

REQUEST FOR CHANGES PURSUANT TO G.S. 150B-21.10

AGENCY: N.C. Medical Care Commission

RULE CITATION: 10A NCAC 13S .0101

**DEADLINE FOR RECEIPT: Thursday, September 19, 2024.**

***PLEASE NOTE: This request may extend to several pages. Please be sure you have reached the end of the document.***

The Rules Review Commission staff has completed its review of this Rule prior to the Commission's next meeting. The Commission has not yet reviewed this Rule and therefore there has not been a determination as to whether the Rule will be approved. You may email the reviewing attorney to inquire concerning the staff recommendation.

In reviewing this Rule, the staff recommends the following changes be made:

*In (6), what underlying conditions would affect the person's ability to work in the clinic?*

Please retype the rule accordingly and resubmit it to our office at 1711 New Hope Church Road, Raleigh, North Carolina 27609.

10A NCAC 13S .0101 is proposed for adoption as follows:

**SUBCHAPTER 13S - LICENSURE OF SUITABLE FACILITIES FOR THE PERFORMANCE OF  
SURGICAL ABORTIONS**

**SECTION .0100 – LICENSURE PROCEDURE**

**10A NCAC 13S .0101 DEFINITIONS**

The following definitions will apply throughout this Subchapter:

- (1) "Abortion" means the termination of a pregnancy as defined in G.S 90-21.81(1c).
- (2) "Clinic" means a freestanding facility neither physically attached nor operated by a licensed hospital for the performance of abortions completed during the first 12 weeks of pregnancy.
- (3) "Division" means the Division of Health Service Regulation of the North Carolina Department of Health and Human Services.
- (4) "Gestational age" means the length of pregnancy as indicated by the date of the first day of the last normal monthly menstrual period, if known, or as determined by ultrasound.
- (5) "Governing authority" means the individual, agency, group, or corporation appointed, elected or otherwise designated, in which the ultimate responsibility and authority for the conduct of the abortion clinic is vested pursuant to Rule .0318 of this Subchapter.
- (6) "Health Screening" means an evaluation of an employee or contractual employee, including tuberculosis testing, to identify any underlying conditions that may affect the person's ability to work in the clinic.
- (7) "New clinic" means one that is not certified as an abortion clinic by the Division as of July 1, 2023, and has not been certified or licensed within the previous six months of the application for licensure.
- (8) "Registered Nurse" means a person who holds a valid license issued by the North Carolina Board of Nursing to practice professional nursing in accordance with the Nursing Practice Act, G.S. 90, Article 9A.

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

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

*Emergency Rule Eff. November 14, 2023;*

*Temporary Adoption Eff. February 8, ~~2024~~-2024;*

*Adopted Eff. January 1, 2025.*

REQUEST FOR CHANGES PURSUANT TO G.S. 150B-21.10

AGENCY: N.C. Medical Care Commission

RULE CITATION: 10A NCAC 13S .0104

**DEADLINE FOR RECEIPT: Thursday, September 19, 2024.**

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In reviewing this Rule, the staff recommends the following changes be made:

*In (a), line 13 and (b), lines 15-16, what standards will the Division use to review and approve the construction documents and specifications?*

Please retype the rule accordingly and resubmit it to our office at 1711 New Hope Church Road, Raleigh, North Carolina 27609.

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

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

~~Prior to issuance of a license pursuant to Rule .0107 of this Section, an applicant for a new clinic shall submit two copies of the building plans to the Division. When the clinic requires a review by the Division and the Department of Insurance, according to the North Carolina State Building Code, 2018 edition, including subsequent amendments and editions. Copies of the Code are available from the International Code Council at <https://codes.icsafe.org/content/NCAPC2018/chapter-1-administrative-code-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.~~

(a) Prior to issuance of a license pursuant to Rule .0107 of this Section, an applicant for a new clinic shall submit one copy of construction documents and specifications to the Division for review and approval.

(b) Any license holder or prospective applicant desiring to make alterations or additions to a clinic or to construct a new clinic, before commencing such alteration, addition or new construction shall submit construction documents and specifications to the Division for review and approval with respect to compliance with this Subchapter.

(c) Approval of construction documents and specifications shall expire one year after the date of approval unless a building permit for the construction has been obtained prior to the expiration date of the approval of construction documents and specifications.

