

RRC STAFF OPINION

PLEASE NOTE: THIS COMMUNICATION IS EITHER 1) ONLY THE RECOMMENDATION OF AN RRC STAFF ATTORNEY AS TO ACTION THAT THE ATTORNEY BELIEVES THE COMMISSION SHOULD TAKE ON THE CITED RULE AT ITS NEXT MEETING, OR 2) AN OPINION OF THAT ATTORNEY AS TO SOME MATTER CONCERNING THAT RULE. THE AGENCY AND MEMBERS OF THE PUBLIC ARE INVITED TO SUBMIT THEIR OWN COMMENTS AND RECOMMENDATIONS (ACCORDING TO RRC RULES) TO THE COMMISSION.

AGENCY: N.C. Department of Health and Human Services/DHSR

RULE CITATION: 10A NCAC 14E .0104, .0112, .0114, .0201, .0202, .0207, .0209, .0210, .0211, .0212, .0315, .0318, .0319, .0320, .0321, .0322, .0323, .0324, .0325, .0326, .0327, .0328, .0329, .0330, and .0331.

DATE ISSUED: October 18, 2023

RECOMMENDED ACTION:

- Approve, but note staff's comment
- Object, based on:
 - Lack of statutory authority (All rules)
 - Unclear or ambiguous
 - Unnecessary
 - Failure to comply with the APA
- Extend the period of review

COMMENT:

In May 2023, Session Law 2023-14 (“the Session Law”) went into effect. In relevant part, Part I of the Session Law repealed G.S. 14-45.1, which had previously been propounded as the basis for the Department of Health and Human Services’ (“the Department”) rules governing abortion clinics. In its place, Section 2.2 of Part II codified the Abortion Clinic Licensure Act (“the Act”) requiring freestanding abortion clinics—those which are neither physically attached to a hospital nor operated by a hospital—to be licensed by the Department. Section 2.4 of Part II provided that the Department was required to adopt rules “necessary to administer” the Act no later than October 1, 2023.

In so doing, the legislature seems to have carefully circumscribed the Department’s rulemaking authority. Section 2.4 states that the rules adopted “shall be necessary to administer the provisions of [Part II].” Looking at Part II, only Section

Brian Liebman
Commission Counsel

2.2, which adds the Abortion Clinic Licensure Act to Article 6 of Chapter 131E of the General Statutes, is pertinent, and again, the Department's authority under the Act is limited in scope. Under the Act, freestanding abortion clinics must obtain a license available from the Department after submission of an application and payment of a fee. The Department is authorized to set the "necessary and reasonable" contents of the application and charge the application fee (G.S. 131E-153.2), take adverse action against a license for "substantial failure to comply" with the Act or rules adopted under its authority (G.S. 131-153.4), inspect clinics (G.S. 131E-153.6), and either penalize (G.S. 131E-153.7) or seek injunctions (G.S. 131E-153.8) against those clinics operating without a license. A grant of rulemaking authority to the Medical Care Commission—which is housed within the Department but is a separate agency for rulemaking purposes—is included (G.S. 131E-153.5).

The above-captioned rules delve into issues that are not specifically governed by any law contained within the Act or any other provision in Part II of Session Law 2023-14. Rules .0104, .0112 and .0114 require clinic owners to receive the Department's review and approval of their building plans prior to licensure (.0104), construction (.0112), and alteration (.0114). The rules in Section .0200 cover "Minimum Standards for Construction and Equipment," and would impose physical plant and sanitation requirements on all freestanding clinics. Section .0300 goes further, and would impose requirements on the "governing authority" of each clinic. Within this Section, the Department attempts to regulate—in granular detail—everything from housekeeping (Rule .0315) and meal service (.0331) to internal management and staffing (Rules .0318, .0323, and .0324), recordkeeping (Rules .0319, .0321, .0322), and provision of care (Rules .0325 to .0329). None of these topics are specifically mentioned in the Act. As such, it is staff's opinion that these rules cannot be "necessary to administer" the statutes contained in the Act, and are thus outside the scope of the Department's rulemaking authority under Section 2.4 of the Session Law.

In response to staff's requests for changes, the agency argues that "the content of all the rules is directly supported by the purpose of the Act," and that "each of the proposed rules are necessary to implement the purpose as stated in G.S. 131E-153(b)." G.S. 131E-153(b) directs that the purpose of the Act "is to provide for the development, establishment, and enforcement of basic standards (1) for the care and treatment of individuals in abortion clinics; and (2) for the maintenance and operation of abortion clinics so as to ensure safe and adequate treatment of such individuals in abortion clinics."

While the agency is correct that G.S. 131E-153(b) enunciates the *purpose* of the Act, this language cannot be read as an open-ended grant of *authority* for the Department to promulgate any rule that could conceivably concern the "basic standards for the care and treatment of individuals in abortion clinics" outside of the boundaries of the statutory scheme. As noted above, these rules impose deep, granular requirements upon clinics with respect to issues that are not mentioned within any

statute contained in the Act. Thus, it is staff's opinion that G.S. 131E-153(b) is not an adequate statutory basis for the above-captioned rules.

Further, staff would draw the Commission's attention to its consideration of the Medical Care Commission's hospital licensure rules in 10A NCAC 13B at the August 2022 meeting. There, the MCC advanced the identical argument that rules covering broad topics not specifically mentioned in the Hospital Licensure Act were authorized by the Act's "purpose" statute, which contains almost identical language to G.S. 131E-153(b). The Commission rejected the MCC's argument and objected to the rules. While the Commission's previous decisions are not binding, it is staff's belief that the nearly identical characteristics of the MCC's hospital licensure rules and the Department's abortion clinic licensure rules, along with their nearly identical statutory language, should be persuasive to the Commission in this instance.

Based on the foregoing, staff recommends objection to the above-captioned rules for lack of statutory authority pursuant to G.S. 150B-21.9(a)(1).

Brian Liebman
Commission Counsel

§ 150B-21.9. Standards and timetable for review by Commission.

(a) Standards. - The Commission must determine whether a rule meets all of the following criteria:

- (1) It is within the authority delegated to the agency by the General Assembly.
- (2) It is clear and unambiguous.
- (3) It is reasonably necessary to implement or interpret an enactment of the General Assembly, or of Congress, or a regulation of a federal agency. The Commission shall consider the cumulative effect of all rules adopted by the agency related to the specific purpose for which the rule is proposed.
- (4) It was adopted in accordance with Part 2 of this Article.

The Commission shall not consider questions relating to the quality or efficacy of the rule but shall restrict its review to determination of the standards set forth in this subsection.

The Commission may ask the Office of State Budget and Management to determine if a rule has a substantial economic impact and is therefore required to have a fiscal note. The Commission must ask the Office of State Budget and Management to make this determination if a fiscal note was not prepared for a rule and the Commission receives a written request for a determination of whether the rule has a substantial economic impact.

(a1) Entry of a rule in the North Carolina Administrative Code after review by the Commission creates a rebuttable presumption that the rule was adopted in accordance with Part 2 of this Article.

(b) Timetable. - The Commission must review a permanent rule submitted to it on or before the twentieth of a month by the last day of the next month. The Commission must review a rule submitted to it after the twentieth of a month by the last day of the second subsequent month. The Commission must review a temporary rule in accordance with the timetable and procedure set forth in G.S. 150B-21.1. (1991, c. 418, s. 1; 1995, c. 507, s. 27.8(f); 2000-140, s. 93.1(a); 2001-424, s. 12.2(b); 2003-229, s. 9.)

GENERAL ASSEMBLY OF NORTH CAROLINA
SESSION 2023

SESSION LAW 2023-14
SENATE BILL 20

AN ACT TO MAKE VARIOUS CHANGES TO HEALTH CARE LAWS AND TO APPROPRIATE FUNDS FOR HEALTH CARE PROGRAMS.

