

# NORTH CAROLINA REGISTER

VOLUME 29 • ISSUE 11 • Pages 1289 - 1481

December 1, 2014

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PUBLISHED BY

*The Office of Administrative Hearings  
Rules Division  
6714 Mail Service Center  
Raleigh, NC 27699-6714  
Telephone (919) 431-3000  
Fax (919) 431-3104*

*Julian Mann III, Director  
Molly Masich, Codifier of Rules  
Dana Vojtko, Publications Coordinator  
Tammara Chalmers, Editorial Assistant  
Lindsay Woy, Editorial Assistant*

Note from the Codifier: The notices published in this Section of the NC Register include the text of proposed rules. The agency must accept comments on the proposed rule(s) for at least 60 days from the publication date, or until the public hearing, or a later date if specified in the notice by the agency. If the agency adopts a rule that differs substantially from a prior published notice, the agency must publish the text of the proposed different rule and accept comment on the proposed different rule for 60 days.

Statutory reference: G.S. 150B-21.2.

TITLE 10A – DEPARTMENT OF HEALTH AND HUMAN SERVICES

These rules seek to provide improvements in the care and safety of women who undergo abortion procedures.

Notice is hereby given in accordance with G.S. 150B-21.2 that the Department of Health and Human Services Director, DHSR intends to adopt the rule cited as 10A NCAC 14E .0308 and amend the rule cited as 10A NCAC 14E .0101, .0104, .0109, .0111, .0201, .0202, .0206, .0207, .0302-.0307, .0309-.0311, .0313, and .0315.

Comments may be submitted to: Nadine Pfeiffer, 2701 Mail Service Center, Raleigh, NC 27699-2701, email DHSR.RulesCoordinator@dhhs.nc.gov.

Comment period ends: January 30, 2015

Link to agency website pursuant to G.S. 150B-19.1(c): <http://www.ncdhhs.gov/dhsr/ruleactions.html>

Procedure for Subjecting a Proposed Rule to Legislative Review: If an objection is not resolved prior to the adoption of the rule, a person may also submit written objections to the Rules Review Commission after the adoption of the Rule. If the Rules Review Commission receives written and signed objections after the adoption of the Rule in accordance with G.S. 150B-21.3(b2) from 10 or more persons clearly requesting review by the legislature and the Rules Review Commission approves the rule, the rule will become effective as provided in G.S. 150B-21.3(b1). The Commission will receive written objections until 5:00 p.m. on the day following the day the Commission approves the rule. The Commission will receive those objections by mail, delivery service, hand delivery, or facsimile transmission. If you have any further questions concerning the submission of objections to the Commission, please call a Commission staff attorney at 919-431-3000.

Proposed Effective Date: April 1, 2015

Public Hearing:

Date: December 19, 2014

Time: 9:00 a.m.

Location: Dorothea Dix Campus, Brown Building, Room 104, 801 Biggs Drive, Raleigh, NC

Reason for Proposed Action: The proposed amendments and adoptions of rules in Chapter 10A NCAC 14E Certifications of Clinics for Abortion are in response to enactment of Session Law 2013-366 s.4(c), Part IV. Amend Women’s Right to Know Act, which became effective on July 29, 2013. This act requires the Department of Health and Human Services to amend rules pertaining to clinics certified by the Department to be suitable facilities for the performance of abortions under G.S. 14-45.1. The Department was authorized to apply any requirement for the licensure of ambulatory surgical centers to the standards applicable to clinics certified by the Department to be suitable facilities for the performance of abortions.

These rules were drafted upon the recommendation of a stakeholder committee consisting of certified abortion clinic representatives, physicians, professional licensing agencies, the public, and DHHS staff. The rule language sets standards by which clinics shall address the on-site recovery phase of patient care, protect patient privacy, provide quality assurance, and ensure that patients with complications receive the necessary medical attention, while not unduly restricting access. In addition, the rules have been revised to be consistent with current medical terminology and standard best practices for the annual inspection process for certified clinics, building code and sanitation requirements, the governing authority responsibilities, the policies and procedures the clinic shall have on site, requirements to be included in the medical record, requirements to be included in personnel records and of clinic personnel, requirements of nursing staff and supervisor, and with procedure room procedures.

