Burgos, Alexander N

Subject: FW: 10A NCAC 13S rules

From: Liebman, Brian R <brian.liebman@oah.nc.gov>
Sent: Monday, September 23, 2024 3:09 PM
To: Black, Shanah <shanah.black@dhhs.nc.gov>; Rules, Oah <oah.rules@oah.nc.gov>; Burgos, Alexander N <alexander.burgos@oah.nc.gov>; Conley, Azzie <azzie.conley@dhhs.nc.gov>
Subject: RE: 10A NCAC 13S rules

Alex and Dana,

These are the final rules, for which I'm recommending approval. Go ahead and file and post on the agenda.

Thanks!

Brian Liebman
Counsel to the North Carolina Rules Review Commission
Office of Administrative Hearings
(984)236-1948
brian.liebman@oah.nc.gov

Burgos, Alexander N

To: Black, Shanah; Liebman, Brian R
Cc: Conley, Azzie
Subject: RE: Medical Care Commission 10A NCAC 13S

From: Black, Shanah <shanah.black@dhhs.nc.gov>
Sent: Monday, September 23, 2024 1:21 PM
To: Liebman, Brian R <brian.liebman@oah.nc.gov>; Burgos, Alexander N <alexander.burgos@oah.nc.gov>
Cc: Conley, Azzie <azzie.conley@dhhs.nc.gov>
Subject: RE: Medical Care Commission 10A NCAC 13S

Done, thank you for all of your help on this!!

From: Liebman, Brian R <brian.liebman@oah.nc.gov>
Sent: Monday, September 23, 2024 1:19 PM
To: Black, Shanah <shanah.black@dhhs.nc.gov>; Burgos, Alexander N <alexander.burgos@oah.nc.gov>
Cc: Conley, Azzie <azzie.conley@dhhs.nc.gov>
Subject: RE: Medical Care Commission 10A NCAC 13S

Great, looks good, except it should say "classified for occupancy" in (a), line 6. 😊

Otherwise, I will be able to recommend approval of all rules.

Please make the above revision, and send the final, amended versions of all rules to oah.rules@oah.nc.gov, copying me and Alex Burgos.

Thanks,
Brian

Brian Liebman
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From: Black, Shanah <shanah.black@dhhs.nc.gov>
Sent: Monday, September 23, 2024 11:39 AM
To: Liebman, Brian R <brian.liebman@oah.nc.gov>; Burgos, Alexander N <alexander.burgos@oah.nc.gov>
Cc: Conley, Azzie <azzie.conley@dhhs.nc.gov>
Subject: RE: Medical Care Commission 10A NCAC 13S

Hey Brian,

Attached is the updated version of the .0201 rule. Thank you so much for your assistance.

Response (a): Issue addressed; removed reference to Chapter as the chapter numbers change periodically.

Response (b): Issue addressed; we reworked subsection (b) to include your proposed language about the applicability of the NC Building Code and the NC Existing Building Code. We are removing the reference to alterations, repairs, rehabilitations, and additions because those issues are already addressed in the NC Building Code and the NC Existing Building Code, and we would like to avoid any confusion about the minimum standard in the rule. Clinics should go directly to the Building Codes to determine the specifics of what would be required when building a new clinic and when conducting alterations, repairs, rehabilitation, and additions.

Response (d): Issue addressed, removed subsection (d) as we have removed all of the defined terms in the revised rule.

Thank you

10A NCAC 13S .0101 is adopted with changes as published in 38:24 NCR 1617–1623 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) "Emergency Case" is defined as a condition manifesting itself by acute symptoms of sufficient severity, including severe pain, such that the absence of immediate medical attention could reasonably be expected to result in placing the individual's health in serious jeopardy, serious impairment to bodily functions, or serious dysfunction of bodily organs.

~~(4)~~(5) "Gestational age" means the length of pregnancy as indicated by the date of the first day of the last normal monthly menstrual period, if known, or as determined by ultrasound.

~~(5)~~(6) "Governing authority" means the individual, agency, group, or corporation appointed, elected or otherwise designated, in which the ultimate responsibility and authority for the conduct of the abortion clinic is vested pursuant to Rule .0318 of this Subchapter.

(7) "Health Care Practitioner" means a physician, nurse practitioner, or physician's assistant licensed and authorized to practice in the state of North Carolina.

~~(6)~~(8) "Health Screening" means an evaluation of an employee or contractual employee, including at a minimum tuberculosis testing or screening, to identify ~~any~~ underlying health conditions that may affect the person's ability to work in the clinic.

~~(7)~~(9) "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.

(10) "Pre-procedure activities" are activities performed prior to the procedure to ensure that the patient is stable, and that the procedure can be safely performed.

(11) "Post-procedure" activities are activities performed after the procedure to ensure that the patient is stable for discharge.

~~(8)~~(12) "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.

(13) "Safe and adequate care" means care that meets the clinical needs of the patient while ~~reasonably~~ preventing harm from occurring.to the patient. ~~occurring.~~

History Note: *Authority G.S. ~~131E-153;~~ 131E-153.5; 143B-165.*
Eff. October 1, 2024.

10A NCAC 13S .0104 is adopted with changes as published in 38:24 NCR 1617-1623 as follows:

10A NCAC 13S .0104 PLANS AND SPECIFICATIONS

(a) Prior to issuance of a license pursuant to ~~Rule .0107 of this Section~~ 10A NCAC 14E .0107, an applicant for a new clinic shall submit one copy of construction documents and specifications to the Division for review and ~~approval.~~ approval consistent with Section .0200 of this Subchapter.

(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;*
Eff. October 1, 2024.

10A NCAC 13S .0201 is adopted with changes as published in 38:24 NCR 1617-1623 as follows:

SECTION .0200 - MINIMUM STANDARDS FOR CONSTRUCTION AND EQUIPMENT

10A NCAC 13S .0201 BUILDING CODE REQUIREMENTS

(a) ~~The physical plant for a clinic licensure and~~ All clinics shall be classified for occupancy as Group B pursuant to the North Carolina Building Code.

(b) ~~The requirements of this section shall apply to clinics~~ ~~requirements contained in this Section shall applying for initial licensure apply to new clinics and to any alterations, repairs, rehabilitation work, or additions which are made to a currently previously licensed facility. clinic. Upon initial licensure, clinics New facilities~~ All new and existing clinics shall meet ~~or exceed minimum~~ the requirements of the North Carolina State Building Codes, as determined by the applicability provisions of the North Carolina Building Code or the North Carolina Existing Building Code.

(c) The North Carolina Building Codes are hereby ~~for Group B occupancy (business office facilities) which is~~ incorporated ~~herein~~ by reference including subsequent amendments and editions. Copies of the North Carolina State Building Codes ~~Code~~ can be obtained from the International Code Council online at https://shop.iccsafe.org/catalogsearch/result/?cat=1010&q=+North+Carolina+Building+code for a cost of eight hundred fifty eight dollars ($858.00) or accessed electronically free of charge at https://www.ncosfm.gov/codes/codes-current-and-past.

~~(c)(d) The definitions of alterations, repairs, rehabilitation work, and additions terms "alteration," "repair," "rehabilitation," and "addition" as used in this Rule shall have the definitions given in Chapter 2 of the North Carolina Existing Building Code.~~

History Note: *Authority G.S. 131E-153.5; 143B-165;*
Eff. October 1, 2024.

10A NCAC 13S .0207 is adopted with changes as published in 38:24 NCR 1617-1623 as follows:

10A NCAC 13S .0207 AREA REQUIREMENTS

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

(1) reception and waiting room;

(2) designated area or areas for pre-procedure and post-procedure activities;

(3) procedure room;

(4) a clean area for self-contained secure medication storage complying with security requirements of ~~state~~ State and federal laws;

(5) area compliant with Clinical Laboratory Improvement Amendments (CLIA) requirements, 42 CFR Part 493, including subsequent amendments and additions, which are hereby incorporated by reference, available at https://www.ecfr.gov/current/title-42/chapter-IV/subchapter-G/part-493 at no cost, ~~requirements~~ in which laboratory testing can be performed;

(6) separate areas for storage and handling of clean and soiled materials;

(7) patient toilet;

(8) personnel toilet facilities;

(9) janitor's closets;

(10) space and equipment for assembling, sterilizing and storing medical and surgical supplies;

(11) storage space for medical records of all media types used by the facility; and

(12) space for charting, communications, counseling, business functions, and other administrative activities.

History Note: *Authority G.S. 131E-153.5; 143B-165;*
Eff. October 1, 2024.

10A NCAC 13S .0212 is adopted with changes as published in 38:24 NCR 1617-1623 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 requirements:

(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:

Area	Pressure Relationship	Minimum Total Air Changes/Hour
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) Piped-in medical gas and vacuum systems, if installed, shall meet the requirements of NFPA-99, category 2 system, which is hereby incorporated by reference including subsequent amendments and editions. Copies of NFPA-99 may be purchased from the National Fire Protection Association online at https://www.nfpa.org/product/nfpa-99-code/p0099code at a cost of one hundred forty-nine dollars ~~($149.00) or accessed electronically free of charge at http://www.nfpa.org.~~ ($149.00).

(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 ten (10) inches above the 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 facilities at a minimum temperature of 100 degrees F. and a maximum temperature of 116 degrees F.

(3) Electrical Requirements.

(a) The facility's paths of egress 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 1 foot 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.

(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;*
Eff. October 1, 2024.

10A NCAC 13S .0318 is adopted with changes as published in 38:24 NCR 1617-1623 as follows:

10A NCAC 13S .0318 GOVERNING AUTHORITY

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

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

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

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

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

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

(3) maintain a policies and procedures manual designed to ensure safe and adequate care for the patients which shall be reviewed, and revised when necessary, at least annually, and shall include provisions for administration and use of the clinic, ~~compliance~~, compliance with statutes and rules applicable to clinics including Subchapters 13S and 14E of Title 10A, compliance with a nationally standard recognized standard of care for infection control, personnel quality assurance, procurement of outside services and consultations, patient care policies, grievance policies, and services offered.

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

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

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

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

History Note: *Authority G.S. ~~131E-153;~~ 131E-153.5; 143B-165.*
Eff. October 1, 2024.

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10A NCAC 13S .0319 is adopted with changes as published in 38:24 NCR 1617-1623 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 ~~a~~ as 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 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) emergency protocols as required by Rule .0326;

(4) policy and procedure for validating the full and true name of the patient;

(5) policy and procedure for abortion procedures performed at the clinic;

(6) policy and procedure for the provision of patient privacy in the recovery area of the clinic;

(7) protocol for determining gestational age as defined in ~~Rule .0101(4)~~ Rule .0101(5) of this Subchapter; and

(8) protocol for referral of patients ~~for whom services have been declined~~ declined services by the clinic. ~~and~~

~~(9) protocol that defines use of space to include opportunities that one area may accommodate various aspects of patient visits.~~

History Note: *Authority G.S. ~~131E-153;~~ 131E-153.5; 143B-165.*
Eff. October 1, 2024.

10A NCAC 13S .0320 is adopted with changes as published in 38:24 NCR 1617-1623 as follows:

10A NCAC 13S .0320 ADMISSION AND DISCHARGE

(a) There shall be on the premises throughout all hours of operation an employee authorized to receive patients and make administrative decisions regarding patients. Administrative decisions include all of the decisions related to a patient's care and services, such as admissions, billing, and services provided.

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

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

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

(1) a fee schedule and any extra charges routinely applied;

(2) the name of the attending physician or physicians and hospital admitting privileges~~, if any~~. In the absence of admitting privileges a statement documenting that the attending physician or physicians does not have admitting privileges ~~to that effect~~ shall be included;

(3) instructions for post-procedure problems and questions as outlined in Rule .0329(d) of this Section;

(4) grievance procedures a patient may follow if dissatisfied with the care and services rendered pursuant to the grievance policy as outlined in .0318(d)(3) of this Section; and

(5) the telephone number for Complaint Intake of the Division.

History Note: *Authority G.S. ~~131E-153;~~ 131E-153.5; 143B-165.*
Eff. October 1, 2024.

10A NCAC 13S .0321 is adopted with changes as published in 38:24 NCR 1617-1623 as follows:

10A NCAC 13S .0321 MEDICAL RECORDS

(a) The clinic shall maintain a complete and permanent record for all patients including:

(1) the date and time of admission and discharge;

(2) the patient's full and true name;

(3) the patient's address;

(4) the patient's date of birth;

(5) the patient's emergency contact information;

(6) the patient's diagnoses;

(7) the ~~patient's duration of pregnancy~~ fetus's gestational age;

(8) the patient's condition on admission and discharge;

(9) a voluntarily-signed consent for each procedure and signature of the physician performing the procedure witnessed by a family member, other patient representative, or facility staff member;

(10) a copy of the signed 72 hour consent and physician declaration as defined in G.S. 90-21.82;

(11) the patient's history and physical examination including identification of pre-existing or current illnesses, drug sensitivities or other idiosyncrasies that may impact the procedure or anesthetic to be administered; and

(12) documentation that indicates all items listed in Rule .0320(d) of this Section were provided to the patient.

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

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

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

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

(1) the patient name;

(2) the estimated ~~length of gestation~~ gestational age;

(3) the type of procedure;

(4) the name of the physician:

(5) the name of the Registered Nurse on duty; and

(6) the date and time of procedure.

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

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

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

History Note: *Authority G.S. ~~131E-153;~~ 131E-153.5; 143B-165.*
Eff. October 1, 2024.

10A NCAC 13S .0322 is adopted with changes as published in 38:24 NCR 1617-1623 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 or resume that includes education, training, experience and references; and

(C) a copy of a valid license (if required).

(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(6)~~ Rule .0101(8) 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.*
Eff. October 1, 2024.

10A NCAC 13S .0323 is adopted with changes as published in 38:24 NCR 1617-1623 as follows:

10A NCAC 13S .0323 CLINIC STAFFING

(a) The clinic shall have an organized 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-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 procedure rooms and recovery area.

History Note: *Authority G.S. ~~131E-153;~~ 131E-153.5; 143B-165.*
Eff. October 1, 2024.

10A NCAC 13S .0324 is adopted with changes as published in 38:24 NCR 1617-1623 as follows:

10A NCAC 13S .0324 QUALITY ASSURANCE

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

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

(c) The committee shall consist of one physician who is not an owner, the chief executive officer or designee, and other health ~~professionals~~ practitioners.

(d) The frequency of meetings and details of data collection shall be defined by the governing authority.

History Note: *Authority G.S. ~~131E-153;~~ 131E-153.5; 143B-165.*
Eff. October 1, 2024.

10A NCAC 13S .0325 is adopted with changes as published in 38:24 NCR 1617-1623 as follows:

10A NCAC 13S .0325 LABORATORY SERVICES

(a) Each clinic shall have the capability to provide or obtain laboratory tests required in connection with the procedure to be performed, and will perform laboratory tests appropriate to their Clinical Laboratory Improvement Amendments (CLIA) certification.

(b) The governing authority shall establish written policies regarding which surgical specimens require examination by a pathologist.

(c) Each patient shall have laboratory testing as determined to be clinically necessary by the physician, or as required by law. A record of the results of any tests performed will be included in the patient's medical record.

(d) The clinic shall maintain a manual in a location accessible by employees, that meets requirements for the level of clinic's CLIA certification. This includes the procedures, instructions, and manufacturer's instructions for each test procedure performed including:

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

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

History Note: *Authority G.S. ~~131E-153;~~ 131E-153.5; 143B-165.*
Eff. October 1, 2024.

10A NCAC 13S .0326 is adopted with changes as published in 38:24 NCR 1617-1623 as follows:

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

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

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

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

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

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

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

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

(1) basic cardio-pulmonary life support;

(2) emergency ~~protocols~~ instructions for:

(A) administration of intravenous fluids;

(B) establishing and maintaining airway support;

(C) oxygen administration;

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

(E) utilizing an automated external defibrillator.

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

(4) ultrasound equipment.

History Note: *Authority G.S. ~~131E-153~~; 131E-153.5; 143B-165.*
Eff. October 1, 2024.

10A NCAC 13S .0327 is adopted with changes as published in 38:24 NCR 1617-1623 as follows:

10A NCAC 13S .0327 OUTPATIENT PROCEDURAL SERVICES

(a) The clinic shall establish procedures for infection control and universal precautions, including cleaning of all patient care areas including procedure rooms.

(b) Tissue Examination:

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

(2) If adequate tissue is not obtained based on the gestational age, the physician performing the procedure shall evaluate for ectopic pregnancy, or an incomplete procedure.

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

History Note: *Authority G.S. ~~131E-153~~; 131E-153.5; 143B-165.*
Eff. October 1, 2024.

10A NCAC 13S .0328 is adopted with changes as published in 38:24 NCR 1617-1623 as follows:

10A NCAC 13S .0328 MEDICATIONS AND SEDATION

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

(b) Medications, including injections shall be administered by a physician, Registered Nurse, and other health care practitioners ~~as defined in G.S. 90-640 (a)~~ practicing within the scope of their license or certification authorized by state laws to administer medications. All medications shall be recorded in the patient's permanent record.

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

History Note: *Authority G.S. ~~131E-153~~; 131E-153.5; 143B-165.*
Eff. October 1, 2024.

10A NCAC 13S .0329 is adopted with changes as published in 38:24 NCR 1617-1623 as follows:

10A NCAC 13S .0329 POST PROCEDURAL CARE

(a) A patient whose pregnancy is terminated shall be observed in the clinic to ensure that no post procedural complications are present. Thereafter, patients may be discharged according to a physician's order and the clinic's protocols.

