

Burgos, Alexander N

Subject: FW: Temporary Rules 10A NCAC 14E - Requests for Changes - October 2023 RRC

From: Liebman, Brian R <brian.liebman@oah.nc.gov>
Sent: Wednesday, December 13, 2023 5:16 PM
To: Corpening, Taylor <taylor.corpening@dhhs.nc.gov>
Cc: Burgos, Alexander N <alexander.burgos@oah.nc.gov>; Premakumar, Rajeev K <raj.premakumar@dhhs.nc.gov>
Subject: RE: Temporary Rules 10A NCAC 14E - Requests for Changes - October 2023 RRC

Thanks so much Taylor.

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

E-mail correspondence to and from this address may be subject to the North Carolina Public Records Law N.C.G.S. Chapter 132 and may be disclosed to third parties.

From: Corpening, Taylor <taylor.corpening@dhhs.nc.gov>
Sent: Wednesday, December 13, 2023 4:24 PM
To: Liebman, Brian R <brian.liebman@oah.nc.gov>
Cc: Burgos, Alexander N <alexander.burgos@oah.nc.gov>; Premakumar, Rajeev K <raj.premakumar@dhhs.nc.gov>
Subject: RE: Temporary Rules 10A NCAC 14E - Requests for Changes - October 2023 RRC

Hi Brian,

I have attached the meeting agenda and emailed the final version of the rules to the OAH.

Thanks,
Taylor Corpening
Rule-making Coordinator
Division of Health Service Regulation
[NC Department of Health and Human Services](#)

Work Cell: 919-896-9371
Office: 919-855-4619
Fax: 919-733-2757
taylor.corpening@dhhs.nc.gov

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

From: Liebman, Brian R <brian.liebman@oah.nc.gov>
Sent: Wednesday, December 13, 2023 3:30 PM
To: Corpening, Taylor <taylor.corpening@dhhs.nc.gov>

Cc: Burgos, Alexander N <alexander.burgos@oah.nc.gov>; Premakumar, Rajeev K <raj.premakumar@dhhs.nc.gov>

Subject: RE: Temporary Rules 10A NCAC 14E - Requests for Changes - October 2023 RRC

Sounds good. Please send the final revised version of all rules to oah.rules@oah.nc.gov, copying me and Alex, and I think we'll be good to go for the meeting.

Brian

Brian Liebman

Counsel to the North Carolina Rules Review Commission

Office of Administrative Hearings

(984)236-1948

brian.liebman@oah.nc.gov

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From: Corpening, Taylor <taylor.corpening@dhhs.nc.gov>

Sent: Wednesday, December 13, 2023 2:43 PM

To: Liebman, Brian R <brian.liebman@oah.nc.gov>

Cc: Burgos, Alexander N <alexander.burgos@oah.nc.gov>; Premakumar, Rajeev K <raj.premakumar@dhhs.nc.gov>

Subject: RE: Temporary Rules 10A NCAC 14E - Requests for Changes - October 2023 RRC

Hi Brian,

Thank you for your email. The meeting is scheduled for Monday, December 18th at 11:30 am. I will get the agenda to you shortly.

Thanks,

Taylor Corpening

Rule-making Coordinator

Division of Health Service Regulation

[NC Department of Health and Human Services](#)

Work Cell: 919-896-9371

Office: 919-855-4619

Fax: 919-733-2757

taylor.corpening@dhhs.nc.gov

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**STATE OF NORTH CAROLINA
DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**MEDICAL CARE COMMISSION QUARTERLY MEETING
DIVISION OF HEALTH SERVICE REGULATION
809 RUGGLES DRIVE, RALEIGH NC 27603
EDGERTON BUILDING
CONFERENCE ROOM – 026A**

OR

TEAMS Video Conference: [Click here to join the meeting](#)

OR

Dial-IN: 1-984-204-1487 / Passcode: 675 543 670#

**December 18, 2023 (Monday)
11:30 a.m.**

Agenda

I. Meeting Opens – Roll Call

II. Chairman’s Comments..... Dr. John Meier

III. Public Meeting Statement..... Dr. John Meier

This meeting of the Medical Care Commission is open to the public but is not a public hearing. Therefore, any discussion will be limited to members of the Commission and staff unless questions are specifically directed by the Commission to someone in the audience.

IV. Ethics Statement..... Dr. John Meier

The State Government Ethics Act requires members to act in the best interest of the public and adhere to the ethical standards and rules of conduct in the State Government Ethics Act, including the duty to continually monitor, evaluate, and manage personal, financial, and professional affairs to ensure the absence of conflicts of interest.

V. New Business

A. Rules for Adoption (Discuss rules)

1. Acute & Home Care Licensure Rules..... Taylor Corpening & A. Conley

Emergency rulemaking to withdraw three emergency abortion rules, which are rendered unnecessary. (Withdrawal of 3 rules)

- **Rules:** 10A NCAC 13S .0106, .0107, & .0109.
See Exhibit A)

VI. Meeting Adjournment

Burgos, Alexander N

Subject: FW: Temporary Rules 10A NCAC 14E - Requests for Changes - October 2023 RRC

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Subject: RE: Temporary Rules 10A NCAC 14E - Requests for Changes - October 2023 RRC

Hey Taylor,

Thanks for the follow up. I think I would feel better about this if, before tomorrow's meeting, I had the meeting date and an agenda for MCC, that would confirm the emergency rules are going to be repealed. In the absence of that, I don't know how I can represent to RRC that the repeal is going to occur, and I'd probably have to recommend objection.

Thanks,
Brian

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

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Burgos, Alexander N

Subject: FW: Temporary Rules 10A NCAC 14E - Requests for Changes - October 2023 RRC

From: Liebman, Brian R <brian.liebman@oah.nc.gov>
Sent: Monday, December 11, 2023 5:38 PM
To: Corpening, Taylor <taylor.corpening@dhhs.nc.gov>
Cc: Burgos, Alexander N <alexander.burgos@oah.nc.gov>; Premakumar, Rajeev K <raj.premakumar@dhhs.nc.gov>
Subject: RE: Temporary Rules 10A NCAC 14E - Requests for Changes - October 2023 RRC

Taylor,

Thanks for the quick turnaround on the edits. One last quibble on .0107 – if you don't have an (a)(2), you can't have an (a)(1). Just collapse it into one sentence and you should be good to go; I think that satisfies the outstanding objection.

On the necessity problem, I cannot advise either DHHS or MCC on how to proceed. What I can tell you is that if the MCC's emergency rules are out of the code by the effective date of the equivalent DHHS temp rule, I think that would avoid an objection. Under 150B-21.1, RRC has 2 business days to transmit an approved temporary rule to the Codifier, and then the Codifier must enter the rule into the Code on the 6th business day following receipt from RRC. Otherwise, to the extent the emergency rule and the equivalent temporary rule overlap, I would have to recommend objection for lack of necessity. Another thing I think I can say is that MCC is its own rulemaking body – I am not aware of any delegation or other provision allowing the *Department* to take action on MCC's rules. Regardless, the MCC emergency rules are not before RRC; emergency rules are reviewed by the Codifier.

The best advice I can give would be for DHHS and MCC to examine 150B's provisions on temporary rules, emergency rules, and effective dates, and see what they think would work in this situation.

Best,
Brian

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

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Brian,

Thank you for the prompt response and feedback on rules 10A NCAC 14E .0106, .0107, and .0109.

History Note and Effective Date

In response to your global concerns regarding the history notes and effective dates, the rules have been updated to remove references to other rules and the effective date of the rules has been updated.

10A NCAC 14E .0107

In response to your remaining objection to 10A NCAC 14E .0107, we have removed section (a)(2) from the rule. We believe this resolves the statutory authority objection.

10A NCAC 14E .0106 and .0109

We are glad that the substantive objections to 10A NCAC 14E .0106 and .0109 regarding initial and renewal applications have been resolved.

On the issue of necessity, the Department agrees that “rulemaking authority [is] explicitly given to the Department” to adopt rules regarding clinic applications. The Medical Care Commission (“MCC”) adopted rules regarding the application process in light of the statutory authority objections from the Commission, and is willing to withdraw the 10A NCAC 13S .0106 and .0109 emergency rules and temporary rulemaking applications. However, the agency is concerned about withdrawing the MCC’s emergency rules prior to the adoption of the temporary rules for the purposes of continuity.

In short, DHHS would like to advance the **Department’s** application rules as temporary rules, 10A NCAC 14E .0106 and .0109, and ultimately withdraw the MCC’s mirror application rules. We would appreciate any input on how to have these rules adopted without necessity objection based on the MCC’s emergency rules.

Thank you,
Taylor Corpening
Rule-making Coordinator
Division of Health Service Regulation
[NC Department of Health and Human Services](http://www.dhhs.nc.gov)

Work Cell: 919-896-9371
Office: 919-855-4619
Fax: 919-733-2757
taylor.corpening@dhhs.nc.gov

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

sender immediately and delete all records of this email.

10A NCAC 14E .0106 is amended under temporary procedures with changes as follows:

10A NCAC 14E .0106 APPLICATION

(a) Prior to the admission of patients, an application from the applicant for a new clinic for certification [licensure] shall be submitted to and approved by the Division. submit an application for licensure and receive approval from the Division.

