

10A NCAC 13S .0101 is proposed for adoption as follows:

**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.

*History Note: Authority G.S. 131E-153; 131E-153.5; 143B-165.*

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10A NCAC 13S .0104 is proposed for adoption as follows:

**10A NCAC 13S .0104 PLANS AND SPECIFICATIONS**

~~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.icsafe.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.~~

(a) Prior to issuance of a license pursuant to Rule .0107 of this Section, an applicant for a new clinic shall submit one copy of construction documents and specifications to the Division for review and approval.

(b) Any license holder or prospective applicant desiring to make alterations or additions to a clinic or to construct a new clinic, before commencing such alteration, addition or new construction shall submit construction documents and specifications to the Division for review and approval with respect to compliance with this Subchapter.

(c) Approval of construction documents and specifications shall expire one year after the date of approval unless a building permit for the construction has been obtained prior to the expiration date of the approval of construction documents and specifications.

*History Note: Authority G.S. 131E-153.5; 143B-165;*

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10A NCAC 13S .0201 is proposed for adoption as follows:

## **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>~~ <https://shop.iccsafe.org/catalogsearch/result/?cat=1010&q=+North+Carolina+Building+code> for a cost of ~~five hundred twenty seven dollars (\$527.00)~~ eight hundred fifty eight dollars (\$858.00) or accessed electronically free of charge at ~~<https://codes.iccsafe.org/content/NCAPC2018/chapter-1-administrative-code>~~ <https://www.ncosfm.gov/codes/codes-current-and-past>.
- (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.

*History Note: Authority G.S. 131E-153.5; 143B-165;*  
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10A NCAC 13S .0207 is proposed for adoption as follows:

### 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;~~ reception and waiting room;
- (2) ~~examining room;~~ designated area or areas for pre-procedure and post-procedure activities;
- (3) ~~preoperative preparation and holding room;~~
- (4) ~~individual patient locker facilities or equivalent;~~
- (5)(3) procedure room;
- (6)(4) ~~recovery room;~~ a clean area for self-contained secure medication storage complying with security requirements of state and federal laws;
- (7)(5) ~~clean workroom;~~ area compliant with Clinical Laboratory Improvement Amendments (CLIA) requirements in which laboratory testing can be performed;
- (8)(6) ~~soiled workroom;~~ separate areas for storage and handling of clean and soiled materials;
- (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)(7) patient toilet;
- (12)(8) ~~personnel lockers and~~ toilet facilities;
- (13) ~~laboratory;~~
- (14) ~~nourishment station with storage and preparation area for serving meals or in-between meal snacks;~~
- (15)(9) janitor's closets;
- (16)(10) ~~adequate~~ space and equipment for assembling, sterilizing and storing medical and surgical supplies;
- (17)(11) storage space for medical records; and records of all media types used by the facility; and
- (18)(12) ~~office space for nurses' charting, doctors' charting, communications, counseling, and counseling,~~ business functions, functions, and other administrative activities.

*History Note: Authority G.S. 131E-153.5; 143B-165;*

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10A NCAC 13S .0212 is proposed for adoption as follows:

### 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
Clean work or		
Clean holding	P	4
(P = positive pressure N = negative pressure)		

(1) Mechanical requirements.

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

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

(P = positive pressure N = negative pressure NR = No Requirement)

(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, NFPA-99, category 2 system, which is hereby incorporated by reference including subsequent amendments and editions. Copies of NFPA 99 2012 NFPA-99 may be purchased from the National Fire Protection Association, 1 Batterymarch Park, P.O. Box 9101, Quincy, MA 02269-9101, Association online at <https://www.nfpa.org/product/nfpa-99-code/p0099> code at a cost of one hundred forty-nine dollars (\$149.00) 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~~ ten (10) inches above the ~~rim of the fixture~~ bottom of the basin with mixing type fixture valves that can be operated without the use of the hands.
- (c) Hot water distribution systems shall provide hot water at hand washing ~~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~~ The facility's 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~~ 1 foot ~~candles~~ candle of illumination at the floor in the event needed for a utility or local lighting circuit failure.
- (b) Electrically operated medical equipment necessary for the safety of the patient shall have, at a minimum, battery backup.
- ~~(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. 131E-153.5; 143B-165;*  
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1 10A NCAC 13S .0318 is proposed for adoption as follows:

2  
3 **10A NCAC 13S .0318 GOVERNING AUTHORITY**

4 (a) The governing authority, as defined in Rule .0101(6) of this Subchapter, shall appoint a chief executive officer or  
5 a designee of the clinic to represent the governing authority and shall define his or her authority and duties in writing.