The General Assembly of North Carolina enacts:

PART I. ABORTION LAW REVISIONS

SECTION 1.1. G.S. 14-45.1 is repealed.

SECTION 1.2. Article 1I of Chapter 90 of the General Statutes reads as rewritten:
"Article 1I.

~~"Woman's Right to Know Act.~~ Abortion Laws.

"§ 90-21.80. Short title.

This act may be cited as ~~the "Woman's Right to Know Act."~~ "Abortion Laws."

"§ 90-21.81. Definitions.

The following definitions apply in this Article:

- (1) Abortion. – A surgical abortion or a medical abortion, as those terms are defined in this section, respectively.
- (1a) Abortion-inducing drug. – A medicine, drug, or any other substance prescribed or dispensed with the intent of terminating the clinically diagnosable pregnancy of a woman, with knowledge that the termination will, with reasonable likelihood, cause the death of the unborn child. This includes the off-label use of drugs such as mifepristone (Mifeprex), misoprostol (Cytotec), and methotrexate, approved by the United States Food and Drug Administration to induce abortions or known to have abortion-inducing properties, prescribed specifically with the intent of causing an abortion, whether or not there exists a diagnosed pregnancy at the time of prescription or dispensing, for the purposes of the woman taking the drugs at a later date to cause an abortion rather than contemporaneously with a clinically diagnosed pregnancy. This definition shall not include drugs that may be known to cause an abortion but are prescribed for other medical indications, such as chemotherapeutic agents and diagnostic drugs.
- (1b) Adverse event. – Any untoward medical occurrence associated with the use of a drug in humans, whether or not considered drug related.
- (1c) ~~Abortion.~~ Surgical abortion. – The use or prescription of any instrument, medicine, drug, or other substance instrument or device intentionally to terminate the pregnancy of a woman known to be pregnant with an intention other than to do any of the following:
 - a. Increase the probability of a live birth.
 - b. Preserve the life or health of the child.
 - c. Remove a dead, unborn child who died as the result of (i) natural causes in utero, (ii) accidental trauma, or (iii) a criminal assault on the pregnant woman or her unborn child which causes the premature termination of the pregnancy.



- (3) The presence or presumed presence of Down syndrome.

...."

SECTION 1.4.(c) G.S. 90-21.6 reads as rewritten:

"§ 90-21.6. Definitions.

For the purposes of Part 2 only of this Article, unless the context clearly requires otherwise:

- (1) Abortion. – As defined in G.S. 90-21.81.
(1a) "Unemancipated minor" or "minor" means any Unemancipated minor or minor. – Any person under the age of 18 who has not been married or has not been emancipated pursuant to Article 35 of Chapter 7B of the General Statutes.
(2) "Abortion" means the use or prescription of any instrument, medicine, drug, or any other substance or device with intent to terminate the pregnancy of a woman known to be pregnant, for reasons other than to save the life or preserve the health of an unborn child, to remove a dead unborn child, or to deliver an unborn child prematurely, by accepted medical procedures in order to preserve the health of both the mother and the unborn child."

SECTION 1.5.(a) Section 1.3 of this Part becomes effective July 1, 2023, and applies to offenses committed on or after that date. The remainder of this Part becomes effective on July 1, 2023.

SECTION 1.5.(b) Prosecutions for offenses committed before the effective date of this Part are not abated or affected by this Part, and the statutes that would be applicable but for this Part remain applicable to those prosecutions.

PART II. SUITABLE FACILITIES FOR THE PERFORMANCE OF SURGICAL ABORTIONS

SECTION 2.1. Article 1I of Chapter 90 of the General Statutes is amended by adding a new section to read:

"§ 90-21.82A. Suitable facilities for the performance of surgical abortions.

- (a) The following definitions apply in this section:
(1) Abortion clinic. – As defined in G.S. 131E-153.1.
(2) Ambulatory surgical facility. – As defined in G.S. 131E-176.
(3) Hospital. – As defined in G.S. 131E-176.
(b) During the first 12 weeks of pregnancy, a physician licensed to practice medicine under this Chapter may perform a surgical abortion in a hospital, an ambulatory surgical facility, or an abortion clinic; provided, however, that (i) the clinic has been licensed by the Department of Health and Human Services to be a suitable facility for the performance of abortions and (ii) the licensed physician performs the abortion in accordance with this Article and Article 1K of this Chapter.
(c) After the twelfth week of pregnancy, a physician licensed to practice medicine under this Chapter may not perform a surgical abortion as permitted under North Carolina law in any facility other than a hospital."

SECTION 2.2. Article 6 of Chapter 131E of the General Statutes is amended by adding a new Part to read:

"Part 4A. Abortion Clinic Licensure.

"§ 131E-153. Title; purpose.

- (a) This Part shall be known as the "Abortion Clinic Licensure Act."
(b) The purpose of this Part is to provide for the development, establishment, and enforcement of basic standards:
(1) For the care and treatment of individuals in abortion clinics; and
(2) For the maintenance and operation of abortion clinics so as to ensure safe and adequate treatment of such individuals in abortion clinics.

"§ 131E-153.1. Definitions.

The following definitions apply in this Part, unless otherwise specified:

- (1) Abortion clinic. – A freestanding facility, that is neither physically attached nor operated by a hospital, for the performance of abortions during the first 12 weeks of pregnancy.
- (2) Commission. – The North Carolina Medical Care Commission.
- (3) Operating room. – A room used for the performance of surgical procedures requiring one or more incisions and that is required to comply with all applicable licensure codes and standards for an operating room.

"§ 131E-153.2. Licensure requirement.

(a) No person shall operate an abortion clinic without a license obtained from the Department.

(b) Applications shall be available from the Department, and each application filed with the Department shall contain all necessary and reasonable information that the Department may by rule require. A license shall be granted to the applicant upon a determination by the Department that the applicant has complied with the provisions of this Part and the rules adopted by the Commission under this Part. The Department shall charge the applicant a nonrefundable annual base license fee in the amount of eight hundred fifty dollars (\$850.00) plus a nonrefundable annual per-operating room fee in the amount of seventy-five dollars (\$75.00).

(c) A license to operate an abortion clinic shall be annually renewed upon the filing and the Department's approval of a renewal application. The renewal application shall be available from the Department and shall contain all necessary and reasonable information that the Department may by rule require.

(d) Each license shall be issued only for the premises and persons named in the application and shall not be transferable or assignable except with the written approval of the Department.

(e) Licenses shall be posted in a conspicuous place on the licensed premises.

"§ 131E-153.3. Fair billing and collections practices for abortion clinics.

All abortion clinics licensed under this Part shall be subject to the fair billing and collections practices set out in G.S. 131E-91.

"§ 131E-153.4. Adverse action on a license.

(a) Subject to subsection (b) of this section, the Department is authorized to deny a new or renewal application for a license and to amend, recall, suspend, or revoke an existing license upon a determination that there has been a substantial failure to comply with the provisions of this Part or the rules adopted under this Part.

(b) Chapter 150B of the General Statutes, the Administrative Procedure Act, shall govern all administrative action and judicial review in cases where the Department has taken the action described in subsection (a) of this section.

"§ 131E-153.5. Rules and enforcement.

(a) The Commission is authorized to adopt, amend, and repeal all rules necessary for the implementation of this Part. These rules shall be no stricter than those issued by the Commission under G.S. 131E-79 of the Ambulatory Surgical Facility Licensure Act.

(b) The Department shall enforce the rules adopted or amended by the Commission with respect to abortion clinics.

"§ 131E-153.6. Inspections.

(a) The Department shall make or cause to be made inspections of abortion clinics as necessary. The Department is authorized to delegate to a State officer, agent, board, bureau, or division of State government the authority to make inspections according to the rules adopted by the Commission. The Department may revoke this delegated authority in its discretion.