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

(c) The application form shall set forth: the ownership, staffing patterns, clinical services to be rendered, [and] professional staff in charge of services, [services,] and general information that would be helpful to the Division's understanding of the clinic's operating program.

(1) Legal identity of the applicant; Name of applicant;

(2) The name or names under which the facility or services are advertised or presented to the public; Name of facility;

(3) The facility's mailing address;

(4) The facility's physical address;

(5)(4) The ownership of the facility, including a description of the legal character of the operating ownership; Ownership disclosure;

(6)(4) The owner of the premises from which services are offered including the name and address of the owner of the premises if different from the owner of the facility; Building owner;

(5) Building owner;

(7)(6) If the facility is operated under a management contract, the name and address of the building's management company; Building management;

(8)(7) A description of the arrangements that have been made for the disposal of pathological waste, products of conception, and sharps, and the name and address of the provider of such services if not performed by the facility; Sanitation services;

(9)(8) The name, specialty, board certifications, and medical license number of the Medical Director; director;

(10)(9) The name, specialty, board certifications, and medical license number of each member of the Other medical staff;

(11)(10) The name, nursing certificate number, and renewal number of the Director of Nursing; nursing;

(12)(11) The name, nursing certificate number, and renewal number of each Other nursing staff member; and staff; and

(13)(12) The name of the consulting pathologist, the name of the consulting pathologist's laboratory, and the address of the laboratory. Consulting pathologist;

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

~~(e) Each certificate [license] must be renewed at the beginning of each calendar year. The governing authority shall file an application for renewal of certification [licensure] with the Division at least 30 days prior to the date of expiration on forms furnished by the Division. Failure to file a renewal application shall result in expiration of the certificate [license] to operate.~~

History Note: Authority ~~G.S. 14-45.1(a);~~ 131E-153; 131E-153.2; S.L. 2023-14, s. [2.2]; 2.4; 10A NCAC 13S .0101, .0104, .0106, .0107, .0109, .0111, .0112, .0114, .0201, .0202, .0207, .0209, .0212, .0315, .0318, .0320, .0322, .0323, .0325, .0330; 10A NCAC 14E .0101, .0111;
 Eff. February 1, 1976;
 Readopted Eff. December 19, 1977;
 Amended Eff. July 1, 1994;
 Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. August 24, 2019;
 Codifier determined that agency's findings of need did not meet criteria for emergency rule on June 22, 2023;
 Emergency Rule Eff. June 30, 2023;
 Repealed Eff. July 1, 2023 pursuant to G.S. ~~150B-21.7; 150B-21.7;~~
 Temporary Amendment Eff. ~~October 27, 2023; December 22, 2023.~~

10A NCAC 14E .0107 is amended under temporary procedures with changes as follows:

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

(a) The Division shall issue a ~~certificate~~ license if it finds the facility can:

(1) Comply with all requirements described in this Subchapter and Subchapter 13S of Title 10A of the North Carolina Administrative Code; Subchapter; and

~~(2) Assure that, in the event that complications arise from the abortion procedure, an OB-GYN board certified Have a board certified OB-GYN or board eligible physician by the American Board of Obstetrics and Gynecology shall be available. available in the event that complications arise from an abortion procedure.~~

(b) Each ~~certificate~~ license shall be issued only for the premises and persons or organizations named in the application and shall not be transferable.

(c) The governing authority shall notify the Division in writing, within 10 working days, of any change in the name of the facility or change in the name of the administrator.

(d) The facility shall report to the Division all incidents, within 10 working days, of vandalism to the facility such as fires, explosions ~~explosions~~, or other action ~~causing disruption of that prevents~~ services ~~from [being provided]~~ providing abortion services.

*History Note: Authority G.S. ~~14-45.1(a)~~; 90-21.81; 90-21.81B; 131E-153; 131E-153.2; S.L. 2023-14, s. ~~2.2~~; 2.4; Eff. February 1, 1976;
Readopted Eff. December 19, 1977;
Amended Eff. July 1, 1994;
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Emergency Rule Eff. June 30, 2023;
Repealed Eff. July 1, 2023 pursuant to G.S. ~~150B-21.7~~; 150B-21.7;
Temporary Amendment Eff. October 27, 2023; December 22, 2023.*

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

10A NCAC 14E .0109 RENEWAL

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

(b) The renewal application form shall set forth:

(1) Legal identity of the applicant; ~~Name of applicant;~~

(2) The name or names under which the facility or services are advertised or presented to the public;
~~Name of facility;~~

(3) The facility's mailing address;

(4) The facility's physical address;

(5)(4) The ownership of the facility, including a description of the legal character of the operating
~~ownership; Ownership disclosure;~~

(6)(4) The owner of the premises from which services are offered including the name and address of the
~~owner of the premises if different from the owner of the facility; Building owner;~~

(5) ~~Building owner;~~

(7)(6) If the facility is operated under a management contract, the name and address of the building's
~~management company; Building management;~~

(8)(7) A description of the arrangements that have been made for the disposal of pathological waste,
~~products of conception, and sharps, and the name and address of the provider of such services if not performed by the facility; Sanitation services;~~

(9)(8) The name, specialty, board certifications, and medical license number of the Medical Director;
~~director;~~

(10)(9) The name, specialty, board certifications, and medical license number of each member of the ~~Other~~
~~medical staff;~~

(11)(10) The name, nursing certificate number, and renewal number of the Director of Nursing; ~~nursing;~~

(12)(11) The name, nursing certificate number, and renewal number of each ~~Other~~ nursing staff member; and
~~staff; and~~

(13)(12) The name of the consulting pathologist, the name of the consulting pathologist's laboratory, and the
~~address of the laboratory. Consulting pathologist;~~

(14)(13) The number of [abortion] procedures performed since initial licensure or the most recent licensure
~~renewal, whichever is later; and during the reporting period; and~~

(15)(14) The number of patients that were transferred to a hospital since initial licensure or the most recent
~~licensure renewal, whichever is later, during a reporting period.~~

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

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

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

History Note: Authority G.S. 14-45.1(a); 131E-269; 131E-153; 131E-153.2; 143B-10; S.L. 2023-14, s. 2.2; ~~2.4~~; 10A NCAC 13S .0101, .0104, .0106, .0107, .0109, .0111, .0112, .0114, .0201, .0202, .0207, .0209, .0212, .0315, .0318, .0327, .0329, .0330; 10A NCAC 14E .0101, .0111; Eff. February 1, 1976; Readopted Eff. December 19, 1977; Amended Eff. October 1, 2015; Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. August 24, 2019; Codifier determined that agency's findings of need did not meet criteria for emergency rule on June 22, 2023; Emergency Rule Eff. June 30, 2023; Repealed Eff. July 1, 2023 pursuant to G.S. ~~150B-21.7~~. 150B-21.7; Temporary Amendment Eff. October 27, 2023. ~~December 22, 2023~~.

Burgos, Alexander N

Subject: FW: Temporary Rules 10A NCAC 14E - Requests for Changes - October 2023 RRC

From: Liebman, Brian R <brian.liebman@oah.nc.gov>

Sent: Friday, December 8, 2023 5:11 PM

To: Corpening, Taylor <taylor.corpening@dhhs.nc.gov>

Cc: Burgos, Alexander N <alexander.burgos@oah.nc.gov>; Premakumar, Rajeev K <raj.premakumar@dhhs.nc.gov>

Subject: RE: Temporary Rules 10A NCAC 14E - Requests for Changes - October 2023 RRC

Taylor,

Thanks for your responses. I have some comments on some of these rules.

Rule .0106 and .0109

As an initial note, I believe the changes made to the text will satisfy the objection on clarity and ambiguity.

I understand why you're doing it, but you cannot cite to other rules in the History Note. Rules cannot form the statutory authority for other rules. Please remove the cites to the 13S and 14E rules. It appears to me that as long as MCC has rules in the Code on the appropriate substantive licensure requirements, it would no longer be an overreach of the Department's authority to ensure those requirements have been complied with during the licensure process.

That said, looking at MCC's 13S rules, it is clear that at 13S .0106 and 13S .0109, MCC adopted emergency rules that are identical (not including the changes you've made in the review process here) to Rules 14E .0106 and .0109. While I would have statutory authority questions as to whether MCC can adopt those rules under rulemaking authority explicitly given to the Department, those rules aren't before RRC at this time. The problem is, they are currently in the Administrative Code. Thus, if the Department were now to adopt 14E .0106 and .0109, they would be duplicating rules already in the Code. That is barred under the APA as unnecessary (see G.S. 150B-19(4) which states an agency may not adopt a rule that "repeats the content of . . . a rule . . .")

Thus, while I think .0106 and .0109 satisfy the existing objections, **they would now be subject to objection on necessity grounds.**

Rule .0107

131E-153.2(b) states that the license "shall be granted to the applicant upon a determination by the Department that the applicant has complied with the provisions of this Part [Part 4A of Article 6 of Chapter 131E, not Part II of the SL] and the Rules adopted by the [Medical Care] Commission under this Part." The requirement for a board certified OBGYN or board eligible physician is not in Part 4A. Thus, given that the language of the statute is explicit as to when the license shall be granted, I don't think you can include the separate requirement of (a)(2).

That said, is there not an identical requirement in the emergency rules adopted by MCC? I looked quickly and couldn't put my finger on it, but it was my impression that MCC adopted the same rules that the Department attempted to adopt, and it's my recollection that requirement was included.

