

SUBCHAPTER 13S — LICENSURE OF SUITABLE FACILITIES FOR THE PERFORMANCE OF SURGICAL ABORTIONS

SECTION .0100 — LICENSURE PROCEDURE

10A NCAC 13S .0101 DEFINITIONS

The following definitions will apply throughout this Subchapter:

- (1) "Abortion" means the termination of a pregnancy as defined in G.S 90-21.81(1c).
- (2) "Clinic" means a freestanding facility neither physically attached nor operated by a licensed hospital for the performance of abortions completed during the first 12 weeks of pregnancy.
- (3) "Division" means the Division of Health Service Regulation of the North Carolina Department of Health and Human Services.
- (4) "Emergency Case" is defined as a condition manifesting itself by acute symptoms of sufficient severity, including severe pain, such that the absence of immediate medical attention could reasonably be expected to result in placing the individual's health in serious jeopardy, serious impairment to bodily functions, or serious dysfunction of bodily organs.
- (5) "Gestational age" means the length of pregnancy as indicated by the date of the first day of the last normal monthly menstrual period, if known, or as determined by ultrasound.
- (6) "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 abortion clinic is vested pursuant to Rule .0318 of this Subchapter.
- (7) "Health Care Practitioner" means a physician, nurse practitioner, or physician's assistant licensed and authorized to practice in the state of North Carolina.
- (8) "Health Screening" means an evaluation of an employee or contractual employee, including at a minimum tuberculosis testing or screening, to identify underlying health conditions that may affect the person's ability to work in the clinic.
- (9) "New clinic" means one that is not certified as an abortion clinic by the Division as of July 1, 2023, and has not been certified or licensed within the previous six months of the application for licensure.
- (10) "Pre-procedure activities" are activities performed prior to the procedure to ensure that the patient is stable, and that the procedure can be safely performed.
- (11) "Post-procedure" activities are activities performed after the procedure to ensure that the patient is stable for discharge.
- (12) "Registered Nurse" means a person who holds a valid license issued by the North Carolina Board of Nursing to practice professional nursing in accordance with the Nursing Practice Act, G.S. 90, Article 9A.
- (13) "Safe and adequate care" means care that meets the clinical needs of the patient while preventing harm from occurring to the patient.

History Note: Authority G.S. 131E-153.5; 143B-165;
Codifier determined that findings of need did not meet criteria for emergency rule on October 30, 2023;
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10A NCAC 13S .0104 PLANS AND SPECIFICATIONS

- (a) Prior to issuance of a license pursuant to 10A NCAC 14E .0107, an applicant for a new clinic shall submit one copy of construction documents and specifications to the Division for review and approval consistent with Section .0200 of this Subchapter.
- (b) Any license holder or prospective applicant desiring to make alterations or additions to a clinic or to construct a new clinic, before commencing such alteration, addition or new construction shall submit construction documents and specifications to the Division for review and approval with respect to compliance with this Subchapter.
- (c) 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.

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10A NCAC 13S .0106 APPLICATION

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10A NCAC 13S .0107 ISSUANCE OF LICENSE

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10A NCAC 13S .0109 RENEWAL

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10A NCAC 13S .0111 INSPECTIONS

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10A NCAC 13S .0112 ALTERATIONS

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10A NCAC 13S .0114 APPROVAL

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SECTION .0200 — MINIMUM STANDARDS FOR CONSTRUCTION AND EQUIPMENT

10A NCAC 13S .0201 BUILDING CODE REQUIREMENTS

- (a) All clinics shall be classified for occupancy as Group B pursuant to the North Carolina Building Code.
- (b) All new and existing clinics shall meet the requirements of the North Carolina State Building Codes, as determined by the applicability provisions of the North Carolina Building Code or the North Carolina Existing Building Code.
- (c) The North Carolina Building Codes are hereby incorporated by reference including subsequent amendments and editions. Copies of the North Carolina State Building Codes can be obtained from the International Code Council online at <https://shop.iccsafe.org/catalogsearch/result/?cat=1010&q=+North+Carolina+Building+code> for a cost of eight hundred fifty eight dollars (\$858.00) or accessed electronically free of charge at <https://www.ncosfm.gov/codes/codes-current-and-past>.