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

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

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

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

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

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

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

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

History Note: *Authority G.S. ~~131E-153~~; 131E-153.5; 143B-165.*
Eff. October 1, 2024.

10A NCAC 13S .0330 is adopted with changes as published in 38:24 NCR 1617-1623 as follows:

10A NCAC 13S .0330 CLEANING OF MATERIALS AND EQUIPMENT

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

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

History Note: *Authority G.S. ~~131E-153~~; 131E-153.5; 143B-165.*
Eff. October 1, 2024.

10A NCAC 13S .0331 is adopted with changes as published in 38:24 NCR 1617-1623 as follows:

10A NCAC 13S .0331 FOOD SERVICE

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

History Note: *Authority G.S. ~~131E-153;~~131E-153.2; 131E-153.5; 143B-165.*
Eff. October 1, 2024.

Burgos, Alexander N

From: Black, Shanah
Sent: Monday, September 23, 2024 1:26 PM
To: Rules, Oah; Liebman, Brian R; Burgos, Alexander N; Conley, Azzie
Subject: 10A NCAC 13S rules
Attachments: 10A NCAC 13S .0101.docx; 10A NCAC 13S .0104.docx; 10A NCAC 13S .0201.docx; 10A NCAC 13S .0207.docx; 10A NCAC 13S .0212.docx; 10A NCAC 13S .0318.docx; 10A NCAC 13S .0319.docx; 10A NCAC 13S .0320.docx; 10A NCAC 13S .0321.docx; 10A NCAC 13S .0322.docx; 10A NCAC 13S .0323.docx; 10A NCAC 13S .0324.docx; 10A NCAC 13S .0325.docx; 10A NCAC 13S .0326.docx; 10A NCAC 13S .0327.docx; 10A NCAC 13S .0328.docx; 10A NCAC 13S .0329.docx; 10A NCAC 13S .0330.docx; 10A NCAC 13S .0331.docx

Good afternoon,

Please see attached final set of rules for RRC to vote on Wednesday.

Thanks!

Shanah Black
Rule-making Coordinator
Division of Health Service Regulation
NC Department of Health and Human Services

Office: 919-855-3481
Fax: 919-733-2757
shanah.black@dhhs.nc.gov

809 Ruggles Drive, Edgerton Building
2701 Mail Service Center
Raleigh, NC 27699-2701

Burgos, Alexander N

Subject: FW: Medical Care Commission 10A NCAC 13S
Attachments: 10A NCAC 13S .0201.docx

From: Black, Shanah <shanah.black@dhhs.nc.gov>
Sent: Monday, September 23, 2024 11:39 AM
To: Liebman, Brian R <brian.liebman@oah.nc.gov>; Burgos, Alexander N <alexander.burgos@oah.nc.gov>
Cc: Conley, Azzie <azzie.conley@dhhs.nc.gov>
Subject: RE: Medical Care Commission 10A NCAC 13S

Hey Brian,

Attached is the updated version of the .0201 rule. Thank you so much for your assistance.

Response (a): Issue addressed; removed reference to Chapter as the chapter numbers change periodically.

Response (b): Issue addressed; we reworked subsection (b) to include your proposed language about the applicability of the NC Building Code and the NC Existing Building Code. We are removing the reference to alterations, repairs, rehabilitations, and additions because those issues are already addressed in the NC Building Code and the NC Existing Building Code, and we would like to avoid any confusion about the minimum standard in the rule. Clinics should go directly to the Building Codes to determine the specifics of what would be required when building a new clinic and when conducting alterations, repairs, rehabilitation, and additions.

Response (d): Issue addressed, removed subsection (d) as we have removed all of the defined terms in the revised rule.

Thank you

10A NCAC 13S .0201 is adopted with changes as published in 38:24 NCR 1617-1623 as follows:

SECTION .0200 - MINIMUM STANDARDS FOR CONSTRUCTION AND EQUIPMENT

10A NCAC 13S .0201 BUILDING CODE REQUIREMENTS

(a) ~~The physical plant for a clinic licensure and~~ All clinics shall be classified occupancy as Group B pursuant to the North Carolina Building Code.

(b) ~~The requirements of this section shall apply to clinics~~ ~~requirements contained in this Section shall applying for initial licensure apply to new clinics and to any alterations, repairs, rehabilitation work, or additions which are made to a currently previously licensed facility. clinic. Upon initial licensure, clinics New facilities~~ All new and existing clinics shall meet ~~or exceed minimum~~ the requirements of the North Carolina State Building Codes, as determined by the applicability provisions of the North Carolina Building Code or the North Carolina Existing Building Code.

(c) The North Carolina Building Codes are hereby ~~for Group B occupancy (business office facilities) which is~~ incorporated ~~herein~~ by reference including subsequent amendments and editions. Copies of the North Carolina State Building Codes ~~Code~~ can be obtained from the International Code Council online at https://shop.iccsafe.org/catalogsearch/result/?cat=1010&q=+North+Carolina+Building+code for a cost of eight hundred fifty eight dollars ($858.00) or accessed electronically free of charge at https://www.ncosfm.gov/codes/codes-current-and-past.

~~(c)(d) The definitions of alterations, repairs, rehabilitation work, and additions terms "alteration," "repair," "rehabilitation," and "addition" as used in this Rule shall have the definitions given in Chapter 2 of the North Carolina Existing Building Code.~~

History Note: *Authority G.S. 131E-153.5; 143B-165;*
Eff. October 1, 2024.

Burgos, Alexander N

Subject: FW: Medical Care Commission 10A NCAC 13S

From: Black, Shanah <shanah.black@dhhs.nc.gov>
Sent: Friday, September 20, 2024 4:21 PM
To: Liebman, Brian R <brian.liebman@oah.nc.gov>; Burgos, Alexander N <alexander.burgos@oah.nc.gov>
Cc: Conley, Azzie <azzie.conley@dhhs.nc.gov>
Subject: Re: Medical Care Commission 10A NCAC 13S

Thanks Brian, I will let the attorneys crafting this rule know. Thanks for the quick response

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From: Liebman, Brian R <brian.liebman@oah.nc.gov>
Sent: Friday, September 20, 2024 4:17:03 PM
To: Black, Shanah <shanah.black@dhhs.nc.gov>; Burgos, Alexander N <alexander.burgos@oah.nc.gov>
Cc: Conley, Azzie <azzie.conley@dhhs.nc.gov>
Subject: RE: Medical Care Commission 10A NCAC 13S

Hi Shanah,

I think we've ironed out everything in all rules except for .0201. I'm not sure that we've addressed the issue I was getting at. Please see the revision below, which I think addresses my concerns and accurately states the agency's intent, as well as reflects how the Building Codes work. Please disregard if the draft below does not express the agency's intent. I consulted Section 101.4 of the Existing Building Code as to when it applies over the Building Code. I also checked Chapter 2 of the Existing Building Code to ensure that the terms used (alteration, repair, rehabilitation, and addition) are defined there.

a. All clinics shall be classified for occupancy as Group B pursuant to Chapter 3 of the North Carolina Building Code.
b. All new and existing clinics shall meet the requirements of the North Carolina State Building Codes, as determined by the applicability provisions of the North Carolina Building Code or the North Carolina Existing Building Code. Alteration, repair, rehabilitation, and addition to existing clinics shall meet the requirements of the North Carolina Existing Building Code.
c. The North Carolina State Building Codes are hereby incorporated by reference, including subsequent amendments and editions. Copies of the North Carolina State Building Codes are available from the International Code Council website at https://shop.iccsafe.org/catalogsearch/result/?cat=1010&q=+North+Carolina+Building+code for a cost of eight hundred fifty eight dollars ($858.00) or accessed electronically free of charge at https://www.ncosfm.gov/codes/codes-current-and-past.
d. The terms "alteration," "repair", "rehabilitation", and "addition" as used in this Rule shall have the definitions given in Chapter 2 of the North Carolina Existing Building Code.

Thanks,
Brian

Brian Liebman

Counsel to the North Carolina Rules Review Commission
Office of Administrative Hearings
(984)236-1948
brian.liebman@oah.nc.gov

Burgos, Alexander N

Subject: FW: Medical Care Commission 10A NCAC 13S

From: Black, Shanah <shanah.black@dhhs.nc.gov>
Sent: Friday, September 20, 2024 12:38 PM
To: Liebman, Brian R <brian.liebman@oah.nc.gov>; Burgos, Alexander N <alexander.burgos@oah.nc.gov>
Cc: Conley, Azzie <azzie.conley@dhhs.nc.gov>
Subject: Re: Medical Care Commission 10A NCAC 13S

Thanks Brian, look forward to hearing from you

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Burgos, Alexander N

Subject: FW: Medical Care Commission 10A NCAC 13S

From: Liebman, Brian R <brian.liebman@oah.nc.gov>
Sent: Friday, September 20, 2024 12:30 PM
To: Black, Shanah <shanah.black@dhhs.nc.gov>; Burgos, Alexander N <alexander.burgos@oah.nc.gov>
Cc: Conley, Azzie <azzie.conley@dhhs.nc.gov>
Subject: RE: Medical Care Commission 10A NCAC 13S

Hi,

In the original versions of the rules you filed with us, the effective dates are all January 1, 2025. However, I do see that the publication in the Register says October 1, 2024, and I think I must have conflated the 13S rules with one of the other sets from DHHS that was published in the same issue, and which has a January 1, 2025 effective date. Anyway, sorry for the false alarm there—going back to the published effective date is not a substantial change, in my opinion.

I'll review the other amendments and get back to you soon.

Thanks!
Brian

Brian Liebman
Counsel to the North Carolina Rules Review Commission
Office of Administrative Hearings
(984)236-1948
brian.liebman@oah.nc.gov

Burgos, Alexander N

Subject: FW: Medical Care Commission 10A NCAC 13S
Attachments: 09.2024 - Medical Care Commission 10A NCAC 13S Responses - BRL Replies 2.0.docx; 10A NCAC 13S .0101.docx; 10A NCAC 13S .0104.docx; 10A NCAC 13S .0201.docx; 10A NCAC 13S .0207.docx; 10A NCAC 13S .0212.docx; 10A NCAC 13S .0318.docx; 10A NCAC 13S .0319.docx; 10A NCAC 13S .0320.docx; 10A NCAC 13S .0321.docx; 10A NCAC 13S .0322.docx; 10A NCAC 13S .0323.docx; 10A NCAC 13S .0324.docx; 10A NCAC 13S .0325.docx; 10A NCAC 13S .0326.docx; 10A NCAC 13S .0327.docx; 10A NCAC 13S .0328.docx; 10A NCAC 13S .0329.docx; 10A NCAC 13S .0330.docx; 10A NCAC 13S .0331.docx

From: Black, Shanah <shanah.black@dhhs.nc.gov>
Sent: Friday, September 20, 2024 12:09 PM
To: Liebman, Brian R <brian.liebman@oah.nc.gov>; Burgos, Alexander N <alexander.burgos@oah.nc.gov>
Cc: Conley, Azzie <azzie.conley@dhhs.nc.gov>
Subject: RE: Medical Care Commission 10A NCAC 13S

Hey Brian,

We are not sure what you are looking at that says the effective date for these rules is Jan 1, 2025. Everything in our records and what was published in the June 17, 2024 NCR on page 1617 says effective date October 1, 2024.

https://files.nc.gov/oah/documents/2024-06/Volume-38-Issue-24-June-17-2024_0.pdf?VersionId=fNSCBiWLc0lV.D7duswo7vfkUAII.6tU

I am attaching the amended rules and the responses to your questions.

Thanks and have a great weekend!!

Request for Changes Pursuant to N.C. Gen. Stat. § 150B-21.10

Staff reviewed these Rules to ensure that each Rule is within the agency's statutory authority, reasonably necessary, clear and unambiguous, and adopted in accordance with Part 2 of the North Carolina Administrative Procedure Act. Following review, staff has issued this document that may request changes pursuant to G.S. 150B-21.10 from your agency or ask clarifying questions.

If the request includes questions, please contact the reviewing attorney to discuss.

In order to properly submit rewritten rules, please refer to the following Rules in the NC Administrative Code:

- Rule 26 NCAC 02C .0108 – The Rule addresses general formatting.
- Rule 26 NCAC 02C .0404 – The Rule addresses changing the introductory statement.
- Rule 26 NCAC 02C .0405 – The Rule addresses properly formatting changes made after publication in the NC Register.

Note the following general instructions:

1. You must submit the revised rule via email to oah.rules@oah.nc.gov. The electronic copy must be saved as the official rule name (XX NCAC XXXX).
2. For rules longer than one page, insert a page number.
3. Use line numbers; if the rule spans more than one page, have the line numbers reset at one for each page.
4. Do not use track changes. Make all changes using manual strikethroughs, underlines and highlighting.
5. You cannot change just one part of a word. For example:
    - Wrong: "~~a~~Association"
    - Right: "~~association~~ Association"
6. Treat punctuation as part of a word. For example:
    - Wrong: "day~~,~~; and"
    - Right: "~~day,~~ day; and"
7. Formatting instructions and examples may be found at: www.ncoah.com/rules/examples.html

If you have any questions regarding proper formatting of edits after reviewing the rules and examples, please contact the reviewing attorney.

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

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

AGENCY: N.C. Medical Care Commission

RULE CITATION: All Rules

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 many rules, there is a citation to G.S. 131E-153. As this statute is describes the purpose of the Act, and does not confer rulemaking authority, it can't be cited in the History Note as authority for these rules. Please delete.
Response: Issue addressed.

While I appreciate the convenience of the formatting, which shows the changes between the temporary rules and these permanent rules, that is not how our rules require permanent adoptions to be formatted. Please reformat per our formatting guide as "Permanent Adoption with no changes from publication", assuming there have been no post-publication changes.
Response: Issue addressed.

https://www.oah.nc.gov/rule-format-examples#RuleFormatExamplesforPublicationintheNCAdministrativeCode-6063

Also, this is part of the formatting, but I wanted to mention it independently, you need to change the headers to include the publication information. You'll see it in the link above, but it should say (using Rule .0101 as an example) "10A NCAC 13S .0101 is adopted as published in 38:24 NCR 1617-1623 as follows:"
Response: Issue addressed.

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

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?
Response: Added "health" to clarify conditions are health conditions that would impact clinics

I assumed they were health conditions. What health conditions are at issue here? What are you testing for?

Response: The clinic gets to decide what health conditions it would like to test. Tuberculosis is generally tested prior to hire. However, there may be other health conditions that the clinic may choose to test, such as Covid 19 or other infectious diseases.

Is there actually a requirement to do health screening? The only place I see "health screening" in the rules is in .0322(f), where records must be available for review by the Division. Based on your response here, if the clinic can test for anything it wants, then by extension it can choose *not* to test. So is this actually a requirement? If so, please specify the minimum required testing. If not, then I think you need to reevaluate the language here and in .0322.

Also note that in Rule .0322(f), you need to update your cross-reference from .0101(6) to .0101(8).
Response: Yes, there is a minimum requirement of TB screening. Issue addressed; cross reference corrected

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

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.

***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 13 and (b), lines 15-16, what standards will the Division use to review and approve the construction documents and specifications?
Response: The construction section of the division will review and approve the construction documents and specifications consistent with section .0200 of chapter 13S, which addresses the construction standards for clinics.

The rule doesn't say that. Please add a cross reference to Section .0200.
Response: Issue addressed; added cross reference.

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

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.

***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:

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?
Response: The provision does not impose a more stringent condition than the existing building code for alteration, repair, rehabilitation or addition. If an alteration, repair, rehabilitation, or addition is made to an existing building, the rule does not require that the entire building comply with the existing building code. In .0201(b) we are requiring buildings licensed for the first time to meet or exceed the minimum requirements of Group B occupancy of the Building Code at the time of initial licensing, which would be 2018 NCSBC if requesting licensure today. For currently licensed facilities that do an alteration, repair, rehabilitation or addition, this will require meeting the requirements of the current Building Code for the changes made to the building.

This is not what your rule says, and the text presents several problems.

In (a), you say only that "a clinic"—without making the distinction between a newly constructed clinic or an existing clinic—must meet the requirements of the 2024 Building Code. This language would appear to apply the 2024 Building Code to **all** clinics. However, in (b) you countermand that and say that Section .0200 only applies to "new clinics and any alterations… made to a previously licensed facility".

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

First, there is ambiguity as to what codes apply to what buildings. The Existing Building Code should apply to any existing, unaltered structures regardless of whether you include it in your rule, but its omission from the Rule creates a question as to what standards you will use to judge a clinic housed in an existing, unaltered structure, for licensure.
Response: Issue addressed with additional text. See below.

Second, there is ambiguity in when (b) applies. The text says that Section .0200 applies to "new clinics" (as opposed to new structures) and alterations, etc to a "previously licensed facility". If a new clinic opens in an existing, unaltered structure, then does Section .0200 apply? What about alterations made to a previously licensed facility that was already built to 2018/2024 standards?
Response: Issue addressed with additional text. Reworked sections (a) and (b) to clarify that existing licensed facilities need to meet the building code and construction rules in effect at the time of initial licensure or certification, and that new clinics, and any alterations, repairs, rehabilitation work, or additions must meet the requirements of Section .0200. As now reworked, all existing licensed clinics must meet the existing North Carolina State Building Code for Group B occupancy.

As I understand from your responses here, your intention is for the following to apply:

New clinics – 2018/2024 Building Code
Existing clinics – 2018/2024 Existing Building Code
Alterations to existing clinics – 2018/2024 Building Code

This is essentially what the Building Codes say. Further, the Building Code classifies ambulatory surgical centers—whose rules are the model for these rules, per the SL—as Group B for occupancy purposes.

