

**North Carolina Medical Care Commission**

**Fiscal Impact Analysis**

**Permanent Rule Adoption without Substantial Economic Impact**

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**Agency:** North Carolina Medical Care Commission (“MCC”)

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**Impact Summary:** State Government: Yes  
Local Government: No  
Private Entities: Yes  
Substantial Impact: No

**Authorizing Statutes:** G.S. 131E-153, 131E-153.2, 131E-153.6; Session Law 2023-14

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**Titles of Rules and N.C. Administrative Code Citation**

10A NCAC 13S .0101 Definitions  
10A NCAC 13S .0104 Plans  
10A NCAC 13S .0201 Building Code Requirements  
10A NCAC 13S .0207 Area Requirements  
10A NCAC 13S .0212 Elements and Equipment  
10A NCAC 13S .0318 Governing Authority  
10A NCAC 13S .0319 Policies and Procedures and Administrative Records  
10A NCAC 13S .0320 Admission and Discharge  
10A NCAC 13S .0321 Medical Records  
10A NCAC 13S .0322 Personnel Records  
10A NCAC 13S .0323 Nursing Service  
10A NCAC 13S .0324 Quality Assurance  
10A NCAC 13S .0325 Laboratory Services  
10A NCAC 13S .0326 Emergency Back-Up Services

10A NCAC 13S .0327 Outpatient Procedural Services

10A NCAC 13S .0328 Medications and Sedation

10A NCAC 13S .0329 Post Procedural Care

10A NCAC 13S .0330 Cleaning of Materials and Equipment

10A NCAC 13S .0331 Food Service

*(See proposed text of these rules in Appendix 1)<sup>1</sup>*

### **Background**

On May 16, 2023, Senate Bill 20 became law as SL 2023-14. This new law entitled “An Act to Make Various Changes to Health Care Laws and to Appropriate Funds for Health Care Programs” revised various state laws governing abortions in North Carolina. In response to Senate Bill 20 the North Carolina Medical Care Commission proposes to adopt the following permanent rules under 10A NCAC 13S – Rules Governing the Licensure of Suitable Facilities for the Performance of Surgical Abortions as permanent rules.

Prior to the passage of Senate Bill 20, abortion clinics were regulated under rules promulgated by the North Carolina Department of Health and Human Services under 10A NCAC 14E – Certifications of Clinics for Abortion. Session Law 2023-14 s2.2, codified at G.S. 131E-153.5, moved authority to promulgate the rules necessary for implementation of the regulation of abortion clinics to the Medical Care Commission. These proposed permanent rules are a continuation of the prior regulatory framework under 10A NCAC 14E but are now proposed for adoption in 10A NCAC 13S under Medical Care Commission authority with updates to comply with S.L. 2023-14.

In addition to updates to comply with the provisions of the session law, numerous technical and formatting revisions have been made to these proposed permanent rules from the former rules in 10A NCAC 14E. Additionally, rule language has been updated to be consistent with current medical terminology, standard best practices, and to align with the requirements in S.L. 2023-14.

Currently, there are 15 abortion clinics licensed by the Division of Health Service Regulation (“Division”) to perform abortion procedures. For the purpose of this fiscal note, the Division assumes the number of clinics will stay constant for the timespan covered by the analysis. The Division based this assumption on historically stable numbers of clinics. All 15 clinics are privately owned. For purposes of this fiscal note, the 10A NCAC 14E rules are used as the baseline, as those rules have been in place since February 1, 1976 and were last amended on October 1, 2015.

Session Law 2023-14 s. 2.2, as codified in G.S. 131E-153.5, authorizes the Medical Care Commission to adopt rules necessary to implement Part II of SL 2023-14. The adoption of these

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<sup>1</sup> Beginning on Page 37 of this document, the appendix also includes the 2019 version of 10A NCAC Subchapter 14 – Certification of Clinics for Abortion which, together with S.L. 2023-14, was used as the baseline for this fiscal note. Included as Appendix 2.

rules will ensure continuity of care for patients and will protect the health and safety of women in obtaining lawful abortions in a clinic regulated by the Division.

## **Rule Adoption**

### **10A NCAC 13S .0101 Definitions**

The Agency is proposing to adopt this permanent rule. The proposed rule updates definitions from 10A NCAC 14E .0101 to align with S.L. 2023-14. In paragraph:

- (1) The term “abortion” has been changed to reference the statutory definition.
- (2) The timeframe that a clinic is able to perform abortions has changed from the first 20 weeks of pregnancy to the first 12 weeks.
- (6) The rule reference for the term “governing authority” has been updated.
- (8) The definition of the term “new clinic” has been updated to mean a clinic that is certified or licensed as of July 1, 2023. There has also been a terminology change in which “licensure” has replaced “certification,” which is also applied in all other rules in this package.
- (9) The definition of “qualified physician” has been removed and a reference to the statutory definition is added to the rule.