6 This person shall be responsible for the management of the clinic, implementation of the policies of the governing  
7 authority and authorized and empowered to carry out the provisions of these Rules.

8 (b) The chief executive officer or designee shall designate, in writing, a person to act on his or her behalf during his  
9 or her absence. In the absence of the chief executive officer or designee, the person on the grounds of the clinic who  
10 is designated by the chief executive officer or designee to be in charge of the clinic shall have access to all areas in  
11 the clinic related to patient care and to the operation of the physical plant.

12 (c) When there is a planned change in ownership or in the chief executive officer, the governing authority of the clinic  
13 shall notify the Division in writing of the change.

14 (d) The clinic's governing authority shall adopt operating policies and procedures that shall:

15 (1) specify the individual to whom responsibility for operation and maintenance of the clinic is  
16 delegated and methods established by the governing authority for holding such individuals  
17 responsible;

18 (2) provide for at least annual meetings of the governing authority, for which minutes shall be  
19 maintained; and

20 (3) maintain a policies and procedures manual designed to ensure safe and adequate care for the patients  
21 which shall be reviewed, and revised when necessary, at least annually, and shall include provisions  
22 for administration and use of the clinic, compliance, personnel quality assurance, procurement of  
23 outside services and consultations, patient care policies, and services offered.

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

27 (f) The governing authority shall provide for the selection and appointment of the professional staff and the granting  
28 of clinical privileges and shall be responsible for the professional conduct of these persons.

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

31 (h) The governing authority shall certify that the physical facilities to be used are adequate to safeguard the health  
32 and safety of patients; of note one area may accommodate various aspects of the patient's visits.

33  
34 *History Note: Authority G.S. 131E-153; 131E-153.5; 143B-165.*

35 *Codifier determined that findings of need did not meet criteria for emergency rule on October 30,*  
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10A NCAC 13S .0319 is proposed for adoption as follows:

**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)~~ (3) emergency protocols as required by Rule .0326;
- ~~(3)(4)~~ (4) policy and procedure for validating the full and true name of the patient;
- ~~(4)(5)~~ (5) policy and procedure for abortion procedures performed at the clinic;
- ~~(5)(6)~~ (6) policy and procedure for the provision of patient privacy in the recovery area of the clinic;
- ~~(6)(7)~~ (7) protocol for determining gestational age as defined in Rule .0101(5) .0101(4) of this Subchapter;
- ~~(7)(8)~~ (8) protocol for referral of patients for whom services have been declined; and
- ~~(9)~~ (9) protocol that defines use of space to include opportunities that one area may accommodate various aspects of patient visits.
- ~~(8)~~ (8) protocol for discharge instructions that informs patients who to contact for post-procedural problems and questions.

*History Note: Authority G.S. 131E-153; 131E-153.5; 143B-165.*

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1 10A NCAC 13S .0320 is proposed for adoption as follows:

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3 **10A NCAC 13S .0320 ADMISSION AND DISCHARGE**

4 (a) There shall be on the premises throughout all hours of operation an employee authorized to receive patients and  
5 make administrative decisions regarding patients.

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

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

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

- 12 (1) a fee schedule and any extra charges routinely applied;  
13 (2) the name of the attending physician or physicians and hospital admitting privileges, if any. In the  
14 absence of admitting privileges a statement to that effect shall be included;  
15 (3) instructions for post-procedure problems and questions as outlined in Rule .0329(d) of this Section;  
16 (4) grievance procedures a patient may follow if dissatisfied with the care and services rendered; and  
17 (5) the telephone number for Complaint Intake of the Division.  
18

19 *History Note: Authority G.S. 131E-153; 131E-153.5; 143B-165.*

20 *Codifier determined that findings of need did not meet criteria for emergency rule on October 30,*  
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25

1 10A NCAC 13S .0321 is proposed for adoption as follows:

3 **10A NCAC 13S .0321 MEDICAL RECORDS**

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

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

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

24 (c) If Rh is negative, the clinic shall explain the significance to the patient and shall record the explanation. The  
25 patient in writing may reject Rh immunoglobulin. A written record of the patient's decision shall be a permanent part  
26 of her medical record.

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

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

- 32 (1) the patient name;
- 33 (2) the estimated length of gestation;
- 34 (3) the type of procedure;
- 35 (4) the name of the physician;
- 36 (5) the name of the Registered Nurse on duty; and
- 37 (6) the date and time of procedure.