Thus, at this time, **I do not believe the existing objection to .0107 has been satisfied.**

Finally, in all three rules, please remember to change your effective dates, as if approved, these rules would not be effective retroactively to 10/27/23.

Thanks,
Brian

Brian Liebman
Counsel to the North Carolina Rules Review Commission
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brian.liebman@oah.nc.gov

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Attachments: 20231208 - Ltr. to B. Liebman re 14E Rules .0106 .0107 .0109.pdf; 10.2023 - DHHS.DHSR Temporary Rules Objection Letter.pdf; 10A NCAC 14E .0106.docx; 10A NCAC 14E .0107.docx; 10A NCAC 14E .0109.docx

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Subject: RE: Temporary Rules 10A NCAC 14E - Requests for Changes - October 2023 RRC

Hi Brian,

Please see the attached letters and revised rules for your review.

Best,
Taylor Corpening
Rule-making Coordinator
Division of Health Service Regulation
[NC Department of Health and Human Services](#)

Work Cell: 919-896-9371
Office: 919-855-4619
Fax: 919-733-2757
taylor.corpening@dhhs.nc.gov

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



NC DEPARTMENT OF
**HEALTH AND
HUMAN SERVICES**

Office of General Counsel

ROY COOPER • Governor

KODY H. KINSLEY • Secretary

JULIE Y. CRONIN • General Counsel

December 8, 2023

VIA EMAIL

Brian Liebman
Commission Counsel
Rules Review Commission
1711 New Hope Church Road
Raleigh, NC 27609
brian.liebman@oah.nc.gov

Re: Rules Review Commission's Objections to Rules 10A NCAC 14E .0106, .0107, and .0109,
Pursuant to G.S. 150B-21.9

Dear Mr. Liebman:

I write in response to your letter dated October 20, 2023 regarding the Rules Review Commission's objection to temporary Rules that the Department had brought before the Commission on October 19, 2023. Specifically, we address in this letter the objections to the following temporary Rules:

10A NCAC 14E .0106
10A NCAC 14E .0107
10A NCAC 14E .0109

In accordance with G.S. 150B-21.1(b1), we offer the following responses to the RRC Staff Opinion adopted by the RRC, and revised rules.

STATUTORY AUTHORITY

- Staff Counsel wrote in its opinion regarding Rules .0106 and .0109:

As explained in the opinion incorporated by reference, it is staff's opinion that the Department of Health and Human Services lacks statutory authority to impose requirements on freestanding abortion clinics which are outside the explicit scope of the Abortion Clinic Licensure Act ("the Act"). While the Department is authorized by

NC DEPARTMENT OF HEALTH AND HUMAN SERVICES • OFFICE OF GENERAL COUNSEL

LOCATION: 101 Blair Drive, Adams Building, Raleigh, NC 27603
MAILING ADDRESS: 2001 Mail Service Center, Raleigh, NC 27699-2001
www.ncdhhs.gov • TEL: 919-855-4890 • FAX: 919-733-3854

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G.S. 131E-153.2 to specify the “necessary and reasonable information” to be contained in the application for licensure, it is staff’s opinion that it would be neither necessary nor reasonable to require an agency to submit information to the Department for approval as part of the licensure process when the Department has no authority to otherwise regulate in those areas.

*Thus, to the extent that the Department seeks to regulate topics such as the clinic’s management, sanitation, recordkeeping, and staffing through the licensure process, **when it is unable to do so directly through other rules**, it is staff’s opinion that the Department lacks statutory authority for Rules .0106 and .0109.*

(emphasis added)

Regarding this opinion, the Department has identified the following sources of authority and offers this response:

G.S. 131E-153.2(b) states that “Applications shall be available from the Department, and each application filed with the Department shall contain all necessary and reasonable information that the Department may by rule require. A license shall be granted to the applicant upon a **determination by the Department that the applicant has complied with the provisions of this Part and the rules adopted by the Commission under this Part.**” (emphasis added)

The Medical Care Commission ("MCC") has adopted emergency rules pursuant to its own statutory authority. Those rules form the basis upon which the Department must determine whether a license shall be granted. Therefore, it is “necessary and reasonable” for the Department to request information that comports with the adopted MCC rules governing the licensure of abortion clinics.

- Staff Counsel wrote in its opinion regarding Rule .0107

*Similarly, in Rule .0107, the Department conditions licensure on a finding that the facility has a board-certified or board-eligible OB-GYN available in the event of complications from an abortion procedure. **While other parts of Session Law 2023-14 appear to contain requirements that a physician perform any surgical abortion and address any complications arising from the procedure**, those requirements do not appear in Part II of the Session Law generally or G.S. 131E-153.2 specifically. The Department cites no other authority for Rule .0107. Consequently, to the extent that the Department conditions licensure on a requirement that has no basis within the Act, it is staff’s opinion that the Department lacks statutory authority for Rule .0107.*

(emphasis added)

Regarding this opinion, the Department has identified the following sources of authority and offers this response:

G.S. 90-21.81B(2) states that an abortion can be legally performed "[d]uring the first 12 weeks of a woman's pregnancy, when the procedure is **performed by a qualified physician licensed to practice medicine in this State in a** hospital, ambulatory surgical center, or **clinic certified by the Department of Health and Human Services to be a suitable facility for the performance of abortions**, in accordance with G.S. 90-21.82A or during the first 12 weeks of a woman's pregnancy when a medical abortion is procured." (emphasis added)

"Qualified physician" is defined in G.S. 90-21.81(7a) as "Any of the following: **(i) a physician who possesses, or is eligible to possess, board certification in obstetrics or gynecology**, (ii) a physician who possesses sufficient training based on established medical standards in safe abortion care, abortion complications, and miscarriage management, or (iii) a physician who performs an abortion in a medical emergency as defined by this Article." (emphasis added)

Taken together, these additional provisions, though outside of Part II of the Session Law, clearly and demonstrably provide authority to the Department to request certification, or eligibility for certification, in obstetrics and gynecology in order to perform abortion procedures in clinics licensed by the Department.

LACK OF CLARITY

- Staff Counsel wrote in its opinion regarding Rules .0106 and .0109:

Thus, it is staff's opinion that both Rules .0106 and .0109 lack clarity to the extent that they fail to specify what information must be provided on the application for licensure and renewal of licensure, respectively.

Regarding this opinion, the Department has revised the rules to clarify the issues raised by Staff Counsel.

Sincerely,

DocuSigned by:

Rajeev Premakumar

31A0CB6C64E748C...

Rajeev K. Premakumar
Deputy General Counsel
Rulemaking Coordinator
N.C. Department of Health and Human Services

cc: Julie Cronin, General Counsel
Taylor Corpening, Division of Health Services Regulation Rulemaking Coordinator

Enclosures

10A NCAC 14E .0106 is amended under temporary procedures with changes as follows:

10A NCAC 14E .0106 APPLICATION

(a) Prior to the admission of patients, an application from the applicant for a new clinic for certification [licensure] shall be submitted to and approved by the Division. submit an application for licensure and receive approval from the Division.

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

(c) The application form shall set forth: the ownership, staffing patterns, clinical services to be rendered, [and] professional staff in charge of services, [services,] and general information that would be helpful to the Division's understanding of the clinic's operating program.

(1) Legal identity of the applicant; Name of applicant;

(2) The name or names under which the facility or services are advertised or presented to the public; Name of facility;

(3) The facility's mailing address;

(4) The facility's physical address;

(5)(4) The ownership of the facility, including a description of the legal character of the operating ownership; Ownership disclosure;

(6)(4) The owner of the premises from which services are offered including the name and address of the owner of the premises if different from the owner of the facility; Building owner;

(5) Building owner;

(7)(6) If the facility is operated under a management contract, the name and address of the building's management company; Building management;

(8)(7) A description of the arrangements that have been made for the disposal of pathological waste, products of conception, and sharps, and the name and address of the provider of such services if not performed by the facility; Sanitation services;

(9)(8) The name, specialty, board certifications, and medical license number of the Medical Director; director;

(10)(9) The name, specialty, board certifications, and medical license number of each member of the Other medical staff;

(11)(10) The name, nursing certificate number, and renewal number of the Director of Nursing; nursing;

(12)(11) The name, nursing certificate number, and renewal number of each Other nursing staff member; and staff; and

(13)(12) The name of the consulting pathologist, the name of the consulting pathologist's laboratory, and the address of the laboratory. Consulting pathologist;

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

~~(e) Each certificate [license] must be renewed at the beginning of each calendar year. The governing authority shall file an application for renewal of certification [licensure] with the Division at least 30 days prior to the date of expiration on forms furnished by the Division. Failure to file a renewal application shall result in expiration of the certificate [license] to operate.~~

*History Note: Authority G.S. ~~14-45.1(a)~~; 131E-153; 131E-153.2; S.L. 2023-14, s. ~~[2-27]~~; 2.4; 10A NCAC 13S .0101, .0104, .0106, .0107, .0109, .0111, .0112, .0114, .0201, .0202, .0207, .0209-.0212, .0315, .0318-.0320, .0322, .0323, .0325, .0330; 10A NCAC 14E .0101, .0111;
 Eff. February 1, 1976;
 Readopted Eff. December 19, 1977;
 Amended Eff. July 1, 1994;
 Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. August 24, 2019;
 Codifier determined that agency's findings of need did not meet criteria for emergency rule on June 22, 2023;
 Emergency Rule Eff. June 30, 2023;
 Repealed Eff. July 1, 2023 pursuant to G.S. ~~150B-21.7~~; 150B-21.7;
 Temporary Amendment Eff. October 27, 2023.*

10A NCAC 14E .0107 is amended under temporary procedures with changes as follows:

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

(a) The Division shall issue a ~~certificate~~ license if it finds the facility can:

- (1) Comply with all requirements described in this Subchapter and Subchapter 13S of Title 10A of the North Carolina Administrative Code; Subchapter; and
- (2) Assure that, in the event that complications arise from the abortion procedure, an OB-GYN board certified Have a board certified OB-GYN or board eligible physician by the American Board of Obstetrics and Gynecology shall be available. available in the event that complications arise from an abortion procedure.