### **Fiscal Impact**

The proposed rule changes should result in incremental improvements to rule clarity and consistency with current practices. This improvement could result in nominal improvements to compliance which, in turn, should help ensure the ongoing health and safety of the public who use the services of the clinics.

### **10A NCAC 13S .0104 Plans and Specifications**

The Agency is proposing to permanently adopt this rule. The proposed rule combines the requirements in Rule 10A NCAC 14E .0104 – Plans, Rule 10A NCAC 14E .0112 – Alterations, and Rule 10A NCAC 14E .0105 – Approval into one rule. Also, the rule title was updated to reflect the combining of these rules, as well as the requirements to submit both construction documents/plans and construction specifications to the Division for review and approval. This new rule title, “Plans and Specifications,” and the requirements listed in this rule provides consistency among other rule sets under the Division’s authority. The proposed changes do not impose any new requirements.

### **Fiscal Impact**

The proposed rule changes should result in incremental improvements to rule clarity and consistency with current practices. This could result in nominal improvements to compliance which, in turn, should help ensure the ongoing health and safety of the public who use the services of the clinics.

## **10A NCAC 13S .0201 Building Code Requirements**

The Agency is proposing to permanently adopt this rule. The changes to this rule as compared to 10A NCAC 14E .0201 are technical changes, updating information concerning access to current editions of the North Carolina State Building Codes and updating cost information for the North Carolina State Building Codes.

### **Fiscal Impact**

The proposed rule changes should result in incremental improvements to rule clarity and consistency with current practices. This could result in nominal improvements to compliance which, in turn, should help ensure the ongoing health and safety of the public who use the services of the clinics.

## **10A NCAC 13S .0207 Area Requirements**

The Agency is proposing to permanently adopt this rule. This rule contains the minimum spaces and areas required in licensed abortion clinics. The proposed language updates these requirements as compared to 10A NCAC 14E .0207 to reflect current practices and industry standards for outpatient procedures. Proposed updates to Rule 13S .0207 as compared to 14E .0207 are listed below:

Revised patient care spaces to reflect clinical services to be provided, and the anticipated acuity level of the patients being served. The revision combined designation areas and included updated wording for certain areas including personnel areas and lab areas. Patient care spaces include counseling areas, pre- and post- procedure areas, and procedure rooms. Specifically, designated area may be combined for pre- and post- procedure care and several storage areas may be combined for designation purposes.

Revised general space requirements to better reflect design elements that are common to areas designated for outpatient services. These design elements include reception and waiting rooms, areas for charting and other administrative activities, areas for the handling and storage of clean and soiled materials, and janitor's closets.

Revised requirements based on common clinical and support for outpatient services. These changes include clinical and support services include secure storage of medications, compliant requirements where laboratory testing is performed, and handling and storage of medical and surgical supplies.

### **Fiscal Impact**

#### **State**

The changes proposed in this rule better reflect the outpatient services to be provided in the clinics. With the adoption of this rule, Construction Section plan review time done by

the Division for the clinics is expected to be slightly reduced due to clarifications on the use of rooms and spaces that the architects and engineers would have to verify on the construction documents. The Construction Section received 3 abortion clinic projects of varying degrees of modifications over the past 5 years. Therefore, the number of these types of projects being reviewed each year is very low; thus, resulting in a negligible impact associated with the permanent adoption of this rule.

#### Abortion Clinic License Holder/Prospective Applicant

The proposed changes align with current building standards for these outpatient service space and also make the rule slightly more flexible as to how to meet the minimum area requirements. For example, the requirement for a “soiled workroom” is replaced with “separate areas for storage and handling of clean and soiled materials.” The rule will achieve the same desired result of keeping soiled materials away from clean materials but without the unnecessary requirement that the soiled materials be in a completely different room. Changes such as these acknowledge that there could be more than one way to achieve the desired result while also allowing the provider to configure their space to achieve an efficient flow of patient care. The proposed rule changes will not require existing facilities to make any changes to their current space configurations. Prospective applicants could benefit from the incrementally increased flexibility if they choose to design their spaces so as to allow them to reduce their square footage, for example. The magnitude of savings would vary greatly depending on the condition and specifications of the existing building being renovated or the construction of a new building as well as individual providers’ preferences and needs.

### **10A NCAC 13S .0212 Elements and Equipment**

The Agency is proposing to permanently adopt this rule. This rule contains minimum mechanical, plumbing, and electrical requirements for licensed abortion clinics. Proposed changes to Rule .0212 as compared to 10A NCAC 14E .0206 are listed below:

The proposed changes are formatting changes to the rule to make it easier to read, the removal of requirements that are no longer applicable and updating the rule to reflect current industry practices in outpatient services.

