

## SUBCHAPTER 13C – LICENSING OF AMBULATORY SURGICAL FACILITIES

### SECTION .0100 – GENERAL

**10A NCAC 13C .0101    RESERVED FOR FUTURE CODIFICATION**

**10A NCAC 13C .0102    RESERVED FOR FUTURE CODIFICATION**

#### **10A NCAC 13C .0103    DEFINITIONS**

In addition to the terms defined in G.S. 131E-214.13, the following terms shall apply throughout this Subchapter, unless the context clearly requires otherwise:

- (1) "Adequate" means, when applied to various areas of services, that the services are satisfactory in meeting a referred to need when measured against professional standards of practice.
- (2) "AAAASF" means American Association for Accreditation of Ambulatory Surgery Facilities.
- (3) "AAAHHC" means Accreditation Association for Ambulatory Health Care.
- (4) "Ancillary nursing personnel" means persons employed to assist registered nurses or licensed practical nurses in the care of patients.
- (5) "Anesthesiologist" means a physician whose specialized training and experience qualify him or her to administer anesthetic agents and to monitor the patient under the influence of these agents. For the purpose of this Subchapter, the term "anesthesiologist" shall not include podiatrists.
- (6) "Anesthetist" means a physician or dentist qualified, as defined in Items (10) and (24) of this Rule, to administer anesthetic agents or a registered nurse qualified, as defined in Items (25) and (27) of this Rule, to administer anesthesia.
- (7) "Authority having jurisdiction" means the Division of Health Service Regulation.
- (8) "Chief executive officer" or "administrator" means a qualified person appointed by the governing authority to act in its behalf in the overall management of the facility and whose office is located in the facility.
- (9) "Current Procedural Terminology (CPT)" means a medical code set developed by the American Medical Association.
- (10) "Dentist" means a person who holds a valid license issued by the North Carolina Board of Dental Examiners to practice dentistry.
- (11) "Department" means the North Carolina Department of Health and Human Services.
- (12) "Director of nursing" means a registered nurse who is responsible to the chief executive officer or administrator and has the authority and direct responsibility for all nursing services and nursing care for the entire facility at all times.
- (13) "Financial assistance" means a policy, including charity care, describing how the organization will provide assistance at its facility. 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 (13)(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.
- (14) "Governing authority" means the individual, agency, group, or corporation appointed, elected, or otherwise designated, in which the ultimate responsibility and authority for the conduct of the ambulatory surgical facility is vested.
- (15) "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.
- (16) "JCAHO" or "Joint Commission" means Joint Commission on Accreditation of Healthcare Organizations.
- (17) "Licensing agency" means the Department of Health and Human Services, Division of Health Service Regulation.
- (18) "Licensed practical nurse (L.P.N.)" means any person licensed as such under the provisions of G.S. 90-171.20(8).
- (19) "Nursing personnel" means registered nurses, licensed practical nurses, and ancillary nursing personnel.

- (20) "Operating room" means a room in which surgical procedures are performed.
- (21) "Patient" means a person admitted to and receiving care in a facility.
- (22) "Person" means an individual, a trust or estate, a partnership or corporation, including associations, joint stock companies and insurance companies; the State, or a political subdivision or instrumentality of the state.
- (23) "Pharmacist" means a person who holds a valid license issued by the North Carolina Board of Pharmacy to practice pharmacy in accordance with G.S. 90-85.3A.
- (24) "Physician" means a person who holds a valid license issued by the North Carolina Medical Board to practice medicine. For the purpose of carrying out these Rules, a "physician" may also mean a person holding a valid license issued by the North Carolina Board of Podiatry Examiners to practice podiatry.
- (25) "Qualified person," when used in connection with an occupation or position, means a person:
  - (a) who has demonstrated through experience the ability to perform the required functions; or
  - (b) who has certification, registration, or other professional recognition.
- (26) "Recovery area" means a room used for the post-anesthesia recovery of surgical patients.
- (27) "Registered nurse" means a person who holds a valid license issued by the North Carolina Board of Nursing to practice nursing as defined in G.S. 90-171.20(7).
- (28) "Surgical suite" means an area that includes one or more operating rooms and one or more recovery rooms.

*History Note: Authority G.S. 131E-149; 131E-214.13; Eff. October 14, 1978; Amended Eff. April 1, 2003; November 1, 1989; Temporary Amendment Eff. December 31, 2014; Amended Eff. September 30, 2015; Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. December 23, 2017.*

## **SECTION .0200 - LICENSING PROCEDURES**

### **10A NCAC 13C .0201 APPLICATION**

(a) A person shall submit an application for a license to establish or maintain an ambulatory surgical facility to the Department in writing on the form provided by the Department. Each application shall contain all necessary and reasonable information that the Department may by rule require, including the following and other pertinent information the Department may deem appropriate to carry out its responsibilities for statistical data collection and long range health planning:

- (1) name of facility,
- (2) address of facility,
- (3) telephone number of facility,
- (4) names of owners,
- (5) names of operator and governing authority,
- (6) name of chief executive officer,
- (7) composition of medical and paramedical staff,
- (8) name of chief of staff,
- (9) director of nursing service,
- (10) number of operating rooms and recovery beds,
- (11) list of surgical procedures to be performed in facility,
- (12) qualification of persons responsible for anesthesia services,
- (13) information regarding use and storage of flammable anesthesia,
- (14) description of laboratory and pathology services,
- (15) name of hospital(s) with which transfer agreement has been made,
- (16) description of arrangements for emergency transportation of patients from the facility,
- (17) description of arrangements for food service, and
- (18) information regarding sanitation inspection and fire inspection.