I think there's some confusion and conflation going on here, between the applicable *code* and the *classification* within the Code. Group B occupancy spans all the various codes. But here, it looks like the sentence "minimum requirements of the North Carolina State Building Code for Group B occupancy" is doing the work of imposing the 2018/2024 Building Code on *all* clinics as well as saying what the occupancy classification is.

Thus, I suggest rewriting (a) to differentiate between which Code applies, and which occupancy applies.
Response: Issue addressed in rule text.

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?
Response: Yes, that is correct

Again, see above – what standards then are used to judge these clinics for licensure?
Response: Issue addressed with additional text.

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

In that case, what do those terms mean?
Response: The terms are defined in the building code. The definitions can be found in the 2018 North Carolina State Building Code located at https://codes.iccsafe.org/content/NCEBC2018/chapter-2-definitions.

If you mean to use the definitions as they appear in the Building Code, I think you need to incorporate them by reference here, pursuant to G.S. 150B-21.6.
Response: Issue addressed in text.

Moreover, if Section .0200 does not apply to existing clinics, then what criteria does the Commission use to determine if they should be licensed?
Response: As stated in .0104, an applicant who submits an application for a new clinic must submit construction documents and specifications for review and approval. Those documents are reviewed for compliance with the physical plant licensure rules contained in Section .0200.

This is not responsive to my question. I asked what you use to judge *existing* clinics, not *new* clinics.
Response: Issue addressed in text.

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

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.

***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:

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?
Response: An "area" in this context is space within the licensed facility not provided with walls that has been designated for a specific function

In (2), line 7, what are "pre-procedure and post-procedure activities"? Please define.
Response: Issue addressed; definitions added to Rule .0101

So, to be clear, you're allowing medical activities to occur in an open space. Does this have privacy ramifications under other State or Federal laws?
Response: No, providers are still required to comply with all privacy laws. Clinics are required to have a policy and procedure to ensure privacy during all medical services.

In (4), line 12, capitalize "state" when referring to the State of North Carolina.
Response: Issue addressed; change made.

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.
Response: Issue addressed, incorporated by reference the applicable federal regulation.

G.S. 150B-21.6 requires not only that you designate whether the incorporation includes subsequent amendments and editions, but also you must "specify in the rule both where copies of the material an be obtained and the cost on the date the rule is adopted of a copy of the material."
Response: Issue addressed; added requested information.

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

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

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.

***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:

Do the requirements of this Rule conflict with those required by the Building Code?
Response: No, the requirements in this rule do not conflict with 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?
Response: Issue addressed; this has been removed from the rule.

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.
Response: This URL is a direct link to the purchase of the most current edition of NFPA 99. The free access versions of all of the NFPAs are available on NFPA's website but there are several steps you must do to access the specific version you need when you get to the website. If this is not acceptable, the agency can provide its physical address where the NFPA-99 can be accessed.

If you can't provide a closer URL or more specific instructions for the free version, then I suppose the physical address would be better.
Response: Given that this is a code that is available for purchase the agency is not able to provide full copies of NFPA-99 free of charge. We have eliminated the free access text from the rule and have kept in the reference and the link to purchase the full NFPA-99 code.

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.
Response: Based on this Rule, the current edition of NFPA 99 would be applicable at the time of licensing, renovation, addition, etc. We have amended the rule to specify subsequent amendments will be applicable.

I don't see a change made. Is it incorrectly formatted?

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

Response: The text was previously added and can be found in lines 25 and 26 of the rule.

Finally, what chapter or section of NFPA-99 are you requiring compliance with? NFPA 99 has 15 chapters and 4 annexes.
Response: The requirement of this Rule is for licensed facilities that provide piped-in medical gas and vacuum systems. These systems are covered in the 2024 edition of NFPA 99 (current version) under Chapter 5. The Rule was left generic in case the applicable chapter changes with each new version of NFPA 99.

In (3)(b), p.3, line 19, is "at a minimum" necessary? Is there something besides battery backup that is relevant here?
Response: Not all electrically operated medical equipment is provided with integral battery backup. Some equipment relies on an emergency electrical system supplied by a generator to identified electrical outlets to operate the equipment when there is a loss of normal power. Since there is no mandated requirement for these facilities to be provided with an emergency electrical system, this Rule is requiring, at a minimum, some type of battery backup system for medical equipment. This could be in the form of an integral battery to the equipment, or an uninterruptable power supply (UPS) in which medical equipment would be connected.

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

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".
Response: Issue addressed, added a comma.

In (d)(3), line 20, define "safe and adequate".
Response: Definition added to the definition section.

Thanks for defining the term, but there are some issues with the definition. First, I think you meant "reasonably preventing harm". That said, what does "reasonable" mean here? When is it unreasonable to prevent harm from occurring? Also, I assume you mean "preventing harm" to the patient, correct?
Response: Issue addressed, revised definition.

In (d)(3), line 21, when is revision "necessary"?
Response: Revisions are necessary when the current policies and procedures would not be able to provide safe and adequate care such as when there are changes to the standards of care applicable to the procedures. For example, changes in the standards of care for infection control may necessitate revisions to the clinics policies and procedures.

In (d)(3), line 22, "compliance" with what?
Response: This means compliance with regulations and standards of care.

Compliance with *what* regulations and *what* standards of care? Specify in the rule.
Response:

In (h), line 31, to whom and in what form is the certification required?
Response: Issue addressed.

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?

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

Response: The criteria are that the physical facilities are able to provide safe and adequate care and are otherwise compliant with section .0200.

You deleted paragraph (h), but I would note that per Rule .0201, Section .0200 only applies to "new" clinics and those that have undergone alteration.
Response: We have altered the text of section .0200 to clarify the physical plant standards that existing clinics must meet.

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).
Response: Issue addressed, section after semicolon removed.

To be clear, you deleted the whole of paragraph (h). Was that your intention?

Response: Yes, that was out intention. The comment was left over from a prior deletion.

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

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.

***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 meant by "essential"? What documents are "non-essential"?
Response: Issues addressed, "essential" removed. Documents identified in rule must be on file in the administrative office in the clinic.

In (a)(7), line 12, did you mean "the clinic as a party"?
Response: Issue addressed, "as" corrected.

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"?
Response: Issue addressed, clarified protocol for a referral of patients for whom the clinic has declined services.

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).
Response: Issue addressed; section removed.

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

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

AGENCY: N.C. Medical Care Commission

RULE CITATION: 10A NCAC 13S .0320

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, what is an "administrative decision regarding patients"?
Response: Issue addressed, administrative decisions include all of the decisions related to a patient's care and services such as admissions, billing, and services provided.

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.
Response: Issue addressed; rule revised.

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?
Response: Issue addressed; added requirement to have grievance policy in .0318. Also, added cross reference in rule .0320.

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

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)?
Response: No, they are the same.

Then in the interests of clarity, it would be best to use the defined term consistently throughout the rules.
Response: Issue addressed in text, used same term throughout.

I think you meant to say the *fetus's* gestational age, rather than the patient's.
Response: Issue addressed; text revised.

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.
Response: Yes, this is the same one as in G.S. 90-21.82. Issue addressed, cross referenced in the rule.

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.
Response: Issue addressed in rule.

In (d), line 27, what qualifications are you requiring for the ultrasound technician?
Response: Issue addressed in rule.

"Trained" and "qualified" are just synonyms. The revision doesn't address the question.
Response: Issue addressed; removed technician qualification and training requirement.

In (e)(2), line 33, is "length of gestation" different than "gestational age"?
Response: No, they are the same.

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

Then in the interests of clarity, it would be best to use the defined term consistently throughout the rules.
Response: Issue addressed; used same term throughout.

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

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".
Response: Issued addressed and the rule text changed.

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

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"?
Response: Significance of the change was that this would not be limited only to nurses.

I'm not sure I understand the response. What would not be limited to nurses?
Response: The clinical staff includes more than just nurses. The clinical staff includes any staff member providing services in the clinic.

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)?
Response: Issue addressed by removing G.S. 90-640.

Well, that doesn't really address the issue. We still don't have a definition of "health care practitioner."
Response: Issue addressed; health care practitioner defined in Rule .0101

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?
Response: Issue addressed, "in the clinic" added to rule.

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

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

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".
Response: Issue addressed in rule text.
This just compounds the issue in Rule .0323. What is the definition of "health practitioner"?

Response: Issue addressed; health care practitioner added to Rule .0101.

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

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…"
Response: Issue addressed, "emergency case" moved to definitions rule.

In (a), line 6, delete the parentheses around "including severe pain", and incorporate into the body of the rule with commas.
Response: Issue addressed, sentenced moved to definition rule.

In (c), line 11, is an "emergency" the same as an "emergency case"? If not, define "emergency".
Response: Yes, this is the same.

Then why not use the defined term throughout your rules, for clarity.
Response: Issue addressed in text.

In (c), line 12, what does it mean to be "familiar" with the written instructions?
Response: Issue addressed in rule text.

The change from "familiar with" to "knowledgeable of" is just semantic. What does it mean to be "knowledgeable of" the instructions? Being aware of their existence? Having read them? Being able to quote them on demand?
Response: Issue addressed in text.

In (c)(1), line 13, what is an "untoward" complication? Please define.
Response: Issue addressed in rule text.

In (d)(2), are the "emergency protocols" different than the "emergency instructions" in (c)?
Response: No, the protocols are not different from the instructions.
Then please use the same terms throughout the rules, for clarity.

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

Response: Issue addressed in text.

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

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?

Response: Issue addressed, G.S. 90-640 taken out.

This just compounds the issue in Rule .0323. What is the definition of "health care practitioner"?

Response: Issue addressed; health care practitioner added to Rule .0101.

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

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

10A NCAC 13S .0101 is adopted with changes as published in 38:24 NCR 1617–1623 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) "Emergency Case" is defined as a condition manifesting itself by acute symptoms of sufficient severity, including severe pain, such that the absence of immediate medical attention could reasonably be expected to result in placing the individual's health in serious jeopardy, serious impairment to bodily functions, or serious dysfunction of bodily organs.

~~(4)~~(5) "Gestational age" means the length of pregnancy as indicated by the date of the first day of the last normal monthly menstrual period, if known, or as determined by ultrasound.

~~(5)~~(6) "Governing authority" means the individual, agency, group, or corporation appointed, elected or otherwise designated, in which the ultimate responsibility and authority for the conduct of the abortion clinic is vested pursuant to Rule .0318 of this Subchapter.

(7) "Health Care Practitioner" means a physician, nurse practitioner, or physician's assistant licensed and authorized to practice in the state of North Carolina.

~~(6)~~(8) "Health Screening" means an evaluation of an employee or contractual employee, including at a minimum tuberculosis testing or screening, to identify ~~any~~ underlying health conditions that may affect the person's ability to work in the clinic.

~~(7)~~(9) "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.

(10) "Pre-procedure activities" are activities performed prior to the procedure to ensure that the patient is stable, and that the procedure can be safely performed.

(11) "Post-procedure" activities are activities performed after the procedure to ensure that the patient is stable for discharge.

~~(8)~~(12) "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.

(13) "Safe and adequate care" means care that meets the clinical needs of the patient while ~~reasonably~~ preventing harm from occurring.to the patient. ~~occurring.~~

History Note: *Authority G.S. ~~131E-153;~~ 131E-153.5; 143B-165.*
Eff. October 1, 2024.

10A NCAC 13S .0104 is adopted with changes as published in 38:24 NCR 1617-1623 as follows:

10A NCAC 13S .0104 PLANS AND SPECIFICATIONS

(a) Prior to issuance of a license pursuant to ~~Rule .0107 of this Section~~ 10A NCAC 14E .0107, an applicant for a new clinic shall submit one copy of construction documents and specifications to the Division for review and ~~approval.~~ approval consistent with Section .0200 of this Subchapter.

(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;*
Eff. October 1, 2024.

10A NCAC 13S .0201 is adopted with changes as published in 38:24 NCR 1617-1623 as follows:

SECTION .0200 - MINIMUM STANDARDS FOR CONSTRUCTION AND EQUIPMENT

10A NCAC 13S .0201 BUILDING CODE REQUIREMENTS

(a) ~~The physical plant for a clinic~~ Existing licensed clinics or portions of existing licensed clinics shall meet ~~licensure and~~ code requirements in effect at the time of licensure or certification, addition, renovation, or alteration.

(b) ~~The requirements of this section shall apply to clinics requirements contained in this Section shall applying for initial licensure apply to new clinics and to any alterations, repairs, rehabilitation work, or additions which are made to a currently previously licensed facility. clinic. Upon initial licensure, clinics New facilities~~ Clinics applying for initial licensure or existing licensed clinics applying for any alterations, repairs, rehabilitation work, or additions 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 https://shop.iccsafe.org/catalogsearch/result/?cat=1010&q=+North+Carolina+Building+code for a cost of eight hundred fifty eight dollars ($858.00) or accessed electronically free of charge at https://www.ncosfm.gov/codes/codes-current-and-past.

(c) The definitions of alterations, repairs, rehabilitation work, and additions as used in this Rule are defined by the North Carolina State Building Code.

History Note: *Authority G.S. 131E-153.5; 143B-165;*
Eff. October 1, 2024.

10A NCAC 13S .0207 is adopted with changes as published in 38:24 NCR 1617-1623 as follows:

10A NCAC 13S .0207 AREA REQUIREMENTS

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

(1) reception and waiting room;

(2) designated area or areas for pre-procedure and post-procedure activities;

(3) procedure room;

(4) a clean area for self-contained secure medication storage complying with security requirements of ~~state~~ State and federal laws;

(5) area compliant with Clinical Laboratory Improvement Amendments (CLIA) requirements, 42 CFR Part 493, including subsequent amendments and additions, which are hereby incorporated by reference, available at https://www.ecfr.gov/current/title-42/chapter-IV/subchapter-G/part-493 at no cost, ~~requirements~~ in which laboratory testing can be performed;

(6) separate areas for storage and handling of clean and soiled materials;

(7) patient toilet;

(8) personnel toilet facilities;

(9) janitor's closets;

(10) space and equipment for assembling, sterilizing and storing medical and surgical supplies;

(11) storage space for medical records of all media types used by the facility; and

(12) space for charting, communications, counseling, business functions, and other administrative activities.

History Note: *Authority G.S. 131E-153.5; 143B-165;*
Eff. October 1, 2024.

10A NCAC 13S .0212 is adopted with changes as published in 38:24 NCR 1617-1623 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 requirements:

(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:

Area	Pressure Relationship	Minimum Total Air Changes/Hour
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) Piped-in medical gas and vacuum systems, if installed, shall meet the requirements of NFPA-99, category 2 system, which is hereby incorporated by reference including subsequent amendments and editions. Copies of NFPA-99 may be purchased from the National Fire Protection Association online at https://www.nfpa.org/product/nfpa-99-code/p0099code at a cost of one hundred forty-nine dollars ~~($149.00) or accessed electronically free of charge at http://www.nfpa.org.~~ ($149.00).

(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 ten (10) inches above the 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 facilities at a minimum temperature of 100 degrees F. and a maximum temperature of 116 degrees F.

(3) Electrical Requirements.

(a) The facility's paths of egress 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 1 foot 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.

(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;*
Eff. October 1, 2024.

10A NCAC 13S .0318 is adopted with changes as published in 38:24 NCR 1617-1623 as follows:

10A NCAC 13S .0318 GOVERNING AUTHORITY

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

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

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

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

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

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

(3) maintain a policies and procedures manual designed to ensure safe and adequate care for the patients which shall be reviewed, and revised when necessary, at least annually, and shall include provisions for administration and use of the clinic, ~~compliance~~, compliance with statutes and rules applicable to clinics including Subchapters 13S and 14E of Title 10A, compliance with a nationally standard recognized standard of care for infection control, personnel quality assurance, procurement of outside services and consultations, patient care policies, grievance policies, and services offered.

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

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

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

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

History Note: *Authority G.S. ~~131E-153;~~ 131E-153.5; 143B-165.*
Eff. October 1, 2024.

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10A NCAC 13S .0319 is adopted with changes as published in 38:24 NCR 1617-1623 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 ~~a~~ as 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 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) emergency protocols as required by Rule .0326;

(4) policy and procedure for validating the full and true name of the patient;

(5) policy and procedure for abortion procedures performed at the clinic;

(6) policy and procedure for the provision of patient privacy in the recovery area of the clinic;

(7) protocol for determining gestational age as defined in ~~Rule .0101(4)~~ Rule .0101(5) of this Subchapter; and

(8) protocol for referral of patients ~~for whom services have been declined~~ declined services by the clinic. ~~and~~

~~(9) protocol that defines use of space to include opportunities that one area may accommodate various aspects of patient visits.~~

History Note: *Authority G.S. ~~131E-153;~~ 131E-153.5; 143B-165.*
Eff. October 1, 2024.

10A NCAC 13S .0320 is adopted with changes as published in 38:24 NCR 1617-1623 as follows:

10A NCAC 13S .0320 ADMISSION AND DISCHARGE

(a) There shall be on the premises throughout all hours of operation an employee authorized to receive patients and make administrative decisions regarding patients. Administrative decisions include all of the decisions related to a patient's care and services, such as admissions, billing, and services provided.

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

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

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

(1) a fee schedule and any extra charges routinely applied;

(2) the name of the attending physician or physicians and hospital admitting privileges~~, if any~~. In the absence of admitting privileges a statement documenting that the attending physician or physicians does not have admitting privileges ~~to that effect~~ shall be included;

(3) instructions for post-procedure problems and questions as outlined in Rule .0329(d) of this Section;

(4) grievance procedures a patient may follow if dissatisfied with the care and services rendered pursuant to the grievance policy as outlined in .0318(d)(3) of this Section; and

(5) the telephone number for Complaint Intake of the Division.