The requirements being removed and the associated impacts are described as follows:

Temperature and humidity in procedure and recovery room were removed. The reason this was removed is because a recovery room is no longer required to be a separate room and the standard of care for outpatient services has been updated for the procedure room.

Item (1)(f) was updated to reflect space/room requirements listed in Rule .0207. The pressure relationships and total air changes are consistent with industry standards for these named spaces/rooms. The remainder of .0212(b)(i)-(vii) was relocated for formatting

purposes and the requirements were added into (1)(a)-(f). This includes the updates to reflect the designated area changes made in Rule .0207.

Item 2(a) updates information concerning online access to NFPA 99, as well as updates the current cost for NFPA 99.

Item (2) (d) that requires floor drains not to be installed and (e) that requires the building drainage avoid installation above the procedure room are proposed to be removed since these requirements are not the standard of care for these outpatient services.

Item (3)(c) is proposed to be removed. Requirements on the location of ground fault protected receptacles are governed by the North Carolina Electrical Code.

Item (3)(d) is proposed to be removed. The requirement for a smoke detector within 15 feet of each procedure or recovery room entrance is not required because inhalation anesthesia is not used for the rooms in a concentration level that would result in a fire. The requirements for fire safety will be regulated by the Building Code.

### **Fiscal Impact**

#### State

The changes proposed in this rule will result in a negligible impact for the State. Proposed changes better reflect the outpatient services to be provided in these clinics. With the adoption of this rule, Construction Section plan review time for abortion clinics is expected to be reduced due to the reduction in the number of mechanical, plumbing, and electrical requirements. Since only 3 abortion clinic projects were submitted for review and approval over the past 5 years, time saved for the review of these projects will be absorbed within the normal plan reviews for the Construction Section.

#### Abortion Clinic License Holder/Prospective Applicant

The adoption of this rule would result in a fiscal impact for abortion clinic license holders or prospective applicants. Changes could provide savings to owners of clinics doing renovation/construction in the future, but there would be no impact to existing licensed clinics. The magnitude of savings will vary widely based on desired design features of the clinic, existing conditions and age of the building, whether the building is a new build or renovation, local building and fire codes that are more stringent, population being served by the clinic, and many possible additional factors. It stands to reason that reducing the requirements could result in some amount of cost savings to applicants, but there are too many variables to estimate. Presumably, renovations would not be undertaken unless it was financially feasible and benefits would outweigh the costs to the owners.

### Abortion Clinic Patients

The adoption of this rule would result in no fiscal impact for abortion clinic patients. The mechanical, plumbing, and electrical system requirements are consistent with the industry standard for outpatient services.

### **10A NCAC 13S .0315 Housekeeping**

The Agency is proposing to permanently adopt this rule. This rule contains minimum cleaning requirements for licensed abortion clinics. This rule is the same as the prior 10A NCAC 14E .0315 rule.

#### **Fiscal Impact**

No fiscal impact associated with the permanent adoption of this rule.

### **10A NCAC 13S .0318 Governing Authority**

The Agency is proposing to permanently adopt this rule. The proposed changes to this rule as compared to 10A NCAC 14E .0302 provide clarity and consistency with the proposed permanent 13S .0207 rule and authorizes the governing body to determine the utilization of space to accommodate various aspects of patient visits.

#### **Fiscal Impact**

No fiscal impact associated with the permanent adoption of this rule.

### **10A NCAC 13S .0319 Policies and Procedures and Administrative Records**

The Agency is proposing to permanently adopt this rule. The proposed changes to this rule as compared to 10A NCAC 14E .0303 require a policy and procedure for the governing authority to designate space in compliance with the language that was added into the proposed permanent 13S .0318 rule. The Rule removed item (c)(8), referral of patients, because this is addressed in .0320 Admissions and Discharge.

#### **Fiscal Impact**

No fiscal impact associated with the permanent adoption of this rule.

### **10A NCAC 13S .0320 Admission and Discharge**

The Agency is proposing to permanently adopt this rule. This rule requires an employee to be onsite with patients and for patients to only be admitted by a physician licensed in North

Carolina. The rule requires that a patient be transferred to a hospital if not discharged 12 hours after the procedure. The rule requires that the patient be provided information in writing including the fee schedule, doctor's name, post procedure instructions, and the number for complaint. This rule is the same as the prior 10A NCAC 14E .0304 rule for admission and discharge.

**Fiscal Impact**

No fiscal impact associated with the permanent adoption of this rule.

**10A NCAC 13S .0321 Medical Records**

The Agency is proposing to permanently adopt this rule. The proposed changes to this rule as compared to 10A NCAC 14E .0305 clarify medical records requirements by combining listed items and removing duplicative items.

**Fiscal Impact**

No fiscal impact associated with the permanent adoption of this rule.

**10A NCAC 13S .0322 Personnel Records**

The Agency is proposing to permanently adopt this rule. The proposed changes to this rule as compared to 10A NCAC 14E .0306 remove redundancies and combined items to provide clarification of the personnel record requirements.

