

**Fiscal Impact Analysis for
Permanent Rule Amendments and Adoption without Substantial Economic Impact**

10A NCAC 14E Certifications of Clinics for Abortion

Agency Proposing Rule Change

North Carolina Department of Health and Human Services

Contact Persons

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Fiscal Impact Summary

Federal Government	No Impact
State Government	Yes, but not substantial impact.
Local Government	No Impact
Certified Providers	Yes, but not substantial impact.

Titles of Rule Changes and Statutory Citations

**See proposed text of these rules in the Appendix*

10A NCAC 14E Certification of Clinics for Abortion

Section .0100 – Certification Procedure

- Definitions 10A NCAC 14E .0101 (Amend)
- Plans 10A NCAC 14E .0104 (Amend)
- Renewal 10A NCAC 14E .0109 (Amend)
- Inspections 10A NCAC 14E .0111 (Amend)

Section .0200 – Minimum Standards for Construction and Equipment

- Building Code Requirements 10A NCAC 14E .0201 (Amend)
- Sanitation 10A NCAC 14E .0202 (Amend)
- Elements and Equipment 10A NCAC 14E .0206 (Amend)
- Area Requirements 10A NCAC 14E .0207 (Amend)

Section .0300 – Administration

- Governing Authority 10A NCAC 14E .0302 (Amend)
- Policies and Procedures and Administrative Records 10A NCAC 14E .0303 (Amend)
- Admission and Discharge 10A NCAC 14E .0304 (Amend)
- Medical Records 10A NCAC 14E .0305 (Amend)
- Personnel Records 10A NCAC 14E .0306 (Amend)
- Nursing Service 10A NCAC 14E .0307 (Amend)
- Quality Assurance 10A NCAC 14E .0308 (Adopt)
- Laboratory Services 10A NCAC 14E .0309 (Amend)

- Emergency Back-up Services 10A NCAC 14E .0310 (Amend)
- Surgical Services 10A NCAC 14E .0311 (Amend)
- Post Operative Care 10A NCAC 14E .0313 (Amend)
- Housekeeping 10A NCAC 14E .0315 (Amend)

Statutory Authority

Gen. Stat. § 14-45.1(a)
Gen. Stat. § 90-21.83
Gen. Stat. § 131E-269
Gen. Stat. § 143B-10
S.L. 2013-366 s.4(c)

Background

Session Law 2013-366 s.4(c) directs the Department of Health and Human Services to amend the certification rules applicable to abortion clinics to ensure that “standards for clinics address the on-site recovery phase of patient care at the clinic, protect patient privacy, provide quality assurance, and ensure that patients with complications receive the necessary medical attention, while not unduly restricting access.” The law also allows for the Department to apply requirements of licensed ambulatory surgical facilities to the standards applicable to clinics certified to perform abortions to ensure a higher level of patient safety.

The rule adoption and amendments presented in this fiscal analysis are the result of consultation with various stakeholders, including several physicians from various clinical backgrounds. The proposed amendments strengthen existing regulations to assure quality of care, improve patient safety and privacy, and provide accountability during and after abortion procedures without restricting access to the procedure.

In addition to addressing the provisions of the session law, numerous technical and formatting revisions have been made as well. The rules for certification of abortion clinics have not been updated in nearly 20 years. Rule language has been amended to be consistent with current medical terminology and standard best practices.

Currently, there are 16 free-standing clinics in North Carolina that are certified by the Division of Health Service Regulation (DHSR) to perform abortion procedures. Clinics are certified in accordance with the rules in Subchapter 10A NCAC 14E of the N.C. Administrative Code. These rules are specific to free-standing abortion clinics under 10A NCAC 14E and are not applicable to licensed hospitals or ambulatory surgical facilities. For the purpose of this fiscal note, the Division assumes that 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.

Summary of Anticipated Fiscal Impact:

As mentioned previously, the proposed rule amendments apply to certified abortion clinics in North Carolina. Table 1 below presents a summary of the estimate costs and benefits to the different entities involved.

Table 1. Summary of Estimated Impact on Affected Parties*

Entity and Impact	FY 2015-16	FY 2016-17	FY 2017-18
<i>Costs</i>			
State government			
- Inspection staff time costs	\$20,800	\$20,800	\$20,800
<i>Providers</i>			
- Capital expenses (privacy curtain + AED)	\$26,700	\$0	\$0
- Inspection Nursing Staff Time Cost	\$16,500	\$16,500	\$16,500
- Additional Nursing Staff Costs	unquantified	unquantified	unquantified
- 24/7 Phone Triage	\$38,400	\$38,400	\$38,400
- Contract MD for QI	\$38,400	\$38,400	\$38,400
- Operations Costs (Governing Authority + QI Program)	unquantified	unquantified	unquantified
<i>Total Costs to Providers</i>	\$120,000	\$93,300	\$93,300
Total Costs	\$140,800	\$114,100	\$114,100
<i>Benefits</i>			
Providers – construction plans, medical record retention	unquantified	unquantified	unquantified
Patients **	Unquantified benefits to patients from improvement of safety and quality of care		

* Given the lack of available information the estimates impacts assume that the reoccurring costs and benefits would stay constant over the three years. Also, the numbers above do not provide a complete picture as information is lacking about some of the costs and benefits the clinics are expected to incur.

** The cost to the patient may be increased to offset the increase in cost incurred by the clinics.

Summary of Revisions and Anticipated Fiscal Impact

Rule .0101 – *Definitions* is proposed for amendment to clarify language and terms used throughout the rules consistent with S.L. 2013-366 s.4(c).

Fiscal Impact

No fiscal impact associated with amending this rule.

Rule .0104 – *Plans* is proposed for amendment to clarify the procedure for submission of construction plans for clinics and reduces the number of plan copies required from three to two. This rule applies to the construction of new facilities.

Fiscal Impact

The agency assumes that there would likely be a minimal cost savings to future certified providers if one less copy of the construction plans were required. Due to lack of data, the cost savings is unable to be determined at this time.

Rule .0109 – *Renewal* is proposed for amendment to clarify that clinic are required to pay a non-refundable certificate renewal application fee of \$700.00 pursuant to G.S. 131E-269 that has been in effect since 2005.

Fiscal Impact

No fiscal impact associated with amending this rule. The fee was established in statute close to 10 years ago and certified providers have been paying the fee annually.

Rule .0111 – *Inspections* is proposed for amendment to require access to the clinic and its records by authorized representatives of the Division to conduct inspections of the clinic to verify compliance with certification rules. Inspections are conducted annually pursuant to S.L. 2013-366 as prescribed in the N.C.G.A. Joint Conference Committee Report on the Continuation, Expansion, and Capital Budgets, Section G, page G9, Item 51, and to be conducted as necessary. This rule also requires that when non-compliance has been identified, the facility shall submit a corrective action plan to the Division within 10 days of receipt of notice of non-compliance.