Fiscal impact (check all that apply).

- State funds affected
- Environmental permitting of DOT affected Analysis submitted to Board of Transportation
- Local funds affected
- Substantial economic impact (≥\$1,000,000)
- Approved by OSBM
- No fiscal note required by G.S. 150B-21.4

CHAPTER 14 – DIRECTOR, DIVISION OF HEALTH SERVICE REGULATION

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. 90-21.6.
- (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.

- ~~(2)~~(3) "Complication" includes but is not limited to hemorrhage, infection, uterine perforation, cervical ~~laceration~~—laceration, or retained products of conception.
- ~~(3)~~(4) "Division" means the Division of Health Service Regulation of the North Carolina Department of Health and Human Services.
- ~~(4)~~(5) "~~Fetal age~~"—"Gestational age" means the length of pregnancy as indicated by the date of ~~conception~~—the first day of the last normal monthly menstrual period, if known, or as determined by ultrasound.
- ~~(5)~~(6) "Governing authority" means the individual, ~~agency or group~~—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~~—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.
- ~~(6)~~(8) "New ~~facility~~"—clinic" means one that is not certified as an abortion clinic by the Division as of July 1, ~~1994~~,—2014, and has not been certified within the previous six months of the application for certification.
- (9) "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, Article 9A, Chapter 90 of the North Carolina General Statutes.

Authority G.S. 14-45.1(a); 143B-10; S.L. 2013-366, s. 4(c).

10A NCAC 14E .0104 PLANS

~~Three~~—Prior to issuance of a certificate pursuant to Rule .0107 of this Subchapter, a clinic shall submit two copies of the plans ~~will be required to the division for certification purposes—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 is available from the International Code Council at [http://www.ecodes.biz/ecodes\\_support/Free\\_Resources/2012NorthCarolina/12NorthCarolina\\_main.html](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.

Authority G.S. 14-45.1(a); 143B-10.

10A NCAC 14E .0109 RENEWAL

Each certificate, unless previously suspended or revoked, shall be renewable annually ~~without charge~~—upon the filing of an ~~application~~—application, payment of the non-refundable renewal fee as defined in G.S. 131E-269, and its—approval by the Division.

Authority G.S. 14-45.1(a); 131E-269; 143B-10.

10A NCAC 14E .0111 INSPECTIONS

- ~~(a)~~ The Division shall make such inspections as it may deem necessary. Any clinic certified by the Division to perform abortions shall be subject to inspections by authorized representatives of the Division annually and as it may deem necessary as a condition of holding such license.
- (b) The Division shall have authority to investigate any complaint relative to the care, ~~treatment~~—treatment, or ~~complications~~—complication of any patient.
- (c) Authorized representatives of the Division shall make their identities known to the person in charge prior to inspection of the clinic.
- ~~(e)~~(d) Representatives of the Division may review any records in any medium necessary to determine compliance with the ~~rules~~—rules of this Subchapter, while maintaining the confidentiality of the complainant and the patient, unless otherwise required by law.
- ~~(e)~~ An inspection shall be considered 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.
- (f) 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.
- (g) A clinic shall file a plan of correction for cited deficiencies within 10 business days of receipt. The Division shall review and respond to a written plan of correction within 10 business days of receipt.

Authority G.S. 14-45.1(a); 90-21.83; 143B-10; S.L. 2013-366, s. 4(c).

SECTION .0200 – MINIMUM STANDARDS FOR CONSTRUCTION AND EQUIPMENT

10A NCAC 14E .0201 BUILDING CODE REQUIREMENTS

(a) The physical plant for a ~~facility~~—clinic must 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—amendments and editions.~~ Copies of ~~The North Carolina Building Code, Volume One, General Construction,~~ may be obtained for thirty dollars (\$30.00) from the N.C. Department of Insurance, P.O. 26387, Raleigh, NC 27611. the Code can be obtained from the International Code Council

online at <http://www.iccsafe.org>, or accessed electronically free of charge at <http://www.ecodes.biz>.