History Note: Authority G.S. 131E-153.5; 143B-165;
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10A NCAC 13S .0202 SANITATION

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10A NCAC 13S .0207 AREA REQUIREMENTS

The following areas shall comply with Rule .0212 of this Section, and are minimum requirements for clinics that are licensed by the Division to perform abortions:

- (1) reception and waiting room;
- (2) designated area or areas for pre-procedure and post-procedure activities;
- (3) procedure room;
- (4) a clean area for self-contained secure medication storage complying with security requirements of State and federal laws;
- (5) area compliant with Clinical Laboratory Improvement Amendments (CLIA) requirements, 42 CFR Part 493, including subsequent amendments and additions, which are hereby incorporated by reference, available at <https://www.ecfr.gov/current/title-42/chapter-IV/subchapter-G/part-493> at no cost, in which laboratory testing can be performed;
- (6) separate areas for storage and handling of clean and soiled materials;
- (7) patient toilet;
- (8) personnel toilet facilities;
- (9) janitor's closets;
- (10) space and equipment for assembling, sterilizing and storing medical and surgical supplies;
- (11) storage space for medical records of all media types used by the facility; and
- (12) space for charting, communications, counseling, business functions, and other administrative activities.

History Note: Authority G.S. 131E-153.5; 143B-165;
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10A NCAC 13S .0209 ELEVATOR

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10A NCAC 13S .0210 CORRIDORS

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10A NCAC 13S .0211 DOORS

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10A NCAC 13S .0212 ELEMENTS AND EQUIPMENT

The physical plant shall provide equipment to carry out the functions of the clinic with the following requirements:

- (1) Mechanical requirements.
 - (a) All fans serving exhaust systems shall be located at the discharge end of the system.
 - (b) The ventilation system shall be designed and balanced to provide the pressure relationships detailed in Sub-Item (f) of this Rule.
 - (c) All ventilation or air conditioning systems shall have a minimum of one filter bed with a minimum filter efficiency of a MERV 8.
 - (d) Ventilation systems serving the procedure rooms shall not be tied in with toilets, soiled holding, or janitors' closets if the air is to be recirculated in any manner.
 - (e) Air handling duct systems shall not have duct linings.
 - (f) The following general air pressure relationships to adjacent areas and ventilation rates shall apply:

Area	Pressure Relationship	Minimum Total Air Changes/Hour
Toilets	N	4
Janitor's closet	N	6
Soiled holding	N	6
Clean holding	NR	2

(N = negative pressure NR = No Requirement)
- (2) Plumbing And Other Piping Systems.
 - (a) Piped-in medical gas and vacuum systems, if installed, shall meet the requirements of NFPA-99, category 2 system, which is hereby incorporated by reference including subsequent amendments and editions. Copies of NFPA-99 may be purchased from the

- National Fire Protection Association online at <https://www.nfpa.org/product/nfpa-99-code/p0099code> at a cost of one hundred forty-nine dollars (\$149.00).
- (b) Lavatories and sinks for use by medical personnel shall have the water supply spout mounted so that its discharge point is a minimum distance of ten (10) inches above the bottom of the basin with mixing type fixture valves that can be operated without the use of the hands.
 - (c) Hot water distribution systems shall provide hot water at hand washing facilities at a minimum temperature of 100 degrees F. and a maximum temperature of 116 degrees F.
- (3) Electrical Requirements.
- (a) The facility's paths of egress to the outside shall have at a minimum, listed battery backup lighting units of one and one-half hour capability that will automatically provide at least one foot candle of illumination at the floor in the event needed for a utility or local lighting circuit failure.
 - (b) Electrically operated medical equipment necessary for the safety of the patient shall have, at a minimum, battery backup.
- (4) Buildings systems and medical equipment shall have preventative maintenance conducted as recommended by the equipment manufacturers' or installers' literature to assure operation in compliance with manufacturer's instructions.