Fiscal Impact

Pursuant to S.L. 2013-366, the Division has begun conducting annual inspections of all clinics certified to perform abortion procedures. The inspection process requires two DHSR Nurse Consultants, one Journey level, and one Contributing level. An on-site annual inspection takes an average of 30 hours to complete (15 hours per nurse). The average hourly salary rate for the Journey level nurse is \$33. The average hourly salary rate for the Contributing level nurse is \$30. Assuming a constant benefits rate of 34%, the hourly total compensation for the Journey and Contributing level Nurse Consultants is \$44 and \$39, respectively. There are currently 16 certified abortion clinics that will undergo annual inspection.

The annual opportunity costs for DHSR staff time for conducting an inspection is approximately \$700 for the Journey level nurse and approximately \$600 for the Contributing level nurse for a

total cost per clinic of \$1,300. The total annual cost for inspecting all 16 clinics is estimated at \$20,800. Additional funds needed to conduct these inspections were appropriated for this purpose in S.L. 2013-360.

The clinics would also incur an opportunity cost of their staff's time related to the inspections. The agency assumes that a nurse at each clinic would need to be present for the duration of the inspection, i.e. 30 hours. According to data from the Bureau of Labor Statistics, the average hourly salary of a Registered Nurse in North Carolina in 2013 was \$28.51¹ and the total compensation factor nationally in 2013 for occupations in the health care industry was about 20%.² Based on this data, the analysis estimates that the opportunity cost an hour of the clinic's staff time to participate in the inspection would be \$34. Therefore, the opportunity cost per clinic from the annual inspection is estimated at \$1,030, and the total cost for the 16 clinics would be about \$16,000 per year.

It should be noted that the opportunity cost estimate provided is based on one annual inspection per clinic per year with few to no deficiencies cited. Inspections where violations are found may require additional Nurse Consultant time both on-site and in the office when writing the inspection report. This estimate also do not take into consideration that follow-up inspections may be required in some cases. Similarly, the estimated opportunity cost to the clinics does not take into account additional staff time needed for follow-up inspections and time and financial cost to address deficiencies and file a corrective action plan. Currently, the Division inspects clinics every five to seven years, and a shorter follow-up inspection is required about 50% of the time. Given that the proposed rules would require annual inspections, the DHSR expects that the need for follow-up inspections would decrease substantially. As a result, it is difficult for to predict how many of these additional inspections would occur per year and any difference in the resulting costs for clinics; therefore, these costs associated with follow-up inspections are not included in the estimated cost from the proposed rule.

Table 2. Estimated Cost of Annual Inspections

Requirement	Number of Clinics	Cost per clinic	Total Statewide Cost
Annual Inspection – cost to DHSR	16	\$1,300	\$20,800
Annual Inspection – cost to clinics	16	\$1,030	\$16,500
TOTAL COSTS			\$37,300

Rule .0201 – Building Code Requirements is proposed for amendment to include the availability of the building codes electronically at no charge from the International Code Council Web site. This option has been available but not included in the current version of the rule.

Fiscal Impact

¹ Bureau of Labor Statistics. May 2013 State Occupational Employment and Wage Estimates: North Carolina. http://www.bls.gov/oes/current/oes_nc.htm

² Bureau of Labor Statistics. “ <http://www.bls.gov/web/eci/echistrynaics.pdf>

No fiscal impact associated with amending this rule.

Rule .0202 – *Sanitation* is proposed for amendment to update the address for the N.C. Department of Environment and Natural Resources (DENR) and to provide a reference to 15A NCAC 18A rules electronically at no charge from the DENR Web site.

Fiscal Impact

No fiscal impact associated with amending this rule.

Rule .0206 – *Elements and Equipment* is proposed for amendment to provide access to the latest versions of the National Fire Protection Association (NFPA) standards and availability of the standards at no charge from the NFPA Web site. The amendments also seek to bolster patient safety by specifying relative humidity in procedure and recovery rooms which is consistent with Centers for Medicare & Medicaid (CMS) standards for other types of health care facilities, including ambulatory surgical facilities. This measure strengthens infection control standards in clinics as higher moisture levels can increase the spread of bacteria and the likelihood of infections.

Fiscal Impact

No fiscal impact associated with amending this rule because the proposed rule changes lower the threshold of humidity in the procedure and recovery areas. All existing equipment and any future equipment will have the capability of achieving a higher threshold for humidity, and no significant additional increase in the monthly electric bill is expected. Therefore, little to no cost is associated with the rule revision.

Rule .0207 – *Area Requirements* is proposed for amendment to require compliance with the criteria contained in Rule .0206, and also contains technical and formatting corrections as needed.

Fiscal Impact

No fiscal impact associated with amending this rule.

Rule .0302 – *Person in Authority (changed to “Governing Authority”)* is proposed for amendment to define clearly the roles for clinic administration. These changes ensure accountability for providing safe and quality care in compliance with 10A NCAC 14E regulations. These requirements are comparable to those of licensed ambulatory surgical facilities, specifically rules 10A NCAC 13C .0301 and .0302. The proposed rule requires that a Chief Executive Officer (CEO) or his/her designee be responsible for the management of the clinic, including implementation of policies and compliance with regulations. The rule also defines that individual’s authority and duties, and requires a person to serve in his/her absence to be named in writing. In addition, the Division shall be notified of any change in clinic ownership or CEO. The rule also requires that the Governing Authority adopt policies and procedures to ensure safe and professional care of patients, including verification that any outside vendor providing services in or for the clinic meets the same standards that the clinic has to meet. The Governing Authority is also responsible for the selection and appointment of

professional staff and granting of clinical privileges, and is responsible for the professional conduct of those individuals.

Fiscal Impact

Based on feedback from currently certified clinic owners, the requirements included in this revision are consistent with current practices and have little to no anticipated fiscal impact on existing clinics. The area that may present an opportunity cost for clinics that they may or may not have incurred prior to the rule amendment, is that annual meetings would now be required and minutes taken of those meetings. Some providers have acknowledged that as owners and operators they currently meet frequently with clinic management and ownership to discuss clinic administration and issues, and that the rule will now formalize and require documentation of these efforts. The rule change will require the Governing Authority of each clinic to meet at least annually and maintain records of those meetings. Since the current practices of each clinic are not known and can vary greatly, the estimated impact of this portion of the rule amendment is unable to be determined.

Rule .0303 – Policies and Procedures and Administrative Records is proposed for amendment to define more clearly the requirement for clinics to establish certain policies and procedures to protect patient safety and provide quality care. Policies and procedures shall be kept in a manual accessible to employees, medical staff, and contractual physicians so they may understand their clinical responsibilities and clinic operations. The policies addressed in this part of the rule are consistent with current clinic practices and have no impact on existing clinics.

The only additional policy required of current certified clinics is the provision of patient privacy in the recovery area of the clinic. Clinics may choose the method by which they provide patient privacy.

Fiscal Impact

The proposed amendments to this rule will have a fiscal impact on certified abortion clinic providers. The cost of providing privacy in the recovery area is the only anticipated expense to existing clinics. Table 3 below provides a range of cost estimates depending on the different means of ensuring privacy.