(b) Notwithstanding the provisions of G.S. 8-53 or any other provision of law relating to the confidentiality of communications between physician and patient, the representatives of the

Department who make these inspections may review any writing or other record in any recording medium that pertains to the admission, discharge, medication, treatment, medical condition, or history of persons who are or have been patients of the facility being inspected unless that patient objects, in writing, to review of that patient's records. Physicians, psychologists, psychiatrists, nurses, and anyone else involved in giving treatment at or through a facility who may be interviewed by representatives of the Department may disclose to these representatives information related to an inquiry, notwithstanding the existence of the physician-patient privilege in G.S. 8-53 or any other rule of law; provided, however, that the patient has not made written objection to this disclosure. The facility, its employees, and any person interviewed during these inspections shall be immune from liability for damages resulting from the disclosure of any information to the Department. Any confidential or privileged information received from review of records or interviews shall be kept confidential by the Department and not disclosed without written authorization of the patient or legal representative, or unless disclosure is ordered by a court of competent jurisdiction. The Department shall institute appropriate policies and procedures to ensure that this information is not disclosed without authorization or court order. The Department shall not disclose the name of anyone who has furnished information concerning a facility without the consent of that person. Neither the names of persons furnishing information nor any confidential or privileged information obtained from records or interviews shall be considered "public records" within the meaning of G.S. 132-1. Prior to releasing any information or allowing any inspections referred to in this section, the patient must be advised in writing by the facility that the patient has the right to object, in writing, to this release of information or review of the records and that by objecting, in writing, the patient may prohibit the inspection or release of the records.

"§ 131E-153.7. Penalties.

A person who owns in whole or in part or operates an abortion clinic without a license is guilty of a Class 3 misdemeanor and upon conviction will be subject only to a fine of not more than fifty dollars (\$50.00) for the first offense and not more than five hundred dollars (\$500.00) for each subsequent offense. Each day of continuing violation after conviction is considered a separate offense.

"§ 131E-153.8. Injunction.

(a) Notwithstanding the existence or pursuit of any other remedy, the Department may, in the manner provided by law, maintain an action in the name of the State for injunction or other process against any person or governmental unit to restrain or prevent the establishment, conduct, management, or operation of an abortion clinic without a license.

(b) If any person shall hinder the proper performance of duty of the Secretary or a representative in carrying out the provisions of this Part, the Secretary may institute an action in the superior court of the county in which the hindrance occurred for injunctive relief against the continued hindrance, irrespective of all other remedies at law.

(c) Actions under this section shall be in accordance with Article 37 of Chapter 1 of the General Statutes and Rule 65 of the Rules of Civil Procedure."

SECTION 2.3. G.S. 131E-272 reads as rewritten:

"§ 131E-272. Initial licensure fees for new facilities.

The following fees are initial licensure fees for new facilities and are applicable as follows:

Facility Type	Number of Beds	Initial License Fee	Initial Bed Fee
Adult Care Licensure	More than 6	\$400.00	\$19.00
	6 or Fewer	\$350.00	\$ -
Acute and Home Care General Acute Hospitals	1-49	\$550.00	\$19.00
	50-99	\$750.00	\$19.00
	100-199	\$950.00	\$19.00

	200-399	\$1150.00	\$19.00
	400-699	\$1550.00	\$19.00
	700+	\$1950.00	\$19.00
Other Hospitals		\$1050.00	\$19.00
Home Care	-	\$560.00	\$ -
Ambulatory Surgical Ctrs.	-	\$900.00	\$85.00
Hospice (Free Standing)	-	\$450.00	\$ -
Abortion Clinics	-	\$750.00 \$850.00	\$ -
Cardiac Rehab. Centers	-	\$425.00	\$ -
Nursing Home & L&C			
Nursing Homes		\$470.00	\$19.00
All Others		\$ -	\$19.00
Mental Health Facilities			
Nonresidential		\$265.00	\$ -
Non ICF/IID	6 or fewer	\$350.00	\$ -
ICF/IID only	6 or fewer	\$900.00	\$ -
Non ICF/IID	More than 6	\$525.00	\$19.00
ICF/IID only	More than 6	\$850.00	\$19.00."

SECTION 2.4. No later than October 1, 2023, the Department of Health and Human Services shall adopt the rules necessary to administer this Part.

SECTION 2.5. Section 2.4 of this Part becomes effective July 1, 2023. The remainder of this Part becomes effective on October 1, 2023.

PART III. BORN-ALIVE ABORTION SURVIVORS PROTECTION

SECTION 3.(a) Chapter 90 of the General Statutes is amended by adding a new Article to read:

"Article 1M.

"Born-Alive Abortion Survivors Protection Act.

"§ 90-21.140. Definitions.

As used in this Article, the following definitions apply:

- (1) Abortion. – As defined in G.S. 90-21.81.
- (2) Attempt to perform an abortion. – As defined in G.S. 90-21.81.
- (3) Born alive. – With respect to a member of the species *Homo sapiens*, this term means the complete expulsion or extraction from his or her mother of that member, at any stage of development, who after such expulsion or extraction breathes or has a beating heart, pulsation of the umbilical cord, or definite movement of voluntary muscles, regardless of whether the umbilical cord has been cut, and regardless of whether the expulsion or extraction occurs as a result of natural or induced labor, cesarean section, or induced abortion.

"§ 90-21.141. Findings.

The General Assembly makes the following findings:

- (1) If an abortion results in the live birth of an infant, the infant is a legal person for all purposes under the laws of North Carolina and entitled to all the protections of such laws.
- (2) Any infant born alive after an abortion or within a hospital, clinic, or other facility has the same claim to the protection of the law that would arise for any newborn, or for any person who comes to a hospital, clinic, or other facility for screening and treatment or otherwise becomes a patient within its care.

RRC STAFF OPINION

PLEASE NOTE: THIS COMMUNICATION IS EITHER 1) ONLY THE RECOMMENDATION OF AN RRC STAFF ATTORNEY AS TO ACTION THAT THE ATTORNEY BELIEVES THE COMMISSION SHOULD TAKE ON THE CITED RULE AT ITS NEXT MEETING, OR 2) AN OPINION OF THAT ATTORNEY AS TO SOME MATTER CONCERNING THAT RULE. THE AGENCY AND MEMBERS OF THE PUBLIC ARE INVITED TO SUBMIT THEIR OWN COMMENTS AND RECOMMENDATIONS (ACCORDING TO RRC RULES) TO THE COMMISSION.

AGENCY: **Medical Care Commission**

RULE CITATION: 10A NCAC 13B .3801, .3903, .4103, .4104, .4106, .4305, .4603, .4801, .4805, .5102, .5105, .5406, .5408, .5411

RECOMMENDED ACTION:

- Approve, but note staff's comment
- X Object, based on:
 - X Lack of statutory authority (All Rules)
 - Unclear or ambiguous
 - Unnecessary
 - Failure to comply with the APA
- Extend the period of review

COMMENT:

These rules set standards for the licensing of hospitals, and are before RRC as part of the agency's scheduled readoption. The rules cover a broad array of aspects including hospital staffing, administration, and the provision of medical care. Among other things, these rules include detailed requirements that hospitals hire and maintain certain personnel, job responsibilities and required credentials for such personnel, requirements and policy statements relating to the preservation of medical records, standards for the provision of emergency services, standards for organization of neonatal care, requirements for the establishment and review of safety standards for imaging services, requirements for the establishment and review of written infection control policies and procedures, and staffing and discharge requirements for inpatient rehabilitation facilities.

