or G.S. 90-171.32.
(13) "Medication" means "drug" as defined in Item (9) of this Rule.
(14) "Nurse Aide" means any individual providing nursing or nursing-related services to patients in a facility, and is not a licensed health professional, a qualified dietitian or someone who volunteers to provide such services without pay, and who is listed in a Nurse Aide Registry pursuant to G.S. 131E-255.
(15) "Nurse Aide Trainee" means an individual who has not completed an approved nurse aide training course by the Department in accordance with 10A NCAC 13O .0301, herein incorporated by reference including subsequent amendments and editions, and competency evaluation and is demonstrating knowledge, while performing tasks that they have been found proficient in by an instructor. These tasks shall be performed under the supervision of a registered nurse. The term does not apply to volunteers.
(16) "Nursing Facility" means that portion of a nursing home certified under Title XIX of the Social Security Act (Medicaid) as in compliance with federal program standards for nursing facilities. It is often used synonymous with the term "nursing home," the usual prerequisite level for state licensure for nursing facility (NF) certification and Medicare skilled nursing facility (SNF) certification.
(17) "Nurse in Charge" means the nurse to whom duties for a specified number of patients and staff for a specified period of time have been delegated, such as for Unit A on the 7-3 or 3-11 shift.
(18) "On Duty" means personnel who are awake, dressed, and responsive to patient needs and present in the facility performing assigned duties.
(19) "Patient" means any person admitted for care to a skilled nursing or intermediate care facility.
(20) "Physician" means as defined in G.S. 90-9.1 or G.S. 90-9.2.
(21) "Qualified Dietitian" means as defined in 42 CFR 483.60(a)(1), herein incorporated by reference including subsequent amendments and editions. Electronic copies of 42 CFR 483.60 can be obtained free of charge at https://www.ecfr.gov/cgi-bin/text-idx?SID=1260800a39929487f0ca55b0ab5e710b&mc=true&tpl=/ecfrbrowse/Title42/42cfrv5_02.tpl#0 .
(22) "Registered Nurse" means as defined in G.S. 90, Article 9A.
(23) "Resident" means as defined in G.S.131D-2.1.
(24) "Supervisor-in-Charge" means a duly licensed nurse to whom supervisory duties have been delegated by the Director of Nursing.
(25) "Ventilator dependence" means physiological dependency by a patient on the use of a ventilator for more than eight hours a day.

History Note: *Authority G.S. 131E-79;*
Eff. February 1, 1986;
Amended Eff. March 1, 1990;
Temporary Amendment Eff. October 1, 1990 For a Period of 142 Days to Expire on February 28, 1991;
Amended Eff. February 1, 1993; December 1, 1991; March 1, 1991;
Readopted Eff. April 1, 2020.

10A NCAC 13B .1903 INSPECTIONS

(a) Any hospital with beds licensed by the Department under Section .1900 of these Rules may be inspected by one or more authorized representatives of the Department at any time. Generally, inspections will be conducted between the hours of 8:00 a.m. and 6:00 p.m., Monday through Friday. However, complaint investigations shall be conducted at the most appropriate time for investigating allegations of the complaint.
(b) At the time of inspection, any authorized representative of the Department shall make his presence known to the administrator or other person in charge who shall cooperate with such representative and facilitate the inspection.

History Note: *Authority G.S. 131E-79; 42 U.S.C. 1396 r (a);*

Eff. February 1, 1986;
Amended Eff. March 1, 1990;
Temporary Amendment Eff. October 1, 1990 For a Period of 142 Days to Expire on February 28, 1991;
Amended Eff. March 1, 1991;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. July 22, 2017.

10A NCAC 13B .1904 PROCEDURE FOR APPEAL

A hospital with nursing facility or adult care home beds may appeal any decision of the Department to deny, revoke or alter a license by making such an appeal in accordance with G.S. Chapter 150B.

History Note: *Authority G.S. 131E-79; 42 U.S.C. 1396 r (a);*
Eff. February 1, 1986;
Amended Eff. March 1, 1990;
Temporary Amendment Eff. October 1, 1990 For a Period of 142 Days to Expire on February 28, 1991;
Amended Eff. March 1, 1991;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. July 22, 2017.

10A NCAC 13B .1905 ADMISSIONS

(a) No patient shall be admitted except under the orders of a duly licensed physician.
(b) The facility shall acquire prior to or at the time of admission orders from the attending physician for the immediate care of the patient or resident.
(c) Within 48 hours of admission, the facility shall acquire medical information which shall include current medical findings, diagnosis, rehabilitation potential, a summary of the hospital stay if the patient is being transferred from a hospital, and orders for the ongoing care of the patient.
(d) If a patient is admitted from somewhere other than a hospital, a physical examination shall be performed either within 5 days prior to admission or within 48 hours following admission.
(e) Hospitals offering nursing facility or domiciliary home care as a new service must prepare a plan of admission which, at a minimum, assures availability of staff time and plans for individual patient assessments, initiation of health care or nursing care plans, and implementation of physician and nursing treatment plans. This plan must be available for inspection during the initial licensure survey prior to issuance of a license.
(f) Only persons who are 18 years of age or older shall be admitted to adult care home beds in a facility.

History Note: *Authority G.S. 131E-79; 42 U.S.C. 1396 r (a);*
Eff. February 1, 1986;
Amended Eff. March 1, 1990;
Temporary Amendment Eff. October 1, 1990 For a Period of 142 Days to Expire on February 28, 1991;
Amended Eff. March 1, 1991;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. July 22, 2017.

10A NCAC 13B .1906 POLICIES AND PROCEDURES

The governing board shall assure written policies and procedures which are available to and implemented by staff. These policies and procedures shall cover at least the following areas:

(1) admissions;
(2) dietary;
(3) discharges with physician orders and patients or residents leaving against physician advice;
(4) gratuities and solicitation which at a minimum shall provide that no owner, operator, agent or employee of a facility nor any member of his family shall accept a gratuity directly or indirectly from an patient or resident in the facility or solicit for any type of contribution;
(5) housekeeping;
(6) infection control which must include, but shall not be limited to, requirements for sterile, aseptic and isolation techniques; and communicable disease screening including, at a minimum, annual tuberculosis screening for all staff and inpatients of the facility;

(7) maintenance of patient medical or health care records including charging or record keeping;
(8) orientation of all facility personnel;
(9) patient or resident care plans, treatment and other health care or nursing care, including but not limited to all policies and procedures required by rules contained in this Subchapter;
(10) patients' or residents' rights;
(11) physical evaluation for residents and patients at least annually;
(12) physician services and utilization of the individual's private physician;
(13) procurement of supplies and equipment to meet individual patient care needs;
(14) protection of patients from abuse and neglect;
(15) range of services provided;
(16) recording and reporting to the department of accidents or incidents occurring to patients in any part of the facility and maintenance of such reports or records;
(17) rehabilitation services;
(18) release of medical record information;
(19) screening and reporting communicable disease to the local health department; and
(20) transfers.

History Note: *Authority G.S. 131E-79;*
Eff. February 1, 1986;
Amended Eff. March 1, 1990;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. July 22, 2017.

10A NCAC 13B .1907 GENERAL

The governing board shall assure that policies and procedures are available and implemented for assessing each patient's or resident's health care needs and planning for meeting identified health care needs. There shall be a system for evaluating the effectiveness of the assessment, planning and implementation (delivery of care processes) for each patient or resident.

History Note: *Authority G.S. 131E-79;*
Eff. February 1, 1986;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. July 22, 2017.

10A NCAC 13B .1908 FREQUENCY: METHOD AND CONTENT OF ASSESSMENT: PLANNING

Each patient's and resident's condition must be assessed on a regular, periodic basis, at least quarterly, with appropriate notation and updating of the health care plan. Health care planning for each patient and resident shall be an on-going process and must include, but shall not be limited to, the following:

(1) data which is systematically and continuously collected about his or her health status; the data shall be recorded so as to be accessible and communicated to all staff involved in the patient's or resident's care;
(2) current problems or needs identified and prioritized from a completed assessment relevant to the patient's or resident's response to aging, illness and general health status; and
(3) a current plan of care developed in conjunction with the patient or resident or legal guardian that includes measurable time related goals and approaches, or measures to be employed by various disciplines in order to achieve the identified goals.

History Note: *Authority G.S. 131E-79;*
Eff. February 1, 1986;
Amended Eff. March 1, 1990;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. July 22, 2017.

10A NCAC 13B .1909 IMPLEMENTATION OF HEALTH PLAN

All parts of the plan of care shall be assigned to specific disciplines or staff as indicated in the plan of care to assure that health care and rehabilitative services are performed daily and documented for those patients and residents who require such services.

History Note: *Authority G.S. 131E-79;*
Eff. February 1, 1986;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. July 22, 2017.

10A NCAC 13B .1910 NURSING/HEALTH CARE ADMINISTRATION AND SUPERVISION

(a) A licensed facility shall have a director of nursing service who shall be responsible for the overall organization and management of all nursing services and shall be currently licensed to practice as a registered nurse by the North Carolina Board of Nursing in accordance with G.S. 90, Article 9A.

(b) The Director of Nursing shall not serve as administrator or assistant administrator.

(c) A licensed facility with nursing facilities shall provide a full-time director of nursing on duty at least eight hours per day, five days a week. A registered nurse shall relieve the Director of Nursing (be in charge of nursing) during the Director's absence.

(d) A licensed facility shall employ and assign registered nurses, licensed practical nurses, nurse aides and nurse aide trainees for duties in accordance with G.S. 90, Article 9A.

(e) The Director of Nursing shall cause the following to be accomplished:

(1) establishment and implementation of nursing policies and procedures which shall include, but shall not be limited to the following:
  (A) assessment of and planning for patients' nursing care or health care needs, and implementation of nursing or health care plans;
  (B) daily charting of any unusual occurrences or acute episodes related to patient care, and progress notes written monthly reporting each patient's performance in accordance with identified goals and objectives and each patient's progress toward rehabilitative nursing goals;
  (C) assurance of the delivery of nursing services in accordance with physicians' orders, nursing care plans and the facility's policies and procedures;
  (D) notification of emergency physicians or on-call physicians;
  (E) infection control to prevent cross-infection among patients and staff;
  (F) reporting of deaths;
  (G) emergency reporting of fire, patient and staff accidents or incidents, or other emergency situations;
  (H) use of protective devices or restraints to assure that each patient or resident is restrained in accordance with physician orders and the facility's policies, and that the restrained patient or resident is appropriately evaluated and released at a minimum of every two hours;
  (I) special skin care and decubiti care;
  (J) bowel and bladder training;
  (K) maintenance of proper body alignment and restorative nursing care;
  (L) supervision of and assisting patients with feeding;
  (M) intake and output observation and reporting for those patients whose condition warrants monitoring of their fluid balance. This will include those patients on intravenous fluids or tube feedings, and patients with kidney failure and temperatures elevated to 102 degrees Fahrenheit or above;
  (N) catheter care; and
  (O) procedures used in caring for patients in the facility;
(2) development of written job descriptions for nursing personnel;
(3) periodic assessment of the nursing department with identification of personnel requirements as they relate to patient care needs and reporting same to the administrator;
(4) a planned orientation and continuing inservice education program for nursing employees and documentation of staff attendance and subject matter covered during inservice education programs;
(5) provision of appropriate reference materials for the nursing department, which includes a Physician's Desk Reference or comparable drug reference, policy and procedure manual, and medical dictionary for each nursing station; and
(6) establishment of operational procedures to assure that appropriate supplies and equipment are available to nursing staff as determined by individual patient care needs.

History Note: *Authority G.S. 131E-79; 42 U.S.C. 1396 r (a);*

Eff. February 1, 1986;
Amended Eff. March 1, 1990;
Temporary Amendment Eff. October 1, 1990 For a Period of 142 Days to Expire on February 28, 1991;
Amended Eff. March 1, 1991;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. July 22, 2017.

10A NCAC 13B .1911 VACANT DIRECTOR OF NURSING POSITION

(a) The administrator shall notify the Department within 72 hours when the director of nursing position becomes vacant and shall provide the name and license number of the individual who is acting director or the replacement for the director of nursing.

(b) A facility shall not operate without either a director of nursing or acting director or nursing.

(c) The administrator shall employ a director of nursing within 30 days after a position becomes vacant. A vacancy which exceeds 30 days shall be reviewed by the Department for action relative to licensure status of the facility.

History Note: *Authority G.S. 131E-79;*
Eff. February 1, 1986;
Amended Eff. March 1, 1990;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. July 22, 2017.

10A NCAC 13B .1912 NURSE STAFFING REQUIREMENTS

(a) A licensed facility shall provide licensed nursing personnel sufficient to accomplish the following:

(1) patient needs assessment,
(2) patient care planning, and
(3) supervisory functions in accordance with the level of patient or resident care advertised or offered by the facility.

The facility also shall provide other nursing personnel sufficient to assure that at least activities of daily living, personal grooming, restorative nursing actions and other health care needs as identified in each patient's or resident's plan of care are met.

(b) A licensed multi-storied facility (one having more than one story) shall provide at least one person on duty on each patient care floor at all times.

(c) Daily direct patient care nursing staff, licensed and unlicensed, shall equal or exceed 2.1 nursing hours per patient. (This is sometimes referred to as nursing hours per patient day or NHPPD or NH/PD.)

(1) Inclusive in these figures is the requirement that at least one licensed nurse is on duty for direct patient care at all time; and
(2) Nursing care shall include the services of a registered nurse for at least eight consecutive hours a day, seven days a week. This coverage can be spread over more than one shift if such a need exists. The Director of Nursing may be counted as meeting the requirements for both the Director of Nursing and patient and resident care staffing for facilities of a total census of 60 beds or less.

(d) Nursing support personnel including ward clerks, secretaries, nurse educators and persons in primarily administrative management positions and not actively involved in direct patient care shall not be counted toward compliance with minimum daily requirements for direct care staffing.

(e) All exceptions to meeting minimum staffing requirements shall be reported to the Department at the end of each month. Staffing waivers granted by the federal government for Medicare and Medicaid certified beds shall be accepted for licensure purposes.

(f) The ratio of male to female nurse aides will be determined by the needs of the patients, particularly the numbers of male patients requiring assistance with personal care.

History Note: *Authority G.S. 131E-79; 42 U.S.C. 1396 r (b)(4)(C);*
Eff. February 1, 1986;
Amended Eff. March 1, 1990;
Temporary Amendment Eff. October 1, 1990 For a Period of 142 Days to Expire on February 28, 1991;
Amended Eff. March 1, 1991;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. July 22, 2017.

10A NCAC 13B .1913 RESERVED FOR FUTURE CODIFICATION

10A NCAC 13B .1914 RESERVED FOR FUTURE CODIFICATION

10A NCAC 13B .1915 ADULT CARE HOME PERSONNEL REQUIREMENTS

(a) The administrator shall designate a person to be in charge of the adult care home residents at all times. The nurse in charge of nursing services may also serve as supervisor-in-charge of the adult care home beds.

(b) If adult care home beds are located in a separate building or a separate level of the same building, there shall be a person on duty in the adult care home areas at all times.

(c) A licensed facility shall provide staff to assure that activities of daily living, personal grooming, and assistance with eating are provided to each resident. Medication administration as indicated by each resident's condition or physician's orders shall be carried out as identified in each resident's plan of care.

(d) Adult care home facilities licensed as a part of a combination facility shall comply with the staffing requirements in 10A NCAC 13F .0605 herein incorporated by reference including subsequent amendments and editions.

History Note: *Authority G.S. 131E-79; 42 U.S.C. 1396 r (a);*
Eff. February 1, 1986;
Temporary Amendment Eff. October 1, 1990 For a Period of 142 Days to Expire on February 28, 1991;
Amended Eff. March 1, 1991;
Readopted Eff. April 1, 2020.

10A NCAC 13B .1916 REHABILITATIVE NURSING AND DECUBITUS CARE

Each patient or resident shall be given care to prevent contractures, deformities, and decubiti, including but not limited to:

(1) changing positions of bedfast and chairfast patients or residents every two hours and administering simple preventive care. Documentation of such care and outcome must be included in routine summaries or progress notes;

(2) maintaining proper alignment and joint movement to prevent contractures and deformities, which must be documented in routine summaries or progress notes;

(3) implementing an individualized bowel and bladder training program except for patients or residents whose records are documented that such training is not effective. A monthly summary for patients and quarterly summaries for domiciliary residents shall be written relative to each patient's or resident's performance in the bowel and bladder training program; and

(4) such other services as necessary to meet the needs of the patient.

History Note: *Authority G.S. 131E-79; 42 U.S.C. 1396 r (a);*
Eff. February 1, 1986;
Amended Eff. March 1, 1990;
Temporary Amendment Eff. October 1, 1990 For a Period of 142 Days to Expire on February 28, 1991;
Amended Eff. March 1, 1991;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. July 22, 2017.

10A NCAC 13B .1917 MEDICATION ADMINISTRATION

(a) A licensed facility shall have policies and procedures governing the administration of medications which shall be enforced and implemented by administration and staff. Policies and procedures shall include, but shall not be limited to:

(1) automatic stop orders for treatment and drugs;

(2) accountability of controlled substances as defined by the North Carolina Controlled Substances Act, G.S. 90, Article 5;

(3) dispensing and administering behavior modifying drugs, such as hypnotics, sedatives, tranquilizers, antidepressants and other psychotherapeutic agents; insulin; intravenous fluids and medications; cardiovascular regulating drugs; and antibiotics.

(b) All medications or drugs and treatments shall be administered and discontinued in accordance with signed physician's orders which are recorded in the patient's or resident's medical record.

(1) Only physicians, registered nurses, licensed practical nurses or physician assistants, if in accordance with the assistant's approved practice, shall administer medications.

(2) To ensure accountability, any medication shall be administered by the same licensed personnel who prepared the dose for administration. This Rule does not apply to the dispensing of medications from a pharmacy utilizing a unit of use drug delivery system.

(3) Medications shall be administered within a half hour prior to or half hour after the prescribed time for administration unless precluded by emergency situations.

(4) The person administering medications shall identify each patient or resident in accordance with the facility's policies and procedures prior to administering any medication.

(5) Medication administered to a patient or resident shall be recorded in the patient's or resident's medication administration record immediately after administration in accordance with the facility's policies and procedures.

(6) Omission of medication and the reason for the omission shall be indicated in the patient's or resident's medical record.

(7) The person administering medications which are ordered to be given as needed (PRN) shall justify the need for the same in the patient's or resident's medical record.

(8) Medication administration records shall provide identification of the drug and strength of drug, quantity of drug administered, name of administering employee, title of employee and time of administration.

(c) Self-administration of medications shall be permitted only if prescribed by a physician and directions are printed on the container.

(d) The administration of one patient's or resident's medications to another patient or resident is prohibited except in the case of an emergency. In the event of such an emergency, steps shall be taken to assure that the borrowed medications shall be replaced promptly and so documented.

(e) Verbal orders shall be countersigned by a physician within five days of issuance.

History Note: *Authority G.S. 131E-79;*
Eff. February 1, 1986;
Amended Eff. December 1, 1991; March 1, 1990;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. July 22, 2017.

10A NCAC 13B .1918 TRAINING

(a) A licensed facility shall provide patient or resident care employees a planned orientation and continuing education program emphasizing patient or resident assessment and planning, activities of daily living, personal grooming, rehabilitative nursing or restorative care, other patient or resident care policies and procedures, patients' rights, and staff performance expectations. Attendance and subject matter covered shall be documented for each session, retained in accordance with policy established by the facility, and available for licensure inspections.

(b) The administrator shall assure that employees are oriented within the first week of employment to the facility's philosophy and goals.

(c) Employees shall have specific on-the-job training as necessary to perform their individual job assignment.

(d) A nurse aide trainee may be employed to perform the duties of a nurse aide for a period of time not to exceed four months. During this period of time the nurse aide trainee shall be permitted to perform only those tasks that competence has been demonstrated and documented on the record. Nurse aide I shall meet the training and competency evaluation standards in 10A NCAC 13O .0301, incorporated herein by reference including subsequent amendments and editions. A record of nurse aide qualifications shall be maintained for each nurse aide used by a facility and shall be retained in the general personnel files of the facility in accordance with policy established by the facility.

(e) The initial orientation to the facility shall be exclusive of the Nurse Aide I training program. Competency evaluation shall be conducted in each of the following areas:

(1) Observation and documentation,

(2) Basic nursing skills,

(3) Personal care skills,

(4) Mental health and social service needs,

(5) Basic restorative services, and

(6) Residents' Rights.

History Note: *Authority G.S. 131E-79; 42 U.S.C. 1396 r (b)(5);*
Eff. February 1, 1986;
Temporary Rule Eff. October 1, 1990 For a Period of 142 Days to Expire on February 28, 1991;
Amended Eff. March 1, 1991; March 1, 1990;
Readopted Eff. April 1, 2020.

10A NCAC 13B .1919 DENTAL CARE

(a) A dental examination shall be performed at the time of admission with the following information being placed in the patient's or resident's medical or health care record:

(1) type of diet which the patient or resident can best manage (such as normal, soft or pureed);
(2) the presence of infection of gums, teeth, or jaws;
(3) brief descriptions of any removable dental appliances and a statement of their condition; and
(4) indications for dental treatment at the time of admission.

(b) Names of dentists who have agreed to render emergency dental care shall be maintained at each nursing station and at the supervisor's station in a adult care home.

(c) Staff of the facility shall ensure that:

(1) necessary daily dental care is provided;
(2) each patient or resident possesses appropriate toothbrushes and is encouraged and, when necessary, assisted in their use; and
(3) each patient or resident having a removable denture is furnished a receptacle in which to immerse the denture in water overnight.

History Note: *Authority G.S. 131E-79;*
Eff. February 1, 1986;
Amended Eff. March 1, 1990;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. July 22, 2017.

10A NCAC 13B .1920 AVAILABILITY OF PHARMACEUTICAL SERVICES

(a) A licensed facility shall provide pharmaceutical services under the supervision of a pharmacist currently licensed to practice pharmacy in North Carolina.

(b) A facility shall be responsible for obtaining drugs, therapeutic nutrients and related products prescribed or ordered by a physician for patients or residents in the facility.

(c) Services shall include documented on-site pharmaceutical reviews accomplished at least every 31 calendar days for all patients and residents.

History Note: *Authority G.S. 131E-79;*
Eff. February 1, 1986;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. July 22, 2017.

10A NCAC 13B .1921 DINING FACILITIES

Patients, including wheelchair patients, shall be encouraged to eat at the tables in the dining area and shall be assisted when necessary by non-dietary staff. An overbed table shall be provided for patients who eat in bed. A sturdy tray stand shall be provided for those patients who eat out of bed but are unable to go to the dining area. An overbed table which can be lowered to chair height may substitute for the tray stand.

History Note: *Authority G.S. 131E-79;*
Eff. February 1, 1986;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. July 22, 2017.

10A NCAC 13B .1922 ACTIVITIES AND RECREATION

(a) The administrator shall designate an activities and recreation director to be in charge of activities and recreation for all patients and residents. The activities and recreation director shall have training and experience in directing recreational and group activities. The designated activities and recreation director shall be under the supervision of the

administrator and shall be qualified to meet the needs of the patients and residents. A qualified individual shall be anyone eligible for a N.C. license as an occupational therapist or assistant therapist under G.S. 90-270; anyone eligible for N.C. certification as a recreation therapist or assistant therapist under G.S. 90C-9; anyone with a baccalaureate degree and one year experience; anyone who has completed an approved 36-hour or longer course in activities program management; or anyone not otherwise qualified but receiving at least four hours consultation per month from one who is qualified.

(b) The facility shall maintain and make available a listing of local resources for activities and recreation to be utilized in meeting the needs and interests of all patients and residents.

(c) Restoration to self care and resumption of normal activity shall be one of the main goals of the recreation or activity program. The scope of the activity program shall include:

(1) social activities involving individual and group participation which are designed to promote group relationships;
(2) recreational activities, both indoor and outdoor;
(3) opportunity to participate in activities outside the facility;
(4) religious programs, including the right of each patient and resident to attend the church or religious program of his choice;
(5) creative and expressive activities;
(6) educational activities; and
(7) exercise.

(d) The facility shall have written policies and procedures which are available and implemented by staff that:

(1) attempt to prevent the further mental or physical deterioration for those patients or residents who cannot realistically resume normal activities;
(2) assure opportunities for patient involvement, both individual and group, in both planning and implementing the activity program;
(3) provide patients or residents the opportunity for choice among a variety of activities; and
(4) encourage participation by each patient or resident in social and recreational activities according to individual need and abilities and desires unless the patient's or resident's record contains documentation that he is unable to participate.

(e) Each patient's or resident's activity plan shall be a part of his overall plan of care and shall contain documentation of periodic assessments of the individual's activity needs and interests. A record of activities and individuals participating shall be maintained in the facility.

(f) A licensed facility shall display a monthly activities calendar which includes variety to appeal to different interest groups in the nursing care and adult care home services.

(g) A licensed facility shall provide:

(1) Space for recreational and diversional activities. In hospitals offering new nursing home services, space shall be provided separately from the main living and dining areas; however, these areas may also be used for social activities.
(2) Designated indoor and outdoor activity areas for independent and group needs of patients and residents, and which are:
    (A) accessible to wheelchair and ambulatory patients; and
    (B) of sufficient size to accommodate necessary equipment and permit unobstructed movement of wheelchair and ambulatory patients or personnel responsible for instruction and supervision.
(3) Adequate space to store equipment and supplies without blocking exists or otherwise threatening the health and safety of patients and residents.

(h) There shall be equipment and supplies sufficient to carry out planned programs for both individual and group activities.

History Note: *Authority G.S. 131E-79; 42 U.S.C. 1396 r (a);*
Eff. February 1, 1986;
Amended Eff. March 1, 1990;
Temporary Amendment Eff. October 1, 1990 For a Period of 142 Days to Expire on February 1, 1991;
Amended Eff. March 1, 1991;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. July 22, 2017.

10A NCAC 13B .1923 SOCIAL SERVICES

(a) The administrator shall designate an employee to be responsible for the provision of social services. This person shall be known as the social services director. Subsequent to the effective date of the rules contained in this Subchapter any newly designated person must be a graduate of a four year college or university with one year's experience in the health care or long-term care field or have an equivalent combination of education and experience. An equivalent combination of education and experience means the number of years of education leading to a baccalaureate or associate degree plus the number of years of long-term nursing facility experience equal to five years; or eligible for certification as a social worker pursuant to G.S. 90B-7. The social services director shall have authority to carry out provisions contained in Rule .1923(b) of this Section.

(b) Each patient's or resident's plan of care shall contain a written plan for meeting his individual social needs and involving his active participation, the plan shall provide for:

(1) needed assistance in meeting the patient's or resident's physical, social and emotional needs through consultation with the patient or resident or his legal guardian, and relative, physician or others;

(2) assisting the patient or resident in adjusting to his environment, for referral to other supporting resources, for protective services, for financial services and for assistance at the time of discharge or transfer into a new environment;

(3) the utilization of caseworkers employed by the county department of social services in the case of recipients of public assistance and for the utilization of appropriate persons with experience and training in the general area of social work in the case of those not on public assistance.

(c) Discharge planning shall be in keeping with each patient's and resident's discharge needs. These are as follows:

(1) The administrator shall assure that a medical order for discharge including any special instructions for meeting rehabilitation potential is obtained from all patients or residents except when a patient or resident leaves against a physician's order or advice; and

(2) The social services director shall coordinate discharge instructions and assure that patients and residents and their families are instructed in accordance with discharge orders.

History Note: *Authority G.S. 131E-79;*
Eff. February 1, 1986;
Amended Eff. March 1, 1990;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. July 22, 2017.

10A NCAC 13B .1924 RESTRAINTS

(a) Patients and residents shall be restrained only by physician orders.

(b) The nurse in charge shall be responsible for making the decision relative to necessity for, type and duration of restraint in emergency situations requiring restraints while contacting the physician. The nurse also shall be responsible for documenting same in the patient's or resident's record.

(c) The type of restraint used and the time of application and removal shall be recorded by a licensed nurse in the patient's or resident's record.

History Note: *Authority G.S. 131E-79;*
Eff. February 1, 1986;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. July 22, 2017.

10A NCAC 13B .1925 REQUIRED SPACES

(a) A combination or nursing facility shall meet the following requirements for bedrooms, dining, recreation, and common use areas:

(1) single bedrooms shall be provided with not less than 100 square feet of floor area;

(2) bedrooms with more than one bed shall be provided with not less than 80 square feet of floor area per bed;

(3) dining, recreation, and common use areas shall:

(A) total not less than 25 square feet of floor area per bed for skilled nursing and intermediate care beds;

(B) total not less than 30 square feet of floor area per bed for adult care home beds; and

(C) be contiguous to patient and resident bedrooms.

(b) Floor space for the following rooms, areas, and furniture shall not be included in the floor areas required by Paragraph (a) of this Rule:

(1) toilet rooms;
(2) vestibules;
(3) bath areas;
(4) closets;
(5) lockers;
(6) built-in furniture;
(7) movable wardrobes;
(6) corridors; and
(7) areas for physical and occupational therapy.

History Note: *Authority G.S. 131E-79;*
Eff. February 1, 1986;
Readopted Eff. April 1, 2020.

10A NCAC 13B .1926 NURSING HOME PATIENT OR RESIDENT RIGHTS

(a) Written policies and procedures shall be developed and enforced to implement requirements in G.S. 131E-115 et seq. (Nursing Home Patients' Bill of Rights) concerning the rights of patients and residents. The administrator shall make these policies and procedures known to the staff, patients and residents, and families of patients and residents and shall ensure their availability to the public by placing them in a conspicuous place.

(b) Any violation of patient rights contained in G.S. 131E-117 shall be determined by representatives of the Department by investigation or survey.

(c) If a licensed facility is found to be in violation of any of the rights contained in G.S. 131E-117, the Department shall impose penalties for each violation as provided by G.S. 131E-129.

(d) When the Department has been notified that corrective action has been taken for each violation, verification of same shall be made by a representative of the Department.

(e) The Department shall calculate a total of all fines levied against a facility based on the number of violations and the number of days and patients or residents involved in each violation.

(f) The Department shall mail a statement to the facility showing a total fine for each violation and a total of fines due to be paid for all violations. The facility shall pay the penalty within 60 days unless a hearing is requested under G.S. Chapter 150B.

(g) When it is found that a violation of G.S. 131E-117 has occurred but corrective action was taken prior to the date of discovery, fines shall be calculated and assessed in accordance with (e) and (f) of this Rule.

(h) In matters of patient abuse, neglect or misappropriation the definitions shall have the meanings defined for abuse, neglect and exploitation respectively as contained in the North Carolina PROTECTION OF THE ABUSED, NEGLECTED OR EXPLOITED DISABLED ADULT ACT, G.S. 108A-99 et seq.

History Note: *Authority G.S. 131E-79; 42 U.S.C. 1396 r (e)(2)(B);*
Eff. February 1, 1986;
Amended Eff. March 1, 1990;
Temporary Amendment Eff. October 1, 1990 For a Period of 142 Days to Expire on February 28, 1991;
Amended Eff. March 1, 1991;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. July 22, 2017.