Table 3. Estimated Cost of Different Options for Privacy Curtains

Options	Cost
Folding Privacy Screen on Wheels *	\$175.00
Three Panel Privacy Screen	\$350.00
Track Basic / Curtain Basic	\$271.50
Track High / Curtain High	\$1100.00

For the purpose of this fiscal analysis, cost estimates are based on the use of a wheeled folding privacy curtain, which would be one of the options a clinic may consider to ensure compliance. A wheeled privacy curtain can be placed between each patient to provide privacy in a recovery area. Based on a sample survey of vendors, the DHSR Construction Section estimates the lower cost of this type of privacy curtain to be approximately \$175 each. Generally, clinics do not have more than four or five patients in a recovery area at one time. If each clinic purchases four

curtains to accommodate five patients at any one time in the recovery area, the total one-time cost to each clinic would be approximately \$700. For the combined 16 currently certified clinics, the statewide total would be approximately \$11,200.

Wheeled privacy curtains are not the only option for certified clinics for the provision of privacy for patients. Providers may opt to use other means such as partitions, walls, etc., however, for the purpose of this analysis, estimates were based on what seems to be the most cost-effective and readily available manner in which to comply with the rule. The figures in this analysis are an estimate, and it can be reasonably assumed that the actual cost may be either higher or lower depending on the provider and vendors used.

Table 4. Estimated Cost of Provision of Privacy

Requirement	Number Clinics	Cost per clinic	Total Statewide Cost
Wheeled Privacy Curtain*	16	\$700	\$11,200
TOTAL COSTS			\$11,200

* Estimated using \$175 per wheeled privacy curtain and four curtains per clinic.

Rule .0304 – Admission and Discharge is proposed for amendment to address technical and formatting changes within the rule.

Fiscal Impact

No fiscal impact associated with amending this rule.

Rule .0305 – Medical Records is proposed for amendment to update medical terminology and medical practices, and to modify records retention requirements to be consistent with the longest time required by federal record retention requirements under the Clinical Laboratory Improvement Amendments (CLIA) program. To be consistent with the CLIA program, the number of years that medical records must be maintained by the clinic was reduced from 20 to 10 years. There are also technical and formatting changes throughout this rule.

Fiscal Impact

No significant fiscal impact associated with amending this rule. Certified abortion clinics currently comply with these standards under the CLIA program. It can be reasonably assumed that there may be a minimal cost savings for certified clinics related to record storage since the number of years required for storing the records is reduced. Since this depends on the provider and method of storing records, it cannot be determined if there would be a cost savings, and if there were, an estimate of the savings.

Rule .0306 – Personnel Records is proposed for amendment to specify documentation that shall be included in an employee’s personnel record and requires the minimum age of any employee having direct responsibility for patient care to be at least 18 years of age. It also requires the minimum age of all other personnel working in the clinic, whether paid or unpaid, with no direct patient care responsibilities to be 16 years of age or older.

Fiscal Impact

No fiscal impact associated with amending this rule. Based on agency staff's best professional knowledge, clinics are unlikely to hire minors in positions that require interaction with the patients.

Rule .0307 – *Nursing Services* is proposed for amendment to require an organized nursing staff under the supervision of a nursing supervisor accountable to the Chief Executive Officer or his/her designee, and require an adequate number of licensed and ancillary nursing personnel sufficient to manage the needs of patients in the clinic. The nursing supervisor is also responsible for developing a nursing policy manual and job descriptions for all nursing services personnel. This rule amendment seeks to strengthen nursing supervision and accountability in the clinic to improve the quality of care and increase patient safety.

An assessment of the staffing patterns utilized by all existing clinics revealed that they are currently in compliance with this revision. No additional staff is identified as necessary to comply with this change.

Fiscal Impact

Little to no fiscal impact is anticipated as a result of this rule amendment. Based on information provided by certified abortion clinics on their certificate renewal applications, all clinics in the state have a Registered Nurse (RN) on staff in the clinic. It can be reasonably assumed that the Governing Authority of a clinic may choose to utilize existing resources and designate the existing RN on staff as the Nursing Supervisor. In this case, it could be assumed that there would be no additional staffing cost to the clinic to meet these requirements. In addition, certified clinics currently have nursing policies and job descriptions for staff. Therefore, there would be little to no fiscal impact in that area as well.

Rule .0308 – *Quality Assurance* is proposed for adoption to establish a quality assurance program to monitor and evaluate the provision of patient care and prevent the repeat of any deficiencies in patient care. The quality assurance committee reports to the clinic's Governing Authority and is responsible for evaluating the clinic's compliance with policies, procedures, and state and federal regulations. It is also responsible for developing certain policies including peer review, tissue inspection, infection control procedures, and others. The committee membership requires at least one physician who is not the owner, the chief executive officer or designee, which will assist in providing an independent, objective review of clinic procedures and documentation. The committee may also include other health professionals as needed. Each clinic's quality assurance committee is required to meet at least quarterly and maintain documentation of its activities for 10 years. In addition, the clinic will be responsible for providing training and education to staff related to issues identified by the quality assurance committee.

The quality assurance requirements included in this proposed rule are consistent with the requirements of rule 10A NCAC 13C .0306 governing such programs in ambulatory surgical facilities.

Fiscal Impact

No significant fiscal impact associated with amending this rule. It is anticipated that each currently certified clinic would be required to contract with a physician who is not the owner to serve on the quality assurance committee. Although there is a lack of data provided regarding potential costs to contract with a physician for this purpose, the cost is estimated at \$100 per hour for six hours per quarter based on information provided by some clinics. At this rate, the annual cost to each clinic would be approximately \$2,400. For all 16 existing clinics, the estimated statewide annual cost would be approximately \$38,400.

Table 5. Estimated Cost of Contract Physician for QI Program

Requirement	Cost per hour	Total number hours annually	Number Clinics	Total Cost per Clinic	Total Statewide Costs
Contract Physician	\$100	24*	16	\$2,400	\$38,400
TOTAL COSTS					\$38,400

* *Estimated using six hours per quarter for four quarters per year.*

Also worthy of noting, some certified clinics have some quality assurance measures currently in place. However, the current measures may not meet all of the requirements of this rule. It can be assumed, though, that even if clinics have quality assurance measures in place, some additional staff time will be required to meet and maintain the quality assurance program and documentation requirements. There could also be a cost of staff time to comply with the requirement that the committee meet on a quarterly basis. Due to the lack of data and information regarding each clinic’s current quality assurance efforts and the staff who would participate in the meetings, the agency cannot estimate how much staff time (and cost) would be incurred in the establishment and maintenance of a formal quality assurance program.

In addition, there is a minimal amount of opportunity cost to the state government in that the clinic’s quality assurance program will be included in the clinic’s annual inspection by the Division. At this time, there is no data or information to support a calculation of cost to the state. There is no estimate of how long it would take a surveyor to monitor this area for compliance or predict the number and types of issues that may arise and result in more survey time. General costs of survey inspections are calculated in relation to rule 10A NCAC .0111 of this analysis.