(b) Each ~~certificate~~ license shall be issued only for the premises and persons or organizations named in the application and shall not be transferable.

(c) The governing authority shall notify the Division in writing, within 10 working days, of any change in the name of the facility or change in the name of the administrator.

(d) The facility shall report to the Division all incidents, within 10 working days, of vandalism to the facility such as fires, explosions ~~explosions~~, or other action ~~causing disruption of that prevents~~ services ~~from [being provided]~~ providing abortion services.

*History Note: Authority G.S. ~~14-45.1(a)~~; 90-21.81; 90-21.81B; 131E-153; 131E-153.2; S.L. 2023-14, s. ~~2.27~~; 2.4; Eff. February 1, 1976;
Readopted Eff. December 19, 1977;
Amended Eff. July 1, 1994;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. August 24, 2019;
Codifier determined that agency's findings of need did not meet criteria for emergency rule on June 22, 2023;
Emergency Rule Eff. June 30, 2023;
Repealed Eff. July 1, 2023 pursuant to G.S. ~~150B-21.7~~; 150B-21.7;
Temporary Amendment Eff. October 27, 2023.*

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

10A NCAC 14E .0109 RENEWAL

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

(b) The renewal application form shall set forth:

(1) Legal identity of the applicant; ~~Name of applicant;~~

(2) The name or names under which the facility or services are advertised or presented to the public;
~~Name of facility;~~

(3) The facility's mailing address;

(4) The facility's physical address;

(5)(4) The ownership of the facility, including a description of the legal character of the operating
~~ownership; Ownership disclosure;~~

(6)(4) The owner of the premises from which services are offered including the name and address of the
~~owner of the premises if different from the owner of the facility; Building owner;~~

(5) ~~Building owner;~~

(7)(6) If the facility is operated under a management contract, the name and address of the building's
~~management company; Building management;~~

(8)(7) A description of the arrangements that have been made for the disposal of pathological waste,
~~products of conception, and sharps, and the name and address of the provider of such services if not performed by the facility; Sanitation services;~~

(9)(8) The name, specialty, board certifications, and medical license number of the Medical Director;
~~director;~~

(10)(9) The name, specialty, board certifications, and medical license number of each member of the ~~Other~~
~~medical staff;~~

(11)(10) The name, nursing certificate number, and renewal number of the Director of Nursing; ~~nursing;~~

(12)(11) The name, nursing certificate number, and renewal number of each ~~Other~~ nursing staff member; and
~~staff; and~~

(13)(12) The name of the consulting pathologist, the name of the consulting pathologist's laboratory, and the
~~address of the laboratory. Consulting pathologist;~~

(14)(13) The number of [abortion] procedures performed since initial licensure or the most recent licensure
~~renewal, whichever is later; and during the reporting period; and~~

(15)(14) The number of patients that were transferred to a hospital since initial licensure or the most recent
~~licensure renewal, whichever is later, during a reporting period.~~

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

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

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

4
 5 *History Note:* Authority G.S. ~~14-45.1(a); 131E-269; 131E-153; 131E-153.2; 143B-10; S.L. 2023-14, s. ~~2.2;~~ 2.4;~~
 6 ~~10A NCAC 13S .0101, .0104, .0106, .0107, .0109, .0111, .0112, .0114, .0201, .0202, .0207, .0209-~~
 7 ~~.0212, .0315, .0318-.0327, .0329, .0330; 10A NCAC 14E .0101, .0111;~~
 8 Eff. February 1, 1976;
 9 Readopted Eff. December 19, 1977;
 10 Amended Eff. October 1, 2015;
 11 Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. August 24,
 12 2019;
 13 Codifier determined that agency's findings of need did not meet criteria for emergency rule on June
 14 22, 2023;
 15 Emergency Rule Eff. June 30, 2023;
 16 Repealed Eff. July 1, 2023 pursuant to G.S. ~~150B-21.7; 150B-21.7;~~
 17 Temporary Amendment Eff. October 27, 2023.
 18
 19

Burgos, Alexander N

Subject: FW: Temporary Rules 10A NCAC 14E - Requests for Changes - October 2023 RRC

From: Corpening, Taylor <taylor.corpening@dhhs.nc.gov>
Sent: Tuesday, November 28, 2023 10:58 AM
To: Liebman, Brian R <brian.liebman@oah.nc.gov>
Cc: Burgos, Alexander N <alexander.burgos@oah.nc.gov>; Premakumar, Rajeev K <raj.premakumar@dhhs.nc.gov>
Subject: RE: Temporary Rules 10A NCAC 14E - Requests for Changes - October 2023 RRC

Hello Brian,

That is correct. Thank you!

Best,
Taylor Corpening
Rule-making Coordinator
Division of Health Service Regulation
[NC Department of Health and Human Services](#)

Work Cell: 919-896-9371
Office: 919-855-4619
Fax: 919-733-2757
taylor.corpening@dhhs.nc.gov

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

From: Liebman, Brian R <brian.liebman@oah.nc.gov>
Sent: Tuesday, November 28, 2023 10:35 AM
To: Corpening, Taylor <taylor.corpening@dhhs.nc.gov>
Cc: Burgos, Alexander N <alexander.burgos@oah.nc.gov>; Premakumar, Rajeev K <raj.premakumar@dhhs.nc.gov>
Subject: RE: Temporary Rules 10A NCAC 14E - Requests for Changes - October 2023 RRC

Hi Taylor,

I'll let the Commission know about the withdrawals. To be clear, you're leaving .0106, .0107, and .0109 in place, correct?

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: Temporary Rules 10A NCAC 14E - Requests for Changes - October 2023 RRC

From: Corpening, Taylor <taylor.corpening@dhhs.nc.gov>

Sent: Thursday, November 16, 2023 11:20 AM

To: Liebman, Brian R <brian.liebman@oah.nc.gov>

Cc: Burgos, Alexander N <alexander.burgos@oah.nc.gov>; Premakumar, Rajeev K <raj.premakumar@dhhs.nc.gov>

Subject: RE: Temporary Rules 10A NCAC 14E - Requests for Changes - October 2023 RRC

Hello Brian,

The Department respectfully requests withdrawal from consideration for the following 10A NCAC 14E temporary rules:

.0104
.0112
.0114
.0201
.0202
.0207
.0209
.0210
.0211
.0212
.0315
.0318-.0331

Thank you!

Taylor Corpening
Rule-making Coordinator
Division of Health Service Regulation
[NC Department of Health and Human Services](#)

Work Cell: 919-896-9371
Office: 919-855-4619
Fax: 919-733-2757
taylor.corpening@dhhs.nc.gov

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

Burgos, Alexander N

Subject: FW: Temporary Rules 10A NCAC 14E - Requests for Changes - October 2023 RRC

Alexander Burgos

Paralegal
Office of Administrative Hearings
1711 New Hope Church Road
Raleigh NC, 27609
(984) 236-1940
Alexander.burgos@oah.nc.gov

From: Corpening, Taylor <taylor.corpening@dhhs.nc.gov>
Sent: Wednesday, November 15, 2023 4:29 PM
To: Liebman, Brian R <brian.liebman@oah.nc.gov>
Cc: Burgos, Alexander N <alexander.burgos@oah.nc.gov>; Premakumar, Rajeev K <raj.premakumar@dhhs.nc.gov>
Subject: RE: Temporary Rules 10A NCAC 14E - Requests for Changes - October 2023 RRC

Okay, thank you for the clarification.

See you tomorrow!

Taylor Corpening
Rule-making Coordinator
Division of Health Service Regulation
[NC Department of Health and Human Services](#)

Work Cell: 919-896-9371
Office: 919-855-4619
Fax: 919-733-2757
taylor.corpening@dhhs.nc.gov

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

From: Liebman, Brian R <brian.liebman@oah.nc.gov>
Sent: Wednesday, November 15, 2023 4:27 PM
To: Corpening, Taylor <taylor.corpening@dhhs.nc.gov>
Cc: Burgos, Alexander N <alexander.burgos@oah.nc.gov>; Premakumar, Rajeev K <raj.premakumar@dhhs.nc.gov>
Subject: RE: Temporary Rules 10A NCAC 14E - Requests for Changes - October 2023 RRC

Taylor,

In the last communication I have from the Department, they indicated that they would be bringing revised rules to the Commission at the December meeting. As those rules will not be before the Commission for review this month, it is staff's understanding that there will be no action taken this month. I can't guarantee that a Commissioner won't have a

question about them, so it would be best if you or someone else from the Department was in attendance (in person or Webex) just in case.