10A NCAC 13B .1927 BRAIN INJURY LONG-TERM CARE PHYSICIAN SERVICES

(a) For nursing facility patients located in designated brain injury long-term care units, there shall be an attending physician who is responsible for the patient's specialized care program. The intensity of the program requires that there shall be direct patient contact by a physician at least once per week and more often as the patient's condition warrants. Each patient's interdisciplinary, long-term care program shall be developed and implemented under the supervision of a physiatrist (a physician trained in Physical Medicine and Rehabilitation) or a physician of equivalent training and experience.

(b) If a physiatrist or physician of equivalent training or experience, is not available on a weekly basis to the facility, the facility shall provide for weekly medical management of the patient, by another physician. In addition, oversight for the patient's interdisciplinary, long-term care program shall be provided by a qualified consultant physician who visits

patients monthly, makes recommendations for and approves the interdisciplinary care plan, and provides consultation as requested to the physician who is managing the patient on a weekly basis.
(c) The attending physician shall actively participate in individual case conferences or care planning sessions and shall review and sign discharge summaries and records within 15 days of patient discharge. When patients are to be discharged to either another health care facility or a residential setting the attending physician shall assure that the patient has been provided with a discharge plan which incorporates optimum utilization of community resources and post discharge continuity of care and services.

History Note: *Authority G.S. 131E-79;*
Eff. December 1, 1991;
Amended Eff. February 1, 1993;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. July 22, 2017.

10A NCAC 13B .1928 BRAIN INJURY LONG-TERM CARE PROGRAM REQUIREMENTS

History Note: *Authority G.S. 131E-79;*
Eff. December 1, 1991;
Amended Eff. February 1, 1993;
Expired Eff. August 1, 2017 pursuant to G.S. 150B-21.3A.

10A NCAC 13B .1929 SPECIAL NURSING REQUIREMENTS FOR BRAIN INJURY LONG-TERM CARE

Direct care nursing personnel staffing ratio (NH/PD) established in Rule .1912 of this Section shall not be applied to nursing services for patients who require brain injury long-term care, due to their more intensive maintenance and nursing needs. The minimum direct care nursing staff shall be 5.5 hrs. per patient day allocated on a per shift basis as the facility chooses to appropriately meet the patient's needs. It is also required that regardless of how low the patient census the direct care nursing staff shall not fall below a registered nurse and a nurse aide I at any time during a 24-hour period.

History Note: *Authority G.S. 131E-79;*
Eff. December 1, 1991;
Amended Eff. February 1, 1993;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. July 22, 2017.

10A NCAC 13B .1930 VENTILATOR DEPENDENCE

The general requirements in this Subchapter shall apply when applicable. In addition, facilities having patients requiring the use of ventilators for more than eight hours a day must meet the following requirements:

(1) Respiratory therapy shall be provided and supervised by a respiratory therapist currently registered by the National Board for Respiratory Care. The respiratory therapist shall:
    (a) make, as a minimum, weekly on-site assessments of each patient receiving ventilator support with corresponding progress notes;
    (b) be on-call 24 hours daily; and
    (c) assist the pulmonologist and nursing staff in establishing ventilator policies and procedures, including emergency policies and procedures.
(2) Direct nursing care staffing shall be in accordance with Rule .1912 of this Section.

History Note: *Authority G.S. 131E-79;*
Eff. December 1, 1991;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. July 22, 2017.

10A NCAC 13B .1931 PHYSICIAN SERVICES FOR VENTILATOR DEPENDENT PATIENTS

Hospitals with nursing facility beds with ventilator dependent care patients shall contract with a physician who is licensed to practice in North Carolina with Board Certification and who has specialized training in pulmonary medicine. This physician shall be responsible for respiratory services and shall:

(1) establish, with the respiratory therapist and nursing staff, appropriate ventilator policies and procedures, including emergency procedures;

(2) assess each ventilator patient's status at least monthly with corresponding progress notes;
(3) be available on an emergency basis; and
(4) participate in individual patient case planning.

History Note: *Authority G.S. 131E-79;*
Eff. December 1, 1991;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. July 22, 2017.

10A NCAC 13B .1932 EMERGENCY ELECTRICAL SERVICE

(a) A minimum of one dedicated emergency branch circuit per bed is required for ventilator dependent patients in addition to the normal system receptacle at each bed location required by the National Electrical Code. This emergency circuit shall be provided with a minimum of two duplex receptacles identified for emergency use. Additional emergency branch circuits/receptacles shall be provided where the electrical life support needs of the patient exceed the minimum requirements stated in this Paragraph. Each emergency circuit serving ventilator dependent patients shall be fed from the automatically transferred critical branch of the essential electrical system. This Paragraph shall apply to both new and existing facilities.

(b) Heating equipment provided for ventilator dependent patient bedrooms shall be connected to the critical branch of the essential electrical system and arranged for delayed automatic or manual connection to the emergency power source if the heating equipment depends upon electricity for proper operation. This Paragraph shall apply to both new and existing facilities.

(c) Task lighting connected to the automatically transferred critical branch of the essential electrical system shall be provided for each ventilator dependent patient bedroom. This Paragraph shall apply to both new and existing facilities.

History Note: *Authority G.S. 131E-79;*
Eff. December 1, 1991;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. July 22, 2017.

SECTION .2000 – SPECIALIZED REHABILITATIVE AND HABILITATIVE SERVICES

10A NCAC 13B .2001 ADMISSIONS TO THE HIV DESIGNATED UNIT
10A NCAC 13B .2002 DISCHARGE OF PATIENTS FROM THE HIV DESIGNATED UNIT
10A NCAC 13B .2003 HIV DESIGNATED UNIT POLICIES AND PROCEDURES
10A NCAC 13B .2004 PHYSICIAN SERVICES IN A HIV DESIGNATED UNIT
10A NCAC 13B .2005 SPECIAL NURSING REQUIREMENTS FOR A HIV DESIGNATED UNIT
10A NCAC 13B .2006 SPECIALIZED STAFF EDUCATION FOR THE HIV DESIGNATED UNIT
10A NCAC 13B .2007 USE OF INVESTIGATIONAL DRUGS ON THE HIV DESIGNATED UNIT
10A NCAC 13B .2008 SOCIAL WORK SERVICES IN A HIV DESIGNATED UNIT

History Note: *Authority G.S. 131E-79;*
Eff. February 1, 1993;
Expired Eff. August 1, 2017 pursuant to G.S. 150B-21.3A.

10A NCAC 13B .2009 RESERVED FOR FUTURE CODIFICATION

10A NCAC 13B .2010 RESERVED FOR FUTURE CODIFICATION

10A NCAC 13B .2011 RESERVED FOR FUTURE CODIFICATION

10A NCAC 13B .2012 RESERVED FOR FUTURE CODIFICATION

10A NCAC 13B .2013 RESERVED FOR FUTURE CODIFICATION

10A NCAC 13B .2014 RESERVED FOR FUTURE CODIFICATION

10A NCAC 13B .2015 RESERVED FOR FUTURE CODIFICATION

10A NCAC 13B .2016 RESERVED FOR FUTURE CODIFICATION

10A NCAC 13B .2017 RESERVED FOR FUTURE CODIFICATION

10A NCAC 13B .2018 RESERVED FOR FUTURE CODIFICATION

10A NCAC 13B .2019 RESERVED FOR FUTURE CODIFICATION

10A NCAC 13B .2020 DEFINITIONS

The following definitions shall apply to inpatient rehabilitation facilities or units only:

(1) "Case management" means the coordination of services, for a given patient, between disciplines so that the patient may reach optimal rehabilitation through the judicious use of resources.

(2) "Comprehensive, inpatient rehabilitation program" means a program for the treatment of persons with functional limitations or chronic disabling conditions who have the potential to achieve a significant improvement in activities of daily living. A comprehensive, rehabilitation program utilizes a coordinated and integrated, interdisciplinary approach, directed by a physician, to assess patient needs and to provide treatment and evaluation of physical, psycho-social and cognitive deficits.

(3) "Inpatient rehabilitation facility or unit" means a free-standing facility or a unit (unit pertains to contiguous dedicated beds and spaces) within an existing licensed health service facility approved in accordance with G.S. 131E, Article 9 to establish inpatient, rehabilitation beds and to provide a comprehensive, inpatient rehabilitation program.

(4) "Medical consultations" means consultations which the rehabilitation physician or the attending physician determine are necessary to meet the acute medical needs of the patient and do not include routine medical needs.

(5) "Occupational therapist" means any individual licensed in the State of North Carolina as an occupational therapist in accordance with the provisions of G.S. 90, Article 18D.

(6) "Occupational therapist assistant" means any individual licensed in the State of North Carolina as an occupational therapist assistant in accordance with the provisions of G.S. 90, Article 18D.

(7) "Psychologist" means a person licensed as a practicing psychologist in accordance with G.S. 90, Article 18A.

(8) "Physiatrist" means a licensed physician who has completed a physical medicine and rehabilitation residency training program approved by the Accreditation Council of Graduate Medical Education or the American Osteopathic Association.

(9) "Physical therapist" means any person licensed in the State of North Carolina as a physical therapist in accordance with the provisions of G.S. 90, Article 18B.

(10) "Physical therapist assistant" means any person duly licensed in the State of North Carolina as a physical therapist assistant in accordance with the provisions of G.S. 90-270.24, Article 18B.

(11) "Recreational therapist" means a person certified by the State of North Carolina Therapeutic Recreational Certification Board.

(12) "Rehabilitation nurse" means a registered nurse licensed in North Carolina, with training, either academic or on-the-job, in physical rehabilitation nursing and at least one year experience in physical rehabilitation nursing.

(13) "Rehabilitation aide" means an unlicensed assistant who works under the supervision of a registered nurse, licensed physical therapist or occupational therapist in accordance with the appropriate occupational licensure laws governing his or her supervisor and consistent with staffing requirements as set forth in Rule .2027 of this Section. The rehabilitation aide shall be listed on the North Carolina Nurse Aide Registry and have received additional staff training as listed in Rule .2028 of this Section.

(14) "Rehabilitation physician" means a physiatrist or a physician who is qualified, based on education, training and experience regardless of specialty, of providing medical care to rehabilitation patients.

(15) "Social worker" means a person certified by the North Carolina Social Work Certification and Licensure Board in accordance with G.S. 90B-3.

(16) "Speech and language pathologist" means any person licensed in the State of North Carolina as a speech and language pathologist in accordance with the provisions of G.S. 90, Article 22.

History Note: *Authority G.S. 131E-79; 143B-165;*
Eff. May 1, 1993;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. July 22, 2017.

10A NCAC 13B .2021 PHYSICIAN REQS FOR INPATIENT REHABILITATION FACILITIES OR UNITS
10A NCAC 13B .2022 ADMISSION CRITERIA FOR INPATIENT REHABILITATION FACILITIES OR UNITS
10A NCAC 13B .2023 COMPREHENSIVE INPATIENT REHABILITATION EVALUATION
10A NCAC 13B .2024 COMPREHENSIVE INPATIENT REHABILITATION INTERDISCIPLINARY TREAT/PLAN
10A NCAC 13B .2025 DISCHARGE CRITERIA FOR INPATIENT REHABILITATION FACILITIES OR UNITS
10A NCAC 13B .2026 COMPREHENSIVE REHABILITATION PERSONNEL ADMINISTRATION
10A NCAC 13B .2027 COMPREHENSIVE INPATIENT REHABILITATION PROGRAM STAFFING REQS
10A NCAC 13B .2028 STAFF TRAINING FOR INPATIENT REHABILITATION FACILITIES OR UNIT
10A NCAC 13B .2029 EQUIPMENT REQS/COMPREHENSIVE INPATIENT REHABILITATION PROGRAMS
10A NCAC 13B .2030 PHYSICAL FACILITY REQS/INPATIENT REHABILITATION FACILITIES OR UNITS
10A NCAC 13B .2031 ADDITIONAL REQUIREMENTS FOR TRAUMATIC BRAIN INJURY PATIENTS
10A NCAC 13B .2032 ADDITIONAL REQUIREMENTS FOR SPINAL CORD INJURY PATIENTS

History Note: *Authority G.S. 131E-79; 143B-165;*
Eff. May 1, 1993;
Amended Eff. December 1, 1993;
Expired Eff. August 1, 2017 pursuant to G.S. 150B-21.3A.

10A NCAC 13B .2033 DEEMED STATUS FOR INPATIENT REHABILITATION FACILITIES OR UNITS

(a) If an inpatient rehabilitation facility or unit with a comprehensive inpatient rehabilitation program is surveyed and accredited by the Joint Commission for the Accreditation of Health Care Organizations (JCAHO) or the Commission on Accreditation of Rehabilitation Facilities (CARF) and has been approved by the Department in accordance with Article 9 Chapter 131E of the North Carolina General Statutes, the Department deems the facility to be in compliance with Rules .2020 through .2030 and .2033 of this Section.

(b) Deemed status shall be provided only if the inpatient rehabilitation facility or unit provides copies of survey reports to the Division. The JCAHO report shall show that the facility or unit was surveyed for rehabilitation services. The CARF report shall show that the facility or unit was surveyed for comprehensive rehabilitation services. The facility or unit shall sign an agreement (Memorandum of Understanding) specifying these terms.

(c) The inpatient rehabilitation facility or unit shall be subject to inspections or complaint investigations by representatives of the Department at any time. If the facility or unit is found not to be in compliance with the rules listed in Paragraph (a) of this Rule, the facility shall submit a plan of correction and be subject to a follow-up visit to assure compliance.

(d) If the inpatient rehabilitation facility or unit loses or does not renew its accreditation, the facility or unit shall notify the Division in writing within 30 days.

History Note: *Authority G.S. 131E-79;*
Eff. May 1, 1993;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. July 22, 2017.

SECTION .2100 – TRANSPARENCY IN HEALTH CARE COSTS

10A NCAC 13B .2101 DEFINITIONS

In addition to the terms defined in G.S. 131E-214.13, the following terms shall apply throughout this Section, unless text indicates to the contrary:

(1) "Current Procedural Terminology (CPT)" means a medical code set developed by the American Medical Association.

(2) "Diagnostic related group (DRG)" means a system to classify hospital cases assigned by a grouper program based on ICD (International Classification of Diseases) diagnoses, procedures, patient's age, sex, discharge status, and the presence of complications or co-morbidities.

(3) "Department" means the North Carolina Department of Health and Human Services.

(4) "Financial assistance" means a policy, including charity care, describing how the organization will provide assistance at its hospital(s) and any other facilities. Financial assistance includes free or discounted health services provided to persons who meet the organization's criteria for financial assistance and are unable to pay for all or a portion of the services. Financial assistance does not include:

(a) bad debt;

(b) uncollectable charges that the organization recorded as revenue but wrote off due to a patient's failure to pay;

(c) the cost of providing such care to the patients in Sub-Item (4)(b) of this Rule; or

(d) the difference between the cost of care provided under Medicare or other government programs, and the revenue derived therefrom.

(5) "Healthcare Common Procedure Coding System (HCPCS)" means a three-tiered medical code set consisting of Level I, II and III services and contains the CPT code set in Level I.

History Note: *Authority G.S. 131E-214.13;*
Temporary Adoption Eff. December 31, 2014;
Eff. September 30, 2015.

10A NCAC 13B .2102 REPORTING REQUIREMENTS

(a) The Department shall establish the lists of the statewide 100 most frequently reported DRGs, 20 most common outpatient imaging procedures, and 20 most common outpatient surgical procedures performed in the hospital setting to be used for reporting the data required in Paragraphs (c) through (e) of this Rule. The lists shall be determined annually based upon data provided by the certified statewide data processor. The Department shall make the lists available on its website. The methodology to be used by the certified statewide data processor for determining the lists shall be based on the data collected from all licensed facilities in the State in accordance with G.S. 131E-214.2 as follows:

(1) the 100 most frequently reported DRGs shall be based upon all hospital's discharge data that has been assigned a DRG based on the Centers for Medicare & Medicaid Services grouper for each patient record, then selecting the top 100 to be provided to the Department;

(2) the 20 most common imaging procedures shall be based upon all outpatient data for both hospitals and ambulatory surgical facilities and represent all occurrences of the diagnostic radiology imaging codes section of the CPT codes, then selecting the top 20 to be provided to the Department; and

(3) the 20 most common outpatient surgical procedures shall be based upon the primary procedure code from the ambulatory surgical facilities and represent all occurrences of the surgical codes section of the CPT codes, then selecting the top 20 to be provided to the Department.

(b) Information required or reported in Paragraphs (a), (c), (d), and (i) of this Rule shall be posted on the Department's website at: http://www.ncdhhs.gov/dhsr/ahc and may be accessed at no cost.

(c) In accordance with G.S. 131E-214.13, all licensed hospitals shall report the data required in Paragraph (e) of this Rule related to the statewide 100 most frequently reported DRGs to the certified statewide data processor in a format provided by the certified statewide processor. Commencing with the reporting period ending September 30, 2015, an annual data report shall be submitted that includes all sites operated by the licensed hospital. Each annual report shall be submitted by the due date of January 1.

(d) In accordance with G.S. 131E-214.13, all licensed hospitals shall report the data required in Paragraph (e) of this Rule related to the statewide 20 most common outpatient imaging procedures and the statewide 20 most common outpatient surgical procedures to the certified statewide data processor in a format provided by the certified statewide processor. This report shall include the related primary CPT and HCPCS codes. Commencing with the reporting period

ending September 30, 2015, an annual data report shall be submitted that includes all sites operated by the licensed hospital. Each annual report shall be submitted by January 1.

(e) The reports as described in Paragraphs (c) and (d) of this Rule shall be specific to each reporting hospital and shall include:

(1) the average gross charge for each DRG, CPT code, or procedure without a public or private third party payer source;

(2) the average negotiated settlement on the amount that will be charged for each DRG, CPT code, or procedure as required for patients defined in Subparagraph (e)(1) of this Rule. The average negotiated settlement shall be calculated using the average amount charged all patients eligible for the hospital's financial assistance policy, including self-pay patients;

(3) the amount of Medicaid reimbursement for each DRG, CPT code, or procedure, including all supplemental payments to and from the hospital;

(4) the amount of Medicare reimbursement for each DRG, CPT code, or procedure; and

(5) on behalf of patients who are covered by a Department of Insurance licensed third-party and teachers and State employees, the lowest, average, and highest amount of payments made for each DRG, CPT code, or procedure by each of the hospital's top five largest health insurers.

(A) each hospital shall determine its five largest health insurers based on the dollar volume of payments received from those insurers;

(B) the lowest amount of payment shall be reported as the lowest payment from each of the five insurers on the DRG, CPT code, or procedure;

(C) the average amount of payment shall be reported as the arithmetic average of each of the five health insurers payment amounts;

(D) the highest amount of payment shall be reported as the highest payment from each of the five insurers on the DRG, CPT code, or procedure; and

(E) the identity of the top five largest health insurers shall be redacted prior to submission.

(f) The data reported, as defined in Paragraphs (c) through (e) of this Rule, shall reflect the payments received from patients and health insurers for all closed accounts. For the purpose of this Rule, "closed accounts" are patient accounts with a zero balance at the end of the data reporting period.

(g) A minimum of three data elements shall be required for reporting under Paragraphs (c) and (d) of this Rule.

(h) The information submitted in the report shall be in compliance with the federal Health Insurance Portability and Accountability Act of 1996, 45 CFR Part 164.

(i) The Department shall provide the location of each licensed hospital and all specific hospital data reported pursuant to this Rule on its website. Hospitals shall be grouped by category on the website. On each quarterly report, hospitals shall determine one category that most accurately describes the type of facility. The categories are:

(1) "Academic Medical Center Teaching Hospital," means a hospital as defined in Policy AC-3 of the N.C. State Medical Facilities Plan. The N.C. State Medical Facilities Plan may be accessed at: http://www.ncdhhs.gov/dhsr/ncsmfp at no cost.

(2) "Teaching Hospital," means a hospital that provides medical training to individuals, provided that such educational programs are accredited by the Accreditation Council for Graduated Medical Education to receive graduate medical education funds from the Centers for Medicare & Medicaid Services.

(3) "Community Hospital," means a general acute hospital that provides diagnostic and medical treatment, either surgical or nonsurgical, to inpatients with a variety of medical conditions, and that may provide outpatient services, anatomical pathology services, diagnostic imaging services, clinical laboratory services, operating room services, and pharmacy services, that is not defined by the categories listed in this Subparagraph and Subparagraphs (i)(1), (2), or (5) of this Rule.

(4) "Critical Access Hospital," means a hospital defined in the Centers for Medicare & Medicaid Services' State Operations Manual, Chapter 2 – The Certification Process, 2254D – Requirements for Critical Access Hospitals (Rev. 1, 05-21-04), including all subsequent updates and revisions. The manual may be accessed at the website: http://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/som107ap_a_hospitals.pdf at no cost.

(5) "Mental Health Hospital," means a hospital providing psychiatric services pursuant to G.S. 131E-176(21).

History Note: *Authority G.S. 131E-214.4; 131E-214.13;*
Temporary Adoption Eff. December 31, 2014;

Eff. September 30, 2015;
Temporary Amendment Eff. March 31, 2016;
Amended Eff. January 31, 2017.

SECTION .2200 - RESERVED FOR FUTURE CODIFICATION

10A NCAC 13B .2200 RESERVED FOR FUTURE CODIFICATION

SECTION .2300 - RESERVED FOR FUTURE CODIFICATION

10A NCAC 13B .2300 RESERVED FOR FUTURE CODIFICATION

SECTION .2400 - RESERVED FOR FUTURE CODIFICATION

10A NCAC 13B .2400 RESERVED FOR FUTURE CODIFICATION

SECTION .2500 - RESERVED FOR FUTURE CODIFICATION

10A NCAC 13B .2500 RESERVED FOR FUTURE CODIFICATION

SECTION .2600 - RESERVED FOR FUTURE CODIFICATION

10A NCAC 13B .2600 RESERVED FOR FUTURE CODIFICATION

SECTION .2700 - RESERVED FOR FUTURE CODIFICATION

10A NCAC 13B .2700 RESERVED FOR FUTURE CODIFICATION

SECTION .2800 - RESERVED FOR FUTURE CODIFICATION

10A NCAC 13B .2800 RESERVED FOR FUTURE CODIFICATION

SECTION .2900 - RESERVED FOR FUTURE CODIFICATION

10A NCAC 13B .2900 RESERVED FOR FUTURE CODIFICATION

SECTION .3000 - GENERAL INFORMATION

10A NCAC 13B .3001 DEFINITIONS

Notwithstanding Section .1900 of this Subchapter, the following definitions shall apply throughout this Subchapter unless the context indicates to the contrary:

(1) "Appropriate" means suitable or fitting, or conforming to standards of care as established by professional organizations, including Association of Professionals in Infection Control and Epidemiology (APIC), American Medical Association (AMA) and American Nurses Association (ANA).

(2) "Authority having jurisdiction" means the Division of Health Service Regulation.

(3) "Certified Dietary Manager" or "CDM" means an individual who is certified by the Certifying Board of the Dietary Managers and meets the standards and qualification as referenced in the "Dietary Manager Training Program Requirements." These standards include any subsequent amendments and editions of the referenced manual. Copies of the "Dietary Manager Training Program Requirements" may be obtained free of charge at https://www.cbdmonline.org/.

(4) "Competence" means the state or quality of being able to perform specific functions well; skill; and ability.

(5) "Construction documents" means final building plans and specifications for the construction of a facility that a governing body submits to the Construction Section for approval as specified in Rule .3102 of this Subchapter.
(6) "Construction Section" means the Construction Section of the Division of Health Service Regulation.
(7) "Continuous" means ongoing or uninterrupted, 24 hours per day.
(8) "CRNA" means a Certified Registered Nurse Anesthetist who meets the criteria set forth in G.S. 90-171.21(d)(4).
(9) "Credentialed" means that the individual having a given title or position has been credited with the right to exercise official responsibilities to provide specific patient care and treatment services, within defined limits, based upon the individual's license, education, training, experience, competence, and judgment.
(10) "Department" means the Department of Health and Human Services.
(11) "Dietetics" means as defined in G.S. 90-352.
(12) "Dietitian" means a person who meets the criteria set forth in G.S. 90, Article 25.
(13) "Direct Supervision" means the state of being under the control of a supervisor, manager, or other person of authority.
(14) "Division" means the Division of Health Service Regulation.
(15) "Facility" means a hospital as defined in G.S. 131E-76.
(16) "Full-time equivalent" means a unit of measure of employee work time that is equal to the number of hours that one full-time employee would work during one calendar year if the employee worked eight hours a day, five days a week, and 52 weeks a year; i.e. 2,080 hours per year.
(17) "Governing body" means the authority as defined in G.S. 131E-76.
(18) "Imaging" means a reproduction or representation of a body or body part for diagnostic purposes by radiologic intervention that may include conventional fluoroscopic exam, magnetic resonance, nuclear or radio-isotope scan.
(19) "Invasive procedure" means a procedure involving puncture or incision of the skin, insertion of an instrument or foreign material into the body (excluding venipuncture and intravenous therapy).
(20) "License" means formal permission to provide services as granted by the State.
(21) "Medical staff" means the formal organization that is comprised of individuals who have sought and obtained clinical privileges in a facility. As defined by the facility's medical staff bylaws, rules and regulations, those members of the medical staff who regularly and routinely admit patients to a facility constitute the active medical staff.
(22) "Mission statement" means a written statement of the philosophy and beliefs of the organization or hospital as approved by the governing body.
(23) "Neonate" means the newborn from birth to one month.
(24) "Nurse executive" means a registered nurse who is the director of nursing services or a representative of decentralized nursing management staff.
(25) "Nurse midwife" means a person who meets the criteria as set forth in G.S. 90-171.21(d)(4).
(26) "Nursing facility" means as defined in G.S. 131E-116(2).
(27) "Nursing staff" means the registered nurses, licensed practical nurses, nurse aides, and others under nurse supervision, who provide patient care. The term also includes clerical personnel who work in clinical areas under nurse supervision.
(28) "Nutrition and Dietetic Technician Registered" means as defined by the Academy of Nutrition and Dietetics. A copy of the requirements can be obtained at https://www.eatrightpro.org/about-us/what-is-an-rdn-and-dtr/what-is-a-nutrition-and-dietetics-technician-registered at no cost.
(29) "Nutrition therapy" ranges from intervention and counseling on diet modification to administration of specialized nutrition therapies as determined necessary to manage a condition or treat illness or injury. Specialized nutrition therapies include supplementation with medical foods, enteral and parenteral nutrition. Nutrition therapy integrates information from the nutrition assessment with information on food and other sources of nutrients and meal preparation consistent with cultural background and socioeconomic status.
(30) "Observation bed" means a bed used for no more than 24-hours, to evaluate and determine the condition and disposition of a patient and is not considered a part of the hospital's licensed bed capacity.
(31) "Patient" means any person receiving diagnostic or medical services at a hospital.

(32) "Pharmacist" means as defined in G.S. 90-85.3.
(33) "Physical Rehabilitation Services" means any combination of physical therapy, occupational therapy, speech therapy, or vocational rehabilitation.
(34) "Physician" means a person who meets the criteria set forth in G.S.90-9.1 or G.S. 90-9.2.
(35) "Provisional license" means a hospital license recognizing less than full compliance with the licensure rules.
(36) "Qualified" means having complied with the specific conditions for employment or the performance of a function.
(37) "Reference" means to use in consultation to obtain information.
(38) "Special Care Unit" means a unit or area of a hospital that includes a critical care unit, an intermediate care unit, or a pediatric care unit.
(39) "Unit" means a designated area of the hospital for the delivery of patient care services.

History Note: *Authority G.S. 131E-79;*
RRC Objection due to lack of Statutory Authority Eff. July 13, 1995;
Eff. January 1, 1996;
Readopted Eff. April 1, 2020.

SECTION .3100 - PROCEDURE

10A NCAC 13B .3101 GENERAL REQUIREMENTS

(a) An application for licensure shall be submitted to the Division prior to a license being issued or patients admitted.
(b) An existing facility shall not sell, lease, or subdivide a portion of its bed capacity without the approval of the Division.
(c) Application forms may be obtained by contacting the Division.
(d) The Division shall be notified in writing 30 days prior to the occurrence of any of the following:
(1) addition or deletion of a licensable service;
(2) increase or decrease in bed capacity;
(3) change of chief executive officer;
(4) change of mailing address;
(5) ownership change; or
(6) name change.
(e) Each application shall contain the following information:
(1) legal identity of applicant;
(2) name or names used to present the hospital or services to the public;
(3) name of the chief executive officer;
(4) ownership disclosure;
(5) bed complement;
(6) bed utilization data;
(7) accreditation data;
(8) physical plant inspection data; and
(9) service data.
(f) A license shall include only facilities or premises within a single county.

History Note: *Authority G.S. 131E-79;*
Eff. January 1, 1996;
Amended Eff. April 1, 2003;
Readopted Eff. April 1, 2020.

10A NCAC 13B .3102 PLAN APPROVAL

(a) For the purposes of this Rule, the Guidelines for the Design and Construction of Hospitals and Outpatient Facilities that is incorporated by reference in Rule .6105 of this Subchapter shall be referred to as the "FGI Guidelines."
(b) The definitions as set forth in Rule .6003 of this Subchapter shall apply to this Rule.
(c) The facility design and construction shall be in accordance with this Rule and the standards set forth in Sections .6000 through .6200 of this Subchapter.

(d) The site where the facility is located shall:

(1) be approved by the Construction Section prior to the construction of a new facility or the construction of an addition to an existing facility;

(2) be free from noise from railroads, freight yards, main traffic arteries, and schools and children's playgrounds; and

(3) not be exposed to smoke, odors, or dust from industrial plants.

(e) Prior to the construction of a new facility or the construction of an addition or alteration to an existing facility, the governing body shall submit paper copies of the following to the Construction Section for review and approval:

(1) one set of schematic design drawings;

(2) one set of design development drawings; and

(3) one set of construction documents and specifications.

(f) If the North Carolina State Building Code Administrative Code and Policies requires the North Carolina Department of Insurance to review and approve the construction documents and specifications, the governing body shall submit a copy of the construction documents and specifications to the North Carolina Department of Insurance.

(g) The governing body shall submit a functional program that complies with Section 1.2-2 Functional Program of the FGI Guidelines with each submittal cited in Paragraph (e) of this Rule.

(h) The governing body shall:

(1) prepare any component of the safety risk assessment required by Section 1.2-3 Safety Risk Assessment of the FGI Guidelines; and

(2) submit any component of the safety risk assessment prepared to the Construction Section with each submittal cited in Paragraph (e) of this Rule.

(i) In order to maintain compliance with the standards established in this Rule and Sections .6000 through .6200 of this Subchapter, the governing body shall obtain written approval from the Construction Section for any changes made during the construction of the facility in the same manner as set forth in Paragraph (e) of this Rule.

(j) Two weeks prior to the anticipated construction completion date, the governing body shall notify the Construction Section of the anticipated construction completion date in writing either by U.S. Mail at the Division of Health Service Regulation, Construction Section, 2705 Mail Service Center, Raleigh, NC, 27699-2705 or by e-mail at DHSR.Construction.Admin@dhhs.nc.gov.

(k) Construction documents and building construction, including the operation of all building systems, shall be approved in writing by the Construction Section prior to licensure or patient occupancy.