(b) The person shall make application for a license for a new facility or for the renewal of a license for an existing facility. Applications for licensure for a new facility shall be submitted at least 120 days prior to opening.

(c) Any ambulatory surgical facility desiring licensure which is in operation at the time of promulgation of any applicable rules or regulations shall be given a reasonable time, not to exceed one year from the date of such promulgation, within which to comply with such rules and regulations.

*History Note: Authority G.S. 131E-147; 131E-149;  
Eff. October 14, 1978;  
Amended Eff. November 1, 1989;  
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. December 23, 2017.*

#### **10A NCAC 13C .0202 REQUIREMENTS FOR ISSUANCE OF LICENSE**

(a) Upon application for a license from a facility never before licensed, a representative of the Department shall make an inspection of that facility. Every building, institution, or establishment that has been issued a license shall be inspected for compliance with the rules found in this Subchapter. An ambulatory surgery facility shall be deemed to meet licensure requirements if the ambulatory surgery facility is accredited by The Joint Commission, AAAHC, or AAAASF. Accreditation shall not exempt a facility from statutory or rule requirements for licensure nor shall it prohibit the Department from conducting inspections as provided in this Rule to determine compliance with all requirements.

(b) If the applicant has been issued a Certificate of Need and is found to be in compliance with the rules found in this Subchapter, then the Department shall issue a license to expire on December 31 of each year.

(c) The Department shall be notified at the time of:

- (1) any change of the owner or operator;
- (2) any change of location;
- (3) any change as to a lease; and
- (4) any transfer, assignment, or other disposition or change of ownership or control of 20 percent or more of the capital stock or voting rights thereunder of a corporation that is the operator or owner of an ambulatory surgical facility, or any transfer, assignment, or other disposition of the stock or voting rights thereunder of such corporation that results in the ownership or control of more than 20 percent of the stock or voting rights thereunder of such corporation by any person.

A new application shall be submitted to the Department in the event of such a change or changes.

(d) The Department shall not grant a license until the plans and specifications that are stated in Section .1400 of this Subchapter, covering the construction of new buildings, additions, or material alterations to existing buildings are approved by the Department.

(e) The facility design and construction shall be in accordance with the licensure rules for ambulatory surgical facilities found in this Subchapter, the North Carolina State Building Code, and local municipal codes.

(f) Submission of Plans.

- (1) When construction or remodeling of a facility is planned, one copy of construction documents and specifications shall be submitted by the owner or owner's appointed representative to the Department for review and approval. Schematic design drawings and design development drawings may be submitted for approval prior to the required submission of construction documents.
- (2) Approval of construction documents and specifications shall be obtained from the Department prior to licensure. Approval of construction documents and specifications shall expire one year after the date of approval unless a building permit for the construction has been obtained prior to the expiration date of the approval of construction documents and specifications.
- (3) The plans shall include a plot plan showing the size and shape of the entire site and the location of all existing and proposed facilities.

(g) To qualify for licensure or license renewal, each facility shall provide to the Division, with its application, an attestation statement in a form provided by the Division verifying compliance with the requirements defined in Rule .0301(d) of this Subchapter.

*History Note: Authority G.S. 131E-91; 131E-147; 131E-149;  
Eff. October 14, 1978;  
Amended Eff. April 1, 2003;  
Temporary Amendment Eff. May 1, 2014;  
Amended Eff. November 1, 2014;  
Readopted Eff. January 1, 2021.*

### **10A NCAC 13C .0203   SUSPENSION OR REVOCATION: AMBULATORY SURGICAL FACILITY**

License suspensions and revocations shall be governed by G.S. 131E-148.

*History Note:    Authority G.S. 131E-148; 131E-149; 143B-165;  
                  Eff. October 14, 1978;  
                  Amended Eff. November 1, 1989;  
                  Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. December 23,  
                  2017;  
                  Amended Eff. January 1, 2021.*

### **10A NCAC 13C .0204   TYPE OF FACILITY DEEMED TO BE LICENSED**

An ambulatory surgical facility shall be deemed a suitable facility for the performance of abortions pursuant to G.S. 14-45.1(a).

*History Note:    Authority G.S. 14-45.1; 131E-147; 131E-149;  
                  Eff. June 30, 1980;  
                  Amended Eff. November 1, 1989;  
                  Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. December 23,  
                  2017.*

### **10A NCAC 13C .0205   ITEMIZED CHARGES**

(a) The facility shall either present an itemized list of charges to all discharged patients or 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 facility, collections agency, or other assignee asserts the patient has an obligation to pay the bill.

(b) If requested, the facility shall present an itemized list of charges to each patient or his or her 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 listing shall include each specific chargeable item or service in the following service areas:

- (1)     Surgery (facility fee);
- (2)     Anesthesiology;
- (3)     Pharmacy;
- (4)     Laboratory;
- (5)     Radiology;
- (6)     Prosthetic and Orthopedic appliances; and
- (7)     Other professional services.