1 (f) Medical records shall be the property of the clinic and shall be preserved or retained in the State of North Carolina  
2 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  
3 case the record must be retained until three years after the client's 18th birthday, regardless of change of clinic  
4 ownership or administration. Such medical records shall be made available to the Division upon request and shall not  
5 be removed from the premises where they are retained except by subpoena or court order.

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

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

10  
11 *History Note: Authority G.S. 131E-153; 131E-153.5; 143B-165.*

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10A NCAC 13S .0322 is proposed for adoption as follows:

### 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 or resume for employment that includes education, training, experience and references; and

~~(C) a resume of education and work experience;~~

~~(D)(C)~~ a copy of a valid license (if required). ~~(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)~~ .0101(6) of this Subchapter, education, training, and verification of professional certification shall be available for review by the Division.

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1 10A NCAC 13S .0323 is proposed for adoption as follows:

2  
3 **10A NCAC 13S .0323 CLINIC STAFFING NURSING SERVICE**

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

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

7 (1) provision of nursing services to patients; and

8 (2) developing a nursing policy and procedure manual and written job descriptions for nursing  
9 personnel.

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

13 (d) There shall be at least one Registered Nurse ~~with experience in post-operative or post-partum care~~ who is currently  
14 licensed to practice professional nursing in North Carolina, or other health care practitioner as defined in G.S. 90-640

15 (a) practicing within the scope of their license or certification who is basic life support (BLS) certified and authorized  
16 by state laws to administer medications as required for analgesia, nausea, vomiting, or other indications on duty in the  
17 ~~clinic~~ at all times patients are in the clinic, procedure rooms and recovery area.

18  
19 History Note: Authority G.S. 131E-153; 131E-153.5; 143B-165.

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10A NCAC 13S .0324 is proposed for adoption as follows:

**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 frequency of meetings and details of data collection shall be defined by the governing authority. 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.~~

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10A NCAC 13S .0325 is proposed for adoption under permanent procedures as follows:

### **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.~~ performed, and will perform laboratory tests appropriate to their Clinical Laboratory Improvement Amendments (CLIA) certification.

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

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

(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)(d)~~ 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: meets requirements for the level of clinic's CLIA certification. This includes the procedures, instructions, and manufacturer's instructions for each test procedure performed including:

(1) ~~sources of reagents, 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. 131E-153; 131E-153.5; 143B-165.*

*Codifier determined that findings of need did not meet criteria for emergency rule on October 30, 2023;*

*Emergency Rule Eff. November 14, 2023;*

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*Adopted Eff. January 1, 2025.*

10A NCAC 13S .0326 is proposed for adoption as follows:

### **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) All clinics shall have written emergency instructions for clinic staff to carry out in the event of an emergency. All clinic personnel shall be familiar and capable of carrying out written emergency instructions:

(1) Instructions shall be followed in the event of an emergency, any untoward anesthetic, medical or procedural complications, or other conditions making transfer to an emergency department and/or hospitalization of a patient necessary.

(2) The instructions shall include arrangements for immediate contact of emergency medical services when indicated and when advanced cardiac life support is needed.

(3) When emergency medical services are not indicated, the instructions shall include procedures for timely escort of the patient to the hospital or to an appropriate licensed health care professional.

~~(e) 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; and

~~(E) —utilizing a suction machine; and~~

~~(F)(E) utilizing an automated external defibrillator; defibrillator.~~

(3) emergency lighting available in the procedure room as set forth in Rule .0212 of this Subchapter; and

(4) ultrasound equipment.

*History Note: Authority G.S. 131E-153; 131E-153.5; 143B-165.*

1                   *Codifier determined that findings of need did not meet criteria for emergency rule on October 30,*  
2                   *2023;*  
3                   *Emergency Rule Eff. November 14, 2023;*  
4                   *Temporary Adoption Eff. February 8, ~~2024~~ 2024;*  
5                   *Adopted Eff. January 1, 2025.*  
6

1 10A NCAC 13S .0327 is proposed for adoption as follows:

2  
3 **10A NCAC 13S .0327 OUTPATIENT PROCEDURAL SURGICAL SERVICES**

4 (a) ~~The procedure room shall be maintained exclusively for surgical procedures and shall be so designed and~~  
5 ~~maintained to provide an environment free of contamination.~~ The clinic shall establish procedures for infection control  
6 and universal ~~precautions.~~ precautions, including appropriate cleaning of all patient care areas including procedure  
7 rooms.