Rule .0309 – Laboratory Services is proposed for amendment to update medical terminology and medical practices. The rule also requires that clinics assure that a manual of procedures and instruction for each test procedure be kept in a location accessible to staff.

Fiscal Impact

No fiscal impact associated with amending this rule.

Rule .0310 – Emergency Back-up Services is proposed for amendment to ensure safe and quality care by requiring the certified abortion clinic to develop plans for intervention in cases that require emergency care and stabilization. Clinics shall have written plans for the transfer of emergency cases to a nearby hospital. In addition, a written agreement between the clinic and a

nearby hospital is required to facilitate the transfer of patients in an emergency situation. However, in the event the clinic is unable to secure such an agreement, documentation of efforts to secure this agreement is required. Also important to note is that, according to the federal Emergency Medical Treatment and Labor Act (EMTALA), hospitals are required to treat unstable patients who present at the hospital. Because of this federal requirement, transfer agreements between clinics and hospitals are becoming obsolete. This rule also contains updates to current terminology and medical practices.

This rule also clarifies emergency protocols required at the clinic, including procedures, personnel, and suitable equipment for handling emergency situations. One required piece of emergency equipment, which was not previously required, is the addition of an automated external defibrillator (AED) for provision of emergency resuscitative care at the clinic. It can be reasonably assumed that most, if not all, clinics will have to purchase an AED device to comply with this rule. This is a one-time cost for each clinic.

The emergency protocol requirements included in this proposed rule are consistent with the requirements of rule 10A NCAC 13C .0403 governing such measures in ambulatory surgical facilities.

Fiscal Impact

No significant fiscal impact associated with amending this rule. As stated above, an AED device will be required at each certified clinic. It can be reasonably assumed that most, if not all, clinics will have to purchase an AED device to comply with this rule. Upon inquiry of AED vendors, it was discovered that a base model capable of meeting the rule requirement could be obtained at a cost of approximately \$970 per unit. For all 16 existing clinics, the statewide cost is estimated to be \$15,520. This is a one-time cost for each clinic. No maintenance cost for the AED device is expected and the life span of such devices is about 10 years.

Table 6. Estimated Cost of AED Device*

Requirement	Cost per unit	Total Number Clinics	Total Cost per Clinic	Total Statewide Costs
Automated External Defibrillator (AED)	\$970	16	\$970	\$15,520
TOTAL COSTS				\$15,520

* Cost based on Phillips™ Heartstart® On-site® model estimate.

Rule .0311 – Surgical Services is proposed for amendment to update medical terminology and standard medical practices. These changes reflect current practices utilized by existing certified clinics.

Fiscal Impact

No fiscal impact associated with amending this rule as certified clinics are currently in compliance with the practices required in this rule.

Rule .0313 – Post Operative Care is proposed for amendment establishes clear criteria to assure patient safety after the abortion procedure and discharge from the clinic. The rule also requires the availability of a person 24 hours a day, seven days a week for patients experiencing complications from the abortion procedure and prohibits use of a recorded phone message. The clinic must also have a defined protocol for triaging post-operative calls that establishes a pathway for physician contact to ensure on-going care. This rule also includes updated medical terminology and formatting corrections.

Fiscal Impact

No significant fiscal impact associated with amending this rule. No additional physicians would need to be on call. As stated above, certified clinics will be required to establish a 24/7 telephone service for patients experiencing complications after discharge from the clinic. This is anticipated to be an on-going cost for each clinic. Based on inquiries of businesses providing answering services capable of meeting the requirements detailed in this rule, the estimated average cost to contract for this service is approximately \$2,400 annually. For the 16 existing clinics, this would have an estimated statewide cost of approximately \$38,400 annually.

Table 7. Estimated Cost of 24/7 Triage Phone Service*

Requirement	Cost per contract*	Total Number Clinics	Total Cost per Clinic	Total Statewide Costs
Dedicated phone manned 24/7 w/ triage capabilities	\$2,400	16	\$2,400	\$38,400
TOTAL COSTS				\$38,400

**Based on an annual contract of \$200 per month per year.*

Rule .0315 – Housekeeping is proposed for amendment to make technical corrections and update references to other state agencies.

Fiscal Impact

No fiscal impact associated with amending this rule.

Conclusion

In compliance with Senate Bill 353, the proposed rules included in this rule package and fiscal analysis address the on-site recovery phase of patient care, protect patient privacy, provide quality assurance, and ensure that patients with complications receive the necessary medical attention they require, while not unduly restricting access to abortion procedures. These proposed rules include true improvements in the care and safety of women who undergo abortion procedures, including:

- Improved post-op care to ensure patients discharged are in stable condition,
- Strengthening of emergency back-up services through the 24-hour, 7-day week on-call service,

- Required organized nursing staff under the supervision of a registered nurse,
- Clearly defined roles for clinic administration, which provides additional accountability,
- New quality assurance measures to monitor the provision of patient care and prevent the repeat of any deficiencies in patient care,
- Requirement of better records on medical equipment and clinic personnel,
- All direct patient care workers must be at least 18,
- A 24-hour telephone number is required for patients to use in the event that any complication occurs,
- Clinic must have a defined protocol for triaging post-operative calls,
- Improved privacy measures for patients in recovery, and
- Requirement for AED device for emergency situations.

In addition, the standards set forth in Subchapter 10A NCAC 14E, *Certifications of Clinics for Abortions*, are now updated and consistent with both current medical terminology and medical clinic practices, as well as general formatting style.

In the first year when the proposed rules will go into effect, the total cost impact on certified providers is estimated at \$120,000, which is roughly \$7,500 per clinic. In the years following, clinics are expected to incur a cost of approximately \$5,800 per clinic. Clinics would also incur additional costs related to the opportunity costs of their staff's time from drafting procedures and manuals, participating in quality assurance quarterly meetings, maintaining appropriate records, taking corrective actions related to deficiencies identified during inspections, etc. Additionally, the state will sustain the costs of inspecting abortion clinics at an approximate cost of \$20,800 per year, or about \$1,300 per clinic.

What is unquantifiable at this time (due to lack of data on the rate of infections, patient transfers to hospital, etc.), but is certainly a real benefit to patients of certified abortion clinics, is the expected improvements in patient safety and quality of care that will result from implementation of these new requirements.