(d) The facility shall indicate on the initial or renewal license application that patient bills are itemized, or that each patient or his or her representative is formally advised of the patient's right to request an itemized listing within three years of receipt of a non-itemized bill.

*History Note:    Authority G.S. 131E-91; 131E-147.1; S.L. 2013-382, s. 13.1;  
                  Eff. December 1, 1991;  
                  Temporary Amendment Eff. May 1, 2014;  
                  Amended Eff. November 1, 2014;  
                  Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. December 23,  
                  2017.*

### **10A NCAC 13C .0206   REPORTING REQUIREMENTS**

(a) The Department shall establish the lists of the statewide 20 most common outpatient imaging procedures and 20 most common outpatient surgical procedures performed in the ambulatory surgical facility setting to be used for reporting the data required in Paragraphs (c) and (d) 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 20 most common imaging procedures shall be based upon all outpatient data for 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
  - (2) 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) All information required by 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 ambulatory surgical facilities shall report the data required in Paragraph (d) 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. Each annual report shall be submitted by January 1.
- (d) The report as described in Paragraph (c) of this Rule shall be specific to each reporting ambulatory surgical facility and shall include:
- (1) the average gross charge for each 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 CPT code or procedure as required for patients defined in Subparagraph (d)(1) of this Rule. The average negotiated settlement shall be calculated using the average amount charged all patients eligible for the facility's financial assistance policy, including self-pay patients;
  - (3) the amount of Medicaid reimbursement for each CPT code or procedure, including all supplemental payments to and from the ambulatory surgical facility;
  - (4) the amount of Medicare reimbursement for each 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 CPT code or procedure by each of the facility's top five largest health insurers.
    - (A) each ambulatory surgical facility 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 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 CPT code or procedure; and
    - (E) the identity of the top five largest health insurers shall be redacted prior to submission.
- (e) The data reported, as defined in Paragraphs (c) and (d) 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.
- (f) A minimum of three data elements shall be required for reporting under Paragraph (c) of this Rule.
- (g) The information submitted in the report shall be in compliance with the federal Health Insurance Portability and Accountability Act of 45 CFR Part 164.
- (h) The Department shall provide all specific ambulatory surgical facility data reported pursuant to this Rule on its website.

*History Note: Authority G.S. 131E-147.1; 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 .0300 – GOVERNING AUTHORITY MANAGEMENT**

### **10A NCAC 13C .0301 GOVERNING AUTHORITY**

- (a) The facility's governing authority shall adopt bylaws or other operating policies and procedures to assure that:

- (1) a named individual is identified who is responsible for the overall operation and maintenance of the facility. The governing authority shall have methods in place for the oversight of the individual's performance;
  - (2) annual meetings of the governing authority shall be conducted if the governing authority consists of two or more individuals. Minutes shall be maintained of such meetings;
  - (3) a policy and procedure manual is created that is designed to ensure professional and safe care for the patients. The manual shall be reviewed annually and revised in accordance with facility policy. The manual shall include provisions for administration and use of the facility, compliance, personnel quality assurance, procurement of outside services and consultations, patient care policies, and services offered; and
  - (4) annual reviews and evaluations of the facility's policies, management, and operation are conducted.
- (b) When services such as dietary, laundry, or therapy services are purchased from others, the governing authority shall be responsible for assuring the supplier meets the same local and State standards the facility would have to meet if it were providing those services using its own staff.
- (c) The governing authority shall provide for the selection and appointment of the professional staff and the granting of clinical privileges and shall be responsible for the professional conduct of these persons.
- (d) The governing authority shall establish 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 20 most common outpatient imaging procedures and 20 most common outpatient surgical procedures based on the primary Current Procedure Terminology Code (CPT). 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, 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 ambulatory surgical facility involving the doctrine of necessities, in accordance with G.S. 131E-91(d)(5); and
  - (9) a policy for handling debts arising from the provision of care by the ambulatory surgical facility to a minor, in accordance with G.S. 131E-91(d)(6).

*History Note: Authority G.S. 131E-91; 131E-147.1; 131E-149; 131E-214.13(f); 131E-214.14; Eff. October 14, 1978; Amended Eff. November 1, 1989; November 1, 1985; December 24, 1979; Temporary Amendment Eff. May 1, 2014; Amended Eff. November 1, 2014; Readopted Eff. January 1, 2021.*

#### **10A NCAC 13C .0302 CHIEF EXECUTIVE OFFICER OR ADMINISTRATOR**

- (a) The governing authority shall appoint a qualified person as chief executive officer of the facility to represent the governing authority and shall define his authority and duties in writing. He shall be responsible for the management of the facility, implementation of the policies of the governing authority and authorized and empowered to carry out the provisions of these regulations.
- (b) The chief executive officer shall designate, in writing, a qualified person to act in his behalf during his absence. In the absence of the chief executive officer, the person on the grounds of the facility who is designated by the chief executive officer to be in charge of the facility shall have reasonable access to all areas in the facility related to patient care and to the operation of the physical plant.
- (c) When there is a planned change in ownership or in the chief executive officer, the governing authority of the facility shall notify the Department.