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

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

*Emergency Rule Eff. November 14, 2023;*

*Temporary Adoption Eff. February 8, 2024-2024;*

*Adopted Eff. January 1, 2025.*

REQUEST FOR CHANGES PURSUANT TO G.S. 150B-21.10

AGENCY: N.C. Medical Care Commission

RULE CITATION: 10A NCAC 13S .0201

**DEADLINE FOR RECEIPT: Thursday, September 19, 2024.**

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In reviewing this Rule, the staff recommends the following changes be made:

*What are you requiring with (b)? I have a few concerns here.*

*For one, I understand that new construction has to comply with the Building Code, but what about existing buildings? The Existing Building Code already defines “addition”, “alteration”, “change in occupancy”, “existing building”, “rehabilitation”, and “repair”, and provides for when existing buildings have to comply with the current Code or with the version of the Code in effect at the time of construction. Does this provision impose a more stringent condition than the Existing Building Code—i.e. are you saying all existing buildings have to come up to 2024 Code levels upon alteration, repair, rehabilitation, or addition, regardless of what the Existing Building Code says?*

*Secondly, are you saying that Section .0200 does not apply to currently licensed clinics unless and until there are alterations, repairs, rehabilitation work, or additions? In that case, what do those terms mean? Moreover, if Section .0200 does not apply to existing clinics, then what criteria does the Commission use to determine if they should be licensed?*

Please retype the rule accordingly and resubmit it to our office at 1711 New Hope Church Road, Raleigh, North Carolina 27609.

Brian Liebman  
Commission Counsel  
Date submitted to agency: September 5, 2024

10A NCAC 13S .0201 is proposed for adoption as follows:

## **SECTION .0200 - MINIMUM STANDARDS FOR CONSTRUCTION AND EQUIPMENT**

### **10A NCAC 13S .0201 BUILDING CODE REQUIREMENTS**

- (a) The physical plant for a clinic shall meet or exceed minimum requirements of the North Carolina State Building Code for Group B occupancy (business office facilities) which is incorporated herein by reference including subsequent amendments and editions. Copies of the Code can be obtained from the International Code Council online at ~~<http://shop.iccsafe.org/north-carolina-doi-discounts?ref=NC>~~ <https://shop.iccsafe.org/catalogsearch/result/?cat=1010&q=+North+Carolina+Building+code> for a cost of ~~five hundred twenty seven dollars (\$527.00)~~ eight hundred fifty eight dollars (\$858.00) or accessed electronically free of charge at ~~<https://codes.iccsafe.org/content/NCAPC2018/chapter-1-administrative-code>~~ <https://www.ncosfm.gov/codes/codes-current-and-past>.
- (b) The requirements contained in this Section shall apply to new clinics and to any alterations, repairs, rehabilitation work, or additions which are made to a previously licensed facility.

*History Note: Authority G.S. 131E-153.5; 143B-165;*  
*Codifier determined that findings of need did not meet criteria for emergency rule on October 30, 2023;*  
*Emergency Rule Eff. November 14, 2023;*  
*Temporary Adoption Eff. February 8, ~~2024~~ 2024;*  
*Adopted Eff. January 1, 2025.*

REQUEST FOR CHANGES PURSUANT TO G.S. 150B-21.10

AGENCY: N.C. Medical Care Commission

RULE CITATION: 10A NCAC 13S .0207

**DEADLINE FOR RECEIPT: Thursday, September 19, 2024.**

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In reviewing this Rule, the staff recommends the following changes be made:

*Throughout the Rule, I noticed that the term “area” has been substituted for “room” in the temporary rule. What is an “area” in this context?*

*In (2), line 7, what are “pre-procedure and post-procedure activities”? Please define.*

*In (4), line 12, capitalize “state” when referring to the State of North Carolina.*

*In (5), line 13, what are the Clinical Laboratory Improvement Amendments requirements? It looks to me like these are federal regulations promulgated by the CDC. Please confirm, and if so, incorporate by reference pursuant to G.S. 150B-21.6.*

Please retype the rule accordingly and resubmit it to our office at 1711 New Hope Church Road, Raleigh, North Carolina 27609.