Brian Liebman
Commission Counsel
Issued August 5, 2022

It is staff's opinion that the set of rules before you exceeds the grasp of the agency's statutory authority. The Medical Care Commission ("MCC" or the "Commission") draws its rulemaking authority from G.S. 131E-79(a), which states: "The Commission shall promulgate rules **necessary to implement this Article**[" referring to Article 5 of Chapter 131E, titled the "Hospital Licensure Act."

Review of the Hospital Licensure Act reveals that while certain provisions of Article 5 go on to discuss *inter alia*, aspects of license enforcement, requirements for granting or denying hospital privileges, discharge from facilities, and confidentiality of medical records, the statute generally directs *the hospital*, rather than MCC, to develop the policies, procedures, and requirements that are a condition of licensure. Hospitals must submit any plans and specifications for their facilities to MCC upon application for a license, and MCC may request information related to hospital operations during the application process, but MCC is not empowered to specifically set those requirements, policies, and procedures by rule.

Moreover, the rules before you delve into issues that are not specifically governed by the Hospital Licensure Act, and as such cannot be "necessary to implement" those statutes. *Inter alia*, there is no statutory requirement that a hospital maintain the position of nurse executive (Rule .3801) or medical director (Rule .4104), or maintain certain levels of inpatient rehabilitation staffing (Rule .5408). There are no statutory requirements related to preservation of medical records, other than that they are confidential and are not public records under Chapter 132 (Rule .3903). There are no statutory requirements related to establishment of emergency services procedures (Rule .4103). The word "neonatal" does not appear within Article 5 (Rule .4305), nor does any reference to radiological services (Rules .4801 and .4805). Part 4 of Article 5 deals with discharge from hospitals, yet only makes requirements related to a patient's refusal to leave, and fair billing practices. There are no discharge criteria required by Article 5 (Rule .5406).

To this, the agency makes two principal responses. MCC argues that its authority to adopt the rules before you stems from G.S. 131E-75, which is the title and purpose section of the Hospital Licensure Act. Therein, the legislature directed that Article 5's purpose was to "establish hospital licensing requirements which promote public health, safety and welfare and to provide for the development, establishment and enforcement of basic standards for the care and treatment of patients in hospitals." G.S. 131E-75(b) (2021). Thus, the agency contends that in determining whether to issue, deny, or take any other action with respect to a hospital's

license, it is “required to assess if a hospital is meeting the ‘requirements which promote public health, safety, and welfare....’” and is consequently *required* to establish “operational minimum standards”—a phrase that does not appear within Article 5 of Chapter 131E—for hospitals through rulemaking. The agency goes on to argue that there is no requirement for the General Assembly to specifically enumerate “every area of rule promulgation with any of the agencies creating rules for licensing,” bolstering its point by referring to several allegedly equivalent statutory provisions.

As an initial matter, with respect to the agency’s reference to other rules not currently before RRC, staff cannot and does not opine as to whether those agencies have authority under their respective statutes to adopt the cited rules. The scope of this opinion is limited to the Rules submitted for review by MCC. Here, the agency is authorized only to “promulgate rules necessary to implement” Article 5 of Chapter 131E. G.S. 131E-79(b) (2021). While the agency is correct that G.S. 131E-75 enunciates the *purpose* of the other provisions of Article 5, this language cannot be read as an open-ended grant of *authority* for MCC to promulgate any rule that could conceivably “promote public health, safety and welfare” or concern the “basic standards for the care and treatment of patients in hospitals” outside of the boundaries of the statutory scheme. As noted above, the rules impose deep, granular requirements upon hospitals with respect to issues that are at best tangentially referenced within the bounds of Article 5, and at worst mentioned nowhere within these statutes. Thus, it is staff’s opinion that G.S. 131E-75(b) is not an adequate statutory basis for the rules before you.

Finally, MCC appears to argue that it has additional rulemaking authority for these rules under G.S. 143B-165(6), which states:

- (6) The Commission [MCC] has the duty to adopt rules and regulations and standards with respect to the different types of hospitals to be licensed under the provisions of **Article 13A of Chapter 131** of the General Statutes of North Carolina (emphasis added).

The General Assembly repealed Chapter 131 and replaced it with Chapter 131E in 1983. Specifically, the pre-existing Hospital Licensing Act (Article 13A, Chapter 131) was replaced with the Hospital Licensure Act (Article 5, Chapter 131E), which contained the current text of G.S. 131E-79(a) providing MCC with rulemaking authority. While the current iteration of the statutory scheme replaces Article 13A of Chapter 131, there is no evidence that the legislature intended, by citing to the repealed statutes, to refer to Article 5, Chapter 131E. *See Lundsford v. Mills*, 367 N.C. 618, 623, 766 S.E.2d 297, 301 (2014) (in ascertaining legislative intent, one

should “give effect to the words actually used in a statute and not . . . delete words used or . . . insert words not used.”). Contrarily, the legislature refers explicitly to Chapter 131E elsewhere within G.S. 143B-165. *See, e.g.*, G.S. 131E-165(11) (2021) (“The Commission is authorized to adopt such rules as may be necessary to carry out the provisions of Part C of Article 6, and Article 10, of Chapter 131E of the General Statutes of North Carolina.”). If the legislature wished for G.S. 143B-165 to refer to Article 5 of Chapter 131E, it could have amended the statutory text. As it chose not to, but rather included a new, independent grant of rulemaking authority within Article 5, it is staff’s opinion that G.S. 143B-165(6) does not provide MCC with an additional source of rulemaking authority with respect to hospital licensure.

Consequently, staff recommends RRC object for lack of statutory authority.

Brian Liebman
Commission Counsel
Issued August 5, 2022

(c) The Department is authorized to develop statewide plans for the construction and maintenance of hospitals, medical centers and related facilities, or other plans necessary in order to meet the requirements and receive the benefits of applicable federal legislation.

(d) The Department is authorized to adopt rules to carry out the intent and purposes of this Article.

(e) The Department shall be responsible for doing all acts necessary to authorize the State to receive the full benefits of any federal statutes enacted for the construction and maintenance of hospitals, health centers or allied facilities.

(f) The Medical Care Commission shall make grants-in-aid to counties, cities, towns and subdivisions of government to acquire real estate and construct hospital facilities, including the reconstruction, remodeling or addition to any hospital facilities acquired by municipalities or subdivisions of government for use as community hospitals. These appropriations and funds made available by the State shall be allocated, apportioned and granted for the purposes of this Article and for other purposes in accordance with the rules adopted by the Medical Care Commission. The Medical Care Commission may furnish financial and other types of aid and assistance to any nonprofit hospital owned and operated by a corporation or association, no part of the net earnings of which inures, or may lawfully inure, to the benefit of any private shareholder or individual, upon the same terms and conditions as this aid and financial assistance is granted to municipalities and subdivisions of government.

(g) The Department may make available to any eligible hospital, clinic, or other medical facility operated by the State any unallocated federal sums or balances remaining after all grants-in-aid for local approvable projects made by the Department have been completed, disbursed or encumbered. (1945, c. 1096; 1947, c. 933, ss. 3, 5; 1949, c. 592; 1951, c. 1183, s. 1; 1971, c. 134; 1973, c. 476, s. 152; c. 1090, s. 1; 1979, c. 504, ss. 8, 14; 1983, c. 775, s. 1.)

§§ 131E-71 through 131E-74. Reserved for future codification purposes.

Article 5.

Hospital Licensure Act.

Part 1. Article Title and Definitions.

§ 131E-75. Title; purpose.

(a) This Article shall be known as the "Hospital Licensure Act."

(b) The purpose of this article is to establish hospital licensing requirements which promote public health, safety and welfare and to provide for the development, establishment and enforcement of basic standards for the care and treatment of patients in hospitals. (1947, c. 933, s. 6; 1983, c. 775, s. 1.)

§ 131E-76. Definitions.