(l) When the Construction Section approves the construction documents and specifications, they shall provide the governing body with an approval letter. The Construction Section's approval of the construction documents and specifications shall expire 12 months after the issuance of the approval letter, unless the governing body has obtained a building permit for construction. If the Construction Section's approval has expired, the governing body may obtain a renewed approval of the construction documents and specifications from the Construction Section as follows:

(1) If the standards established in this Rule and Sections .6000 through .6200 of this Subchapter have not changed, the governing body shall request a renewed approval of the construction documents and specifications from the Construction Section.

(2) If the standards established in this Rule and Sections .6000 through .6200 of this Subchapter have changed, the governing body shall:

(A) submit revised construction documents and specifications meeting the current standards established in this Rule and Sections .6000 through .6200 of this Subchapter to the Construction Section; and

(B) obtain written approval of the revised construction documents and specifications from the Construction Section.

(m) Bassinets in a Neonatal Level I nursery as specified in Rule .6228 of this Subchapter shall not be included in a facility's bed capacity; however, no more bassinets shall be placed in service than the number allowed by the requirements set forth in Rule .6228 of this Subchapter. Beds in Neonatal Level II, III, and IV nurseries as specified in Rule .6228 of this Subchapter shall be included in a facility's bed capacity.

History Note: *Authority G.S. 131E-77; 131E-79;*
Eff. January 1, 1996;
Temporary Amendment Eff. March 15, 2002;
Amended Eff. April 1, 2003;
Readopted Eff. April 1, 2019.

10A NCAC 13B .3103 CLASSIFICATION OF MEDICAL FACILITIES

(a) For purpose of this Subchapter the classification of "hospital" shall be restricted to facilities that provide as their functions diagnostic services and medical and nursing care in the treatment of acute stages of illness. On the basis of specialized facilities and services available, the Division shall license each such hospital according to the following medical types:

(1) general acute care hospital;
(2) rehabilitation hospital;
(3) critical access hospital; or
(4) long term acute care hospital which is a hospital which has been classified and certified as a long term care hospital pursuant to 42 CFR Part 412.

(b) All other inpatient medical facilities accepting patients requiring skilled nursing services but which are not operated as a part of any hospital within the above meaning shall be considered to be operating as a nursing home and, therefore, are not subject to licensure pursuant to this Subchapter.

History Note: *Authority G.S. 131E-79;*
Eff. January 1, 1996;
Amended Eff. June 1, 2005;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. July 22, 2017.

10A NCAC 13B .3104 LENGTH OF LICENSE

Licenses shall remain in effect until one of the following occurs:

(1) Division imposes an administrative sanction which specifies license expiration;
(2) change of ownership;
(3) closure;
(4) change of site;
(5) failure to comply with Rule .3105 of this Section.

History Note: *Authority G.S. 131E-79;*
Eff. January 1, 1996;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. July 22, 2017.

10A NCAC 13B .3105 STATISTICAL INFORMATION

Utilization data shall be submitted annually upon request by the Division. Forms for collection of this data will be forward to each facility by the Division.

History Note: *Authority G.S. 131E-79;*
Eff. January 1, 1996;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. July 22, 2017.

10A NCAC 13B .3106 LICENSURE SURVEYS

(a) Prior to the initial issuance of a license to operate a facility, the Division shall conduct a survey to determine compliance with rules promulgated pursuant to G.S. 131E-79.

(b) The Division may conduct an investigation of a complaint in any facility.

(c) Facilities that are accredited through an accrediting body approved pursuant to section 1865(a) of the Social Security Act shall not be subject to routine inspections.

(d) The Division shall survey non-accredited facilities at least once every three years.

History Note: *Authority G.S. 131E-79; 131E-80;*
Eff. January 1, 1996;
Amended Eff. October 1, 2010;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. July 22, 2017.

10A NCAC 13B .3107 DENIAL, AMENDMENT OR REVOCATION OF LICENSE

(a) The Department may deny any licensure application upon becoming aware that the applicant is not in compliance with any applicable provision of the Certificate of Need law located in G.S. 131E, Article 9 and the rules adopted under that law.
(b) The Department may amend a license by reducing it from a full license to a provisional license whenever the Department finds that:

(1) the licensee has failed to comply with the provisions of G.S. 131E, Article 5 and the rules promulgated under that article;
(2) there is a probability that the licensee can remedy the licensure deficiencies within a length of time not to exceed the expiration date on the license; and
(3) there is a probability that the licensee will be able thereafter to remain in compliance with the hospital licensure rules for the foreseeable future.

(c) The Department shall also amend a license to provisional status by specifically prohibiting a licensee from providing certain services, for which it has been found to be out of compliance with G.S. 131E, Articles 5 or 9. In all cases the Department shall give the licensee written notice of the amendment of the license. This notice shall be given by registered or certified mail or by personal service and shall set forth:

(1) the length of the provisional license;
(2) the factual allegations;
(3) the statutes and rules alleged to be violated; and
(4) notice of the facility's right to a contested case hearing on the amendment of the license.

(d) The provisional license shall be effective immediately upon its receipt by the licensee and shall be posted in a prominent location, accessible to public view, within the licensed premises in lieu of the full license. The provisional license shall remain in effect until:

(1) the Department restores the licensee to full licensure status;
(2) the Department revokes the licensee's license; or
(3) the end of the licensee's licensure period. If a licensee has a provisional license at the time that the licensee submits a renewal application, the license, if renewed, shall also be a provisional license unless the Department determines that the licensee can be returned to full licensure status. A decision to issue a provisional license is stayed during the pendency of an administrative appeal and the licensee may continue to display its full license during the appeal.

(e) The Department shall revoke a license whenever:

(1) The Department finds that:
    (A) the licensee has failed to comply with the provisions of G.S. 131E, Article 5 and the rules promulgated under that article; and
    (B) it is not probable that the licensee can remedy the licensure deficiencies within a length of time acceptable to the Department; or
(2) The Department finds that:
    (A) The licensee has failed to comply with the provisions of G.S. 131E, Article 5; and
    (B) although the licensee may be able to remedy the deficiencies within a reasonable time, it is not probable that the licensee will be able to remain in compliance with hospital licensure rules for the foreseeable future; or
(3) The Department finds that the licensee has failed to comply with any of the provisions of G.S. 131E, Article 5 and the rules promulgated thereunder that endangers the health, safety or welfare of the patients in the facility.

The issuance of a provisional license is not a procedural prerequisite to the revocation of a license pursuant to Subparagraphs (e)(1), (2) or (3) of this Rule.

History Note: *Authority G.S. 131E-79;*
Eff. January 1, 1996;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. July 22, 2017.

10A NCAC 13B .3108 SUSPENSION OF ADMISSIONS

(a) The Department may amend a license, pursuant to G.S. 131E-78, by suspending the admission of any new patients to any facility when the conditions in the facility are detrimental to the health or safety of the patients in the facility.
(b) The Department shall notify the facility by registered or certified mail or by personal service of the decision to suspend admissions. Such notice will include:

(1) the period of the suspension;
(2) factual allegations;
(3) citation of statutes and rules alleged to be violated; and
(4) notice of the facility's right to a contested case hearing.

(c) The suspension shall be effective when the notice is served or on the date specified in the notice of suspension, whichever is later. The suspension shall remain effective for the period specified in the notice or until the facility demonstrates to the Department that conditions are no longer detrimental to the health and safety of the patient.

(d) The facility shall not admit new patients during the effective period of the suspension.

History Note: *Authority G.S. 131E-79;*
Eff. January 1, 1996;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. July 22, 2017.

10A NCAC 13B .3109 PROCEDURE FOR APPEAL

A facility may appeal any decision of the Department to deny, revoke or amend a license or any decision to suspend admissions by making such an appeal in accordance with G.S. 150B.

History Note: *Authority G.S. 131E-78; 131E-79;*
Eff. January 1, 1996;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. July 22, 2017.

10A NCAC 13B .3110 ITEMIZED CHARGES

(a) The facility shall provide an itemized list of charges to discharged patients or the facility shall include on patients' bills that are not itemized, notification of the right to request an itemized bill within three years of receipt of the non-itemized bill or so long as the hospital, a collections agency, or other assignee asserts the patient has an obligation to pay the bill.

(b) If requested, the facility shall provide an itemized list of charges to the patient or the patient's representative. This list shall detail in language comprehensible to an ordinary layperson the specific nature of the charges or expenses incurred by the patient.

(c) The itemized listing shall include each specific chargeable item or service in the following service areas:
(1) room rate;
(2) laboratory;
(3) radiology and nuclear medicine;
(4) surgery;
(5) anesthesiology;
(6) pharmacy;
(7) emergency services;
(8) outpatient services;
(9) specialized care;
(10) extended care;
(11) prosthetic and orthopedic appliances; and
(12) professional services provided by the facility.

History Note: *Authority G.S. 131E-79; 131E-91;*
Eff. January 1, 1996;
Temporary Amendment Eff. May 1, 2014;
Amended Eff. November 1, 2014;
Readopted Eff. April 1, 2020.

10A NCAC 13B .3111 TEMPORARY CHANGE IN BED CAPACITY

(a) A hospital may temporarily increase its bed capacity by up to 10 percent over its licensed bed capacity, as determined by the administrator, by utilizing observational beds for inpatients for a period of no more than 60 consecutive days following approval by the Division of Health Service Regulation.

(b) To qualify for a temporary change in licensed capacity, the hospital census shall be at least 90 percent of its licensed bed capacity, excluding beds that are under renovation or construction, and the hospital must demonstrate conditions requiring the temporary increase that may include but are not limited to the following:

(1) natural disaster;
(2) catastrophic event; or
(3) disease epidemic.

(c) The Division may approve a temporary increase in licensed beds only if:

(1) It is determined that the request has met the requirements of Paragraphs (a) and (b) of this Rule; and
(2) The hospital administrator certifies that the physical facilities to be used are adequate to safeguard the health and safety of patients. However this approval shall be revoked if the Division determines, as a result of a physical site visit, that these safeguards are not adequate to safeguard the health and safety of patients.

History Note: *Authority G.S. 131E-79;*
Eff. April 1, 2003;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. July 22, 2017.

SECTION .3200 - GENERAL HOSPITAL REQUIREMENTS

10A NCAC 13B .3201 HOSPITAL REQUIREMENTS

A facility shall have all of the following:

(1) an organized governing body;
(2) a chief executive officer;
(3) an organized medical staff;
(4) an organized nursing staff;
(5) continuous medical services;
(6) continuous nursing services;
(7) permanent on-site facilities for the care of patients 24 hours a day;
(8) a hospital-wide infection control program;
(9) minimum on-site clinical provisions as follows:
    (a) appropriately equipped inpatient care areas;
    (b) nursing care units;
    (c) diagnostic and treatment areas to include on-site laboratory and imaging facilities with the capacity to provide immediate response to patient emergencies;
    (d) pharmaceutical services in compliance with the Pharmacy Laws of North Carolina;
    (e) facilities to assure the sterilization of equipment and supplies;
    (f) medical records services;
    (g) provision for social work services;
    (h) current reference sources to meet staff needs; and
    (i) nutrition services.
(10) minimum supportive capabilities or facilities as follows:
    (a) nutrition and dietetic services;
    (b) scheduled general and preventive maintenance services for building, services and biomedical equipment;
    (c) capability for obtaining police and fire protection, emergency transportation, grounds-keeping, and snow removal;
    (d) personnel recruitment, training and continuing education;
    (e) business management capability;
    (f) short and long-range planning capability;
    (g) financial plan to provide continuity of operation under both normal and emergency conditions;
    (h) provision for patient, employee, and visitor safety; and
    (i) policies for preventive and corrective maintenance including procedures to be followed in the event of a breakdown of essential equipment.
(11) facilities must comply with construction rules in Sections .6000 - .6200 of this Subchapter.

(12) a risk management program as follows:
  (a) a specific staff member shall be assigned responsibility for development and administration of the program;
  (b) a written policy statement evidencing a current commitment to the risk management program together with written procedures, policies and educational programs applicable to a risk management program which are reviewed at least every three years and updated as necessary;
  (c) established lines of communication between the risk management program and other functions relating to quality of patient care, safety, and professional staff performance; and
  (d) a written report of the activities of the risk management program shall be annually submitted to the governing body.

(13) a quality assessment and improvement program which provides:
  (a) continuous assessment and evaluation of patient care and related services in all services and departments;
  (b) a designated individual to coordinate the quality assessment and improvement program who will assist in the establishment of quality assessment and improvement plans and reporting methods for each service and department;
  (c) a committee made up of representatives of the medical and nursing staff, administration, and other services or departments as defined by the hospital to coordinate the program, meet at least quarterly and maintain minutes of the meetings and committee activities; and
  (d) for each service and department as defined by the hospital to be involved in the continuous assessment, monitoring and evaluation of patient care and related services.

History Note: *Authority G.S. 131E-75; 131E-79;*
Eff. January 1, 1996;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. July 22, 2017.

10A NCAC 13B .3202 ADMISSION AND DISCHARGE

(a) The facility shall provide written admission and discharge, and referral policies.
(b) There shall be on the premises at all times an employee authorized to receive patients and to make arrangements for their disposition.
(c) A patient shall be admitted only under the care of a member of the medical staff meeting the provisions of Section .3700 of this Subchapter.
(d) The facility shall take appropriate precautions to protect the safety and legal rights of patients and employees.
(e) The facility shall maintain a complete and permanent record of all outpatients and inpatients including the date and time of admission and discharge. Effort shall be made to verify the full and true name, address, date of birth, nearest of kin, provisional diagnosis, condition on admission and discharge, referring physicians, attending physician or service.
(f) Facility staff shall provide at the time of admission an identification bracelet, band, or other suitable device for positive identification of each patient.
(g) No mentally competent adult shall be detained by the facility against his will, except as authorized by law.

History Note: *Authority G.S. 131E-75; 131E-79;*
Eff. January 1, 1996;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. July 22, 2017.

10A NCAC 13B .3203 DISCHARGE PLANNING

(a) Discharge planning shall be an integral part of in-patient hospitalization.
(b) The facility shall have written policies and procedures governing discharge planning. These shall include but need not be limited to the following:

(1) appropriate screening to determine the need for discharge planning;
(2) methods to facilitate the provision of follow-up care;
(3) information to be given to the patient or his family or other persons involved in caring for the patient on matters such as the patient's condition; his health care needs; the amount of activity he should engage in; any necessary medical regimens including drugs, nutrition therapy, appointments or other forms of therapy; sources of additional help from other agencies; and procedures to follow in case of complications; and

(4) procedures for assisting the patient and his family in gaining information regarding financial assistance in paying bills incurred as a result of the hospitalization, including how to receive assistance from the various federal and State government programs.

History Note: *Authority G.S. 131E-79;*
Eff. January 1, 1996;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. July 22, 2017.

10A NCAC 13B .3204 TRANSFER AGREEMENT

(a) Any facility that does not provide hospital based nursing facility service shall maintain written agreements with institutions offering this kind of care. Such agreements shall provide for the transfer and admission of patients who no longer require the services of the hospital but do require nursing facility services.

(b) A patient shall not be transferred to another medical care facility unless prior arrangements for admission have been made. Clinical records to provide continuity of care shall accompany the patient.

History Note: *Authority G.S. 131E-79;*
Eff. January 1, 1996;
Readopted Eff. April 1, 2020.

10A NCAC 13B .3205 DISCHARGE OF MINOR OR INCOMPETENT

Individuals who cannot legally consent to his or her own care shall be discharged to the custody of parents, legal guardian, person standing in loco parentis, or patient representative pursuant to 42 CFR 483.12(a)(1) herein incorporated by reference with subsequent amendments and editions, unless otherwise directed by the parent or guardian, or court of competent jurisdiction. This regulation may be accessed at https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/CertificationandComplianc/Hospitals at no cost. If the parent or guardian directs that discharge be made otherwise, he or she shall so state in writing, and the statement shall become a part of the permanent medical record of the patient.

History Note: *Authority G.S. 131E-79;*
Eff. January 1, 1996;
Readopted Eff. April 1, 2020.

SECTION .3300 - PATIENT'S BILL OF RIGHTS

10A NCAC 13B .3301 PRINCIPLE

It is the purpose of these requirements to promote the interests and well-being of the patients in facilities subject to this Subchapter even in those instances where the interests of the patients may be in opposition to the interests of the facility. The facility has the right to expect the patient to fulfill patient responsibilities as may be stated in the facilities' policies affecting patient care and conduct.

History Note: *Authority G.S. 131E-79;*
Eff. January 1, 1996;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. July 22, 2017.

10A NCAC 13B .3302 MINIMUM PROVISIONS OF PATIENT'S BILL OF RIGHTS

This Rule does not apply to patients in licensed nursing facility beds since these individuals are granted rights pursuant to G.S. 131E-117. A patient in a hospital facility subject to this Rule has the following rights pursuant to 42 CFR 482.13, which is hereby incorporated by reference including subsequent amendments and editions. This regulation can be accessed at https://www.ecfr.gov/cgi-bin/text-idx?SID=e867c7c6cbfeb689406afea7d88e8a80&mc=true&node=pt42.5.482&rgn=div5#se42.5.482_113 at no cost:

(1) A patient has the right to respect, dignity, and comfort.

(2) A patient has the right, upon request, to be given the name of his or her attending physician, the names of all other physicians participating in his or her care, and the names and functions of other health care persons having contact with the patient.

(3) A patient has the right to privacy concerning his or her own medical care program. Case discussion, consultation, examination, and treatment are considered confidential and shall be conducted privately pursuant to 42 CFR 482.13(c)(1):

(4) A patient has the right to know what facility rules and regulations apply to his or her conduct as a patient.

(5) A patient has the right to expect emergency procedures to be implemented without delay.

(6) A patient has the right to quality care and professional standards that are maintained and reviewed.

(7) A patient has the right to information in laymen's terms, concerning his or her diagnosis, treatment and prognosis, including information about alternative treatments and possible complications. When it is not possible or medically advisable to give such information to the patient, the information shall be given on his or her behalf to the patient's designee.

(8) Except for emergencies, a physician must obtain informed consent prior to the start of any procedure or treatment.

(9) A patient has the right to be advised when a physician is considering the patient as a part of a medical care research program or donor program. Informed consent shall be obtained prior to participation in such a program. The patient or legally responsible party may refuse to continue in any program that he or she has previously given informed consent. An Institutional Review Board (IRB) may waive or alter the informed consent requirement if it reviews and approves a research study in accordance with federal regulations for the protection of human research subjects including U.S. Department of Health and Human Services (HHS) regulations under 45 CFR Part 46 and U.S. Food and Drug Administration (FDA) regulations under 21 CFR Parts 50 and 56. 45 CFR Part 46 and 21 CFR Parts 50 and 56 are incorporated by reference, including subsequent amendments and editions. These regulations may be accessed at https://www.hhs.gov/ohrp/regulations-and-policy/regulations/common-rule/index.html at no cost. For any research study proposed for conduct under an FDA "Exception from Informed Consent Requirements for Emergency Research" or an HHS "Emergency Research Consent Waiver" that waives informed consent but community consultation and public disclosure about the research are required, any facility proposing to be engaged in the research study shall also verify that the proposed research study has been registered with the North Carolina Medical Care Commission. When the IRB has authorized the start of the community consultation process required for emergency research, but before the beginning of that process, notice of the proposed research study shall be provided to the North Carolina Medical Care Commission. The notice shall include:

(a) the title of the research study;

(b) a description of the research study, including a description of the population to be enrolled;

(c) a description of the planned community consultation process, including proposed meeting dates and times;

(d) instructions for opting out of the research study; and

(e) contact information including mailing address and phone number for the IRB and the principal investigator.

The Medical Care Commission may publish all or part of the above information in the North Carolina Register, in accordance with 26 NCAC 02C .0307, and may require the institution proposing to conduct the research study to attend a public meeting convened by a Medical Care Commission member in the community where the proposed research study is to take place to present and discuss the study or the community consultation process proposed.

(10) A patient has the right to refuse any drugs, treatment or procedure offered by the facility, and a physician shall inform the patient of his or her right to refuse any drugs, treatment or procedures and of the medical consequences of the patient's refusal of any drugs, treatment or procedure.

(11) A patient has the right to assistance in obtaining consultation with another physician at the patient's request and expense.

(12) A patient has the right to medical and nursing services without discrimination based upon race, color, religion, sex, sexual orientation, gender identity, national origin or source of payment.

(13) A patient who does not speak English shall have access to an interpreter.

(14) A patient or his or her designee has the right to have all records pertaining to his or her medical care treated as confidential except as otherwise provided by law or third party contractual arrangements. A patient's access to medical records may be restricted by the patient's attending physician. If the physician restricts the patient's access to information in the patient's medical record, the physician shall

record the reasons on the patient's medical record. Access shall be restricted only for medical reason. A patient's designee shall have access to the information in the patient's medical records even if the attending physician restricts the patient's access to those records.

(15) A patient has the right not to be awakened by hospital staff unless it is medically necessary.

(16) The patient has the right to be free from duplication of medical and nursing procedures as determined by the attending physician.

(17) The patient has the right to medical and nursing treatment that avoids unnecessary physical and mental discomfort.

(18) When medically permissible, a patient may be transferred to another facility only after he or his next of kin or other legally responsible representative has received complete information and an explanation concerning the needs for and alternatives to such a transfer. The facility that the patient is to be transferred must first have accepted the patient for transfer.

(19) The patient has the right to examine and receive a detailed explanation of his bill.

(20) The patient has a right to information and counseling on the availability of known financial resources for his health care.

(21) A patient has the right to be informed upon discharge of his or her continuing health care requirements following discharge and the means for meeting them.

(22) A patient shall not be denied the right of access to an individual or agency who is authorized to act on his or her behalf to assert or protect the rights set out in this Section.

(23) A patient has the right to be informed of his rights at the earliest possible time in the course of his or her hospitalization.

(24) A patient has the right to designate visitors who shall receive the same visitation privileges as the patient's immediate family members, regardless of whether the visitors are legally related to the patient.

History Note: *Authority G.S. 131E-75; 131E-79; 143B-165;*
RRC Objection due to ambiguity Eff. July 13, 1995;
Eff. January 1, 1996;
Temporary Amendment Eff. April 1, 2005;
Amended Eff. January 1, 2011; May 1, 2008; November 1, 2005;
Readopted Eff. April 1, 2020.

10A NCAC 13B .3303 PROCEDURE

(a) The facility shall develop and implement procedures to inform patients of his or her rights. Copies of the facilities' Patient's Bill of Rights shall be made available through one of the following ways:

(1) locations posted in a public place in the facility in addition to copies available upon request; or

(2) provided a copy to each patient or responsible party upon admission or as soon after admission as is feasible.

(b) The address and telephone number of the Acute and Home Care Licensure and Certification Section in the Department responsible for the enforcement of the provisions of this Rule shall be posted.

(c) The facility shall adopt procedures to ensure a comprehensive investigation of violations of patients' rights and to ensure their enforcement pursuant to 42 CFR 483.12(a)(2) herein incorporated by reference including subsequent amendments and editions. This regulation may be accessed at https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/CertificationandComplianc/Hospitals at no cost. These procedures shall ensure that:

(1) a system is established to identify formal written complaints;

(2) written complaints are recorded and investigated;

(3) investigation and resolution of complaints shall be conducted; and

(4) disciplinary and education procedures shall be developed for members of the hospital and medical staff who are noncompliant with facility policies.

(d) The Division shall investigate or refer to other State agencies all complaints within the jurisdiction of the rules in this Subchapter.

History Note: *Authority G.S. 131E-79;*
Eff. January 1, 1996;
Readopted Eff. April 1, 2020.

SECTION .3400 - SUPPLEMENTAL RULES FOR THE LICENSURE OF CRITICAL ACCESS HOSPITALS

10A NCAC 13B .3401 SUPPLEMENTAL RULES

The rules of this Section pertain only to designated Critical Access Hospitals in accordance with 42 CFR 485 Subpart F. The general requirements of this Subchapter shall apply to such facilities except where they are specifically waived or modified by the rules of this Section.

History Note: *Authority G.S. 131E-79;*
Eff. January 1, 1996;
Amended Eff. November 1, 2004;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. July 22, 2017.

10A NCAC 13B .3402 DEFINITIONS

The following definitions shall apply throughout this Section, unless context otherwise clearly indicates to the contrary:

(1) "Available" means provided directly by the facility or by written agreement with a qualified provider of the service within one hour driving time.

(2) "Critical Access Hospital" means a facility designated by the North Carolina Office of Rural Health in accordance with 42 CFR 485 Subpart F.

History Note: *Authority G.S. 131E-79;*
Eff. January 1, 1996;
Amended Eff. November 1, 2004;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. July 22, 2017;
Amended Eff. October 1, 2019.

10A NCAC 13B .3403 LICENSURE APPLICATION

10A NCAC 13B .3404 FEDERALLY CERTIFIED PRIMARY CARE HOSPITAL

History Note: *Authority G.S. 131E-79;*
Eff. January 1, 1996;
Repealed Eff. November 1, 2004.

10A NCAC 13B .3405 DESIGNATED CRITICAL ACCESS HOSPITALS

The requirements of 10A NCAC 13B shall apply to Critical Access Hospitals with the following modifications:

(1) Autopsy facilities required in Rule .4907 of this Subchapter are not required provided that the facility has in effect a written agreement with another facility meeting Rule .4907 of this Subchapter for providing autopsy services.

(2) Radiological services required in Section .4800 and Rule .6210 of this Subchapter are not required provided that the facility has a written agreement with another licensed facility meeting the requirements of Section .4800 and Rule .6210 of this Subchapter which makes radiological service available.

(3) Emergency services required in Rules .4102-.4110 of this Subchapter are not required. Emergency response capability set forth in Rule .4101 of this Subchapter shall be provided. Medical staff shall require that facility personnel are capable of initiating life-saving measures at a first-aid level of response for any patient or person in need of such services. This shall include:
   (a) Establishing protocols or agreements with any facility providing emergency services;
   (b) Initiating basic cardio-pulmonary resuscitation according to the American Red Cross or American Heart Association standards;
   (c) Availability of intravenous fluids and supplies required to establish intravenous access; and
   (d) Availability of first-line emergency drugs as specified by the medical staff.

(4) Anesthesia services required in Section .4600 of this Subchapter are not required in hospitals not offering outpatient surgery services.

(5) Food services required in Section .4700 of this Subchapter shall be provided for inpatients directly or made available through contractual arrangements.

(6) "Observation bed" as defined in Rule .3001(32) of this Subchapter does not apply. For purposes of this Section, "Observation bed" means a bed used for no more than 48-hours, to evaluate and determine the condition and disposition of a patient and is not considered a part of the hospital's licensed bed capacity.

History Note: *Authority G.S. 131E-79;*
Eff. January 1, 1996;
Amended Eff. November 1, 2004;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. July 22, 2017.

SECTION .3500 - GOVERNANCE AND MANAGEMENT

10A NCAC 13B .3501 GOVERNING BODY

(a) The governing body, owner, or the person or persons designated by the owner as the governing body shall be responsible for ensuring that the objectives specified in the facility's governing documents, such as the charter or resolution, are attained.

(b) The governing body shall be the final authority for decisions for which the facility administration, the medical staff, and the facility personnel are directly or indirectly responsible within the facility.

(c) A local advisory board shall be established to provide non-binding advice to the governing body regarding the health, safety, and welfare of the community, if the facility is owned by an organization or persons outside of North Carolina. A local advisory board shall include members from the county where the facility is located.

History Note: *Authority G.S. 131E-75; 131E-79;*
Eff. January 1, 1996;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. July 22, 2017;
Amended Eff. July 1, 2020.

10A NCAC 13B .3502 REQUIRED FACILITY BYLAWS, POLICIES, RULES, AND REGULATIONS

(a) The governing body shall adopt written bylaws, policies, rules, and regulations in accordance with all requirements contained in this Subchapter and in accordance with the community responsibility of the facility. The written bylaws, policies, rules, and regulations shall:

(1) state the objectives;

(2) describe the powers and duties of the governing body officers and committees and the responsibilities of the chief executive officer;

(3) state the qualifications for governing body membership, the procedures for selecting members, and the terms of service for members, officers and committee chairmen;

(4) describe the authority delegated to the chief executive officer and to the medical staff. No assignment, referral, or delegation of authority by the governing body shall relieve the governing body of its responsibility for the conduct of the facility. The governing body shall retain the right to rescind any such delegation;

(5) require governing body approval of the bylaws of any auxiliary organizations established by the facility;

(6) require the governing body to review and approve the bylaws of the medical staff;

(7) establish procedures for processing and evaluating the applications for medical staff membership and for the granting of clinical privileges;

(8) establish a procedure for implementing, disseminating, and enforcing a Patient's Bill of Rights as set forth in Rule .3302 of this Subchapter and in compliance with G.S. 131E-117; and

(9) require the governing body to institute procedures to provide for:

(A) orientation of newly elected governing body members to board functions and procedures;

(B) the development of procedures for periodic reexamination of the relationship of the governing body to the total facility community; and

(C) the recording of minutes of all governing body and executive committee meetings and the dissemination of those minutes, or summaries thereof, after the governing body and executive committee meetings to all members of the governing body.

(b) The governing body shall provide written policies and procedures to assure billing and collection practices in accordance with G.S. 131E-91. These policies and procedures shall include:

(1) a financial assistance policy as defined in G.S. 131E-214.14(b)(3);
(2) how a patient may obtain an estimate of the charges for the statewide 100 most frequently reported Diagnostic Related Groups (DRGs), where applicable, 20 most common outpatient imaging procedures, and 20 most common outpatient surgical procedures. The policy shall require that the information be provided to the patient in writing, either electronically or by mail, within three business days;
(3) how a patient or patient's representative may dispute a bill;
(4) issuance of a refund within 45 days of the patient receiving notice of the overpayment when a patient has overpaid the amount due to the facility;
(5) providing written notification to the patient or patient's representative at least 30 days prior to submitting a delinquent bill to a collections agency;
(6) providing the patient or patient's representative with the facility's charity care and financial assistance policies, if the facility is required to file a Schedule H, federal form 990;
(7) the requirement that a collections agency, entity, or other assignee obtain written consent from the facility prior to initiating litigation against the patient or patient's representative;
(8) a policy for handling debts arising from the provision of care by the facility involving the doctrine of necessaries, in accordance with G.S. 131E-91(d)(5); and
(9) a policy for handling debts arising from the provision of care by the facility to a minor, in accordance with G.S. 131E-91(d)(6).

(c) The governing body shall ensure that the bylaws, rules, and regulations of the medical staff and the bylaws, rules, policies, and regulations of the facility shall not be in conflict.

(d) The written policies, rules, and regulations shall be reviewed every three years, revised as necessary, and dated to indicate when last reviewed or revised.

(e) To qualify for licensure or license renewal, each facility must provide to the Division, upon application, an attestation statement in a form provided by the Division verifying compliance with the requirements of this Rule.

(f) On an annual basis, on the license renewal application provided by the Division, the facility shall provide to the Division the direct website address to the facility's financial assistance policy. This Paragraph applies only to facilities required to file a Schedule H, federal form 990.

History Note: *Authority G.S. 131E-79; 131E-91; 131E-214.8; 131E-214.13(f); 131E-214.14;*
Eff. January 1, 1996;
Temporary Amendment Eff. May 1, 2014;
Amended Eff. November 1, 2014;
Readopted Eff. July 1, 2020.