APPENDIX

10A NCAC 14E .0101 is proposed for amendment as follows:

10A NCAC 14E .0101 DEFINITIONS

The following definitions will apply throughout this Subchapter:

- (1) “Abortion” means the termination of a pregnancy as defined in G.S. 90-21.6.
- ~~(2)~~ (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)~~ (3) "Complication" includes but is not limited to hemorrhage, infection, uterine perforation, cervical ~~laceration~~ laceration, or retained products of conception.
- ~~(4)~~ (4) "Division" means the Division of Health Service Regulation of the North Carolina Department of Health and Human Services.
- ~~(5)~~ (5) ~~"Fetal age"~~ “Gestational age” means the length of pregnancy as indicated by the date of ~~conception~~ the first day of the last normal monthly menstrual period, if known, or as determined by ultrasound.
- ~~(6)~~ (6) "Governing authority" means the individual, ~~agency or group~~ agency, group, or corporation appointed, elected or otherwise designated, in which the ultimate responsibility and authority for the conduct of the abortion clinic is ~~vested~~ vested pursuant to Rule .0302 of this Subchapter.
- (7) “Health Screening” means an evaluation of an employee or contractual employee, including tuberculosis testing, to identify any underlying conditions that may affect the person’s ability to work in the clinic.
- ~~(8)~~ (8) "New ~~facility~~ clinic" means one that is not certified as an abortion clinic by the Division as of July 1, ~~1994~~, 2014, and has not been certified within the previous six months of the application for certification.
- (9) “Registered Nurse” means a person who holds a valid license issued by the North Carolina Board of Nursing to practice professional nursing in accordance with the Nursing Practice Act, Article 9A, Chapter 90 of the North Carolina General Statutes.

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. April 1, 2015; July 1, 1994; December 1, 1989; June 30, 1980.

10A NCAC 14E .0104 is proposed for amendment as follows:

10A NCAC 14E .0104 PLANS

Three Prior to issuance of a certificate pursuant to Rule .0107 of this Subchapter, a clinic shall submit two copies of the plans ~~will be required to the division~~ for certification ~~purposes~~ purposes when the clinic requires a review by the Division and the Department of Insurance, according to the North Carolina Administration and Enforcement Requirements Code, 2012 edition, including subsequent amendments and editions. Copies of the North Carolina Administration Code is available from the International Code Council at http://www.ecodes.biz/ecodes_support/Free_Resources/2012NorthCarolina/12NorthCarolina_main.html 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. 1977;
Amended Eff. April 1, 2015.*

10A NCAC 14E .0109 is proposed for amendment as follows:

10A NCAC 14E .0109 RENEWAL

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

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

10A NCAC 14E .0111 is proposed for amendment as follows:

10A NCAC 14E .0111 INSPECTIONS

- (a) ~~The Division shall make such inspections as it may deem necessary.~~ Any clinic certified by the Division to perform abortions shall be subject to inspections by authorized representatives of the Division annually and as it may deem necessary as a condition of holding such license.
- (b) The Division shall have authority to investigate any complaint relative to the care, ~~treatment~~ treatment, or ~~complications~~ complication of any patient.
- (c) Authorized representatives of the Division shall make their identities known to the person in charge prior to inspection of the clinic.
- (~~e~~) (d) Representatives of the Division may review any records in any medium necessary to determine compliance with the ~~rules~~, Rules of this Subchapter, while maintaining the confidentiality of the complainant and the patient, unless otherwise required by law.
- (e) An inspection shall be considered whenever the purpose of the inspection is to determine whether the clinic complies with the Rules of this Subchapter or whenever there is reason to believe that some condition exists which is not in compliance with the Rules of this Subchapter.
- (f) The clinic shall allow the Division to have immediate access to its premises and the records necessary to conduct an inspection and determine compliance with the Rules of this Subchapter.
- (g) A clinic shall file a plan of correction for cited deficiencies within 10 business days of receipt. The Division shall review and respond to a written plan of correction within 10 business days of receipt.

History Note: Authority G.S. 14-45.1(a); G.S.90-21.83; 143B-10; S.L.2013-366 s.4(c);
 Eff. February 1, 1976;
 Readopted Eff. December 19, 1977;
 Amended Eff. April 1, 2015, July 1, 1994.

10A NCAC 14E .0201 is proposed for amendment as follows:

10A NCAC 14E .0201 BUILDING CODE REQUIREMENTS

(a) The physical plant for a ~~facility~~ clinic must meet or exceed minimum requirements of the North Carolina State Building Code for Group B occupancy (business office facilities) which is incorporated herein by reference including subsequent ~~amendments.~~ amendments and editions. Copies of ~~The North Carolina Building Code, Volume One, General Construction, may be obtained for thirty dollars (\$30.00) from the N.C. Department of Insurance, P.O. 26387, Raleigh, NC 27611.~~ the Code can be obtained from the International Code Council online at <http://www.iccsafe.org>, or accessed electronically free of charge at <http://www.ecodes.biz>.

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

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

10A NCAC 14E .0202 is proposed for amendment as follows:

10A NCAC 14E .0202 SANITATION

~~Abortion clinics~~ Clinics that are certified by the Division to perform abortions must comply with the ~~rules~~ Rules governing the sanitation of hospitals, nursing and rest homes, sanitariums, sanatoriums and educational and other institutions, contained in 15A NCAC 18A .1300 which is hereby incorporated by reference including subsequent amendments and editions. Copies of 15A NCAC 18A .1300 may be obtained at no charge from the Division of Public Health, Environmental Health Section ~~Environmental Health Services, Division of Environmental Health,~~ N.C. Department of Environment and Natural Resources, 1630 1632 Mail Service Center, Raleigh, NC ~~27699-1630.~~ 27699-1632, or accessed electronically free of charge from the Office of Administrative Hearings at <http://www.ncoah.com>.

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

10A NCAC 14E .0206 is proposed for amendment as follows:

10A NCAC 14E .0206 ELEMENTS AND EQUIPMENT

The physical plant shall provide ~~appropriate elements and~~ equipment to carry out the functions of the ~~facility~~ clinic with the following minimum requirements:

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

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

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

Area	Pressure Relationship	Minimum Air Changes/Hour
Procedure	P	6
Recovery	P	6
Soiled work, janitor's <u>Janitor's</u> closet, toilets, <u>Toilets.</u>		
Soiled holding	N	10
Clean work or		
Clean holding	P	4

(P = positive pressure N = negative pressure)

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

(a) Medical Gas and Vacuum Systems

- (i) Piped-in medical gas and vacuum systems, if installed, shall meet the requirements of ~~NFPA 99-1990,~~ NFPA-99-2012, type one system, which is hereby incorporated by reference including subsequent amendments and editions. Copies of ~~NFPA 99-1990~~ NFPA-99-2012 may be purchased from the National Fire Protection Association, 1 Batterymarch Park, P.O. Box 9101, Quincy, MA 02269-9101, ~~for twenty eight dollars and fifty cents (\$28.50).~~ or accessed electronically free of charge at <http://www.nfpa.org>.
- (ii) If inhalation anesthesia is used in any concentration, the facility must meet the requirements of ~~NFPA 70-1993~~ NFPA 70-2011 and ~~NFPA 99-1990,~~ NFPA 99-2012, current editions relating to inhalation anesthesia, which are hereby incorporated by reference including subsequent amendments and editions. Copies of ~~NFPA 70-1993~~ NFPA 70-2011 and ~~NFPA 99-1990~~ NFPA 99-2012 may be purchased from the National Fire Protection Association, 1 Batterymarch Park, P.O. Box 9101, Quincy, MA 02269-9101, ~~for thirty two dollars and fifty cents (\$32.50) and twenty eight dollars and fifty cents (\$28.50) respectively.~~ or accessed electronically free of charge at <http://www.nfpa.org>.

