

SUBCHAPTER 14E - CERTIFICATIONS OF CLINICS FOR ABORTION

SECTION .0100 - CERTIFICATION PROCEDURE

10A NCAC 14E .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(1).
- (2) "Clinic" means a freestanding facility (a facility neither physically attached nor operated by a licensed hospital) for the performance of abortions completed during the first 20 weeks of pregnancy.
- (3) "Complication" includes but is not limited to hemorrhage, infection, uterine perforation, cervical laceration, or retained products of conception.
- (4) "Division" means the Division of Health Service Regulation of the North Carolina Department of Health and Human Services.
- (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 .0302 of this Subchapter.
- (7) "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.
- (8) "New clinic" means one that is not certified as an abortion clinic by the Division as of July 1, 2014, and has not been certified within the previous six months of the application for certification.
- (9) "Qualified Physician" means a licensed physician who advises, procures, or causes a miscarriage or abortion as defined in G.S. 14-45.1(g).
- (10) "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.

History Note: Authority G.S. 14-45.1(a); 14-45.1(g); 143B-10; S.L. 2013-366, s. 4(c);
Eff. February 1, 1976;
Readopted Eff. December 19, 1977;
Amended Eff. October 1, 2015; July 1, 1994; December 1, 1989; June 30, 1980.

10A NCAC 14E .0102 CONFERENCE

Before proceeding with construction and operational plans, a potential sponsor or owner of a freestanding abortion clinic shall discuss with the staff of the Division of Health Service Regulation the scope of the proposed facility. This will provide an opportunity for the owner and the Division's staff to discuss certification requirements.

History Note: Authority G.S. 14-45.1(a); 143B-10;
Eff. February 1, 1976;
Readopted Eff. December 19, 1977.

10A NCAC 14E .0103 CHANGES

All stages of the plans from schematics through working drawings shall be reviewed by the Division's staff each time a change is made.

History Note: Authority G.S. 14-45.1(a); 143B-10;
Eff. February 1, 1976;
Readopted Eff. December 19, 1977.

10A NCAC 14E .0104 PLANS

Prior to issuance of a certificate pursuant to Rule .0107 of this Section, a clinic shall submit two copies of the building plans to the Division for certification purposes when the clinic requires a review by the Division and the Department of Insurance, according to the North Carolina Administration and Enforcement Requirements Code, 2012 edition, including subsequent amendments and editions. Copies of the North Carolina Administration Code

are available from the International Code Council at http://www.ecodes.biz/ecodes_support/Free_Resources/2012NorthCarolina/12NorthCarolina_main.html 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.

History Note: Authority G.S. 14-45.1(a); 143B-10;
Eff. February 1, 1976;
Readopted Eff. December 19, 1977;
Amended Eff. October 1, 2015.

10A NCAC 14E .0105 APPROVAL

Approval from the Division of Health Service Regulation, the Division of Environmental Health, and the Department of Insurance should be obtained before construction is commenced.

History Note: Authority G.S. 14-45.1(a); 143B-10;
Eff. February 1, 1976;
Readopted Eff. December 19, 1977;
Amended Eff. December 1, 1989.

10A NCAC 14E .0106 APPLICATION

- (a) Prior to the admission of patients, an application from the clinic for certification shall be submitted to and approved by the Division.
- (b) Application forms may be obtained by contacting the Division.
- (c) The application form shall set forth the ownership, staffing patterns, clinical services to be rendered, professional staff in charge of services, and general information that would be helpful to the Division's understanding of the clinic's operating program.
- (d) After construction requirements in Section .0200 of this Subchapter have been met and the application for certification has been received and approved, the Division shall conduct an on-site, certification survey.
- (e) Each certificate must be renewed at the beginning of each calendar year. The governing authority shall file an application for renewal of certification with the Division at least 30 days prior to the date of expiration on forms furnished by the Division. Failure to file a renewal application shall result in expiration of the certificate to operate.