*History Note: Authority G.S. 131E-149;*

*Eff. October 14, 1978;*

*Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. December 23, 2017.*

#### **10A NCAC 13C .0303 ADMINISTRATIVE RECORDS**

(a) The following essential documents and references shall be on file in the administrative office of the facility:

- (1) appropriate documents evidencing control and ownerships, such as deeds, leases, or corporation or partnership papers;
- (2) bylaws of policies and procedures of the governing authority;
- (3) minutes of the governing authority meetings if applicable;
- (4) minutes of the facility's professional and administrative staff meetings;
- (5) a current copy of these regulations;
- (6) reports of inspections, reviews, and corrective actions taken related to licensure; and
- (7) contracts and agreements related to licensure to which the facility is a party.

(b) All operating licenses, permits and certificates shall be appropriately displayed on the licensed premises.

*History Note: Authority G.S. 131E-149;*

*Eff. October 14, 1978;*

*Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. December 23, 2017.*

#### **10A NCAC 13C .0304 SURGICAL PROCEDURES PERFORMED**

A current listing of all types of surgical procedures offered by the facility shall be available.

*History Note: Authority G.S. 131E-149;*

*Eff. October 14, 1978;*

*Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. December 23, 2017.*

#### **10A NCAC 13C .0305 PERSONNEL**

(a) Personnel Records

- (1) A record of each employee shall be maintained which includes the following:
  - (A) employee's identification;
  - (B) resume of education and work experience;
  - (C) verification of valid license (if required), education, training, and prior employment experience; and
  - (D) verification of references.
- (2) Personnel records shall be confidential.
- (3) Notwithstanding the requirement found in Subparagraph (a)(2) of this Rule, representatives of the Department conducting an inspection of the facility shall have the right to inspect personnel records.

(b) Job Descriptions

- (1) Every position shall have a written description which adequately describes the duties of the position.
- (2) Each job description shall include position title, authority, specific responsibilities and minimum qualifications. Qualifications shall include education, training, experience, special abilities and license or certification required.
- (3) Job descriptions shall be reviewed annually, kept current and given to each employee when assigned to the position and whenever the job description is changed.

(c) Orientation shall be provided to familiarize each new employee with the facility, its policies, and job responsibilities.

(d) All persons having direct responsibility for patient care shall be at least 18 years of age. All other employees working in the facility shall be not less than 16 years of age.

(e) The governing authority shall be responsible for insuring health standards for employees which are consistent with recognized professional practices for the prevention and transmission of communicable diseases.

*History Note: Authority G.S. 131E-149;*

*Eff. October 14, 1978;*

*Amended Eff. November 1, 1989; December 24, 1979;  
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. December 23,  
2017.*

#### **10A NCAC 13C .0306 QUALITY ASSURANCE**

(a) The governing authority shall establish a quality assurance program for the purpose of providing standards of care for the facility. The program shall include the establishment of a committee which shall evaluate:

- (1) appropriateness and necessity of surgical procedures performed, and
- (2) compliance with facility procedure and policies.

The committee shall determine corrective action if indicated.

(b) The committee shall consist of at least one physician or dentist (who is not an owner), the chief executive officer (or his designee), and other health professionals as indicated. There shall be at least one meeting of the committee quarterly.

(c) The functions of the committee shall include development of policies for selection of patients, review of credentials for staff privileges, peer review, tissue review, establishment of infection control procedures, and approval of additional surgical procedures to be performed in the facility.

(d) Records shall be kept of the activities of the committee. These records shall include as a minimum:

- (1) reports made to the governing authority;
- (2) minutes of committee meetings including date, time, persons attending, description and results of cases reviewed, and recommendations made by the committee; and
- (3) information on any corrective action taken.

(e) Appropriate orientation, training or education programs shall be conducted as necessary to correct deficiencies which are uncovered as a result of the quality assurance program.

*History Note: Authority G.S. 131E-149;  
Eff. October 14, 1978;  
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. December 23,  
2017.*

### **SECTION .0400 - MEDICAL AND SURGICAL SERVICES**

#### **10A NCAC 13C .0401 MEDICAL SERVICES**

(a) All patients admitted to the facility shall be under the direct care of a physician or dentist.

(b) The facility shall have available an anesthetist and he or she shall be available to administer regional or general anesthesia.

(c) Any patient undergoing general or regional anesthesia shall, prior to surgery, have a history and physical examination, relative to the intended procedure, performed by a licensed physician or a dentist who has successfully completed a postgraduate program in oral and maxillofacial surgery accredited by the American Dental Association. Results of the examination and the preoperative diagnosis shall be recorded in the patient's chart prior to surgery.

(d) The attending physician and dentist, prior to surgery, shall obtain written, informed consent of the patient or legal guardian for surgery and shall record this in the patient's medical record.

(e) The facility shall have the capability of obtaining blood and blood products to meet emergency situations.