- (b) Lavatories and sinks for use by medical personnel shall have the water supply spout mounted so that its discharge point is a minimum distance of five inches above the rim of the fixture with mixing type fixture valves ~~which~~ that can be operated without the use of the hands.
 - (c) Hot water distribution systems shall provide hot water at hand washing and bathing facilities at a minimum temperature of 100 degrees F. and a maximum temperature of 116 degrees F.
 - (d) Floor drains shall not be installed in procedure rooms.
 - (e) Building drainage and waste systems shall be designed to avoid installations in the ceiling directly above procedure rooms.
- (3) ~~Electrical Requirements~~ Requirements.
- (a) Procedure and recovery rooms, and paths of egress from these rooms to the outside shall have at a minimum, listed battery backup lighting units of one and one-half hour capability that will automatically provide at least five foot candles of illumination at the floor in the event ~~of~~ needed for a utility or local lighting circuit failure.
 - (b) Essential electrically operated medical equipment necessary for the safety of the patient shall have, at a minimum, battery backup.
 - (c) Receptacles located within six feet of sinks or lavatories shall be ground-fault protected.
 - (d) ~~Provide at~~ At least one wired-in, ionization-type smoke detector shall be within 15 feet of each procedure or recovery room entrance.
- (4) ~~Each facility and its grounds shall be maintained to minimize hazards and enhance safety for staff and patients.~~ Buildings systems and medical equipment must have preventative maintenance conducted as recommended by the equipment manufacturers' or installers' literature to assure ~~satisfactory operation.~~ operation in compliance with manufacturer's instructions.

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

10A NCAC 14E .0207 is proposed for amendment as follows:

10A NCAC 14E .0207 AREA REQUIREMENTS

The following areas shall comply with Rule .0206 of this Section, and are considered minimum requirements for clinics that are certified by the Division to perform abortions: ~~abortion clinics:~~

- (1) ~~Receiving~~ receiving area;
- (2) ~~Examining~~ examining room;
- (3) ~~Preoperative~~ preoperative preparation and holding room;
- (4) ~~Individual~~ individual patient locker facilities or equivalent;
- (5) ~~Operating procedure~~ operating procedure room;
- (6) ~~Recovery~~ recovery room;
- (7) ~~Clean~~ clean workroom;
- (8) ~~Soiled~~ soiled workroom;
- (9) ~~Medicine~~ medicine room (~~may~~ may be defined as area in the clean workroom if a self-contained secure cabinet complying with security requirements of state and federal laws is ~~provided~~); provided;
- (10) ~~Linen Storage. Separate~~ separate and distinct areas for storage and handling clean and soiled ~~linen shall be provided~~; linen;
- (11) ~~Patient~~ patient toilet;
- (12) ~~Personnel~~ personnel lockers and toilet facilities;
- (13) ~~Laboratory~~; laboratory;
- (14) ~~Nourishment~~ nourishment station with storage and preparation area for serving meals or in-between meal snacks;
- (15) ~~Janitor's~~ janitor's closets appropriately located;
- (16) ~~Adequate~~ adequate space and equipment for assembling, sterilizing and storing medical and surgical supplies;
- (17) ~~Storage~~ storage space for medical records; and
- (18) ~~Office~~ office space for nurses' charting, doctors' charting, communications, counseling, and business functions.

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

10A NCAC 14E .0302 is proposed for amendment as follows:

SECTION .0300 – ~~ADMINISTRATION~~ GOVERNING AUTHORITY

10A NCAC 14E .0302 ~~PERSON IN AUTHORITY~~ GOVERNING AUTHORITY

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

(a) The governing authority, as defined in Rule .0101(6) of this Subchapter, shall appoint a chief executive officer or a designee of the clinic to represent the governing authority and shall define his or her authority and duties in writing. This person shall be responsible for the management of the clinic, implementation of the policies of the governing authority and authorized and empowered to carry out the provisions of these Rules.

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

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

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

- (1) specify the individual to whom responsibility for operation and maintenance of the clinic is delegated and methods established by the governing authority for holding such individuals responsible;
- (2) provide for at least annual meetings of the governing authority, for which minutes shall be maintained; and
- (3) maintain a policies and procedures manual designed to ensure professional and safe care for the patients which shall be reviewed, and revised when necessary, at least annually, and shall include provisions for administration and use of the clinic, compliance, personnel quality assurance, procurement of outside services and consultations, patient care policies and services offered.

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

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

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

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

Eff. February 1, 1976;

Readopted Eff. December 19, 1977;

Amended Eff. April 1, 2015; December 1, 1989.

10A NCAC 14E .0303 is proposed for amendment as follows:

10A NCAC 14E .0303 POLICIES AND PROCEDURES AND ADMINISTRATIVE RECORDS

(a) The following essential documents and references shall be on file in the administrative office of the clinic:

- (1) documents evidencing control and ownerships, such as deeds, leases, or incorporation or partnership papers;
- (2) policies and procedures of the governing authority, as required by Rule .0302 of this Section;
- (3) minutes of the governing authority meetings, if applicable;
- (4) minutes of the clinic's professional and administrative staff meetings;
- (5) a current copy of the Rules of this Subchapter;
- (6) reports of inspections, reviews, and corrective actions taken related to licensure; and
- (7) contracts and agreements related to licensure to which the clinic is a party.

(b) All operating licenses, permits, and certificates shall be displayed on the licensed premises.

(c) The governing authority shall prepare a manual of clinic policies and procedures for use by employees, medical staff, and contractual physicians to assist them in understanding their responsibilities within the organizational framework of the clinic. These shall include:

- (1) ~~Patient~~ patient selection and exclusion ~~criteria,~~ criteria; and clinical discharge ~~criteria,~~ criteria;
- (2) ~~policy and procedure for validating the full and true name of the patient;~~
- (~~2~~) (3) ~~Policy~~ policy and procedure for each type of abortion procedure performed at the ~~clinic,~~ clinic;
- (4) ~~policy and procedure for the provision of patient privacy in the recovery area of the clinic;~~
- (~~3~~) (5) ~~Protocol~~ protocol for determining gestational age as defined in Rule .0101(5) of this Subchapter;
~~fetal age.~~
- (4) (6) ~~Protocol~~ protocol for referral of patients for whom services have been ~~declined,~~ declined; and
- (5) (7) ~~Protocol~~ protocol for discharge instructions that informs patients who to contact for post-procedural ~~emergencies,~~ problems and questions.