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

*Authority G.S. 14-45.1(a); 143B-10.*

**10A NCAC 14E .0202 SANITATION**

~~Abortion clinics—Clinics~~ that are certified by the Division to perform abortions must comply with the ~~rules—Rules~~ governing the sanitation of hospitals, nursing and rest homes, sanitariums, sanatoriums and educational 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 Environmental Health Services, Division of Environmental Health, N.C. Department of Environment and Natural Resources, 1630-1632 Mail Service Center, Raleigh, NC ~~27699-1630; 27699-1632~~, or accessed electronically free of charge from the Office of Administrative Hearings at <http://www.ncoah.com>.

*Authority G.S. 14-45.1(a); 143B-10.*

**10A NCAC 14E .0206 ELEMENTS AND EQUIPMENT**

The physical plant shall provide ~~appropriate elements and~~ equipment to carry out the functions of the ~~facility—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 Paragraph:

Area	Temperature	Relative Humidity
Procedure	70-76 degrees F.	50-60 %
Recovery	75-80 degrees F.	<u>30-60 %</u>

(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 ~~shown herein—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 in ducts serving procedure or recovery rooms—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, <del>janitor's—Janitor's closet,</del> <del>toilets, Toilets,</del>		
Soiled holding	N	10
Clean work or		
Clean holding	P	4

(P = positive pressure N = negative pressure)

(2) Plumbing And Other Piping ~~Systems—Systems.~~

(a) Medical Gas and Vacuum Systems

(i) Piped-in medical gas and vacuum systems, if installed, shall meet the requirements

of ~~NFPA 99-1990, NFPA-99-2012~~, type one system, which is hereby incorporated by reference including subsequent amendments and editions. Copies of ~~NFPA-99-1990~~ NFPA-99-2012 may be purchased from the National Fire Protection Association, 1 Batterymarch Park, P.O. Box 9101, Quincy, MA 02269-9101, ~~for twenty eight dollars and fifty cents (\$28.50).~~ 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 70-1993~~ NFPA 70-2011 and ~~NFPA 99-1990, NFPA 99-2012~~, current editions relating to inhalation anesthesia, which are hereby incorporated by reference including subsequent amendments and editions. Copies of ~~NFPA 70-1993~~ NFPA 70-2011 and ~~NFPA 99-1990~~ NFPA 99-2012 may be purchased from the National Fire Protection Association, 1 Batterymarch Park, P.O. Box 9101, Quincy, MA 02269-9101, ~~for thirty two dollars and fifty cents (\$32.50) and twenty eight dollars and fifty cents (\$28.50) respectively.~~ 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 ~~which~~ 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~~ 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 ~~of~~ needed for a utility or local lighting circuit failure.
  - (b) Essential 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) ~~Provide at~~ At least one wired-in, ionization-type smoke detector shall be within 15 feet of each procedure or recovery room entrance.
- (4) ~~Each facility and its grounds shall be maintained to minimize hazards and enhance safety for staff and patients.~~ Buildings systems and medical equipment must have preventative maintenance conducted as recommended by the equipment manufacturers' or installers' literature to assure satisfactory operation. operation in compliance with manufacturer's instructions.

Authority G.S. 14-45.1(a); 143B-10.

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; ~~abortion clinics:~~

- (1) ~~Receiving~~ receiving area;
- (2) ~~Examining~~ examining room;
- (3) ~~Preoperative~~ preoperative preparation and holding room;
- (4) ~~Individual~~ individual patient locker facilities or equivalent;
- (5) ~~Operating~~ procedure room;
- (6) ~~Recovery~~ recovery room;
- (7) ~~Clean~~ clean workroom;
- (8) ~~Soiled~~ soiled workroom;
- (9) ~~Medicine~~ medicine room (~~may~~ 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~~); provided;

