

Note from the Codifier: The OAH website includes notices and the text of proposed temporary rules as required by G.S. 150B-21.1(a1). Prior to the agency adopting the temporary rule, the agency must hold a public hearing no less than five days after the rule and notice have been published and must accept comments for at least 15 business days.
For questions, you may contact the Office of Administrative Hearings at 984-236-1850 or email oah.postmaster@oah.nc.gov.

TITLE 10A – DEPARTMENT OF HEALTH AND HUMAN SERVICES

Notice is hereby given in accordance with G.S. 150B-21.1 that the Medical Care Commission intends to adopt the rules cited as 10A NCAC 13S .0101, .0104, .0106, .0107, .0109, .0111, .0112, .0114, .0201, .0202, .0207, .0209-.0212, .0315, and .0318-.0331.

Codifier of Rules received for publication the following notice and proposed temporary rules on: October 30, 2023.

Public Hearing:

Date: November 14, 2023

Time: 1:00 p.m.

Location: Williams Building, Room 123B, 1800 Umstead Drive, Dorothea Dix Campus, Raleigh, NC 27603

Reason for Proposed Temporary Action: A serious and unforeseen threat to the public health, safety or welfare. The effective date of a recent act of the General Assembly or of the U.S. Congress, cite: SL2023-14, Part I, Section 1.1 and Part II, Section 2.4, effective date: July 1, 2023. On May 16, 2023, Senate Bill 20 became law as S.L. 2023-14. This new law entitled “An Act to Make Various Changes to Health Care Laws and to Appropriate Funds for Health Care Programs” made revisions to various state laws governing abortions in North Carolina. Effective October 1, 2023, the North Carolina Medical Care Commission was authorized to “adopt, amend, and repeal all rules necessary for the implementation” of Part II of S.L. 2023-14. Current rules governing the certification of abortion clinics are found in Subchapter 14E of Title 10A of the Administrative Code. However, the Rules Review Commission objected to the presence of those rules as adopted by the Department of Health and Human Services, Division of Health Services Regulation on the basis of a lack of statutory authority. The consequence of that determination is that the existing rules governing abortion clinics are at imminent risk of being removed from the Administrative Code. The adoption of emergency rules will ensure continuity of care for patients, will resolve any uncertainty about the rules applicable to impacted providers from October 1st until the Medical Care Commission is able to promulgate temporary or permanent rules, and will protect the health and safety of people obtaining reproductive health care. Therefore, the Medical Care Commission seeks to adopt Subchapter 13S of Title 10A under emergency procedures.

Comment Procedures: Comments from the public shall be directed to: Taylor Corpening, 809 Ruggles Drive; 2701 Mail Service Center, Raleigh, NC 27699; email dhsr.rulescoordinator@dhhs.nc.gov. The comment period begins November 13, 2023 and ends December 6, 2023.

CHAPTER 13 - NC MEDICAL CARE COMMISSION

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) "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.
- (5) "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.
- (6) "Health Screening" means an evaluation of an employee or contractual employee, including tuberculosis testing, to identify any underlying conditions that may affect the person's ability to work in the clinic.
- (7) "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.
- (8) "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.

Authority G.S. 131E-153; 131E-153.5; 143B-165.

10A NCAC 13S .0104 PLANS

Prior to issuance of a license pursuant to Rule .0107 of this Section, an applicant for a new clinic shall submit two copies of the building plans to the Division. When the clinic requires a review by the Division and the Department of Insurance, according to the North Carolina State Building Code, 2018 edition, including subsequent amendments and editions. Copies of the Code are available from the International Code Council at <https://codes.iccsafe.org/content/NCAPC2018/chapter-1-administrative-code> at no cost. When the local jurisdiction has authority from the North Carolina Building Code Council to review the plans, the clinic shall submit only one copy of the plans to the Division. In that case, the clinic shall submit an additional set of plans directly to the local jurisdiction.

Authority G.S. 131E-153; 131E-153.5; 143B-165.

10A NCAC 13S .0106 APPLICATION

(a) Prior to the admission of patients, an applicant for a new clinic shall submit an application for licensure and receive approval from the Division.

(b) Application forms may be obtained by contacting the Division at 2712 Mail Service Center Raleigh, NC 27699-2712.