10A NCAC 13S .0207 is proposed for adoption as follows:

### 10A NCAC 13S .0207 AREA REQUIREMENTS

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

- (1) ~~receiving area;~~ reception and waiting room;
- (2) ~~examining room;~~ designated area or areas for pre-procedure and post-procedure activities;
- (3) ~~preoperative preparation and holding room;~~
- (4) ~~individual patient locker facilities or equivalent;~~
- (5)(3) procedure room;
- (6)(4) ~~recovery room;~~ a clean area for self-contained secure medication storage complying with security requirements of state and federal laws;
- (7)(5) ~~clean workroom;~~ area compliant with Clinical Laboratory Improvement Amendments (CLIA) requirements in which laboratory testing can be performed;
- (8)(6) ~~soiled workroom;~~ separate areas for storage and handling of clean and soiled materials;
- (9) ~~a clean area for self-contained secure medication storage complying with security requirements of state and federal laws is provided;~~
- (10) ~~separate and distinct areas for storage and handling of clean and soiled linen;~~
- (11)(7) patient toilet;
- (12)(8) ~~personnel lockers and~~ toilet facilities;
- (13) ~~laboratory;~~
- (14) ~~nourishment station with storage and preparation area for serving meals or in-between meal snacks;~~
- (15)(9) janitor's closets;
- (16)(10) ~~adequate~~ space and equipment for assembling, sterilizing and storing medical and surgical supplies;
- (17)(11) storage space for medical records; and records of all media types used by the facility; and
- (18)(12) ~~office space for nurses' charting, doctors' charting, communications, counseling, and counseling,~~ business functions, functions, and other administrative activities.

*History Note: Authority G.S. 131E-153.5; 143B-165;*  
*Codifier determined that findings of need did not meet criteria for emergency rule on October 30, 2023;*  
*Emergency Rule Eff. November 14, 2023;*  
*Temporary Adoption Eff. February 8, 2024-2024;*  
*Adopted Eff. January 1, 2025.*



REQUEST FOR CHANGES PURSUANT TO G.S. 150B-21.10

AGENCY: N.C. Medical Care Commission

RULE CITATION: 10A NCAC 13S .0212

**DEADLINE FOR RECEIPT: Thursday, September 19, 2024.**

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In reviewing this Rule, the staff recommends the following changes be made:

*Do the requirements of this Rule conflict with those required by the Building Code?*

*In (1)(f), p. 2, line 23, you have a notation for “P = positive pressure” and yet that doesn’t seem to be in your chart. Is that intentional?*

*In (2)(a)(i), line 33, is there a more direct URL for the portion of NFPA-99 you’re incorporating by reference? I could not find a free online version on the NFPA website.*

*Also, with respect to NFPA-99, which version are you requiring compliance with? The temporary rule specified the 2012 version, the permanent rule does not so specify.*

*Finally, what chapter or section of NFPA-99 are you requiring compliance with? NFPA 99 has 15 chapters and 4 annexes.*

*In (3)(b), p.3, line 19, is “at a minimum” necessary? Is there something besides battery backup that is relevant here?*

Please retype the rule accordingly and resubmit it to our office at 1711 New Hope Church Road, Raleigh, North Carolina 27609.

10A NCAC 13S .0212 is proposed for adoption as follows:

### 10A NCAC 13S .0212 ELEMENTS AND EQUIPMENT

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

~~(1) Mechanical requirements:~~

~~(a) Temperatures and humidities:~~

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

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

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

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

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

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

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

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

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

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

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

Toilets,		
Soiled holding	N	10
Clean work or		
Clean holding	P	4
(P = positive pressure N = negative pressure)		

(1) Mechanical requirements.

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

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

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

(2) Plumbing And Other Piping Systems.

(a) Medical Gas and Vacuum Systems

- (i) ~~—Piped-in medical gas and vacuum systems, if installed, shall meet the requirements of NFPA 99 2012, category 1 system, NFPA-99, category 2 system, which is hereby incorporated by reference including subsequent amendments and editions. Copies of NFPA 99 2012 NFPA-99 may be purchased from the National Fire Protection Association, 1 Batterymarch Park, P.O. Box 9101, Quincy, MA 02269 9101, Association online at <https://www.nfpa.org/product/nfpa-99-code/p0099>code at a cost of one hundred forty-nine dollars (\$149.00) or accessed electronically free of charge at <http://www.nfpa.org>.~~
- (ii) ~~—The facility must meet the inhalation anesthesia requirements of NFPA 70 2020 and NFPA 99 2021, which are hereby incorporated by reference including subsequent amendments and editions. Copies of NFPA 70 2011 and NFPA 99 2012 may be purchased from the National Fire Protection Association, 1~~