History Note: Authority G.S. 14-45.1(a);
Eff. February 1, 1976;
Readopted Eff. December 19, 1977;
Amended Eff. July 1, 1994.

10A NCAC 14E .0107 ISSUANCE OF CERTIFICATE

- (a) The Division shall issue a certificate if it finds the facility can:
 - (1) Comply with all requirements described in this Subchapter; and
 - (2) Assure that, in the event that complications arise from the abortion procedure, an OB-GYN board certified or board eligible physician shall be available.
- (b) Each certificate 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 causing disruption of services.

History Note: Authority G.S. 14-45.1(a);
Eff. February 1, 1976;
Readopted Eff. December 19, 1977;
Amended Eff. July 1, 1994.

10A NCAC 14E .0108 POSTING

Certificates shall be posted in a conspicuous place on the premises.

History Note: Authority G.S. 14-45.1(a); 143B-10;
Eff. February 1, 1976;
Readopted Eff. December 19, 1977.

10A NCAC 14E .0109 RENEWAL

Each certificate, unless previously suspended or revoked, pursuant to the applicable rules and statutes shall be renewable annually upon the filing of an application, payment of the non-refundable renewal fee as defined in G.S. 131E-269, and approval by the Division.

History Note: Authority G.S. 14-45.1(a); 131E-269; 143B-10;
Eff. February 1, 1976;
Readopted Eff. December 19, 1977;
Amended Eff. October 1, 2015.

10A NCAC 14E .0110 REVOCATION

The Department shall deny, suspend, or revoke a certificate in any case where it finds that substantial failure to comply with these regulations renders the facility unsuitable for the performance of abortions.

History Note: Authority G.S. 14-45.1(a); 143B-10; 150B;
Eff. February 1, 1976;
Amended Eff. December 1, 1989.

10A NCAC 14E .0111 INSPECTIONS

(a) Any clinic certified 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 shall be conducted whenever the purpose of the inspection is to determine whether the clinic complies with the rules of this Subchapter or whenever there is reason to believe that some condition exists which is not in compliance with the rules of this Subchapter.

(b) The Division shall have authority to investigate any complaint relative to the care, treatment, or complication of any patient.

(c) Representatives of the Division shall make their identities known to the person in charge prior to inspection of the clinic.

(d) Representatives of the Division may review any records in any medium necessary to determine compliance with the rules of this Subchapter, while maintaining the confidentiality of the complainant and the patient, unless otherwise required by law.

(e) 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.

(f) A clinic shall file a 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.

History Note: Authority G.S. 14-45.1(a); 14-45.1(a1); 143B-10; S.L. 2013-366, s. 4(c);
Eff. February 1, 1976;
Readopted Eff. December 19, 1977;
Amended Eff. October 1, 2015; July 1, 1994.

10A NCAC 14E .0112 ALTERATIONS

Any certificate holder or prospective applicant desiring to make specified types of alteration or addition to a clinic or to construct a new clinic, before commencing such alteration, addition or new construction shall submit plans and specifications therefor to the Division for preliminary inspection and approval or recommendations with respect to compliance with the regulations and standards herein authorized.

History Note: Authority G.S. 14-45.1(a); 143B-10;
Eff. February 1, 1976;

*Readopted Eff. December 19, 1977;
Amended Eff. December 1, 1989.*

SECTION .0200 - MINIMUM STANDARDS FOR CONSTRUCTION AND EQUIPMENT

10A NCAC 14E .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 <http://www.ecodes.biz>.

(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 certified facility.

*History Note: Authority G.S. 14-45.1(a); 143B-10;
Eff. February 1, 1976;
Readopted Eff. December 19, 1977;
Amended Eff. October 1, 2015; July 1, 1994; December 1, 1989.*

10A NCAC 14E .0202 SANITATION

Clinics that are certified 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 <http://www.ncoah.com>.

*History Note: Authority G.S. 14-45.1(a); 143B-10;
Eff. February 1, 1976;
Readopted Eff. December 19, 1977;
Amended Eff. October 1, 2015; July 1, 1994.*

10A NCAC 14E .0203 ELEVATOR

(a) In multi-story buildings, at least one elevator for patient use shall be provided.