(c) The application form shall set forth:

- (1) Name of applicant;
- (2) Name of facility;
- (3) Ownership disclosure;
- (4) Building owner;
- (5) Building owner;
- (6) Building management;
- (7) Sanitation services;
- (8) Medical director;
- (9) Other medical staff;
- (10) Director of nursing;
- (11) Other nursing staff; and
- (12) Consulting pathologist.

(d) After construction requirements in Section .0200 of this Subchapter have been met and the application for licensure has been received and approved, the Division shall conduct an on-site, licensure survey.

Authority G.S. 131E-153; 131E-153.2; 131E-153.5; 143B-165.

10A NCAC 13S .0107 ISSUANCE OF LICENSE

(a) The Division shall issue a license if it finds the facility can:

- (1) Comply with all requirements described in this Subchapter; and
- (2) Have a board certified OB-GYN or board eligible physician by the American Board of Obstetrics and Gynecology shall be available in the event that complications arise from an abortion procedure.

(b) Each license shall be issued only for the premises and persons or organizations named in the application and shall not be transferable.

(c) The governing authority shall notify the Division in writing, within 10 working days, of any change in the name of the facility or change in the name of the administrator.

(d) The facility shall report to the Division all incidents, within 10 working days, of vandalism to the facility such as fires, explosions, or other action that prevents services from providing abortion services.

Authority G.S. 131E-153; 131E-153.2; 131E-153.5; 143B-165.

10A NCAC 13S .0109 RENEWAL

(a) Each license, renewed at the beginning of each calendar year.

(b) The renewal application form shall set forth:

- (1) Name of applicant;
- (2) Name of facility;
- (3) Ownership disclosure;
- (4) Building owner;
- (5) Building owner;
- (6) Building management;
- (7) Sanitation services;
- (8) Medical director;
- (9) Other medical staff;
- (10) Director of nursing;
- (11) Other nursing staff;
- (12) Consulting pathologist;
- (13) The number of procedures performed during the reporting period; and
- (14) The number of patients that were transferred to a hospital during a reporting period.

(c) Upon the filing of a renewal application, the clinic must pay a non-refundable renewal fee as defined in G.S. 131E-153.2.

(d) An application for renewal of licensure must be filed with the Division at least 30 days prior to the date of expiration. Renewal application forms shall be furnished by the Division.

(e) Failure to file a renewal application shall result in expiration of the license to operate.

Authority G.S. 131E-153; 131E-153.2; 131E-153.5; 143B-165.

10A NCAC 13S .0111 INSPECTIONS

(a) Any clinic licensed by the Division to perform abortions shall be inspected by representatives of the Division annually and as it may deem necessary as a condition of holding such license. An inspection may be conducted whenever the Division receives a complaint alleging the clinic is not in compliance with the rules of the Subchapter.

(b) Representatives of the Division shall make their identities known to the clinic staff prior to inspection of the clinic.

(c) Representatives of the Division may review any records in any medium necessary to determine compliance with the rules of this Subchapter. The Department shall maintain the confidentiality of the complainant and the patient, unless otherwise required by law.

(d) The clinic shall allow the Division to have immediate access to its premises and the records necessary to conduct an inspection and determine compliance with the rules of this Subchapter.

(e) A clinic shall file a written plan of correction for cited deficiencies within 10 business days of receipt of the report of the survey. The Division shall review and respond to a written plan of correction within 10 business days of receipt of the corrective action plan.

Authority G.S. 131E-153; 131E-153.2; 131E-153.5; 131E-153.6; 143B-165.

10A NCAC 13S .0112 ALTERATIONS

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 plans and specifications to the Division for preliminary inspection and approval or recommendations with respect to compliance with this Subchapter.

Authority G.S. 131E-153; 131E-153.5; 143B-165.

10A NCAC 13S .0114 APPROVAL

(a) Approval of building plans shall be obtained from the Division of Health Service Regulation, in accordance with the rules in Section .0200 of this Subchapter.

(b) Approval of building plans 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 building plans.

Authority G.S. 131E-153; 131E-153.5; 143B-165.

SECTION .0200 - MINIMUM STANDARDS FOR CONSTRUCTION AND EQUIPMENT

10A NCAC 13S .0201 BUILDING CODE REQUIREMENTS

(a) The physical plant for a clinic shall meet or exceed minimum requirements of the North Carolina State Building Code for Group B occupancy (business office facilities) which is incorporated herein by reference including subsequent amendments and editions. Copies of the Code can be obtained from the International Code Council online at <http://shop.iccsafe.org/north-carolina-doi.discounts?ref=NC> for a cost of five hundred twenty-seven dollars (\$527.00) or accessed electronically free of charge at <https://codes.iccsafe.org/content/NCAPC2018/chapter-1-administrative-code>.