~~Batterymarch Park, P.O. Box 9101, Quincy, MA 02269 9101, or accessed electronically free of charge at <http://www.nfpa.org>.~~

- (b) Lavatories and sinks for use by medical personnel shall have the water supply spout mounted so that its discharge point is a minimum distance of ~~five~~ ten (10) inches above the ~~rim of the fixture~~ bottom of the basin with mixing type fixture valves that can be operated without the use of the hands.
- (c) Hot water distribution systems shall provide hot water at hand washing ~~and bathing~~ facilities at a minimum temperature of 100 degrees F. and a maximum temperature of 116 degrees F.
- ~~(d) Floor drains shall not be installed in procedure rooms.~~
- ~~(e) Building drainage and waste systems shall be designed to avoid installations in the ceiling directly above procedure rooms.~~

(3) Electrical Requirements.

- (a) ~~Procedure and recovery rooms, and~~ The facility's paths of egress ~~from these rooms~~ to the outside shall have at a minimum, listed battery backup lighting units of one and one-half hour capability that will automatically provide at least ~~five~~ 1 foot ~~candles~~ candle of illumination at the floor in the event needed for a utility or local lighting circuit failure.
- (b) Electrically operated medical equipment necessary for the safety of the patient shall have, at a minimum, battery backup.
- ~~(c) Receptacles located within six feet of sinks or lavatories shall be ground fault protected.~~
- ~~(d) At least one wired in, ionization type smoke detector shall be within 15 feet of each procedure or recovery room entrance.~~

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

*History Note: Authority G.S. 131E-153.5; 143B-165;*  
*Codifier determined that findings of need did not meet criteria for emergency rule on October 30, 2023;*  
*Emergency Rule Eff. November 14, 2023;*  
*Temporary Adoption Eff. February 8, ~~2024-2024~~;*  
*Adopted Eff. January 1, 2025.*

REQUEST FOR CHANGES PURSUANT TO G.S. 150B-21.10

AGENCY: N.C. Medical Care Commission

RULE CITATION: 10A NCAC 13S .0318

**DEADLINE FOR RECEIPT: Thursday, September 19, 2024.**

**PLEASE NOTE: This request may extend to several pages. Please be sure you have reached the end of the document.**

The Rules Review Commission staff has completed its review of this Rule prior to the Commission's next meeting. The Commission has not yet reviewed this Rule and therefore there has not been a determination as to whether the Rule will be approved. You may email the reviewing attorney to inquire concerning the staff recommendation.

In reviewing this Rule, the staff recommends the following changes be made:

*In (a), line 7, add a comma following “authority”.*

*In (d)(3), line 20, define “safe and adequate”.*

*In (d)(3), line 21, when is revision “necessary”?*

*In (d)(3), line 22, “compliance” with what?*

*In (h), line 31, to whom and in what form is the certification required?*

*In (h), line 31, under what criteria will it be judged that the physical facilities are “adequate” to safeguard the health and safety of patients?*

*In (h), line 32, what do you mean that one “area” may “accommodate various aspects of the patient’s visits”? Moreover, this is permissive language and does not appear to meet the definition of a rule in G.S. 150B-2(8a).*

Please retype the rule accordingly and resubmit it to our office at 1711 New Hope Church Road, Raleigh, North Carolina 27609.

1 10A NCAC 13S .0318 is proposed for adoption as follows:

2  
3 **10A NCAC 13S .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 safe and adequate care for the patients  
21 which shall be reviewed, and revised when necessary, at least annually, and shall include provisions  
22 for administration and use of the clinic, compliance, personnel quality assurance, procurement of  
23 outside services and consultations, patient care policies, and services offered.

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

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

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

31 (h) The governing authority shall certify that the physical facilities to be used are adequate to safeguard the health  
32 and safety of patients; of note one area may accommodate various aspects of the patient's visits.