As used in this article, unless otherwise specified:

(1) "Commission" means the North Carolina Medical Care Commission.

(1a) "Critical access hospital" means a hospital which has been designated as a critical access hospital by the North Carolina Department of Health and Human Services, Office of Research, Demonstrations and Rural Health Development. To be designated as a critical access hospital under this subdivision, the hospital must be certified as a critical access hospital pursuant to 42 CFR Part 485

1 10A NCAC 14E .0104 is amended under temporary procedures with changes as follows:

2

3 **10A NCAC 14E .0104 PLANS**

4 Prior to issuance of a ~~certificate~~ license pursuant to Rule .0107 of this Section, ~~a~~ an applicant for a new clinic shall
 5 submit two copies of the building plans to the ~~Division~~ Division. ~~[for] certification [licensure] purposes [purposes of~~
 6 ~~becoming licensed.]when~~ When the clinic requires a review by the Division and the Department of Insurance,
 7 according to the North Carolina ~~Administration and Enforcement Requirements Code, 2012 State Building Code,~~
 8 2018 edition, including subsequent amendments and editions. Copies of the ~~North Carolina Administration~~ Code are
 9 available from the International Code Council at
 10 ~~http://www.ecodes.biz/ecodes-support/Free-Resources/2012NorthCarolina/12NorthCarolina-main.html~~
 11 https://codes.iccsafe.org/content/NCAPC2018/chapter-1-administrative-code at no cost. When the local jurisdiction
 12 has authority from the North Carolina Building Code Council to review the plans, the clinic shall submit only one
 13 copy of the plans to the Division. In that case, the clinic shall submit an additional set of plans directly to the local
 14 jurisdiction.

15

16 History Note: Authority G.S. 14-45.1(a); ~~[143B-10;]~~ 131E-153; 131E-153.2; S.L. 2023-14, s. ~~[2.2;]~~ 2.4;
 17 *Eff. February 1, 1976;*
 18 *Readopted Eff. December 19, 1977;*
 19 *Amended Eff. October 1, 2015;*
 20 *Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. August 24,*
 21 *2019;*
 22 *Codifier determined that agency's findings of need did not meet criteria for emergency rule on June*
 23 *22, 2023;*
 24 *Emergency Rule Eff. June 30, 2023;*
 25 *Repealed Eff. July 1, 2023 pursuant to G.S. ~~150B-21.7.~~ 150B-21.7.*
 26 *Temporary Amendment Eff. October 27, 2023.*

1 10A NCAC 14E .0109 is amended under temporary procedures with changes as follows:

3 **10A NCAC 14E .0109 RENEWAL**

4 ~~(a)~~ Each certificate, license, ~~unless previously suspended or revoked, pursuant to the applicable rules and statutes~~
5 ~~shall be renewable annually renewed at the beginning of each calendar year. upon the filing of an application, payment~~
6 ~~of the non refundable renewal fee as defined in G.S. 131E-269, 131E-153.2, and approval by the Division.~~

7 (b) The renewal application form shall set forth:

8 ~~(1) Name of applicant;~~

9 ~~(2) Name of facility;~~

10 ~~(3) Ownership disclosure;~~

11 ~~(4) Building owner;~~

12 ~~(5) Building owner;~~

13 ~~(6) Building management;~~

14 ~~(7) Sanitation services;~~

15 ~~(8) Medical director;~~

16 ~~(9) Other medical staff;~~

17 ~~(10) Director of nursing;~~

18 ~~(11) Other nursing staff;~~

19 ~~(12) Consulting pathologist;~~

20 ~~(13) The number of procedures performed during the reporting period; and~~

21 ~~(14) The number of patients that were transferred to a hospital during a reporting period.~~

22 ~~((b))(c) Upon the filing of a renewal application, the clinic must pay a non-refundable renewal fee as defined in G.S.~~
23 ~~131E-153.2.~~

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

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

27
28 *History Note: Authority G.S. 14-45.1(a); 131E-269; 131E-153; 131E-153.2; 143B-10; S.L. 2023-14, s. 2.2; 2.4;*
29 *Eff. February 1, 1976;*
30 *Readopted Eff. December 19, 1977;*
31 *Amended Eff. October 1, 2015;*
32 *Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. August 24,*
33 *2019;*
34 *Codifier determined that agency's findings of need did not meet criteria for emergency rule on June*
35 *22, 2023;*
36 *Emergency Rule Eff. June 30, 2023;*
37 *Repealed Eff. July 1, 2023 pursuant to G.S. 150B-21.7. 150B-21.7;*

1
2
3

Temporary Amendment Eff. October 27, 2023.

1 10A NCAC 14E .0112 is amended under temporary procedures with changes as follows:

2

3 **10A NCAC 14E .0112 ALTERATIONS**

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

8

9 *History Note:* Authority *G.S. 14-45.1(a);* ~~[143B-10;]~~ 131E-153; *S.L. 2023-14, s. [2-2;]2.4;*

10 *Eff. February 1, 1976;*

11 *Readopted Eff. December 19, 1977;*

12 *Amended Eff. December 1, 1989;*

13 *Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. August 24,*
14 *2019;*

15 *Codifier determined that agency's findings of need did not meet criteria for emergency rule on June*
16 *22, 2023;*

17 *Emergency Rule Eff. June 30, 2023;*

18 *Repealed Eff. July 1, 2023 pursuant to G.S. ~~150B-21.7.~~ 150B-21.7.*

19 *Temporary Amendment Eff. October 27, 2023.*

1 10A NCAC 14E .0114 is adopted under temporary procedures with changes as follows:

2

3 **10A NCAC 14E .0114 APPROVAL**

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

8 (b) Approval of [~~construction documents and specifications~~] building plans shall expire one year after the date of
9 approval unless a building permit for the construction has been obtained prior to the expiration date of the approval
10 of ~~construction documents and specifications~~ building plans.

11

12 *History Note:* Authority G.S. [~~143B-10;~~] 131E-153; ~~S.L. 2013-366, s. 4(e); S.L. 2023-14, s. 2.2;~~ 2.4;

13 Emergency Adoption Eff. July 18, 2023. 2023;

14 Temporary Adoption Eff. October 27, 2023.

1 10A NCAC 14E .0201 is amended under temporary procedures with changes as follows:

2
3 **SECTION .0200 - MINIMUM STANDARDS FOR CONSTRUCTION AND EQUIPMENT**

4
5 **10A NCAC 14E .0201 BUILDING CODE REQUIREMENTS**

6 (a) The physical plant for a clinic shall meet or exceed minimum requirements of the North Carolina State Building
7 Code for Group B occupancy (business office facilities) which is incorporated herein by reference including
8 subsequent amendments and editions. Copies of the Code can be obtained from the International Code Council online
9 at <http://shop.iccsafe.org/north-carolina-doi.discounts?ref=NC> for a cost of five hundred twenty-seven dollars
10 (\$527.00) or accessed electronically free of charge at <http://www.ecodes.biz>.

11 <https://codes.iccsafe.org/content/NCAPC2018/chapter-1-administrative-code>.