History Note: *Authority G.S. ~~131E-153;~~ 131E-153.5; 143B-165.*
Eff. October 1, 2024.

10A NCAC 13S .0321 is adopted with changes as published in 38:24 NCR 1617-1623 as follows:

10A NCAC 13S .0321 MEDICAL RECORDS

(a) The clinic shall maintain a complete and permanent record for all patients including:

(1) the date and time of admission and discharge;

(2) the patient's full and true name;

(3) the patient's address;

(4) the patient's date of birth;

(5) the patient's emergency contact information;

(6) the patient's diagnoses;

(7) the ~~patient's duration of pregnancy~~ fetus's gestational age;

(8) the patient's condition on admission and discharge;

(9) a voluntarily-signed consent for each procedure and signature of the physician performing the procedure witnessed by a family member, other patient representative, or facility staff member;

(10) a copy of the signed 72 hour consent and physician declaration as defined in G.S. 90-21.82;

(11) the patient's history and physical examination including identification of pre-existing or current illnesses, drug sensitivities or other idiosyncrasies that may impact the procedure or anesthetic to be administered; and

(12) documentation that indicates all items listed in Rule .0320(d) of this Section were provided to the patient.

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

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

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

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

(1) the patient name;

(2) the estimated ~~length of gestation~~ gestational age;

(3) the type of procedure;

(4) the name of the physician:

(5) the name of the Registered Nurse on duty; and

(6) the date and time of procedure.

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

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

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

History Note: *Authority G.S. ~~131E-153;~~ 131E-153.5; 143B-165.*
Eff. October 1, 2024.

10A NCAC 13S .0322 is adopted with changes as published in 38:24 NCR 1617-1623 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 or resume that includes education, training, experience and references; and

(C) a copy of a valid license (if required).

(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(6)~~ Rule .0101(8) 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.*
Eff. October 1, 2024.

10A NCAC 13S .0323 is adopted with changes as published in 38:24 NCR 1617-1623 as follows:

10A NCAC 13S .0323 CLINIC STAFFING

(a) The clinic shall have an organized 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-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 procedure rooms and recovery area.

History Note: *Authority G.S. ~~131E-153;~~ 131E-153.5; 143B-165.*
Eff. October 1, 2024.

10A NCAC 13S .0324 is adopted with changes as published in 38:24 NCR 1617-1623 as follows:

10A NCAC 13S .0324 QUALITY ASSURANCE

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

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

(c) The committee shall consist of one physician who is not an owner, the chief executive officer or designee, and other health ~~professionals~~ practitioners.

(d) The frequency of meetings and details of data collection shall be defined by the governing authority.

History Note: *Authority G.S. ~~131E-153;~~ 131E-153.5; 143B-165.*
Eff. October 1, 2024.

10A NCAC 13S .0325 is adopted with changes as published in 38:24 NCR 1617-1623 as follows:

10A NCAC 13S .0325 LABORATORY SERVICES

(a) Each clinic shall have the capability to provide or obtain laboratory tests required in connection with the procedure to be performed, and will perform laboratory tests appropriate to their Clinical Laboratory Improvement Amendments (CLIA) certification.

(b) The governing authority shall establish written policies regarding which surgical specimens require examination by a pathologist.

(c) Each patient shall have laboratory testing as determined to be clinically necessary by the physician, or as required by law. A record of the results of any tests performed will be included in the patient's medical record.

(d) The clinic shall maintain a manual in a location accessible by employees, that meets requirements for the level of clinic's CLIA certification. This includes the procedures, instructions, and manufacturer's instructions for each test procedure performed including:

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

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

History Note: *Authority G.S. ~~131E-153;~~ 131E-153.5; 143B-165.*
Eff. October 1, 2024.

10A NCAC 13S .0326 is adopted with changes as published in 38:24 NCR 1617-1623 as follows:

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

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

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

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

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

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

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

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

(1) basic cardio-pulmonary life support;

(2) emergency ~~protocols~~ instructions for:

(A) administration of intravenous fluids;

(B) establishing and maintaining airway support;

(C) oxygen administration;

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

(E) utilizing an automated external defibrillator.

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

(4) ultrasound equipment.

History Note: *Authority G.S. ~~131E-153~~; 131E-153.5; 143B-165.*
Eff. October 1, 2024.

10A NCAC 13S .0327 is adopted with changes as published in 38:24 NCR 1617-1623 as follows:

10A NCAC 13S .0327 OUTPATIENT PROCEDURAL SERVICES

(a) The clinic shall establish procedures for infection control and universal precautions, including cleaning of all patient care areas including procedure rooms.

(b) Tissue Examination:

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

(2) If adequate tissue is not obtained based on the gestational age, the physician performing the procedure shall evaluate for ectopic pregnancy, or an incomplete procedure.

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

History Note: *Authority G.S. ~~131E-153~~; 131E-153.5; 143B-165.*
Eff. October 1, 2024.

10A NCAC 13S .0328 is adopted with changes as published in 38:24 NCR 1617-1623 as follows:

10A NCAC 13S .0328 MEDICATIONS AND SEDATION

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

(b) Medications, including injections shall be administered by a physician, Registered Nurse, and other health care practitioners ~~as defined in G.S. 90-640 (a)~~ practicing within the scope of their license or certification authorized by state laws to administer medications. All medications shall be recorded in the patient's permanent record.

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

History Note: *Authority G.S. ~~131E-153~~; 131E-153.5; 143B-165.*
Eff. October 1, 2024.

10A NCAC 13S .0329 is adopted with changes as published in 38:24 NCR 1617-1623 as follows:

10A NCAC 13S .0329 POST PROCEDURAL CARE

(a) A patient whose pregnancy is terminated shall be observed in the clinic to ensure that no post procedural complications are present. Thereafter, patients may be discharged according to a physician's order and the clinic's protocols.

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

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

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

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

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

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

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

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

History Note: *Authority G.S. ~~131E-153~~; 131E-153.5; 143B-165.*
Eff. October 1, 2024.

10A NCAC 13S .0330 is adopted with changes as published in 38:24 NCR 1617-1623 as follows:

10A NCAC 13S .0330 CLEANING OF MATERIALS AND EQUIPMENT

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

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

History Note: *Authority G.S. ~~131E-153~~; 131E-153.5; 143B-165.*
Eff. October 1, 2024.

10A NCAC 13S .0331 is adopted with changes as published in 38:24 NCR 1617-1623 as follows:

10A NCAC 13S .0331 FOOD SERVICE

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

History Note: *Authority G.S. ~~131E-153;~~131E-153.2; 131E-153.5; 143B-165.*
Eff. October 1, 2024.

Burgos, Alexander N

Subject: FW: Medical Care Commission 10A NCAC 13S

From: Conley, Azzie <azzie.conley@dhhs.nc.gov>
Sent: Thursday, September 19, 2024 9:50 PM
To: Liebman, Brian R <brian.liebman@oah.nc.gov>; Black, Shanah <shanah.black@dhhs.nc.gov>; Burgos, Alexander N <alexander.burgos@oah.nc.gov>
Subject: Re: Medical Care Commission 10A NCAC 13S

.0321
Fetus' gestational age is correct.

Thank you,
Azzie

Get Outlook for iOS

Burgos, Alexander N

Subject: FW: Medical Care Commission 10A NCAC 13S

From: Black, Shanah <shanah.black@dhhs.nc.gov>
Sent: Thursday, September 19, 2024 5:30 PM
To: Liebman, Brian R <brian.liebman@oah.nc.gov>; Burgos, Alexander N <alexander.burgos@oah.nc.gov>
Cc: Conley, Azzie <azzie.conley@dhhs.nc.gov>
Subject: RE: Medical Care Commission 10A NCAC 13S

Hey Brian,

Hope you are having a good week, and thank you for your quick response.

We will get this back to you tomorrow.

Thanks

Burgos, Alexander N

Subject: FW: Medical Care Commission 10A NCAC 13S
Attachments: 09.2024 - Medical Care Commission 10A NCAC 13S Responses - BRL Replies 2.0.docx

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From: Liebman, Brian R <brian.liebman@oah.nc.gov>
Sent: Thursday, September 19, 2024 5:20 PM
To: Black, Shanah <shanah.black@dhhs.nc.gov>; Burgos, Alexander N <alexander.burgos@oah.nc.gov>
Cc: Conley, Azzie <azzie.conley@dhhs.nc.gov>
Subject: RE: Medical Care Commission 10A NCAC 13S

Hi Shanah,

Hope all is well. I have a few additional notes on some of the rules, in blue. Also, I noticed that you've changed your effective dates on at least one of the rules from January 1, 2025 to October 1, 2024. That would be a substantial change under G.S. 150B-21.2(g), and would require republication.

Please send your responses and revisions by tomorrow at 5:00 pm.

Thanks!
Brian

Brian Liebman
Counsel to the North Carolina Rules Review Commission
Office of Administrative Hearings
(984)236-1948
brian.liebman@oah.nc.gov

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

AGENCY: N.C. Medical Care Commission

RULE CITATION: All Rules

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 many rules, there is a citation to G.S. 131E-153. As this statute is describes the purpose of the Act, and does not confer rulemaking authority, it can't be cited in the History Note as authority for these rules. Please delete.
Response: Issue addressed.

While I appreciate the convenience of the formatting, which shows the changes between the temporary rules and these permanent rules, that is not how our rules require permanent adoptions to be formatted. Please reformat per our formatting guide as "Permanent Adoption with no changes from publication", assuming there have been no post-publication changes.
Response: Issue addressed.

https://www.oah.nc.gov/rule-format-examples#RuleFormatExamplesforPublicationintheNCAdministrativeCode-6063

Also, this is part of the formatting, but I wanted to mention it independently, you need to change the headers to include the publication information. You'll see it in the link above, but it should say (using Rule .0101 as an example) "10A NCAC 13S .0101 is adopted as published in 38:24 NCR 1617-1623 as follows:"
Response: Issue addressed.

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

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?
Response: Added "health" to clarify conditions are health conditions that would impact clinics

I assumed they were health conditions. What health conditions are at issue here? What are you testing for?

Response: The clinic gets to decide what health conditions it would like to test. Tuberculosis is generally tested prior to hire. However, there may be other health conditions that the clinic may choose to test, such as Covid 19 or other infectious diseases.

Is there actually a requirement to do health screening? The only place I see "health screening" in the rules is in .0322(f), where records must be available for review by the Division. Based on your response here, if the clinic can test for anything it wants, then by extension it can choose *not* to test. So is this actually a requirement? If so, please specify the minimum required testing. If not, then I think you need to reevaluate the language here and in .0322.

Also note that in Rule .0322(f), you need to update your cross-reference from .0101(6) to .0101(8).

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

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.

***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 13 and (b), lines 15-16, what standards will the Division use to review and approve the construction documents and specifications?
Response: The construction section of the division will review and approve the construction documents and specifications consistent with section .0200 of chapter 13S, which addresses the construction standards for clinics.

The rule doesn't say that. Please add a cross reference to Section .0200.
Response: Issue addressed; added cross reference.

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

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.

***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:

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?
Response: The provision does not impose a more stringent condition than the existing building code for alteration, repair, rehabilitation or addition. If an alteration, repair, rehabilitation, or addition is made to an existing building, the rule does not require that the entire building comply with the existing building code. In .0201(b) we are requiring buildings licensed for the first time to meet or exceed the minimum requirements of Group B occupancy of the Building Code at the time of initial licensing, which would be 2018 NCSBC if requesting licensure today. For currently licensed facilities that do an alteration, repair, rehabilitation or addition, this will require meeting the requirements of the current Building Code for the changes made to the building.

This is not what your rule says, and the text presents several problems.

In (a), you say only that "a clinic"—without making the distinction between a newly constructed clinic or an existing clinic—must meet the requirements of the 2024 Building Code. This language would appear to apply the 2024 Building Code to **all** clinics. However, in (b) you countermand that and say that Section .0200 only applies to "new clinics and any alterations… made to a previously licensed facility".

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

First, there is ambiguity as to what codes apply to what buildings. The Existing Building Code should apply to any existing, unaltered structures regardless of whether you include it in your rule, but its omission from the Rule creates a question as to what standards you will use to judge a clinic housed in an existing, unaltered structure, for licensure.
Response: Issue addressed with additional text. See below.

Second, there is ambiguity in when (b) applies. The text says that Section .0200 applies to "new clinics" (as opposed to new structures) and alterations, etc to a "previously licensed facility". If a new clinic opens in an existing, unaltered structure, then does Section .0200 apply? What about alterations made to a previously licensed facility that was already built to 2018/2024 standards?
Response: Issue addressed with additional text. Reworked sections (a) and (b) to clarify that existing licensed facilities need to meet the building code and construction rules in effect at the time of initial licensure or certification, and that new clinics, and any alterations, repairs, rehabilitation work, or additions must meet the requirements of Section .0200. As now reworked, all existing licensed clinics must meet the existing North Carolina State Building Code for Group B occupancy.

As I understand from your responses here, your intention is for the following to apply:

New clinics – 2018/2024 Building Code
Existing clinics – 2018/2024 Existing Building Code
Alterations to existing clinics – 2018/2024 Building Code

This is essentially what the Building Codes say. Further, the Building Code classifies ambulatory surgical centers—whose rules are the model for these rules, per the SL—as Group B for occupancy purposes.

I think there's some confusion and conflation going on here, between the applicable *code* and the *classification* within the Code. Group B occupancy spans all the various codes. But here, it looks like the sentence "minimum requirements of the North Carolina State Building Code for Group B occupancy" is doing the work of imposing the 2018/2024 Building Code on *all* clinics as well as saying what the occupancy classification is.

Thus, I suggest rewriting (a) to differentiate between which Code applies, and which occupancy applies.

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?
Response: Yes, that is correct

Again, see above – what standards then are used to judge these clinics for licensure?
Response: Issue addressed with additional text.

In that case, what do those terms mean?

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

Response: The terms are defined in the building code. The definitions can be found in the 2018 North Carolina State Building Code located at https://codes.iccsafe.org/content/NCEBC2018/chapter-2-definitions.

If you mean to use the definitions as they appear in the Building Code, I think you need to incorporate them by reference here, pursuant to G.S. 150B-21.6.
Response: Issue addressed in text.

Moreover, if Section .0200 does not apply to existing clinics, then what criteria does the Commission use to determine if they should be licensed?
Response: As stated in .0104, an applicant who submits an application for a new clinic must submit construction documents and specifications for review and approval. Those documents are reviewed for compliance with the physical plant licensure rules contained in Section .0200.

This is not responsive to my question. I asked what you use to judge *existing* clinics, not *new* clinics.
Response: Issue addressed in text.

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

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.

***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:

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?
Response: An "area" in this context is space within the licensed facility not provided with walls that has been designated for a specific function

In (2), line 7, what are "pre-procedure and post-procedure activities"? Please define.
Response: Issue addressed; definitions added to Rule .0101

So, to be clear, you're allowing medical activities to occur in an open space. Does this have privacy ramifications under other State or Federal laws?
Response: No, providers are still required to comply with all privacy laws. Clinics are required to have a policy and procedure to ensure privacy during all medical services.

In (4), line 12, capitalize "state" when referring to the State of North Carolina.
Response: Issue addressed; change made.

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.
Response: Issue addressed, incorporated by reference the applicable federal regulation.

G.S. 150B-21.6 requires not only that you designate whether the incorporation includes subsequent amendments and editions, but also you must "specify in the rule both where copies of the material an be obtained and the cost on the date the rule is adopted of a copy of the material."
Response: Issue addressed; added requested information.

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

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

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.

***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:

Do the requirements of this Rule conflict with those required by the Building Code?
Response: No, the requirements in this rule do not conflict with 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?
Response: Issue addressed; this has been removed from the rule.

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.
Response: This URL is a direct link to the purchase of the most current edition of NFPA 99. The free access versions of all of the NFPAs are available on NFPA's website but there are several steps you must do to access the specific version you need when you get to the website. If this is not acceptable, the agency can provide its physical address where the NFPA-99 can be accessed.

If you can't provide a closer URL or more specific instructions for the free version, then I suppose the physical address would be better.
Response: Given that this is a code that is available for purchase the agency is not able to provide full copies of NFPA-99 free of charge. We have eliminated the free access text from the rule and have kept in the reference and the link to purchase the full NFPA-99 code.

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.
Response: Based on this Rule, the current edition of NFPA 99 would be applicable at the time of licensing, renovation, addition, etc. We have amended the rule to specify subsequent amendments will be applicable.

I don't see a change made. Is it incorrectly formatted?

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

Response: The text was previously added and can be found in lines 25 and 26 of the rule.

Finally, what chapter or section of NFPA-99 are you requiring compliance with? NFPA 99 has 15 chapters and 4 annexes.
Response: The requirement of this Rule is for licensed facilities that provide piped-in medical gas and vacuum systems. These systems are covered in the 2024 edition of NFPA 99 (current version) under Chapter 5. The Rule was left generic in case the applicable chapter changes with each new version of NFPA 99.

In (3)(b), p.3, line 19, is "at a minimum" necessary? Is there something besides battery backup that is relevant here?
Response: Not all electrically operated medical equipment is provided with integral battery backup. Some equipment relies on an emergency electrical system supplied by a generator to identified electrical outlets to operate the equipment when there is a loss of normal power. Since there is no mandated requirement for these facilities to be provided with an emergency electrical system, this Rule is requiring, at a minimum, some type of battery backup system for medical equipment. This could be in the form of an integral battery to the equipment, or an uninterruptable power supply (UPS) in which medical equipment would be connected.

