

Note from the Codifier: The OAH website includes notices and the text of proposed temporary rules as required by G.S. 150B-21.1(a1). Prior to the agency adopting the temporary rule, the agency must hold a public hearing no less than five days after the rule and notice have been published and must accept comments for at least 15 business days. For questions, you may contact the Office of Administrative Hearings at 984-236-1850 or email oah.postmaster@oah.nc.gov.

TITLE 10A – DEPARTMENT OF HEALTH AND HUMAN SERVICES

Notice is hereby given in accordance with G.S. 150B-21.1 that the Department of Health and Human Services intends to amend the rules cited as 10A NCAC 14E .0101, .0102, .0104, .0106-.0112, .0201, .0202, .0207, and .0315.

Codifier of Rules received for publication the following notice and proposed temporary rules on: June 20, 2023.

Public Hearing:

Date: July 19, 2023

Time: 10:00 a.m.

Location: Dorothea Dix Park, Brown Building, Room 104, 801 Biggs Drive, Raleigh, NC 27603

Reason for Proposed Temporary Action: A serious and unforeseen threat to the public health, safety or welfare. The effective date of a recent act of the General Assembly or of the U.S. Congress, cite: SL2023-14, Part I, Section 1.1 and Part II, Section 2.4, effective date: July 1, 2023. On May 16, 2023, Senate Bill 20 became law as S.L. 2023-14. This new law entitled “An Act to Make Various Changes to Health Care Laws and to Appropriate Funds for Health Care Programs” revised various state laws governing abortions in North Carolina. The Department was made aware of the proposed changes on May 2, 2023, when a Proposed Conference Committee Substitute was issued that made the changes to the State’s abortion laws. The revisions in Part I and Section 2.4 of Part II of the law go into effect on July 1, 2023, less than 2 months after the Department became aware of the proposed changes. Among other changes, S.L. 2023-14 makes significant changes to defining when an abortion is lawful. Current rules governing the certification of abortion clinics are found in Subchapter 14E of Title 10A of the Administrative Code. Given the changes to the law that will become effective July 1, the Department is making certain amendments to the existing rules under temporary procedures to conform with those provisions in S.L. 2023-14 that become effective on July 1st. The adoption of temporary rule amendments will ensure continuity of care for patients, will resolve any uncertainty about the rules applicable to impacted providers until the Department is able to promulgate permanent rules, and will protect the health and safety of people obtaining reproductive health care, and to provide certainty to medical providers. Therefore, the Department seeks to amend Subchapter 14E of Title 10A under temporary procedures.

Comment Procedures: Comments from the public shall be directed to: Nadine Pfeiffer, 809 Ruggles Drive, 2701 Mail Service Center, Raleigh, NC 27699-2701; email DHSR.RulesCoordinator@dhhs.nc.gov. The comment period begins June 28, 2023 and ends July 20, 2023.

CHAPTER 14 - DIRECTOR, DIVISION OF HEALTH SERVICE REGULATION

SUBCHAPTER 14E - ~~CERTIFICATIONS OF CLINICS FOR ABORTION~~ LICENSURE OF SUITABLE FACILITIES FOR THE PERFORMANCE OF SURGICAL ABORTIONS

SECTION .0100 – ~~CERTIFICATION~~ 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(1)~~. 90-21.81(1c).
- (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~~ 12 weeks of pregnancy.
- (3) "Complication" includes but is not limited to hemorrhage, infection, uterine perforation, cervical laceration, or retained products of conception.
- (4) "Division" means the Division of Health Service Regulation of the North Carolina Department of Health and Human Services.
- (5) "Gestational age" means the length of pregnancy as indicated by the date of the first day of the last normal monthly menstrual period, if known, or as determined by ultrasound.
- (6) "Governing authority" means the individual, agency, group, or corporation appointed, elected or otherwise designated, in which the ultimate responsibility and authority for the conduct of the abortion clinic is vested pursuant to Rule .0302 of this Subchapter.
- (7) "Health Screening" means an evaluation of an employee or contractual employee, including tuberculosis testing, to identify any underlying conditions that may affect the person's ability to work in the clinic.
- (8) "New clinic" means one that is not certified as an abortion clinic by the Division as of July 1, ~~2014~~, 2023, and has not been certified or licensed within the previous six months of the application for ~~certification~~. licensure.
- (9) "Qualified Physician" means a licensed physician who advises, procures, or causes a miscarriage or abortion as defined in G.S. ~~14-45.1(g)~~. 90-21.81(7a).