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

14
15 *History Note: Authority G.S. 14-45.1(a); ~~143B-10;~~ 131E-153; S.L. 2013-366, s. 4(e); S.L. 2023-14, s. ~~2.2;~~ 2.4;*
16 *Eff. February 1, 1976;*
17 *Readopted Eff. December 19, 1977;*
18 *Amended Eff. October 1, 2015; July 1, 1994; December 1, 1989;*
19 *Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. August 24,*
20 *2019;*
21 *Codifier determined that agency's findings of need did not meet criteria for emergency rule on June*
22 *22, 2023;*
23 *Emergency Rule Eff. June 30, 2023;*
24 *Repealed Eff. July 1, 2023 pursuant to G.S. ~~150B-21.7.~~ 150B-21.7;*
25 *Temporary Amendment Eff. October 27, 2023.*

1 10A NCAC 14E .0202 is amended under temporary procedures with changes as follows:

2

3 **10A NCAC 14E .0202 SANITATION**

4 Clinics that are ~~certified~~ licensed by the Division to perform abortions shall comply with the Rules governing the
5 sanitation of hospitals, nursing homes, adult care homes, and other institutions, contained in 15A NCAC 18A .1300
6 which is hereby incorporated by reference including subsequent amendments and editions. Copies of 15A NCAC 18A
7 .1300 may be obtained at no charge from the Division of Public Health, Environmental Health Section, 1632 Mail
8 Service Center, Raleigh, NC 27699-1632, or accessed electronically free of charge from the Office of Administrative
9 Hearings at ~~<https://www.oah.nc.gov/>~~ <https://reports.oah.state.nc.us/ncac.asp>.

10

11 *History Note:* Authority *G.S. 14-45.1(a);* ~~*[143B-10];*~~ ~~*[131E-153];*~~ ~~*S.L. 2013-366, s. 4(e);*~~ ~~*S.L. 2023-14, s. [2.2];*~~ ~~*[2.4];*~~
12 *Eff. February 1, 1976;*
13 *Readopted Eff. December 19, 1977;*
14 *Amended Eff. August 1, 2019; October 1, 2015; July 1, 1994;*
15 *Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. August 24,*
16 *2019;*
17 *Codifier determined that agency's findings of need did not meet criteria for emergency rule on June*
18 *22, 2023;*
19 *Emergency Rule Eff. June 30, 2023;*
20 *Repealed Eff. July 1, 2023 pursuant to G.S. ~~150B-21.7;~~ 150B-21.7;*
21 *Temporary Amendment Eff. October 27, 2023.*

1 10A NCAC 14E .0207 is amended under temporary procedures with changes as follows:

2

3 **10A NCAC 14E .0207 AREA REQUIREMENTS**

4 The following areas shall comply with Rule .0206 .0212 of this Section, and are considered minimum requirements
5 for clinics that are ~~certified~~ licensed by the Division to perform abortions:

- 6 (1) receiving area;
- 7 (2) examining room;
- 8 (3) preoperative preparation and holding room;
- 9 (4) individual patient locker facilities or equivalent;
- 10 (5) procedure room;
- 11 (6) recovery room;
- 12 (7) clean workroom;
- 13 (8) soiled workroom;
- 14 (9) a clean area for medicine room may be defined as area in the clean workroom if a self-contained
15 secure ~~cabinet~~ medication storage complying with security requirements of state and federal laws
16 is provided;
- 17 (10) separate and distinct areas for storage and handling of clean and soiled linen;
- 18 (11) patient toilet;
- 19 (12) personnel lockers and toilet facilities;
- 20 (13) laboratory;
- 21 (14) nourishment station with storage and preparation area for serving meals or in-between meal snacks;
- 22 (15) janitor's closets;
- 23 (16) adequate space and equipment for assembling, sterilizing and storing medical and surgical supplies;
- 24 (17) storage space for medical records; and
- 25 (18) office space for nurses' charting, doctors' charting, communications, counseling, and business
26 functions.

27

28 *History Note: Authority G.S. ~~14-45.1(a)~~; 143B-10; 131E-153; S.L. 2013-366, s. 4(e); S.L. 2023-14, s. 2.2; 2.4*
29 *Eff. February 1, 1976;*
30 *Readopted Eff. December 19, 1977;*
31 *Amended Eff. October 1, 2015; December 24, 1979;*
32 *Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. August 24,*
33 *2019;*
34 *Codifier determined that agency's findings of need did not meet criteria for emergency rule on June*
35 *22, 2023;*
36 *Emergency Rule Eff. June 30, 2023;*
37 *Repealed Eff. July 1, 2023 pursuant to G.S. ~~150B-21.7~~. 150B-21.7;*

1

Temporary Amendment Eff. October 27, 2023.

1 10A NCAC 14E .0209 is adopted under temporary procedures with changes as follows:

2

3 **10A NCAC 14E .0209 ELEVATOR**

4 (a) In multi-story buildings, [the clinic shall provide] at least one elevator for patient ~~use shall be provided.~~ use.

5 (b) At least one dimension of the elevator cab shall be six and one-half feet to accommodate stretcher patients.

6 (c) The elevator door shall have an opening of no less than three feet in width, which is minimum for stretcher use.

7

8 *History Note:* Authority G.S. ~~[143B-10;]~~ [131E-153; S.L. 2013-366, s. 4(e); S.L. 2023-14, s. ~~[2.2;]~~ 2.4;

9 Emergency Adoption Eff. July 18, 2023. 2023;

10 Temporary Adoption Eff. October 27, 2023.

1 10A NCAC 14E .0210 is adopted under temporary procedures with changes as follows:

2

3 **10A NCAC 14E .0210 CORRIDORS**

4 The width of [patient use] corridors shall be [no] sufficient to allow for patient evacuation by stretcher, but in no case
5 shall patient use corridors be less than 60 inches.

6

7 *History Note: Authority [~~143B-10;~~ 131E-153; S.L. 2013-366, s. 4(e); S.L. 2023-14, s. ~~2.2;~~ 2.4;*

8 *Emergency Adoption Eff. July 18, ~~2023;~~ 2023;*

9 *Temporary Adoption Eff. October 27, 2023.*

1 10A NCAC 14E .0211 is adopted under temporary procedures with changes as follows:

2

3 **10A NCAC 14E .0211 DOORS**

4 Minimum width of doors to all rooms needing access for stretchers shall be three feet. No door shall swing into
5 corridors in a manner that might obstruct traffic flow or reduce the required corridor width except doors to spaces ~~such~~
6 as small closets not subject to occupancy.

7

8 *History Note:* Authority [~~143B-10;~~] 131E-153; ~~S.L. 2013-366, s. 4(e);~~ S.L. 2023-14, s. [2.2;]2.4;

9 Emergency Adoption Eff. July 18, 2023. 2023;

10 Temporary Adoption Eff. October 27, 2023.

1 10A NCAC 14E .0212 is adopted under temporary procedures with changes as follows:

2
3 **10A NCAC 14E .0212 ELEMENTS AND EQUIPMENT**

4 The physical plant shall provide equipment to carry out the functions of the clinic with the following minimum
5 requirements:

6 (1) Mechanical requirements.

7 (a) Temperatures and humidities:

8 (i) The mechanical systems shall be designed to provide the temperature and
9 humidities shown in this Sub-Item:

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

13 (b) All air supply and exhaust systems for the procedure suite and recovery area shall be
14 mechanically operated. All fans serving exhaust systems shall be located at the discharge
15 end of the system. The ventilation rates shown herein shall be considered as minimum
16 acceptable rates.

17 (i) The ventilation system shall be designed and balanced to provide the pressure
18 relationships detailed in Sub-Item (b)(vii) of this Rule.

19 (ii) All air supplied to procedure rooms shall be delivered at or near the ceiling of the
20 room and all exhaust or return from the area shall be removed near the floor level
21 at not less than three inches above the floor.

22 (iii) Corridors shall not be used to supply air to or exhaust air from any procedure or
23 recovery room except to maintain required pressure relationships.

24 (iv) All ventilation or air conditioning systems serving procedure rooms shall have a
25 minimum of one filter bed with a minimum filter efficiency of 80 percent.

26 (v) Ventilation systems serving the procedure or recovery rooms shall not be tied in
27 with the soiled holding or work rooms, janitors' ~~closets~~ closets, or locker rooms
28 if the air is to be recirculated in any manner.

29 (vi) Air handling duct systems shall not have duct linings.