33  
34 *History Note: Authority G.S. 131E-153; 131E-153.5; 143B-165.*

35 *Codifier determined that findings of need did not meet criteria for emergency rule on October 30,*  
36 *2023;*

37 *Emergency Rule Eff. November 14, 2023;*

- 1                    *Temporary Adoption Eff. February 8, ~~2024~~ 2024:*
- 2                    *Adopted Eff. January 1, 2025.*
- 3

REQUEST FOR CHANGES PURSUANT TO G.S. 150B-21.10

AGENCY: N.C. Medical Care Commission

RULE CITATION: 10A NCAC 13S .0319

**DEADLINE FOR RECEIPT: Thursday, September 19, 2024.**

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In reviewing this Rule, the staff recommends the following changes be made:

*In (a), line 4, what is meant by “essential”? What documents are “non-essential”?*

*In (a)(7), line 12, did you mean “the clinic as a party”?*

*In (c)(8), line 24, why is this in the passive tense? Are third parties refusing service on behalf of the patient? Otherwise, should this read “protocol for referral of patients who have declined service”?*

*In (c)(9), lines 25-26, are you requiring abortion clinics to use one “area” for multiple purposes? If so, you need to say that. Otherwise, this is permissive language that doesn’t meet the definition of a rule in G.S. 150B-2(8a).*

Please retype the rule accordingly and resubmit it to our office at 1711 New Hope Church Road, Raleigh, North Carolina 27609.

Brian Liebman  
Commission Counsel

Date submitted to agency: September 5, 2024



10A NCAC 13S .0319 is proposed for adoption as follows:

**10A NCAC 13S .0319      POLICIES AND PROCEDURES AND ADMINISTRATIVE RECORDS**

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

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

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

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

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

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

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

*Emergency Rule Eff. November 14, 2023;*

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*Adopted Eff. January 1, 2025.*

REQUEST FOR CHANGES PURSUANT TO G.S. 150B-21.10

AGENCY: N.C. Medical Care Commission

RULE CITATION: 10A NCAC 13S .0320

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In reviewing this Rule, the staff recommends the following changes be made:

*In (a), line 5, what is an “administrative decision regarding patients”?*

*In (d)(2), lines 13-14, a statement to what effect shall be included? That the physician lacks hospital admitting privileges? Please revise for specificity.*

*In (d)(4), line 16, are clinics required to have grievance procedures elsewhere in these rules? If so, please cross-reference. If not, what if a clinic has no grievance procedures?*

Please retype the rule accordingly and resubmit it to our office at 1711 New Hope Church Road, Raleigh, North Carolina 27609.

Brian Liebman  
Commission Counsel

Date submitted to agency: September 5, 2024

1 10A NCAC 13S .0320 is proposed for adoption as follows:

2  
3 **10A NCAC 13S .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 make administrative decisions 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 hospital  
9 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 or physicians and hospital admitting privileges, if any. In the  
14 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. 131E-153; 131E-153.5; 143B-165.*

20 *Codifier determined that findings of need did not meet criteria for emergency rule on October 30,*  
21 *2023;*

22 *Emergency Rule Eff. November 14, 2023;*

23 *Temporary Adoption Eff. February 8, ~~2024~~ 2024;*

24 *Adopted Eff. January 1, 2025.*  
25

REQUEST FOR CHANGES PURSUANT TO G.S. 150B-21.10

AGENCY: N.C. Medical Care Commission

RULE CITATION: 10A NCAC 13S .0321

**DEADLINE FOR RECEIPT: Thursday, September 19, 2024.**

**PLEASE NOTE: This request may extend to several pages. Please be sure you have reached the end of the document.**

The Rules Review Commission staff has completed its review of this Rule prior to the Commission's next meeting. The Commission has not yet reviewed this Rule and therefore there has not been a determination as to whether the Rule will be approved. You may email the reviewing attorney to inquire concerning the staff recommendation.

In reviewing this Rule, the staff recommends the following changes be made:

*In (a)(7), line 11, is “duration of pregnancy” different than “gestational age” as defined in Rule .0101(4)?*

*In (a)(10), line 15, what consent and declaration are you referring to? Is it the one in G.S. 90-21.82? If so, consider a cross-reference to the statute.*

*In (c), lines 24-25, who is the sentence “the patient in writing may reject Rh immunoglobulin” regulating? You don’t have authority to regulate patients, only facilities.*

*In (d), line 27, what qualifications are you requiring for the ultrasound technician?*

*In (e)(2), line 33, is “length of gestation” different than “gestational age”?*

Please retype the rule accordingly and resubmit it to our office at 1711 New Hope Church Road, Raleigh, North Carolina 27609.

