

**North Carolina Department of Health and Human Services, Division of Health Service
Regulation, Acute and Home Care Licensure and Certification Section
Fiscal Impact Analysis
Permanent Rule Adoption without Substantial Economic Impact**

Agency: NC Department of Health and Human Services
Division of Health Service Regulation

Agency Contact: Taylor Corpening, DHSR Rule Review Manager: 919-896-9371
Raj Premakumar, DHHS Deputy General Counsel: 919-855-4800

Impact Summary: State Government: Minimal unquantified benefits
Local Government: No
Private Entities: Minimal unquantified benefits
Federal Government: No
Substantial Impact: No

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

Titles of Rules and N.C. Administrative Code Citation

10A NCAC 14E .0101 Definitions
10A NCAC 14E .0106 Applications
10A NCAC 14E .0107 Issuance of License
10A NCAC 14E .0109 Renewal
10A NCAC 14E .0111 Inspections
(See proposed text of these rules in Appendix)

Background

The rules in Subchapter 14E of Title 10A of the Administrative Code (“14E rules”) were first promulgated by the North Carolina Department of Health and Human Services (“Department”) on February 1, 1976 to regulate the construction and operation of abortion clinics under its authorizing statute, G.S. 14.-45.1(a). The rules promulgated in 1976 included 10A NCAC 14E .0101, .0106, .0107, .0109, and .0111 (“five rules”) listed above. On May 16, 2023, Senate Bill 20 became law as SL 2023-14 (“New Law”). 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. The New Law repealed the authority in G.S. 14.-45.1(a) for the 14 E rules effective July 1, 2023, and replaced it with authority in Part 4A of Chapter 131E of the General Statutes. Part 4A gave the Medical Care Commission authority to adopt the rules necessary to implement Part 4A and gave the Department authority to adopt rules necessary for licensure requirements and to administer Part 4A. The five rules listed above are the 14E rules that the Rules Review Commission has deemed to remain under the authority of the Department.

Pursuant to the authority in New Law, and prior to repeal of G.S. 14.-45.1(a), the Department adopted emergency rules on June 19, 2023 and the five rules were entered into the Administrative Code on June 3, 2023. On September 18, 2023, the Department adopted temporary rules for the five rules. The Rules Review Commission approved the five temporary rules at its October 19, 2023 meeting and the rules were entered into the Administrative Code on October 27, 2024 (rules

.0101 and .0111) and December 22, 2023 (.0106, .0107, .0109.) The five rules up for permanent adoption are essentially the rules that have been in place for years with the addition of amendments to the language to align with the requirements in the New Law and technical changes recommended by the Rules Review Commission. By providing consistency and clarity, the proposed rules will help ensure continuity of care for patients and will support the ongoing protection of the health and safety of women in obtaining lawful abortions in clinics regulated by the Department.

Rules Proposed for Adoption

10A NCAC 14E .0101 Definitions

This proposed rule updates four of the existing definitions to align with the New Law, as follows:

- (1) The term “abortion” has been amended 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 to align with statute.
- (5) The rule reference for the term “governing authority” has been updated to reference the Medical Care Commission rule for governing authority.
- (7) 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 terminology change in which “licensure” has replaced “certification,” which is also applied in all other rules in this package.

10A NCAC 14E .0106 Applications

This proposed rule provides details about the procedures a clinic must follow to apply for licensure, including what information is necessary on the application for licensure and how to obtain applications from the Division. This rule reflects existing procedures; as such, there will not be any impacts from this rule other than an incremental improvement to clarity. Note that Paragraph (d) references Subchapter 13S since the construction requirements are now part of the Medical Care Commission rules.

10A NCAC 14E .0107 Issuance of License

This proposed rule outlines requirements related to the issuance of a license to a facility. Note that Paragraph (a) references both Subchapter 14E and Subchapter 13S since the New Law requires compliance with the Medical Care Commission rules in addition to the Department’s rules. Although not a part of the regulatory baseline due to questions of statutory authority, note that the proposed permanent rule does not contain an earlier provision that requires a facility to assure that an OB-GYN board-certified or board eligible physician must be available in the event of complications. Under existing statute and the proposed rules, other medical professionals are able to provide care in the event of complications.

10A NCAC 14E .0109 Renewal

This proposed rule provides details about the process a facility must follow to renew its license on an annual basis, including what information must be provided with an application, the consequences of failing to file a renewal application in time, and a reference to the renewal fee required by statute. This rule reflects existing procedures; as such, there will not be any impacts from this rule other than an incremental improvement in clarity.