*History Note: Authority G.S. 14-45.1(a); G.S.90-21.83; 143B-10; S.L.2013-366 s.4(c);
Eff. February 1, 1976;
Readopted Eff. December 19, 1977;
Amended Eff. April 1, 2015; July 1, 1994.*

10A NCAC 14E .0304 is proposed for amendment as follows:

10A NCAC 14E .0304 ADMISSION AND DISCHARGE

- (a) There shall be on the premises throughout all hours of operation an employee authorized to receive patients and to make administrative decisions on their disposition.
- (b) All patients shall be admitted only under the care of a physician who is currently licensed to practice medicine in North Carolina.
- (c) Any patient not discharged within 12 hours following the abortion procedure shall be transferred to a general hospital.
- (d) Following admission and prior to obtaining the consent for ~~surgery required by Rule .0305(a) of this Section~~, the procedure, representatives of the clinic's management shall provide to each patient the following information:
- (1) ~~A~~ a fee schedule and any extra charges routinely applied;
 - (2) ~~The~~ the name of the attending physician(s) and hospital admitting privileges, if any. In the absence of admitting privileges a statement to that effect shall be included;
 - (3) ~~Instructions~~ instructions for post-procedure ~~emergencies~~ problems and questions as outlined in Rule .0313(d) of this Section;
 - (4) ~~Grievance~~ grievance procedures a patient may follow if dissatisfied with the care and services rendered; and
 - (5) ~~The~~ the telephone number of the Complaints Investigation Branch of the Division.

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

10A NCAC 14E .0305 is proposed for amendment as follows:

10A NCAC 14E .0305 MEDICAL RECORDS

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

- (1) the date and time of admission and discharge;
- (2) the patient's full and true name;
- (3) the patient's address;
- (4) the patient's date of birth;
- (5) the patient's emergency contact information;
- (6) the patient's diagnoses;
- (7) the patient's duration of pregnancy;
- (8) the patient's condition on admission and discharge;
- (9) a witnessed, voluntarily-signed consent for each surgery or procedure and signature of the physician performing the procedure;
- (10) the patient's history and physical examination including identification of pre-existing or current illnesses, drug sensitivities or other idiosyncrasies having a bearing on the procedure or anesthetic to be administered; and
- (11) documentation that indicates all items listed in Rule .0304(d) of this Section were provided to the patient.

(b) All other pertinent information such as pre- and ~~post-operative~~ post-procedure instructions, laboratory report, drugs administered, report of ~~operation~~ abortion procedure, and follow-up ~~instruction~~ instruction, including family planning ~~advice~~ advice, shall be recorded and authenticated.

(c) If Rh is negative, the significance shall be explained to the patient and so recorded. The patient in writing may reject Rh immunoglobulin, ~~or accept the appropriate desensitization material.~~ A written record of the patient's decision shall be a permanent part of her medical record.

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

(e) The ~~facility~~ clinic shall maintain a daily procedure log of all patients receiving abortion services. This log shall contain at least the following: patient name, estimated length of gestation, type of procedure, name of physician, name of RN on duty, and date and time of procedure.

- (1) patient name;
- (2) estimated length of gestation;

- (3) type of procedure;
- (4) name of physician;
- (5) name of Registered Nurse on duty; and
- (6) date and time of procedure.

(f) Medical records shall be the property of the clinic and shall be preserved or retained in the State of North Carolina for a period of not less than at least 20 10 years from the date of the most recent discharge, unless the client is a minor, in which case the record must be retained until three years after the client's 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 ~~facility~~ clinic shall have a written plan for destruction of medical records to identify information to be retained and the manner of destruction to ensure confidentiality of all material.

(h) Should a ~~facility~~ clinic cease operation, arrangements shall be made for preservation of records for at least ~~20~~ 10 years. The clinic shall ~~notify the Division, in writing, concerning the arrangements.~~ send written notification to the Division of these arrangements.

*History Note: Authority G.S. 14-45.1(a); G.S.90-21.83; 143B-10; S.L.2013-366 s.4(c);
 Eff. February 1, 1976;
 Readopted Eff. December 19, 1977;
 Amended Eff. April 1, 2015; July 1, 1994; December 1, 1989.*

10A NCAC 14E .0306 is proposed for amendment as follows:

10A NCAC 14E .0306 PERSONNEL RECORDS

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

(b) Personnel Records:

(1) A record of each employee shall be maintained which includes the following:

(A) employee's identification;

(B) resume of education and work experience;

(C) verification of valid license (if required), education, training, and prior employment experience; and

(D) verification of references.

(2) Personnel records shall be confidential.

(3) Notwithstanding the requirement found in Subparagraph (b)(2) of this Rule, representatives of the Division conducting an inspection of the clinic shall have the right to inspect personnel records.

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

(1) The ~~facility~~ clinic shall have a written description which describes the duties of every position.

(2) Each job description shall include position title, authority, specific ~~responsibilities~~ responsibilities, and minimum qualifications. Qualifications shall include education, training, experience, special ~~abilities~~ abilities, and valid license or certification required.

(3) The ~~facility~~ clinic shall review annually ~~and~~ and, if needed, update all job ~~descriptions, and~~ descriptions. The clinic shall provide ~~a current copy~~ the updated job description to each employee or contractual employee assigned to the position.

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

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

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

~~(g)~~ (g) Employee and contractual employee records for health ~~screening,~~ screening as defined in Rule .0101(7) of this Subchapter, education, training and verification of professional certification shall be available for review by the Division.

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

Eff. February 1, 1976;

Readopted Eff. December 19, 1977;

Amended Eff. April 1, 2015; July 1, 1994.

10A NCAC 14E .0307 is proposed for amendment as follows:

10A NCAC 14E .0307 NURSING SERVICE

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

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

(1) provision of nursing services to patients; and

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

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

~~(a)~~ (d) There shall be a minimum of at least one registered nurse Registered Nurse with experience in post-operative or post-partum care who is currently licensed to practice professional nursing in North Carolina on duty in the clinic at all times when patients are in the facility. clinic.

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

*History Note: Authority G.S. 14-45.1(a); 143B-10; G.S.90-21.83; S.L.2013-366 s.4(c);
Eff. February 1, 1976;
Readopted Eff. December 19, 1977;
Amended Eff. February 1, 2015; December 1, 1989.*

10A NCAC 14E .0308 is proposed for adoption as follows:

10A NCAC 14E .0308 ~~RESERVED FOR FUTURE CODIFICATION~~ **QUALITY ASSURANCE**

(a) The governing authority shall establish a quality assurance program for the purpose of providing standards of care for the clinic. The program shall include the establishment of a committee that shall evaluate compliance with clinic procedures and policies.

(b) The committee shall determine corrective action, if necessary.

(c) The committee shall consist of at least one physician who is not an owner, the chief executive officer or designee, and other health professionals as indicated. The committee shall meet at least once per quarter.

(d) The functions of the committee shall include development of policies for selection of patients, approval for adoption of policies, review of credentials for staff privileges, peer review, tissue inspection, establishment of infection control procedures, and approval of additional procedures to be performed in the clinic.

(e) Records shall be kept of the activities of the committee for a period not less than 10 years. These records shall include:

(1) reports made to the governing authority;

(2) minutes of committee meetings including date, time, persons attending, description and results of cases reviewed, and recommendations made by the committee; and

(3) information on any corrective action taken.

(f) Orientation, training or education programs shall be conducted to correct deficiencies that are uncovered as a result of the quality assurance program.