**Fiscal Impact**

No fiscal impact associated with the permanent adoption of this rule.

**10A NCAC 13S .0323 Clinic Staffing**

The Agency is proposing to permanently adopt this rule. The proposed changes to this rule as compared to 10A NCAC 14E .0307 remove the requirements for nursing experience in a postpartum or post-operative care and expand the opportunity for utilization of other qualified health care practitioners to manage the care of patients. The proposed rule replaces the term "Nursing Services" with the term "Clinic Staffing" to be more inclusive and increase the opportunity for RN employment. The postpartum or post-operative care that was previously required is not the skill set necessary for providing nursing services for this outpatient services in a clinic. Additionally, a Registered Nurse, Nurse Practitioner, Physician Assistant, or an additional Physician in the clinic has the knowledge base to provide patient safety necessary for this outpatient procedure to meet the onsite staffing requirement in .0323(d). The regulated community requested this change based on assessment of staffing needs for this outpatient service.



### **Fiscal Impact**

This rule change could benefit both existing licensed clinics as well as future clinics by expanding the potential pool of candidates, making it easier to fill critical nursing positions. It will also allow clinics to determine the most efficient use of their existing staff while ensuring the safety of patients. A larger pool of individuals, especially nurses, will be able to fulfill responsibilities. An unintended potential benefit of this enhanced flexibility is that clinics may save money by not requiring an additional salaried worker on site when unnecessary. Whether or not clinics realize this benefit will vary by clinic depending on their existing staffing levels and needs and on the future availability of practitioners to fill available positions.

### **10A NCAC 13S .0324 Quality Assurance**

The Agency is proposing to permanently adopt this rule. The proposed changes to this rule as compared to 10A NCAC 14E .0308 authorize the governing body to develop guidelines to address the individual needs of the clinic and is consistent with other standards of care for licensed healthcare providers. The responsibilities of the governing body is included in the definition .0101. The changes to the language in the rule allows the governing body to develop systems that fit the individualized facility. The facility is still required to maintain record keeping per the policy of the governing authority. The prior language in 14E .0308(f) is removed because the purpose of (f) is encompassed in .0324(b). The Rule requires the quality improvement committee to evaluate processes and maintain systems to demonstrate compliance with all the regulations. The proposed permanent rule 13S .0318 additionally outlines the responsibilities of the governing authority in policy and procedure to maintain safe treatment. To restate in this rule is redundant.

### **Fiscal Impact**

No fiscal impact associated with the permanent adoption of this rule.

### **10A NCAC 13S .0325 Laboratory Services**

The Agency is proposing to permanently adopt this rule. The proposed changes to this rule as compared to 10A NCAC 14E .0309 clarifies that a clinic must comply with the requirements under the Clinical Laboratory Improvement Amendments (CLIA) program and have a CLIA certificate as required by federal law. The different certificates determine the level work that can be performed in the lab. This certification was previously required by federal law so the change from 14E does not create a fiscal impact. The former 14E rule had a list of lab tests. This changes grant decision making based on clinical expertise for medically necessary lab services. The doctor will decide which lab tests are necessary for each patient.

### **Fiscal Impact**

Adoption of this rule will allow increased flexibility for a physician to order only the labs deemed medically necessary for an individual patient. This could result in cost savings for the patient. The most likely savings would come from a patient not having to pay for the Rh factor test when it's deemed not necessary. There is no way for the Division to predict the likelihood or magnitude of these savings. It is important to note that the decision as to which labs to order will continue to be made by the physician on a patient-by-patient basis.

### **10A NCAC 13S .0326 Emergency Back-Up Services**

The Agency is proposing to permanently adopt this rule. The proposed changes to this rule as compared to 10A NCAC 14E .0310 remove the requirement for the clinic to have a transfer agreement signed by a hospital. This requirement has been removed because hospitals are no longer providing signed transfer agreements. Emergency rooms are required to admit patients so a signed agreement is unnecessary for transfer.

This proposed rule also clarifies the minimum requirements for providing treatment in an emergency situation to include defining emergency instructions, staff training, and standard protocols of health care. These additional written instructions were requested by the regulated community.

The equipment was also updated to include the removal of utilization of suction machine as it is not used in this type of facility.

### **Fiscal Impact**

As a result of the rule, some facilities may need to update their existing written emergency protocols to include specific instructions. This could involve minimal time and material costs to the clinics for providing these written instructions. Although emergency protocols are already required, having clear written instructions in place could provide incrementally better outcomes with patient care in the rare case of an emergency.

### **10A NCAC 13S .0327 Outpatient Procedural Services**

The Agency is proposing to permanently adopt this rule. The proposed changes to this rule as compared to 10A NCAC 14E .0311 provide clarification and consistency in the oversight of procedure rooms and standards of infection control. The proposed rule replaces the term "Surgical Services" with the term "Outpatient Procedural Services" to be consistent with medical language used by providers to describe the provided services.