- (10) "Registered Nurse" means a person who holds a valid license issued by the North Carolina Board of Nursing to practice professional nursing in accordance with the Nursing Practice Act, G.S. 90, Article 9A.

Authority G.S. 14-45.1(a); 14-45.1(g); 143B-10; S.L. 2013-366, s. 4(e); S.L. 2023-14, s. 2.4.

10A NCAC 14E .0102 CONFERENCE

Before proceeding with construction and operational plans, a potential sponsor or owner of a freestanding abortion clinic shall discuss with the staff of the Division of Health Service Regulation the scope of the proposed facility. This will provide an opportunity for the owner and the Division's staff to discuss ~~certification~~ licensure requirements.

Authority G.S. 14-45.1(a); 143B-10; S.L. 2023-14, s. 2.4.

10A NCAC 14E .0104 PLANS

Prior to issuance of a ~~certificate~~ license pursuant to Rule .0107 of this Section, a clinic shall submit two copies of the building plans to the Division for ~~certification~~ licensure purposes when the clinic requires a review by the Division and the Department of Insurance, according to the North Carolina Administration and Enforcement Requirements Code, 2012 edition, including subsequent amendments and editions. Copies of the North Carolina Administration Code are available from the International Code Council at http://www.ecodes.biz/ecodes_support/Free_Resources/2012NorthCarolina/12NorthCarolina_main.html at no cost. When the local jurisdiction has authority from the North Carolina Building Code Council to review the plans, the clinic shall submit only one copy of the plans to the Division. In that case, the clinic shall submit an additional set of plans directly to the local jurisdiction.

Authority G.S. 14-45.1(a); 143B-10; S.L. 2023-14, s. 2.4.

10A NCAC 14E .0106 APPLICATION

- (a) Prior to the admission of patients, an application from the clinic for ~~certification~~ licensure shall be submitted to and approved by the Division.
- (b) Application forms may be obtained by contacting the Division.
- (c) The application form shall set forth the ownership, staffing patterns, clinical services to be rendered, professional staff in charge of services, and general information that would be helpful to the Division's understanding of the clinic's operating program.
- (d) After construction requirements in Section .0200 of this Subchapter have been met and the application for ~~certification~~ licensure has been received and approved, the Division shall conduct an on-site, ~~certification~~ licensure survey.
- (e) Each ~~certificate~~ license must be renewed at the beginning of each calendar year. The governing authority shall file an application for renewal of ~~certification~~ licensure with the Division at least 30 days prior to the date of expiration on forms furnished by the Division. Failure to file a renewal application shall result in expiration of the ~~certificate~~ license to operate.

Authority G.S. 14-45.1(a); 131E-153.2; S.L. 2023-14, s. 2.4.

10A NCAC 14E .0107 ISSUANCE OF ~~CERTIFICATE~~ LICENSE

- (a) The Division shall issue a ~~certificate~~ license if it finds the facility can:
- (1) Comply with all requirements described in this Subchapter; and
 - (2) Assure that, in the event that complications arise from the abortion procedure, an OB-GYN board certified or board eligible physician shall be available.
- (b) Each ~~certificate~~ 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 causing disruption of services.

Authority G.S. 14-45.1(a); 131E-153.2; S.L. 2023-14, s. 2.4.

10A NCAC 14E .0108 POSTING

~~Certificates~~ Licenses shall be posted in a conspicuous place on the premises.

Authority G.S. 14-45.1(a); 143B-10; S.L. 2023-14, s. 2.4.

10A NCAC 14E .0109 RENEWAL

Each ~~certificate~~, license, unless previously suspended or revoked, pursuant to the applicable rules and statutes shall be renewable annually upon the filing of an application, payment of the non-refundable renewal fee as defined in G.S. ~~131E-269~~, 131E-153.2, and approval by the Division.

Authority G.S. 14-45.1(a); 131E-269; 131E-153.2; 143B-10; S.L. 2023-14, s. 2.4.

10A NCAC 14E .0110 REVOCATION

The Department shall deny, suspend, or revoke a ~~certificate~~ license in any case where it finds that substantial failure to comply with these regulations renders the facility unsuitable for the performance of abortions.

Authority G.S. 14-45.1(a); ~~131E-153.2~~; 143B-10; 150B-23; S.L. 2023-14, s. 2.4.