(b) The requirements contained in this Section shall apply to new clinics and to any alterations, repairs, rehabilitation work, or additions which are made to a previously licensed facility.

Authority G.S. 131E-153; 131E-153.5; 143B-165.

10A NCAC 13S .0202 SANITATION

Clinics that are licensed by the Division to perform abortions shall comply with the Rules governing the sanitation of hospitals, nursing homes, adult care homes, and other institutions, contained in 15A NCAC 18A .1300 which is hereby incorporated by reference including subsequent amendments and editions. Copies of 15A NCAC 18A .1300 may be obtained at no charge from the Division of Public Health, Environmental Health Section, 1632 Mail Service Center, Raleigh, NC 27699-1632, or accessed electronically free of charge from the Office of Administrative Hearings at <https://reports.oah.state.nc.us/ncac.asp>.

Authority G.S. 131E-153; 131E-153.5; 143B-165.

10A NCAC 13S .0207 AREA REQUIREMENTS

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

- (1) receiving area;
- (2) examining room;
- (3) preoperative preparation and holding room;
- (4) individual patient locker facilities or equivalent;
- (5) procedure room;
- (6) recovery room;
- (7) clean workroom;
- (8) soiled workroom;

- (9) a clean area for self-contained secure medication storage complying with security requirements of state and federal laws is provided;
- (10) separate and distinct areas for storage and handling of clean and soiled linen;
- (11) patient toilet;
- (12) personnel lockers and toilet facilities;
- (13) laboratory;
- (14) nourishment station with storage and preparation area for serving meals or in-between meal snacks;
- (15) janitor's closets;
- (16) adequate space and equipment for assembling, sterilizing and storing medical and surgical supplies;
- (17) storage space for medical records; and
- (18) office space for nurses' charting, doctors' charting, communications, counseling, and business functions.

Authority G.S. 131E-153; 131E-153.5; 143B-165.

10A NCAC 13S .0209 ELEVATOR

- (a) In multi-story buildings, the clinic shall provide at least one elevator for patient use.
- (b) At least one dimension of the elevator cab shall be six and one-half feet to accommodate stretcher patients.
- (c) The elevator door shall have an opening of no less than three feet in width, which is minimum for stretcher use.

Authority G.S. 131E-153; 131E-153.5; 143B-165.

10A NCAC 13S .0210 CORRIDORS

The width of patient use corridors shall be no less than 60 inches.

Authority 131E-153; 131E-153.5; 143B-165.

10A NCAC 13S .0211 DOORS

Minimum width of doors to all rooms needing access for stretchers shall be three feet. No door shall swing into corridors in a manner that might obstruct traffic flow or reduce the required corridor width except doors to spaces not subject to occupancy.

Authority 131E-153; 131E-153.5; 143B-165.

10A NCAC 13S .0212 ELEMENTS AND EQUIPMENT

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

- (1) Mechanical requirements.
 - (a) Temperatures and humidities:
 - (i) The mechanical systems shall be designed to provide the temperature and humidities shown in this Sub-Item:

Area	Temperature	Relative Humidity
Procedure	70-76 degrees F.	50-60%
Recovery	75-80 degrees F.	30-60%
 - (b) All air supply and exhaust systems for the procedure suite and recovery area shall be mechanically operated. All fans serving exhaust systems shall be located at the discharge end of the system. The ventilation rates shown herein shall be considered as minimum acceptable rates.
 - (i) The ventilation system shall be designed and balanced to provide the pressure relationships detailed in Sub-Item (b)(vii) of this Rule.
 - (ii) All air supplied to procedure rooms shall be delivered at or near the ceiling of the room and all exhaust or return from the area shall be removed near the floor level at not less than three inches above the floor.
 - (iii) Corridors shall not be used to supply air to or exhaust air from any procedure or recovery room except to maintain required pressure relationships.
 - (iv) All ventilation or air conditioning systems serving procedure rooms shall have a minimum of one filter bed with a minimum filter efficiency of 80 percent.
 - (v) Ventilation systems serving the procedure or recovery rooms shall not be tied in with the soiled holding or work rooms, janitors' closets, or locker rooms if the air is to be recirculated in any manner.
 - (vi) Air handling duct systems shall not have duct linings.
 - (vii) The following general air pressure relationships to adjacent areas and ventilation rates shall apply:

Area	Pressure Relationship	Minimum Air Changes/Hour
Procedure	P	6
Recovery	P	6
Soiled work, Janitor's closet, Toilets,		
Soiled holding	N	10

- (2) Plumbing And Other Piping Systems.
- (a) Medical Gas and Vacuum Systems
- (i) Piped-in medical gas and vacuum systems, if installed, shall meet the requirements of NFPA-99-2012, category 1 system, which is hereby incorporated by reference including subsequent amendments and editions. Copies of NFPA-99-2012 may be purchased from the National Fire Protection Association, 1 Batterymarch Park, P.O. Box 9101, Quincy, MA 02269-9101, or accessed electronically free of charge at <http://www.nfpa.org>.
- (ii) The facility must meet the inhalation anesthesia requirements of NFPA 70-2020 and NFPA 99-2021, which are hereby incorporated by reference including subsequent amendments and editions. Copies of NFPA 70-2011 and NFPA 99-2012 may be purchased from the National Fire Protection Association, 1 Batterymarch Park, P.O. Box 9101, Quincy, MA 02269-9101, or accessed electronically free of charge at <http://www.nfpa.org>.
- (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 five inches above the rim of the fixture 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 and bathing facilities at a minimum temperature of 100 degrees F. and a maximum temperature of 116 degrees F.
- (d) Floor drains shall not be installed in procedure rooms.
- (e) Building drainage and waste systems shall be designed to avoid installations in the ceiling directly above procedure rooms.
- (3) Electrical Requirements.
- (a) Procedure and recovery rooms, and paths of egress from these rooms 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 five foot candles 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.
- (c) Receptacles located within six feet of sinks or lavatories shall be ground-fault protected.
- (d) At least one wired-in, ionization-type smoke detector shall be within 15 feet of each procedure or recovery room entrance.
- (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.

Authority G.S. 131E-153; 131E-153.5; 143B-165.

SECTION .0300 – SERVICES

10A NCAC 13S .0315 HOUSEKEEPING

In addition to the standards set forth in Rule .0202 of this Subchapter, clinics that are licensed by the Division to perform abortions shall meet the following standards:

- (1) the floors, walls, woodwork, and windows must be cleaned at least daily;
- (2) the premises must be kept free from rodents and insect infestation;
- (3) bath and toilet facilities must be maintained in a clean and sanitary condition consistent with 15A NCAC 18A .1312;
and
- (4) linen that comes directly in contact with the patient shall be provided for each individual patient. No such linen shall be interchangeable from one patient to another before being cleaned, sterilized, or laundered.

Copies of 15A NCAC 18A .1300 may be obtained at no charge from the Division of Public Health, Environmental Health Section, 1632 Mail Service Center, Raleigh, NC, 27699-1632, or accessed electronically free of charge from the Office of Administrative Hearings at <https://www.oah.nc.gov/>.

Authority G.S. 131E-153; 131E-153.5; 143B-165.

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, personnel quality assurance, procurement of outside services and consultations, patient care 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.

Authority G.S. 131E-153; 131E-153.5; 143B-165.

10A NCAC 13S .0319 POLICIES AND PROCEDURES AND ADMINISTRATIVE RECORDS

(a) The following essential 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 is 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 contractual 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) policy and procedure for validating the full and true name of the patient;
- (4) policy and procedure for abortion procedures performed at the clinic;
- (5) policy and procedure for the provision of patient privacy in the recovery area of the clinic;
- (6) protocol for determining gestational age as defined in Rule .0101(5) of this Subchapter;
- (7) protocol for referral of patients for whom services have been declined; and
- (8) protocol for discharge instructions that informs patients who to contact for post-procedural problems and questions.

Authority G.S. 131E-153; 131E-153.5; 143B-165.

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.

(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, if any. In the absence of admitting privileges a statement to that effect 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; and
- (5) the telephone number for Complaint Intake of the Division.

Authority G.S. 131E-153; 131E-153.5; 143B-165.

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 patient's duration of pregnancy;
 - (8) the patient's condition on admission and discharge;
 - (9) a voluntarily-signed consent for each surgery or procedure and signature of the physician performing the procedure witnessed by a family member, other patient representative, or facility staff member;
 - (10) 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
 - (11) 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. The patient in writing may reject Rh immunoglobulin. A written record of the patient's decision shall be a permanent part of her medical record.
- (d) An ultrasound examination shall be performed by a technician qualified in ultrasonography 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 length of gestation;
 - (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.