### **Fiscal Impact**

No fiscal impact associated with the permanent adoption of this rule.

### **10A NCAC 13S .0328 Medications and Sedation**

The Agency is proposing to permanently adopt this rule. The proposed changes to this rule as compared to 10A NCAC 14E .0312 replaces the term “anesthesia” with the term “sedation” to be reflective of standards of care provided within abortion clinics and contrary to the definition of anesthesia. Sedation is a lower-level anesthesia and is the correct terminology for what is used in the clinic. This is not a change in the procedure but better reflects the correct terminology for what is currently being used in facilities. This terminology change will not result in a change to the service and therefore will not have a fiscal impact.

#### **Fiscal Impact**

No fiscal impact associated with the permanent adoption of this rule.

### **10A NCAC 13S .0329 Post Procedural Care**

The Agency is proposing to permanently adopt this rule. The proposed changes to this rule as compared to 10A NCAC 14E .0313 replaces the term “operative” with the term “procedural” to be consistent with medical language used by providers to describe the provided services.

#### **Fiscal Impact**

No fiscal impact associated with the permanent adoption of this rule.

### **10A NCAC 13S .0330 Cleaning of Materials and Equipment**

The Agency is proposing to permanently adopt this rule. This rule requires sterilization of equipment and methods for cleaning. This rule is the same as the prior 14E 10A NCAC .0314 rule.

#### **Fiscal Impact**

No fiscal impact associated with the permanent adoption of this rule.

### **10A NCAC 13S .0331 Food Service**

The Agency is proposing to permanently adopt this rule. This rule requires snacks and drink to be available for patients. This rule is the same as the prior 14E 10A NCAC .0316 rule.

## **Fiscal Impact**

No fiscal impact associated with the permanent adoption of this rule.

## **Summary**

The content of the nineteen (19) rules is directly supported by the purpose of the S.L. 2023-14, which makes the adoption of these rules necessary to ensure that Part II of SL 2023-14 can be effectively implemented by the Medical Care Commission and administered by the Department of Health and Human Services. Consistent with Section 2.4 of S.L. 2023-14, the Medical Care Commission has determined that each of the 19 rules are necessary to implement Part 4A of Chapter 131E of the General Statutes. The biggest driving factor behind the proposed rules is the continued protection of the health, safety, and wellbeing of women obtaining lawful abortions in a clinic regulated by the Division, continuing the prior regulatory scheme under 10A NCAC 14E, with limited changes and updates.

As measured from the baseline conditions, there are no quantifiable costs or benefits associated with the proposed rules. Most changes to the proposed Subchapter 13S, as compared to the former Subchapter 14E rules, are for the purpose of providing clarity and consistency with the S.L. 2023-14 and aligning with current industry standards for outpatient services. This could result in nominal improvements to compliance of regulated clinics which, in turn, should help ensure the ongoing health and safety of the public who use their services.

There are several proposed changes that will allow for increased flexibility as to how licensed clinics comply with the minimum requirements. These include configuring their space to maximize efficient flow of patient care (Rule 13S .0207) and updating mechanical, plumbing, and electrical requirements to meet the standard of care for outpatient, rather than surgical, services (Rule 13S .0212). These rule changes could result in potential savings for owners of clinics doing renovation/construction in the future. The magnitude of savings will vary widely based on factors such as desired design features of the clinic, existing condition and age of the building, whether the building is a new build or renovation, and local building and fire codes. Another proposed change will expand the types of practitioners qualified to provide nursing services in an outpatient clinic (Rule 13S .0323). This change could benefit both existing licensed clinics as well as future clinics by expanding the potential pool of candidates to fill critical nursing positions and allowing clinics to determine the most efficient use of their existing staff while ensuring the safety of patients. Lastly, a change to the Laboratory Services requirements (Rule 13S .0325) will allow increased flexibility for a physician to order only the labs deemed medically necessary for an individual patient. The most likely savings would come from a patient not having to pay for the Rh factor test when deemed not necessary. This could result in cost savings for the patient, but there is no way for the Division to predict the likelihood or magnitude of these savings. It is important to note that the decision as to which labs to order will continue to be made by the physician on a patient-by-patient basis.

One proposed change could result in minimal one-time costs for licensed clinics to update their emergency protocols to include specific written emergency instructions. Having clear written

instructions in place could result in incremental improvements to patient outcomes in the rare case of an emergency.

The proposed rules will not require any procedural changes nor additional workload or staffing for the State above existing requirements, as compared to the prior requirements under 10A NCAC 14E. There could be minimal time cost savings to the Division from a reduction in the number of requirements for construction plan review. There have been only three abortion clinic projects of varying degrees of renovation submitted to the Division for review and licensing over the past five years; as such, any time cost savings from these changes are expected to be negligible.