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

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".
Response: Issue addressed, added a comma.

In (d)(3), line 20, define "safe and adequate".
Response: Definition added to the definition section.

Thanks for defining the term, but there are some issues with the definition. First, I think you meant "reasonably preventing harm". That said, what does "reasonable" mean here? When is it unreasonable to prevent harm from occurring? Also, I assume you mean "preventing harm" to the patient, correct?
Response: Issue addressed, revised definition.

In (d)(3), line 21, when is revision "necessary"?
Response: Revisions are necessary when the current policies and procedures would not be able to provide safe and adequate care such as when there are changes to the standards of care applicable to the procedures. For example, changes in the standards of care for infection control may necessitate revisions to the clinics policies and procedures.

In (d)(3), line 22, "compliance" with what?
Response: This means compliance with regulations and standards of care.

Compliance with *what* regulations and *what* standards of care? Specify in the rule.
Response:

In (h), line 31, to whom and in what form is the certification required?
Response: Issue addressed.

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?

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

Response: The criteria are that the physical facilities are able to provide safe and adequate care and are otherwise compliant with section .0200.

You deleted paragraph (h), but I would note that per Rule .0201, Section .0200 only applies to "new" clinics and those that have undergone alteration.
Response: We have altered the text of section .0200 to clarify the physical plant standards that existing clinics must meet.

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).
Response: Issue addressed, section after semicolon removed.

To be clear, you deleted the whole of paragraph (h). Was that your intention?

Response: Yes, that was out intention. The comment was left over from a prior deletion.

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

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.

***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 meant by "essential"? What documents are "non-essential"?
Response: Issues addressed, "essential" removed. Documents identified in rule must be on file in the administrative office in the clinic.

In (a)(7), line 12, did you mean "the clinic as a party"?
Response: Issue addressed, "as" corrected.

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"?
Response: Issue addressed, clarified protocol for a referral of patients for whom the clinic has declined services.

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).
Response: Issue addressed; section removed.

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

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

AGENCY: N.C. Medical Care Commission

RULE CITATION: 10A NCAC 13S .0320

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, what is an "administrative decision regarding patients"?
Response: Issue addressed, administrative decisions include all of the decisions related to a patient's care and services such as admissions, billing, and services provided.

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.
Response: Issue addressed; rule revised.

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?
Response: Issue addressed; added requirement to have grievance policy in .0318. Also, added cross reference in rule .0320.

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

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)?
Response: No, they are the same.

Then in the interests of clarity, it would be best to use the defined term consistently throughout the rules.
Response: Issue addressed in text, used same term throughout.

I think you meant to say the *fetus's* gestational age, rather than the patient's.

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.
Response: Yes, this is the same one as in G.S. 90-21.82. Issue addressed, cross referenced in the rule.

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.
Response: Issue addressed in rule.

In (d), line 27, what qualifications are you requiring for the ultrasound technician?
Response: Issue addressed in rule.

"Trained" and "qualified" are just synonyms. The revision doesn't address the question.
Response: Issue addressed; removed technician qualification and training requirement.

In (e)(2), line 33, is "length of gestation" different than "gestational age"?
Response: No, they are the same.

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

Then in the interests of clarity, it would be best to use the defined term consistently throughout the rules.
Response: Issue addressed; used same term throughout.

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

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".
Response: Issued addressed and the rule text changed.

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

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"?
Response: Significance of the change was that this would not be limited only to nurses.

I'm not sure I understand the response. What would not be limited to nurses?
Response: The clinical staff includes more than just nurses. The clinical staff includes any staff member providing services in the clinic.

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)?
Response: Issue addressed by removing G.S. 90-640.

Well, that doesn't really address the issue. We still don't have a definition of "health care practitioner."
Response: Issue addressed; health care practitioner defined in Rule .0101

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?
Response: Issue addressed, "in the clinic" added to rule.

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

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

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".
Response: Issue addressed in rule text.
This just compounds the issue in Rule .0323. What is the definition of "health practitioner"?

Response: Issue addressed; health care practitioner added to Rule .0101.

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

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…"
Response: Issue addressed, "emergency case" moved to definitions rule.

In (a), line 6, delete the parentheses around "including severe pain", and incorporate into the body of the rule with commas.
Response: Issue addressed, sentenced moved to definition rule.

In (c), line 11, is an "emergency" the same as an "emergency case"? If not, define "emergency".
Response: Yes, this is the same.

Then why not use the defined term throughout your rules, for clarity.
Response: Issue addressed in text.

In (c), line 12, what does it mean to be "familiar" with the written instructions?
Response: Issue addressed in rule text.

The change from "familiar with" to "knowledgeable of" is just semantic. What does it mean to be "knowledgeable of" the instructions? Being aware of their existence? Having read them? Being able to quote them on demand?
Response: Issue addressed in text.

In (c)(1), line 13, what is an "untoward" complication? Please define.
Response: Issue addressed in rule text.

In (d)(2), are the "emergency protocols" different than the "emergency instructions" in (c)?
Response: No, the protocols are not different from the instructions.
Then please use the same terms throughout the rules, for clarity.

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

Response: Issue addressed in text.

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

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?

Response: Issue addressed, G.S. 90-640 taken out.

This just compounds the issue in Rule .0323. What is the definition of "health care practitioner"?

Response: Issue addressed; health care practitioner added to Rule .0101.

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

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

Burgos, Alexander N

From: Black, Shanah
Sent: Wednesday, September 18, 2024 4:21 PM
To: Liebman, Brian R; Burgos, Alexander N
Cc: Conley, Azzie
Subject: Medical Care Commission 10A NCAC 13S
Attachments: 09.2024 - Medical Care Commission 10A NCAC 13S Responses - BRL Replies.docx; 10A NCAC 13S .0101.docx; 10A NCAC 13S .0104.docx; 10A NCAC 13S .0201.docx; 10A NCAC 13S .0207.docx; 10A NCAC 13S .0212.docx; 10A NCAC 13S .0318.docx; 10A NCAC 13S .0319.docx; 10A NCAC 13S .0320.docx; 10A NCAC 13S .0321.docx; 10A NCAC 13S .0322.docx; 10A NCAC 13S .0323.docx; 10A NCAC 13S .0324.docx; 10A NCAC 13S .0325.docx; 10A NCAC 13S .0326.docx; 10A NCAC 13S .0327.docx; 10A NCAC 13S .0328.docx; 10A NCAC 13S .0329.docx; 10A NCAC 13S .0330.docx; 10A NCAC 13S .0331.docx

Good afternoon,

Hope you having a good day.

Please see attached the additional responses and changes to the 10A NCAC 13S rules.

Let us know if you have additional questions or need additional information.

Thanks

Shanah Black
Rule-making Coordinator
Division of Health Service Regulation
NC Department of Health and Human Services

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Fax: 919-733-2757
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809 Ruggles Drive, Edgerton Building
2701 Mail Service Center
Raleigh, NC 27699-2701

Request for Changes Pursuant to N.C. Gen. Stat. § 150B-21.10

Staff reviewed these Rules to ensure that each Rule is within the agency's statutory authority, reasonably necessary, clear and unambiguous, and adopted in accordance with Part 2 of the North Carolina Administrative Procedure Act. Following review, staff has issued this document that may request changes pursuant to G.S. 150B-21.10 from your agency or ask clarifying questions.

If the request includes questions, please contact the reviewing attorney to discuss.

In order to properly submit rewritten rules, please refer to the following Rules in the NC Administrative Code:

- Rule 26 NCAC 02C .0108 – The Rule addresses general formatting.
- Rule 26 NCAC 02C .0404 – The Rule addresses changing the introductory statement.
- Rule 26 NCAC 02C .0405 – The Rule addresses properly formatting changes made after publication in the NC Register.

Note the following general instructions:

1. You must submit the revised rule via email to oah.rules@oah.nc.gov. The electronic copy must be saved as the official rule name (XX NCAC XXXX).
2. For rules longer than one page, insert a page number.
3. Use line numbers; if the rule spans more than one page, have the line numbers reset at one for each page.
4. Do not use track changes. Make all changes using manual strikethroughs, underlines and highlighting.
5. You cannot change just one part of a word. For example:
    - Wrong: "~~a~~Association"
    - Right: "~~association~~ Association"
6. Treat punctuation as part of a word. For example:
    - Wrong: "day~~,~~; and"
    - Right: "~~day,~~ day; and"
7. Formatting instructions and examples may be found at: www.ncoah.com/rules/examples.html

If you have any questions regarding proper formatting of edits after reviewing the rules and examples, please contact the reviewing attorney.

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

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

AGENCY: N.C. Medical Care Commission

RULE CITATION: All Rules

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 many rules, there is a citation to G.S. 131E-153. As this statute is describes the purpose of the Act, and does not confer rulemaking authority, it can't be cited in the History Note as authority for these rules. Please delete.
Response: Issue addressed.

While I appreciate the convenience of the formatting, which shows the changes between the temporary rules and these permanent rules, that is not how our rules require permanent adoptions to be formatted. Please reformat per our formatting guide as "Permanent Adoption with no changes from publication", assuming there have been no post-publication changes.
Response: Issue addressed.

https://www.oah.nc.gov/rule-format-examples#RuleFormatExamplesforPublicationintheNCAdministrativeCode-6063

Also, this is part of the formatting, but I wanted to mention it independently, you need to change the headers to include the publication information. You'll see it in the link above, but it should say (using Rule .0101 as an example) "10A NCAC 13S .0101 is adopted as published in 38:24 NCR 1617-1623 as follows:"
Response: Issue addressed.

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

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?
Response: Added "health" to clarify conditions are health conditions that would impact clinics

I assumed they were health conditions. What health conditions are at issue here? What are you testing for?
Response: The clinic gets to decide what health conditions it would like to test. Tuberculosis is generally tested prior to hire. However, there may be other health conditions that the clinic may choose to test, such as Covid 19 or other infectious diseases.

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

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.

***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 13 and (b), lines 15-16, what standards will the Division use to review and approve the construction documents and specifications?
Response: The construction section of the division will review and approve the construction documents and specifications consistent with section .0200 of chapter 13S, which addresses the construction standards for clinics.

The rule doesn't say that. Please add a cross reference to Section .0200.
Response: Issue addressed; added cross reference.

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

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.

***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:

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?
Response: The provision does not impose a more stringent condition than the existing building code for alteration, repair, rehabilitation or addition. If an alteration, repair, rehabilitation, or addition is made to an existing building, the rule does not require that the entire building comply with the existing building code. In .0201(b) we are requiring buildings licensed for the first time to meet or exceed the minimum requirements of Group B occupancy of the Building Code at the time of initial licensing, which would be 2018 NCSBC if requesting licensure today. For currently licensed facilities that do an alteration, repair, rehabilitation or addition, this will require meeting the requirements of the current Building Code for the changes made to the building.

This is not what your rule says, and the text presents several problems.

In (a), you say only that "a clinic"—without making the distinction between a newly constructed clinic or an existing clinic—must meet the requirements of the 2024 Building Code. This language would appear to apply the 2024 Building Code to **all** clinics. However, in (b) you countermand that and say that Section .0200 only applies to "new clinics and any alterations… made to a previously licensed facility".

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

First, there is ambiguity as to what codes apply to what buildings. The Existing Building Code should apply to any existing, unaltered structures regardless of whether you include it in your rule, but its omission from the Rule creates a question as to what standards you will use to judge a clinic housed in an existing, unaltered structure, for licensure.
Response: Issue addressed with additional text. See below.

Second, there is ambiguity in when (b) applies. The text says that Section .0200 applies to "new clinics" (as opposed to new structures) and alterations, etc to a "previously licensed facility". If a new clinic opens in an existing, unaltered structure, then does Section .0200 apply? What about alterations made to a previously licensed facility that was already built to 2018/2024 standards?
Response: Issue addressed with additional text. Reworked sections (a) and (b) to clarify that existing licensed facilities need to meet the building code and construction rules in effect at the time of initial licensure or certification, and that new clinics, and any alterations, repairs, rehabilitation work, or additions must meet the requirements of Section .0200. As now reworked, all existing licensed clinics must meet the existing North Carolina State Building Code for Group B occupancy.

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?
Response: Yes, that is correct

Again, see above – what standards then are used to judge these clinics for licensure?
Response: Issue addressed with additional text.

In that case, what do those terms mean?
Response: The terms are defined in the building code. The definitions can be found in the 2018 North Carolina State Building Code located at https://codes.iccsafe.org/content/NCEBC2018/chapter-2-definitions.

If you mean to use the definitions as they appear in the Building Code, I think you need to incorporate them by reference here, pursuant to G.S. 150B-21.6.
Response: Issue addressed in text.

Moreover, if Section .0200 does not apply to existing clinics, then what criteria does the Commission use to determine if they should be licensed?
Response: As stated in .0104, an applicant who submits an application for a new clinic must submit construction documents and specifications for review and approval. Those documents are reviewed for compliance with the physical plant licensure rules contained in Section .0200.

This is not responsive to my question. I asked what you use to judge *existing* clinics, not *new* clinics.
Response: Issue addressed in text.

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

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

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.

***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:

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?
Response: An "area" in this context is space within the licensed facility not provided with walls that has been designated for a specific function

In (2), line 7, what are "pre-procedure and post-procedure activities"? Please define.
Response: Issue addressed; definitions added to Rule .0101

So, to be clear, you're allowing medical activities to occur in an open space. Does this have privacy ramifications under other State or Federal laws?
Response: No, providers are still required to comply with all privacy laws. Clinics are required to have a policy and procedure to ensure privacy during all medical services.

In (4), line 12, capitalize "state" when referring to the State of North Carolina.
Response: Issue addressed; change made.

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.
Response: Issue addressed, incorporated by reference the applicable federal regulation.

G.S. 150B-21.6 requires not only that you designate whether the incorporation includes subsequent amendments and editions, but also you must "specify in the rule both where copies of the material an be obtained and the cost on the date the rule is adopted of a copy of the material."
Response: Issue addressed; added requested information.

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

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

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.

***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:

Do the requirements of this Rule conflict with those required by the Building Code?
Response: No, the requirements in this rule do not conflict with 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?
Response: Issue addressed; this has been removed from the rule.

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.
Response: This URL is a direct link to the purchase of the most current edition of NFPA 99. The free access versions of all of the NFPAs are available on NFPA's website but there are several steps you must do to access the specific version you need when you get to the website. If this is not acceptable, the agency can provide its physical address where the NFPA-99 can be accessed.

If you can't provide a closer URL or more specific instructions for the free version, then I suppose the physical address would be better.
Response: Given that this is a code that is available for purchase the agency is not able to provide full copies of NFPA-99 free of charge. We have eliminated the free access text from the rule and have kept in the reference and the link to purchase the full NFPA-99 code.

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.
Response: Based on this Rule, the current edition of NFPA 99 would be applicable at the time of licensing, renovation, addition, etc. We have amended the rule to specify subsequent amendments will be applicable.

I don't see a change made. Is it incorrectly formatted?

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

Response: The text was previously added and can be found in lines 25 and 26 of the rule.

Finally, what chapter or section of NFPA-99 are you requiring compliance with? NFPA 99 has 15 chapters and 4 annexes.
Response: The requirement of this Rule is for licensed facilities that provide piped-in medical gas and vacuum systems. These systems are covered in the 2024 edition of NFPA 99 (current version) under Chapter 5. The Rule was left generic in case the applicable chapter changes with each new version of NFPA 99.

In (3)(b), p.3, line 19, is "at a minimum" necessary? Is there something besides battery backup that is relevant here?
Response: Not all electrically operated medical equipment is provided with integral battery backup. Some equipment relies on an emergency electrical system supplied by a generator to identified electrical outlets to operate the equipment when there is a loss of normal power. Since there is no mandated requirement for these facilities to be provided with an emergency electrical system, this Rule is requiring, at a minimum, some type of battery backup system for medical equipment. This could be in the form of an integral battery to the equipment, or an uninterruptable power supply (UPS) in which medical equipment would be connected.

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

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".
Response: Issue addressed, added a comma.

In (d)(3), line 20, define "safe and adequate".
Response: Definition added to the definition section.

Thanks for defining the term, but there are some issues with the definition. First, I think you meant "reasonably preventing harm". That said, what does "reasonable" mean here? When is it unreasonable to prevent harm from occurring? Also, I assume you mean "preventing harm" to the patient, correct?
Response: Issue addressed, revised definition.

In (d)(3), line 21, when is revision "necessary"?
Response: Revisions are necessary when the current policies and procedures would not be able to provide safe and adequate care such as when there are changes to the standards of care applicable to the procedures. For example, changes in the standards of care for infection control may necessitate revisions to the clinics policies and procedures.

In (d)(3), line 22, "compliance" with what?
Response: This means compliance with regulations and standards of care.

Compliance with *what* regulations and *what* standards of care? Specify in the rule.
Response:

In (h), line 31, to whom and in what form is the certification required?
Response: Issue addressed.

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?

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

Response: The criteria are that the physical facilities are able to provide safe and adequate care and are otherwise compliant with section .0200.

You deleted paragraph (h), but I would note that per Rule .0201, Section .0200 only applies to "new" clinics and those that have undergone alteration.
Response: We have altered the text of section .0200 to clarify the physical plant standards that existing clinics must meet.

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).
Response: Issue addressed, section after semicolon removed.

To be clear, you deleted the whole of paragraph (h). Was that your intention?

Response: Yes, that was out intention. The comment was left over from a prior deletion.

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

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.

***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 meant by "essential"? What documents are "non-essential"?
Response: Issues addressed, "essential" removed. Documents identified in rule must be on file in the administrative office in the clinic.