*History Note: Authority G.S. 131E-149;  
Eff. October 14, 1978;  
Amended Eff. November 1, 1985;  
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. December 23,  
2017.*

#### **10A NCAC 13C .0402 SURGICAL SERVICES**

(a) The governing authority shall delineate surgical privileges for each physician and dentist performing surgery in accordance with criteria which it has established provided, however, that no physician or dentist may be given privileges to perform surgical procedures for which he or she does not have privileges to perform at the hospital with which the facility has a transfer agreement as provided in Paragraph (a) in Rule .0403 of this Section.

(b) A roster of medical personnel having surgical and anesthesia privileges at the facility specifying the privileges and limitations of each, shall be readily obtainable by the person in charge of the surgical suite.



(c) The administrator or his designee shall maintain a chronological register of all surgical procedures performed. This shall include type of procedure performed, type of anesthesia used, personnel participating, post operative diagnosis and any unusual or untoward occurrence.

*History Note:* Authority G.S. 131E-149;  
Eff. October 14, 1978;  
Amended Eff. April 1, 2003;  
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. December 23, 2017.

#### **10A NCAC 13C .0403 EMERGENCY CASES**

(a) Each facility shall have a written plan for the transfer of emergency cases to a nearby hospital when hospitalization becomes necessary.

(b) There shall be procedures, personnel and suitable equipment to handle medical emergencies which may arise in connection with services provided by the facility.

(c) There shall be a written agreement between the facility and a nearby hospital to facilitate the transfer of patients who are in need of emergency care. A facility which has documentation of its efforts to establish such a transfer agreement with a hospital which provides emergency services and has been unable to secure such an agreement shall be considered to be in compliance with this Rule.

*History Note:* Authority G.S. 131E-149;  
Eff. October 14, 1978;  
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. December 23, 2017.

### **SECTION .0500 - ANESTHESIA SERVICES**

#### **10A NCAC 13C .0501 PROVIDING ANESTHESIA SERVICES**

Only a physician, dentist, qualified anesthetist, or qualified anesthesiologist as defined in Rule .0103 of this Subchapter, shall administer anesthetic agents. Podiatrists shall administer only local anesthesia. The governing authority shall establish written policies and procedures concerning the provision of anesthesia services, including the designation of those persons authorized to administer anesthetics in accordance with State law.

*History Note:* Authority G.S. 131E-149;  
Eff. October 14, 1978;  
Readopted Eff. January 1, 2021.

#### **10A NCAC 13C .0502 EQUIPMENT**

All equipment for the administration of anesthetics shall be readily available, kept clean or sterile, and maintained in good working condition.

*History Note:* Authority G.S. 131E-149;  
Eff. October 14, 1978;  
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. December 23, 2017.

#### **10A NCAC 13C .0503 POST ANESTHESIA NOTE**

Patient's anesthesiologist or anesthetist shall write a post anesthetic follow-up note prior to the patient's discharge. The note shall include the general condition of the patient and any instructions to the patient pertaining to his care and protection.

*History Note:* Authority G.S. 131E-149;  
Eff. October 14, 1978;  
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. December 23, 2017.

**10A NCAC 13C .0504 REQUIREMENT OF PERSON TRAINED IN CPR**

A person with training and experience in cardio-pulmonary resuscitation shall be on the premises of the facility until all surgical patients are discharged.

*History Note: Authority G.S. 131E-149;  
Eff. October 14, 1978;  
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. December 23, 2017.*

**SECTION .0600 - PATHOLOGY SERVICES**

**10A NCAC 13C .0601 PROVISION FOR LABORATORY TESTS**

(a) Each facility shall have the capability of providing or obtaining laboratory tests required in connection with the surgery to be performed.

(b) The governing authority shall establish written policies requiring examination by a pathologist of all surgical specimens except for those types of specimens which the governing authority has determined do not require examination.

*History Note: Authority G.S. 131E-149;  
Eff. October 14, 1978;  
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. December 23, 2017.*

**10A NCAC 13C .0602 DISPOSAL OF WASTE**

Methods for the disposal of pathological waste, contaminated dressings and other similar material shall meet the approval of governing local and state authorities.

*History Note: Authority G.S. 131E-149;  
Eff. October 14, 1978;  
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. December 23, 2017.*

**SECTION .0700 - RADIOLOGY SERVICES**

**10A NCAC 13C .0701 PROVISION FOR RADIOLOGY SERVICES**

Each facility shall have the capability of providing or obtaining diagnostic radiology services in connection with the surgery to be performed.

*History Note: Authority G.S. 131E-149;  
Eff. October 14, 1978;  
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. December 23, 2017.*

**10A NCAC 13C .0702 REGULATIONS FOR PERFORMED SERVICES**

Radiation protection shall be provided in accordance with the rules adopted by the Radiation Protection Commission found in 10A NCAC 15. Records shall be kept of annual checks and calibration of all ionizing radiation therapy equipment used in the facility.

*History Note: Authority G.S. 131E-149;  
Eff. October 14, 1978;  
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. December 23, 2017;  
Amended Eff. January 1, 2021.*

**SECTION .0800 - PHARMACEUTICAL SERVICES**

#### **10A NCAC 13C .0801 DRUG DISPENSING**

The governing authority, with the advice of a registered pharmacist, shall assure that there are appropriate methods, procedures and controls for obtaining, dispensing, and administering drugs and biologicals.