10A NCAC 13B .3503 FUNCTIONS

(a) The governing body shall:

(1) provide management, physical resources, and personnel determined by the governing body to be required to meet the needs of patients for treatment as authorized by the facility's license;
(2) require facility administration to establish a quality control mechanism that includes a risk management component and an infection control program;
(3) formulate short-range and long-range plans as defined in the facility bylaws, policies, rules, and regulations;
(4) conform to all applicable State and federal laws, rules, and regulations, and applicable local ordinances;
(5) provide for the control and use of the physical and financial resources of the facility;
(6) review the annual audit, budget, and periodic reports of the financial operations of the facility;
(7) consider the recommendation of the medical staff in granting and defining the scope of clinical privileges to individuals in accordance with medical staff bylaws requirements for making such

recommendations and the facility bylaws established by the governing body for the review and final determination of such recommendations;

(8) require that applicants be informed of the disposition of their application for medical staff membership or clinical privileges in accordance with the facility bylaws established by the governing body, after an application has been submitted;

(9) review and approve the medical staff bylaws, rules, and regulations;

(10) delegate to the medical staff the authority to:

(A) evaluate the professional competence of medical staff members and applicants for medical staff membership and clinical privileges; and

(B) recommend to the governing body initial medical staff appointments, reappointments, and assignments or curtailments of privileges;

(11) require that resources be made available to address the emotional and spiritual needs of patients either directly or through referral or arrangement with community agencies;

(12) maintain communication with the medical staff which may be established through:

(A) meetings with the executive committee of the medical staff;

(B) service by the president of the medical staff as a member of the governing body with or without a vote;

(C) appointment of individual medical staff members to the medical review committee; or

(D) a joint conference committee that will be a committee of the governing body and the medical staff composed of equal representatives of each of the governing body, the chairman of the board or designee, the medical staff, and the chief of the medical staff or designee, respectively;

(13) require the medical staff to establish controls that are designed to provide that standards of ethical professional practices are met;

(14) provide administrative staff support to facilitate utilization review and infection control within the facility, to support quality control and any other medical staff functions required by this Subchapter or by the facility bylaws;

(15) meet the following disclosure requirements:

(A) provide data required by the Division;

(B) disclose the facility's average daily inpatient charge upon request of the Division; and

(C) disclose the identity of persons owning five percent or more of the facility as well as the facility's officers and members of the governing body upon request;

(16) establish a procedure for reporting the occurrence and disposition of allegations of abuse or neglect of patients and incidents involving quality of care or physical environment at the facility. These procedures shall require that:

(A) incident reports are analyzed and summarized by a designated party; and

(B) corrective action is taken based upon the analysis of incident reports;

(17) in a facility with one or more units, or portions of units, however described, utilized for psychiatric or substance abuse treatment, adopt policies implementing the provisions of G.S. 122C, Article 3, and Article 5, Parts, 2, 3, 4, 5, 7, and 8;

(18) develop arrangements for the provision of extended care and other long-term healthcare services. Such services shall be provided in the facility or by outside resources through a transfer agreement or referrals;

(19) provide and implement a written plan for the care or for the referral, or both, of patients who require mental health or substance abuse services while in the facility;

(20) develop a conflict of interest policy which shall apply to all governing body members and facility administration. All governing body members shall execute a conflict of interest statement; and

(21) conduct direct consultations with the medical staff at least twice during the year.

(b) For the purposes of this Rule, "direct consultations" means the governing body, or a subcommittee of the governing body, meets with the leader(s) of the medical staff(s), or his or her designee(s) either face-to-face or via a telecommunications system permitting immediate, synchronous communication.

(c) The direct consultations shall consist of discussions of matters related to the quality of medical care provided to the hospital's patients, including quality matters arising out of the following:

(1) the scope and complexity of services offered by the facility;

(2) specific clinical populations served by the facility;

(3) limitations on medical staff membership other than peer review or corrective action in individual cases;
(4) circumstances relating to medical staff access to a facility resource; or
(5) any issues of patient safety and quality of care that a hospital's quality assessment and performance improvement program might identify as needing the attention of the governing body in consultation with the medical staff.

(d) For the purposes of this Rule, "specific clinical populations" includes those individuals who may be treated at the facility by the medical staff in place at the time of the consultation.

History Note: *Authority G.S. 131E-14.2; 131E-79; 42 CFR 482.12; 42 CFR 482.22;*
Eff. January 1, 1996;
Readopted Eff. July 1, 2020.

SECTION .3600 - MANAGEMENT AND ADMINISTRATION OF OPERATIONS

10A NCAC 13B .3601 CHIEF EXECUTIVE OFFICER

(a) The governing body shall designate a chief executive officer whose qualifications, authority, responsibilities and duties shall be defined in a written statement adopted by the governing body.

(b) The chief executive officer shall be the designated representative of the governing body and may be given any one or more or all of the responsibilities set out in Rule .3602 of this Section.

History Note: *Authority G.S. 131E-79;*
Eff. January 1, 1996;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. July 22, 2017.

10A NCAC 13B .3602 RESPONSIBILITIES

The governing body shall adopt written policies, rules, and regulations that specify the officer or officers that shall:

(1) act for the chief executive officer in his absence;
(2) manage the facility consonant with its expressed aims and policies;
(3) attend meetings of the governing body and appropriate meetings of the medical staff;
(4) implement policies adopted by the governing body for the operation of the facility;
(5) organize the administrative functions of the facility, delegate duties and establish formal means of accountability on the part of subordinates;
(6) establish such facility departments as are indicated, provide for departmental and interdepartmental meetings and attend or be represented at such meetings, and appoint hospital departmental representatives to medical staff committees where appropriate or when requested to do so by the medical staff;
(7) appoint the heads of administrative departments;
(8) report to the governing body and to the medical staff on the overall activities of the facility as well as on appropriate federal, State and local developments that affect health care in the facility;
(9) review the annual audit of the financial operations of the facility and acting upon recommendations therein;
(10) provide fiscal planning and financial management of the facility including the provision of annual budgets and periodic financial status reports to the governing board;
(11) develop in cooperation with the departmental heads and other appropriate staff, an overall organizational plan for the facility which will coordinate the functions, services and departments of the facility, when possible; and
(12) require that the agreements with service providers, such as laundry, laboratory and imaging, specifically indicate that compliance will be maintained with applicable State rules as would apply to the same services if provided directly by the facility.

History Note: *Authority G.S. 131E-79;*
Eff. January 1, 1996;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. July 22, 2017.

10A NCAC 13B .3603 PERSONNEL POLICIES AND PRACTICES

The facility shall develop, establish and maintain personnel policies and practices which support sound patient care. The policies shall be in writing and made available to all employees, and they shall be reviewed periodically but no less often than once every three years. The date of the most recent review shall be indicated on the written policies. A procedure shall be established for notifying employees of changes in the established personnel policies.

History Note: *Authority G.S. 131E-79;*
Eff. January 1, 1996;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. July 22, 2017.

10A NCAC 13B .3604 JOB DESCRIPTIONS

The facility shall develop and make available to the employee a written job description for each type of job in the facility, including the chief executive officer and heads of departments. Each job description shall include a written description of the education, experience, license, certification, or other qualifications required for the position.

History Note: *Authority G.S. 131E-79;*
Eff. January 1, 1996;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. July 22, 2017.

10A NCAC 13B .3605 PERSONNEL RECORDS

(a) The facility shall maintain accurate and complete personnel records for each facility employee during the term of employment and for two years thereafter. The chief executive officer may designate an individual to carry out this assignment.

(b) Personnel records shall be maintained under such conditions as may be required by state or federal law and shall contain at least the following:

(1) information regarding the employee's education, training and experience and clinical competence, including, if applicable, professional licensure status and license number, sufficient to verify the employee's qualifications for the job for which he is employed. Such information shall be kept current. Applicants for positions requiring a licensed person shall be hired only after obtaining verification of their licenses from the appropriate board;

(2) current information relative to periodic work performance evaluations;

(3) records of such pre-employment health examinations and of subsequent health services rendered to the employees as are necessary to determine that all facility employees are physically able to perform the essential duties of their positions.

History Note: *Authority G.S. 131E-79;*
Eff. January 1, 1996;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. July 22, 2017.

10A NCAC 13B .3606 EDUCATION PROGRAMS

The facility shall provide new employee orientation and continuing education programs for all employees to maintain the skills necessary for the performance of their duties and learn new developments in health care. Records shall be maintained of all orientation and educational programs, and of the participants.

History Note: *Authority G.S. 131E-79;*
Eff. January 1, 1996;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. July 22, 2017.

10A NCAC 13B .3607 PERSONNEL HEALTH REQUIREMENTS

Employees shall have pre-employment medical examinations and interim examinations in accordance with medical criteria established by the facility.

History Note: *Authority G.S. 131E-79;*
Eff. January 1, 1996;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. July 22, 2017.

10A NCAC 13B .3608 INSURANCE
The governing board shall have in place an insurance program which provides for the protection of the physical and financial resources of the facility.

History Note: *Authority G.S. 131E-79;*
Eff. January 1, 1996;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. July 22, 2017.

10A NCAC 13B .3609 AUDIT OF FINANCIAL OPERATIONS
An audit of the financial operations of the facility shall be performed by a public accountant at least once a year.

History Note: *Authority G.S. 131E-79;*
Eff. January 1, 1996;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. July 22, 2017.

SECTION .3700 - MEDICAL STAFF

10A NCAC 13B .3701 GENERAL PROVISIONS
(a) The facility shall have a self-governed medical staff that shall be accountable to the governing body for the quality of care provided by individuals with medical staff membership and clinical privileges to provide medical services in the facility. Facility policy shall provide that individuals with clinical privileges shall perform only services within the scope of individual privileges granted.
(b) Minutes required by the rules of this Section shall reflect all transactions, conclusions, and recommendations of meetings. Minutes shall be prepared and retained in accordance with a policy established by the facility and medical staff, and available for inspection by members of the medical staff and governing body, respectively, unless such minutes include confidential peer review information that is not accessible to others in accordance with any law protecting the confidentiality.

History Note: *Authority G.S. 131E-79;*
Eff. January 1, 1996;
Readopted Eff. July 1, 2020.

10A NCAC 13B .3702 ESTABLISHMENT

History Note: *Authority G.S. 131E-79;*
Eff. January 1, 1996;
Repealed Eff. July 1, 2020.

10A NCAC 13B .3703 APPOINTMENT
(a) The governing body may grant, deny, renew, modify, suspend, or terminate medical staff membership and clinical privileges after consideration of the recommendation made by the medical staff in accordance with the bylaws established by the medical staff and approved by the governing body for making such recommendations, and the facility bylaws established by the governing body for review and final determination of such recommendations.
(b) Review of an applicant for medical staff membership and the granting of clinical privileges shall follow procedures set forth in the bylaws, rules, and regulations of the medical staff. These procedures shall require the following:
(1) a signed application for medical staff membership, specifying date of birth, year and school of graduation, date of licensure, statement of postgraduate or special training and experience, and a statement of the scope of the clinical privileges sought by the applicant;
(2) verification by the facility of the applicant's qualifications as stated in the application, including any required continuing education; and
(3) written notice to the applicant from the governing body regarding appointment or reappointment, which specifies the approval or denial of clinical privileges and the scope of the privileges if granted.
(c) Members of the medical staff and others granted clinical privileges in the facility shall hold current licenses to practice in North Carolina.

(d) Medical staff appointments shall be reviewed at least once every two years by the medical staff in accordance with the bylaws established by the medical staff and approved by the governing body, and shall be followed with recommendations made to the governing body for review and a final determination.
(e) The facility shall maintain a file containing performance information for each medical staff member. Representatives of the Division shall have access to these files in accordance with, and subject to the limitations and restrictions set forth in, G.S. 131E-80; however, to the extent that the same includes confidential medical review information, such information shall be reviewable and confidential in accordance with G.S. 131E-80(d) and other applicable law.
(f) Minutes shall be taken and maintained of all meetings of the medical staff and governing body that concern the granting, denying, renewing, modifying, suspending or terminating of clinical privileges.

History Note: *Authority G.S. 131E-79; 42 CFR 482.12(a)(10); 42 CFR 482.22(a)(1);*
Eff. January 1, 1996;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. July 22, 2017;
Amended Eff. July 1, 2020.

10A NCAC 13B .3704 ESTABLISHMENT AND CATEGORIES OF MEDICAL STAFF MEMBERSHIP
(a) The medical staff shall be established in accordance with the bylaws of the facility and organized in accordance with the bylaws, rules, and regulations of the medical staff. After considering the recommendations of the medical staff, the governing body of the facility may, in accordance with G.S. 131E-85, grant medical staff membership and clinical privileges to qualified, licensed practitioners in accordance with their training, experience, and demonstrated competence and judgment in accordance with the medical staff bylaws, rules, and regulations.
(b) Every facility shall have an active medical staff, as defined by the medical staff bylaws, rules, and regulations, to deliver medical services within the facility and to administer medical staff functions. The members of the active medical staff shall be eligible to vote at medical staff meetings and to hold medical staff office positions as determined by the medical staff bylaws, rules, and regulations and shall be responsible for recommendations made to the governing body regarding the organization and administration of the medical staff. Medical staff office positions shall be determined in the medical staff bylaws, rules, and regulations.
(c) The active medical staff may establish other categories for membership in the medical staff. These categories for membership shall be identified and defined in the medical staff bylaws. Examples of membership categories include:
(1) active medical staff;
(2) associate medical staff;
(3) courtesy medical staff;
(4) temporary medical staff;
(5) consulting medical staff;
(6) honorary medical staff; or
(7) other staff classifications.
The medical staff bylaws shall describe the authority, duties, privileges, and voting rights for each membership category consistent with applicable law, rules, and regulations and requirements of facility accrediting bodies.

History Note: *Authority G.S. 131E-79;*
Eff. January 1, 1996;
Readopted Eff. July 1, 2020.

10A NCAC 13B .3705 MEDICAL STAFF BYLAWS, RULES, AND REGULATIONS
(a) The active medical staff shall develop and adopt, subject to the approval of the governing body, a set of bylaws, rules, and regulations to establish a framework for self-governance of medical staff activities and accountability to the governing body.
(b) The medical staff bylaws, rules, and regulations shall provide for the following:
(1) organizational structure;
(2) qualifications for medical staff membership;
(3) procedures for granting or renewing, denying, modifying, suspending, and revoking clinical privileges;
(4) procedures for disciplinary or corrective actions;
(5) procedures for fair hearing and appellate review mechanisms for denying, modifying, suspending, and revoking clinical privileges;
(6) composition, functions and attendance of standing committees;

(7) policies for completion of medical records;
(8) formal liaison between the medical staff and the governing body;
(9) methods developed to formally verify that each medical staff member on appointment or reappointment agrees to abide by current medical staff bylaws, rules, and regulations, and the facility bylaws, rules, policies, and regulations;
(10) procedures for participation in quality assurance functions by medical staff members;
(11) the process for the selection and election and removal of medical staff officers; and
(12) procedures for the proposal, adoption, and amendment, and approval of medical staff bylaws, rules, and regulations.

(c) Neither the medical staff, the governing body, nor the facility administration may unilaterally amend the medical staff bylaws, rules, and regulations.

(d) Neither the medical staff, the governing body, nor the facility administration may waive any provision of the medical staff bylaws, rules, and regulations, except in an emergency circumstance. For purposes of this Rule, an "emergency circumstance" means a situation of urgency that justifies immediate action and when there is not sufficient time to follow the applicable provisions and procedures of the medical staff bylaws. Examples of an emergency circumstance include an immediate threat to the life or health of an individual or the public, a natural disaster, or a judicial or regulatory order. The duration of a waiver permitted by this Rule will be only so long as the emergency circumstance exists.

History Note: *Authority G.S. 131E-79;*
Eff. January 1, 1996;
Readopted Eff. July 1, 2020.

10A NCAC 13B .3706 ORGANIZATION AND RESPONSIBILITIES OF THE MEDICAL STAFF

(a) The medical staff shall be organized to accomplish its required functions as established by the governing body and medical staff bylaws, rules, and regulations and provide for the election or appointment of its own officers.

(b) There shall be an executive committee, or its equivalent, which represents the medical staff, that has responsibility for the effectiveness of all medical activities of the staff, and that acts for the medical staff.

(c) The following functions shall be performed by the medical staff:
(1) credentialing review;
(2) medical records review;
(3) drug utilization review;
(4) radiation safety review;
(5) blood usage review;
(6) bylaws review;
(7) medical review;
(8) peer review; and
(9) recommendations for discipline or corrective action of medical staff members.

(d) The medical staff shall ensure that minutes are prepared for each medical staff, departmental, and committee meeting.

History Note: *Authority G.S. 131E-79;*
Eff. January 1, 1996;
Readopted Eff. July 1, 2020.

10A NCAC 13B .3707 MEDICAL ORDERS

(a) No medication or treatment shall be administered or discontinued except in response to the order of a member of the medical staff in accordance with policies, rules, and regulations established by the facility and medical staff and as provided in Paragraph (f) of this Rule.

(b) Such orders shall be dated and recorded directly in the patient medical record. A method shall be established to safeguard against fraudulent recordings.

(c) All orders for medication or treatment shall be authenticated according to medical staff and facility policies, rules, or regulations. The order shall be taken by personnel qualified by medical staff bylaws, rules, and regulations, and shall include the date, time, and name of persons who gave the order, and the full signature of the person taking the order.

(d) The names of drugs shall be recorded in full and not abbreviated except where approved by the active medical staff.

(e) The active medical staff shall establish a written policy in conjunction with the pharmacy committee or its equivalent for all medications not specifically prescribed as to time or number of doses to be automatically stopped after a

reasonable time limit, but no more than 14 days. The prescriber shall be notified according to established policies and procedures at least 24 hours before an order is automatically stopped.
(f) For patients who are under the continuing care of an out-of-state physician but are temporarily located in North Carolina, a facility may process the out-of-state physician's prescriptions or orders for diagnostic or therapeutic studies which maintain and support the patient's continued program of care, where the authenticity and currency of the prescriptions or orders can be verified by the physician who prescribed or ordered the treatment requested by the patient, and where the facility verifies that the out-of-state physician is licensed to prescribe or order the treatment.

History Note: *Authority G.S. 131E-75; 131E-79;*
Eff. January 1, 1996;
Amended Eff. April 1, 2005; August 1, 1998;
Readopted Eff. July 1, 2020.

10A NCAC 13B .3708 MEDICAL STAFF RESPONSIBILITIES FOR QUALITY IMPROVEMENT REVIEW

(a) The medical staff shall have in effect a system to review care provided at the facility by members of the medical staff, to assess quality, to provide a process for quality improvement, and to monitor the outcome of quality improvement activities.
(b) The medical staff shall establish criteria for the evaluation of the quality of care.
(c) The facility shall have a written plan that generates reports to permit identification of patient care problems and that establishes a system to use this data to document and identify interventions. The plan shall be approved by the medical staff, facility administration, and the governing body.
(d) The medical staff shall establish a policy to maintain a review process of the care provided by members of the medical staff to all patients in every medical department of the facility. The medical staff shall have a policy to schedule meetings to examine the review process and results. The review process shall include both practitioners and allied health professionals from the medical staff.
(e) Minutes shall be prepared for all meetings reviewing quality improvement and shall reflect all of the transactions, conclusions, and recommendations of the meeting.

History Note: *Authority G.S. 131E-79;*
Eff. January 1, 1996;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. July 22, 2017;
Amended Eff. July 1, 2020.

SECTION .3800 - NURSING SERVICES

10A NCAC 13B .3801 NURSE EXECUTIVE

(a) Whether the facility utilizes a centralized or decentralized organizational structure, a nurse executive shall be responsible for the coordination of nursing organizational functions.
(b) A nurse executive shall develop facility wide patient care programs, policies and procedures that describe how the nursing care needs of patients are assessed, met and evaluated.
(c) The nurse executive shall develop and adopt, subject to the approval of the facility, a set of administrative policies and procedures to establish a framework to accomplish required functions.
(d) There shall be scheduled meetings, at least every 60 days, of the members of the nursing staff to evaluate the quality and efficiency of nursing services. Minutes of these meetings shall be maintained.
(e) The nurse executive shall be responsible for:

(1) the development of a written organizational plan which describes the levels of accountability and responsibility within the nursing organization;
(2) identification of standards and policies and procedures related to the delivery of nursing care;
(3) planning for and the evaluation of the delivery of nursing care delivery system;
(4) establishment of a mechanism to validate qualifications, knowledge, and skills of nursing personnel;
(5) provision of orientation and educational opportunities related to expected nursing performance, and maintenance of records pertaining thereto;
(6) implementation of a system for performance evaluation;
(7) provision of nursing care services in conformance with the North Carolina Nursing Practice Act;

(8) assignment of nursing staff to clinical or managerial responsibilities based upon educational preparation, in conformance with licensing laws and an assessment of current competence; and
(9) staffing nursing units with sufficient personnel in accordance with a written plan.

History Note: *Authority G.S. 131E-79;*
Eff. January 1, 1996.

10A NCAC 13B .3802 NURSING STAFF

(a) Licensed nurses and other nursing personnel shall be qualified by training, education, experience and demonstrated abilities to provide nursing care within their scope of practice.
(b) Staffing schedules which reflect personnel assignment by date and service unit shall be kept on file for at least three years by hospital management.
(c) The facility shall establish policies for the provision of services for all contractual agreement personnel that include at a minimum the following:
(1) verification of licensure or certification by the appropriate occupational board;
(2) delivery and documentation of care;
(3) participation on interdisciplinary care planning activities; and
(4) supervision of contractual agreement personnel.

History Note: *Authority G.S. 131E-79;*
Eff. January 1, 1996;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. July 22, 2017.

10A NCAC 13B .3803 NURSING POLICIES AND PROCEDURES

(a) Nursing policies and procedures shall be available to the nursing staff in each nursing care unit and service area and shall include the following:
(1) method of noting diagnostic and therapeutic orders;
(2) method of assigning nursing care of patients;
(3) infection control measures;
(4) patient safety measurers; and
(5) method of implementing orders for medication or treatment.
(b) Each unit shall have relevant clinical reference materials available. The following shall be provided to each unit:
(1) a facility formulary or comparable drug reference;
(2) a policy and procedure manual; and
(3) a medical dictionary.
(c) The facility shall provide a program of inservice education which shall be maintained and documented for all nursing staff personnel. Annual inservices shall include infection control measures, cardiopulmonary resuscitation and fire and safety.
(d) Nursing care policies and procedures shall be reviewed at least every three years by the nursing staff and facility management and revised as necessary. They shall include the date to indicate the time of the most recent review or revision.

History Note: *Authority G.S. 131E-79;*
Eff. January 1, 1996;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. July 22, 2017.

10A NCAC 13B .3804 PATIENT CARE

(a) Each patient's need for nursing care related to his or her admission shall be determined by a registered nurse. Patient needs shall be reassessed when warranted by the patient's condition.
(b) Each patient's nursing care shall be based upon assessed needs and shall be coordinated with the therapies of other disciplines.
(c) The patient's medical record shall include documentation of:
(1) the initial assessment and reassessments of patient clinical status;
(2) patient care needs;
(3) interventions performed to meet the patient's nursing care needs;

(4) implementation of physician's orders;
(5) the nursing care provided; and
(6) the patient's response to, and the outcomes of, the care provided.

(d) Each plan of care shall be initiated within 24 hours of admission. The plan of care shall become a part of the clinical record.

(e) The nursing care plan shall be readily available to all physicians and facility personnel involved with the care of the patient.

History Note: *Authority G.S. 131E-79;*
Eff. January 1, 1996;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. July 22, 2017.

SECTION .3900 - MEDICAL RECORD SERVICES

10A NCAC 13B .3901 ORGANIZATION

(a) The facility shall establish a medical record service. It shall be directed, staffed and equipped to accurately process, index, and file all medical records. Orientation, on-the-job training and inservice programs for medical records personnel shall be provided.

(b) The medical record service shall be equipped to enable its personnel to maintain medical records so that they are readily accessible and secure from unauthorized use.

History Note: *Authority G.S. 131E-79;*
Eff. January 1, 1996;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. July 22, 2017.

10A NCAC 13B .3902 MANAGER

(a) The medical records service shall be directed and supervised by a qualified medical records manager. If the manager is not a registered record administrator or an accredited records technician, the facility shall retain a person with those qualifications on a part-time or consulting basis.

(b) The manager of the medical record service shall advise, administer, supervise and perform work involved in the development, analysis, maintenance and use of medical records and reports.

(c) Where the manager is employed on a part-time or consulting basis, he or she shall organize the department, train the regular personnel and make periodic visits to the facility. The manager shall evaluate the records and the operation of the service and document the visits by written reports. A written contract specifying his or her duties and responsibilities shall be kept on file and made available for inspection by the Division's surveyor.

(d) The manager of the medical record service shall maintain a system of identification and filing to facilitate the prompt location of medical record of any patient.

(e) The manager of the medical records service shall store medical records in such a manner as to provide protection from loss, damage, and unauthorized access.

History Note: *Authority G.S. 131E-79;*
RRC Objection due to lack of Statutory Authority Eff. July 13, 1995;
Eff. January 1, 1996;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. July 22, 2017.

10A NCAC 13B .3903 PRESERVATION OF MEDICAL RECORDS

(a) The manager of medical records service shall maintain medical records, whether original, computer media, or microfilm, for a minimum of 11 years following the discharge of an adult patient.

(b) The manager of medical records shall maintain medical records of a patient who is a minor until the patient's 30th birthday.

(c) If a hospital discontinues operation, its management shall make known to the Division where its records are stored. Records shall be stored in a business offering retrieval services for at least 11 years after the closure date.

(d) The hospital shall give public notice prior to destruction of its records, to permit former patients or representatives of former patients to claim the record of the former patient. Public notice shall be in at least two forms: written notice to the

former patient or their representative and display of an advertisement in a newspaper of general circulation in the area of the facility.
(e) The manager of medical records may authorize the microfilming of medical records. Microfilming may be done on or off the premises. If done off the premises, the facility shall provide for the confidentiality and safekeeping of the records. The original of microfilmed medical records shall not be destroyed until the medical records department has had an opportunity to review the processed film for content.
(f) Nothing in this Section shall be construed to prohibit the use of automation in the medical records service, provided that all of the provisions in this Rule are met and the information is readily available for use in patient care.
(g) Only personnel authorized by state laws and Health Insurance Portability and Accountability Act regulations shall have access to medical records. Where the written authorization of a patient is required for the release or disclosure of health information, the written authorization of the patient or authorized representative shall be maintained in the original record as authority for the release or disclosure.
(h) Medical records are the property of the hospital, and they shall not be removed from the facility jurisdiction except through a court order. Copies shall be made available for authorized purposes such as insurance claims and physician review.

History Note: *Authority G.S. 90-21.20B; 131E-79; 131E-97;*
Eff. January 1, 1996;
Amended Eff. July 1, 2009.

10A NCAC 13B .3904 PATIENT ACCESS
The manager of medical records shall provide patients or patient designees, when requested, access to or a copy of their medical records, or both. Upon the death of a patient, the executor of the decedent's estate, or in the absence of an executor, the next of kin responsible for the disposition of the remains, shall have access to all medical records of the deceased patient. The patient or the patient's next of kin may be charged for the cost of reproducing copies.

History Note: *Authority G.S. 131E-79;*
Eff. January 1, 1996;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. July 22, 2017.

10A NCAC 13B .3905 PATIENT MEDICAL RECORDS
(a) Hospital management shall maintain medical records for each patient treated or examined in the facility.
(b) The medical record or medical record system shall provide data for each episode of care and treatment rendered by the facility.
(c) Where the medical record does not combine all episodes of inpatient, outpatient and emergency care, the medical records system shall:
(1) assemble, upon request of the physician, any or all divergently located components of the medical record when a patient is admitted to the facility or appears for outpatient or clinic services; or
(2) require placing copies of pertinent portions of each inpatient's medical record, such as the discharge resume, the operative note and the pathology report, in the outpatient or combined outpatient emergency unit record file as directed by the medical staff.
(d) The manager of medical records shall ensure that:
(1) each patient's medical record is complete, readily accessible and available to the professional staff concerned with the care and treatment of the patient;
(2) all clinical information pertaining to a patient is incorporated in his medical record;
(3) all entries in the record are dated and authenticated by the person making the entry;
(4) symbols and abbreviations are used only when they have been approved by the medical staff and when there exists a legend to explain them;
(5) verbal orders include the date and signature of the person recording them. They shall be given and authenticated in accordance with the provisions of Rule .3707(c) of this Subchapter; and
(6) records of patients discharged are completed within 30 days following discharge or disciplinary action is initiated as defined in the medical staff bylaws.

History Note: *Authority G.S. 131E-75; 131E-79; 143B-165;*
Eff. January 1, 1996;

Amended Eff, April 1, 2005;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. July 22, 2017.

10A NCAC 13B .3906 CONTENTS

(a) The medical record shall contain sufficient information to justify the diagnosis, verify the treatment and document the course of treatment and results accurately.

(b) All in-patient records shall include the following information:

(1) identification data (name, address, age, sex) and, when the identification data is not obtainable, the reason for such;
(2) date and time of admission and discharge;
(3) medical history:
  (A) chief complaint;
  (B) details of the present illness;
  (C) relevant past, social, and family histories; and
  (D) reports of relevant physical examinations;
(4) diagnostic and therapeutic orders;
(5) reports of procedures, tests and their results;
(6) provisional or admitting diagnosis;
(7) evidence of appropriate informed consent or a written statement explaining why consent was not obtained;
(8) clinical observations, including results of therapy;
(9) record of medication and treatment administration;
(10) progress notes of all disciplines;
(11) conclusions at termination of hospitalization or evaluation and treatment;
(12) all relevant diagnosis established by the time of discharge;
(13) consultation reports;
(14) surgical record, including anesthesia record, pre-operative diagnosis, surgeon's operative report and post-operative orders and any instructions given to the patient or family; and
(15) autopsy findings, if performed.

History Note: *Authority G.S. 131E-79;*
Eff. January 1, 1996;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. July 22, 2017.

10A NCAC 13B .3907 MEDICAL RECORDS REVIEW

The medical staff shall review medical records periodically for completeness and shall:

(1) establish requirements regarding completion of medical records, including a system for disciplinary actions for those who do not complete records in a timely manner; and
(2) make recommendations to the medical records department regarding clinical information sufficient for medical care evaluation.

History Note: *Authority G.S. 131E-79;*
Eff. January 1, 1996;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. July 22, 2017.

SECTION .4000 - OUTPATIENT SERVICES

10A NCAC 13B .4001 ORGANIZATION

(a) The facility shall establish and maintain outpatient care services in accordance with the facility's written mission statement.

(b) The relationship of outpatient services to other divisions within the facility, including channels of responsibility and authority, shall be documented and made available for review by the facility.

(c) The facility shall vest the direction of outpatient services in one or more individuals whose qualifications, authority and duties are defined in writing.

(d) The facility shall establish and maintain procedures for the review and evaluation of outpatient services.

(e) Each medical staff member shall have privileges delineated in accordance with criteria established by the medical staff by-laws, rules, or regulations.

History Note: *Authority G.S. 131E-79;*
Eff. January 1, 1996;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. July 22, 2017.

10A NCAC 13B .4002 STAFFING

(a) The director of outpatient services shall require that ambulatory care services are staffed with sufficient personnel in accordance with a written plan.
(b) The responsibility for the delivery of outpatient services by the professional staff shall be defined and documented by the director of ambulatory care services.
(c) The facility shall provide education programs specifically related to outpatient care for the staff and document the extent of participation in education and training programs.