In (a)(7), line 12, did you mean "the clinic as a party"?
Response: Issue addressed, "as" corrected.

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"?
Response: Issue addressed, clarified protocol for a referral of patients for whom the clinic has declined services.

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).
Response: Issue addressed; section removed.

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

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

AGENCY: N.C. Medical Care Commission

RULE CITATION: 10A NCAC 13S .0320

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, what is an "administrative decision regarding patients"?
Response: Issue addressed, administrative decisions include all of the decisions related to a patient's care and services such as admissions, billing, and services provided.

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.
Response: Issue addressed; rule revised.

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?
Response: Issue addressed; added requirement to have grievance policy in .0318. Also, added cross reference in rule .0320.

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

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)?
Response: No, they are the same.

Then in the interests of clarity, it would be best to use the defined term consistently throughout the rules.
Response: Issue addressed in text, used same term throughout.

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.
Response: Yes, this is the same one as in G.S. 90-21.82. Issue addressed, cross referenced in the rule.

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.
Response: Issue addressed in rule.

In (d), line 27, what qualifications are you requiring for the ultrasound technician?
Response: Issue addressed in rule.

"Trained" and "qualified" are just synonyms. The revision doesn't address the question.
Response: Issue addressed; removed technician qualification and training requirement.

In (e)(2), line 33, is "length of gestation" different than "gestational age"?
Response: No, they are the same.

Then in the interests of clarity, it would be best to use the defined term consistently throughout the rules.

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

Response: Issue addressed; used same term throughout.

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

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".
Response: Issued addressed and the rule text changed.

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

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.

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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"?
Response: Significance of the change was that this would not be limited only to nurses.

I'm not sure I understand the response. What would not be limited to nurses?
Response: The clinical staff includes more than just nurses. The clinical staff includes any staff member providing services in the clinic.

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)?
Response: Issue addressed by removing G.S. 90-640.

Well, that doesn't really address the issue. We still don't have a definition of "health care practitioner."
Response: Issue addressed; health care practitioner defined in Rule .0101

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?
Response: Issue addressed, "in the clinic" added to rule.

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

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

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".
Response: Issue addressed in rule text.
This just compounds the issue in Rule .0323. What is the definition of "health practitioner"?

Response: Issue addressed; health care practitioner added to Rule .0101.

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

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…"
Response: Issue addressed, "emergency case" moved to definitions rule.

In (a), line 6, delete the parentheses around "including severe pain", and incorporate into the body of the rule with commas.
Response: Issue addressed, sentenced moved to definition rule.

In (c), line 11, is an "emergency" the same as an "emergency case"? If not, define "emergency".
Response: Yes, this is the same.

Then why not use the defined term throughout your rules, for clarity.
Response: Issue addressed in text.

In (c), line 12, what does it mean to be "familiar" with the written instructions?
Response: Issue addressed in rule text.

The change from "familiar with" to "knowledgeable of" is just semantic. What does it mean to be "knowledgeable of" the instructions? Being aware of their existence? Having read them? Being able to quote them on demand?
Response: Issue addressed in text.

In (c)(1), line 13, what is an "untoward" complication? Please define.
Response: Issue addressed in rule text.

In (d)(2), are the "emergency protocols" different than the "emergency instructions" in (c)?
Response: No, the protocols are not different from the instructions.
Then please use the same terms throughout the rules, for clarity.

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

Response: Issue addressed in text.

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

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?

Response: Issue addressed, G.S. 90-640 taken out.

This just compounds the issue in Rule .0323. What is the definition of "health care practitioner"?

Response: Issue addressed; health care practitioner added to Rule .0101.

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

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

10A NCAC 13S .0101 is adopted with changes as published in 38:24 NCR 1617–1623 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) "Emergency Case" is defined as a condition manifesting itself by acute symptoms of sufficient severity, including severe pain, such that the absence of immediate medical attention could reasonably be expected to result in placing the individual's health in serious jeopardy, serious impairment to bodily functions, or serious dysfunction of bodily organs.

~~(4)~~(5) "Gestational age" means the length of pregnancy as indicated by the date of the first day of the last normal monthly menstrual period, if known, or as determined by ultrasound.

~~(5)~~(6) "Governing authority" means the individual, agency, group, or corporation appointed, elected or otherwise designated, in which the ultimate responsibility and authority for the conduct of the abortion clinic is vested pursuant to Rule .0318 of this Subchapter.

(7) "Health Care Practitioner" means a physician, nurse practitioner, or physician's assistant licensed and authorized to practice in the state of North Carolina.

~~(6)~~(8) "Health Screening" means an evaluation of an employee or contractual employee, including tuberculosis testing, to identify any underlying health conditions that may affect the person's ability to work in the clinic.

~~(7)~~(9) "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.

(10) "Pre-procedure activities" are activities performed prior to the procedure to ensure that the patient is stable, and that the procedure can be safely performed.

(11) "Post-procedure" activities are activities performed after the procedure to ensure that the patient is stable for discharge.

~~(8)~~(12) "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.

(13) "Safe and adequate care" means care that meets the clinical needs of the patient while ~~reasonably~~ preventing harm from occurring.to the patient. ~~occurring.~~

History Note: *Authority G.S. ~~131E-153;~~ 131E-153.5; 143B-165.*
Eff. October 1, 2024.

10A NCAC 13S .0104 is adopted with changes as published in 38:24 NCR 1617-1623 as follows:

10A NCAC 13S .0104 PLANS AND SPECIFICATIONS

(a) Prior to issuance of a license pursuant to ~~Rule .0107 of this Section~~ 10A NCAC 14E .0107, an applicant for a new clinic shall submit one copy of construction documents and specifications to the Division for review and ~~approval.~~ approval consistent with Section .0200 of this Subchapter.

(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;*
Eff. October 1, 2024.

10A NCAC 13S .0201 is adopted with changes as published in 38:24 NCR 1617-1623 as follows:

SECTION .0200 - MINIMUM STANDARDS FOR CONSTRUCTION AND EQUIPMENT

10A NCAC 13S .0201 BUILDING CODE REQUIREMENTS

(a) ~~The physical plant for a clinic~~ Existing licensed clinics or portions of existing licensed clinics shall meet licensure and code requirements in effect at the time of licensure or certification, addition, renovation, or alteration; however, all clinics 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 https://shop.iccsafe.org/catalogsearch/result/?cat=1010&q=+North+Carolina+Building+code for a cost of eight hundred fifty eight dollars ($858.00) or accessed electronically free of charge at https://www.ncosfm.gov/codes/codes-current-and-past.

(b) Except as specified in subsection .0201(a) for existing clinics, ~~The~~ 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.~~ clinic.

(c) The definitions of alterations, repairs, rehabilitation work, and additions as used in this Rule are defined by the North Carolina State Building Code.

History Note: *Authority G.S. 131E-153.5; 143B-165;*
Eff. October 1, 2024.

10A NCAC 13S .0207 is adopted with changes as published in 38:24 NCR 1617-1623 as follows:

10A NCAC 13S .0207 AREA REQUIREMENTS

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

(1) reception and waiting room;

(2) designated area or areas for pre-procedure and post-procedure activities;

(3) procedure room;

(4) a clean area for self-contained secure medication storage complying with security requirements of ~~state~~ State and federal laws;

(5) area compliant with Clinical Laboratory Improvement Amendments (CLIA) requirements, 42 CFR Part 493, including subsequent amendments and additions, which are hereby incorporated by reference, available at https://www.ecfr.gov/current/title-42/chapter-IV/subchapter-G/part-493 at no cost, ~~requirements~~ in which laboratory testing can be performed;

(6) separate areas for storage and handling of clean and soiled materials;

(7) patient toilet;

(8) personnel toilet facilities;

(9) janitor's closets;

(10) space and equipment for assembling, sterilizing and storing medical and surgical supplies;

(11) storage space for medical records of all media types used by the facility; and

(12) space for charting, communications, counseling, business functions, and other administrative activities.

History Note: *Authority G.S. 131E-153.5; 143B-165;*
Eff. October 1, 2024.

10A NCAC 13S .0212 is adopted with changes as published in 38:24 NCR 1617-1623 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 requirements:

(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:

Area	Pressure Relationship	Minimum Total Air Changes/Hour
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) Piped-in medical gas and vacuum systems, if installed, shall meet the requirements of NFPA-99, category 2 system, which is hereby incorporated by reference including subsequent amendments and editions. Copies of NFPA-99 may be purchased from the National Fire Protection Association online at https://www.nfpa.org/product/nfpa-99-code/p0099code at a cost of one hundred forty-nine dollars ~~($149.00) or accessed electronically free of charge at http://www.nfpa.org.~~ ($149.00).

(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 ten (10) inches above the 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 facilities at a minimum temperature of 100 degrees F. and a maximum temperature of 116 degrees F.

(3) Electrical Requirements.

(a) The facility's paths of egress 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 1 foot 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.

(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;*
Eff. October 1, 2024.

10A NCAC 13S .0318 is adopted with changes as published in 38:24 NCR 1617-1623 as follows:

10A NCAC 13S .0318 GOVERNING AUTHORITY

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

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

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

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

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

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

(3) maintain a policies and procedures manual designed to ensure safe and adequate care for the patients which shall be reviewed, and revised when necessary, at least annually, and shall include provisions for administration and use of the clinic, ~~compliance~~, compliance with statutes and rules applicable to clinics including Subchapters 13S and 14E of Title 10A, compliance with a nationally standard recognized standard of care for infection control, personnel quality assurance, procurement of outside services and consultations, patient care policies, grievance policies, and services offered.

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

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

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

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

History Note: *Authority G.S. ~~131E-153;~~ 131E-153.5; 143B-165.*
Eff. October 1, 2024.

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10A NCAC 13S .0319 is adopted with changes as published in 38:24 NCR 1617-1623 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 ~~a~~ as 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 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) emergency protocols as required by Rule .0326;

(4) policy and procedure for validating the full and true name of the patient;

(5) policy and procedure for abortion procedures performed at the clinic;

(6) policy and procedure for the provision of patient privacy in the recovery area of the clinic;

(7) protocol for determining gestational age as defined in Rule .0101(4) of this Subchapter; and

(8) protocol for referral of patients ~~for whom services have been declined~~ declined services by the clinic. ~~and~~

~~(9) protocol that defines use of space to include opportunities that one area may accommodate various aspects of patient visits.~~

History Note: *Authority G.S. ~~131E-153;~~ 131E-153.5; 143B-165.*
Eff. October 1, 2024.

10A NCAC 13S .0320 is adopted with changes as published in 38:24 NCR 1617-1623 as follows:

10A NCAC 13S .0320 ADMISSION AND DISCHARGE

(a) There shall be on the premises throughout all hours of operation an employee authorized to receive patients and make administrative decisions regarding patients. Administrative decisions include all of the decisions related to a patient's care and services, such as admissions, billing, and services provided.

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

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

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

(1) a fee schedule and any extra charges routinely applied;

(2) the name of the attending physician or physicians and hospital admitting privileges~~, if any~~. In the absence of admitting privileges a statement documenting that the attending physician or physicians does not have admitting privileges ~~to that effect~~ shall be included;

(3) instructions for post-procedure problems and questions as outlined in Rule .0329(d) of this Section;

(4) grievance procedures a patient may follow if dissatisfied with the care and services rendered pursuant to the grievance policy as outlined in .0318(d)(3) of this Section; and

(5) the telephone number for Complaint Intake of the Division.

History Note: *Authority G.S. ~~131E-153;~~ 131E-153.5; 143B-165.*
Eff. October 1, 2024.

10A NCAC 13S .0321 is adopted with changes as published in 38:24 NCR 1617-1623 as follows:

10A NCAC 13S .0321 MEDICAL RECORDS

(a) The clinic shall maintain a complete and permanent record for all patients including:

(1) the date and time of admission and discharge;

(2) the patient's full and true name;

(3) the patient's address;

(4) the patient's date of birth;

(5) the patient's emergency contact information;

(6) the patient's diagnoses;

(7) the patient's ~~duration of pregnancy~~ gestational age;

(8) the patient's condition on admission and discharge;

(9) a voluntarily-signed consent for each procedure and signature of the physician performing the procedure witnessed by a family member, other patient representative, or facility staff member;

(10) a copy of the signed 72 hour consent and physician declaration as defined in G.S. 90-21.82;

(11) the patient's history and physical examination including identification of pre-existing or current illnesses, drug sensitivities or other idiosyncrasies that may impact the procedure or anesthetic to be administered; and

(12) documentation that indicates all items listed in Rule .0320(d) of this Section were provided to the patient.

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

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

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

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

(1) the patient name;

(2) the estimated ~~length of gestation~~ gestational age;

(3) the type of procedure;

(4) the name of the physician:

(5) the name of the Registered Nurse on duty; and

(6) the date and time of procedure.

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

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

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

History Note: *Authority G.S. ~~131E-153;~~ 131E-153.5; 143B-165.*
Eff. October 1, 2024.

10A NCAC 13S .0322 is adopted with changes as published in 38:24 NCR 1617-1623 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 or resume that includes education, training, experience and references; and

(C) a copy of a valid license (if required).

(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(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.*
Eff. October 1, 2024.

10A NCAC 13S .0323 is adopted with changes as published in 38:24 NCR 1617-1623 as follows:

10A NCAC 13S .0323 CLINIC STAFFING

(a) The clinic shall have an organized 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-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 procedure rooms and recovery area.

History Note: *Authority G.S. ~~131E-153;~~ 131E-153.5; 143B-165.*
Eff. October 1, 2024.

10A NCAC 13S .0324 is adopted with changes as published in 38:24 NCR 1617-1623 as follows:

10A NCAC 13S .0324 QUALITY ASSURANCE

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

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

(c) The committee shall consist of one physician who is not an owner, the chief executive officer or designee, and other health ~~professionals~~ practitioners.

(d) The frequency of meetings and details of data collection shall be defined by the governing authority.

History Note: *Authority G.S. ~~131E-153;~~ 131E-153.5; 143B-165.*
Eff. October 1, 2024.

10A NCAC 13S .0325 is adopted with changes as published in 38:24 NCR 1617-1623 as follows:

10A NCAC 13S .0325 LABORATORY SERVICES

(a) Each clinic shall have the capability to provide or obtain laboratory tests required in connection with the procedure to be performed, and will perform laboratory tests appropriate to their Clinical Laboratory Improvement Amendments (CLIA) certification.

(b) The governing authority shall establish written policies regarding which surgical specimens require examination by a pathologist.

(c) Each patient shall have laboratory testing as determined to be clinically necessary by the physician, or as required by law. A record of the results of any tests performed will be included in the patient's medical record.

(d) The clinic shall maintain a manual in a location accessible by employees, that meets requirements for the level of clinic's CLIA certification. This includes the procedures, instructions, and manufacturer's instructions for each test procedure performed including:

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

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

History Note: *Authority G.S. ~~131E-153;~~ 131E-153.5; 143B-165.*
Eff. October 1, 2024.

10A NCAC 13S .0326 is adopted with changes as published in 38:24 NCR 1617-1623 as follows:

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

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

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

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

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

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

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

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

(1) basic cardio-pulmonary life support;

(2) emergency ~~protocols~~ instructions for:

(A) administration of intravenous fluids;

(B) establishing and maintaining airway support;

(C) oxygen administration;

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

(E) utilizing an automated external defibrillator.

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

(4) ultrasound equipment.

History Note: *Authority G.S. ~~131E-153~~; 131E-153.5; 143B-165.*
Eff. October 1, 2024.

10A NCAC 13S .0327 is adopted with changes as published in 38:24 NCR 1617-1623 as follows:

10A NCAC 13S .0327 OUTPATIENT PROCEDURAL SERVICES

(a) The clinic shall establish procedures for infection control and universal precautions, including cleaning of all patient care areas including procedure rooms.

(b) Tissue Examination:

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

(2) If adequate tissue is not obtained based on the gestational age, the physician performing the procedure shall evaluate for ectopic pregnancy, or an incomplete procedure.

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

History Note: *Authority G.S. ~~131E-153~~; 131E-153.5; 143B-165.*
Eff. October 1, 2024.

10A NCAC 13S .0328 is adopted with changes as published in 38:24 NCR 1617-1623 as follows:

10A NCAC 13S .0328 MEDICATIONS AND SEDATION

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

(b) Medications, including injections shall be administered by a physician, Registered Nurse, and other health care practitioners ~~as defined in G.S. 90-640 (a)~~ practicing within the scope of their license or certification authorized by state laws to administer medications. All medications shall be recorded in the patient's permanent record.

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

History Note: *Authority G.S. ~~131E-153~~; 131E-153.5; 143B-165.*
Eff. October 1, 2024.

10A NCAC 13S .0329 is adopted with changes as published in 38:24 NCR 1617-1623 as follows:

10A NCAC 13S .0329 POST PROCEDURAL CARE

(a) A patient whose pregnancy is terminated shall be observed in the clinic to ensure that no post procedural complications are present. Thereafter, patients may be discharged according to a physician's order and the clinic's protocols.

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

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

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

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

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

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

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

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

History Note: *Authority G.S. ~~131E-153~~; 131E-153.5; 143B-165.*
Eff. October 1, 2024.

10A NCAC 13S .0330 is adopted with changes as published in 38:24 NCR 1617-1623 as follows:

10A NCAC 13S .0330 CLEANING OF MATERIALS AND EQUIPMENT

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

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

History Note: *Authority G.S. ~~131E-153~~; 131E-153.5; 143B-165.*
Eff. October 1, 2024.