Brian

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

E-mail correspondence to and from this address may be subject to the North Carolina Public Records Law N.C.G.S. Chapter 132 and may be disclosed to third parties.

From: Corpening, Taylor <taylor.corpening@dhhs.nc.gov>
Sent: Wednesday, November 15, 2023 3:49 PM
To: Liebman, Brian R <brian.liebman@oah.nc.gov>
Cc: Burgos, Alexander N <alexander.burgos@oah.nc.gov>; Premakumar, Rajeev K <raj.premakumar@dhhs.nc.gov>
Subject: RE: Temporary Rules 10A NCAC 14E - Requests for Changes - October 2023 RRC

Hi Brian,

I see that the 14E rules are designated as a NO ACTION item for tomorrow's RRC meeting. Do you mind explaining what this means?

Thanks,

Taylor Corpening
Rule-making Coordinator
Division of Health Service Regulation
[NC Department of Health and Human Services](https://www.ncdhhs.gov/)

Work Cell: 919-896-9371
Office: 919-855-4619
Fax: 919-733-2757
taylor.corpening@dhhs.nc.gov

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

Burgos, Alexander N

Subject: FW: Temporary Rules 10A NCAC 14E - Requests for Changes - October 2023 RRC
Attachments: Brian Liebman Letter and Sec. Kody Kinsley denial of DHSR rules_.pdf

From: Corpening, Taylor <taylor.corpening@dhhs.nc.gov>
Sent: Friday, October 27, 2023 10:49 AM
To: Liebman, Brian R <brian.liebman@oah.nc.gov>
Cc: Burgos, Alexander N <alexander.burgos@oah.nc.gov>; Premakumar, Rajeev K <raj.premakumar@dhhs.nc.gov>
Subject: RE: Temporary Rules 10A NCAC 14E - Requests for Changes - October 2023 RRC

Hi Brian!

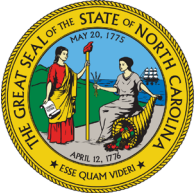
Please see the attached letter.

Best,
Taylor Corpening
Rule-making Coordinator
Division of Health Service Regulation
[NC Department of Health and Human Services](#)

Office: 919-855-4619
Fax: 919-733-2757
taylor.corpening@dhhs.nc.gov

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

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NC DEPARTMENT OF
**HEALTH AND
HUMAN SERVICES**

Office of General Counsel

ROY COOPER • Governor

KODY H. KINSLEY • Secretary

JULIE Y. CRONIN • General Counsel

October 27, 2023

VIA EMAIL

Brian Liebman
Commission Counsel
Rules Review Commission
1711 New Hope Church Road
Raleigh, NC 27609
brian.liebman@oah.nc.gov

Re: Rules Review Commission's Objections to Rules 10A NCAC 14E .0104, .0106, .0107, .0109, .0112, .0114, .0201, .0202, .0207, .0209, .0210, .0211, .0315, .0318, .0319, .0320, .0321, .0322, .0323, .0324, .0325, .0326, .0327, .0328, .0329, .0330, and .0331 Pursuant to G.S. 150B-21.9

Dear Mr. Liebman,

I write regarding the status of the 10 NCAC 14E rules referenced in your enclosed letter to Secretary Kinsley dated October 20, 2023. In the October 20, 2023 letter, you stated:

At its meeting on October 19, 2023, the Rules Review Commission objected to the above-captioned temporary Rules in accordance with G.S. 150B-21.1(b). Specifically, the RRC adopted the opinions of counsel attached hereto and incorporated by reference.

Please respond to this letter in accordance with the provisions of G.S. 150B-21.1(b1) or (b2). If you have any questions regarding the Rules Review Commission's action, please let me know.

In follow up to your correspondence, the Division's Rulemaking Coordinator emailed you on October 24, 2023, to clarify whether the thirty-day period in G.S. 150B-21.1(b1), as amended, applied to your objections under G.S. 150B-21.9. The email asked;

Does this provision [of G.S. 150B-21.1(b1)] only extend to the revision or submission of the statement of need form, and if so, will the rules be returned to the Department if a supplemental or new statement of need is not submitted within 30

NC DEPARTMENT OF HEALTH AND HUMAN SERVICES • OFFICE OF GENERAL COUNSEL

LOCATION: 101 Blair Drive, Adams Building, Raleigh, NC 27603
MAILING ADDRESS: 2001 Mail Service Center, Raleigh, NC 27699-2001
www.ncdhhs.gov • TEL: 919-855-4890 • FAX: 919-733-3854

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days of notification (by our count, Monday, November 19, 2023)? Or can we respond as we have previously with additional responses to statutory authority within your stated objections with that process not being governed by the 30 day statement of need clock?

In response, you stated, “I think that’s a question that’s best answered by DHHS’ general counsel, rather than me.” The following is the Department’s response and request for any clarification the Commission and counsel has to offer.

In your Staff Opinion included with the letter, you objected to Rules .0106, .0107, and 0109 “for lack of statutory authority pursuant to G.S. 150B-21.9(a)(1) and for lack of clarity pursuant to G.S. 150B-21.9(a)(2).” In your Staff Opinion addressing the remaining rules, you objected “for lack of statutory authority pursuant to G.S. 150B-21.9(a)(1).” We note that the objection letter and staff opinion do not reference the Department’s Statements of Need, and the Rules Review Commission (“Commission”) identified no deficiency in the Statements of Need either at their October 19, 2023, meeting or in the enclosed materials. Therefore, the Commission did not make a finding that the Department’s Statement of Need does not meet the criteria in G.S. 150B-21.1(a). Rather, the Commission’s objections were based on a lack of statutory authority and lack of clarity pursuant to G.S. 150B-21.9(a)(1) and (2).

The recently passed budget, S.L. 2023-134, amended Section 21.1 of the Administrative Procedure Act. As amended, the first sentence of G.S. 150B-21.1(b1) states:

If the Commission or its designee finds that the statement does not meet the criteria listed in subsection (a) of this section or that the rule does not meet the standards in G.S. 150B-21.9, the Commission or its designee must immediately notify the head of the agency.

(emphasis added). The first sentence of G.S. 150B-21.1(b1) makes it clear that the Commission may find either (1) that the statement of need does not meet the criteria of 150B-21.1(a) **or, alternatively**, that the rule does not meet the standards of G.S. 150B-21.9.

The next section of G.S. 150B-21.1(b1), as amended, **only** concerns supplementing or amending the **statement of need**, and does not reference alterations to the rule pursuant to an objection under G.S. 150B-21.9:

The agency may supplement its **statement of need** with additional findings or submit a **new statement within 30 days of the notification**. If the agency fails to supplement its **statement of need with additional findings or submit a new statement** to the Commission **within 30 days**, or submits written notice **within 30 days** to the Commission that the agency does not intend to **supplement its statement of need with additional findings or submit a new statement**, the Commission or its designee shall immediately return the rule to the agency. If the agency provides **additional findings or submits a new statement within 30 days of the notification**, the Commission or its designee must review **the additional findings or new statement** within five business days after the agency submits **the additional findings or new statement**.

(emphasis added). It is our interpretation of this portion of the statute that the thirty-day timeline for supplementing the “statement of need with additional findings” or submitting “a new statement [of need]” applies only to a Commission finding that “the statement [of need] does not meet the criteria listed in [G.S. 150B-21.1].”

The remainder of G.S. 150B-21.1(b1) again references objections pursuant to G.S. 150B-21.9, but does so without reference to a thirty-day period for the agency to respond:

If the Commission or its designee again finds that the statement does not meet the criteria listed in subsection (a) of this section or that the rule does not meet the standards in G.S. 150B-21.9, the Commission or its designee must immediately notify the head of the agency and return the rule to the agency. When the Commission returns a rule to an agency in accordance with this subsection, the agency may file an action for declaratory judgment within 30 days after notification of the return of the rule by the Commission in Wake County Superior Court pursuant to Article 26 of Chapter 1 of the General Statutes.

(emphasis added). Based upon your stated objections to these rules under G.S. 150B-21.9, it is our understanding that the objections **do not** concern the statement of need and, therefore, the thirty-day timeframe outlined in G.S. 150B-21.1(b1) does **not** apply.

Rather, it is our understanding that our response to the objections pursuant to G.S. 150B-21.9 will be heard in the ordinary course of business, as has historically been the practice of the Commission. We plan to submit revisions to the rules in anticipation of these rules being on the Commission’s December meeting agenda.

If you disagree with our interpretation, please advise of your position at your earliest convenience.

Sincerely,

DocuSigned by:

Julie Cronin

924BDED4A4CA4A7...

Julie Cronin

General Counsel

N.C. Department of Health and Human Services

cc: Taylor Corpening, Rulemaking Coordinator
Enclosures



**STATE OF NORTH CAROLINA
OFFICE OF ADMINISTRATIVE HEARINGS**

October 20, 2023

Kody Kinsley, Secretary
Department of Health and Human Services
Sent via email only: kody.kinsley@dhhs.nc.gov

Re: Objection to Rules 10A NCAC 14E .0104, .0106, .0107, .0109, .0112, .0114, .0201, .0202, .0207, .0209, .0210, .0211, .0212, .0315, .0318, .0319, .0320, .0321, .0322, .0323, .0324, .0325, .0326, .0327, .0328, .0329, .0330, and .0331.