History Note: *Authority G.S. 131E-79;*
Eff. January 1, 1996;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. July 22, 2017.

10A NCAC 13B .4003 POLICIES AND PROCEDURES

(a) The provision of outpatient services shall be guided by written policies and procedures which shall be developed by the facility and approved by the medical staff. The policies and procedures shall be reviewed by the medical staff at least every three years.
(b) The policies shall include the following:
(1) patient access to outpatient services;
(2) the process of obtaining informed consent;
(3) the location, storage and procurement of medications, supplies and equipment; and
(4) the mechanism to be used to contact patients for necessary follow-up.

History Note: *Authority G.S. 131E-79;*
Eff. January 1, 1996;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. July 22, 2017.

10A NCAC 13B .4004 OUTPATIENT SURGICAL AND ANESTHESIA SERVICES

(a) When surgical or anesthesia services are provided in an outpatient setting, the facility shall require that the medical staff approve all types of surgical procedures to be offered. The facility shall maintain and make available a current listing of approved outpatient procedures.
(b) The facility shall define the scope of anesthesia services that may be provided, the locations where such anesthesia services may be administered and who shall provide anesthesia services.
(c) The facility shall require that standards for informed consent, history and physical examination, preoperative studies, administration of anesthesia, medical records and discharge criteria meet the same standards of care as apply for inpatient surgery unless otherwise specified by the medical staff.
(d) The facility shall provide for back-up service by other departments in the case of emergencies or complications.

History Note: *Authority G.S. 131E-79;*
Eff. January 1, 1996;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. July 22, 2017.

10A NCAC 13B .4005 MEDICAL RECORDS

(a) The manager of outpatient services shall require that a record of outpatient care and services for each patient is maintained either in the ambulatory care services or medical records department.
(b) The facility shall develop a system of identification and filing to prepare for safe storage and prompt retrieval of records upon subsequent inpatient or outpatient visits.
(c) The facility shall establish medical records procedures which include provisions for maintaining the confidentiality of patient information and for the release of information to authorized individuals.

History Note: *Authority G.S. 131E-79;*
Eff. January 1, 1996;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. July 22, 2017.

SECTION .4100 - EMERGENCY SERVICES

10A NCAC 13B .4101 EMERGENCY RESPONSE CAPABILITY REQUIRED

The medical staff of each facility shall require that facility personnel are capable of initiating life-saving measures at a first-aid level of response for any patient or person in need of such services. This shall include:

(1) initiating basic cardio-respiratory resuscitation according to American Red Cross or American Heart Association standards;
(2) availability of first-line emergency drugs as specified by the medical staff;
(3) availability of IV fluids and supplies required to establish IV access; and
(4) establishing protocols or agreements for the transfer of patients to a facility for a higher level of care when these services are not available on site.

History Note: *Authority G.S. 131E-79;*
Eff. January 1, 1996;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. July 22, 2017.

10A NCAC 13B .4102 CLASSIFICATION OF OPTIONAL EMERGENCY SERVICES

(a) Any facility providing emergency services shall classify its capability in providing such services according to the following criteria:

(1) Level I:
  (A) the facility shall have a comprehensive, 24-hour-per-day emergency service with at least one physician experienced in emergency care on duty in the emergency care area;
  (B) the facility shall have in-hospital physician coverage by members of the medical staff or by senior-level residents for at least medical, surgical, orthopedic, obstetric, gynecologic, pediatric and anesthesia services;
  (C) services of other medical and surgical specialists shall be available; and
  (D) the facility shall provide prompt access to labs, radiology, operating suites, critical care and obstetric units and other services as defined by the governing body.
(2) Level II:
  (A) the facility shall have 24-hour per day emergency service with at least one physician experienced in emergency care on duty in the emergency care area; and
  (B) the facility shall have consultation available within 30 minutes by members of the medical staff or by senior level residents to meet the needs of the patient. Consultation by phone is acceptable.
(3) Level III: The facility shall have emergency service available 24 hours per day with at least one physician available to the emergency care area within 30 minutes through a medical staff call roster.

(b) Facilities seeking trauma center designation shall comply with G.S. 131E-162.
(c) The location of the emergency access area shall be identified by clearly visible signs.

History Note: *Authority G.S. 131E-79;*
RRC objection due to lack of statutory authority Eff. July 13, 1995;
Eff. January 1, 1996;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. July 22, 2017.

10A NCAC 13B .4103 PROVISION OF EMERGENCY SERVICES

(a) Any of any facility providing emergency services shall establish and maintain policies requiring appropriate medical screening, treatment and transfer services for any individual who presents to the facility emergency department and on whose behalf treatment is requested regardless of that person's ability to pay for medical services and without delay to inquire about the individual's method of payment.

(b) Any facility providing emergency services under this Section shall install, operate and maintain, on a 24-hour per day basis, an emergency two-way radio licensed by the Federal Communications Commission in the Public Safety Radio Service capable of establishing voice radio communication with ambulance units transporting patients to said facility or having any written procedure or agreement for handling emergency services with the local ambulance service, rescue squad or other trained medical personnel.
(c) All communication equipment shall be in compliance with current rules established by North Carolina Rules for Basic Life Support/Ambulance Service (10 NCAC 3D .1100) adopted by reference with all subsequent amendments. Referenced rules are available at no charge from the Office of Emergency Medical Services, 2707 Mail Service Center, Raleigh, N.C. 27699-2707.

History Note: *Authority G.S. 131E-79;*
Eff. January 1, 1996.

10A NCAC 13B .4104 MEDICAL DIRECTOR
(a) The governing body shall establish the qualifications, duties, and authority of the director of emergency services. Appointments shall be recommended by the medical staff and approved by the governing body.
(b) The medical staff credentials committee shall approve the mechanism for emergency privileges for physicians employed for brief periods of time such as evenings, weekends or holidays.
(c) Level I and II emergency services shall be directed and supervised by a physician with experience in emergency care.
(d) Level III services shall be directed and supervised by a physician with experience in emergency care or through a multi-disciplinary medical staff committee. The chairman of this committee shall serve as director of emergency medical services.

History Note: *Authority G.S. 131E-79;*
RRC objection due to lack of statutory authority Eff. July 13, 1995;
Eff. January 1, 1996.

10A NCAC 13B .4105 NURSING
(a) Level I and Level II emergency services shall have one or more registered nurses assigned and on duty within the emergency service area at all times.
(b) A Level III emergency service shall have a registered nurse available on at least an on-call, in-house basis at all times.
(c) The facility shall document that all emergency services nursing personnel shall have orientation, training and continuing education in the reception and care of emergency patients.

History Note: *Authority G.S. 131E-79;*
Eff. January 1, 1996;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. July 22, 2017.

10A NCAC 13B .4106 POLICIES AND PROCEDURES
Each emergency department shall establish written policies and procedures which specify the scope and conduct of patient care to be provided in the emergency areas. They shall include the following:

(1) the location, storage, and procurement of medications, blood, supplies, equipment and the procedures to be followed in the event of equipment failure;
(2) the initial management of patients with burns, hand injuries, head injuries, fractures, multiple injuries, poisoning, animal bites, gunshot or stab wounds and other acute problems;
(3) the provision of care to an unemancipated minor not accompanied by a parent or guardian, or to an unaccompanied unconscious patient;
(4) management of alleged or suspected child, elder or adult abuse;
(5) the management of pediatric emergencies;
(6) the initial management of patients with actual or suspected exposure to radiation;
(7) management of alleged or suspected rape victims;
(8) the reporting of individuals dead on arrival to the proper authorities;
(9) the use of standing orders;
(10) tetanus and rabies prevention or prophylaxis; and

(11) the dispensing of medications in accordance with state and federal laws.

History Note: *Authority G.S. 131E-79;*
Eff. January 1, 1996.

10A NCAC 13B .4107 EMERGENCY RECORDS

(a) The facility shall require all levels of emergency departments to maintain a continuous control register on each patient seen for services which shall include at least the name, age, sex, date, time, and means of arrival, nature of complaint, disposition, and time of discharge.

(b) The facility shall maintain a record for each patient seeking emergency care. This shall include:

(1) patient identification, time and means of arrival;
(2) pertinent history and physical findings and patient vital signs;
(3) diagnostic and therapeutic orders;
(4) clinical observations including results of treatment;
(5) reports of procedures, tests and results;
(6) diagnostic impression; and
(7) discharge or transfer summary of treatment including final disposition, the patient's condition, and any instructions given to the patient and or family for follow-up care.

History Note: *Authority G.S. 131E-79;*
Eff. January 1, 1996;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. July 22, 2017.

10A NCAC 13B .4108 OBSERVATION BEDS

When observation beds are used, the facility shall implement written policies and procedures that address the type of patient use, the mechanism for providing appropriate clinical monitoring, the length of time services may be provided in this setting and documentation requirements.

History Note: *Authority G.S. 131E-79;*
Eff. January 1, 1996;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. July 22, 2017.

10A NCAC 13B .4109 TRANSFER

(a) The facility shall establish and implement protocols for stabilization and transportation of emergency patients.

(b) A facility with specialized capabilities, such as burn units, shock-trauma units and neonatal intensive care units, shall not refuse to accept an appropriate transfer for those services if the hospital has the capacity to treat the individual.

(c) The facility shall not transfer a patient until the receiving organization has consented to accept the patient and the patient is sufficiently stable for transport.

(d) If the patient or the person acting on the patient's behalf refuses transfer, the facility staff shall:

(1) explain to the individual or his representative the risks and benefits of transfer; and
(2) shall request the patient's or his representative's refusal of transfer in writing.

(e) The facility shall forward at the time of transfer a copy of all medical records related to the emergency condition for which the individual has presented.

History Note: *Authority G.S. 131E-79;*
Eff. January 1, 1996;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. July 22, 2017.

10A NCAC 13B .4110 DISASTER AND MASS CASUALTY PROGRAM

(a) The facility shall describe:

(1) the level of emergency services available during an external disaster;
(2) the emergency department's role in the facility's external disaster plan;
(3) procedures to be followed in the event of an internal disaster; and
(4) the facility's connection to other community services such as fire, police and the American Red Cross.

(b) The medical staff and governing body shall approve the plan, review it and revise it if needed, annually.

(c) The plan shall:

(1) provide for prompt medical attention for all emergency patients as their needs may dictate;
(2) include protocols for handling non-emergency cases;
(3) establish medical staff coverage procedures or methods;
(4) specify drugs, solutions and equipment to be continuously available;
(5) provide for the evacuation and transfer for all inpatients as their needs may indicate in the event of an internal disaster; and
(6) include mutual support agreements with area providers.

(d) Schedules, names and telephone numbers of all physicians and others on emergency duty shall be maintained by the facility.
(e) Names and telephone numbers of those to be contacted in the event of an internal disaster shall be maintained by the facility.

History Note: *Authority G.S. 131E-79;*
Eff. January 1, 1996;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. July 22, 2017.

SECTION .4200 - SPECIAL CARE UNITS

10A NCAC 13B .4201 ORGANIZATION

(a) The governing body shall approve the type and scope of special care units.
(b) The facility shall document the relationship of the special care units to the other departments within the hospital, including channels of responsibility and authority.
(c) The facility shall provide necessary equipment and supplies for delivery of nursing care specific to the unit population for each special care unit.
(d) The facility shall provide sufficient emergency drugs and equipment to meet anticipated needs as determined by the medical staff.
(e) The governing body shall delegate to the medical and nursing staff the responsibility to develop policies and procedures concerning the scope and provision of safe care in each unit.

History Note: *Authority G.S. 131E-79;*
Eff. January 1, 1996;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. July 22, 2017.

10A NCAC 13B .4202 MEDICAL STAFF

(a) The governing body shall provide that each special care unit or group of similar units be directed by qualified members of the medical staff whose clinical and administrative privileges have been approved by the governing board.
(b) The governing body shall designate the director to be responsible for making decisions in consultation with the physician responsible for the patient, for the disposition of a patient when patient load exceeds optimal operation capacity.
(c) The governing body shall require that the medical staff provide medical staff coverage sufficient to meet the specific needs of the patients on a 24-hour basis.

History Note: *Authority G.S. 131E-79;*
Eff. January 1, 1996;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. July 22, 2017.

10A NCAC 13B .4203 NURSING STAFF

The supervision of nursing care for each special care unit shall be provided by a qualified registered nurse and shall include the following:

(1) unit-specific orientation and competency evaluation for each staff member;
(2) a staffing plan based upon the needs of the patient population which is implemented to ensure a sufficient number of qualified Registered Nurses are on duty when patients are in the unit;
(3) assessment, planning, implementation and evaluation of nursing care which is documented according to policy; and

(4) delivery of nursing care in accordance with the North Carolina Nurse Practice Act.

History Note: *Authority G.S. 131E-79;*
RRC objection due to lack of statutory authority Eff. July 13, 1995;
Eff. January 1, 1996;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. July 22, 2017.

10A NCAC 13B .4204 POLICIES AND PROCEDURES

(a) The facility in conjunction with the medical and nursing staff shall develop written policies and procedures which guide the provision of care in a special care unit. These policies and procedures shall be approved by the medical staff and include:

(1) patient admission and discharge criteria;
(2) notification of appropriate medical staff for changes in the condition of the patient;
(3) use of standing orders and emergency protocols;
(4) designation of staff members authorized to perform special procedures and special circumstances requiring such authorization;
(5) patient care procedures, including medication administration;
(6) infection control;
(7) pertinent safety practices;
(8) use of equipment and procedures to be followed in the event of equipment failure;
(9) regulations governing visitors and traffic control; and
(10) role of special care unit in internal and external disaster plans.

(b) The governing body shall review, update and approve regularly, but at least every three years, its policies and procedures.

History Note: *Authority G.S. 131E-79;*
Eff. January 1, 1996;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. July 22, 2017.

SECTION .4300 - MATERNAL - NEONATAL SERVICES

10A NCAC 13B .4301 ORGANIZATION MATERNAL SERVICES

(a) The governing body shall approve the scope of obstetric services offered based upon the level of patient need, qualifications of the credentialed staff, and resources of the facility.

(b) The following capabilities and minimum services shall be made available when obstetric services are provided:

(1) identification of high-risk mothers and fetuses;
(2) continuous electronic fetal monitoring;
(3) cesarean delivery capability within 30 minutes of decision;
(4) blood or fresh frozen plasma for transfusion;
(5) anesthesia on a 24-hour or on-call basis;
(6) radiology and ultrasound examination;
(7) stabilization of unexpectedly small or sick neonates before transfer;
(8) neonatal resuscitation;
(9) laboratory services on a 24-hour or on-call basis;
(10) consultation and transfer agreements;
(11) assessment and care for the neonates; and
(12) nursery or other appropriate space for care of the neonates.

(c) In a facility without intensive care nursery services, the facility management shall establish and maintain a plan for the stabilization and transportation of sick newborns to a regional neonatal unit.

History Note: *Authority G.S. 131E-79;*
Eff. January 1, 1996;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. July 22, 2017.

10A NCAC 13B .4302 MEDICAL STAFF MATERNAL SERVICES

(a) The medical staff shall require that each birth be attended by a physician or certified nurse midwife who has documented evidence of current competence and appropriate privileges.
(b) At all times medical staff with obstetrical privileges shall be available within 30 minutes to provide services and attend deliveries. An on-call schedule shall be available to the Division for review.

History Note: *Authority G.S. 131E-79;*
Eff. January 1, 1996;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. July 22, 2017.

10A NCAC 13B .4303 NURSING SERVICES MATERNAL SERVICES
(a) The nurse executive or the decentralized nursing management staff shall designate a registered nurse who has education, training, and experience in obstetrical care as supervisor of obstetrical services.
(b) A registered nurse shall be responsible for providing the type and amount of nursing care needed by each patient. A staffing plan shall be available to the Division for review.

History Note: *Authority G.S. 131E-79;*
RRC objection due to lack of statutory authority Eff. July 13, 1995;
Eff. January 1, 1996;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. July 22, 2017.

10A NCAC 13B .4304 POLICIES AND PROCEDURES MATERNAL SERVICES
(a) The provision of patient care shall be guided by written policies and procedures developed by the medical and nursing staff and approved by the medical staff.
(b) Written policies shall relate to at least the following:
(1) a system for informing the physician or certified nurse midwife responsible for a patient of the following:
(A) the patient's admission;
(B) the onset of labor; and
(C) pertinent information about progress of labor or changes in patient's condition.
(2) emergency response protocols for patients who demonstrate evidence of maternal, fetal or neonatal distress;
(3) a program to prevent isoimmunization of RH-negative mothers;
(4) administration of oxytocic agents when used for induction or stimulation of labor;
(5) the use and administration of analgesics and anesthetics;
(6) administration of magnesium sulfate when and for the treatment preeclampsia;
(7) the location and storage of medications, supplies, and special equipment;
(8) the method of identification for the neonates;
(9) assessment and care of the neonates;
(10) provision of resuscitation, stabilization, and preparation for the transport of sick neonates at any hour; and
(11) an infection control plan.
(c) Accurate and complete medical records shall be provided for each obstetric patient.

History Note: *Authority G.S. 131E-79;*
Eff. January 1, 1996;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. July 22, 2017.

10A NCAC 13B .4305 ORGANIZATION OF NEONATAL SERVICES
(a) The governing body shall approve the scope of all neonatal services and the facility shall classify its capability in providing a range of neonatal services using the following criteria:
(1) LEVEL I: Full-term and pre-term neonates that are stable without complications. This may include, small for gestational age or large for gestational age neonates.
(2) LEVEL II: Neonates or infants that are stable without complications but require special care and frequent feedings; infants of any weight who no longer require Level III or LEVEL IV neonatal

services, but who still require more nursing hours than normal infant. This may include infants who require close observation in a licensed acute care bed

(3) LEVEL III: Neonates or infants that are high-risk, small (or approximately 32 and less than 36 completed weeks of gestational age) but otherwise healthy, or sick with a moderate degree of illness that are admitted from within the hospital or transferred from another facility requiring intermediate care services for sick infants, but not requiring intensive care. The beds in this level may serve as a "step-down" unit from Level IV. Level III neonates or infants require less constant nursing care, but care does not exclude respiratory support.

(4) LEVEL IV (Neonatal Intensive Care Services): High-risk, medically unstable or critically ill neonates approximately under 32 weeks of gestational age, or infants, requiring constant nursing care or supervision not limited to continuous cardiopulmonary or respiratory support, complicated surgical procedures, or other intensive supportive interventions.

(b) The facility shall provide for the availability of equipment, supplies, and clinical support services.

(c) The medical and nursing staff shall develop and approve policies and procedures for the provision of all neonatal services.

History Note: *Authority G.S. 131E-79;*
Eff. January 1, 1996;
Temporary Amendment Eff. March 15, 2002;
Amended Eff. April 1, 2003.

10A NCAC 13B .4306 MEDICAL STAFF OF NEONATAL SERVICES

The medical staff shall require that the director or other designated physician in charge of the neonatal special or intensive care unit has training and experience in care of the neonate.

History Note: *Authority G.S. 131E-79;*
Eff. January 1, 1996;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. July 22, 2017.

10A NCAC 13B .4307 NURSING STAFF OF NEONATAL SERVICES

(a) The nurse executive or the decentralized nursing management staff shall designate a registered nurse who has training and experience in the care of neonates as supervisor of neonatal services.

(b) A registered nurse shall be responsible for providing the type and amount of nursing care needed by each patient. A staffing plan shall be available to the Division for review.

(c) The nursing staff shall provide educational opportunities for parents of neonates on routine care and procedures needed by the neonate.

(d) The nursing staff shall provide opportunities for parental participation in care of the neonate to facilitate bonding and family adjustment to the neonate's needs.

History Note: *Authority G.S. 131E-79;*
RRC objection due to lack of statutory authority Eff. July 13, 1995;
Eff. January 1, 1996;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. July 22, 2017.

10A NCAC 13B .4308 POLICIES AND PROCEDURES OF NEONATAL SERVICES

(a) The provision of neonatal care at all levels shall be guided by written policies and procedures developed and approved by the medical and nursing staffs.

(b) The policies and procedures shall include but are not limited to:

(1) emergency resuscitation and stabilization of the neonate;
(2) equipment for routine and emergency care of the neonate;
(3) continuous oxygen supply and means of administration including ventilators;
(4) administration of medications;
(5) insertion and care of invasive lines;
(6) prevention of infectious diseases or processes; and
(7) family involvement in care of the neonate.

(c) The medical and nursing staff shall review, update and approve its policies and procedures every three years.

History Note: *Authority G.S. 131E-79;*
Eff. January 1, 1996;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. July 22, 2017.

SECTION .4400 - RESPIRATORY CARE SERVICES

10A NCAC 13B .4401 ORGANIZATION

(a) The governing body shall appoint a medical director of the respiratory care service who is an anesthesiologist, pulmonologist or other qualified physician.
(b) The facility shall appoint a qualified individual as the director of respiratory care services.
(c) When the facility is without a distinct respiratory care service, the facility shall:
(1) designate the department responsible for the delivery of respiratory care services;
(2) designate a person to supervise the delivery of respiratory care services; and
(3) establish and maintain policies and procedures for the delivery of respiratory care services offered.

History Note: *Authority G.S. 131E-79;*
RRC objection due to lack of statutory authority Eff. July 13, 1995;
Eff. January 1, 1996;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. July 22, 2017.

10A NCAC 13B .4402 STAFFING

(a) Staffing numbers shall be determined by the types and complexities of the services offered.
(b) The director of the service shall provide for the availability of trained respiratory technicians, Certified Respiratory Therapy Technicians, registry eligible or Registered Respiratory Therapist needed for the scope of services offered.

History Note: *Authority G.S. 131E-79;*
Eff. January 1, 1996;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. July 22, 2017.

10A NCAC 13B .4403 POLICIES AND PROCEDURES

The facility shall establish and maintain written policies and procedures for the services offered. These shall include but are not limited to:
(1) scope of services and treatment offered;
(2) medication administration;
(3) cleaning, assembly and storage of equipment;
(4) safety;
(5) infection control;
(6) documentation of delivered care or treatments; and
(7) care and supervision of all ventilated patients.

History Note: *Authority G.S. 131E-79;*
Eff. January 1, 1996;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. July 22, 2017.

SECTION .4500 - PHARMACY SERVICES AND MEDICATION ADMINISTRATION

10A NCAC 13B .4501 PROVISION OF SERVICE

The facility shall provide for pharmaceutical services which are administered in accordance with the pharmacy laws of North Carolina including but not limited to G.S. 90 and G.S. 106.

History Note: *Authority G.S. 131E-79;*
Eff. January 1, 1996;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. July 22, 2017.

10A NCAC 13B .4502 PHARMACIST

(a) The pharmacy service shall be directed by a pharmacist licensed by the State of North Carolina. If a facility has a limited service as defined by the N.C. Board of Pharmacy, a part-time director of pharmacy shall have responsibility for control and dispensing of drugs.

(b) The director of pharmacy shall be responsible to the chief executive officer or his designee for developing, supervising, and coordinating all the activities of pharmacy services throughout the facility.

(c) The director of pharmacy shall require that the pharmacists are trained in the specialized functions of facility pharmacy.

(d) The dispensing of drugs in the absence of a pharmacist shall be done by facility staff under the direct supervision of staff approved by the pharmacy committee and who are responsible for following policies established by the pharmacy committee.

History Note: *Authority G.S. 131E-79;*
RRC objection due to lack of statutory authority Eff. July 13, 1995;
Eff. January 1, 1996;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. July 22, 2017.

10A NCAC 13B .4503 STAFF

The director of pharmacy shall be assisted by additional pharmacists and such other personnel as the activities of the pharmacy may require to meet the pharmaceutical needs of the patients served.

History Note: *Authority G.S. 131E-79;*
Eff. January 1, 1996;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. July 22, 2017.

10A NCAC 13B .4504 PHARMACY COMMITTEE

(a) A pharmacy committee or its equivalent, to include physicians, registered nurses, pharmacists and the administrator or designee shall be established.

(b) The committee shall meet at least quarterly, record its proceedings and report to the medical staff. It shall assist in the formulation of broad professional policies regarding the evaluation, appraisal, selection, procurement, storage, distribution, use and safety procedures, and all other matters relating to drugs in the facility. This shall include a mechanism to review and evaluate adverse drug reactions and drug usage evaluations, offering appropriate recommendations, actions, and follow-up if necessary. The committee shall:

(1) serve as an advisory group to the medical staff and the pharmacy director on matters pertaining to drug selection;
(2) develop an ongoing mechanism to review a formulary or drug list for use in the hospital;
(3) recommend and develop policies regarding the use and control of investigational drugs and research in the use of U.S. Food and Drug Administration approved drugs;
(4) evaluate clinical data concerning new drugs or preparations requested for use in the facility;
(5) make recommendations concerning drugs to be stocked on the nursing units and by other services;
(6) establish mechanisms which will prevent formulary duplication;
(7) establish policies and procedures that address therapeutic drug substitution;
(8) establish a policy describing the duration of drug therapy or number of doses for all medication orders; and
(9) make recommendations regarding medication administration policies and procedures.

History Note: *Authority G.S. 131E-79;*
Eff. January 1, 1996;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. July 22, 2017.

10A NCAC 13B .4505 PHARMACY FACILITIES

(a) The facility shall provide sufficient space for the pharmaceutical service to carry out its professional and administrative functions.

(b) Equipment shall be provided for the storage, preparation, dispensing, distributing and safeguarding of drugs throughout the hospital.

History Note: *Authority G.S. 131E-79;*
Eff. January 1, 1996;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. July 22, 2017.

10A NCAC 13B .4506 SUPPLIES

The director of pharmacy shall maintain an inventory of drugs and pharmaceutical devices to meet the needs of the patients as described in the facility's formulary.

History Note: *Authority G.S. 131E-79;*
Eff. January 1, 1996;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. July 22, 2017.

10A NCAC 13B .4507 STORAGE

(a) All drugs and related pharmaceutical supplies located throughout the facility shall be under the control of the pharmacy service.
(b) All areas where drugs and related pharmaceutical supplies are stored shall be monitored at least monthly by the pharmacy service.
(c) The director of pharmacy shall require that corresponding records are maintained of drug inventory variances and the corrective action taken.

History Note: *Authority G.S. 131E-79;*
Eff. January 1, 1996;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. July 22, 2017.

10A NCAC 13B .4508 RESERVED FOR FUTURE CODIFICATION

10A NCAC 13B .4509 SECURITY

(a) The director of pharmacy shall require that all drugs and related pharmaceutical supplies be stored in a lockable environment except when under the direct supervision of personnel authorized by the pharmacy committee to handle drugs.
(b) Controlled substances and other drugs the facility deems subject to abuse shall be stored as outlined in the U.S. Controlled Substance Act, 21 CFR 1301.41 and the N.C. Controlled Substances Act, G.S. 90, Article 5. These rules are available from the N.C. Drug Control Unit of the N.C. Division of Mental health, Development Disabilities & Substance Abuse Services, 3008 Mail Service Center, Raleigh, NC 27699-3008 (919-733-1765) without charge to current registrants.
(c) All keys and other locking devices to the pharmacy and controlled substances throughout the facility shall be under the control of the director of pharmacy and the facility management.

History Note: *Authority G.S. 131E-79;*
Eff. January 1, 1996;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. July 22, 2017;
Amended Eff. October 1, 2019.

10A NCAC 13B .4510 RECORDS

(a) The director of pharmacy shall provide that all drug transactions of the pharmacy shall be recorded as described in policies approved by the pharmacy committee.
(b) The director of pharmacy shall establish and maintain a system of records and bookkeeping in accordance with the policies of the facility in order to maintain adequate control over the requisitioning and dispensing of all drugs and pharmaceutical supplies and over patient billing for all drugs and pharmaceutical supplies.
(c) The director of pharmacy shall maintain records for all drugs purchased, ordered, dispensed, distributed, returned and disposed of in accordance with the pharmacy laws of North Carolina from the pharmacy.
(d) Verbal orders for drugs shall be subject to medical staff policies.

History Note: *Authority G.S. 131E-79;*
Eff. January 1, 1996;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. July 22, 2017.

10A NCAC 13B .4511 MEDICATION ADMINISTRATION

(a) A facility shall establish and maintain policies and procedures governing the administration of medications which shall be enforced and implemented by administration and staff. Policies and procedures shall include:

(1) accountability of controlled substances as defined by the G.S. 90, Article 5; and

(2) storage, distribution, administration and monitoring the effects of medications.

(b) All medications and treatments shall be administered and discontinued in accordance with signed medical staff orders which are recorded in the patient's medical record.

(c) The categories of staff that are privileged to administer medications shall be delineated by the operational policies of the facility. These policies shall be in agreement with current rules of North Carolina Occupational Boards for each category of staff.

(d) Medications shall be scheduled and administered according to the established policies of the facility.

(e) Variances to the medication administration policy shall be reviewed and evaluated by the nurse executive or her designee.

(f) The person administering medications shall identify each patient in accordance with the facility's policies and procedures prior to administering any medication.

(g) Medication administered to a patient shall be recorded in the patient's medication administration record immediately after administration in accordance with the facility's policies and procedures.

(h) Omission of medication and the reason for the omission shall be indicated in the patient's medical record.

(i) The person administering medications which are ordered to be given as needed (PRN) shall justify the need for the same in the patient's medical record.

(j) Medication administration records shall provide identification of the drug and strength of drug, quantity of drug administered, route administered, name and title of person administering the medication, and time and date of administration.

(k) Self-administration of medications shall be permitted only if prescribed by the medical staff. Directions must be printed on the container.

(l) The administration of one patient's medications to another patient is prohibited except in the case of an emergency. In the event of such as emergency, steps shall be taken by a pharmacist to ensure that the borrowed medications shall be replaced and so documented.

(m) Verbal orders shall be signed in accordance with Rule .3707(c) of this Subchapter.

History Note: *Authority G.S. 131E-79;*
Eff. January 1, 1996;
Amended Eff. November 1, 2005; May 1, 2005;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. July 22, 2017.

10A NCAC 13B .4512 MEDICATIONS DISPENSED

(a) Except as provided in Paragraph (c) of this Rule, the pharmacy shall dispense only those drugs which are listed in one or more of the references listed in Paragraph (b) of this Rule. No drug which is listed in Paragraph (b) of this Rule shall be used for any purpose which is not approved by the U.S. Food and Drug Administration unless the use has been approved by the facility's pharmacy committee.

(b) References:

(1) United States Pharmacopoeia;

(2) National Drug Formulary;

(3) Evaluations of Drug Interactions by the American Pharmaceutical Association;

(4) American Hospital Formulary Service; and

(5) Other references approved by the Pharmacy Committee.

(c) Any drug approved for use as an investigational drug or otherwise by the U.S. Food and Drug Administration but not listed in Paragraph (b) of this Rule may be used in accordance with standards established by the facility's pharmacy committee, or its equivalent and approved by the U.S. Food and Drug Administration, Dockets Management Branch, Room 1061, 5630 Fishers Lane, Rockfield, Maryland 20852, at a cost dependent on the material requested.

History Note: *Authority G.S. 131E-79;*
Eff. January 1, 1996;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. July 22, 2017;
Amended Eff. October 1, 2019.