Brian Liebman  
Commission Counsel

Date submitted to agency: September 5, 2024

1 10A NCAC 13S .0321 is proposed for adoption as follows:

3 **10A NCAC 13S .0321 MEDICAL RECORDS**

4 (a) The clinic shall maintain a complete and permanent record 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) a copy of the signed 72 hour consent and physician declaration;
- 16 (11) the patient's history and physical examination including identification of pre-existing or current
- 17 illnesses, drug sensitivities or other idiosyncrasies that may impact the procedure or anesthetic to be
- 18 administered; and
- 19 (12) documentation that indicates all items listed in Rule .0320(d) of this Section were provided to the
- 20 patient.

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

24 (c) If Rh is negative, the clinic shall explain the significance to the patient and shall record the explanation. The  
25 patient in writing may reject Rh immunoglobulin. A written record of the patient's decision shall be a permanent part  
26 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, the clinic shall arrange for preservation of records for at least 10 years. The clinic  
9 shall send written notification to the Division of these arrangements.

10  
11 *History Note: Authority G.S. 131E-153; 131E-153.5; 143B-165.*

12 *Codifier determined that findings of need did not meet criteria for emergency rule on October 30,*  
13 *2023;*

14 *Emergency Rule Eff. November 14, 2023;*

15 *Temporary Adoption Eff. February 8, ~~2024~~-2024;*

16 *Adopted Eff. January 1, 2025.*  
17

REQUEST FOR CHANGES PURSUANT TO G.S. 150B-21.10

AGENCY: N.C. Medical Care Commission

RULE CITATION: 10A NCAC 13S .0322

**DEADLINE FOR RECEIPT: Thursday, September 19, 2024.**

**PLEASE NOTE: This request may extend to several pages. Please be sure you have reached the end of the document.**

The Rules Review Commission staff has completed its review of this Rule prior to the Commission's next meeting. The Commission has not yet reviewed this Rule and therefore there has not been a determination as to whether the Rule will be approved. You may email the reviewing attorney to inquire concerning the staff recommendation.

In reviewing this Rule, the staff recommends the following changes be made:

*In (a)(1)(B), line 7, consider moving “or resume” after “for employment” so that it reads “application for employment or resume”.*

Please retype the rule accordingly and resubmit it to our office at 1711 New Hope Church Road, Raleigh, North Carolina 27609.

10A NCAC 13S .0322 is proposed for adoption as follows:

### 10A NCAC 13S .0322 PERSONNEL RECORDS

#### (a) Personnel Records:

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

(A) the employee's identification;

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

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

~~(D)(C)~~ a copy of a valid license (if required). ~~(if required), education, training, and prior employment experience; and~~

~~(E) a list of references.~~

(2) Personnel records shall be confidential.

(3) Representatives of the Division conducting an inspection of the clinic shall have the right to inspect personnel records.

#### (b) Job Descriptions:

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

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

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

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

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

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

(f) Employee and contractual employee records for health screening as defined in Rule ~~.0101(7)~~ .0101(6) of this Subchapter, education, training, and verification of professional certification shall be available for review by the Division.

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

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

*Emergency Rule Eff. November 14, 2023;*

*Temporary Adoption Eff. February 8, ~~2024~~ 2024;*



1                    *Adopted Eff. January 1, 2025.*

2

REQUEST FOR CHANGES PURSUANT TO G.S. 150B-21.10

AGENCY: N.C. Medical Care Commission

RULE CITATION: 10A NCAC 13S .0323

**DEADLINE FOR RECEIPT: Thursday, September 19, 2024.**

***PLEASE NOTE: This request may extend to several pages. Please be sure you have reached the end of the document.***

The Rules Review Commission staff has completed its review of this Rule prior to the Commission's next meeting. The Commission has not yet reviewed this Rule and therefore there has not been a determination as to whether the Rule will be approved. You may email the reviewing attorney to inquire concerning the staff recommendation.

In reviewing this Rule, the staff recommends the following changes be made:

*In (a), line 4, what is the significance, for the sake of clarity, of the change from “nursing staff” to “clinical staff”?*

*In (d), line 14, with respect to the definition of “health care practitioner”, and the cross-reference to G.S. 90-640, I’m not sure the statutory reference provides clarity. In 90-640, which is entitled “Identification badges required”, the definition of “health care practitioner” is “an individual who is licensed, certified, or registered to engage in the practice of medicine, nursing, dentistry, pharmacy, or any related occupation involving the direct provision of health care to patients.” Here, wouldn’t anyone working in the clinic be “engaging in... [a] related occupation involving the direct provision of health care to patients”? In other words, how does the definition in 90-640 limit who is required to be on duty (more on that below)?*

*In (d), line 16, what does “on duty” mean in this context? I generally don’t comment on deletions, but I’m particularly interested in the meaning given that the temporary rule qualified “on duty” by requiring the person to be “in the clinic”. Thus, if you’re not requiring the person to be in the clinic, what does “on duty” mean?*

Please retype the rule accordingly and resubmit it to our office at 1711 New Hope Church Road, Raleigh, North Carolina 27609.