(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.

*History Note: Authority G.S. 14-45.1(a); 143B-10;
Eff. February 1, 1976;
Readopted Eff. December 19, 1977.*

10A NCAC 14E .0204 CORRIDORS

The width of corridors shall be sufficient to allow for patient evacuation by stretcher, but in no case shall patient-use corridors be less than 60 inches.

*History Note: Authority G.S. 14-45.1(a);
Eff. February 1, 1976;
Readopted Eff. December 19, 1977;
Amended Eff. July 1, 1994.*

10A NCAC 14E .0205 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 such as small closets not subject to occupancy.

History Note: Authority G.S. 14-45.1(a);

*Eff. February 1, 1976;
 Readopted Eff. December 19, 1977;
 Amended Eff. July 1, 1994.*

10A NCAC 14E .0206 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
Clean work or Clean holding	P	4

(P = positive pressure N = negative pressure)

(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, type one 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) If inhalation anesthesia is used in any concentration, the facility must meet the requirements of NFPA 70-2011 and NFPA 99-2012, current editions relating to inhalation anesthesia, 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.

*History Note: Authority G.S. 14-45.1(a); 143B-10;
Eff. February 1, 1976;
Readopted Eff. December 19, 1977;
Amended Eff. October 1, 2015; July 1, 1994; December 1, 1989.*

10A NCAC 14E .0207 AREA REQUIREMENTS

The following areas shall comply with Rule .0206 of this Section, and are considered minimum requirements for clinics that are certified 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) medicine room may be defined as area in the clean workroom if a self-contained secure cabinet complying with security requirements of state and federal laws is provided;
- (10) separate and distinct areas for storage and handling 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.

History Note: Authority G.S. 14-45.1(a); 143B-10;
Eff. February 1, 1976;
Readopted Eff. December 19, 1977;
Amended Eff. October 1, 2015; December 24, 1979.

10A NCAC 14E .0208 SHARED SERVICES

When there is written indication that services are to be shared or purchased, appropriate modifications or deletions in space requirements may be anticipated.

History Note: Authority G.S. 14-45.1(a); 143B-10;
Eff. February 1, 1976;
Readopted Eff. December 19, 1977.

SECTION .0300 - ADMINISTRATION

10A NCAC 14E .0301 OWNERSHIP

The ownership of the abortion clinic shall be fully disclosed to the Division.

History Note: Authority G.S. 14-45.1(a); 143B-10;
Eff. February 1, 1976;
Readopted Eff. December 19, 1977.

SECTION .0300 – GOVERNING AUTHORITY

10A NCAC 14E .0302 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 professional and safe 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 patient care.

*History Note: Authority G.S. 14-45.1(a); 143B-10; S.L. 2013-366, s. 4(c);
Eff. February 1, 1976;
Readopted Eff. December 19, 1977;
Amended Eff. October 1, 2015; December 1, 1989.*

10A NCAC 14E .0303 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 .0302 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 licensure to which 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; and clinical discharge criteria;
 - (2) policy and procedure for validating the full and true name of the patient;
 - (3) policy and procedure for each type of abortion procedure performed at the clinic;
 - (4) policy and procedure for the provision of patient privacy in the recovery area of the clinic;
 - (5) protocol for determining gestational age as defined in Rule .0101(5) of this Subchapter;
 - (6) protocol for referral of patients for whom services have been declined; and
 - (7) protocol for discharge instructions that informs patients who to contact for post-procedural problems and questions.

*History Note: Authority G.S. 14-45.1(a); 143B-10; S.L. 2013-366 s. 4(c);
Eff. February 1, 1976;
Readopted Eff. December 19, 1977;
Amended Eff. October 1, 2015; July 1, 1994.*

10A NCAC 14E .0304 ADMISSION AND DISCHARGE

- (a) There shall be on the premises throughout all hours of operation an employee authorized to receive patients and to make administrative decisions on their disposition.
- (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 general hospital.
- (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(s) 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 .0313(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.