Authority G.S. 131E-153; 131E-153.5; 143B-165.

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 that includes education, training, experience and references;
 - (C) a resume of education and work experience;
 - (D) a copy of a valid license (if required), education, training, and prior employment experience; and
 - (E) a list of references.
 - (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(7) of this Subchapter, education, training, and verification of professional certification shall be available for review by the Division.

Authority G.S. 131E-153; 131E-153.5; 143B-165.

10A NCAC 13S .0323 NURSING SERVICE

- (a) The clinic shall have an organized nursing 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 with experience in post-operative or post-partum care who is currently licensed to practice professional nursing in North Carolina on duty in the clinic at all times patients are in the clinic.

Authority G.S. 131E-153; 131E-153.5; 143B-165.

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 at least one physician who is not an owner, the chief executive officer or designee, and other health professionals. The committee shall meet at least once per quarter.
- (d) The functions of the committee shall include development of policies for selection of patients, approval for adoption of policies, review of credentials for staff privileges, peer review, tissue inspection, establishment of infection control procedures, and approval of additional procedures to be performed in the clinic.
- (e) Records shall be kept of the activities of the committee for a period not less than 10 years. These records shall include:
- (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.
- (f) The clinic shall conduct orientation, training, or education programs to correct deficiencies that are uncovered as a result of the quality assurance program.

Authority G.S. 131E-153; 131E-153.5; 143B-165.

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.
- (b) The governing authority shall establish written policies regarding which surgical specimens require examination by a pathologist.
- (c) Each patient shall have the following performed and a record of the results placed in the patient's medical record prior to the abortion:
- (1) pregnancy testing, except when a positive diagnosis of pregnancy has been established by ultrasound;
 - (2) anemia testing (hemoglobin or hematocrit); and
 - (3) Rh factor testing.
- (d) Patients requiring the administration of blood shall be transferred to a local hospital having blood bank facilities.
- (e) The clinic shall maintain a manual in a location accessible by employees, that includes the procedures, instructions, and manufacturer's instructions for each test procedure performed, including:
- (1) sources of reagents, standard and calibration procedures, and quality control procedures; and
 - (2) information concerning the basis for the listed "normal" ranges.
- (f) The clinic shall perform and document, at least quarterly, calibration of equipment and validation of test results.

Authority G.S. 131E-153; 131E-153.5; 143B-165.

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. 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.
- (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) The clinic shall have a written agreement between the clinic and a hospital to facilitate the transfer of patients who are in need of emergency care. A clinic that has documentation of its efforts to establish such a transfer agreement with a hospital that provides emergency services and has been unable to secure such an agreement shall be considered to be in compliance with this Rule.
- (d) The clinic shall provide intervention for emergency situations. These provisions shall include:
- (1) basic cardio-pulmonary life support;
 - (2) emergency protocols 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;
 - (E) utilizing a suction machine; and
 - (F) 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.

Authority G.S. 131E-153; 131E-153.5; 143B-165.

10A NCAC 13S .0327 SURGICAL SERVICES

(a) The procedure room shall be maintained exclusively for surgical procedures and shall be so designed and maintained to provide an environment free of contamination. The clinic shall establish procedures for infection control and universal precautions.

(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.

Authority G.S. 131E-153; 131E-153.5; 143B-165.

10A NCAC 13S .0328 MEDICATIONS AND ANESTHESIA

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

(b) Any medications shall be administered by a physician or Registered Nurse and shall be recorded in the patient's permanent record.

(c) The anesthesia 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 anesthesia. It does not mean the physician must be present in the room when the anesthesia is administered.

Authority G.S. 131E-153; 131E-153.5; 143B-165.

10A NCAC 13S .0329 POST-OPERATIVE CARE

(a) A patient whose pregnancy is terminated shall be observed in the clinic to ensure that no post-operative 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 operating physician is incapable of managing.

Authority G.S. 131E-153; 131E-153.5; 143B-165.

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.

Authority G.S. 131E-153; 131E-153.5; 143B-165.

10A NCAC 13S .0331 FOOD SERVICE

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

Authority G.S. 131E-153; 131E-153.2; 131E-153.5; 143B-165.