10A NCAC 13B .4513 DRUG DISTRIBUTION SYSTEMS

(a) The pharmacy committee shall develop written policies and procedures pertaining to the intra-facility drug distribution system. In developing such policies the committee shall utilize representatives of other disciplines within the facility, including nursing services.

(b) The label of each patient's individual medication container shall bear all information required by the Pharmacy Laws of North Carolina.

(c) The pharmacist, with the advice and guidance of the pharmacy committee or its equivalent, shall be responsible for specifications as to quality, quantity and source of supplies of all drugs.

(d) There shall be a formulary or list of drugs accepted for use in the facility which shall be developed and amended as necessary by the pharmacy committee.

History Note: *Authority G.S. 131E-79;*
Eff. January 1, 1996;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. July 22, 2017.

10A NCAC 13B .4514 EMERGENCY PHARMACEUTICAL SERVICES

The director of pharmacy shall be responsible for emergency pharmaceutical services as currently described in the Pharmacy Laws of North Carolina.

History Note: *Authority G.S. 131E-79;*
Eff. January 1, 1996;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. July 22, 2017.

10A NCAC 13B .4515 DISPOSITION

Drugs, and pharmaceutical devices which are outdated, visibly deteriorated, unlabeled, inadequately labeled, recalled, discontinued or obsolete shall be identified by a pharmacist and shall be disposed of in compliance with applicable state and federal laws and regulations.

History Note: *Authority G.S. 131E-79;*
Eff. January 1, 1996;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. July 22, 2017.

10A NCAC 13B .4516 COMMERCIAL PHARMACEUTICAL SERVICE

A facility using an outside pharmacist or pharmaceutical service must have a contract with that pharmacist or service. As part of the contract, the pharmacist or service shall be required to maintain at least the standards for operation of the pharmaceutical services outlined in this Subchapter.

History Note: *Authority G.S. 131E-79;*
Eff. January 1, 1996;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. July 22, 2017.

SECTION .4600 - SURGICAL AND ANESTHESIA SERVICES

10A NCAC 13B .4601 ORGANIZATION

(a) The governing body shall approve the types of surgery and types of anesthesia services to be available throughout the hospital consistent with identified needs and resources.

(b) The facility shall require that surgical or anesthesia procedures are performed only when the necessary equipment and personnel are available.

(c) A facility that provides surgical or obstetric services shall provide anesthesia services on a 24-hour basis.

(d) The requirements and standards identified in this Section apply when any patient, in any setting, receives for any purpose, by any route:

(1) general, spinal or other major regional anesthesia; or
(2) sedation or analgesia that may result in the loss of protective reflexes; or
(3) surgery or other invasive procedure while receiving such anesthesia.

History Note: *Authority G.S. 131E-79;*
Eff. January 1, 1996;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. July 22, 2017.

10A NCAC 13B .4602 DIRECTOR OF SURGICAL SERVICES

(a) Each department or service providing surgical services shall be directed by members of the medical staff whose clinical and administrative privileges have been approved by the governing body.
(b) The medical staff shall establish and maintain a system for monitoring and evaluating the quality and appropriateness of the care and treatment of surgical patients, and for monitoring the clinical performance of all individuals with clinical privileges.
(c) In facilities where there is no anesthesiologist on staff the facility shall:

(1) with review of the medical staff, establish a consultation agreement with a board-certified or board-eligible anesthesiologist for the purpose of establishing policies and procedures that relate to the safe administration of anesthesia in all departments or services of the facility;
(2) assume the responsibility for establishing general policies for anesthesia services; and
(3) establish a line of communication and supervision for staff.

History Note: *Authority G.S. 131E-79;*
Eff. January 1, 1996;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. July 22, 2017.

10A NCAC 13B .4603 SURGICAL AND ANESTHESIA STAFF

(a) The facility shall develop processes which require that each individual provides only those services for which proof of licensure and competency can be demonstrated.
(b) The facility shall require that:

(1) when anesthesia is administered, a qualified physician is immediately available in the facility to provide care in the event of a medical emergency;
(2) a roster of practitioners with a delineation of current surgical and anesthesia privileges is available and maintained for the service;
(3) an on-call schedule of surgeons with privileges to be available at all times for emergency surgery and for post-operative clinical management is maintained;
(4) the operating room is supervised by a qualified registered nurse or doctor of medicine or osteopathy; and
(5) an operating room register which shall include date of the operation, name and patient identification number, names of surgeons and surgical assistants, name of anesthetists, type of anesthesia given, pre- and post-operative diagnosis, type and duration of surgical procedure, and the presence or absence of complications in surgery is maintained.

History Note: *Authority G.S. 131E-79;*
Eff. January 1, 1996.

10A NCAC 13B .4604 DIRECTION OF ANESTHESIA SERVICES

(a) The facility shall be organized, directed and integrated with other related services or departments of the facility.
(b) The department of anesthesia shall require that all anesthetics are administered according to procedures established in medical staff rules. In facilities where there is no department of anesthesia, the medical staff shall assume the responsibility for establishing general policies and for supervising the administration of anesthetics.
(c) The facility shall provide that anesthesia services be directed by a member, or members, of the medical staff whose responsibilities shall be approved by the governing body and shall include:

(1) establishment of criteria and procedures for the evaluation of the quality of all anesthesia care rendered;
(2) review of clinical privileges for all licensed practitioners whose primary clinical activity is the provision of anesthesia services; and
(3) establishment of written policies and procedures for anesthesia services.

History Note: *Authority G.S. 131E-79;*
Eff. January 1, 1996;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. July 22, 2017.

10A NCAC 13B .4605 POLICIES AND PROCEDURES

(a) The director of surgical services shall develop policies and procedures for surgical and anesthesia services which shall be available to the medical, surgical, anesthesia staff and nursing personnel.
(b) The facility shall require that policies on anesthesia procedures include the delineation of pre-anesthesia and post-anesthesia responsibilities.
(c) The facility shall require that the policies listed in this Paragraph are followed and that each surgical patient's record contain the following documentation:
(1) a complete history and physical documented in the record of every patient prior to surgery, including clinical indications for the surgical procedure;
(2) written evidence of informed consent, in the patient's record before surgery. If prior written consent was not obtained, the record shall contain a written explanation of why prior consent was not obtained;
(3) an evaluation of the patient and anesthesia planned, documented according to medical staff bylaws by an individual qualified to administer anesthesia services. Re-evaluation of the patient immediately prior to the induction of anesthesia shall be performed prior to surgery;
(4) an operative report describing techniques, findings, tissue removed or altered, and pre and post-surgical diagnosis. This report must be written or dictated following surgery and signed by the surgeon in compliance with medical staff rules;
(5) an intraoperative anesthesia record including the dosage of all drugs and agents used, the duration of anesthesia, and the type and amount of all fluids or blood and blood products administered shall be documented;
(6) evaluation and documentation of the postoperative status of the patient on admission to and discharge from the post-anesthesia recovery area.
(d) The director of anesthesia services shall establish criteria for discharge and facility management shall require that a physician or CRNA with appropriate clinical privileges be responsible for the decision to discharge a patient from a post-anesthesia recovery area.
(e) The facility shall establish regulations governing visitors and traffic control.

History Note: *Authority G.S. 131E-79;*
Eff. January 1, 1996;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. July 22, 2017.

SECTION .4700 - NUTRITION AND DIETETIC SERVICES

10A NCAC 13B .4701 PROVISION OF SERVICES

The nutrition and dietetic services shall be organized, directed, staffed and integrated with other facility departments to provide optimal nutritional therapy and quality food service to patients. Nutrition therapy shall apply the principles of the science of nutrition and be administered in accordance with the law and rules including but not limited to G.S. 90, Article 25.

History Note: *Authority G.S. 131E-79;*
Eff. January 1, 1996;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. July 22, 2017.

10A NCAC 13B .4702 ORGANIZATION

(a) The nutrition and dietetic services shall be under the full-time direction of a person who is trained or experienced in food services administration and therapeutic diets. The director shall be one of the following:

(1) A qualified dietitian;
(2) Bachelor's degree in Foods and Nutrition or Food Service Management;
(3) Dietetic Technician Registered (DTR); or
(4) Certified Dietary Manager (CDM); or
(5) An individual who is enrolled in a program to complete the minimum qualifications in Paragraph (a)(1)(2)(A)(B)(C) of this Rule.

(b) The nutrition and dietetic services of the facility shall have at least one dietitian either full-time, part-time, or as consultant. The qualifications of the dietitian shall be included in the personnel files. If the director of nutrition and dietetic services is not a registered dietitian, there shall be an established method of communication between the director and the dietitian which ensures that the dietitian supervises the nutritional aspects of patient care and ensures that quality nutritional care is provided to patients. Dietitians or qualified designees shall attend and participate in meetings relevant to patient nutritional care, including but not limited to patient care conferences and discharge planning.

(c) When a dietitian serves only in a consultant capacity, the facility management shall establish and maintain a written contract with the individual defining the responsibilities of the dietician including requirements for submission of written reports to the hospital administrator and the director of the nutrition and dietetic services describing the extent and quality of the services provided. Frequency of visits of the consultant dietitian shall be defined in the contract. The consultant dietitian shall provide, on site, no less than eight hours of service every two weeks to provide the nutritional aspects of patient care including but not limited to the following:

(1) approval of regular and modified menus, including standardized recipes;
(2) performance of nutritional assessments;
(3) development of nutrition care plans;
(4) provision of nutrition therapy;
(5) participation in development of policies and procedures; and
(6) monitoring and evaluation of the effectiveness and appropriateness of nutrition and dietetic services.

(d) The facility shall establish and maintain written policies and procedures to govern all nutrition and dietetic service activities. These policies shall be developed by the nutrition and dietetic services in cooperation with personnel from other departments or services which are involved with nutrition and dietetic services and they shall be reviewed at least every three years, revised as necessary, and dated to indicate the time of last review. Administrative policies and procedures concerning food procurement, preparation, and service shall be written by the director of the nutrition and dietetic services. Nutritional care policies and procedures shall be written by the qualified dietitian. The nutrition and dietetic service policies and procedures shall include, but not be limited to the following:

(1) provision of food and nutrition therapy prescriptions/orders;
(2) development, approval and provision of regular and modified menus, including standardized recipes;
(3) food purchasing, storage, inventory, preparation and service;
(4) identification system designed to ensure that each patient receives appropriate diet as ordered;
(5) ancillary dietetic services, as appropriate, including food storage and kitchens on patient care units, formula supply, cafeterias, vending operations and ice making;
(6) preparation, storage, distribution, and administration of enteral nutrition programs;
(7) assessment and monitoring of patients receiving enteral and total parenteral nutrition;
(8) personal hygiene and health of dietetic personnel;
(9) infection control measures to minimize the possibility of contamination and transfer of infection, including establishment of monitoring procedure to ensure that personnel are free from communicable infections and open skin lesions; and
(10) pertinent safety practices, including control of electrical, flammable, mechanical, and radiation hazards.

(e) Nutrition and dietetic services shall be provided by qualified personnel under supervision to meet needs of patients. The director of the nutrition and dietetic services shall require that personnel assigned to the department perform all functions necessary to meet the nutritional needs of patients. The director or qualified designee shall attend and participate in meetings, including that of department heads, and function as an integral member of the facility.

(f) A facility which has a contract with an outside food management service, shall require as a part of the contract that the company complies with all applicable requirements and standards outlined in Section .4700 of this Subchapter for such service. The contract shall be available for review by the Division.

History Note: *Authority G.S. 131E-79;*
RRC objection due to lack of statutory authority Eff. July 13, 1995;
Eff. January 1, 1996;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. July 22, 2017.

10A NCAC 13B .4703 SANITATION AND SAFETY

(a) The nutrition and dietetic service shall comply with current laws and rules for sanitation as promulgated by the Commission for Public Health, including but not limited to 15A NCAC 18A .1300. Copies of 15A NCAC 18A .1300 may be obtained at no charge from the Environmental Health Section, Division of Public Health, N.C. Department of Health and Human Services, 1632 Mail Service Center, Raleigh, NC 27699-1632. The facilities and equipment of the nutrition and dietetic services shall also comply with applicable and safety laws and rules.

(b) Sufficient space and equipment shall be provided for the nutrition and dietetic services to accomplish the following:

(1) store food and nonfood supplies under sanitary and secure conditions;
(2) store food separately from nonfood supplies. When storage facilities are limited, paper products may be stored with food supplies;
(3) prepare and distribute food, including therapeutic diets;
(4) clean and sanitize utensils and dishes apart from food preparation areas; and
(5) allow personnel to perform their duties.

(c) Cleaning schedules and instructions for cleaning all equipment and work and storage areas shall be posted and followed in the nutrition and dietetic services area and accessible to all nutrition and dietetics staff. Procedures for cleaning all equipment and work areas shall be followed consistently and documented to safeguard the health of the patient.

History Note: *Authority G.S. 131E-79;*
Eff. January 1, 1996;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. July 22, 2017;
Amended Eff. October 1, 2019.

10A NCAC 13B .4704 DISTRIBUTION OF FOOD

(a) Food shall be transported and displayed pursuant to the rules adopted by the Commission for Public Health.

(b) At the time of serving, the temperature of hot foods shall be no less than:

(1) Hot liquids - 150 degrees Fahrenheit (minimum);
(2) Hot Cereal - 150 degrees Fahrenheit (minimum);
(3) Hot Soups - 130 degrees Fahrenheit (minimum); and
(4) Other hot foods - 110 degrees Fahrenheit (minimum).

(c) At the time of serving, the temperature of cold foods shall be no more than:

(1) Cold liquids - 50 degrees Fahrenheit (maximum); and
(2) Other cold foods - 65 degrees Fahrenheit (maximum).

History Note: *Authority G.S. 131E-79;*
Eff. January 1, 1996;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. July 22, 2017.

10A NCAC 13B .4705 NUTRITIONAL SUPPORT

(a) The administration of the nutritional support shall be directed by a qualified dietitian. Observations and information pertinent to nutrition therapy shall be documented in the medical record of the patient.

(b) The facility shall have a current nutrition care manual accessible to hospital personnel. The nutrition care manual shall be reviewed every three years, revised as necessary by a qualified dietitian, and approved jointly by the nutrition service and medical staff.

(c) Therapeutic diets and enteral and parenteral nutrition therapy shall be prescribed in written orders on the medical records and provided as ordered.

(d) The nutrition care manual shall reflect the standards for nutrition care in accordance with those referenced in the most current edition of "Recommended Dietary Allowance" of the Food and Nutrition Board of the National Research Council of the National Academy of Sciences which are hereby incorporated by reference. These standards include any subsequent amendments and editions of the referenced material and are available from the National Academy Press, 2101

Constitution Avenue, N.W., Lockbox 285, Washington, D.C. 20055 at a cost of six dollars ($6.00) per copy. The nutrition deficiencies of any modified diet that is not in compliance with the recommended dietary allowances shall be specified in the nutrition care manual.
(e) The qualified dietitian shall be responsible for the development of a nutritional care plan in compliance with medical staff's orders to meet the nutritional needs of the patient. The nutrition care plan shall be included in the medical record of the patient on his discharge plan and transfer orders to the extent necessary for continuity of care. Facilities with long term care units shall have at least a three week menu cycle in the long term care units.

History Note: *Authority G.S. 131E-79;*
RRC objection due to lack of statutory authority Eff. July 13, 1995;
Eff. January 1, 1996;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. July 22, 2017.

SECTION .4800 - DIAGNOSTIC IMAGING

10A NCAC 13B .4801 ORGANIZATION

(a) Imaging services shall be under the supervision of a full-time radiologist, consulting radiologist, or a physician experienced in the particular imaging modality and the physician in charge must have the credentials required by facility policies.
(b) Activities of the imaging service may include radio-therapy.
(c) All imaging equipment shall be operated under professional supervision by qualified personnel trained in the use of imaging equipment and knowledgeable of all applicable safety precautions required by the North Carolina Department of Environment and Natural Resources, Division of Environmental Health Radiation Protection Section. Copies of regulations are available from the N.C. Department of Environment and Natural Resources, Radiation Protection Section, 3825 Barrett Drive, Raleigh, NC 27609 at a cost of sixteen dollars ($16.00) each.

History Note: *Authority G.S. 131E-79;*
RRC objection due to lack of statutory authority and ambiguity Eff. July 13, 1995;
Eff. January 1, 1996.

10A NCAC 13B .4802 RECORDS

(a) A documented record on each imaging examination shall be included in the patient's medical record.
(b) Imaging reports shall be signed by the physician interpreting the study.
(c) Copies of current reports made by private physicists or governing authority surveying the radiographic facilities shall be available to the Division.

History Note: *Authority G.S. 131E-79;*
Eff. January 1, 1996;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. July 22, 2017.

10A NCAC 13B .4803 STAFFING

(a) The staffing of the imaging department shall be determined by the radiologist in charge or by another person designated by hospital management.
(b) There shall be a minimum of one radiologic technologist available to the department on at least an on-call basis.

History Note: *Authority G.S. 131E-79;*
Eff. January 1, 1996;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. July 22, 2017.

10A NCAC 13B .4804 MONITORING RADIATION EXPOSURE OF PERSONNEL

(a) The facility shall establish procedures for the monitoring of personnel and shall maintain a record for each individual working in the area of radiation where there is a reasonable probability of receiving one-fourth of the maximum permissible dose.

(b) Records documenting the monitoring of personnel receiving radiation exposure through the use of film badges or dosimeters must also be maintained by the facility. Readings from badges or dosimeters shall be recorded on at least a monthly basis.
(c) Upon termination of employment, each employee shall be provided with a summary of his exposure record.
(d) Permanent records of radiological exposure on all monitored personnel shall be maintained for review by the Division.

History Note: *Authority G.S. 131E-79;*
Eff. January 1, 1996;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. July 22, 2017.

10A NCAC 13B .4805 SAFETY
(a) The facility shall require that all imaging equipment is operated under the supervision of a physician and by qualified personnel.
(b) The facility shall require that proper caution is exercised to protect all persons from exposure to radiation.
(c) Safety inspections of the imaging department, including equipment, shall be conducted by the North Carolina Division of Environmental Health, Radiation Protection Services Section. Copies of the report shall be available for review by the Division.
(d) The governing authority shall appoint a radiation safety committee. The committee shall include but is not limited to:
(1) a physician experienced in the handling of radio-active isotopes and their therapeutic use; and
(2) other representatives of the medical staff.
(e) All radio-active isotopes, whether for diagnostic, therapeutic, or research purposes shall be received, handled, and disposed of in accordance with the requirements of the North Carolina Department of Environment and Natural Resources, Division of Environmental Health, Radiation Protection Services Section. Copies of regulations are available from the North Carolina Department of Environment, Health, and Natural Resources, Division of Radiation Protection, 3825 Barrett Drive, Raleigh, NC 27609 at a cost of six dollars ($6.00) each.

History Note: *Authority G.S. 131E-79;*
Eff. January 1, 1996.

10A NCAC 13B .4806 NUCLEAR MEDICINE SERVICES
When nuclear medicine services are offered, the facility shall establish and maintain written policies and procedures for the provision of those services which shall provide for the safety of patients and staff, management of radioactive isotopes and the maintenance of equipment according to the manufacturers' recommendations.

History Note: *Authority G.S. 131E-79;*
Eff. January 1, 1996;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. July 22, 2017.

SECTION .4900 - LABORATORY SERVICES AND PATHOLOGY

10A NCAC 13B .4901 ORGANIZATION
The laboratory shall be under the supervision of a clinical pathologist, or a physician who has training in clinical laboratory diagnosis designated by the governing body.

History Note: *Authority G.S. 131E-79;*
Eff. January 1, 1996;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. July 22, 2017.

10A NCAC 13B .4902 RECORDS
(a) All requests for laboratory services shall be documented.
(b) All reports of laboratory services performed, including autopsy, shall be placed in the patient's medical record.
(c) Records of proficiency testing appropriate to the scope of services offered shall be available to the Division for review.

(d) Records of equipment calibration and quality controls as recommended by the manufacturer shall be maintained and be available to the Division for review.

History Note: *Authority G.S. 131E-79;*
Eff. January 1, 1996;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. July 22, 2017.

10A NCAC 13B .4903 STAFFING

The laboratory supervisor or his appointed designee, shall require that:

(1) procedures and tests conducted are within the scope of the laboratory as approved by the hospital;
(2) at least one qualified medical technologist is available at all times; and
(3) qualified staff are available to carry out the functions of the laboratory.

History Note: *Authority G.S. 131E-79;*
Eff. January 1, 1996;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. July 22, 2017.

10A NCAC 13B .4904 TESTS

(a) Laboratory tests to be performed on a patient at the time of admission (if any) shall be established by the medical staff and be approved by the governing board of the hospital. In the event the medical staff and governing body elect not to establish routine laboratory tests for new admissions, the request for such tests shall be left to the discretion of the attending medical staff members.
(b) Serological tests for patients admitted shall be optional with the hospital. However, there shall be records indicating that obstetrical patients have had a serological test during their current pregnancy.
(c) When laboratories outside of the facility are used, such laboratories shall be approved by the governing body and medical staff of the facility. In case of such usage, a legible copy of the laboratory report must be included in the patient record.

History Note: *Authority G.S. 131E-79;*
Eff. January 1, 1996;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. July 22, 2017.

10A NCAC 13B .4905 TISSUE REMOVAL AND DISPOSAL

(a) The medical staff shall establish and maintain written policies for pathological examination of tissue and specimens removed during surgery.
(b) Pathological waste disposal shall comply with the rules Governing the Sanitation of Hospitals, Nursing and Rest Homes, Sanitariums, Sanatoriums, and Educational and Other Institutions, contained in 15A NCAC 18A .1300. Copies of 15A NCAC 18A .1300 may be obtained at no charge from the Environmental Health Section, Division of Public Health, N.C. Department of Health and Human Services, 1632 Mail Service Center, Raleigh, NC 27699-1632.

History Note: *Authority G.S. 131E-79;*
Eff. January 1, 1996;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. July 22, 2017;
Amended Eff. October 1, 2019.

10A NCAC 13B .4906 BLOOD BANK

(a) Facilities which provide for procurement, storage and transfusion of blood shall meet the standards of the American Association of Blood Banks as outlined in the most current edition of Standards of Blood Banks and Transfusion Services, which is incorporated by reference, including all subsequent amendments and additions, and which is available from the American Association of Blood Banks, 8101 Glenbrook Road, Bethesda, Maryland 20814-2749 at a cost of thirty-three dollars and fifty cents ($33.50) per copy.
(b) The governing body shall approve the pathologist or physician as physician-in-charge of the blood bank service.
(c) Records shall be kept on file indicating the receipt and disposition of all blood handled. Care shall be taken to ascertain that blood administered has not exceeded its expiration date, and meets all criteria for safe administration.

(d) The facility shall make arrangements to secure on short notice all necessary supplies of blood, typed and cross-matched as required, for emergencies.

History Note: *Authority G.S. 131E-79;*
Eff. January 1, 1996;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. July 22, 2017.

10A NCAC 13B .4907 MORGUE AND AUTOPSY FACILITIES

(a) Morgue and autopsy services shall be provided either on site or by written agreement with a facility that provides those services.
(b) Procedures for the transport and storage of deceased patients shall be established and maintained by the facility.
(c) Procedures for post mortem cleaning of patients with diagnosed contagious diseases shall be established and maintained by the facility.

History Note: *Authority G.S. 131E-79;*
Eff. January 1, 1996;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. July 22, 2017.

SECTION .5000 - PHYSICAL REHABILITATION SERVICES

10A NCAC 13B .5001 ORGANIZATION

The facility shall designate an individual responsible for the administration and supervision of each rehabilitation service.

History Note: *Authority G.S. 131E-79;*
Eff. January 1, 1996;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. July 22, 2017.

10A NCAC 13B .5002 DELIVERY OF CARE

(a) A member of the medical staff shall be responsible for the general medical care of the inpatient.
(b) The delivery of all rehabilitation services shall be provided by practitioners credentialed or licensed in their respective fields.

History Note: *Authority G.S. 131E-79;*
RRC objection due to lack of statutory authority Eff. July 13, 1995;
Eff. January 1, 1996;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. July 22, 2017.

10A NCAC 13B .5003 POLICIES AND PROCEDURES

The facility shall establish and maintain written policies and procedures that include but are not limited to:

(1) provision for assessment and evaluation of the services performed;
(2) safety measures;
(3) infection control measures; and
(4) procedures for referral to other facilities for services not available on site.

History Note: *Authority G.S. 131E-79;*
Eff. January 1, 1996;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. July 22, 2017.

10A NCAC 13B .5004 PATIENT RECORDS

The patient record shall contain documentation of physical rehabilitation services utilized that include but is not limited to:

(1) diagnosis to support the services requested;
(2) assessment of patient's rehabilitative status;
(3) re-assessment and progress of patient's rehabilitative status;
(4) individualized plan of care and goals of rehabilitation; and

(5) discharge plan.

History Note: *Authority G.S. 131E-79;*
Eff. January 1, 1996;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. July 22, 2017.

10A NCAC 13B .5005 CARDIAC REHABILITATION PROGRAM

When a facility elects to provide an outpatient cardiac rehabilitation program, the program shall be subject to 10 NCAC 3S, Sections .0300 - .1000, which are incorporated by reference with all subsequent amendments. Referenced rules are available from the North Carolina Department of Health and Human Services, Division of Health Service Regulation, Licensure and Certification Section, 2711 Mail Service Center, Raleigh, NC 27699 at a cost of three dollars ($3.00) each.

History Note: *Authority G.S. 131E-79;*
Eff. January 1, 1996;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. July 22, 2017.

SECTION .5100 - INFECTION CONTROL

10A NCAC 13B .5101 ORGANIZATION

(a) The governing body shall establish and maintain an infection control program that includes all patient care and patient care support services and departments for the surveillance, prevention and control of infection.
(b) The infection control committee shall include representatives of the medical staff, nursing staff, administration and the person directly responsible for the surveillance program activities.
(c) The infection control committee shall assume responsibility for the infection control program.
(d) The facility shall designate a person to manage the infection control, prevention and surveillance program.
(e) The infection control committee shall involve facility departments and services as needed to maintain the infection control program.

History Note: *Authority G.S. 131E-79;*
Eff. January 1, 1996;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. July 22, 2017.

10A NCAC 13B .5102 POLICY AND PROCEDURES

(a) Each facility department or service shall establish and maintain written infection control policies and procedures. These shall include but are not limited to:

(1) the role and scope of the service or department in the infection control program;
(2) the role and scope of surveillance activities in the infection control program;
(3) the methodology used to collect and analyze data, maintain a surveillance program on nosocomial infection, and the control and prevention of infection;
(4) the specific precautions to be used to prevent the transmission of infection and isolation methods to be utilized;
(5) the method of sterilization and storage of equipment and supplies, including the reprocessing of disposable items;
(6) the cleaning of patient care areas and equipment;
(7) the cleaning of non-patient care areas; and
(8) exposure control plans.

(b) The infection control committee shall approve all infection control policies and procedures. The committee shall review all policies and procedures at least every three years and indicate the last date of review.
(c) The infection control committee shall meet at least quarterly and maintain minutes of meetings.

History Note: *Authority G.S. 131E-79;*
Eff. January 1, 1996.

10A NCAC 13B .5103 LAUNDRY SERVICE

The facility shall provide, directly or by contract, a laundry service or department that provides the following:

(1) 24 hour a day availability of clean linen for patient care needs; and
(2) delivery of clean linen and removal of soiled linen in a manner that reduces the spread of infection.

History Note: *Authority G.S. 131E-79;*
Eff. January 1, 1996;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. July 22, 2017.

10A NCAC 13B .5104 ENVIRONMENTAL SERVICES

The facility shall require that environmental services (housekeeping) provide the following:

(1) 24 hour a day availability of personnel or supplies and equipment for the cleaning of patient rooms, patient care equipment, and the cleaning of spills;
(2) a routine cleaning schedule for all areas of the facility to assist in the prevention and spread of disease; and
(3) removal and appropriate disposal of waste materials including biologicals.

History Note: *Authority G.S. 131E-79;*
Eff. January 1, 1996;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. July 22, 2017.

10A NCAC 13B .5105 STERILE SUPPLY SERVICES

The facility shall provide for the following:

(1) decontamination and sterilization of equipment and supplies;
(2) monitoring of sterilizing equipment on a routine schedule;
(3) establishment of policies and procedures for the use of disposable items; and
(4) establishment of policies and procedures addressing shelf life of stored sterile items.

History Note: *Authority G.S. 131E-79;*
Eff. January 1, 1996.

SECTION .5200 - PSYCHIATRIC SERVICES

10A NCAC 13B .5201 PSYCHIATRIC OR SUBSTANCE ABUSE SERVICES: APPLICABILITY OF RULES

The rules contained in this Section shall apply to all psychiatric and substance abuse services provided by any facility.

History Note: *Authority G.S. 131E-79;*
Eff. January 1, 1996;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. July 22, 2017.

10A NCAC 13B .5202 DEFINITIONS APPLICABLE TO PSYCHIATRIC OR SUBSTANCE ABUSE SERVICES

(a) "Certified counselor" means an alcoholism, drug abuse or substance abuse counselor who is certified by the North Carolina Substance Abuse Professional Certification Board.
(b) "Certified substance abuse counselor/supervisor" means an individual who is a "certified counselor" as defined in 10 NCAC 3C .5202(a) and is designated by the North Carolina Substance Abuse Professional Certification Board as a qualified substance abuse supervisor.
(c) "Clinical/professional supervision" means regularly scheduled assistance by a qualified mental health, professional or a qualified substance abuse professional to a staff member who is providing direct, therapeutic intervention to a client or clients. The purpose of clinical supervision is to ensure that each client receives appropriate treatment or habilitation which is consistent with accepted standards of practice and the needs of the client.
(d) "Detoxification service" means a unit or department whose primary purpose is the medical management or care of persons who are under the influence of alcohol or drugs.
(e) "Direct care staff" means an individual who provides active direct care, treatment, or rehabilitation or habilitation services to clients on a continuous and regularly scheduled basis.

(f) "Psychiatric nurse" means an individual who is licensed to practice as a registered nurse in North Carolina by the North Carolina Board of Nursing; and has:

(1) a graduate degree from an accredited master's level program in psychiatric mental health nursing with two years of experience; or

(2) a master's degree in behavioral science with two years of supervised clinical experience in psychiatric mental health nursing; or

(3) a baccalaureate degree in behavioral science with four years of supervised clinical experience in psychiatric mental health nursing.

(g) "Psychiatric service" means an inpatient or outpatient unit or department whose primary purpose is the treatment of mental illness. It also means the mental health treatment provided in such a unit or department.

(h) "Psychiatric social worker" means an individual who holds a master's degree in social work from an accredited school of social work and has two years of clinical social work experience.

(i) "Psychiatrist" means an individual who is licensed to practice medicine in North Carolina and who has completed an accredited training program in psychiatry.

(j) "Psychologist" means an individual licensed to practice psychology in North Carolina by the North Carolina State Board of Examiners of Practicing Psychologists.

(k) "Qualified mental health professional" means any one of the following: psychiatrist, psychiatric nurse, practicing psychologist, psychiatric social worker, an individual with at least a masters degree in a related human service field and two years of supervised clinical experience in mental health services or an individual with a baccalaureate degree in a related human service field and four years of supervised clinical experience in mental health services.