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10A NCAC 13S .0315 HOUSEKEEPING

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10A NCAC 13S .0318 GOVERNING AUTHORITY

- (a) The governing authority, as defined in Rule .0101(6) of this Subchapter, shall appoint a chief executive officer or a designee of the clinic to represent the governing authority and shall define his or her authority and duties in writing. This person shall be responsible for the management of the clinic, implementation of the policies of the governing authority, and authorized and empowered to carry out the provisions of these Rules.
- (b) The chief executive officer or designee shall designate, in writing, a person to act on his or her behalf during his or her absence. In the absence of the chief executive officer or designee, the person on the grounds of the clinic who is designated by the chief executive officer or designee to be in charge of the clinic shall have access to all areas in the clinic 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 clinic shall notify the Division in writing of the change.
- (d) The clinic's governing authority shall adopt operating policies and procedures that shall:
 - (1) specify the individual to whom responsibility for operation and maintenance of the clinic is delegated and methods established by the governing authority for holding such individuals responsible;
 - (2) provide for at least annual meetings of the governing authority, for which minutes shall be maintained; and
 - (3) maintain a policies and procedures manual designed to ensure safe and adequate care for the patients which shall be reviewed, and revised when necessary, at least annually, and shall include provisions for administration and use of the clinic, compliance with statutes and rules applicable to clinics including Subchapters 13S and 14E of Title 10A, compliance with a nationally standard

recognized standard of care for infection control, personnel quality assurance, procurement of outside services and consultations, patient care policies, grievance policies, and services offered.

(e) When the clinic contracts with outside vendors to provide services such as laundry or therapy services, the governing authority shall be responsible to assure the supplier meets the same local and State standards the clinic would have to meet if it were providing those services itself using its own staff.

(f) 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.

(g) The governing authority shall be responsible for ensuring the availability of supporting personnel to meet patient needs and to provide safe and adequate treatment.

*History Note: Authority G.S. 131E-153.5; 143B-165;
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10A NCAC 13S .0319 POLICIES AND PROCEDURES AND ADMINISTRATIVE RECORDS

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

- (1) documents evidencing control and ownerships, such as deeds, leases, or incorporation or partnership papers;
- (2) policies and procedures of the governing authority, as required by Rule .0318 of this Section;
- (3) minutes of the governing authority meetings;
- (4) minutes of the clinic's professional and administrative staff meetings;
- (5) a current copy of the rules of this Subchapter;
- (6) reports of inspections, reviews, and corrective actions taken related to licensure; and
- (7) contracts and agreements related to care and services provided by the clinic as a party.

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

(c) The governing authority shall prepare a manual of clinic policies and procedures for use by employees, medical staff, and physicians to assist them in understanding their responsibilities within the organizational framework of the clinic. These shall include:

- (1) patient selection and exclusion criteria;
- (2) clinical discharge criteria;
- (3) emergency protocols as required by Rule .0326;
- (4) policy and procedure for validating the full and true name of the patient;
- (5) policy and procedure for abortion procedures performed at the clinic;
- (6) policy and procedure for the provision of patient privacy in the recovery area of the clinic;
- (7) protocol for determining gestational age as defined in Rule .0101(5) of this Subchapter; and
- (8) protocol for referral of patients declined services by the clinic.

*History Note: Authority G.S. 131E-153.5; 143B-165;
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10A NCAC 13S .0320 ADMISSION AND DISCHARGE

(a) There shall be on the premises throughout all hours of operation an employee authorized to receive patients and make administrative decisions regarding patients. Administrative decisions include all of the decisions related to a patient's care and services, such as admissions, billing, and services provided.

(b) All patients shall be admitted only under the care of a physician who is currently licensed to practice medicine in North Carolina.

(c) Any patient not discharged within 12 hours following the abortion procedure shall be transferred to a hospital licensed pursuant to Chapter 131E, Article 5 of the General Statutes.