*History Note: Authority G.S. 131E-149;  
Eff. October 14, 1978;  
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. December 23, 2017.*

#### **10A NCAC 13C .0802 REGULATIONS FOR DISPENSING**

When the facility maintains its own pharmaceutical services, it shall comply with applicable regulations adopted by the North Carolina Board of Pharmacy pursuant to General Statute 90-85.

*History Note: Authority G.S. 131E-149;  
Eff. October 14, 1978;  
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. December 23, 2017;  
Amended Eff. September 1, 2019.*

### **SECTION .0900 - NURSING SERVICES**

#### **10A NCAC 13C .0901 NURSING ADMINISTRATION**

(a) The facility shall have an organized nursing Department under the supervision of a director of nursing who is currently licensed as a registered nurse and who has responsibility and accountability for all nursing services.

(b) The director of nursing shall be responsible and accountable to the chief executive officer for:

- (1) provision of nursing services to patients;
- (2) developing a nursing policy and procedure manual and written job descriptions for nursing personnel.

*History Note: Authority G.S. 131E-149;  
Eff. October 14, 1978;  
Amended Eff. December 24, 1979;  
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. December 23, 2017.*

#### **10A NCAC 13C .0902 NURSING PERSONNEL**

(a) Licensed and ancillary nursing personnel shall be on duty to assure that staffing levels meet the nursing needs of patients in the facility and their individual nursing care needs.

(b) At least one registered nurse shall be in the facility during the hours of operation. Nursing personnel shall be assigned to duties consistent with their training and experience.

*History Note: Authority G.S. 131E-149;  
Eff. October 14, 1978;  
Readopted Eff. January 1, 2021.*

### **SECTION .1000 - MEDICAL RECORDS SERVICES**

#### **10A NCAC 13C .1001 MEDICAL RECORD SYSTEM**

The facility shall maintain a medical record system designed to provide readily available information on each patient. The medical record system shall be under the supervision of a designated qualified person.

*History Note: Authority G.S. 131E-149;  
Eff. October 14, 1978;  
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. December 23, 2017.*

### **10A NCAC 13C .1002 INDIVIDUAL PATIENT RECORDS**

(a) Each patient's medical record shall be maintained in accordance with professional standards and shall include at least the following information:

- (1) patient's identification, including name, address, date of birth, next of kin and a patient number;
- (2) admitting diagnosis;
- (3) preoperative history and physical examination pertaining to the procedure to be performed;
- (4) anesthesia report;
- (5) surgeon's operative report;
- (6) anesthesiologist's or anesthesiologist's report if applicable;
- (7) pertinent laboratory, pathology and X-ray reports;
- (8) postoperative orders and follow-up care;
- (9) discharge summary, including discharge diagnosis;
- (10) record of informed consent; and
- (11) physician's, dentist's, and nurse's progress notes.

(b) The administrator shall be responsible for safeguarding information on the medical record against loss, tampering, or use by unauthorized persons.

(c) Medical records shall be the property of the facility and shall not be moved from the premises wherein they are filed except by subpoena or court order.

(d) For licensing purposes the length of time that medical records are to be retained is dependent upon the need for their use in continuing patient care and for legal, research, or educational purposes. This length of time shall not be less than 20 years.

(e) Should a facility cease operation, there shall be an arrangement for preservation of records to insure compliance with these regulations. The Department shall be notified, in writing, concerning the arrangements.

*History Note: Authority G.S. 131E-149;  
Eff. October 14, 1978;  
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. December 23, 2017.*

### **SECTION .1100 - SURGICAL FACILITIES AND EQUIPMENT**

#### **10A NCAC 13C .1101 OPERATING SUITE**

(a) Each operating suite shall be adequately equipped for the types of procedures to be performed.

(b) Each recovery area shall be adequately equipped for the proper care of post anesthesia recovery of surgical patients.

(c) The following equipment shall be available in the operating suite and recovery area:

- (1) cardio-pulmonary resuscitation drugs and intubation equipment,
- (2) cardiac monitor,
- (3) resuscitator including oxygen and suction equipment,
- (4) suitable surgical instruments customarily available for the planned surgical procedure,
- (5) defibrillator, and
- (6) tracheostomy set.

*History Note: Authority G.S. 131E-149;  
Eff. October 14, 1978;  
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. December 23, 2017.*

#### **10A NCAC 13C .1102 CARE OF OPERATING SUITE**

(a) Dry sweeping and dusting shall be prohibited in treatment areas.

(b) Adequate and conveniently located spaces shall be provided for the storage of janitorial supplies and equipment.

*History Note: Authority G.S. 131E-149;  
Eff. October 14, 1978;  
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. December 23, 2017.*

## SECTION .1200 - FUNCTIONAL SAFETY

### 10A NCAC 13C .1201 GENERAL

- (a) The governing authority shall develop written policies and procedures designed to enhance safety within the facility and on its grounds and minimize hazards to patients, staff and visitors.
- (b) The policies and procedures shall include establishment of the following:
- (1) safety rules and practices pertaining to personnel, equipment, gases, liquids, drugs;
  - (2) provisions for reporting and the investigation of accidental events regarding patients, visitors and personnel (incidents) and corrective action taken;
  - (3) provision for dissemination of safety-related information to employees and users of the facility; and
  - (4) provision for syringe and needle storage, handling and disposal.
- (c) Smoking shall be permitted only in designated areas which shall not include patient care and treatment areas.