10A NCAC 14E .0111 Inspections

This proposed rule outlines the requirements that a clinic must follow as far as allowing the Division to perform annual inspections and to review records to determine compliance with the rules. In Paragraph (a), the rule also specifies that the Division *may* conduct an inspection in response to a complaint that alleges the clinic is not in compliance with the rules of Subchapter 14E. This is a slight change from earlier versions of this rule wherein Paragraph (a) stated that the Division *shall* conduct an inspection in response to a complaint. This change is intended to clarify 1) that the Division has discretion as to when an inspection is warranted; and 2) the Division should only investigate complaints that fall within the scope of its regulations. In any case, the proposed rule will not result in a change from existing practice.

Anticipated Fiscal Impacts

The content of the five rules is directly supported by the purpose of the New Law, which makes the adoption of these rules necessary to ensure that Part II of S.L. 2023-14 can be effectively administered by the Department. Consistent with Section 2.4 of S.L. 2023-14, the Department has determined that each of the five proposed rules are necessary to administer Part 4A of Chapter 131E of the General Statutes. The ability of providers to operate abortion clinics and the requirement on the Department to regulate abortion clinics has been in place since 1976. The proposed rules themselves do not require any changes to procedures or fees for clinics, nor additional workload or staffing for the Department above existing requirements. Neither the federal government nor local government regulates these clinics, so the rules will have no federal or local government impact.

The biggest driving factor behind the proposed rule changes is the continued protection of the health, safety, and wellbeing of women obtaining lawful abortions in a clinic regulated by the Department. These rules maintain the former standards and regulations to help ensure the clinics have continued regulatory oversight. The rules do provide additional clarity which should help regulated clinics understand the standards by which to operate. This could result in possible improvements to compliance with the regulations, although any such improvements attributable to the rule clarity are likely to be minimal. North Carolina currently has 15 clinics, all privately owned, that are in operation.

The New Law required that “certification” be changed to “licensure” in these rules. The Department anticipates that this wording change may make it incrementally more clear to providers that they are lawfully operating a clinic, that they are deemed “licensed,” and that they are therefore subject to the regulations.

As measured from the baseline conditions, there are no quantifiable economic costs or benefits associated with the proposed rules for adoption. The permanent rules are for the purpose of providing clarity and consistency with the New Law. While these five rules will not result in a change to the baseline regulatory condition, they could have a small positive impact to the regulated community, the public, and the Department from improved rule clarity. Improved rule clarity could result in minimal 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 14E .0101 is proposed for adoption as follows:

**SUBCHAPTER 14E - LICENSURE OF SUITABLE FACILITIES FOR THE PERFORMANCE OF
SURGICAL ABORTIONS**

SECTION .0100 – LICENSURE 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(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.

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;

Codifier determined that agency's findings of need did not meet criteria for emergency rule on June 22, 2023;

Emergency Rule Eff. June 30, 2023;

Repealed Eff. July 1, 2023 pursuant to G.S. 150B-21.7;

Temporary Adoption Eff. October 27, 2023;

Amended Eff. September 1, 2024.

10A NCAC 14E .0106 is proposed for adoption as follows:

10A NCAC 14E .0106 APPLICATION

(a) Prior to the admission of patients, applicant for a new clinic shall submit an application for licensure and receive approval from the Division.

(b) Application forms may be obtained by contacting the Division at 2712 Mail Service Center Raleigh, NC 27699-2712.

(c) The application form shall set forth:

- (1) Legal identity of the applicant;
- (2) The name or names under which the facility or services are advertised or presented to the public;
- (3) The facility's mailing address;
- (4) The facility's physical address;
- (5) The ownership of the facility, including a description of the legal character of the operating ownership;
- (6) The owner of the premises from which services are offered including the name and address of the owner of the premises if different from the owner of the facility;
- (7) If the facility is operated under a management contract, the name and address of the building's management company;
- (8) A description of the arrangements that have been made for the disposal of pathological waste, products of conception, and sharps, and the name and address of the provider of such services if not performed by the facility;
- (9) The name, specialty, board certifications, and medical license number of the Medical Director;
- (10) The name, specialty, board certifications, and medical license number of each member of the medical staff;
- (11) The name, nursing certificate number, and renewal number of the Director of Nursing;
- (12) The name, nursing certificate number, and renewal number of each nursing staff member; and
- (13) The name of the consulting pathologist, the name of the consulting pathologist's laboratory, and the address of the laboratory.