- (10) ~~Linen Storage. Separate~~ separate and distinct areas for storage and handling clean and soiled ~~linen shall be provided; linen;~~
- (11) ~~Patient~~ patient toilet;
- (12) ~~Personnel~~ personnel lockers and toilet facilities;
- (13) ~~Laboratory; laboratory;~~
- (14) ~~Nourishment~~ nourishment station with storage and preparation area for serving meals or in-between meal snacks;
- (15) ~~Janitor's~~ janitor's closets appropriately located;
- (16) ~~Adequate~~ adequate space and equipment for assembling, sterilizing and storing medical and surgical supplies;
- (17) ~~Storage~~ storage space for medical records; and
- (18) ~~Office~~ office space for nurses' charting, doctors' charting, communications, counseling, and business functions.

*Authority G.S. 14-45.1(a); 143B-10.*

SECTION .0300 –GOVERNING AUTHORITY

10A NCAC 14E .0302 GOVERNING AUTHORITY

~~The governing authority shall designate a person to have authority and responsibility for the administrative and professional functions of the clinic.~~

(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 qualified person to act in his or her behalf during his 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 reasonable 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.

(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.

*Authority G.S. 14-45.1(a); 90-21.83; 143B-10; S.L. 2013-366, s. 4(c).*

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, if applicable;
- (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~~ patient selection and exclusion criteria, criteria; and clinical discharge criteria, criteria;
- (2) policy and procedure for validating the full and true name of the patient;
- (2)(3) ~~Policy~~ 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;

- ~~(3)(5) Protocol~~ protocol for determining gestational age as defined in Rule .0101(5) of this Subchapter; ~~fetal age.~~
- ~~(4)(6) Protocol~~ protocol for referral of patients for whom services have been ~~declined~~ declined; and
- ~~(5)(7) Protocol~~ protocol for discharge instructions that informs patients who to contact for post-procedural ~~emergencies.~~ problems and questions.

- (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 witnessed, voluntarily-signed consent for each surgery or procedure and signature of the physician performing the procedure;
- (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.

Authority G.S. 14-45.1(a); 90-21.83; 143B-10; S.L. 2013-366, s. 4(c).

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 ~~surgery required by Rule .0305(a) of this Section,~~ the procedure, representatives of the clinic's management shall provide to each patient the following information:
  - (1) ~~A~~ a fee schedule and any extra charges routinely applied;
  - (2) ~~The~~ 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~~ instructions for post-procedure emergencies ~~problems and questions~~ as outlined in Rule .0313(d) of this Section;
  - (4) ~~Grievance~~ grievance procedures a patient may follow if dissatisfied with the care and services rendered; and
  - (5) ~~The~~ the telephone number of the Complaints Investigation Branch of the Division.

Authority G.S. 14-45.1(a); 143B-10.

10A NCAC 14E .0305 MEDICAL RECORDS

- (a) A complete and permanent record shall be maintained for all patients ~~including~~ including the date and time of admission and discharge; the full and true name; address; date of birth; nearest of kin; diagnoses; duration of pregnancy; condition on admission and discharge; referring and attending physician; a witnessed, voluntarily signed consent for each surgery or procedure and signature of the physician performing the procedure; and the physician's authenticated history and physical examination including identification of pre-existing or current illnesses, drug sensitivities or other idiosyncrasies having a bearing on the operative procedure or anesthetic to be administered.
  - (1) the date and time of admission and discharge;
  - (2) the patient's full and true name;
  - (3) the patient's address;

- (b) All other pertinent information such as pre- and ~~post-operative~~ post-procedure instructions, laboratory report, drugs administered, report of ~~operation~~ abortion procedure, and follow-up ~~instruction~~ instruction, including family planning ~~advice~~ advice, shall be recorded and authenticated.
- (c) If Rh is negative, the significance shall be explained to the patient and so recorded. The patient in writing may reject Rh immunoglobulin or ~~accept the appropriate desensitization material.~~ 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 posted~~ results, including gestational age, placed in the patient's medical record for any patient who is scheduled for an abortion procedure.
- (e) The ~~facility~~ clinic shall maintain a daily procedure log of all patients receiving abortion services. This log shall contain at least the following: patient name, estimated length of gestation, type of procedure, name of physician, name of RN on duty, and date and time of procedure.
  - (1) patient name;
  - (2) estimated length of gestation;
  - (3) type of procedure;
  - (4) name of physician;
  - (5) name of Registered Nurse on duty; and
  - (6) 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~~ at least 20 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 18<sup>th</sup> 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 ~~facility~~ 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 ~~facility~~ clinic cease operation, arrangements shall be made for preservation of records for at least ~~20~~ 10 years. The clinic shall ~~notify the Division, in writing, concerning the~~