Brian Liebman  
Commission Counsel

Date submitted to agency: September 5, 2024

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

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

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

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

(1) provision of nursing services to patients; and

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

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

(d) There shall be at least one Registered Nurse ~~with experience in post-operative or post-partum care~~ who is currently licensed to practice professional nursing in North Carolina, or other health care practitioner as defined in G.S. 90-640 (a) practicing within the scope of their license or certification who is basic life support (BLS) certified and authorized by state laws to administer medications as required for analgesia, nausea, vomiting, or other indications on duty in the clinic at all times patients are in the clinic; procedure rooms and recovery area.

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

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

*Emergency Rule Eff. November 14, 2023;*

*Temporary Adoption Eff. February 8, 2024, 2024;*

*Adopted Eff. January 1, 2025.*

REQUEST FOR CHANGES PURSUANT TO G.S. 150B-21.10

AGENCY: N.C. Medical Care Commission

RULE CITATION: 10A NCAC 13S .0324

**DEADLINE FOR RECEIPT: Thursday, September 19, 2024.**

**PLEASE NOTE: This request may extend to several pages. Please be sure you have reached the end of the document.**

The Rules Review Commission staff has completed its review of this Rule prior to the Commission's next meeting. The Commission has not yet reviewed this Rule and therefore there has not been a determination as to whether the Rule will be approved. You may email the reviewing attorney to inquire concerning the staff recommendation.

In reviewing this Rule, the staff recommends the following changes be made:

*In (c), line 10, please define "health professionals".*

Please retype the rule accordingly and resubmit it to our office at 1711 New Hope Church Road, Raleigh, North Carolina 27609.

Brian Liebman  
Commission Counsel

Date submitted to agency: September 5, 2024

1 10A NCAC 13S .0324 is proposed for adoption as follows:

2  
3 **10A NCAC 13S .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 to achieve and maintain compliance with clinic  
8 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 frequency of meetings and details of data collection shall be defined by the governing authority. The functions~~  
12 ~~of the committee shall include development of policies for selection of patients, approval for adoption of policies,~~  
13 ~~review of credentials for staff privileges, peer review, tissue inspection, establishment of infection control procedures,~~  
14 ~~and approval of additional procedures to be performed in the clinic.~~

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

17 ~~(1) reports made to the governing authority;~~

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

20 ~~(3) information on any corrective action taken.~~

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

23  
24 *History Note: Authority G.S. 131E-153; 131E-153.5; 143B-165.*

25 *Codifier determined that findings of need did not meet criteria for emergency rule on October 30,*  
26 *2023;*

27 *Emergency Rule Eff. November 14, 2023;*

28 *Temporary Adoption Eff. February 8, 2024; 2024;*

29 *Adopted Eff. January 1, 2025.*

REQUEST FOR CHANGES PURSUANT TO G.S. 150B-21.10

AGENCY: N.C. Medical Care Commission

RULE CITATION: 10A NCAC 13S .0326

**DEADLINE FOR RECEIPT: Thursday, September 19, 2024.**

***PLEASE NOTE: This request may extend to several pages. Please be sure you have reached the end of the document.***

The Rules Review Commission staff has completed its review of this Rule prior to the Commission's next meeting. The Commission has not yet reviewed this Rule and therefore there has not been a determination as to whether the Rule will be approved. You may email the reviewing attorney to inquire concerning the staff recommendation.

In reviewing this Rule, the staff recommends the following changes be made:

*In (a), line 5, consider moving the definition of “emergency case” to your definitions rule. In any case, please format the definition according to our style guide. It should look like: “Emergency case” means a condition...”*

*In (a), line 6, delete the parentheses around “including severe pain”, and incorporate into the body of the rule with commas.*

*In (c), line 11, is an “emergency” the same as an “emergency case”? If not, define “emergency”.*

*In (c), line 12, what does it mean to be “familiar” with the written instructions?*

*In (c)(1), line 13, what is an “untoward” complication? Please define.*

*In (d)(2), are the “emergency protocols” different than the “emergency instructions” in (c)?*

Please retype the rule accordingly and resubmit it to our office at 1711 New Hope Church Road, Raleigh, North Carolina 27609.