*History Note: Authority G.S. 14-45.1(a); 143B-10;
Eff. February 1, 1976;
Readopted Eff. December 19, 1977;
Amended Eff. October 1, 2015; July 1, 1995; July 1, 1994; December 1, 1989.*

10A NCAC 14E .0305 MEDICAL RECORDS

- (a) A complete and permanent record shall be maintained 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 having a bearing on the procedure or anesthetic to be administered; and
 - (11) documentation that indicates all items listed in Rule .0304(d) of this Section were provided to the patient.
- (b) All other pertinent information such as pre- and post-procedure instructions, laboratory report, drugs administered, report of abortion procedure, and follow-up instruction, including family planning advice, shall be recorded and authenticated by signature, date, and time.
- (c) If Rh is negative, the significance shall be explained to the patient and so recorded. 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 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 physician;
 - (5) the name of 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, arrangements shall be made 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. 14-45.1(a); 143B-10; S.L. 2013-366, s. 4(c);
Eff. February 1, 1976;
Readopted Eff. December 19, 1977;
Amended Eff. October 1, 2015; July 1, 1994; December 1, 1989.

10A NCAC 14E .0306 PERSONNEL RECORDS

- (a) Personnel Records:
- (1) A record of each employee shall be maintained that includes the following:
 - (A) employee's identification;
 - (B) application for employment that includes education, training, experience and references;
 - (C) resume of education and work experience;
 - (D) verification of valid license (if required), education, training, and prior employment experience; and

- (E) verification of references.
 - (2) Personnel records shall be confidential.
 - (3) Notwithstanding the requirement found in Subparagraph (b)(2) of this Rule, 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.

History Note: Authority G.S. 14-45.1(a); 14-45.1(a1); 143B-10; S.L. 2013-366, s. 4(c);
Eff. February 1, 1976;
Readopted Eff. December 19, 1977;
Amended Eff. October 1, 2015; July 1, 1994.

10A NCAC 14E .0307 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 and accountability for all nursing services.
- (b) The nursing supervisor shall be responsible and accountable to the chief executive officer or designee 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.

History Note: Authority G.S. 14-45.1(a); 143B-10; S.L. 2013-366, s. 4(c);
Eff. February 1, 1976;
Readopted Eff. December 19, 1977;
Amended Eff. October 1, 2015; December 1, 1989.

10A NCAC 14E .0308 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.
- (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) Orientation, training, or education programs shall be conducted to correct deficiencies that are uncovered as a result of the quality assurance program.

History Note: Authority G.S. 14-45.1(a); 143B-10; S.L. 2013-366, s. 4(c); Eff. October 1, 2015.

10A NCAC 14E .0309 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 requiring examination by a pathologist of all surgical specimens except for those types of specimens that the governing authority has determined do not require examination.

(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.

History Note: Authority G.S. 14-45.1(a); 143B-10; S.L. 2013-366, s. 4(c); Eff. February 1, 1976; Readopted Eff. December 19, 1977; Amended Eff. October 1, 2015; July 1, 1994; December 1, 1989; October 28, 1981.

10A NCAC 14E .0310 EMERGENCY BACK-UP SERVICES

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

(b) The clinic shall have procedures, personnel, and suitable equipment to handle medical emergencies 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 .0206 of this Subchapter; and

- (4) ultrasound equipment.

*History Note: Authority G.S. 14-45.1(a); 143B-10; S.L. 2013-366, s. 4(c);
Eff. February 1, 1976;
Readopted Eff. December 19, 1977;
Amended Eff. October 1, 2015; July 1, 1994; December 24, 1979.*

10A NCAC 14E .0311 SURGICAL SERVICES

(a) The procedure room shall be maintained exclusively for surgical procedures and shall be so designed and maintained to provide an atmosphere free of contamination by pathogenic organisms. 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, ectopic pregnancy or an incomplete procedure shall be considered and evaluated by the physician performing the procedure.
- (3) The clinic shall establish procedures for obtaining, identifying, storing, and transporting specimens.