North Carolina currently has 15 clinics in operation, all of which are privately owned. Neither the federal government nor local government owns or operates these clinics, so the rules will have no federal or local government impact. As compared to the baseline, the proposed rules are expected to have minimal, unquantifiable benefits and costs to the regulated community and minimal, unquantifiable benefits to the Division. These costs and benefits will not exceed \$1 million in a year; as such, there will not be a substantial economic impact as a result of the proposed rules.

APPENDIX 1 (Rules proposed for permanent adoption)

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.*

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

*Emergency Rule Eff. November 14, 2023;*

*Temporary Adoption Eff. February 8, 2024;*

*Adopted Eff. October 1, 2024.*

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

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

- (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;  
Codifier determined that findings of need did not meet criteria for emergency rule on October 30, 2023;  
Emergency Rule Eff. November 14, 2023;  
Temporary Adoption Eff. February 8, 2024;  
Adopted Eff. October 1, 2024.*

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

(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;  
Codifier determined that findings of need did not meet criteria for emergency rule on October 30, 2023;  
Emergency Rule Eff. November 14, 2023;  
Temporary Adoption Eff. February 8, 2024;  
Adopted Eff. October 1, 2024.*



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 minimum requirements for clinics that are licensed by the Division to perform abortions:

- (1) reception and waiting room;
- (2) designated area or areas for pre-procedure and post-procedure activities;
- (3) procedure room;
- (4) a clean area for self-contained secure medication storage complying with security requirements of state and federal laws;
- (5) area compliant with Clinical Laboratory Improvement Amendments (CLIA) requirements in which laboratory testing can be performed;
- (6) separate areas for storage and handling of clean and soiled materials;
- (7) patient toilet;
- (8) personnel toilet facilities;
- (9) janitor's closets;
- (10) space and equipment for assembling, sterilizing and storing medical and surgical supplies;
- (11) storage space for medical records of all media types used by the facility; and
- (12) space for charting, communications, counseling, business functions, and other administrative activities.

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

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

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

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

- (2) Plumbing And Other Piping Systems.
  - (a) Piped-in medical gas and vacuum systems, if installed, shall meet the requirements of NFPA-99, category 2 system, which is hereby incorporated by reference including subsequent amendments and editions. Copies of NFPA-99 may be purchased from the National Fire Protection Association online at <https://www.nfpa.org/product/nfpa-99-code/p0099code> at a cost of one hundred forty-nine dollars (\$149.00) 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 ten (10) inches above the bottom of the basin with mixing type fixture valves that can be operated without the use of the hands.

- (c) Hot water distribution systems shall provide hot water at hand washing facilities at a minimum temperature of 100 degrees F. and a maximum temperature of 116 degrees F.
- (3) Electrical Requirements.
- (a) The facility's paths of egress to the outside shall have at a minimum, listed battery backup lighting units of one and one-half hour capability that will automatically provide at least 1 foot candle of illumination at the floor in the event needed for a utility or local lighting circuit failure.
  - (b) Electrically operated medical equipment necessary for the safety of the patient shall have, at a minimum, battery backup.
- (4) Buildings systems and medical equipment shall have preventative maintenance conducted as recommended by the equipment manufacturers' or installers' literature to assure operation in compliance with manufacturer's instructions.

*History Note: Authority G.S. 131E-153.5; 143B-165;  
Codifier determined that findings of need did not meet criteria for emergency rule on October 30, 2023;  
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10A NCAC 13S .0315 is proposed for adoption as follows:

### SECTION .0300 – SERVICES

#### 10A NCAC 13S .0315 HOUSEKEEPING

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

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

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

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

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10A NCAC 13S .0318 is proposed for adoption as follows:

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

- (a) The governing authority, as defined in Rule .0101(6) of this Subchapter, shall appoint a chief executive officer or a designee of the clinic to represent the governing authority and shall define his or her authority and duties in writing. This person shall be responsible for the management of the clinic, implementation of the policies of the governing authority and authorized and empowered to carry out the provisions of these Rules.
- (b) The chief executive officer or designee shall designate, in writing, a person to act on his or her behalf during his or her absence. In the absence of the chief executive officer or designee, the person on the grounds of the clinic who is designated by the chief executive officer or designee to be in charge of the clinic shall have access to all areas in the clinic related to patient care and to the operation of the physical plant.
- (c) When there is a planned change in ownership or in the chief executive officer, the governing authority of the clinic shall notify the Division in writing of the change.
- (d) The clinic's governing authority shall adopt operating policies and procedures that shall:
- (1) specify the individual to whom responsibility for operation and maintenance of the clinic is delegated and methods established by the governing authority for holding such individuals responsible;
  - (2) provide for at least annual meetings of the governing authority, for which minutes shall be maintained; and
  - (3) maintain a policies and procedures manual designed to ensure safe and adequate care for the patients which shall be reviewed, and revised when necessary, at least annually, and shall include provisions for administration and use of the clinic, compliance, personnel quality assurance, procurement of outside services and consultations, patient care policies, and services offered.
- (e) When the clinic contracts with outside vendors to provide services such as laundry or therapy services, the governing authority shall be responsible to assure the supplier meets the same local and State standards the clinic would have to meet if it were providing those services itself using its own staff.
- (f) The governing authority shall provide for the selection and appointment of the professional staff and the granting of clinical privileges and shall be responsible for the professional conduct of these persons.
- (g) The governing authority shall be responsible for ensuring the availability of supporting personnel to meet patient needs and to provide safe and adequate treatment.
- (h) The governing authority shall certify that the physical facilities to be used are adequate to safeguard the health and safety of patients; of note one area may accommodate various aspects of the patient's visits.