30 (vii) The following general air pressure relationships to adjacent areas and ventilation
31 rates shall apply:

<u>Area</u>	<u>Pressure Relationship</u>	<u>Minimum Air</u> <u>Changes/Hour</u>
<u>Procedure</u>	<u>P</u>	<u>6</u>
<u>Recovery</u>	<u>P</u>	<u>6</u>
<u>Soiled work,</u>		
<u>Janitor's closet,</u>		

1 (c) Receptacles located within six feet of sinks or lavatories shall be ground-fault protected.

2 (d) At least one wired-in, ionization-type smoke detector shall be within 15 feet of each
3 procedure or recovery room entrance.

4 (4) Buildings systems and medical equipment shall have preventative maintenance conducted as
5 recommended by the equipment manufacturers' or installers' literature to assure operation in
6 compliance with manufacturer's instructions.

7
8 *History Note: Authority G.S. ~~[143B-10;]~~ 131E-153; S.L. 2013-366, s. 4(e); S.L. 2023-14, s. ~~[2.2;]~~ 2.4;*

9 *Emergency Adoption Eff. July 18, 2023. 2023;*

10 *Temporary Adoption Eff. October 27, 2023.*

1 10A NCAC 14E .0315 is amended under temporary procedures with changes as follows:

2
3 **10A NCAC 14E .0315 HOUSEKEEPING**

4 In addition to the standards set forth in Rule .0202 of this Subchapter, Clinics clinics that are certified licensed by the
5 Division to perform abortions shall meet the following standards: ~~for sanitation as required by the Division of Public~~
6 ~~Health, Environmental Health Section, in the rules and regulations governing the sanitation of hospitals, nursing~~
7 ~~homes, adult care homes, and other institutions, set forth in 15A NCAC 18A .1300, including subsequent amendments~~
8 ~~and editions, with special emphasis on the following:~~

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

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

20
21 *History Note: Authority G.S. 14-45.1(a); ~~[143B-10;]~~ 131E-153; S.L. 2013-366, s. 4(e); S.L. 2023-14, s. ~~[2.2;]~~ 2.4;*
22 *Eff. February 1, 1976;*
23 *Readopted Eff. December 19, 1977;*
24 *Amended Eff. August 1, 2019; October 1, 2015; December 1, 1989;*
25 *Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. August 24,*
26 *2019;*
27 *Codifier determined that agency's findings of need did not meet criteria for emergency rule on June*
28 *22, 2023;*
29 *Emergency Rule Eff. June 30, 2023;*
30 *Repealed Eff. July 1, 2023 pursuant to G.S. ~~150B-21.7.~~ 150B-21.7.*
31 *Temporary Amendment Eff. October 27, 2023.*

1 10A NCAC 14E .0318 is adopted under temporary procedures with changes as follows:

2
3 **10A NCAC 14E .0318 GOVERNING AUTHORITY**

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

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

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

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

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

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

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

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

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

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

32
33 *History Note: Authority G.S. ~~143B-10;~~ 131E-153; S.L. 2013-366, s. 4(e); S.L. 2023-14, s. ~~2.2;~~ 2.4;*
34 *Emergency Adoption Eff. July 18, 2023- 2023;*
35 *Temporary Adoption Eff. October 27, 2023.*

1 10A NCAC 14E .0319 is adopted under temporary procedures with changes as follows:

2
3 **10A NCAC 14E .0319 POLICIES AND PROCEDURES AND ADMINISTRATIVE RECORDS**

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

- 5 (1) documents evidencing control and ownerships, such as deeds, leases, or incorporation or partnership
6 papers;
7 (2) policies and procedures of the governing authority, as required by Rule .0318 of this Section;
8 (3) minutes of the governing authority meetings;
9 (4) minutes of the clinic's professional and administrative staff meetings;
10 (5) a current copy of the rules of this Subchapter;
11 (6) reports of inspections, reviews, and corrective actions taken related to licensure; and
12 (7) contracts and agreements related to [licensure] care and services [to which] provided by the clinic
13 is a party.

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

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

- 18 (1) patient selection and exclusion criteria; ~~and clinical discharge criteria;~~
19 (2) clinical discharge criteria;
20 ~~(2)~~ (3) policy and procedure for validating the full and true name of the patient;
21 ~~(3)~~(4) policy and procedure for [each type of] abortion [procedure] procedures performed at the clinic;
22 ~~(4)~~(5) policy and procedure for the provision of patient privacy in the recovery area of the clinic;
23 ~~(5)~~(6) protocol for determining gestational age as defined in Rule .0101(5) of this Subchapter;
24 ~~(6)~~(7) protocol for referral of patients for whom services have been declined; and
25 ~~(7)~~(8) protocol for discharge instructions that informs patients who to contact for post-procedural problems
26 and questions.

27
28 *History Note:* Authority G.S. ~~[143B-10; 131E-153]~~; S.L. 2013-366, s. 4(e); S.L. 2023-14, s. ~~[2.2];~~ 2.4;
29 *Emergency Adoption Eff. July 18, 2023. 2023;*
30 *Temporary Adoption Eff. October 27, 2023.*

1 10A NCAC 14E .0320 is adopted under temporary procedures with changes as follows:

2

3 **10A NCAC 14E .0320 ADMISSION AND DISCHARGE**

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

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

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

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

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

18

19 *History Note: Authority G.S. [~~143B-10;~~131E-153; S.L. 2013-366, s. 4(e); S.L. 2023-14, s. [~~2-2;~~2.4;*
20 *Emergency Adoption Eff. July 18, 2023; 2023;*
21 *Temporary Adoption Eff. October 27, 2023.*

1 10A NCAC 14E .0321 is adopted under temporary procedures with changes as follows:

2
3 **10A NCAC 14E .0321 MEDICAL RECORDS**

4 (a) The clinic shall maintain ~~[A]~~ a complete and permanent record ~~[shall be maintained]~~ for all patients including:

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

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

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

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

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

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

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

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

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

10
11 *History Note: Authority G.S. ~~[143B-10]; [131E-153]; S.L. 2013-366, s. 4(e); S.L. 2023-14, s. [2-2]; 2.4;~~*
12 *Emergency Adoption Eff. July 18, ~~2023~~ 2023;*
13 *Temporary Adoption Eff. October 27, 2023.*

1 10A NCAC 14E .0322 is adopted under temporary procedures with changes as follows:

2
3 **10A NCAC 14E .0322 PERSONNEL RECORDS**

4 (a) Personnel Records:

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

6 (A) the employee's identification;

7 (B) the application for employment that includes education, training, experience and
8 references;

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

10 (D) [verification of] a copy of a valid license (if required), education, training, and prior
11 employment experience; and

12 (E) [verification] a list of references.

13 (2) Personnel records shall be confidential.

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

17 (b) Job Descriptions:

18 (1) The clinic shall have a written description that describes the duties of every position.

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

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

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

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

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

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

32
33 *History Note:* Authority G.S. ~~[143B-10;]~~ ~~131E-153;~~ S.L. 2013-366, s. 4(e); S.L. 2023-14, s. ~~[2.2;]~~ 2.4;
34 *Emergency Adoption Eff. July 18, 2023- 2023;*
35 *Temporary Adoption Eff. October 27, 2023.*

1 10A NCAC 14E .0323 is adopted under temporary procedures with changes as follows:

2

3 **10A NCAC 14E .0323 NURSING SERVICE**

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

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

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

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

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

14 (d) There shall be at least one Registered Nurse with experience in post-operative or post-partum care who is currently
15 licensed to practice professional nursing in North Carolina on duty in the clinic at all times patients are in the clinic.