8 (b) Tissue Examination:

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

16  
17 *History Note: Authority G.S. 131E-153; 131E-153.5; 143B-165.*

18 *Codifier determined that findings of need did not meet criteria for emergency rule on October 30,*  
19 *2023;*

20 *Emergency Rule Eff. November 14, 2023;*

21 *Temporary Adoption Eff. February 8, ~~2024.~~ 2024.*

22 *Adopted Eff. January 1, 2025.*

1 10A NCAC 13S .0328 is proposed for adoption as follows:

2  
3 **10A NCAC 13S .0328 MEDICATIONS AND ~~ANESTHESIA~~ SEDATION**

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

5 (b) ~~Any medications shall be administered by a physician or Registered Nurse and~~ Medications, including injections  
6 shall be administered by a physician, Registered Nurse, and other health care practitioners as defined in G.S. 90-640

7 (a) practicing within the scope of their license or certification authorized by state laws to administer medications. All  
8 medications shall be recorded in the patient's permanent record.

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

13  
14 *History Note: Authority G.S. 131E-153; 131E-153.5; 143B-165.*

15 *Codifier determined that findings of need did not meet criteria for emergency rule on October 30,*  
16 *2023;*

17 *Emergency Rule Eff. November 14, 2023;*

18 *Temporary Adoption Eff. February 8, ~~2024~~, 2024;*

19 *Adopted Eff. January 1, 2025.*  
20

1 10A NCAC 13S .0329 is proposed for adoption as follows:

2  
3 **10A NCAC 13S .0329 POST-~~OPERATIVE~~ PROCEDURAL CARE**

4 (a) A patient whose pregnancy is terminated shall be observed in the clinic to ensure that no post-~~operative-procedural~~  
5 complications are present. Thereafter, patients may be discharged according to a physician's order and the clinic's  
6 protocols.

7 (b) Any patient having a complication known or suspected to have occurred during or after the performance of the  
8 abortion shall be transferred to a hospital for evaluation or admission.

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

10 (1) the patient shall be able to move independently with a stable blood pressure and pulse; and

11 (2) bleeding and pain are assessed to be stable and not a concern for discharge.

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

14 (1) symptoms and complications to be looked for; and

15 (2) a dedicated telephone number to be used by the patients should any complication occur or question  
16 arise. This number shall be answered by a person 24 hours a day, seven days a week.

17 (e) The clinic shall have a defined protocol for triaging post-operative calls and complications. This protocol shall  
18 establish a pathway for physician contact to ensure ongoing care of complications that the ~~operating~~ clinic's physician  
19 is incapable of managing.

20  
21 *History Note: Authority G.S. 131E-153; 131E-153.5; 143B-165.*

22 *Codifier determined that findings of need did not meet criteria for emergency rule on October 30,*  
23 *2023;*

24 *Emergency Rule Eff. November 14, 2023;*

25 *Temporary Adoption Eff. February 8, ~~2024~~, 2024;*

26 *Adopted Eff. January 1, 2025.*  
27

1 10A NCAC 13S .0330 is proposed for adoption as follows:

2  
3 **10A NCAC 13S .0330 CLEANING OF MATERIALS AND EQUIPMENT**

4 (a) All supplies and equipment used in patient care shall be cleaned or sterilized between use for different patients.

5 (b) Methods of cleaning, handling, and storing all supplies and equipment shall be such as to prevent the transmission  
6 of infection through their use as determined by the clinic through their governing authority.

7  
8 *History Note: Authority G.S. 131E-153; 131E-153.5; 143B-165.*

9 *Codifier determined that findings of need did not meet criteria for emergency rule on October 30,*  
10 *2023;*

11 *Emergency Rule Eff. November 14, 2023;*

12 *Temporary Adoption Eff. February 8, ~~2024~~ 2024;*

13 *Adopted Eff. January 1, 2025.*  
14



1 10A NCAC 13S .0331 is proposed for adoption as follows:

2  
3 **10A NCAC 13S .0331 FOOD SERVICE**

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

5  
6 *History Note: Authority G.S. 131E-153;131E-153.2; 131E-153.5; 143B-165.*

7 *Codifier determined that findings of need did not meet criteria for emergency rule on October 30,*  
8 *2023;*

9 *Emergency Rule Eff. November 14, 2023;*

10 *Temporary Adoption Eff. February 8, ~~2024~~, 2024;*

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12