Dear Secretary Kinsley:

At its meeting on October 19, 2023, the Rules Review Commission objected to the above-captioned temporary Rules in accordance with G.S. 150B-21.1(b). Specifically, the RRC adopted the opinions of counsel attached hereto and incorporated by reference.

Please respond to this letter in accordance with the provisions of G.S. 150B-21.1(b1) or (b2). If you have any questions regarding the Rule Review Commission's action, please let me know.

Sincerely,

Brian Liebman
Commission Counsel

cc: Taylor Corpening, Rulemaking Coordinator

Donald Robert van der Vaart, Director
Chief Administrative Law Judge

John C. Evans
Senior Administrative Law Judge

An Equal Employment Opportunity Employer

1711 New Hope Church Road, Raleigh, NC 27609
Telephone: (984) 236-1850 | Facsimile: (984) 236-1871
www.oah.nc.gov

RRC STAFF OPINION

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

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

RULE CITATION: 10A NCAC 14E .0106, .0107, and .0109.

DATE ISSUED: October 18, 2023

RECOMMENDED ACTION:

- Approve, but note staff's comment
- X Object, based on:
 - X Lack of statutory authority (all rules)
 - X Unclear or ambiguous (.0106 and .0109)
 - Unnecessary
 - Failure to comply with the APA
- Extend the period of review

COMMENT:

Staff hereby incorporates by reference the staff opinion issued October 18, 2023 recommending objection to Rules 10A NCAC 14E .0104, .0112, .0114, .0201, .0202, .0207, .0209, .0210, .0211, .0212, .0315, .0318, .0319, .0320, .0321, .0322, .0323, .0324, .0325, .0326, .0327, .0328, .0329, .0330, and .0331.

Statutory Authority

Under Rule .0106, the Department sets out the contents of an application for licensure for new freestanding abortion clinics. Rule .0109 sets out the contents for an application to renew this license. In both Rules, the Department requires that the application set forth details related to the building's management, sanitation services, the clinic's medical director and medical staff, the director of nursing and nursing staff, and the consulting pathologist. Additionally, in Rule .0109(b), the Department requires that an agency seeking renewal of a license specify "the number of procedures performed during the reporting period" and "the number of patients that were transferred to a hospital during a reporting period."

Brian Liebman
Commission Counsel

As explained in the opinion incorporated by reference, it is staff's opinion that the Department of Health and Human Services lacks statutory authority to impose requirements on freestanding abortion clinics which are outside the explicit scope of the Abortion Clinic Licensure Act ("the Act"). While the Department is authorized by G.S. 131E-153.2 to specify the "necessary and reasonable information" to be contained in the application for licensure, it is staff's opinion that it would be neither necessary nor reasonable to require an agency to submit information to the Department for approval as part of the licensure process when the Department has no authority to otherwise regulate in those areas.

Thus, to the extent that the Department seeks to regulate topics such as the clinic's management, sanitation, recordkeeping, and staffing through the licensure process, when it is unable to do so directly through other rules, it is staff's opinion that the Department lacks statutory authority for Rules .0106 and .0109.

Similarly, in Rule .0107, the Department conditions licensure on a finding that the facility has a board-certified or board-eligible OB-GYN available in the event of complications from an abortion procedure. While other parts of Session Law 2023-14 appear to contain requirements that a physician perform any surgical abortion and address any complications arising from the procedure, those requirements do not appear in Part II of the Session Law generally or G.S. 131E-153.2 specifically. The Department cites no other authority for Rule .0107. Consequently, to the extent that the Department conditions licensure on a requirement that has no basis within the Act, it is staff's opinion that the Department lacks statutory authority for Rule .0107.

Lack of Clarity

Notwithstanding the Department's lack of statutory authority for these Rules, the language of both Rules fails to clearly state what information the Department would require as part of the licensure application and renewal application. In paragraph (c) of Rule .0106 and paragraph (b) of Rule .0109, the Department states that the application form shall set forth "ownership disclosure", "building owner", "building management", "sanitation services", "medical director", "other medical staff", "Director of nursing", "other nursing staff", and "Consulting pathologist."

Neither rule states what information a clinic must provide about each topic. For instance, it is entirely unclear what details an applicant must provide about "sanitation services," or what "other medical staff" might mean. While the Rule specifies that the "name" of the applicant must be provided, it makes no such requirement for "medical director" or "Director of nursing." Ostensibly a clinic could comply by providing the directors' names and addresses, or by simply certifying that they employ individuals in each role. Further, "building owner" is repeated twice, for reasons unclear to staff, and it is unclear what difference, if any, there is between the "ownership disclosure" and "building owner".

Additionally, in Rule .0109(b), the Department further requires that an agency seeking renewal of a license specify "the number of procedures performed during the reporting period" and "the number of patients that were transferred to a hospital during a reporting period." The Department does not define the term "procedure" nor the term "reporting period." As such, it is unclear what information the clinic is required to preserve and report to the Department.

Thus, it is staff's opinion that both Rules .0106 and .0109 lack clarity to the extent that they fail to specify what information must be provided on the application for licensure and renewal of licensure, respectively.

Based on the foregoing, staff recommends objection to the above-captioned rules for lack of statutory authority pursuant to G.S. 150B-21.9(a)(1) and for lack of clarity pursuant to G.S. 150B-21.9(a)(2).

Brian Liebman
Commission Counsel

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

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

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

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

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

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

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

**GENERAL ASSEMBLY OF NORTH CAROLINA
SESSION 2023**

**SESSION LAW 2023-14
SENATE BILL 20**

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

The General Assembly of North Carolina enacts:

PART I. ABORTION LAW REVISIONS

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

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

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

"§ 90-21.80. Short title.

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

"§ 90-21.81. Definitions.

The following definitions apply in this Article:

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



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

...."

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

"§ 90-21.6. Definitions.

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

(1) Abortion. – As defined in G.S. 90-21.81.

(1a) "Unemancipated minor" or "minor" means any Unemancipated minor or minor. – Any person under the age of 18 who has not been married or has not been emancipated pursuant to Article 35 of Chapter 7B of the General Statutes.

(2) "Abortion" means the use or prescription of any instrument, medicine, drug, or any other substance or device with intent to terminate the pregnancy of a woman known to be pregnant, for reasons other than to save the life or preserve the health of an unborn child, to remove a dead unborn child, or to deliver an unborn child prematurely, by accepted medical procedures in order to preserve the health of both the mother and the unborn child."

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

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

PART II. SUITABLE FACILITIES FOR THE PERFORMANCE OF SURGICAL ABORTIONS

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

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

(a) The following definitions apply in this section:

(1) Abortion clinic. – As defined in G.S. 131E-153.1.

(2) Ambulatory surgical facility. – As defined in G.S. 131E-176.

(3) Hospital. – As defined in G.S. 131E-176.

(b) During the first 12 weeks of pregnancy, a physician licensed to practice medicine under this Chapter may perform a surgical abortion in a hospital, an ambulatory surgical facility, or an abortion clinic; provided, however, that (i) the clinic has been licensed by the Department of Health and Human Services to be a suitable facility for the performance of abortions and (ii) the licensed physician performs the abortion in accordance with this Article and Article 1K of this Chapter.

(c) After the twelfth week of pregnancy, a physician licensed to practice medicine under this Chapter may not perform a surgical abortion as permitted under North Carolina law in any facility other than a hospital."

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

"Part 4A. Abortion Clinic Licensure.

"§ 131E-153. Title; purpose.

(a) This Part shall be known as the "Abortion Clinic Licensure Act."

(b) The purpose of this Part is to provide for the development, establishment, and enforcement of basic standards:

(1) For the care and treatment of individuals in abortion clinics; and

(2) For the maintenance and operation of abortion clinics so as to ensure safe and adequate treatment of such individuals in abortion clinics.

"§ 131E-153.1. Definitions.

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

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

"§ 131E-153.2. Licensure requirement.

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

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

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

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

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

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

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

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

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

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

"§ 131E-153.5. Rules and enforcement.

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

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

"§ 131E-153.6. Inspections.

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

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

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

"§ 131E-153.7. Penalties.

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

"§ 131E-153.8. Injunction.

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

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

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

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

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

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

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

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

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

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

PART III. BORN-ALIVE ABORTION SURVIVORS PROTECTION

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

"Article 1M.

"Born-Alive Abortion Survivors Protection Act.

"§ 90-21.140. Definitions.

As used in this Article, the following definitions apply:

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

"§ 90-21.141. Findings.

The General Assembly makes the following findings:

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

RRC STAFF OPINION

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

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

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

DATE ISSUED: October 18, 2023

RECOMMENDED ACTION:

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

COMMENT:

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

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

Brian Liebman
Commission Counsel

2.2, which adds the Abortion Clinic Licensure Act to Article 6 of Chapter 131E of the General Statutes, is pertinent, and again, the Department's authority under the Act is limited in scope. Under the Act, freestanding abortion clinics must obtain a license available from the Department after submission of an application and payment of a fee.