Brian Liebman  
Commission Counsel

Date submitted to agency: September 5, 2024

1 10A NCAC 13S .0326 is proposed for adoption as follows:

3 **10A NCAC 13S .0326 EMERGENCY BACK-UP SERVICES**

4 (a) Each clinic shall have a written plan for the transfer of emergency cases from the clinic to the closest hospital  
5 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, personnel, and equipment to handle medical emergencies as defined above  
10 which may arise in connection with services provided by the clinic.

11 (c) All clinics shall have written emergency instructions for clinic staff to carry out in the event of an emergency. All  
12 clinic personnel shall be familiar and capable of carrying out written emergency instructions:

13 (1) Instructions shall be followed in the event of an emergency, any untoward anesthetic, medical or  
14 procedural complications, or other conditions making transfer to an emergency department and/or  
15 hospitalization of a patient necessary.

16 (2) The instructions shall include arrangements for immediate contact of emergency medical services when  
17 indicated and when advanced cardiac life support is needed.

18 (3) When emergency medical services are not indicated, the instructions shall include procedures for timely  
19 escort of the patient to the hospital or to an appropriate licensed health care professional.

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

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

25 (1) basic cardio-pulmonary life support;

26 (2) emergency protocols for:

27 (A) administration of intravenous fluids;

28 (B) establishing and maintaining airway support;

29 (C) oxygen administration;

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

31 ~~(E) —utilizing a suction machine; and~~

32 ~~(F)(E) utilizing an automated external defibrillator; defibrillator.~~

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

35 (4) ultrasound equipment.

36  
37 *History Note: Authority G.S. 131E-153; 131E-153.5; 143B-165.*

1           *Codifier determined that findings of need did not meet criteria for emergency rule on October 30,*  
2           *2023;*

3           *Emergency Rule Eff. November 14, 2023;*

4           *Temporary Adoption Eff. February 8, ~~2024~~ 2024;*

5           *Adopted Eff. January 1, 2025.*

6



REQUEST FOR CHANGES PURSUANT TO G.S. 150B-21.10

AGENCY: N.C. Medical Care Commission

RULE CITATION: 10A NCAC 13S .0328

**DEADLINE FOR RECEIPT: Thursday, September 19, 2024.**

**PLEASE NOTE:** *This request may extend to several pages. Please be sure you have reached the end of the document.*

The Rules Review Commission staff has completed its review of this Rule prior to the Commission's next meeting. The Commission has not yet reviewed this Rule and therefore there has not been a determination as to whether the Rule will be approved. You may email the reviewing attorney to inquire concerning the staff recommendation.

In reviewing this Rule, the staff recommends the following changes be made:

*In (b), line 6, with respect to the definition of “health care practitioner”, and the cross-reference to G.S. 90-640, I’m not sure the statutory reference provides clarity. In 90-640, which is entitled “Identification badges required”, the definition of “health care practitioner” is “an individual who is licensed, certified, or registered to engage in the practice of medicine, nursing, dentistry, pharmacy, or any related occupation involving the direct provision of health care to patients.” Here, wouldn’t anyone working in the clinic be “engaging in... [a] related occupation involving the direct provision of health care to patients”? In other words, how does the definition in 90-640 limit who may administer medications?*

Please retype the rule accordingly and resubmit it to our office at 1711 New Hope Church Road, Raleigh, North Carolina 27609.

1 10A NCAC 13S .0328 is proposed for adoption as follows:

2  
3 **10A NCAC 13S .0328 MEDICATIONS AND ~~ANESTHESIA~~ SEDATION**

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 and~~ Medications, including injections  
6 shall be administered by a physician, Registered Nurse, and other health care practitioners as defined in G.S. 90-640

7 (a) practicing within the scope of their license or certification authorized by state laws to administer medications. All  
8 medications shall be recorded in the patient's permanent record.

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

13  
14 *History Note: Authority G.S. 131E-153; 131E-153.5; 143B-165.*

15 *Codifier determined that findings of need did not meet criteria for emergency rule on October 30,*  
16 *2023;*

17 *Emergency Rule Eff. November 14, 2023;*

18 *Temporary Adoption Eff. February 8, ~~2024~~, 2024;*

19 *Adopted Eff. January 1, 2025.*