(d) Following admission and prior to obtaining the consent for the procedure, representatives of the clinic's management shall provide to each patient the following information:

- (1) a fee schedule and any extra charges routinely applied;
- (2) the name of the attending physician or physicians and hospital admitting privileges. In the absence of admitting privileges a statement documenting that the attending physician or physicians does not have admitting privileges shall be included;
- (3) instructions for post-procedure problems and questions as outlined in Rule .0329(d) of this Section;
- (4) grievance procedures a patient may follow if dissatisfied with the care and services rendered pursuant to the grievance policy as outlined in Rule .0318(d)(3) of this Section; and
- (5) the telephone number for Complaint Intake of the Division.

*History Note: Authority G.S. 131E-153.5; 143B-165;
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10A NCAC 13S .0321 MEDICAL RECORDS

(a) The clinic shall maintain a complete and permanent record for all patients including:

- (1) the date and time of admission and discharge;
- (2) the patient's full and true name;
- (3) the patient's address;
- (4) the patient's date of birth;
- (5) the patient's emergency contact information;
- (6) the patient's diagnoses;
- (7) the fetus's gestational age;
- (8) the patient's condition on admission and discharge;
- (9) a voluntarily-signed consent for each procedure and signature of the physician performing the procedure witnessed by a family member, other patient representative, or facility staff member;
- (10) a copy of the signed 72 hour consent and physician declaration as defined in G.S. 90-21.82;
- (11) the patient's history and physical examination including identification of pre-existing or current illnesses, drug sensitivities or other idiosyncrasies that may impact the procedure or anesthetic to be administered; and
- (12) documentation that indicates all items listed in Rule .0320(d) of this Section were provided to the patient.

(b) The clinic shall record and authenticate by signature, date, and time all other pertinent information such as pre- and post-procedure instructions, laboratory reports, drugs administered, report of abortion procedure, and follow-up instruction, including family planning advice.

(c) If Rh is negative, the clinic shall explain the significance to the patient and shall record the explanation. A written record of the patient's decision shall be a permanent part of her medical record.

(d) An ultrasound examination shall be performed and the results, including gestational age, placed in the patient's medical record for any patient who is scheduled for an abortion procedure.

(e) The clinic shall maintain a daily procedure log of all patients receiving abortion services. This log shall contain at least the following:

- (1) the patient name;
- (2) the estimated gestational age;
- (3) the type of procedure;
- (4) the name of the physician;
- (5) the name of the Registered Nurse on duty; and
- (6) the date and time of procedure.

(f) Medical records shall be the property of the clinic and shall be preserved or retained in the State of North Carolina for a period of not less than 10 years from the date of the most recent discharge, unless the client is a minor, in which case the record must be retained until three years after the client's 18th birthday, regardless of

change of clinic ownership or administration. Such medical records shall be made available to the Division upon request and shall not be removed from the premises where they are retained except by subpoena or court order.

(g) The clinic shall have a written plan for destruction of medical records to identify information to be retained and the manner of destruction to ensure confidentiality of all material.

(h) Should a clinic cease operation, the clinic shall arrange for preservation of records for at least 10 years. The clinic shall send written notification to the Division of these arrangements.

*History Note: Authority G.S. 131E-153.5; 143B-165;
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10A NCAC 13S .0322 PERSONNEL RECORDS

(a) Personnel Records:

- (1) A record of each employee shall be maintained that includes the following:
 - (A) the employee's identification;
 - (B) the application for employment or resume that includes education, training, experience and references; and
 - (C) a copy of a valid license (if required).
- (2) Personnel records shall be confidential.
- (3) Representatives of the Division conducting an inspection of the clinic shall have the right to inspect personnel records.

(b) Job Descriptions:

- (1) The clinic shall have a written description that describes the duties of every position.
- (2) Each job description shall include position title, authority, specific responsibilities, and minimum qualifications. Qualifications shall include education, training, experience, special abilities, and valid license or certification required.
- (3) The clinic shall review annually and, if needed, update all job descriptions. The clinic shall provide the updated job description to each employee or contractual employee assigned to the position.

(c) All persons having direct responsibility for patient care shall be at least 18 years of age.