(l) "Qualified substance abuse professional" means an individual who is:

(1) certified by the North Carolina Substance Abuse Professional Certification Board;

(2) certified by the National Consortium of Chemical Dependency Nurses, Inc;

(3) certified by the National Nurses Society on Addictions; or

(4) a graduate of a college or university with a baccalaureate or advanced degree in a human service related field with documentation of at least two years of supervised experience in the profession of alcoholism and drug abuse counseling.

(m) "Restraint" means the limitation of one's freedom of movement and includes the following:

(1) mechanical restraint which means restraint of a client with the intent of controlling behavior with mechanical devices which include, but are not limited to, cuff, ankle straps, sheets or restraining shirts; or

(2) physical restraint which means restraint of a client until calm. As used in these Rules, the term physical restraint does not apply to the use of professionally recognized methods for therapeutic holds of brief duration (five minutes or less).

(n) "Restrictive facility" means a facility so designated by the Division of Health Service Regulation which uses mechanical restraint or seclusion in accordance with G.S. 122C-60 in order to restrain a client's freedom of movement.

(o) "Seclusion" means isolating a client in a separate locked room for the purpose of controlling a client's behavior.

(p) "Substance abuse service" means inpatient or outpatient unit or department whose primary purpose is the treatment of chemical dependency. It also means the chemical dependency treatment provided in such a unit or department.

History Note: *Authority G.S. 131E-79;*
RRC objection due to lack of statutory authority Eff. July 13, 1995;
Eff. January 1, 1996;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. July 22, 2017.

10A NCAC 13B .5203 STAFFING FOR PSYCHIATRIC OR SUBSTANCE ABUSE SERVICES

(a) General Requirements:

(1) A physician shall be present in the facility or on call 24 hours per day. The medical appraisal and medical treatment of each patient shall be the responsibility of a physician;

(2) Each facility shall determine its overall staffing requirements based upon the age categories (child, adolescent, adult, elderly), clinical characteristics, treatment requirements and numbers of patients;

(3) There shall be a sufficient number of appropriately qualified clinical and support staff to assess and address the clinical needs of the patients;

(4) Staff members shall have training or experience in the provision of care in each of the age categories assigned for treatment.

(b) Psychiatric Services:

(1) Staff coverage for psychiatric services shall include at least one each of the following: psychiatrist, psychiatric nurse, psychologist, and psychiatric social worker;

(2) A qualified mental health professional shall be available by telephone or page and able to reach the facility within 30 minutes on a 24 hour basis;

(3) Each clinical or direct care staff member who is not a qualified mental health professional shall receive professional supervision from a qualified mental health professional;

(4) When detoxification services are provided, there shall be liaison and consultation with a qualified substance abuse professional prior to the discharge of a client.

(c) Substance Abuse Services:

(1) At least one registered nurse shall be on duty during each shift;

(2) Certified substance abuse counselors or qualified substance abuse professionals shall be employed at the ratio of one staff member for each 10 inpatients or fraction thereof. In documented instances of bona fide shortages of certified persons, uncertified individuals expecting to become certified may be employed for a maximum of 38 months without qualifications;

(3) The facility shall have a minimum of two staff members providing care, treatment and services directly to patients on duty at all times and maintain a shift ratio of one staff member for each 20 or less inpatients with the following exceptions:

(A) When there are minor inpatients there shall be staff available on the ratio of one staff member for each five minor inpatients or fraction thereof during each shift from 7:00 a.m. - 11:00 p.m.;

(B) When detox services are offered there shall be no less than one staff member for each nine inpatients or fraction thereof on each shift.

History Note: *Authority G.S. 131E-79;*
Eff. January 1, 1996;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. July 22, 2017.

10A NCAC 13B .5204 PSYCHIATRIC OR SUBSTANCE ABUSE SERVICES RECORD REQUIREMENTS

(a) In addition to the general record keeping requirements of 10A NCAC 13B .3906, specialized assessment and treatment plans for individuals undergoing psychiatric or substance abuse treatment are as follows:

(1) Within 24 hours following admission each individual shall have a completed admission assessment. The initial assessment shall include the reason for admission, admitting diagnosis, mental status including suicide potential, diagnostic tests or evaluations, and a determination of the need for additional information to include the potential for the physical abuse of self or others and a family assessment when a minor is involved;

(2) Within 72 hours following admission, a preliminary individual treatment plan shall be completed and implemented; and

(3) Within five days following admission, a comprehensive individual treatment plan shall be developed and implemented. For outpatient services, the plan shall be developed and implemented within 30 days of admission to treatment.

(b) Individual treatment plans for psychiatric and substance abuse patients shall be developed in partnership with the patient or individual acting on behalf of the patient. Clinical responsibility for the development and implementation of the plan shall be clearly designated. Minimum components of the comprehensive treatment plan shall include diagnosis and time specific short and long term measurable goals, strategies for reaching goals, and staff responsibility for plan implementation. The plan shall be revised as medically or clinically indicated.

(c) Progress notes shall be entered in each individual's record. Included is information which may have a significant impact on the individual's condition or expected outcome such as family conferences or major events related to the patient. Patient status shall be documented each shift for any inpatient psychiatric or substance abuse services, and on a per visit basis for outpatient psychiatric and substance abuse services.

(d) For each individual to whom substance abuse services are provided, a written plan for aftercare services shall be developed which minimally includes:

(1) plan for delivering aftercare services, including the aftercare services which are provided; and

(2) provision for agreements with individuals or organizations if aftercare services are not provided directly by the facility.

History Note: *Authority G.S. 131E-79;*
Eff. January 1, 1996;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. July 22, 2017.

10A NCAC 13B .5205 SECLUSION

At least one seclusion room shall be provided in all hospitals licensed to provide a psychiatric program, a substance abuse program or both.

History Note: *Authority G.S. 131E-79;*
Eff. January 1, 1996;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. July 22, 2017.

10A NCAC 13B .5206 COMPLIANCE WITH STATUTORY REQUIREMENTS

(a) Facilities providing psychiatric or substance abuse services shall develop procedures to protect the rights of psychiatric and substance abuse patients in accordance with North Carolina statutes addressing the rights of psychiatric and substance abuse patients. Statutes addressing such rights are as follows:

(1) G.S. 122C-51. Declaration of policy on clients' rights;
(2) G.S. 122C-52. Right to confidentiality;
(3) G.S. 122C-53. Exceptions; client;
(4) G.S. 122C-54. Exceptions; abuse reports and court proceedings;
(5) G.S. 122C-55. Exceptions; care and treatment;
(6) G.S. 122C-56. Exceptions; research and planning;
(7) G.S. 122C-57. Right to treatment and consent to treatment;
(8) G.S. 122C-58. Civil rights and civil remedies;
(9) G.S. 122C-59. Use of corporal punishment;
(10) G.S. 122C-60. Use of physical restraints or seclusion;
(11) G.S. 122C-61. Treatment rights in 24-hour facilities;
(12) G.S. 122C-62. Additional rights in 24-hour facilities;
(13) G.S. 122C-65. Offenses relating to clients; and
(14) G.S. 122C-66. Protection from abuse and exploitation; reporting.

(b) Facilities providing psychiatric or substance abuse services shall develop procedures to protect confidentiality of information regarding communicable disease and conditions in compliance with G.S. 130A-143.

History Note: *Authority G.S. 131E-79;*
Eff. January 1, 1996;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. July 22, 2017.

10A NCAC 13B .5207 PSYCHIATRIC OR SUBSTANCE ABUSE OUTPATIENT SERVICES

Partial hospitalization, outpatient and day treatment facilities shall be subject to 10A NCAC 27G .1100, 10A NCAC 27G .3500, and 10A NCAC 27G .3700 respectively, which are incorporated by reference with all subsequent amendments. Referenced rules are available from the N.C. Division of Mental Health, Developmental Disabilities, and Substance Abuse Services, Advocacy, Client Rights and Quality Improvement Section, 3009 Mail Service Center, Raleigh, NC 27699-3009 at a cost of five dollars and seventy-five cents ($5.75) per copy.

History Note: *Authority G.S. 131E-79;*
Eff. January 1, 1996;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. July 22, 2017.

SECTION .5300 - NURSING AND ADULT CARE HOME BEDS

10A NCAC 13B .5301 THE LICENSURE OF NURSING AND ADULT CARE HOME BEDS IN A HOSPITAL

When a facility has nursing facility beds or adult care home beds, the beds shall be provided under the hospital's license as provided in Rule .3101 of this Subchapter. The nursing facility beds and the adult care home beds shall be subject to the rules in 10A NCAC 13D with the exception that the following rules shall not apply: 10A NCAC 13D .2001(4); .2101 - .2108; .2201; .2208; .2209; .2211; .2212; .2302; .2401; .2402; .2503; .2504; .2602; .2607; .2701; and .2901. With these exceptions, the rules in 10A NCAC 13D are incorporated by reference with all subsequent amendments. Referenced rules are available from the NC Division of Health Service Regulation, 2711 Mail Service Center, Raleigh, N.C. 27699-2711 at a cost of six dollars ($6.00) per copy.

History Note: *Authority G.S. 131E-79;*
Eff. March 1, 1996;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. July 22, 2017;
Amended Eff. October 1, 2019.

SECTION .5400 - COMPREHENSIVE INPATIENT REHABILITATION

10A NCAC 13B .5401 DEFINITIONS

The following definitions shall apply to inpatient rehabilitation facilities or units only:

(1) "Case management" means the coordination of services, for a given patient, between disciplines so that the patient may reach optimal rehabilitation through the judicious use of resources.

(2) "Comprehensive, inpatient rehabilitation program" means a program for the treatment of persons with functional limitations or chronic disabling conditions who have the potential to achieve a significant improvement in activities of daily living. A comprehensive, rehabilitation program shall utilize a coordinated and integrated, interdisciplinary approach, directed by a physician, to assess patient needs and to provide treatment and evaluation of physical, psycho-social and cognitive deficits.

(3) "Inpatient rehabilitation facility or unit" means a free-standing facility or a unit (unit pertains to contiguous dedicated beds and spaces) approved in accordance with G.S. 131E, Article 9 to establish inpatient, rehabilitation beds and to provide a comprehensive, inpatient rehabilitation program within an existing licensed health service facility.

(4) "Medical consultations" means consultations which the rehabilitation physician or the attending physician determine are necessary to meet the acute medical needs of the patient and do not include routine medical needs.

(5) "Occupational therapist" means any individual licensed in the State of North Carolina as an occupational therapist in accordance with the provisions of G.S. 90, Article 18D.

(6) "Occupational therapist assistant" means any individual licensed in the State of North Carolina as an occupational therapist assistant in accordance with the provisions of G.S. 90, Article 18D.

(7) "Psychologist" means a person licensed as a practicing psychologist in accordance with G.S. 90, Article 18A.

(8) "Physiatrist" means a licensed physician who has completed a physical medicine and rehabilitation residency training program approved by the Accreditation Council of Graduate Medical Education or the American Osteopathic Association.

(9) "Physical therapist" means any person licensed in the State of North Carolina as a physical therapist in accordance with the provisions of G.S. 90, Article 18B.

(10) "Physical therapist assistant" means any person licensed in the State of North Carolina as a physical therapist assistant in accordance with the provisions of G.S. 90-270.24, Article 18B.

(11) "Recreational therapist" means a person certified by the State of North Carolina Therapeutic Recreational Certification Board.

(12) "Rehabilitation aide" means an unlicensed assistant who works under the supervision of a registered nurse, licensed physical therapist or occupational therapist in accordance with the appropriate occupational licensure laws governing his or her supervisor and consistent with staffing requirements as set forth in Rule .5508 of this Section. The rehabilitation aide shall be listed on the North Carolina Nurse Aide Registry and have received additional staff training as listed in Rule .5509 of this Section.

(13) "Rehabilitation nurse" means a registered nurse licensed in North Carolina, with training, either academic or on-the-job, in physical rehabilitation nursing and at least one year experience in physical rehabilitation nursing.

(14) "Rehabilitation physician" means a physiatrist or a physician who is qualified, based on education, training and experience regardless of specialty, of providing medical care to rehabilitation patients.

(15) "Social worker" means a person certified by the North Carolina Social Work Certification and Licensure Board in accordance with G.S. 90B-3.

(16) "Speech and language pathologist" means any person licensed in the State of North Carolina as a speech and language pathologist in accordance with the provisions of G.S. 90, Article 22.

History Note: *Authority G.S. 131E-79;*
RRC Objection due to lack of statutory authority Eff. January 18, 1996;
Eff. May 1, 1996;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. July 22, 2017.

10A NCAC 13B .5402 PHYSICIAN REQUIREMENTS FOR INPATIENT REHABILITATION FACILITIES OR UNITS

(a) In a rehabilitation facility or unit, a physician shall participate in the provision and management of rehabilitation services and in the provision of medical services.

(b) In a rehabilitation facility or unit, a rehabilitation physician shall be responsible for a patient's interdisciplinary treatment plan. Each patient's interdisciplinary treatment plan shall be developed and implemented under the supervision of a rehabilitation physician.

(c) The rehabilitation physician shall participate in the preliminary assessment within 48 hours of admission, prepare a plan of care and direct the necessary frequency of contact based on the medical and rehabilitation needs of the patient. The frequency shall be appropriate to justify the need for comprehensive inpatient rehabilitation care.

(d) An inpatient rehabilitation facility or unit's contract or agreements with a rehabilitation physician shall require that the rehabilitation physician shall participate in individual case conferences or care planning sessions and shall review and sign discharge summaries and records. When patients are to be discharged to another health care facility, the discharging facility shall ensure that the patient has been provided with a discharge plan which incorporates post discharge continuity of care and services. When patients are to be discharged to a residential setting, the facility shall ensure that the patient has been provided with a discharge plan that incorporates the utilization of community resources when available and when included in the patient's plan of care.

(e) The intensity of physician medical services and the frequency of regular contacts for medical care for the patient shall be determined by the patient's pathophysiologic needs.

(f) Where the attending physician of a patient in an inpatient rehabilitation facility or unit orders medical consultations for the patient, such consultations shall be provided by qualified physicians within 48 hours of the physician's order. In order to achieve this result, the contracts or agreements between inpatient rehabilitation facilities or units and medical consultants shall require that such consultants render the requested medical consultation within 48 hours.

(g) An inpatient rehabilitation facility or unit shall have a written procedure for setting the qualifications of the physicians, rendering physical rehabilitation services in the facility or unit.

History Note: *Authority G.S. 131E-79;*
RRC Objection due to lack of statutory authority Eff. January 18, 1996;
Eff. May 1, 1996;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. July 22, 2017.

10A NCAC 13B .5403 ADMISSION CRITERIA FOR INPATIENT REHABILITATION FACILITIES OR UNITS

(a) The facility shall have written criteria for admission to the inpatient rehabilitation facility or unit. A description of programs or services for screening the suitability of a given patient for placement shall be available to staff and referral sources.

(b) For patients found unsuitable for admission to the inpatient rehabilitation facility or unit, there shall be documentation of the reasons.

(c) Within 48 hours of admission, a preliminary assessment shall be completed by members of the interdisciplinary team to insure the appropriateness of placement and to identify the immediate needs of the patients.

(d) Patients admitted to an inpatient rehabilitation facility or unit must be able to tolerate a minimum of three hours of rehabilitation therapy, five days a week, including at least two of the following rehabilitation services: physical therapy, occupational therapy or speech therapy.

(e) Patients admitted to an inpatient rehabilitation facility or unit must be medically stable, have a prognosis indicating a progressively improved medical condition and have the potential for increased independence.

History Note: *Authority G.S. 131E-79;*
Eff. March 1, 1996;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. July 22, 2017.

10A NCAC 13B .5404 COMPREHENSIVE INPATIENT REHABILITATION EVALUATION

(a) A comprehensive, inpatient rehabilitation evaluation is required for each patient admitted to an inpatient rehabilitation facility or unit. At a minimum this evaluation shall include the reason for referral, a summary of the patient's clinical condition, functional strengths and limitations, and indications for specific services. This evaluation shall be completed within three days.

(b) Each patient shall be evaluated by the interdisciplinary team to determine the need for any of the following services: medical, dietary, occupational therapy, physical therapy, prosthetics and orthotics, psychological assessment and therapy, therapeutic recreation, rehabilitation medicine, rehabilitation nursing, therapeutic counseling or social work, vocational rehabilitation evaluation and speech-language pathology.

History Note: *Authority G.S. 131E-79;*
Eff. March 1, 1996;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. July 22, 2017.

10A NCAC 13B .5405 COMPREHENSIVE INPATIENT REHABILITATION INTER-DISCIPLINARY TREAT/PLAN

(a) The interdisciplinary treatment team shall develop an individual treatment plan for each patient within seven days after admission. The plan shall include evaluation findings and information about the following:

(1) prior level of function;
(2) current functional limitations;
(3) specific service needs;
(4) treatment, supports and adaptations to be provided;
(5) specified treatment goals;
(6) disciplines responsible for implementation of separate parts of the plan; and
(7) anticipated time frames for the accomplishment of specified long-term and short-term goals.

(b) The treatment plan shall be reviewed by the interdisciplinary team at least every other week. All members of the interdisciplinary team, or a representative of their discipline, shall attend each meeting. Documentation of each review shall include progress toward defined goals and identification of any changes in the treatment plan.

(c) The treatment plan shall include provisions for all of the services identified as needed for the patient in the comprehensive inpatient rehabilitation evaluation completed in accordance with Rule .5404 of this Section.

(d) Each patient shall have a designated case manager who shall be responsible for the coordination of the patient's individualized treatment plan. The case manager shall be responsible for promoting the program's responsiveness to the needs of the patient and shall participate in all team conferences concerning the patient's progress toward the accomplishment of specified goals. Any of the professional staff involved in the patient's care may be the designated case manager for one or more cases.

History Note: *Authority G.S. 131E-79;*
Eff. March 1, 1996;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. July 22, 2017.

10A NCAC 13B .5406 DISCHARGE CRITERIA FOR INPATIENT REHABILITATION FACILITIES OR UNITS

(a) Discharge planning shall be an integral part of the patient's treatment plan and shall begin upon admission to the facility. After established goals have been reached, or a determination has been made that care in a less intensive setting would be appropriate, or that further progress is unlikely, the patient shall be discharged to an appropriate setting. Other reasons for discharge may include an inability or unwillingness of patient or family to cooperate with the planned therapeutic program or medical complications that preclude a further intensive rehabilitative effort. The facility shall involve the patient, family, staff members and referral sources in discharge planning.

(b) The case manager shall facilitate the discharge or transfer process in coordination with the facility social worker.
(c) If a patient is being referred to another facility for further care, appropriate documentation of the patient's current status shall be forwarded with the patient. A formal discharge summary shall be forwarded within 48 hours following discharge and shall include the reasons for referral, the diagnosis, functional limitations, services provided, the results of services, referral action recommendations and activities and procedures used by the patient to maintain and improve functioning.

History Note: *Authority G.S. 131E-79;*
Eff. March 1, 1996.

10A NCAC 13B .5407 COMPREHENSIVE REHABILITATION PERSONNEL ADMINISTRATION
(a) The facility shall have qualified staff members, consultants and contract personnel to provide services to the patients admitted to the inpatient rehabilitation facility or unit.
(b) Personnel shall be employed or provided by contractual agreement in sufficient types and numbers to meet the needs of all patients admitted for comprehensive rehabilitation.
(c) Written agreements shall be maintained by the facility when services are provided by contract on an ongoing basis.

History Note: *Authority G.S. 131E-79;*
RRC Objection due to lack of statutory authority Eff. January 18, 1996;
Eff. May 1, 1996;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. July 22, 2017.

10A NCAC 13B .5408 COMPREHENSIVE INPATIENT REHABILITATION PROGRAM STAFFING REQUIREMENTS
(a) The staff of the inpatient rehabilitation facility or unit shall include at a minimum:
(1) the inpatient rehabilitation facility or unit shall be supervised by a rehabilitation nurse. The facility shall identify the nursing skills necessary to meet the needs of the rehabilitation patients in the unit and assign staff qualified to meet those needs;
(2) the minimum nursing hours per patient in the rehabilitation unit shall be 5.5 nursing hours per patient day. At no time shall direct care nursing staff be less than two full-time equivalents, one of which must be a registered nurse;
(3) the inpatient rehabilitation unit shall employ or provide by contractual agreements sufficient therapist to provide a minimum of three hours of specific (physical, occupational or speech) or combined rehabilitation therapy services per patient day;
(4) physical therapy assistants and occupational therapy assistants shall be supervised on-site by physical therapists or occupational therapists;
(5) rehabilitation aides shall have documented training appropriate to the activities to be performed and the occupational licensure laws of his or her supervisor. The overall responsibility for the on-going supervision and evaluation of the rehabilitation aide remains with the registered nurse as identified in Subparagraph (a)(1) of this Rule. Supervision by the physical therapist or by the occupational therapist is limited to that time when the therapist is on-site and directing the rehabilitation activities of the aide; and
(6) hours of service by the rehabilitation aide are counted toward the required nursing hours when the aide is working under the supervision of the nurse. Hours of service by the rehabilitation aide are counted toward therapy hours during that time the aide works under the immediate, on-site supervision of the physical therapist or occupational therapist. Hours of service shall not be dually counted for both services. Hours of service by rehabilitation aides in performing nurse-aide duties in areas of the facility other than the rehabilitation unit shall not be counted toward the 5.5 hour minimum nursing requirement described for the rehabilitation unit.
(b) Additional personnel shall be provided as required to meet the needs of the patient, as defined in the comprehensive inpatient rehabilitation evaluation.

History Note: *Authority G.S. 131E-79;*
RRC Objection due to lack of statutory authority Eff. January 18, 1996;
Eff. May 1, 1996.

10A NCAC 13B .5409 STAFF TRAINING FOR INPATIENT REHABILITATION FACILITIES OR UNIT

Prior to the provision of care, all rehabilitation personnel, excluding physicians, assigned to the rehabilitation unit shall be provided training or shall provide documentation of training that includes at a minimum the following:

(1) active and passive range of motion;
(2) assistance with ambulation;
(3) transfers;
(4) maximizing functional independence;
(5) the psycho-social needs of the rehabilitation patient;
(6) the increased safety risks of rehabilitation training (including falls and the use of restraints);
(7) proper body mechanics;
(8) nutrition, including dysphagia and restorative eating;
(9) communication with the aphasic and hearing impaired patient;
(10) behavior modification;
(11) bowel and bladder training; and
(12) skin care.

History Note: *Authority G.S. 131E-79;*
RRC Objection due to lack of statutory authority Eff. January 18, 1996;
Eff. May 1, 1996;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. July 22, 2017.

10A NCAC 13B .5410 EQUIPMENT REQUIREMENTS/COMPREHENSIVE INPATIENT REHABILITATION PROGRAMS

(a) The facility shall provide each discipline with the necessary equipment and treatment methods to achieve the short and long-term goals specified in the comprehensive inpatient rehabilitation interdisciplinary treatment plans for patients admitted to these facilities or units.
(b) Each patient's needs for a standard wheelchair or a specially designed wheelchair or additional devices to allow safe and independent mobility within the facility shall be met.
(c) Special physical therapy and occupational therapy equipment for use in fabricating positioning devices for beds and wheelchairs shall be provided including splints, casts, cushions, wedges and bolsters.
(d) Physical therapy devices shall be provided, including a mat, table, parallel bars, sliding boards, and special adaptive bathroom equipment.

History Note: *Authority G.S. 131E-79;*
Eff. March 1, 1996;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. July 22, 2017.

10A NCAC 13B .5411 PHYSICAL FACILITY REQUIREMENTS/INPATIENT REHABILITATION FACILITIES OR UNIT

(a) The inpatient rehabilitation facility or unit shall be in a designated area and shall be used for the specific purpose of providing a comprehensive inpatient rehabilitation program.
(b) The floor area of a single bedroom shall be sufficient for the patient or the staff to easily transfer the patient from the bed to a wheelchair and to maneuver a 180 degree turn with a wheelchair on at least one-side of the bed.
(c) The floor area of a multi-bed bedroom shall be sufficient for the patient or the staff to easily transfer the patient from the bed to a wheelchair and to maneuver a 180 degree turn with a wheelchair between beds.
(d) Each patient room shall meet the following requirements:

(1) maximum room capacity of no more than four patients;
(2) operable windows;
(3) a nurse call system designed to meet the special needs of rehabilitation patients;
(4) in single and two-bed rooms with private toilet room, the lavatory may be located in the toilet room;
(5) a wardrobe or closet for each patient which is wheelchair accessible and arranged to allow the patient to access the contents;
(6) a chest of drawers or built-in drawer storage with mirror above, which is wheelchair accessible; and

(7) a bedside table for toilet articles and personal belongings.

(e) Space for emergency equipment such as resuscitation carts shall be provided and shall be under direct control of the nursing staff, in proximity to the nurse's station and out of traffic.

(f) Patients' bathing facilities shall meet the following specifications:

(1) there shall be at least one shower stall or one bathtub for each 15 beds not individually served. Each tub or shower shall be in an individual room or privacy enclosure which provides space for the private use of the bathing fixture, for drying and dressing and for a wheelchair and an assisting attendant;

(2) showers in central bathing facilities shall be at least five feet square without curbs and designed to permit use by a wheelchair patient;

(3) at least one five-foot-by-seven-foot shower shall be provided which can accommodate a stretcher and an assisting attendant.

(g) Patients' toilet rooms and lavatories shall meet the following specifications:

(1) the size of toilet room shall permit a wheelchair, a staff person and appropriate wheel-to-water closet transfers;

(2) a lavatory in the room shall permit wheelchair access;

(3) lavatories serving patients shall:

(A) allow wheelchairs to extend under the lavatory; and

(B) have water supply spout mounted so that its discharge point is a minimum of five inches above the rim of the fixture; and

(4) lavatories used by patients and by staff shall be equipped with blade-operated supply valves.

(h) The space provided for physical therapy, occupational therapy and speech therapy by all inpatient rehabilitation facilities or units may be shared but shall, at a minimum, include:

(1) office space for staff;

(2) office space for speech therapy evaluation and treatment;

(3) waiting space;

(4) training bathroom which includes toilet, lavatory and bathtub;

(5) gymnasium or exercise area;

(6) work area such as tables or counters suitable for wheelchair access;

(7) treatment areas with available privacy curtains or screens;

(8) an activities of daily living training kitchen with sink, cooking top (secured when not supervised by staff), refrigerator and counter surface for meal preparation;

(9) storage for clean linens, supplies and equipment;

(10) janitor's closet accessible to the therapy area with floor receptor or service sink and storage space for housekeeping supplies and equipment (one closet or space may serve more than one area of the inpatient rehabilitation facility or unit); and

(11) hand washing facilities.

(i) For social work and psychological services the following shall be provided:

(1) office space for staff;

(2) office space for private interviewing and counseling for all family members; and

(3) work space for testing, evaluation and counseling.

(j) If prosthetics and orthotics services are provided, the following space shall be made available as necessary:

(1) work space for technician; and

(2) space for evaluation and fittings (with provisions for privacy).

(k) If vocational therapy services are provided, the following space shall be made available as necessary:

(1) office space for staff;

(2) work space for vocational services activities such as prevocational and vocational evaluation;

(3) training space;

(4) storage for equipment; and

(5) counseling and placement space.

(l) Recreational therapy space requirements shall include the following:

(1) activities space;

(2) storage for equipment and supplies;

(3) office space for staff; and

(4) access to male and female toilets.

(m) The following space shall be provided for patient's dining, recreation and day areas:

(1) sufficient room for wheelchair movement and wheelchair dining seating;
(2) if food service is cafeteria type, adequate width for wheelchair maneuvers, queue space within the dining area (and not in a corridor) and a serving counter low enough to view food;
(3) total space for inpatients, a minimum of 25 square feet per bed;
(4) for outpatients participating in a day program or partial day program, 20 square feet when dining is a part of the program and 10 square feet when dining is not a part of the program;
(5) storage for recreational equipment and supplies, tables and chairs; and
(6) the patient dining, recreation and day area spaces shall be provided with windows that have glazing of an area not less than eight percent of the floor area of the space, and at least one-half of the required window area must be operable.

(n) A laundry shall be available and accessible for patients.

History Note: *Authority G.S. 131E-79;*
Eff. March 1, 1996.

10A NCAC 13B .5412 ADDITIONAL REQUIREMENTS FOR TRAUMATIC BRAIN INJURY PATIENTS

(a) Inpatient rehabilitation facilities providing services to patients with traumatic brain injuries shall provide staff to meet the needs of patients in accordance with the patient assessment, treatment plan, and physician orders.
(b) The facility shall provide special equipment to meet the needs of patients with traumatic brain injury, including specially designed wheelchairs, tilt tables and standing tables.
(c) The facility shall provide the consulting services of a neuropsychologist.
(d) The facility shall provide continuing education in the care and treatment of brain injury patients for all staff.

History Note: *Authority G.S. 131E-79;*
RRC Objection due to lack of statutory authority Eff. January 18, 1996;
Eff. May 1, 1996;
Readopted Eff. April 1, 2020.

10A NCAC 13B .5413 ADDITIONAL REQUIREMENTS FOR SPINAL CORD INJURY PATIENTS

(a) Inpatient rehabilitation facilities providing services to patients with spinal cord injuries shall provide staff to meet the needs of patients in accordance with the patient assessment, treatment plan, and physician orders.
(b) The facility shall provide special equipment to meet the needs of patients with spinal cord injury, including specially designed wheelchairs, tilt tables and standing tables.
(c) The facility shall provide continuing education in the care and treatment of spinal cord injury patients for all staff.
(d) The facility shall provide specific staff training and education in the care and treatment of spinal cord injury.

History Note: *Authority G.S. 131E-79;*
RRC Objection due to lack of statutory authority Eff. January 18, 1996;
Eff. May 1, 1996;
Readopted Eff. April 1, 2020.

10A NCAC 13B .5414 DEEMED STATUS FOR INPATIENT REHABILITATION FACILITIES OR UNIT

(a) If an inpatient rehabilitation facility or unit with a comprehensive inpatient rehabilitation program is surveyed and accredited by The Joint Commission (TJC) or the Commission on Accreditation of Rehabilitation Facilities (CARF) and has been approved by the Department in accordance with G.S. 131E, Article 9, the Department deems the facility to be in compliance with Rules .5401 through .5413 of this Section.
(b) Deemed status shall be provided only if the inpatient rehabilitation facility or unit provides copies of survey reports to the Department. The TJC report shall show that the facility or unit was surveyed for rehabilitation services. The CARF report shall show that the facility or unit was surveyed for comprehensive rehabilitation services. The facility or unit shall sign an agreement (Memorandum of Understanding) with the Department specifying these terms.
(c) The inpatient rehabilitation facility or unit shall be subject to inspections or complaint investigations by representatives of the Department at any time. If the facility or unit is found not to be in compliance with the rules listed

in Paragraph (a) of this Rule, the facility shall submit a plan of correction and be subject to a follow-up visit to ensure compliance.
(d) If the inpatient rehabilitation facility or unit loses or does not renew its accreditation, the facility or unit shall notify the Division in writing within 30 days.

History Note: *Authority G.S. 131E-79;*
Eff. March 1, 1996;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. July 22, 2017;
Amended Eff. October 1, 2019.