~~arrangements. send written notification to the Division of these arrangements.~~

*Authority G.S. 14-45.1(a); 90-21.83; 143B-10; S.L. 2013-366, s. 4(c).*

10A NCAC 14E .0306 PERSONNEL RECORDS

(a) Application. Each prospective employee or contractual employee must submit an application for employment which includes education, training, experience, and references.

(b) Personnel Records:

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

~~(b)(c)~~ Job Descriptions:

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

(d) All persons having direct responsibility for patient care shall be at least 18 years of age. All other personnel, paid or unpaid, working in the clinic shall be at least 16 years of age.

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

~~(f)~~(f) 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.

~~(g)~~(g) Employee and contractual employee records for health ~~screening~~ 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. 14-45.1(a); 90-21.83; 143B-10; S.L. 2013-366, s. 4(c).*

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 an adequate 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.

~~(a)(d)~~(d) There shall be a minimum of at least one registered nurse 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 when patients are in the ~~facility~~ clinic.

~~(b)~~ There shall be supporting personnel sufficient to meet patient needs and to provide safe patient care.

*Authority G.S. 14-45.1(a); 90-21.83; 143B-10; S.L. 2013-366, s. 4(c).*

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 as indicated. 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.



Authority G.S. 14-45.1(a); 90-21.83; 143B-10; S.L. 2013-366, s. 4(c).

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 which the governing authority has determined do not require examination.

(c) Pre-operative Tests. As a minimum, there shall be performed for each patient the following laboratory tests which must be recorded. 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) Blood and Blood Products. Those patients requiring the administration of blood shall be transferred immediately to a local hospital having blood bank facilities.

(e) The facility shall have instructions 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 facility shall perform and document, at least quarterly, calibration of equipment and validation of test results.

Authority G.S. 14-45.1(a); 90-21.83; 143B-10; S.L. 2013-366, s. 4(c).

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 nearby 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 facility shall provide intervention for emergency situations. These provisions shall include:

- (1) Basic cardio-pulmonary life support;

- (2) Emergency protocols for:
  - (A) Venous access supplies, administration of intravenous fluids;
  - (B) Air way support and oxygen, 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 operating room; procedure room as set forth in Rule .0206 of this Subchapter; and
- (4) Ultrasound equipment.

Authority G.S. 14-45.1(a); 90-21.83; 143B-10; S.L. 2013-366, s. 4(c).

10A NCAC 14E .0311 SURGICAL SERVICES

(a) Facilities. The operating procedure room shall be maintained exclusively for surgical abortion procedures and shall be so designed and maintained to provide an atmosphere free of contamination by pathogenic organisms. The facility 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) The facility shall have written procedures, supplies and equipment available for gross and microscopic evaluation of abortion specimens. If placental or fetal tissue is not identified by gross examination, a microscopic examination must be done on the P.O.C. In cases where the microscopic evaluation is negative for chorionic villi and fetal parts, or the weight of the P.O.C. falls substantially below the appropriate weight range for the fetal age, a microscopic examination by a board certified or board eligible pathologist shall be done on the P.O.C.
- (3) The results of this examination, the findings of further patient evaluation and any subsequent treatment must be recorded in the patient's medical record.
- (2) Based on gestational age, if adequate tissue is not obtained, ectopic pregnancy or an incomplete procedure shall be considered and

evaluated by the physician performing the procedure.