(d) The clinic shall provide an orientation program to familiarize each new employee or contractual employee with the clinic, its policies, and the employee's job responsibilities.

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

(f) Employee and contractual employee records for health screening as defined in Rule .0101(8) of this Subchapter, education, training, and verification of professional certification shall be available for review by the Division.

*History Note: Authority G.S. 131E-153.5; 143B-165;
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10A NCAC 13S .0323 CLINIC STAFFING

(a) The clinic shall have an organized clinical staff under the supervision of a nursing supervisor who is currently licensed as a Registered Nurse and who has responsibility for all nursing services.

(b) The nursing supervisor shall report to the chief executive officer or designee and shall be responsible for:

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

(c) The clinic shall have the number of licensed and ancillary nursing personnel on duty to assure that staffing levels meet the total nursing needs of patients based on the number of patients in the clinic and their individual nursing care needs.

(d) There shall be at least one Registered Nurse who is currently licensed to practice professional nursing in North Carolina, or other health care practitioner practicing within the scope of their license or certification who is basic life support (BLS) certified and authorized by state laws to administer medications as required for analgesia, nausea, vomiting, or other indications on duty in the clinic at all times patients are in the procedure rooms and recovery area.

History Note: Authority G.S. 131E-153.5; 143B-165;
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10A NCAC 13S .0324 QUALITY ASSURANCE

(a) The governing authority shall establish a quality assurance program for the purpose of providing standards of care for the clinic. The program shall include the establishment of a committee that shall evaluate compliance with clinic procedures and policies.

(b) The committee shall determine corrective action, if necessary to achieve and maintain compliance with clinic procedures and policies.

(c) The committee shall consist of one physician who is not an owner, the chief executive officer or designee, and other health practitioners.

(d) The frequency of meetings and details of data collection shall be defined by the governing authority.

History Note: Authority G.S. 131E-153.5; 143B-165;
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10A NCAC 13S .0325 LABORATORY SERVICES

(a) Each clinic shall have the capability to provide or obtain laboratory tests required in connection with the procedure to be performed, and will perform laboratory tests appropriate to their Clinical Laboratory Improvement Amendments (CLIA) certification.

(b) The governing authority shall establish written policies regarding which surgical specimens require examination by a pathologist.

(c) Each patient shall have laboratory testing as determined to be clinically necessary by the physician, or as required by law. A record of the results of any tests performed will be included in the patient's medical record.

(d) The clinic shall maintain a manual in a location accessible by employees, that meets requirements for the level of clinic's CLIA certification. This includes the procedures, instructions, and manufacturer's instructions for each test procedure performed including:

- (1) sources of reagents, and quality control procedures; and
- (2) information concerning the basis for the listed "normal" ranges.

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10A NCAC 13S .0326 EMERGENCY BACK-UP SERVICES

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

(b) The clinic shall have written protocols, personnel, and equipment to handle medical emergencies as defined above which may arise in connection with services provided by the clinic.

(c) All clinics shall have written emergency case instructions for clinic staff to carry out in the event of an emergency. All clinic personnel shall have access to and be capable of carrying out the clinic's written emergency case instructions:

- (1) Instructions shall be followed in the event of an emergency, any unexpected anesthetic, medical or procedural complications, or other conditions making transfer to an emergency department and/or hospitalization of a patient necessary.
 - (2) The instructions shall include arrangements for immediate contact of emergency medical services when indicated and when advanced cardiac life support is needed.
 - (3) When emergency medical services are not indicated, the instructions shall include procedures for timely escort of the patient to the hospital or to an appropriate licensed health care professional.
- (d) The clinic shall provide intervention for emergency cases. These provisions shall include:
- (1) basic cardio-pulmonary life support;
 - (2) emergency instructions for:
 - (A) administration of intravenous fluids;
 - (B) establishing and maintaining airway support;
 - (C) oxygen administration;
 - (D) utilizing a bag-valve-mask resuscitator with oxygen reservoir; and
 - (E) utilizing an automated external defibrillator.
 - (3) emergency lighting available in the procedure room as set forth in Rule .0212 of this Subchapter; and
 - (4) ultrasound equipment.