The Department is authorized to set the "necessary and reasonable" contents of the application and charge the application fee (G.S. 131E-153.2), take adverse action against a license for "substantial failure to comply" with the Act or rules adopted under its authority (G.S. 131-153.4), inspect clinics (G.S. 131E-153.6), and either penalize (G.S. 131E-153.7) or seek injunctions (G.S. 131E-153.8) against those clinics operating without a license. A grant of rulemaking authority to the Medical Care Commission—which is housed within the Department but is a separate agency for rulemaking purposes—is included (G.S. 131E-153.5).

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

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

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

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

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

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

Brian Liebman
Commission Counsel

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

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

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

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

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

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

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

GENERAL ASSEMBLY OF NORTH CAROLINA
SESSION 2023

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 - a. Increase the probability of a live birth.
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 - c. Remove a dead, unborn child who died as the result of (i) natural causes in utero, (ii) accidental trauma, or (iii) a criminal assault on the pregnant woman or her unborn child which causes the premature termination of the pregnancy.



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"§ 90-21.6. Definitions.

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

(1) Abortion. – As defined in G.S. 90-21.81.

(1a) "Unemancipated minor" or "minor" means any Unemancipated minor or minor. – Any person under the age of 18 who has not been married or has not been emancipated pursuant to Article 35 of Chapter 7B of the General Statutes.

(2) "Abortion" means the use or prescription of any instrument, medicine, drug, or any other substance or device with intent to terminate the pregnancy of a woman known to be pregnant, for reasons other than to save the life or preserve the health of an unborn child, to remove a dead unborn child, or to deliver an unborn child prematurely, by accepted medical procedures in order to preserve the health of both the mother and the unborn child."

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

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

PART II. SUITABLE FACILITIES FOR THE PERFORMANCE OF SURGICAL ABORTIONS

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

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

(a) The following definitions apply in this section:

(1) Abortion clinic. – As defined in G.S. 131E-153.1.

(2) Ambulatory surgical facility. – As defined in G.S. 131E-176.

(3) Hospital. – As defined in G.S. 131E-176.

(b) During the first 12 weeks of pregnancy, a physician licensed to practice medicine under this Chapter may perform a surgical abortion in a hospital, an ambulatory surgical facility, or an abortion clinic; provided, however, that (i) the clinic has been licensed by the Department of Health and Human Services to be a suitable facility for the performance of abortions and (ii) the licensed physician performs the abortion in accordance with this Article and Article 1K of this Chapter.

(c) After the twelfth week of pregnancy, a physician licensed to practice medicine under this Chapter may not perform a surgical abortion as permitted under North Carolina law in any facility other than a hospital."

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

"Part 4A. Abortion Clinic Licensure.

"§ 131E-153. Title; purpose.

(a) This Part shall be known as the "Abortion Clinic Licensure Act."

(b) The purpose of this Part is to provide for the development, establishment, and enforcement of basic standards:

(1) For the care and treatment of individuals in abortion clinics; and

(2) For the maintenance and operation of abortion clinics so as to ensure safe and adequate treatment of such individuals in abortion clinics.

"§ 131E-153.1. Definitions.

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

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

"§ 131E-153.2. Licensure requirement.

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

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

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

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

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

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

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

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

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

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

"§ 131E-153.5. Rules and enforcement.

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

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

"§ 131E-153.6. Inspections.

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

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

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

"§ 131E-153.7. Penalties.

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

"§ 131E-153.8. Injunction.

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

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

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

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

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

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

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

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

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

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

PART III. BORN-ALIVE ABORTION SURVIVORS PROTECTION

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

"Article 1M.

"Born-Alive Abortion Survivors Protection Act.

"§ 90-21.140. Definitions.

As used in this Article, the following definitions apply:

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

"§ 90-21.141. Findings.

The General Assembly makes the following findings:

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

RRC STAFF OPINION

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

AGENCY: **Medical Care Commission**

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

RECOMMENDED ACTION:

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

COMMENT:

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

Brian Liebman
Commission Counsel
Issued August 5, 2022

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

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

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

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

Brian Liebman
Commission Counsel
Issued August 5, 2022

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

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

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

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

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

Brian Liebman
Commission Counsel
Issued August 5, 2022

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

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

Brian Liebman
Commission Counsel
Issued August 5, 2022

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

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

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

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

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

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

Article 5.

Hospital Licensure Act.

Part 1. Article Title and Definitions.

§ 131E-75. Title; purpose.

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

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

§ 131E-76. Definitions.

As used in this article, unless otherwise specified:

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

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

Burgos, Alexander N

Subject: FW: Temporary Rules 10A NCAC 14E - Requests for Changes - October 2023 RRC

From: Liebman, Brian R <brian.liebman@oah.nc.gov>
Sent: Tuesday, October 24, 2023 3:57 PM
To: Corpening, Taylor <taylor.corpening@dhhs.nc.gov>
Cc: Burgos, Alexander N <alexander.burgos@oah.nc.gov>; Premakumar, Rajeev K <raj.premakumar@dhhs.nc.gov>
Subject: RE: Temporary Rules 10A NCAC 14E - Requests for Changes - October 2023 RRC

Hi Taylor,

I think that's a question that's best answered by DHHS' general counsel, rather than me.

Best,
Brian

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

E-mail correspondence to and from this address may be subject to the North Carolina Public Records Law N.C.G.S. Chapter 132 and may be disclosed to third parties.

From: Corpening, Taylor <taylor.corpening@dhhs.nc.gov>
Sent: Tuesday, October 24, 2023 2:40 PM
To: Liebman, Brian R <brian.liebman@oah.nc.gov>
Cc: Burgos, Alexander N <alexander.burgos@oah.nc.gov>; Premakumar, Rajeev K <raj.premakumar@dhhs.nc.gov>
Subject: RE: Temporary Rules 10A NCAC 14E - Requests for Changes - October 2023 RRC

Thank you, Brian. Appreciate your help understanding this.

The Department does plan on submitting revisions. However, since the next RRC meeting is scheduled for less than thirty days from now, the Department anticipates needing additional time to submit its revisions, which is why we were confirming that those would be taken up at the December meeting.

We are also seeking clarity regarding the provisions you cited. The amended 150B-21.1(b1) states:

(b1) If the Commission or its designee finds that the statement does not meet the criteria listed in subsection (a) of this section or that the rule does not meet the standards in G.S. 150B-21.9, the Commission or its designee must immediately notify the head of the agency. The agency may supplement its statement of need with additional findings or submit a new statement within 30 days of the notification. If the agency fails to supplement its statement of need with additional findings or submit a new statement to the Commission within 30 days, or submits written notice within 30 days to the Commission that the agency does not intend to supplement its statement of need with additional findings or submit a new statement, the Commission or its designee shall immediately return the rule to the agency. If the agency

provides additional findings or submits a new statement, statement within 30 days of the notification, the Commission or its designee must review the additional findings or new statement within five business days after the agency submits the additional findings or new statement.

The language highlighted above states that the agency “may supplement its statement of need with additional findings or submit a new statement within 30 days of the notification.” Does this provision only extend to the revision or submission of the statement of need form, and if so, will the rules be returned to the Department if a supplemental or new statement of need is not submitted within 30 days of notification (by our count, Monday, November 19, 2023)? Or can we respond as we have previously with additional responses to statutory authority within your stated objections with that process not being governed by the 30 day statement of need clock?

We just want to make sure we are following these newly enacted laws governing the temporary rules process appropriately.

As always, thank you for your time and consideration.

Taylor Corpening
Rule-making Coordinator
Division of Health Service Regulation
[NC Department of Health and Human Services](#)

Office: 919-855-4619
Fax: 919-733-2757
taylor.corpening@dhhs.nc.gov

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

Burgos, Alexander N

Subject: FW: Temporary Rules 10A NCAC 14E - Requests for Changes - October 2023 RRC

From: Liebman, Brian R <brian.liebman@oah.nc.gov>

Sent: Tuesday, October 24, 2023 12:50 PM

To: Corpening, Taylor <taylor.corpening@dhhs.nc.gov>

Cc: Burgos, Alexander N <alexander.burgos@oah.nc.gov>; Premakumar, Rajeev K <raj.premakumar@dhhs.nc.gov>

Subject: RE: Temporary Rules 10A NCAC 14E - Requests for Changes - October 2023 RRC

Hi Taylor,

The rules will be on the agenda, but I can't say when they'll be taken up, as that largely depends on whether you are submitting revisions. Can you let me know the Department's plans?

In any event, please see G.S. 150B-21.1(b1) and (b2)—as amended by Part XXI of the budget—for the temporary rule procedures.

Best,
Brian

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

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Burgos, Alexander N

Subject: FW: Temporary Rules 10A NCAC 14E - Requests for Changes - October 2023 RRC

From: Corpening, Taylor <taylor.corpening@dhhs.nc.gov>

Sent: Monday, October 23, 2023 4:18 PM

To: Liebman, Brian R <brian.liebman@oah.nc.gov>

Cc: Burgos, Alexander N <alexander.burgos@oah.nc.gov>; Premakumar, Rajeev K <raj.premakumar@dhhs.nc.gov>

Subject: RE: Temporary Rules 10A NCAC 14E - Requests for Changes - October 2023 RRC

Hello Brian,

Thank you for the letter to Secretary Kinsley on Friday. We are just seeking to confirm: will these rules next be heard at the December RRC meeting?