16

17 *History Note:* Authority G.S. [~~143B-10;~~ 131E-153; S.L. 2013-366, s. 4(e); S.L. 2023-14, s. ~~2.2;~~ 2.4;

18 *Emergency Adoption Eff. July 18, 2023. 2023;*

19 *Temporary Adoption Eff. October 27, 2023.*

1 10A NCAC 14E .0324 is adopted under temporary procedures with changes as follows:

2
3 **10A NCAC 14E .0324 QUALITY ASSURANCE**

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

7 (b) The committee shall determine corrective action, if ~~necessary,~~ necessary to achieve and maintain compliance
8 with clinic procedures and policies.

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

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

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

16 (1) reports made to the governing authority;

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

19 (3) information on any corrective action taken.

20 (f) The clinic shall conduct ~~[Orientation,]~~ orientation, training, or education programs ~~[shall be conducted]~~ to correct
21 deficiencies that are uncovered as a result of the quality assurance program.

22
23 *History Note: Authority G.S. ~~[143B-10,]~~ 131E-153; S.L. 2013-366, s. 4(e); S.L. 2023-14, s. ~~[2.2,]~~ 2.4;*

24 *Emergency Adoption Eff. July 18, 2023; 2023;*

25 *Temporary Adoption Eff. October 27, 2023.*

1 10A NCAC 14E .0325 is adopted under temporary procedures with changes as follows:

2
3 **10A NCAC 14E .0325 LABORATORY SERVICES**

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

6 (b) The governing authority shall establish written policies regarding which surgical specimens require ~~[requiring]~~
7 examination by a ~~[pathologist of all surgical specimens except for those types of specimens that the governing~~
8 ~~authority has determined do not require examination.]~~ pathologist.

9 (c) Each patient shall have the following performed and a record of the results placed in the patient's medical record
10 prior to the abortion:

11 (1) pregnancy testing, except when a positive diagnosis of pregnancy has been established by
12 ultrasound;

13 (2) anemia testing (hemoglobin or hematocrit); and

14 (3) Rh factor testing.

15 (d) Patients requiring the administration of blood shall be transferred to a local hospital having blood bank facilities.

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

18 (1) sources of reagents, standard and calibration procedures, and quality control procedures; and

19 (2) information concerning the basis for the listed "normal" ranges.

20 (f) The clinic shall perform and document, at least quarterly, calibration of equipment and validation of test results.

21
22 *History Note:* Authority G.S. ~~[143B-10;]~~ ~~131E-153;~~ S.L. 2013-366, s. 4(e); S.L. 2023-14, s. ~~[2.2;]~~ 2.4;
23 *Emergency Adoption Eff. July 18, 2023.* 2023;
24 *Temporary Adoption Eff. October 27, 2023.*

1 10A NCAC 14E .0326 is adopted under temporary procedures with changes as follows:

2
3 **10A NCAC 14E .0326 EMERGENCY BACK-UP SERVICES**

4 (a) Each clinic shall have a written plan for the transfer of emergency cases from the clinic to [a nearby] the closest
5 hospital when hospitalization becomes necessary. Emergency case is defined as a condition manifesting itself by acute
6 symptoms of sufficient severity (including severe pain) such that the absence of immediate medical attention could
7 reasonably be expected to result in placing the individual's health in serious jeopardy, serious impairment to bodily
8 functions, or serious dysfunction of bodily organs.

9 (b) The clinic shall have written protocols, [procedures], personnel, and [suitable] equipment to handle medical
10 emergencies as defined above which may arise in connection with services provided by the clinic.

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

15 (d) The clinic shall provide intervention for emergency situations. These provisions shall include:

16 (1) basic cardio-pulmonary life support;

17 (2) emergency protocols for:

18 (A) administration of intravenous fluids;

19 (B) establishing and maintaining airway support;

20 (C) oxygen administration;

21 (D) utilizing a bag-valve-mask resuscitator with oxygen reservoir;

22 (E) utilizing a suction machine; and

23 (F) utilizing an automated external defibrillator;

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

25 and

26 (4) ultrasound equipment.

27
28 *History Note: Authority G.S. [143B-10; 131E-153]; S.L. 2013-366, s. 4(e); S.L. 2023-14, s. [2.2; 2.4];*
29 *Emergency Adoption Eff. July 18, 2023. 2023;*
30 *Temporary Adoption Eff. October 27, 2023.*

1 10A NCAC 14E .0327 is adopted under temporary procedures with changes as follows:

2

3 **10A NCAC 14E .0327 SURGICAL SERVICES**

4 (a) The procedure room shall be maintained exclusively for surgical procedures and shall be so designed and
5 maintained to provide an environment [atmosphere] free of contamination [by pathogenic organisms.] The clinic shall
6 establish procedures for infection control and universal precautions.

7 (b) Tissue Examination:

8 (1) The physician performing the abortion is responsible for examination of all products of conception
9 (P.O.C.) prior to patient discharge. Such examination shall note specifically the presence or absence
10 of chorionic villi and fetal parts, or the amniotic sac. The results of the examination shall be recorded
11 in the patient's medical record.

12 (2) If adequate tissue is not obtained based on the gestational age, the physician performing the
13 procedure shall evaluate for ectopic [pregnaney] pregnancy, or an incomplete [procedure shall be
14 considered and evaluated by the physician performing the]-procedure.

15 (3) The clinic shall establish procedures for obtaining, identifying, storing, and transporting specimens.

16

17 *History Note:* Authority G.S. [~~143B-10;~~131E-153; S.L. 2013-366, s. 4(e); S.L. 2023-14, s. [2.2;]2.4;

18 Emergency Adoption Eff. July 18, 2023- 2023;

19 Temporary Adoption Eff. October 27, 2023.

1 10A NCAC 14E .0328 is adopted under temporary procedures with changes as follows:

2

3 **10A NCAC 14E .0328 MEDICATIONS AND ANESTHESIA**

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

5 (b) Any medications shall be administered by a physician or Registered Nurse [licensed in accordance with G.S. 90-
6 171.30 or G.S. 90-171.32 and must] and shall be recorded in the patient's permanent record.

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

11

12 *History Note:* Authority G.S. [~~143B-10;~~ 131E-153; S.L. 2013-366, s. 4(e); S.L. 2023-14, s. [~~2.2;~~ 2.4;

13 *Emergency Adoption Eff. July 18, 2023. 2023;*

14 *Temporary Adoption Eff. October 27, 2023.*

1 10A NCAC 14E .0329 is adopted under temporary procedures with changes as follows:

2

3 **10A NCAC 14E .0329 POST-OPERATIVE CARE**

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

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

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

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

12 (2) bleeding and pain shall be controlled, are assessed to be stable and not a concern for discharge.

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

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

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

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

21

22 *History Note:* Authority G.S. [143B-10;]131E-153; S.L. 2013-366, s. 4(e); S.L. 2023-14, s. [2.2;]2.4;

23 Emergency Adoption Eff. July 18, 2023; 2023;

24 Temporary Adoption Eff. October 27, 2023.

1 10A NCAC 14E .0330 is adopted under temporary procedures with changes as follows:

2

3 **10A NCAC 14E .0330 CLEANING OF MATERIALS AND EQUIPMENT**

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

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

8

9 *History Note:* Authority G.S. ~~[143B-10; 131E-153]~~; S.L. 2013-366, s. 4(e); S.L. 2023-14, s. ~~2.2;~~ 2.4;

10 *Emergency Adoption Eff. July 18, 2023. 2023;*

11 *Temporary Adoption Eff. October 27, 2023.*

1 10A NCAC 14E .0331 is adopted under temporary procedures as follows:

2

3 **10A NCAC 14E .0331 FOOD SERVICE**

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

5

6 *History Note: Authority G.S. 143B-10; S.L. 2023-14, s. 2.4;*

7 *Emergency Adoption Eff. July 18, ~~2023~~, 2023;*

8 *Temporary Adoption Eff. October 27, 2023.*