10A NCAC 13S .0331 is adopted with changes as published in 38:24 NCR 1617-1623 as follows:

10A NCAC 13S .0331 FOOD SERVICE

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

History Note: *Authority G.S. ~~131E-153;~~131E-153.2; 131E-153.5; 143B-165.*
Eff. October 1, 2024.

Burgos, Alexander N

Subject: FW: September 2024 RRC - 10A NCAC 13S Requests for Changes

From: Black, Shanah <shanah.black@dhhs.nc.gov>
Sent: Tuesday, September 17, 2024 1:31 PM
To: Liebman, Brian R <brian.liebman@oah.nc.gov>
Cc: Conley, Azzie <azzie.conley@dhhs.nc.gov>; Burgos, Alexander N <alexander.burgos@oah.nc.gov>
Subject: RE: September 2024 RRC - 10A NCAC 13S Requests for Changes

Thank you for your speedy response.

Burgos, Alexander N

Subject: FW: September 2024 RRC - 10A NCAC 13S Requests for Changes
Attachments: 09.2024 - Medical Care Commission 10A NCAC 13S Responses - BRL Replies.docx

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From: Liebman, Brian R <brian.liebman@oah.nc.gov>
Sent: Tuesday, September 17, 2024 1:28 PM
To: Black, Shanah <shanah.black@dhhs.nc.gov>
Cc: Conley, Azzie <azzie.conley@dhhs.nc.gov>; Burgos, Alexander N <alexander.burgos@oah.nc.gov>
Subject: RE: September 2024 RRC - 10A NCAC 13S Requests for Changes

Hi Shanah,

Attached, please find my replies, in red, to your responses for most of the rules. Please send in your responses and revisions by Thursday at 5:00 p.m.

Thanks,
Brian

Brian Liebman
Counsel to the North Carolina Rules Review Commission
Office of Administrative Hearings
(984)236-1948
brian.liebman@oah.nc.gov

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

AGENCY: N.C. Medical Care Commission

RULE CITATION: All Rules

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 many rules, there is a citation to G.S. 131E-153. As this statute is describes the purpose of the Act, and does not confer rulemaking authority, it can't be cited in the History Note as authority for these rules. Please delete.
Response: Issue addressed.

While I appreciate the convenience of the formatting, which shows the changes between the temporary rules and these permanent rules, that is not how our rules require permanent adoptions to be formatted. Please reformat per our formatting guide as "Permanent Adoption with no changes from publication", assuming there have been no post-publication changes.
Response: Issue addressed.

https://www.oah.nc.gov/rule-format-examples#RuleFormatExamplesforPublicationintheNCAdministrativeCode-6063

Also, this is part of the formatting, but I wanted to mention it independently, you need to change the headers to include the publication information. You'll see it in the link above, but it should say (using Rule .0101 as an example) "10A NCAC 13S .0101 is adopted as published in 38:24 NCR 1617-1623 as follows:"
Response: Issue addressed.

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

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?
Response: Added "health" to clarify conditions are health conditions that would impact clinics

I assumed they were health conditions. What health conditions are at issue here? What are you testing for?

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

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.

***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 13 and (b), lines 15-16, what standards will the Division use to review and approve the construction documents and specifications?
Response: The construction section of the division will review and approve the construction documents and specifications consistent with section .0200 of chapter 13S, which addresses the construction standards for clinics.

The rule doesn't say that. Please add a cross reference to Section .0200.

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

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.

***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:

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?
Response: The provision does not impose a more stringent condition than the existing building code for alteration, repair, rehabilitation or addition. If an alteration, repair, rehabilitation, or addition is made to an existing building, the rule does not require that the entire building comply with the existing building code. In .0201(b) we are requiring buildings licensed for the first time to meet or exceed the minimum requirements of Group B occupancy of the Building Code at the time of initial licensing, which would be 2018 NCSBC if requesting licensure today. For currently licensed facilities that do an alteration, repair, rehabilitation or addition, this will require meeting the requirements of the current Building Code for the changes made to the building.

This is not what your rule says, and the text presents several problems.

In (a), you say only that "a clinic"—without making the distinction between a newly constructed clinic or an existing clinic—must meet the requirements of the 2024 Building Code. This language would appear to apply the 2024 Building Code to **all** clinics. However, in (b) you countermand that and say that Section .0200 only applies to "new clinics and any alterations… made to a previously licensed facility".

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

First, there is ambiguity as to what codes apply to what buildings. The Existing Building Code should apply to any existing, unaltered structures regardless of whether you include it in your rule, but its omission from the Rule creates a question as to what standards you will use to judge a clinic housed in an existing, unaltered structure, for licensure.

Second, there is ambiguity in when (b) applies. The text says that Section .0200 applies to "new clinics" (as opposed to new structures) and alterations, etc to a "previously licensed facility". If a new clinic opens in an existing, unaltered structure, then does Section .0200 apply? What about alterations made to a previously licensed facility that was already built to 2018/2024 standards?

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?
Response: Yes, that is correct

Again, see above – what standards then are used to judge these clinics for licensure?

In that case, what do those terms mean?
Response: The terms are defined in the building code. The definitions can be found in the 2018 North Carolina State Building Code located at https://codes.iccsafe.org/content/NCEBC2018/chapter-2-definitions.

If you mean to use the definitions as they appear in the Building Code, I think you need to incorporate them by reference here, pursuant to G.S. 150B-21.6.

Moreover, if Section .0200 does not apply to existing clinics, then what criteria does the Commission use to determine if they should be licensed?
Response: As stated in .0104, an applicant who submits an application for a new clinic must submit construction documents and specifications for review and approval. Those documents are reviewed for compliance with the physical plant licensure rules contained in Section .0200.

This is not responsive to my question. I asked what you use to judge *existing* clinics, not *new* clinics.

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

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.

***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:

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?
Response: An "area" in this context is space within the licensed facility not provided with walls that has been designated for a specific function

In (2), line 7, what are "pre-procedure and post-procedure activities"? Please define.
Response: Issue addressed; definitions added to Rule .0101

So, to be clear, you're allowing medical activities to occur in an open space. Does this have privacy ramifications under other State or Federal laws?

In (4), line 12, capitalize "state" when referring to the State of North Carolina.
Response: Issue addressed; change made.

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.
Response: Issue addressed, incorporated by reference the applicable federal regulation.

G.S. 150B-21.6 requires not only that you designate whether the incorporation includes subsequent amendments and editions, but also you must "specify in the rule both where copies of the material an be obtained and the cost on the date the rule is adopted of a copy of the material."

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

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.

***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:

Do the requirements of this Rule conflict with those required by the Building Code?
Response: No, the requirements in this rule do not conflict with 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?
Response: Issue addressed; this has been removed from the rule.

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.
Response: This URL is a direct link to the purchase of the most current edition of NFPA 99. The free access versions of all of the NFPAs are available on NFPA's website but there are several steps you must do to access the specific version you need when you get to the website. If this is not acceptable, the agency can provide its physical address where the NFPA-99 can be accessed.

If you can't provide a closer URL or more specific instructions for the free version, then I suppose the physical address would be better.

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.
Response: Based on this Rule, the current edition of NFPA 99 would be applicable at the time of licensing, renovation, addition, etc. We have amended the rule to specify subsequent amendments will be applicable.

I don't see a change made. Is it incorrectly formatted?

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

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

Response: The requirement of this Rule is for licensed facilities that provide piped-in medical gas and vacuum systems. These systems are covered in the 2024 edition of NFPA 99 (current version) under Chapter 5. The Rule was left generic in case the applicable chapter changes with each new version of NFPA 99.

In (3)(b), p.3, line 19, is "at a minimum" necessary? Is there something besides battery backup that is relevant here?
Response: Not all electrically operated medical equipment is provided with integral battery backup. Some equipment relies on an emergency electrical system supplied by a generator to identified electrical outlets to operate the equipment when there is a loss of normal power. Since there is no mandated requirement for these facilities to be provided with an emergency electrical system, this Rule is requiring, at a minimum, some type of battery backup system for medical equipment. This could be in the form of an integral battery to the equipment, or an uninterruptable power supply (UPS) in which medical equipment would be connected.

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

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".
Response: Issue addressed, added a comma.

In (d)(3), line 20, define "safe and adequate".
Response: Definition added to the definition section.

Thanks for defining the term, but there are some issues with the definition. First, I think you meant "reasonably preventing harm". That said, what does "reasonable" mean here? When is it unreasonable to prevent harm from occurring? Also, I assume you mean "preventing harm" to the patient, correct?

In (d)(3), line 21, when is revision "necessary"?
Response: Revisions are necessary when the current policies and procedures would not be able to provide safe and adequate care such as when there are changes to the standards of care applicable to the procedures. For example, changes in the standards of care for infection control may necessitate revisions to the clinics policies and procedures.

In (d)(3), line 22, "compliance" with what?
Response: This means compliance with regulations and standards of care.

Compliance with *what* regulations and *what* standards of care? Specify in the rule.

In (h), line 31, to whom and in what form is the certification required?
Response: Issue addressed.

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?
Response: The criteria are that the physical facilities are able to provide safe and adequate care and are otherwise compliant with section .0200.

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

You deleted paragraph (h), but I would note that per Rule .0201, Section .0200 only applies to "new" clinics and those that have undergone alteration.

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).
Response: Issue addressed, section after semicolon removed.

To be clear, you deleted the whole of paragraph (h). Was that your intention?

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

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.

***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 meant by "essential"? What documents are "non-essential"?
Response: Issues addressed, "essential" removed. Documents identified in rule must be on file in the administrative office in the clinic.

In (a)(7), line 12, did you mean "the clinic as a party"?
Response: Issue addressed, "as" corrected.

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"?
Response: Issue addressed, clarified protocol for a referral of patients for whom the clinic has declined services.

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).
Response: Issue addressed; section removed.

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

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

AGENCY: N.C. Medical Care Commission

RULE CITATION: 10A NCAC 13S .0320

DEADLINE FOR RECEIPT: Thursday, September 19, 2024.

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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, what is an "administrative decision regarding patients"?
Response: Issue addressed, administrative decisions include all of the decisions related to a patient's care and services such as admissions, billing, and services provided.

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.
Response: Issue addressed; rule revised.

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?
Response: Issue addressed; added requirement to have grievance policy in .0318. Also, added cross reference in rule .0320.

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

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.

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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)?
Response: No, they are the same.

Then in the interests of clarity, it would be best to use the defined term consistently throughout the rules.

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.
Response: Yes, this is the same one as in G.S. 90-21.82. Issue addressed, cross referenced in the rule.

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.
Response: Issue addressed in rule.

In (d), line 27, what qualifications are you requiring for the ultrasound technician?
Response: Issue addressed in rule.

"Trained" and "qualified" are just synonyms. The revision doesn't address the question.

In (e)(2), line 33, is "length of gestation" different than "gestational age"?
Response: No, they are the same.

Then in the interests of clarity, it would be best to use the defined term consistently throughout the rules.

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

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

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".
Response: Issued addressed and the rule text changed.

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

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"?
Response: Significance of the change was that this would not be limited only to nurses.

I'm not sure I understand the response. What would not be limited to nurses?

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)?
Response: Issue addressed by removing G.S. 90-640.

Well, that doesn't really address the issue. We still don't have a definition of "health care practitioner."

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?
Response: Issue addressed, "in the clinic" added to rule.

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

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

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".
Response: Issue addressed in rule text.
This just compounds the issue in Rule .0323. What is the definition of "health practitioner"?

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

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.

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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…"
Response: Issue addressed, "emergency case" moved to definitions rule.

In (a), line 6, delete the parentheses around "including severe pain", and incorporate into the body of the rule with commas.
Response: Issue addressed, sentenced moved to definition rule.

In (c), line 11, is an "emergency" the same as an "emergency case"? If not, define "emergency".
Response: Yes, this is the same.

Then why not use the defined term throughout your rules, for clarity.

In (c), line 12, what does it mean to be "familiar" with the written instructions?
Response: Issue addressed in rule text.

The change from "familiar with" to "knowledgeable of" is just semantic. What does it mean to be "knowledgeable of" the instructions? Being aware of their existence? Having read them? Being able to quote them on demand?

In (c)(1), line 13, what is an "untoward" complication? Please define.
Response: Issue addressed in rule text.

In (d)(2), are the "emergency protocols" different than the "emergency instructions" in (c)?
Response: No, the protocols are not different from the instructions.
Then please use the same terms throughout the rules, for clarity.

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

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

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?

Response: Issue addressed, G.S. 90-640 taken out.

This just compounds the issue in Rule .0323. What is the definition of "health care practitioner"?

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

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

Burgos, Alexander N

Subject: FW: September 2024 RRC - 10A NCAC 13S Requests for Changes
Attachments: 09.2024 - Medical Care Commission 10A NCAC 13S Responses.docx; 10A NCAC 13S .0101.docx; 10A NCAC 13S .0104.docx; 10A NCAC 13S .0201.docx; 10A NCAC 13S .0207.docx; 10A NCAC 13S .0212.docx; 10A NCAC 13S .0318.docx; 10A NCAC 13S .0319.docx; 10A NCAC 13S .0320.docx; 10A NCAC 13S .0321.docx; 10A NCAC 13S .0322.docx; 10A NCAC 13S .0323.docx; 10A NCAC 13S .0324.docx; 10A NCAC 13S .0325.docx; 10A NCAC 13S .0326.docx; 10A NCAC 13S .0327.docx; 10A NCAC 13S .0328.docx; 10A NCAC 13S .0329.docx; 10A NCAC 13S .0330.docx; 10A NCAC 13S .0331.docx

From: Black, Shanah <shanah.black@dhhs.nc.gov>
Sent: Monday, September 16, 2024 4:09 PM
To: Liebman, Brian R <brian.liebman@oah.nc.gov>
Cc: Conley, Azzie <azzie.conley@dhhs.nc.gov>; Burgos, Alexander N <alexander.burgos@oah.nc.gov>
Subject: RE: September 2024 RRC - 10A NCAC 13S Requests for Changes

Good afternoon Brian,

Attached are the revised rules for 10A NCAC 13S along with the responses to your questions.

Please email us if you have any additional questions.

Thanks, Shanah Black

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

AGENCY: N.C. Medical Care Commission

RULE CITATION: All Rules

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 many rules, there is a citation to G.S. 131E-153. As this statute is describes the purpose of the Act, and does not confer rulemaking authority, it can't be cited in the History Note as authority for these rules. Please delete.
Response: Issue addressed.

While I appreciate the convenience of the formatting, which shows the changes between the temporary rules and these permanent rules, that is not how our rules require permanent adoptions to be formatted. Please reformat per our formatting guide as "Permanent Adoption with no changes from publication", assuming there have been no post-publication changes.
Response: Issue addressed.

https://www.oah.nc.gov/rule-format-examples#RuleFormatExamplesforPublicationintheNCAdministrativeCode-6063

Also, this is part of the formatting, but I wanted to mention it independently, you need to change the headers to include the publication information. You'll see it in the link above, but it should say (using Rule .0101 as an example) "10A NCAC 13S .0101 is adopted as published in 38:24 NCR 1617-1623 as follows:"
Response: Issue addressed.

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

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?*
> **Response: Added "health" to clarify conditions are health conditions that would impact clinics**

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

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.

***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 13 and (b), lines 15-16, what standards will the Division use to review and approve the construction documents and specifications?
Response: The construction section of the division will review and approve the construction documents and specifications consistent with section .0200 of chapter 13S, which addresses the construction standards for clinics.

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

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.

***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:

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?
Response: The provision does not impose a more stringent condition than the existing building code for alteration, repair, rehabilitation or addition. If an alteration, repair, rehabilitation, or addition is made to an existing building, the rule does not require that the entire building comply with the existing building code. In .0201(b) we are requiring buildings licensed for the first time to meet or exceed the minimum requirements of Group B occupancy of the Building Code at the time of initial licensing, which would be 2018 NCSBC if requesting licensure today. For currently licensed facilities that do an alteration, repair, rehabilitation or addition, this will require meeting the requirements of the current Building Code for the changes made to the building.

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?
Response: Yes, that is correct

In that case, what do those terms mean?
Response: The terms are defined in the building code. The definitions can be found in the 2018 North Carolina State Building Code located at https://codes.iccsafe.org/content/NCEBC2018/chapter-2-definitions.

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

Moreover, if Section .0200 does not apply to existing clinics, then what criteria does the Commission use to determine if they should be licensed?
Response: As stated in .0104, an applicant who submits an application for a new clinic must submit construction documents and specifications for review and approval. Those documents are reviewed for compliance with the physical plant licensure rules contained in Section .0200.

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

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.

***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:

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?
Response: An "area" in this context is space within the licensed facility not provided with walls that has been designated for a specific function

In (2), line 7, what are "pre-procedure and post-procedure activities"? Please define.
Response: Issue addressed; definitions added to Rule .0101

In (4), line 12, capitalize "state" when referring to the State of North Carolina.
Response: Issue addressed; change made.

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.
Response: Issue addressed, incorporated by reference the applicable federal regulation.

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

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.

***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:

Do the requirements of this Rule conflict with those required by the Building Code?
Response: No, the requirements in this rule do not conflict with 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?
Response: Issue addressed; this has been removed from the rule.

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.
Response: This URL is a direct link to the purchase of the most current edition of NFPA 99. The free access versions of all of the NFPAs are available on NFPA's website but there are several steps you must do to access the specific version you need when you get to the website. If this is not acceptable, the agency can provide its physical address where the NFPA-99 can be accessed.

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.
Response: Based on this Rule, the current edition of NFPA 99 would be applicable at the time of licensing, renovation, addition, etc. We have amended the rule to specify subsequent amendments will be applicable.