*History Note: Authority G.S. 131E-149;  
Eff. October 14, 1978;  
Amended Eff. December 24, 1979;  
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. December 23, 2017.*

### 10A NCAC 13C .1202 PREVENTIVE MAINTENANCE

A schedule of preventive maintenance shall be developed for all of the medical and surgical equipment in the facility to assure satisfactory operation when needed.

*History Note: Authority G.S. 131E-149;  
Eff. October 14, 1978;  
Amended Eff. April 1, 2003;  
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. December 23, 2017.*

## SECTION .1300 - CONTROL AND SANITATION

### 10A NCAC 13C .1301 GENERAL

The governing authority shall employ procedures to minimize sources and transmission of infections. Professionally recognized surveillance methods shall be used. The governing authority shall provide space, equipment, and personnel to assure safe and aseptic treatment and protection of all patients and personnel against cross-infection.

*History Note: Authority G.S. 131E-149;  
Eff. October 14, 1978;  
Amended Eff. November 1, 1989;  
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. December 23, 2017.*

### 10A NCAC 13C .1302 STERILIZATION PROCEDURES

- (a) Policies and procedures shall be established in writing for storage, maintenance and distribution of sterile supplies and equipment.
- (b) Sterile supplies and equipment shall not be mixed with unsterile supplies, and shall be stored in dust proof and moisture free units. They shall be properly labeled.
- (c) Sterilizing equipment shall be available and of the necessary type and capacity to sterilize instruments and operating room materials, as well as laboratory equipment and supplies. The sterilizing equipment shall have design control and safety features intact. The accuracy of instrumentation and equipment shall be checked quarterly by any professionally recognized method and periodic calibration and preventive maintenance shall be provided as necessary, and a log maintained.
- (d) The date of expiration shall be marked on all supplies sterilized in the facility.

*History Note: Authority G.S. 131E-149;  
Eff. October 14, 1978;*

*Amended Eff. November 1, 1989;*  
*Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. December 23, 2017.*

#### **10A NCAC 13C .1303 HOUSEKEEPING**

Operating rooms shall be appropriately cleaned in accordance with established written procedures after each operation. Recovery rooms shall be maintained in a clean condition.

*History Note: Authority G.S. 131E-149;*  
*Eff. October 14, 1978;*  
*Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. December 23, 2017.*

#### **10A NCAC 13C .1304 LINEN AND LAUNDRY**

- (a) An adequate supply of clean linen or disposable materials shall be maintained.
- (b) Provisions for proper laundering of linen and washable goods shall be made. Soiled and clean linen shall be handled and stored separately.
- (c) A sufficient supply of cloth or disposable towels shall be available so that a fresh towel can be used after each handwashing. Towels shall not be shared.

*History Note: Authority G.S. 131E-149;*  
*Eff. October 14, 1978;*  
*Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. December 23, 2017.*

#### **10A NCAC 13C .1305 SANITATION**

- (a) All parts of the facility, the premises and equipment shall be kept clean and free of insects, rodents, litter and rubbish.
- (b) All garbage and waste shall be collected, stored and disposed of in a manner designed to prevent the transmission of disease. Containers shall be washed and sanitized before being returned to work areas. Disposable type containers shall not be reused.

*History Note: Authority G.S. 131E-149;*  
*Eff. October 14, 1978;*  
*Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. December 23, 2017.*

### **SECTION .1400 - PHYSICAL PLANT CONSTRUCTION**

#### **10A NCAC 13C .1401 DEFINITIONS**

In addition to the definitions set forth in G.S. 131E-146, the following definitions shall apply in Section .1400 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 .0202 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 an ambulatory surgical facility as defined in G.S. 131E-146.
- (7) "FGI Guidelines" means the Guidelines for Design and Construction of Outpatient Facilities that is incorporated by reference in Rule .1402 of this Section.

*History Note: Authority G.S. 131E-145; 131E-146; 131E-149;*

*Eff. October 14, 1978;*

*Amended Eff. December 24, 1979;*

*Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. December 23, 2017;*

*Amended Eff. January 1, 2020.*

**10A NCAC 13C .1402 LIST OF REFERENCED GUIDELINES, CODES, STANDARDS, AND REGULATION**

(a) 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 2.3;
- (2) Chapter 2.4;
- (3) Chapter 2.5;
- (4) Chapter 2.6;
- (5) Chapter 2.8;
- (6) Chapter 2.10;
- (7) Chapter 2.11;
- (8) Chapter 2.12;
- (9) Chapter 2.13; and
- (10) Chapter 2.14.

Copies of the FGI Guidelines may be purchased from the Facility Guidelines Institute online at <https://www.fgiguideines.org/guidelines-main/purchase/> at a cost of two hundred dollars (\$200.00) or accessed electronically free of charge at <https://www.fgiguideines.org/guidelines-main/>.