*History Note: Authority G.S. 14-45.1(a); G.S.90-21.83; 143B-10; S.L.2013-366 s.4(c);
Eff. April 1, 2015.*

10A NCAC 14E .0309 is proposed for amendment as follows:

10A NCAC 14E .0309 LABORATORY SERVICES

(a) Each clinic shall have the capability to provide or obtain laboratory tests required in connection with the procedure to be performed.

(b) The governing authority shall establish written policies requiring examination by a pathologist of all surgical specimens except for those types of specimens which the governing authority has determined do not require examination.

~~(a) (c) Pre-operative Tests. As a minimum, there shall be performed for each patient the following laboratory tests which must be recorded~~ Each patient shall have the following performed and a record of the results placed in the patient's medical record prior to the abortion:

- (1) ~~Pregnancy~~ pregnancy testing, except when a positive diagnosis of pregnancy has been established by ultrasound;
- (2) ~~Anemia~~ anemia testing (hemoglobin or hematocrit); and
- (3) Rh factor testing.

~~(b) (d) Blood and Blood Products. Those patients~~ Patients requiring the administration of blood shall be transferred ~~immediately~~ to a local hospital having blood bank facilities.

~~(c) (e) The facility clinic shall have instructions~~ maintain a manual in a location accessible by employees, that includes the procedures, instructions, and manufacturer's instructions for each test procedure performed, including:

- (1) ~~Sources~~ sources of reagents, standard and calibration procedures, and quality control procedures; and
- (2) ~~Information~~ information concerning the basis for the listed "normal" ranges.

~~(d) (f) The facility 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); G.S.90-21.83; 143B-10; S.L.2013-366 s.4(c);
Eff. February 1, 1976;
Readopted Eff. December 19, 1977;
Amended Eff. April 1, 2015; July 1, 1994; December 1, 1989; October 28, 1981.*

10A NCAC 14E .0310 is proposed for amendment as follows:

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

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

(b) The clinic shall have procedures, personnel, and suitable equipment to handle medical emergencies which may arise in connection with services provided by the clinic.

(c) The clinic shall have a written agreement between the clinic and a nearby hospital to facilitate the transfer of patients who are in need of emergency care. A clinic that has documentation of its efforts to establish such a transfer agreement with a hospital that provides emergency services and has been unable to secure such an agreement shall be considered to be in compliance with this Rule.

(d) ~~The facility~~ clinic shall provide intervention for emergency situations. These provisions shall ~~include; include~~ but are not limited to:

- (1) ~~Basic~~ basic cardio-pulmonary life support;
- (2) ~~Emergency~~ emergency protocols for:
 - (a) ~~Venous access supplies,~~ administration of intravenous fluids;
 - (b) ~~Air way support and oxygen,~~ establishing and maintaining airway support;
 - (c) oxygen administration;
 - ~~(d)~~ (d) utilizing a bag-valve-mask resuscitator ~~Bag valve mask unit~~ with oxygen reservoir,
reservoir; and
 - ~~(e)~~ (e) utilizing a Suction ~~suction~~ suction machine; and
 - (f) utilizing an automated external defibrillator;
- (3) ~~Emergency~~ emergency lighting available in the ~~operating room;~~ procedure room as set forth in Rule .0206 of this Subchapter; and
- (4) ~~Ultrasound~~ ultrasound equipment.

*History Note: Authority G.S. 14-45.1(a); G.S.90-21.83; 143B-10; S.L.2013-366 s.4(c);
Eff. February 1, 1976;
Readopted Eff. December 19, 1977;
Amended Eff. April 1, 2015; July 1, 1994; December 24, 1979.*

10A NCAC 14E .0311 is proposed for amendment as follows:

10A NCAC 14E .0311 SURGICAL SERVICES

(a) ~~Facilities.~~ Clinics. The ~~operating procedure~~ room shall be maintained exclusively for ~~surgical~~ abortion procedures and shall be so designed and maintained to provide an atmosphere free of contamination by pathogenic organisms. The ~~facility 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 villi~~, fetal ~~parts parts~~, or the amniotic sac. The results of the examination shall be recorded in the patient's medical record.
- ~~(2) The facility shall have written procedures, supplies and equipment available for gross and microscopic evaluation of abortion specimens. If placental or fetal tissue is not identified by gross examination, a microscopic examination must be done on the P.O.C. In cases where the microscopic evaluation is negative for chorionic villi and fetal parts, or the weight of the P.O.C. falls substantially below the appropriate weight range for the fetal age, a microscopic examination by a board certified or board eligible pathologist shall be done on the P.O.C.~~
- ~~(3) The results of this examination, the findings of further patient evaluation and any subsequent treatment must be recorded in the patient's medical record.~~
- (2) Based on gestational age, if adequate tissue is not obtained, ectopic pregnancy or an incomplete procedure shall be considered and evaluated by the physician performing the procedure.
- ~~(4)~~ (3) The ~~facility clinic~~ shall establish procedures for obtaining, identifying, storing and transporting specimens.
- ~~(5) The facility shall establish a method for follow-up of patients on whom no villi are seen.~~

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

Eff. February 1, 1976;

Readopted Eff. December 19, 1977;

Amended Eff. April 1, 2015; July 1, 1994; December 1, 1989; November 1, 1984; September 1, 1984.

10A NCAC 14E .0313 is proposed for amendment as follows:

10A NCAC 14E .0313 POST-OPERATIVE CARE

- (a) ~~Patients~~ A patient whose pregnancy is terminated on an ambulatory basis ~~should~~ shall be observed in the ~~abortion clinic for a reasonable number of hours, not less than one, to insure~~ to ensure that no immediate post-operative complications are present. Thereafter, patients may be discharged according to a physician's order and the clinic's protocols. ~~such patients may be discharged if their course has been uneventful.~~
- (b) Any patient having an adverse condition or complication known or suspected to have occurred during or after the performance of the abortion shall be transferred to ~~the back-up~~ a hospital for evaluation or admission.
- (c) The following criteria must be documented prior to discharge:
- (1) the patient must be ambulatory with a stable blood pressure and pulse; and
 - (2) bleeding and pain must be controlled.
- ~~(e) Any non-ambulatory patient shall be accompanied by an attending medical or nursing staff member during any transfer within or outside the facility.~~
- (d) Written instructions shall be issued to all patients in accordance with the ~~rules~~ orders of the physician in charge of the abortion service and shall include the following:
- (1) symptoms and complications to be looked ~~for,~~ for; and
 - ~~(2) activities to be avoided;~~
 - ~~(3)~~ (2) specific a dedicated telephone number to be used by the patients should any complication occur or question arise. This number must be answered by a person 24 hours a day, seven days a week. A recorded phone message only is unacceptable.
- (e) The clinic shall have a defined protocol for triaging post-operative calls and complications. This protocol shall establish a pathway for physician contact to ensure ongoing care of complications which the operating physician is incapable of managing.

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

10A NCAC 14E .0315 is proposed for amendment as follows:

10A NCAC 14E .0315 HOUSEKEEPING

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

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

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

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