10A NCAC 14E .0111 INSPECTIONS

(a) Any clinic ~~certified~~ 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 shall be conducted whenever the purpose of the inspection is to determine whether the clinic complies with the rules of this Subchapter or whenever there is reason to believe that some condition exists which is not in compliance with the rules of this Subchapter.

(b) The Division shall have authority to investigate any complaint relative to the care, treatment, or complication of any patient.

(c) Representatives of the Division shall make their identities known to the person in charge prior to inspection of the clinic.

(d) Representatives of the Division may review any records in any medium necessary to determine compliance with the rules of this Subchapter, while maintaining the confidentiality of the complainant and the patient, unless otherwise required by law.

(e) The clinic shall allow the Division to have immediate access to its premises and the records necessary to conduct an inspection and determine compliance with the rules of this Subchapter.

(f) A clinic shall file a plan of correction for cited deficiencies within 10 business days of receipt of the report of the survey. The Division shall review and respond to a written plan of correction within 10 business days of receipt of the corrective action plan.

Authority G.S. 14-45.1(a); ~~14-45.1(a1)~~; 143B-10; S.L. 2013-366, s. 4(e); S.L. 2023-14, s. 2.4.

10A NCAC 14E .0112 ALTERATIONS

Any ~~certificate~~ license holder or prospective applicant desiring to make specified types of alteration or addition to a clinic or to construct a new clinic, before commencing such alteration, addition or new construction shall submit plans and specifications therefor to the Division for preliminary inspection and approval or recommendations with respect to compliance with the regulations and standards herein authorized.

Authority G.S. 14-45.1(a); 143B-10; S.L. 2023-14, s. 2.4.

SECTION .0200 - MINIMUM STANDARDS FOR CONSTRUCTION AND EQUIPMENT

10A NCAC 14E .0201 BUILDING CODE REQUIREMENTS

(a) The physical plant for a clinic shall meet or exceed minimum requirements of the North Carolina State Building Code for Group B occupancy (business office facilities) which is incorporated herein by reference including subsequent amendments and editions. Copies of the Code can be obtained from the International Code Council online at <http://shop.iccsafe.org/north-carolina-doi.discounts?ref=NC> for a cost of five hundred twenty-seven dollars (\$527.00), or accessed electronically free of charge at <http://www.ecodes.biz>.

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

Authority G.S. 14-45.1(a); 143B-10; S.L. 2023-14, s. 2.4.

10A NCAC 14E .0202 SANITATION

Clinics that are ~~certified~~ licensed by the Division to perform abortions shall comply with the Rules governing the sanitation of hospitals, nursing homes, adult care homes, and other institutions, contained in 15A NCAC 18A .1300 which is hereby incorporated by reference including subsequent amendments and editions. Copies of 15A NCAC 18A .1300 may be obtained at no charge from the Division of Public Health, Environmental Health Section, 1632 Mail Service Center, Raleigh, NC 27699-1632, or accessed electronically free of charge from the Office of Administrative Hearings at <https://www.oah.nc.gov/>.

Authority G.S. 14-45.1(a); 143B-10; S.L. 2023-14, s. 2.4.

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~~ licensed by the Division to perform abortions:

- (1) receiving area;
- (2) examining room;
- (3) preoperative preparation and holding room;
- (4) individual patient locker facilities or equivalent;
- (5) procedure room;
- (6) recovery room;
- (7) clean workroom;
- (8) soiled workroom;
- (9) medicine room may be defined as area in the clean workroom if a self-contained secure cabinet complying with security requirements of state and federal laws is provided;
- (10) separate and distinct areas for storage and handling clean and soiled linen;
- (11) patient toilet;

- (12) personnel lockers and toilet facilities;
- (13) laboratory;
- (14) nourishment station with storage and preparation area for serving meals or in-between meal snacks;
- (15) janitor's closets;
- (16) adequate space and equipment for assembling, sterilizing and storing medical and surgical supplies;
- (17) storage space for medical records; and
- (18) office space for nurses' charting, doctors' charting, communications, counseling, and business functions.

Authority G.S. ~~14-45.1(a)~~; 143B-10; S.L. 2023-14, s. 2.4.

SECTION .0300 – GOVERNING AUTHORITY

10A NCAC 14E .0315 HOUSEKEEPING

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

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

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

Authority G.S. ~~14-45.1(a)~~; 143B-10; S.L. 2023-14, s. 2.4.