*History Note: Authority G.S. 14-45.1(a); 143B-10;
Eff. February 1, 1976;
Readopted Eff. December 19, 1977;
Amended Eff. October 1, 2015; July 1, 1994; December 1, 1989; November 1, 1984; September 1, 1984.*

10A NCAC 14E .0312 MEDICATIONS AND ANESTHESIA

(a) Medication

- (1) No medication or treatment shall be given except on written order of a physician.
- (2) Medications must be administered in accordance with the Nurse Practice Act of the State of North Carolina, and must be recorded in the patient's permanent record.

(b) Anesthesia

- (1) The anesthesia must be administered only under the direct supervision of a licensed physician.
- (2) Flammable anesthetics shall be prohibited except when construction, storage and equipment meet the standards of the National Fire Protection Association (N.F.P.A.) incorporated in Bulletin No. 56, "Code for Use of Flammable Anesthetics."

*History Note: Authority G.S. 14-45.1(a); 143B-10;
Eff. February 1, 1976;
Readopted Eff. December 19, 1977.*

10A NCAC 14E .0313 POST-OPERATIVE CARE

(a) A patient whose pregnancy is terminated on an ambulatory basis 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 an adverse condition or 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 ambulatory with a stable blood pressure and pulse; and
- (2) bleeding and pain shall be controlled.

(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.

*History Note: Authority G.S. 14-45.1(a); 143B-10;
Eff. February 1, 1976;
Readopted Eff. December 19, 1977;
Amended Eff. October 1, 2015; December 24, 1979.*

10A NCAC 14E .0314 CLEANING OF MATERIALS AND EQUIPMENT

(a) All supplies and equipment used in patient care shall be properly 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.

*History Note: Authority G.S. 14-45.1(a); 143B-10;
Eff. February 1, 1976;
Readopted Eff. December 19, 1977.*

10A NCAC 14E .0315 HOUSEKEEPING

Clinics that are certified by the Division to perform abortions shall meet the standards for sanitation as required by the Division of Public Health, Environmental Health Section, in the rules and regulations governing the sanitation of hospitals, nursing homes, adult care homes, and other institutions, set forth in 15A NCAC 18A .1300, including subsequent amendments and editions, with special emphasis on the following:

- (1) the floors, walls, woodwork and windows must be cleaned, and accumulated waste material must be removed 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 at all times; 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 <http://www.ncoah.com>.

*History Note: Authority G.S. 14-45.1(a); 143B-10;
Eff. February 1, 1976;
Readopted Eff. December 19, 1977;
Amended Eff. October 1, 2015; December 1, 1989.*

10A NCAC 14E .0316 FOOD SERVICE

(a) Nourishments shall be available and offered to all patients.

(b) Sanitary conditions shall be maintained in accordance with regulations of the North Carolina Sanitation Code administered by the Division of Environmental Health.

*History Note: Authority G.S. 14-45.1(a); 143B-10;
Eff. February 1, 1976;
Readopted Eff. December 19, 1977;
Amended Eff. January 1, 1990.*

SECTION .0400 - MEDICAL STAFF

10A NCAC 14E .0401 QUALIFICATIONS

Every person admitted to practice in the clinic shall qualify by submitting a signed application in writing which shall contain the following data: age, year and school of graduation, date of licensure, statement of postgraduate work, and experience.

History Note: Authority G.S. 14-45.1(a); 143B-10;
Eff. February 1, 1976;
Readopted Eff. December 19, 1977.

10A NCAC 14E .0402 FILE

An individual file for each physician practicing in the clinic shall be maintained. Each file shall contain the information outlined in Rule .0401 of this Section.

History Note: Authority G.S. 14-45.1(a); 143B-10;
Eff. February 1, 1976;
Readopted Eff. December 19, 1977.