Finally, what chapter or section of NFPA-99 are you requiring compliance with? NFPA 99 has 15 chapters and 4 annexes.
Response: The requirement of this Rule is for licensed facilities that provide piped-in medical gas and vacuum systems. These systems are covered in the 2024 edition of NFPA 99 (current version) under Chapter 5. The Rule was left generic in case the applicable chapter changes with each new version of NFPA 99.

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

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

Response: Not all electrically operated medical equipment is provided with integral battery backup. Some equipment relies on an emergency electrical system supplied by a generator to identified electrical outlets to operate the equipment when there is a loss of normal power. Since there is no mandated requirement for these facilities to be provided with an emergency electrical system, this Rule is requiring, at a minimum, some type of battery backup system for medical equipment. This could be in the form of an integral battery to the equipment, or an uninterruptable power supply (UPS) in which medical equipment would be connected.

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

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".
Response: Issue addressed, added a comma.

In (d)(3), line 20, define "safe and adequate".
Response: Definition added to the definition section.

In (d)(3), line 21, when is revision "necessary"?
Response: Revisions are necessary when the current policies and procedures would not be able to provide safe and adequate care such as when there are changes to the standards of care applicable to the procedures. For example, changes in the standards of care for infection control may necessitate revisions to the clinics policies and procedures.

In (d)(3), line 22, "compliance" with what?
Response: This means compliance with regulations and standards of care.

In (h), line 31, to whom and in what form is the certification required?
Response: Issue addressed.

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?
Response: The criteria are that the physical facilities are able to provide safe and adequate care and are otherwise compliant with section .0200.

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).
Response: Issue addressed, section after semicolon removed.

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

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

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.

***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 meant by "essential"? What documents are "non-essential"?
Response: Issues addressed, "essential" removed. Documents identified in rule must be on file in the administrative office in the clinic.

In (a)(7), line 12, did you mean "the clinic as a party"?
Response: Issue addressed, "as" corrected.

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"?
Response: Issue addressed, clarified protocol for a referral of patients for whom the clinic has declined services.

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).
Response: Issue addressed; section removed.

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

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

AGENCY: N.C. Medical Care Commission

RULE CITATION: 10A NCAC 13S .0320

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, what is an "administrative decision regarding patients"?
Response: Issue addressed, administrative decisions include all of the decisions related to a patient's care and services such as admissions, billing, and services provided.

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.
Response: Issue addressed; rule revised.

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?
Response: Issue addressed; added requirement to have grievance policy in .0318. Also, added cross reference in rule .0320.

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

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)?
Response: No, they are the same.

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.
Response: Yes, this is the same one as in G.S. 90-21.82. Issue addressed, cross referenced in the rule.

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.
Response: Issue addressed in rule.

In (d), line 27, what qualifications are you requiring for the ultrasound technician?
Response: Issue addressed in rule.

In (e)(2), line 33, is "length of gestation" different than "gestational age"?
Response: No, they are the same.

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

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.

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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".
Response: Issued addressed and the rule text changed.

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

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.

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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"?
Response: Significance of the change was that this would not be limited only to nurses.

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)?
Response: Issue addressed by removing G.S. 90-640.

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?
Response: Issue addressed, "in the clinic" added to rule.

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

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".
Response: Issue addressed in rule text.

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

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…"
Response: Issue addressed, "emergency case" moved to definitions rule.

In (a), line 6, delete the parentheses around "including severe pain", and incorporate into the body of the rule with commas.
Response: Issue addressed, sentenced moved to definition rule.

In (c), line 11, is an "emergency" the same as an "emergency case"? If not, define "emergency".
Response: Yes, this is the same.

In (c), line 12, what does it mean to be "familiar" with the written instructions?
Response: Issue addressed in rule text.

In (c)(1), line 13, what is an "untoward" complication? Please define.
Response: Issue addressed in rule text.

In (d)(2), are the "emergency protocols" different than the "emergency instructions" in (c)?
Response: No, the protocols are not different from the instructions.

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

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?

Response: Issue addressed, G.S. 90-640 taken out.

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

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

10A NCAC 13S .0101 is adopted with changes as published in 38:24 NCR 1617–1623 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) “Emergency Case” is defined as a condition manifesting itself by acute symptoms of sufficient severity, including severe pain, such that the absence of immediate medical attention could reasonably be expected to result in placing the individual’s health in serious jeopardy, serious impairment to bodily functions, or serious dysfunction of bodily organs.

~~(4)~~(5) "Gestational age" means the length of pregnancy as indicated by the date of the first day of the last normal monthly menstrual period, if known, or as determined by ultrasound.

~~(5)~~(6) "Governing authority" means the individual, agency, group, or corporation appointed, elected or otherwise designated, in which the ultimate responsibility and authority for the conduct of the abortion clinic is vested pursuant to Rule .0318 of this Subchapter.

~~(6)~~(7) "Health Screening" means an evaluation of an employee or contractual employee, including tuberculosis testing, to identify any underlying health conditions that may affect the person's ability to work in the clinic.

~~(7)~~(8) "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.

(9) “Pre-procedure activities” are activities performed prior to the procedure to ensure that the patient is stable, and that the procedure can be safely performed.

(10) “Post-procedure” activities are activities performed after the procedure to ensure that the patient is stable for discharge.

~~(8)~~(11) "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.

(12) “Safe and adequate care” means care that meets the clinical needs of the patient while reasonable preventing harm from occurring.

History Note: *Authority G.S. ~~131E-153;~~ 131E-153.5; 143B-165.*
Eff. October 1, 2024.

10A NCAC 13S .0104 is adopted as published in 38:24 NCR 1617-1623 as follows:

10A NCAC 13S .0104 PLANS AND SPECIFICATIONS

(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;*
Eff. October 1, 2024.

10A NCAC 13S .0201 is adopted as published in 38:24 NCR 1617-1623 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 https://shop.iccsafe.org/catalogsearch/result/?cat=1010&q=+North+Carolina+Building+code for a cost of eight hundred fifty eight dollars ($858.00) or accessed electronically free of charge at 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;*
Eff. October 1, 2024.

10A NCAC 13S .0207 is adopted with changes as published in 38:24 NCR 1617-1623 as follows:

10A NCAC 13S .0207 AREA REQUIREMENTS

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

(1) reception and waiting room;

(2) designated area or areas for pre-procedure and post-procedure activities;

(3) procedure room;

(4) a clean area for self-contained secure medication storage complying with security requirements of ~~state~~ State and federal laws;

(5) area compliant with Clinical Laboratory Improvement Amendments (CLIA), 42 CFR Part 493, including subsequent amendments and additions, requirements in which laboratory testing can be performed;

(6) separate areas for storage and handling of clean and soiled materials;

(7) patient toilet;

(8) personnel toilet facilities;

(9) janitor's closets;

(10) space and equipment for assembling, sterilizing and storing medical and surgical supplies;

(11) storage space for medical records of all media types used by the facility; and

(12) space for charting, communications, counseling, business functions, and other administrative activities.

History Note: *Authority G.S. 131E-153.5; 143B-165;*
Eff. October 1, 2024.

10A NCAC 13S .0212 is adopted with changes as published in 38:24 NCR 1617-1623 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 requirements:

(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:

Area	Pressure Relationship	Minimum Total Air Changes/Hour
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) Piped-in medical gas and vacuum systems, if installed, shall meet the requirements of NFPA-99, category 2 system, which is hereby incorporated by reference including subsequent amendments and editions. Copies of NFPA-99 may be purchased from the National Fire Protection Association online at https://www.nfpa.org/product/nfpa-99-code/p0099code at a cost of one hundred forty-nine dollars ($149.00) 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 ten (10) inches above the 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 facilities at a minimum temperature of 100 degrees F. and a maximum temperature of 116 degrees F.

(3) Electrical Requirements.

(a) The facility's paths of egress 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 1 foot 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.

(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;*
Eff. October 1, 2024.

10A NCAC 13S .0318 is adopted with changes as published in 38:24 NCR 1617-1623 as follows:

10A NCAC 13S .0318 GOVERNING AUTHORITY

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

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

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

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

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

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

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

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

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

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

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

History Note: *Authority G.S. ~~131E-153;~~ 131E-153.5; 143B-165.*
Eff. October 1, 2024.

10A NCAC 13S .0319 is adopted with changes as published in 38:24 NCR 1617-1623 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 ~~a~~ as 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 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) emergency protocols as required by Rule .0326;

(4) policy and procedure for validating the full and true name of the patient;

(5) policy and procedure for abortion procedures performed at the clinic;

(6) policy and procedure for the provision of patient privacy in the recovery area of the clinic;

(7) protocol for determining gestational age as defined in Rule .0101(4) of this Subchapter; and

(8) protocol for referral of patients ~~for whom services have been declined~~ declined services by the clinic. ~~and~~

~~(9) protocol that defines use of space to include opportunities that one area may accommodate various aspects of patient visits.~~

History Note: *Authority G.S. ~~131E-153;~~ 131E-153.5; 143B-165.*
Eff. October 1, 2024.

10A NCAC 13S .0320 is adopted with changes as published in 38:24 NCR 1617-1623 as follows:

10A NCAC 13S .0320 ADMISSION AND DISCHARGE

(a) There shall be on the premises throughout all hours of operation an employee authorized to receive patients and make administrative decisions regarding patients. Administrative decisions include all of the decisions related to a patient's care and services such as admissions, billing, and services provided.

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

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

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

(1) a fee schedule and any extra charges routinely applied;

(2) the name of the attending physician or physicians and hospital admitting privileges~~, if any~~. In the absence of admitting privileges a statement documenting that the attending physician or physicians does not have admitting privileges ~~to that effect~~ shall be included;

(3) instructions for post-procedure problems and questions as outlined in Rule .0329(d) of this Section;

(4) grievance procedures a patient may follow if dissatisfied with the care and services rendered pursuant to the grievance policy as outlined in .0318(d)(3) of this Section; and

(5) the telephone number for Complaint Intake of the Division.

History Note: *Authority G.S. ~~131E-153;~~ 131E-153.5; 143B-165.*
Eff. October 1, 2024.

10A NCAC 13S .0321 is adopted with changes as published in 38:24 NCR 1617-1623 as follows:

10A NCAC 13S .0321 MEDICAL RECORDS

(a) The clinic shall maintain a complete and permanent record for all patients including:

(1) the date and time of admission and discharge;

(2) the patient's full and true name;

(3) the patient's address;

(4) the patient's date of birth;

(5) the patient's emergency contact information;

(6) the patient's diagnoses;

(7) the patient's duration of pregnancy;

(8) the patient's condition on admission and discharge;

(9) a voluntarily-signed consent for each procedure and signature of the physician performing the procedure witnessed by a family member, other patient representative, or facility staff member;

(10) a copy of the signed 72 hour consent and physician declaration as defined in G.S. 90-21.82;

(11) the patient's history and physical examination including identification of pre-existing or current illnesses, drug sensitivities or other idiosyncrasies that may impact the procedure or anesthetic to be administered; and

(12) documentation that indicates all items listed in Rule .0320(d) of this Section were provided to the patient.

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

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

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

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

(1) the patient name;

(2) the estimated length of gestation;

(3) the type of procedure;

(4) the name of the physician:

(5) the name of the Registered Nurse on duty; and

(6) the date and time of procedure.

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

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

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

History Note: *Authority G.S. ~~131E-153;~~ 131E-153.5; 143B-165.*
Eff. October 1, 2024.

10A NCAC 13S .0322 is adopted with changes as published in 38:24 NCR 1617-1623 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 or resume that includes education, training, experience and references; and

(C) a copy of a valid license (if required).

(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(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.*
Eff. October 1, 2024.

10A NCAC 13S .0323 is adopted with changes as published in 38:24 NCR 1617-1623 as follows:

10A NCAC 13S .0323 CLINIC STAFFING

(a) The clinic shall have an organized 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-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 procedure rooms and recovery area.

History Note: *Authority G.S. ~~131E-153;~~ 131E-153.5; 143B-165.*
Eff. October 1, 2024.

10A NCAC 13S .0324 is adopted with changes as published in 38:24 NCR 1617-1623 as follows:

10A NCAC 13S .0324 QUALITY ASSURANCE

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

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

(c) The committee shall consist of one physician who is not an owner, the chief executive officer or designee, and other health ~~professionals~~ practitioners.

(d) The frequency of meetings and details of data collection shall be defined by the governing authority.

History Note: *Authority G.S. ~~131E-153;~~ 131E-153.5; 143B-165.*
Eff. October 1, 2024.

10A NCAC 13S .0325 is adopted with changes as published in 38:24 NCR 1617-1623 as follows:

10A NCAC 13S .0325 LABORATORY SERVICES

(a) Each clinic shall have the capability to provide or obtain laboratory tests required in connection with the procedure to be performed, and will perform laboratory tests appropriate to their Clinical Laboratory Improvement Amendments (CLIA) certification.

(b) The governing authority shall establish written policies regarding which surgical specimens require examination by a pathologist.

(c) Each patient shall have laboratory testing as determined to be clinically necessary by the physician, or as required by law. A record of the results of any tests performed will be included in the patient's medical record.

(d) The clinic shall maintain a manual in a location accessible by employees, that meets requirements for the level of clinic's CLIA certification. This includes the procedures, instructions, and manufacturer's instructions for each test procedure performed including:

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

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

History Note: *Authority G.S. ~~131E-153;~~ 131E-153.5; 143B-165.*
Eff. October 1, 2024.

10A NCAC 13S .0326 is adopted with changes as published in 38:24 NCR 1617-1623 as follows:

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

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

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

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

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

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

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

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

(1) basic cardio-pulmonary life support;

(2) emergency protocols for:

(A) administration of intravenous fluids;

(B) establishing and maintaining airway support;

(C) oxygen administration;

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

(E) utilizing an automated external defibrillator.

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

(4) ultrasound equipment.

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

Eff. October 1, 2024.

10A NCAC 13S .0327 is adopted with changes as published in 38:24 NCR 1617-1623 as follows:

10A NCAC 13S .0327 OUTPATIENT PROCEDURAL SERVICES

(a) The clinic shall establish procedures for infection control and universal precautions, including cleaning of all patient care areas including procedure rooms.

(b) Tissue Examination:

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

(2) If adequate tissue is not obtained based on the gestational age, the physician performing the procedure shall evaluate for ectopic pregnancy, or an incomplete procedure.

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

History Note: *Authority G.S. ~~131E-153~~; 131E-153.5; 143B-165.*
Eff. October 1, 2024.

10A NCAC 13S .0328 is adopted with changes as published in 38:24 NCR 1617-1623 as follows:

10A NCAC 13S .0328 MEDICATIONS AND SEDATION

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

(b) Medications, including injections shall be administered by a physician, Registered Nurse, and other health care practitioners ~~as defined in G.S. 90-640 (a)~~ practicing within the scope of their license or certification authorized by state laws to administer medications. All medications shall be recorded in the patient's permanent record.

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

History Note: *Authority G.S. ~~131E-153~~; 131E-153.5; 143B-165.*
Eff. October 1, 2024.

10A NCAC 13S .0329 is adopted with changes as published in 38:24 NCR 1617-1623 as follows:

10A NCAC 13S .0329 POST PROCEDURAL CARE

(a) A patient whose pregnancy is terminated shall be observed in the clinic to ensure that no post procedural complications are present. Thereafter, patients may be discharged according to a physician's order and the clinic's protocols.

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

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

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

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

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

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

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

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

History Note: *Authority G.S. ~~131E-153~~; 131E-153.5; 143B-165.*
Eff. October 1, 2024.

10A NCAC 13S .0330 is adopted with changes as published in 38:24 NCR 1617-1623 as follows:

10A NCAC 13S .0330 CLEANING OF MATERIALS AND EQUIPMENT

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

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

History Note: *Authority G.S. ~~131E-153~~; 131E-153.5; 143B-165.*
Eff. October 1, 2024.

10A NCAC 13S .0331 is adopted with changes as published in 38:24 NCR 1617-1623 as follows:

10A NCAC 13S .0331 FOOD SERVICE

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

History Note: *Authority G.S. ~~131E-153;~~131E-153.2; 131E-153.5; 143B-165.*
Eff. October 1, 2024.

Burgos, Alexander N

From: Black, Shanah
Sent: Thursday, September 5, 2024 10:55 AM
To: Liebman, Brian R
Cc: Conley, Azzie; Burgos, Alexander N
Subject: RE: September 2024 RRC - 10A NCAC 13S Requests for Changes

Categories: Red Category

Thank you for your assistance. We will get back to you with revisions.

From: Liebman, Brian R <brian.liebman@oah.nc.gov>
Sent: Thursday, September 5, 2024 10:11 AM
To: Black, Shanah <shanah.black@dhhs.nc.gov>
Cc: Conley, Azzie <azzie.conley@dhhs.nc.gov>; Burgos, Alexander N <alexander.burgos@oah.nc.gov>
Subject: September 2024 RRC - 10A NCAC 13S Requests for Changes

Good morning,

I'm the attorney who reviewed the Rules submitted by the Medical Care Commission for the September 2024 RRC meeting. The RRC will formally review these Rules at its meeting on Wednesday, September 25, 2024, at 10:00 a.m. The meeting will be a hybrid of in-person and WebEx attendance, and an evite should be sent to you as we get closer to the meeting. If there are any other representatives from your agency who will want to attend virtually, let me know prior to the meeting, and we will get evites out to them as well.

Please submit the revised Rules and forms to me via email, no later than 5 p.m. on Thursday, September 19, 2024.

In the meantime, please do not hesitate to reach out via email with any questions or concerns.

Thanks,

Brian

Brian Liebman
Counsel to the North Carolina Rules Review Commission
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