(d) After construction requirements in Section .0200 of Subchapter 13S of Title 10A of the North Carolina Administrative Code have been met and the application for licensure has been received and approved, the Division shall conduct an on-site, licensure survey.

History Note: Authority G.S. 131E-153;131E-153.2; S.L. 2023-14, s. 2.4;

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;

Codifier determined that agency's findings of need did not meet criteria for emergency rule on June 22, 2023:

Emergency Rule Eff. June 30, 2023:

Repealed Eff. July 1, 2023 pursuant to G.S. 150B-21.7:

Temporary Amendment Eff. December 22, 2023:

Amended Eff. September 1, 2024.

10A NCAC 14E .0107 is proposed for adoption as follows:

10A NCAC 14E .0107 ISSUANCE OF LICENSE

(a) The Division shall issue a license if it finds the facility can comply with all requirements described in this Subchapter and Subchapter 13S of Title 10A of the North Carolina Administrative Code.

(b) Each license 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 that prevent a service from providing abortion services.

History Note: Authority G.S. 131E-153; 131E-153.2; S.L. 2023-14, s. 2.4;

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;

Codifier determined that agency's findings of need did not meet criteria for emergency rule on June 22, 2023;

Emergency Rule Eff. June 30, 2023;

Repealed Eff. July 1, 2023 pursuant to G.S. 150B-21.7;

Temporary Amendment Eff. December 22, 2023.

Amended Eff. September 1, 2024.

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

10A NCAC 14E .0109 RENEWAL

(a) Each license, renewed at the beginning of each calendar year.

(b) The renewal application form shall set forth:

- (1) Legal identity of the applicant;
- (2) The name or names under which the facility or services are advertised or presented to the public;
- (3) The facility's mailing address;
- (4) The facility's physical address;
- (5) The ownership of the facility, including a description of the legal character of the operating ownership;
- (6) The owner of the premises from which services are offered including the name and address of the owner of the premises if different from the owner of the facility;
- (7) If the facility is operated under a management contract, the name and address of the building's management company;
- (8) A description of the arrangements that have been made for the disposal of pathological waste, products of conception, and sharps, and the name and address of the provider of such services if not performed by the facility;
- (9) The name, specialty, board certifications, and medical license number of the Medical Director;
- (10) The name, specialty, board certifications, and medical license number of each member of the medical staff;
- (11) The name, nursing certificate number, and renewal number of the Director of Nursing;
- (12) The name, nursing certificate number, and renewal number of each nursing staff member;
- (13) The name of the consulting pathologist, the name of the consulting pathologist's laboratory, and the address of the laboratory;
- (14) The number of abortion procedures performed since initial licensure or the most recent licensure renewal, whichever is later; and
- (15) The number of patients that were transferred to a hospital since initial licensure or the most recent licensure renewal, whichever is later.

(c) Upon the filing of a renewal application, the clinic must pay a non-refundable renewal fee as defined in G.S. 131E-153.2.

(d) An application for renewal of licensure must be filed with the Division at least 30 days prior to the date of expiration. Renewal application forms shall be furnished by the Division.

(e) Failure to file a renewal application shall result in expiration of the license to operate.

History Note: Authority G.S. 131E-153; 131E-153.2; 143B-10; S.L. 2023-14, s. 2.4;

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;

Codifier determined that agency's findings of need did not meet criteria for emergency rule on June 22, 2023;

Emergency Rule Eff. June 30, 2023;

Repealed Eff. July 1, 2023 pursuant to G.S. 150B-21.7;

Temporary Amendment Eff. December 22, 2023;

Amended Eff. September 1, 2024.

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

10A NCAC 14E .0111 INSPECTIONS

- (a) Any clinic licensed 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 may be conducted whenever the Division receives a complaint alleging the clinic is not in compliance with the rules of the Subchapter.
- (b) Representatives of the Division shall make their identities known to the clinic staff prior to inspection of the clinic.
- (c) Representatives of the Division may review any records in any medium necessary to determine compliance with the rules of this Subchapter. The Department shall maintain the confidentiality of the complainant and the patient, unless otherwise required by law.
- (d) 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.
- (e) A clinic shall file a written 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. 131E-153; 131E-153.6; S.L. 2023-14, s. 2.4;

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;

Codifier determined that agency's findings of need did not meet criteria for emergency rule on June 22, 2023;

Emergency Rule Eff. June 30, 2023;

Repealed Eff. July 1, 2023 pursuant to G.S. 150B-21.7;

Temporary Amendment Eff. October 27, 2023;

Amended Eff. September 1, 2024.