*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;  
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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 physicians to assist them in understanding their responsibilities within the organizational framework of the clinic. These shall include:

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

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

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

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

- (a) There shall be on the premises throughout all hours of operation an employee authorized to receive patients and make administrative decisions regarding patients.
- (b) All patients shall be admitted only under the care of a physician who is currently licensed to practice medicine in North Carolina.
- (c) Any patient not discharged within 12 hours following the abortion procedure shall be transferred to a hospital licensed pursuant to Chapter 131E, Article 5 of the General Statutes.
- (d) Following admission and prior to obtaining the consent for the procedure, representatives of the clinic's management shall provide to each patient the following information:
  - (1) a fee schedule and any extra charges routinely applied;
  - (2) the name of the attending physician or physicians and hospital admitting privileges, if any. In the absence of admitting privileges a statement to that effect shall be included;
  - (3) instructions for post-procedure problems and questions as outlined in Rule .0329(d) of this Section;
  - (4) grievance procedures a patient may follow if dissatisfied with the care and services rendered; and
  - (5) the telephone number for Complaint Intake of the Division.

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

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

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

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

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

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

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

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

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

(f) Medical records shall be the property of the clinic and shall be preserved or retained in the State of North Carolina for a period of not less than 10 years from the date of the most recent discharge, unless the client is a minor, in which case the record must be retained until three years after the client's 18th birthday, regardless of change of clinic ownership or administration. Such medical records shall be made available to the Division upon request and shall not be removed from the premises where they are retained except by subpoena or court order.

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

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

*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;*

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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 copy of a valid license (if required).
- (2) Personnel records shall be confidential.
- (3) Representatives of the Division conducting an inspection of the clinic shall have the right to inspect personnel records.

(b) Job Descriptions:

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

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

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

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

(f) Employee and contractual employee records for health screening as defined in Rule .0101(6) of this Subchapter, education, training, and verification of professional certification shall be available for review by the Division.

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

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

**10A NCAC 13S .0323 CLINIC STAFFING**

- (a) The clinic shall have an organized clinical staff under the supervision of a nursing supervisor who is currently licensed as a Registered Nurse and who has responsibility for all nursing services.
- (b) The nursing supervisor shall report to the chief executive officer or designee and shall be responsible for:
  - (1) provision of nursing services to patients; and
  - (2) developing a nursing policy and procedure manual and written job descriptions for nursing personnel.
- (c) The clinic shall have the number of licensed and ancillary nursing personnel on duty to assure that staffing levels meet the total nursing needs of patients based on the number of patients in the clinic and their individual nursing care needs.
- (d) There shall be at least one Registered Nurse who is currently licensed to practice professional nursing in North Carolina, or other health care practitioner as defined in G.S. 90-640 (a) practicing within the scope of their license or certification who is basic life support (BLS) certified and authorized by state laws to administer medications as required for analgesia, nausea, vomiting, or other indications on duty at all times patients are in the procedure rooms and recovery area.

*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 include one physician who is not an owner, the chief executive officer or designee, and other health professionals.
- (d) The frequency of meetings and details of data collection shall be defined by the governing authority.

*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;*

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10A NCAC 13S .0325 is proposed for adoption 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, and will perform laboratory tests appropriate to their Clinical Laboratory Improvement Amendments (CLIA) certification.
- (b) The governing authority shall establish written policies regarding which surgical specimens require examination by a pathologist.
- (c) Each patient shall have laboratory testing as determined to be clinically necessary by the physician, or as required by law. A record of the results of any tests performed will be included in the patient's medical record.
- (d) The clinic shall maintain a manual in a location accessible by employees, that meets requirements for the level of clinic's CLIA certification. This includes the procedures, instructions, and manufacturer's instructions for each test procedure performed including:
  - (1) sources of reagents, and quality control procedures; and
  - (2) information concerning the basis for the listed "normal" ranges.