History Note: Authority G.S. 131E-153.5; 143B-165;
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10A NCAC 13S .0327 OUTPATIENT PROCEDURAL SERVICES

(a) The clinic shall establish procedures for infection control and universal precautions, including cleaning of all patient care areas including procedure rooms.

(b) Tissue Examination:

- (1) The physician performing the abortion is responsible for examination of all products of conception (P.O.C.) prior to patient discharge. Such examination shall note specifically the presence or absence of chorionic villi and fetal parts, or the amniotic sac. The results of the examination shall be recorded in the patient's medical record.
- (2) If adequate tissue is not obtained based on the gestational age, the physician performing the procedure shall evaluate for ectopic pregnancy, or an incomplete procedure.
- (3) The clinic shall establish procedures for obtaining, identifying, storing, and transporting specimens.

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10A NCAC 13S .0328 MEDICATIONS AND SEDATION

(a) No medication or treatment shall be given except on written order of a physician.

(b) Medications, including injections shall be administered by a physician, Registered Nurse, and other health care practitioners practicing within the scope of their license or certification authorized by state laws to administer medications. All medications shall be recorded in the patient's permanent record.

(c) The sedation shall be administered only under the direct supervision of a licensed physician. Direct supervision means the physician must be present in the clinic and immediately available to furnish assistance and direction throughout the administration of the sedation. It does not mean the physician must be present in the room when the sedation is administered.

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Eff. October 1, 2024.

10A NCAC 13S .0329 POST PROCEDURAL CARE

- (a) A patient whose pregnancy is terminated shall be observed in the clinic to ensure that no post procedural complications are present. Thereafter, patients may be discharged according to a physician's order and the clinic's protocols.
- (b) Any patient having a complication known or suspected to have occurred during or after the performance of the abortion shall be transferred to a hospital for evaluation or admission.
- (c) The following criteria shall be documented prior to discharge:
 - (1) the patient shall be able to move independently with a stable blood pressure and pulse; and
 - (2) bleeding and pain are assessed to be stable and not a concern for discharge.
- (d) Written instructions shall be issued to all patients in accordance with the orders of the physician in charge of the abortion procedure and shall include the following:
 - (1) symptoms and complications to be looked for; and
 - (2) a dedicated telephone number to be used by the patients should any complication occur or question arise. This number shall be answered by a person 24 hours a day, seven days a week.
- (e) The clinic shall have a defined protocol for triaging post-operative calls and complications. This protocol shall establish a pathway for physician contact to ensure ongoing care of complications that the clinic's physician is incapable of managing.

History Note: Authority G.S. 131E-153.5; 143B-165;
Codifier determined that findings of need did not meet criteria for emergency rule on October 30, 2023;
Emergency Rule Eff. November 14, 2023;
Temporary Adoption Eff. February 8, 2024;
Eff. October 1, 2024.

10A NCAC 13S .0330 CLEANING OF MATERIALS AND EQUIPMENT

- (a) All supplies and equipment used in patient care shall be cleaned or sterilized between use for different patients.
- (b) Methods of cleaning, handling, and storing all supplies and equipment shall be such as to prevent the transmission of infection through their use as determined by the clinic through their governing authority.

History Note: Authority G.S. 131E-153.5; 143B-165;
Codifier determined that findings of need did not meet criteria for emergency rule on October 30, 2023;
Emergency Rule Eff. November 14, 2023;
Temporary Adoption Eff. February 8, 2024;
Eff. October 1, 2024.

10A NCAC 13S .0331 FOOD SERVICE

Nourishments, such as crackers and soft drinks, shall be available and offered to all patients.

History Note: Authority G.S. 131E-153.2; 131E-153.5; 143B-165;
Codifier determined that findings of need did not meet criteria for emergency rule on October 30, 2023;
Emergency Rule Eff. November 14, 2023;

*Temporary Adoption Eff. February 8, 2024;
Eff. October 1, 2024.*