(b) For the purposes of the rules of this Section, the following codes, standards, and regulation are incorporated herein by reference including subsequent amendments and editions. Copies of these codes, standards, and regulation 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 <https://shop.iccsafe.org/> at a cost of six hundred sixty-six dollars (\$666.00) or accessed electronically free of charge at <https://shop.iccsafe.org/state-and-local-codes/north-carolina.html>;
- (2) 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 99, Health Care Facilities Code for a cost of seventy-seven dollars (\$77.00);
  - (E) NFPA 101, Life Safety Code for a cost of one hundred and five dollars and fifty cents (\$105.50);
  - (F) NFPA 255, Standard Method of Test of Surface Burning Characteristics of Building Materials for a cost of forty-two dollars (\$42.00);
  - (G) NFPA 407, Standard for Aircraft Fuel Servicing for a cost of forty-nine dollars (\$49.00);
  - (H) NFPA 705, Recommended Practice for a Field Flame Test for Textiles and Films for a cost of forty-two dollars (\$42.00);
  - (I) NFPA 780, Standard for the Installation of Lightning Protection Systems for a cost of sixty-three dollars and fifty cents (\$63.50);
  - (J) NFPA 801, Standard for Fire Protection for Facilities Handling Radioactive Materials for a cost of forty-nine dollars (\$49.00); and
  - (K) Fire Protection Guide to Hazardous Materials for a cost of one hundred and thirty-five dollars and twenty-five cents (\$135.25).
- (3) 42 CFR Part 416.54 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).

*History Note: Authority G.S. 131E-149;  
Eff. October 14, 1978;  
Amended Eff. December 24, 1979;  
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. December 23, 2017;  
Amended Eff. January 1, 2020.*

**10A NCAC 13C .1403 GENERAL AND EMERGENCY PREPAREDNESS**

(a) A new facility or any addition or alterations to an existing facility whose construction documents were approved by the Construction Section on or after July 1, 2020 shall meet the requirements set forth in:

- (1) the rules of this Section; and
- (2) the FGI Guidelines.

(b) An existing facility whose construction documents were approved by the Construction Section prior to July 1, 2020 shall meet those standards established in the rules of this Section that were in effect at the time the construction documents were approved by the Construction Section. Previous versions of the rules of this Section can be accessed online at <https://info.ncdhhs.gov/dhsr/const/index.html>.

(c) The facility shall develop and maintain an emergency preparedness program as required by 42 CFR Part 416.54 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 416.54 shall be maintained at the facility for at least three years and shall be made available to the Division during an inspection upon request.

(d) Any existing building converted from another use to a new facility shall meet the requirements of Paragraph (a) of this Rule.

*History Note: Authority G.S. 131E-149; 42 CFR Part 416.54;  
Eff. October 14, 1978;  
Amended Eff. April 1, 2003;  
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. December 23, 2017;  
Amended Eff. January 1, 2020.*

**10A NCAC 13C .1404 EQUIVALENCY AND CONFLICTS WITH REQUIREMENTS**

(a) The Division may grant an equivalency to allow an alternate design or functional variation from the requirements in the rules contained in this Section. The equivalency may be granted by the Division if a governing body submits a written equivalency request to the Division that indicates the following:

- (1) the rule citation and the rule requirement that will not be met;
- (2) the justification for the equivalency;
- (3) how the proposed equivalency meets the intent of the corresponding rule requirement; and
- (4) a statement by the governing body that the equivalency request will not 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-149;  
Eff. October 14, 1978;  
Amended Eff. November 1, 1989; December 24, 1979;  
Readopted Eff. January 1, 2020.*

**10A NCAC 13C .1405 MECHANICAL REQUIREMENTS**

**10A NCAC 13C .1406 PLUMBING AND OTHER PIPING SYSTEMS**

**10A NCAC 13C .1407 ELECTRICAL REQUIREMENTS**

*History Note: Authority G.S. 131E-149;  
Eff. October 14, 1978;*



*Amended Eff. April 1, 2003; December 24, 1979;  
Repealed Eff. January 1, 2020.*

**10A NCAC 13C .1408    GENERAL**  
**10A NCAC 13C .1409    LIST OF REFERENCED CODES AND STANDARDS**

*History Note:    Authority G.S. 131E-149;  
                      Eff. April 1, 2003;  
                      Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. December 23,  
                      2017;  
                      Repealed Eff. January 1, 2020.*

**10A NCAC 13C .1410    APPLICATION OF PHYSICAL PLANT REQUIREMENTS**

*History Note:    Authority G.S. 131E-149;  
                      Eff. April 1, 2003;  
                      Repealed Eff. January 1, 2020.*

**10A NCAC 13C .1411    ACCESS AND SAFETY**

Projects involving replacement of, alterations of, and additions to existing licensed facilities shall be planned and phased so that construction will minimize disruptions of facility operations. Facility access, exit ways, safety provisions, and building and life safety systems shall be maintained so that the health and safety of the occupants will not be jeopardized during construction. Additional safety and operating measures shall be planned, documented, and executed to compensate for hazards related to construction or renovation activities to maintain an equivalent degree of health, safety, and operational effectiveness to that required by rules, standards, and codes for a facility not under construction or renovation.

*History Note:    Authority G.S. 131E-149;  
                      Eff. April 1, 2003;  
                      Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. December 23,  
                      2017.*