SECTION .5500 – SUPPLEMENTAL RULES FOR HOSPITALS PROVIDING LIVING ORGAN DONATION TRANSPLANT SERVICES

10A NCAC 13B .5501 APPLICABILITY OF RULES

The rules contained in this Section shall apply to hospitals providing living organ donation transplant services.

History Note: *Authority G.S. 131E-75; 131E-79; 143B-165;*
Eff. April 1, 2006;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. July 22, 2017.

10A NCAC 13B .5502 INDEPENDENT DONOR ADVOCATE TEAM

(a) The facility shall appoint an Independent Donor Advocate Team (IDAT) whose sole purpose is to represent and ensure the well-being of the potential donor, making sure he or she is aware of the risks and benefits of donation and that the choice to donate is voluntary. The IDAT shall ensure the potential donor learns about the entire donation process. This would include the selection of recipients for the transplant, the procedures to be employed for both the donor and recipient, and possible outcomes. Sufficient time for the discussion, supplemented with written materials, must be allowed for comprehension and assimilation of the information about transplantation and the ramifications of donation. Written and verbal presentations shall be in language in accordance with the person's ability to understand.
(b) The IDAT shall consist of a physician, a clinical transplant coordinator, and a social worker or qualified mental health professional as defined in Rule .5202(k) of this Subchapter. The physician shall be the leader of the IDAT. The IDAT members shall have experience in organ transplantation processes and programs and shall be able to act for the interests of the potential donor independent of any financial or facility influence. Based on the outcome of the evaluation of the potential donor pursuant to Rule .5504 of this Section, if the IDAT determines any potential donor is unsuitable for donation, it shall provide the reasons both verbally and in writing.
(c) In order to ensure the well-being of the potential donor, the IDAT shall:

(1) Protect and represent the interests of the potential donor;
(2) Make it clear to the potential donor that the choice to donate is entirely his or hers;
(3) Inform and discuss with the potential donor the medical, psychosocial and financial aspects related to the live donation;
(4) Explain to the potential donor the evaluation process, what it means and his or her option to stop at any time;
(5) Determine the intellectual and emotional ability of the potential donor to understand the legal and ethical aspects of informed choice;
(6) Assess if the potential donor has understood the risks and the benefits and how they impact on his or her own core beliefs and values; and
(7) Identify for the potential donor resources that will be available to provide continuous care during hospitalization and referrals in medicine, psychiatry or social work, which may be needed or required following discharge.

History Note: *Authority G.S. 131E-75; 131E-79; 143B-165;*
Eff. May 1, 2006;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. July 22, 2017.

10A NCAC 13B .5503 INFORMED CHOICE

(a) The potential donor must be free to make an informed independent decision, which has been termed informed choice. Informed choice addresses the decision process of the potential donor as he or she determines whether or not to donate. Informed choice has several aspects. First, the potential donor must know he or she has a choice, meaning he or she can freely decide either to donate or not to donate an organ. Second, the potential donor must be aware of both the risks and benefits of donation. The potential donor must be able to weigh the positive aspects of the donation as well as take into account the technical aspects such as the surgery, recovery, financial impact and any unexpected but potential consequences that may result such as a change in the patient's life, health, insurability, employment or emotional stability.

(b) The person who consents to be a live organ donor shall be:

(1) Legally competent;

(2) Willing to donate;

(3) Free from coercion, including financial coercion, actual or implied;

(4) Medically suitable;

(5) Informed and able to express understanding of the risks and benefits of donation; and

(6) Informed of the risks, benefits and alternative treatment regimens available to the recipient.

(c) A statement signed by the potential donor that his or her participation is completely voluntary and may be withdrawn at any time shall be placed in the medical record.

(d) Understanding

(1) The potential donor shall be able to demonstrate that he or she understands the essential elements of the donation process with emphasis on the risks associated with the procedure;

(2) With the potential donor's permission, the donor's designee, family or next of kin shall be given the opportunity to openly discuss the donor's concerns in a safe and non-threatening environment; and

(3) The potential donor shall understand, agree to, and commit to postoperative follow-up and testing by the facility performing the surgical removal of the organ and subsequent organ transplant.

(e) Disclosure

(1) The donor surgical team and the IDAT shall disclose any facility affiliations to the potential donor;

(2) The potential donor shall have a period of reflection appropriate to the acuity of the clinical condition of the recipient and reaffirmation of the decision to donate subsequent to the completion of the medical work-up and final approval to proceed by the IDAT. After the period of reflection the potential donor may sign the consent for the donation procedure;

(3) Non-English speaking candidates and hearing impaired candidates must be provided with a non-family interpreter who understands the donor's language and culture;

(4) A member of the IDAT shall witness the potential donor signing the consent documents for removal of the donor organ; and

(5) The overall donation process and experience shall be explained to the potential donor and shall be provided in writing to include:

(A) Donor evaluation procedure;

(B) Surgical procedure;

(C) Recuperative period;

(D) Short-term and long term follow-up care;

(E) Alternative donation and transplant procedure;

(F) Potential psychological benefits to donor;

(G) Transplant facility and surgeon-specific statistics of donor and recipient outcomes;

(H) Confidentiality of the donor's information and decisions;

(I) Donor's ability to opt out at any point in the process;

(J) Information about how the facility performing the transplant will attempt to follow the health of the donor; and

(K) Need for the donor to review potential personal insurability for future insurance coverage.

(f) The IDAT shall make the potential donor aware of the following risk factors:

(1) Physical

(A) Potential for surgical complications including risk of donor death;

(B) Potential for organ failure and the need for future organ transplant for the donor;

(C) Potential for other medical complications including long-term complications and complications currently unforeseen;

(D) Scars;

(E) Pain;

(F) Fatigue; and
(G) Abdominal or bowel symptoms such as bloating and nausea.

(2) Psychosocial
(A) Potential for problems with body image;
(B) Possibility of transplant recipient death;
(C) Possibility of transplant recipient rejection and need for re-transplantation;
(D) Possibility of recurrent disease in a transplant recipient;
(E) Possibility of post surgery adjustment problems;
(F) Impact on the donor's family or next of kin;
(G) Impact on the transplant recipient's family or next of kin; and
(H) Potential impact of donation on the donor's lifestyle.

(3) Financial
(A) Out of pocket expenses;
(B) Child care costs;
(C) Possible loss of employment;
(D) Potential impact on the ability to obtain future employment; and
(E) Potential impact on the ability to obtain or afford health and life insurance.

(g) The potential donor shall provide assurance and consent that the following areas have been addressed:
(1) That there is no monetary profit to the potential donor. Coverage for expenses incurred as a result of the organ donation is not considered monetary profit;
(2) That family members or others did not coerce the potential donor into making his or her decision;
(3) That the potential donor has been provided with a general statement of unsuitability for donation if requested. Medical information regarding the potential donor shall not be falsified to provide the donor with an excuse to decline donation;
(4) That the potential donor is intellectually and emotionally capable of participation in a discussion of potential risks and benefits;
(5) That the potential donor has been provided adequate information to ensure his or her understanding regarding the risks of the donation;
(6) That the potential donor has been educated regarding the recipient's options for organs from deceased persons, including risks and outcomes; and
(7) That the potential donor understands that he or she may decline to donate at any time.

(h) Documentation
(1) A medical record, separate and distinct from the transplant recipient's record, shall be maintained to protect donor confidentiality; and
(2) The informed choice process and evaluation protocol shall be documented and placed in the potential donor's medical record.

(i) Decision to Donate. Once the IDAT determines the suitability of the potential donor the IDAT shall discuss with the potential donor's surgical team and transplant team its decision prior to its presentation to the potential donor. If the potential donor wishes to donate, but the IDAT does not agree, the IDAT's opposition shall be so noted in a report to the donor surgeon, who shall document reasons for proceeding against the IDAT advice. The reason why the IDAT has objections shall be explained to the potential donor. For example, the potential donor may not have the ability to understand the information provided to him or her or the donor may be unable to integrate the degree of risk pertinent to his or her situation or there may be a lack of balance between the risks to the potential donor and potential benefits to the transplant recipient. Even if the potential donor is willing to donate his or her organ, the final review and decision whether or not to proceed with the donation rests with the donor surgical team and transplant team.

(j) In cases involving living liver donation, prior to reaching a decision to donate the potential donor shall be provided in writing the U.S. Department of Health and Human Services Advisory Committee on Organ Transplantation (ACOT) recommendations entitled "Living Liver Donor Initial Consent for Evaluation" which is hereby incorporated by reference with all subsequent amendments. The ACOT recommendations can be obtained free of charge via the internet at: http://www.organdonor.gov/acotrecs.html. The items contained in the ACOT recommendations must be explained to the potential donor in language and terms which he or she can understand and then be signed by the donor and the signature witnessed. Subsequent to this, if all the facts show that the potential donor is, in fact, in all respects a viable potential donor, then he or she shall execute the ACOT recommended form entitled "Living Liver Donor Informed Consent for Surgery" which is hereby incorporated by reference with all subsequent amendments. In addition, this form shall comply with G.S. 90-21.13 Informed Consent which is hereby incorporated by reference with all subsequent amendments.

History Note: *Authority G.S. 131E-75; 131E-79; 143B-165;*
Eff. May 1, 2006;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. July 22, 2017.

10A NCAC 13B .5504 EVALUATION PROTOCOL FOR LIVING ORGAN DONORS

Hospitals shall complete the following evaluation protocols prior to living organ donation:

(1) The facility shall confirm the potential donor's ABO blood type.

(2) Only individuals 18 years of age or older shall be considered for living organ donation. The facility shall complete a screening interview with the potential donor which confirms the donor's age, height, weight, demographic information, medical and surgical history, medications, drug or alcohol history, smoking history, and a family or social history. Insurance issues (health and life) shall also be discussed with the potential donor and an attempt shall be made to answer any questions asked by the donor. Written information on the living donor process shall be made available to the potential donor.

(3) The donor surgical team shall determine whether the potential donor shall be excluded based on the medical information or family history: for example, exclusionary criteria may include the presence of diabetes, uncontrolled hypertension, liver, pulmonary or cardiac disease, renal dysfunction or high Body Mass Index (BMI).

(4) An IDAT shall be assigned for the potential donor pursuant to Rule .5502(c) of this Section. The IDAT leader shall not be a physician who is the primary physician of the potential transplant recipient.

(5) The IDAT leader shall conduct a medical evaluation of the potential donor. The medical evaluation shall include a full and frank discussion of the risks associated with the evaluation tests with the potential donor and the donor's chosen designee. If the potential donor wishes to proceed, laboratory and diagnostic tests shall be ordered as necessary.

(6) An IDAT member shall conduct a psychosocial evaluation of the potential donor. The IDAT member shall also discuss financial considerations.

(7) The IDAT shall review the laboratory and diagnostic test results, as well as psychosocial evaluation and discuss them with the donor to decide whether to move forward with the potential donor's evaluation.

(8) The donor surgeon shall evaluate the mortality and morbidity risks associated with donation and disclose those risks to the potential donor with adequate time for any questions to be answered in detail. The donor's designee shall also be present at this appointment.

(9) The IDAT shall perform a final review and makes its recommendation as set out in Rule .5503(i) of this Section.

(10) The hospital shall schedule an appointment for pre-operative screening with the potential donor after the entire process of evaluation is complete. An informed consent as required in Rule .4605(c)(2) of this Subchapter is necessary for the donation and surgical procedure and shall be completed by this time. In addition, where applicable, the potential donor shall be given ample time for autologous blood donation through the American Red Cross.

History Note: *Authority G.S. 131E-75; 131E-79; 143B-165;*
Eff. May 1, 2006;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. July 22, 2017.

10A NCAC 13B .5505 PERIOPERATIVE CARE AND FACILITY SUPPORT

(a) The donor surgical team shall have primary concern and responsibility for the donor's care and welfare throughout his or her entire hospital stay. The donor surgical team consists of the donor surgeon, his or her surgical and medical partners, fellows, residents, and physician assistants or nurse practitioners.

(b) Preoperative Preparation

(1) The facility shall have the ability to allow donors to bank a minimum of one unit of blood before surgery. Facilities shall have the ability to store and transfuse autologous blood;

(2) The transplant coordinator or another team member shall be assigned the responsibility of providing updates to the families of both the donor and transplant recipient during the surgical procedures; and

(3) For live donor liver procedures, surgeries shall be scheduled only when staffing will be available for the postoperative period. If surgery is scheduled on a Thursday or Friday, the hospital shall ensure that

there is adequate attending physician, resident physician, physician assistant or nurse practitioner, and registered nursing coverage during the weekend.

(c) Postoperative Care

(1) After live donor nephrectomy, the patient shall receive post-operative care equivalent to that provided for abdominal procedures under general anesthesia; and

(2) For live liver donors:

(A) Day 0-1: The live adult liver donor shall receive care in the intensive care unit (ICU) or post-anesthesia care unit (PACU);

(B) Day 2: If stable and cleared for transfer by the donor surgical team, the donor shall be cared for in a hospital unit that is dedicated to the care of transplant recipients or a hospital unit in which patients who undergo hepatobiliary resectional surgery are provided care. Liver donors shall not at any time be cared for on any other unit unless a specific medical condition of the donor warrants such a transfer;

(C) The donor shall be evaluated at least daily by a liver transplant attending physician with documentation in the medical record;

(D) The donor surgical team shall be responsible for the clinical management of the donor;

(E) The patient care staff shall be familiar with the common complications associated with the donor and transplant recipient operations and have appropriate monitoring in place to detect these problems if they arise; and

(F) If there is an emergent complication requiring re-operation, these patients shall be prioritized for access to the operating room based on the facility's operating room policies and guidelines.

(d) Medical Staffing. For live donor nephrectomy patients, there shall be continuous physician coverage available for patient evaluation as needed. These patients shall be provided post-operative care equivalent to patients undergoing a nephrectomy.

(e) Nurse Staffing

(1) Nursing staff shall be familiar with recovery of nephrectomy patients. They shall be aware of the signs and symptoms of hypovolemia due to post-operative bleeding or to excessive diuresis. They shall have ready access to the surgical team responsible for the patient's post-operative care;

(2) For live liver donors, nursing staff shall have ongoing education and training in live donor liver transplantation nursing care for both donors and recipients. This shall include education on the pain management issues particular to the donor. The registered nursing to patient ratio in the ICU or PACU level setting shall be appropriate for the acuity level of the patients. For live liver donors, the same registered nurse shall not take care of both the donor and the recipient. For live liver donors, the nursing service shall provide the potential donor with pre-surgical information including, if possible, a tour of the unit before surgery; and

(3) For all donors, the names and beeper numbers of the donor surgical team or team responsible for the donor's post-operative surgical care (e.g. urology service or laparoscopic general surgery service for some donor nephrectomy patients) shall be posted on all units receiving transplant donors.

(f) Radiology. For facilities performing live donor nephrectomies, radiological staff shall be available for pre-operative assessment, peri-operative care, and post-operative follow-up as required.

History Note: *Authority G.S. 131E-75; 131E-79; 143B-165;*
Eff. April 1, 2006;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. July 22, 2017.

10A NCAC 13B .5506 DISCHARGE PLANNING

(a) Pre-Donation. At the time of evaluation by the IDAT, a discussion shall be held between the IDAT social worker and the potential donor and his or her family or next of kin to address the following areas:

(1) Living arrangements after discharge from the surgery or while the donor recuperates until able to travel;

(2) Transportation arrangements from the hospital to the donor's accommodations or back to follow up appointments;

(3) Caregivers to provide assistance or support upon discharge; if the donor has children or other dependents, a plan for the children's or dependent's care while the donor recuperates;

(4) Financial considerations: Encourage donor to discuss with employer about medical leave or disability. This discussion shall include checking with health or life insurance carriers about future "pre-existing conditions" or "exclusions" that may result from donation;
(5) Provided consent is first obtained, referrals to other living organ donors from that particular facility and suggestions from other resources such as publications and websites; and
(6) Emotional issues surrounding the organ donation process.

(b) Day of Discharge
(1) A written discharge plan shall be provided to the donor with the following instructions:
(A) Restrictions on activities;
(B) Permitted activities (i.e. return to work);
(C) Diet;
(D) Pain medication with prescription;
(E) Follow up appointments with surgeon;
(F) Contact numbers for the Independent Donor Advocate Team should the donor have questions, concerns or problems; and
(G) Additional instructions for caregivers, if any.
(2) The discharge plan shall be reviewed with the donor by the facility discharge planner or primary care nurse.

(c) Post Discharge medical follow-up, social, psychological and financial support
(1) Post-operative visits shall be scheduled by the donor with the surgeon to assess the following:
(A) Wound healing;
(B) Signs and symptoms of infections; and
(C) Laboratory results as appropriate to the organ type, as well as any imaging or other diagnostic findings.
(2) Dictated summaries of surgery and follow-up visits shall be sent to the donor's primary care physician by the facility to ensure appropriate medical care.
(3) Referrals shall be made to community agencies to address the donor's emotional and psychological issues if needed or requested by the donor, his or her designee, family, next of kin or the IDAT to;
(A) Provide the donor the opportunity to participate in a support group; and
(B) Provide the donor recognition as determined by the facility.

(d) Any questions or concerns regarding the discharge plan or discharge planning process by the donor, the donor's designee, the donor's next of kin or legally responsible party shall be addressed by facility staff.

History Note: *Authority G.S. 131E-75; 131E-79; 143B-165;*
Eff. April 1, 2006;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. July 22, 2017.

SECTION .5600 - RESERVED FOR FUTURE CODIFICATION

10A NCAC 13B .5600 RESERVED FOR FUTURE CODIFICATION

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SECTION .5800 - RESERVED FOR FUTURE CODIFICATION

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SECTION .5900 - RESERVED FOR FUTURE CODIFICATION

10A NCAC 13B .5900 RESERVED FOR FUTURE CODIFICATION

SECTION .6000 - PHYSICAL PLANT

10A NCAC 13B .6001 LOCATION
10A NCAC 13B .6002 ROADS AND PARKING

History Note: *Authority G.S. 131E-79;*
Eff. January 1, 1996;
Repealed Eff. January 1, 2018.

10A NCAC 13B .6003 DEFINITIONS

In addition to the definitions set forth in G.S. 131E-76, the following definitions shall apply in Sections .6000 through .6200 of this Subchapter:

(1) "Addition" means an extension or increase in floor area or height of a building.
(2) "Alteration" means any construction or renovation to an existing building other than construction of an addition.
(3) "Construction documents" means final building plans and specifications for the construction of a facility that a governing body submits to the Construction Section for approval as specified in Rule .3102 of this Subchapter.
(4) "Construction Section" means the Construction Section of the Division of Health Service Regulation.
(5) "Division" means the Division of Health Service Regulation of the North Carolina Department of Health and Human Services.
(6) "Facility" means a hospital as defined in G.S. 131E-76.

History Note: *Authority G.S. 131E-76; 131E-79; S.L. 2017-174;*
Temporary Adoption Eff. December 1, 2017;
Eff. March 21, 2019

SECTION .6100 – GENERAL REQUIREMENTS

10A NCAC 13B .6101 LIST OF REFERENCED CODES, RULES, REGULATIONS, AND STANDARDS

For the purposes of the rules in this Subchapter, the following codes, rules, regulations, and standards are incorporated herein by reference including subsequent amendments and editions. Copies of these codes, rules, regulations, and standards may be obtained or accessed from the online addresses listed:

(1) the North Carolina State Building Codes with copies that may be purchased from the International Code Council online at http://shop.iccsafe.org/ at a cost of five hundred seventy-one dollars ($571.00) or accessed electronically free of charge at http://codes.iccsafe.org/North%20Carolina.html;
(2) 42 CFR Part 482.41, Condition of Participation: Physical Plant, that is incorporated herein by reference including all subsequent amendments and editions; however, Part 482.41(c)(1) shall not be incorporated by reference. Copies of this regulation may be accessed free of charge at https://www.gpo.gov/fdsys/pkg/CFR-2017-title42-vol5/xml/CFR-2017-title42-vol5-sec482-41.xml or purchased online at https://bookstore.gpo.gov/products/cfr-title-42-pt-482-end-code-federal-regulationspaper-201-7 for a cost of seventy-seven dollars ($77.00);
(3) the following National Fire Protection Association standards, codes, and guidelines with copies of these standards, codes, and guidelines that may be accessed electronically free of charge at https://www.nfpa.org/Codes-and-Standards/All-Codes-and-Standards/List-of-Codes-and-Standards or may be purchased online at https://catalog.nfpa.org/Codes-and-Standards-C3322.aspx for the costs listed:
    (a) NFPA 22, Standard for Water Tanks for Private Fire Protection for a cost of fifty-four dollars ($54.00);
    (b) NFPA 53, Recommended Practice on Materials, Equipment, and Systems Used in Oxygen-Enriched Atmospheres for a cost of fifty-three dollars ($53.00);
    (c) NFPA 59A, Standard for the Production, Storage, and Handling of Liquefied Natural Gas for a cost of fifty-four dollars ($54.00);
    (d) NFPA 255, Standard Method of Test of Surface Burning Characteristics of Building Materials for a cost of forty-two dollars ($42.00);
    (e) NFPA 407, Standard for Aircraft Fuel Servicing for a cost of forty-nine dollars ($49.00);

(f) NFPA 705, Recommended Practice for a Field Flame Test for Textiles and Films for a cost of forty-two dollars ($42.00);
(g) NFPA 780, Standard for the Installation of Lightning Protection Systems for a cost of sixty-three dollars and fifty cents ($63.50);
(h) NFPA 801, Standard for Fire Protection for Facilities Handling Radioactive Materials for a cost of forty-nine dollars ($49.00); and
(i) Fire Protection Guide to Hazardous Materials for a cost of one hundred and thirty-five dollars and twenty-five cents ($135.25);

(4) 42 CFR Part 482.15 Condition of participation: Emergency preparedness with copies of this regulation that may be accessed free of charge at https://www.gpo.gov/fdsys/pkg/CFR-2017-title42-vol5/xml/CFR-2017-title42-vol5-sec482-15.xml or purchased online at https://bookstore.gpo.gov/products/cfr-title-42-pt-482-end-code-federal-regulationspaper-201-7 for a cost of seventy-seven dollars ($77.00);

(5) the "Rules Governing the Sanitation of Hospitals, Nursing Homes, Adult Care Homes, and Other Institutions" 15A NCAC 18A .1300 with copies of these rules that may be accessed electronically free of charge at http://reports.oah.state.nc.us/ncac/title%2015a%20-%20environmental%20quality/chapter%2018%20-%20environmental%20health/subchapter%20a/15a%20ncac%2018a%20.1301.pdf; and

(6) the rules for ambulatory surgical facilities in 10A NCAC 13C, Licensing of Ambulatory Surgical Facilities with copies of these rules that may be accessed electronically free of charge at http://reports.oah.state.nc.us/ncac/title%2010a%20-%20health%20and%20human%20services/chapter%2013%20-%20nc%20medical%20care%20commission/subchapter%20c/subchapter%20c%20rules.pdf.

History Note: *Authority G.S. 131E-79;*
Eff. January 1, 1996;
Readopted Eff. April 1, 2019.

10A NCAC 13B .6102 GENERAL

(a) A new facility or any addition or alteration to an existing facility whose construction documents were approved by the Construction Section on or after April 1, 2019 shall comply with the requirements provided in the codes, regulations, rules, and standards incorporated by reference in Rule .6101(1) through (3) of this Section. An existing facility whose construction documents were approved by the Construction Section prior to April 1, 2019 shall comply with the codes, regulations, rules, and standards incorporated by reference in Rule .6101(1) through (3) of this Section that were in effect at the time construction documents were approved by the Construction Section.

(b) The facility shall develop and maintain an emergency preparedness program as required by 42 CFR Part 482.15 Condition of Participation: Emergency Preparedness. The emergency preparedness program shall be developed with input from the local fire department and local emergency management agency. Documentation required to be maintained by 42 CFR Part 482.15 shall be maintained at the facility for at least three years and shall be made available to the Division during an inspection upon request.

(c) The facility shall comply with the "Rules Governing the Sanitation of Hospitals, Nursing Homes, Adult Care Homes, and Other Institutions," 15A NCAC 18A .1300 of the North Carolina Division of Public Health, Environmental Health Services Section.

History Note: *Authority G.S. 131E-79;*
Eff. January 1, 1996;
Readopted Eff. April 1, 2019.

10A NCAC 13B .6103 EQUIVALENCY AND CONFLICTS WITH REQUIREMENTS

(a) The Division may grant an equivalency to allow an alternate design or functional variation from the requirements in Rule .3102 and the Rules contained in Sections .6000 through .6200 of this Subchapter. The equivalency may be granted by the Division if a governing body submits a written equivalency request to the Division that states the following:

(1) the rule citation and the rule requirement that will not be met;
(2) the justification for the equivalency; and
(3) how the proposed equivalency meets the intent of the corresponding rule requirement.

In determining whether to grant an equivalency request the Division shall consider whether the request will reduce the safety and operational effectiveness of the facility design and layout. The governing body shall maintain a copy of the approved equivalence issued by the Division.
(b) If the rules, codes, or standards contained in this Subchapter conflict, the most restrictive requirement shall apply.

History Note: *Authority G.S. 131E-79;*
Eff. January 1, 1996;
Readopted Eff. April 1, 2019.

10A NCAC 13B .6104 ACCESS AND SAFETY

History Note: *Authority G.S. 131E-79;*
Eff. January 1, 1996;
Repealed Eff. January 1, 2018.

10A NCAC 13B .6105 INCORPORATION BY REFERENCE AND APPLICATION OF THE REQUIREMENTS OF THE FGI GUIDELINES

(a) For the purposes of Sections .6000 through .6200 of this Subchapter, the Guidelines for the Design and Construction of Hospitals and Outpatient Facilities shall be referred to as the FGI Guidelines.
(b) The FGI Guidelines are incorporated herein by reference, including all subsequent amendments and editions; however, the following chapters of the FGI Guidelines shall not be incorporated herein by reference:

(1) Chapter 3.1;
(2) Chapter 3.2;
(3) Chapter 3.3;
(4) Chapter 3.4;
(5) Chapter 3.5;
(6) Chapter 3.6;
(7) Chapter 3.7;
(8) Chapter 3.8;
(9) Chapter 3.9;
(10) Chapter 3.10;
(11) Chapter 3.11;
(12) Chapter 3.12; and
(13) Chapter 3.14.

(c) The FGI Guidelines incorporated by this Rule may be purchased from the Facility Guidelines Institute online at https://www.fgiguidelines.org/guidelines-main/purchase/ at a cost of two hundred dollars ($200.00) or accessed electronically free of charge at https://www.fgiguidelines.org/guidelines-main/.
(d) A new facility or any additions or alterations to an existing facility whose construction documents were approved by the Construction Section on or after January 1, 2018 shall meet the requirements set forth in:

(1) Sections .6000 through .6200 of this Subchapter; and
(2) the edition of the FGI Guidelines that was in effect at the time the construction documents were approved by the Construction Section.

(e) An existing facility whose construction documents were approved by the Construction Section prior to January 1, 2018 shall meet those standards established in Sections .6000 through .6200 of this Subchapter that were in effect at the time the construction documents were approved by the Construction Section.
(f) Any existing building converted from another use to a new facility shall meet the requirements of Paragraph (d) of this Rule.
(g) Previous versions of the Rules of Sections .6000 through .6200 of this Subchapter can be accessed online at https://www.ncdhhs.gov/dhsr/const/index.html.

History Note: *Authority G.S. 131E-79; S.L. 2017-174;*
Temporary Adoption Eff. December 1, 2017;
Eff. March 21, 2019.

SECTION .6200 - CONSTRUCTION REQUIREMENTS

10A NCAC 13B .6201 MEDICAL, SURGICAL AND POST-PARTUM CARE UNIT
10A NCAC 13B .6202 SPECIAL CARE UNIT
10A NCAC 13B .6203 NEONATAL LEVEL I AND LEVEL II NURSERY UNIT
10A NCAC 13B .6204 NEONATAL LEVEL III AND LEVEL IV NURSERY
10A NCAC 13B .6205 PSYCHIATRIC UNIT
10A NCAC 13B .6206 SURGICAL DEPARTMENT REQUIREMENTS

History Note: *Authority G.S. 131E-79;*
Eff. January 1, 1996;
Amended Eff. November 1, 2004;
Repealed Eff. January 1, 2018.

10A NCAC 13B .6207 OUTPATIENT SURGICAL FACILITIES
(a) If a facility elects to share outpatient surgical facilities with inpatient surgical facilities, the outpatient operating room and support areas shall meet the requirements set forth in Sections .6000 through .6200 of this Subchapter.
(b) If a facility elects to provide separate, non-sharable outpatient surgical facilities, the operating rooms and support areas shall meet the requirements set forth in 10A NCAC 13C .1400.

History Note: *Authority G.S. 131E-79;*
Eff. January 1, 1996;
Readopted Eff. April 1, 2019.

10A NCAC 13B .6208 OBSTETRICAL DEPARTMENT SERVICES
10A NCAC 13B .6209 EMERGENCY SERVICES
10A NCAC 13B .6210 IMAGING SERVICES
10A NCAC 13B .6211 LABORATORY SERVICES
10A NCAC 13B .6212 MORGUE
10A NCAC 13B .6213 PHARMACY SERVICES
10A NCAC 13B .6214 DIETARY SERVICES
10A NCAC 13B .6215 ADMINISTRATION
10A NCAC 13B .6216 MEDICAL RECORDS SERVICES
10A NCAC 13B .6217 CENTRAL MEDICAL AND SURGICAL SUPPLY SERVICES
10A NCAC 13B .6218 GENERAL STORAGE
10A NCAC 13B .6219 LAUNDRY SERVICES
10A NCAC 13B .6220 PHYSICAL REHABILITATION SERVICES
10A NCAC 13B .6221 ENGINEERING SERVICES
10A NCAC 13B .6222 WASTE PROCESSING
10A NCAC 13B .6223 DETAILS AND FINISHES
10A NCAC 13B .6224 ELEVATOR REQUIREMENTS
10A NCAC 13B .6225 MECHANICAL REQUIREMENTS
10A NCAC 13B .6226 PLUMBING AND OTHER PIPING SYSTEMS REQUIREMENTS
10A NCAC 13B .6227 ELECTRICAL REQUIREMENTS

History Note: *Authority G.S. 131E-79;*
Eff. January 1, 1996;
Amended July 1, 1996;
Repealed Eff. January 1, 2018.

10A NCAC 13B .6228 NEONATAL LEVEL I, II, III, AND IV NURSERIES
A facility that provides neonatal services as specified in Rule .4305 of this Subchapter shall meet the requirements of the FGI Guidelines as follows:

(1) a Neonatal Level I nursery shall comply with the requirements of Sections 2.2-2.12 Nursery Unit and 2.2-2.12.3.1 Newborn Nursery;

(2) a Neonatal Level II nursery shall comply with the requirements of Sections 2.2-2.12 Nursery Unit and 2.2-2.12.3.3 Continuing Care Nursery;

(3) a Neonatal Level III nursery shall comply with the requirements of Section 2.2-2.10 Neonatal Intensive Care Unit; and

(4) a Neonatal Level IV nursery shall comply with the requirements of Section 2.2-2.10 Neonatal Intensive Care Unit.

History Note: *Authority G.S. 131E-79; S.L. 2017-174;*
Temporary Adoption Eff. December 1, 2017;
Eff. March 21, 2019.