*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;  
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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.

(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 an automated external defibrillator.

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

(4) ultrasound equipment.

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

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

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

**10A NCAC 13S .0327    OUTPATIENT PROCEDURAL SERVICES**

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

(b) Tissue Examination:

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

*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;*

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

**10A NCAC 13S .0328    MEDICATIONS AND SEDATION**

- (a) No medication or treatment shall be given except on written order of a physician.
- (b) Medications, including injections shall be administered by a physician, Registered Nurse, and other health care practitioners as defined in G.S. 90-640 (a) practicing within the scope of their license or certification authorized by state laws to administer medications. All medications shall be recorded in the patient's permanent record.
- (c) The sedation shall be administered only under the direct supervision of a licensed physician. Direct supervision means the physician must be present in the clinic and immediately available to furnish assistance and direction throughout the administration of the sedation. It does not mean the physician must be present in the room when the sedation is administered.

*History Note:    Authority G.S. 131E-153; 131E-153.5; 143B-165.  
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10A NCAC 13S .0329 is proposed for adoption as follows:

**10A NCAC 13S .0329 POST PROCEDURAL CARE**

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

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

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

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

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

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

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

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

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

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

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APPENDIX 2 (For REGULATORY BASELINE)

**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;*

*Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. August 24, 2019.*

**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;*

*Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. August 24, 2019.*

#### **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;*

*Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. August 24, 2019.*

#### **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](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;*

*Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. August 24, 2019.*

#### **10A NCAC 14E .0105 APPROVAL**

(a) Approval of construction documents and specifications shall be obtained from the Division of Health Service Regulation, in accordance with the rules in Section .0200 of this Subchapter. The construction documents and specifications require additional approval from the Department of Health and Human Services, Division of Public Health, Environmental Health Section, and the Department of Insurance.

(b) 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. 14-45.1(a); 143B-10;  
Eff. February 1, 1976;  
  
Readopted Eff. December 19, 1977; Amended  
Eff. December 1, 1989;  
  
Readopted Eff. February 1, 2021.*

#### **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;  
  
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. August 24, 2019.*

#### **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;*

*Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. August 24, 2019.*

#### **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;*

*Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. August 24, 2019.*

#### **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;*

*Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. August 24, 2019.*

#### **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-23;*

*Eff. February 1, 1976;*

*Amended Eff. December 1, 1989;*



*Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. August 24, 2019.*

#### **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;*

*Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. August 24, 2019.*

#### **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;*

*Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. August 24, 2019.*



## 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;*

*Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. August 24, 2019.*

### 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 <https://www.oah.nc.gov/>.

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

*Readopted Eff. December 19, 1977;*

*Amended Eff. August 1, 2019; October 1, 2015; July 1, 1994;*

*Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. August 24, 2019.*

### 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;*

*Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. August 24, 2019.*

#### **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;*

*Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. August 24, 2019.*

#### **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;*

*Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. August 24, 2019.*

#### **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
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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 NFPA99-2012 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

992012 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;*

*Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. August 24, 2019.*

#### **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;*

*Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. August 24, 2019.*

#### **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;*

*Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. August 24, 2019.*

## SECTION .0300 – GOVERNING AUTHORITY

### 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;*

*Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. August 24, 2019.*

### 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;*



*Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. August 24, 2019.*

**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;*

*Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. August 24, 2019.*

**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;*

*Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. August 24, 2019.*

### **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;*

*Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. August 24, 2019.*

### **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;*

*Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. August 24, 2019.*

#### **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;*

*Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. August 24, 2019.*

#### **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;*

*Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. August 24, 2019.*

### **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;*

*Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. August 24, 2019.*

#### **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;*

*Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. August 24, 2019.*

#### **10A NCAC 14E .0312 MEDICATIONS AND ANESTHESIA**

- (a) No medication or treatment shall be given except on written order of a physician.
- (b) Any medications shall be administered by a Registered Nurse licensed in accordance with G.S. 90-171.30 or G.S. 90-171.32 and must be recorded in the patient's permanent record.
- (c) The anesthesia shall be administered only under the direct supervision of a licensed physician.

*History Note: Authority G.S. 14-45.1(a); 14-45.1(g); 143B-10;*

*Eff. February 1, 1976;*

*Readopted Eff. December 19, 1977;*

*Readopted Eff. February 1, 2021.*

#### **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;*

*Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. August 24, 2019.*

#### **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;*

*Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. August 24, 2019.*

#### **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 <https://www.oah.nc.gov/>.

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

*Readopted Eff. December 19, 1977;*

*Amended Eff. August 1, 2019; October 1, 2015; December 1, 1989;*

*Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. August 24, 2019.*

#### **10A NCAC 14E .0316 FOOD SERVICE**

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

*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;*

*Readopted Eff. February 1, 2021.*



## 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;*

*Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. August 24, 2019.*

### 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;*

*Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. August 24, 2019.*