- (4)(3) ~~The facility clinic shall establish procedures for obtaining, identifying, storing and transporting specimens.~~
- (5) ~~The facility shall establish a method for follow up of patients on whom no villi are seen.~~

Authority G.S. 14-45.1(a); 143B-10.

10A NCAC 14E .0313 POST-OPERATIVE CARE

(a) ~~Patients~~ A patient whose pregnancy is terminated on an ambulatory basis ~~should~~ shall be observed in the ~~abortion clinic for a reasonable number of hours, not less than one, to insure to~~ ensure that no immediate post-operative complications are present. Thereafter, patients may be discharged according to a physician's order and the clinic's protocols, such patients may be discharged if their course has been uneventful.

(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 ~~the back up~~ a hospital for evaluation or admission.

(c) The following criteria must be documented prior to discharge:

- (1) the patient must be ambulatory with a stable blood pressure and pulse; and
- (2) bleeding and pain must be controlled.

~~(e) Any non-ambulatory patient shall be accompanied by an attending medical or nursing staff member during any transfer within or outside the facility.~~

(d) Written instructions shall be issued to all patients in accordance with the ~~rules~~ orders of the physician in charge of the abortion service and shall include the following:

- (1) symptoms and complications to be looked ~~for~~ for; and
- (2) ~~activities to be avoided,~~
- (3)(2) ~~specific~~ a dedicated telephone number to be used by the patients should any complication occur or question arise. This number must be answered by a person 24 hours a day, seven days a week. A recorded phone message only is unacceptable.

(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 which the operating physician is incapable of managing.

Authority G.S. 14-45.1(a); 143B-10.

10A NCAC 14E .0315 HOUSEKEEPING

~~Abortion clinics~~ Clinics that are certified by the Division to perform abortions shall meet the standards for sanitation as required by the Division of Environmental Health-Public Health, Environmental Health Section, in the rules and regulations governing the sanitation of private hospitals, nursing and rest homes, sanitariums, sanatoriums, and educational and other institutions, 10 NCAC 10A, set forth in 15A NCAC 18A .1300,

including subsequent amendments and editions, with special emphasis on the following:

- (1) ~~There must be cleaning of such a frequency as to maintain the floors, walls, woodwork and windows in a manner to minimize the spread of dust particles in the atmosphere. Accumulated~~ must be cleaned, and accumulated waste material must be removed at least ~~daily~~ daily;
- (2) ~~The~~ the premises must be kept free from rodents and insect ~~infestation~~ infestation;
- (3) ~~Bath~~ bath and toilet facilities must be maintained in a clean and sanitary condition at all ~~times~~ times; and
- (4) ~~Linen~~ linen that comes directly in contact with the patient shall be provided as needed for each individual patient. No such linen shall be interchangeable from one patient to another before being properly 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.ncogh.com>.

Authority G.S. 14-45.1(a); 143B-10.

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*Notice is hereby given in accordance with G.S. 150B-21.2 that the Commission for Public Health intends to adopt the rules cited as 10A NCAC 43K .0101, .0102 and .0103.*

Link to agency website pursuant to G.S. 150B-19.1(c): <http://cph.publichealth.nc.gov/>

Proposed Effective Date: *April 1, 2015*

Public Hearing:  
Date: *January 5, 2015*  
Time: *10:00 a.m.*  
Location: *Cardinal Room, 5605 Six Forks Road, Raleigh, NC*

*Reason for Proposed Action: SL 2013-45 required that Public Health adopt temporary and permanent rules to include pulse oximetry screening for critical congenital heart defects (CCHD) in the Newborn Screening Program so that newborns in North Carolina are screened at 24 to 48 hours of age for this defect. CCHD potentially affects up to 200 newborns each year in North Carolina. Timely diagnosis can prevent major disease complications and death which are possible outcomes if critical congenital heart defects are not detected. The proposed permanent rules replace the temporary rules, which expire April 21, 2015. The permanent rules assure that all medical facilities and attending providers of neonates and infants in NC (as defined in the rules) are using a consistent screening protocol based on national standards. The rules also assure that all medical facilities and attending providers of neonates and*