Best,

Taylor Corpening

Rule-making Coordinator

Division of Health Service Regulation

[NC Department of Health and Human Services](#)

Office: 919-855-4619

Fax: 919-733-2757

taylor.corpening@dhhs.nc.gov

809 Ruggles Drive, Edgerton Building

2701 Mail Service Center

Raleigh, NC 27699-2701

this email.

Burgos, Alexander N

From: Liebman, Brian R
Sent: Friday, October 20, 2023 4:57 PM
To: Secretary Kinsley
Cc: Corpening, Taylor; Kinsley, Kody; Burgos, Alexander N
Subject: DHHS Temporary Rules Objection Letter
Attachments: 10.2023 - DHHS.DHSR Temporary Rules Objection Letter.pdf

Good afternoon, Secretary Kinsley,

Attached, please find a letter regarding the Rules Review Commission's objection to DHHS's temporary rules.

Please let me know if you have any concerns or questions about the Commission's action.

Sincerely,

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

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Burgos, Alexander N

Subject: FW: Temporary Rules 10A NCAC 14E - Requests for Changes - October 2023 RRC

From: Liebman, Brian R <brian.liebman@oah.nc.gov>

Sent: Friday, October 20, 2023 3:36 PM

To: Corpening, Taylor <taylor.corpening@dhhs.nc.gov>

Cc: Burgos, Alexander N <alexander.burgos@oah.nc.gov>; Premakumar, Rajeev K <raj.premakumar@dhhs.nc.gov>

Subject: RE: Temporary Rules 10A NCAC 14E - Requests for Changes - October 2023 RRC

Hi Taylor,

Under G.S. 150B-21.1(b1), I have to send the objection letter to the head of the agency, which of course would be Secretary Kinsley. I will need an email for him.

Can you send me his email?

Thanks!

Brian

Brian Liebman

Counsel to the North Carolina Rules Review Commission

Office of Administrative Hearings

(984)236-1948

brian.liebman@oah.nc.gov

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Burgos, Alexander N

Subject: FW: Temporary Rules 10A NCAC 14E - Requests for Changes - October 2023 RRC

From: Corpening, Taylor <taylor.corpening@dhhs.nc.gov>

Sent: Wednesday, October 18, 2023 1:39 PM

To: Liebman, Brian R <brian.liebman@oah.nc.gov>

Cc: Burgos, Alexander N <alexander.burgos@oah.nc.gov>; Premakumar, Rajeev K <raj.premakumar@dhhs.nc.gov>

Subject: RE: Temporary Rules 10A NCAC 14E - Requests for Changes - October 2023 RRC

Hi Brian,

Listed are the people (other than myself) from the Department attending tomorrow's meeting:

Eric Hunt

Azzie Conley

Raj Premakumar

Julie Cronin

Jeff Harms (virtual)

There are no interconnectivity issues with .0101 and .0111.

Taylor Corpening

Rule-making Coordinator

Division of Health Service Regulation

[NC Department of Health and Human Services](#)

Office: 919-855-4619

Fax: 919-733-2757

taylor.corpening@dhhs.nc.gov

809 Ruggles Drive, Edgerton Building

2701 Mail Service Center

Raleigh, NC 27699-2701

Burgos, Alexander N

Subject: FW: Temporary Rules 10A NCAC 14E - Requests for Changes - October 2023 RRC

From: Liebman, Brian R <brian.liebman@oah.nc.gov>

Sent: Wednesday, October 18, 2023 12:09 PM

To: Corpening, Taylor <taylor.corpening@dhhs.nc.gov>

Cc: Burgos, Alexander N <alexander.burgos@oah.nc.gov>; Premakumar, Rajeev K <raj.premakumar@dhhs.nc.gov>

Subject: RE: Temporary Rules 10A NCAC 14E - Requests for Changes - October 2023 RRC

Oh, one last thing. Unless you have an objection, I will send the last version of the Rules (sent Tuesday at 11:46 am) to oah.rules@oah.nc.gov as the final rules for the Commission's consideration.

Brian Liebman

Counsel to the North Carolina Rules Review Commission

Office of Administrative Hearings

(984)236-1948

brian.liebman@oah.nc.gov

E-mail correspondence to and from this address may be subject to the North Carolina Public Records Law N.C.G.S. Chapter 132 and may be disclosed to third parties.

Burgos, Alexander N

Subject: FW: Temporary Rules 10A NCAC 14E - Requests for Changes - October 2023 RRC
Attachments: 10.2023 - DHHS Temp Rules Staff Opinion 10A NCAC 14E .0106, .0107, and .0109.pdf; 10.2023 - DHHS Temp Rules Staff Opinion 10A NCAC 14E.pdf

From: Liebman, Brian R <brian.liebman@oah.nc.gov>
Sent: Wednesday, October 18, 2023 12:07 PM
To: Corpening, Taylor <taylor.corpening@dhhs.nc.gov>
Cc: Burgos, Alexander N <alexander.burgos@oah.nc.gov>; Premakumar, Rajeev K <raj.premakumar@dhhs.nc.gov>
Subject: RE: Temporary Rules 10A NCAC 14E - Requests for Changes - October 2023 RRC

Taylor,

Thanks for all your work on these. Unfortunately, I will be recommending objection to almost all of the rules, with the exception of Rules .0101 and .0111. Please see the attached staff opinions.

I assume you and someone else from the Department will be attending tomorrow's meeting. Please let me know who, so I can tell the Commission to expect you.

Finally, if you could please let me know if there are any interconnectivity concerns with allowing .0101 and .0111 to go into effect without the other rules, should the Commission object, I'd appreciate it.

Thanks,
Brian

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

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Burgos, Alexander N

Subject: FW: Temporary Rules 10A NCAC 14E - Requests for Changes - October 2023 RRC

From: Liebman, Brian R <brian.liebman@oah.nc.gov>

Sent: Tuesday, October 17, 2023 2:34 PM

To: Corpening, Taylor <taylor.corpening@dhhs.nc.gov>

Cc: Burgos, Alexander N <alexander.burgos@oah.nc.gov>; Premakumar, Rajeev K <raj.premakumar@dhhs.nc.gov>

Subject: RE: Temporary Rules 10A NCAC 14E - Requests for Changes - October 2023 RRC

Thanks, Taylor. I'll get back to you with my recommendations shortly.

Brian

Brian Liebman

Counsel to the North Carolina Rules Review Commission

Office of Administrative Hearings

(984)236-1948

brian.liebman@oah.nc.gov

E-mail correspondence to and from this address may be subject to the North Carolina Public Records Law N.C.G.S. Chapter 132 and may be disclosed to third parties.

Burgos, Alexander N

Subject: FW: Temporary Rules 10A NCAC 14E - Requests for Changes - October 2023 RRC
Attachments: Response Request for Technical Changes Temp Rules 10A NCAC 14E 10-17-23.docx; 10A NCAC 14E .0101.docx; 10A NCAC 14E .0104.docx; 10A NCAC 14E .0106.docx; 10A NCAC 14E .0107.docx; 10A NCAC 14E .0109.docx; 10A NCAC 14E .0111.docx; 10A NCAC 14E .0112.docx; 10A NCAC 14E .0201.docx; 10A NCAC 14E .0202.docx; 10A NCAC 14E .0207.docx; 10A NCAC 14E .0315.docx; 10A NCAC 14E .0114.docx; 10A NCAC 14E .0209.docx; 10A NCAC 14E .0210.docx; 10A NCAC 14E .0211.docx; 10A NCAC 14E .0212.docx; 10A NCAC 14E .0318.docx; 10A NCAC 14E .0319.docx; 10A NCAC 14E .0320.docx; 10A NCAC 14E .0321.docx; 10A NCAC 14E .0322.docx; 10A NCAC 14E .0323.docx; 10A NCAC 14E .0324.docx; 10A NCAC 14E .0325.docx; 10A NCAC 14E .0326.docx; 10A NCAC 14E .0327.docx; 10A NCAC 14E .0328.docx; 10A NCAC 14E .0329.docx; 10A NCAC 14E .0330.docx

From: Corpening, Taylor <taylor.corpening@dhhs.nc.gov>
Sent: Tuesday, October 17, 2023 11:44 AM
To: Liebman, Brian R <brian.liebman@oah.nc.gov>
Cc: Burgos, Alexander N <alexander.burgos@oah.nc.gov>; Premakumar, Rajeev K <raj.premakumar@dhhs.nc.gov>
Subject: RE: Temporary Rules 10A NCAC 14E - Requests for Changes - October 2023 RRC

Hi Brian,

Attached are the responses to your questions, as well as updated copies of the rules including the Department's changes. Please note that for the rules for which you have no statutory authority objection, we have made substantive edits in response to your comments. Additionally, we have updated the history note and statutory authority in all of the rules to address your concern about the specificity of section 2.2 of S.L 2023-14.

Taylor Corpening
Rule-making Coordinator
Division of Health Service Regulation
[NC Department of Health and Human Services](#)

Office: 919-855-4619
Fax: 919-733-2757
taylor.corpening@dhhs.nc.gov

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.

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

AGENCY: North Carolina Department of Health and Human Services/DHSR

RULE CITATION: All Rules

DEADLINE FOR RECEIPT: Friday, October 13, 2023.

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:

*Each of your rules cites G.S. 143B-10 in the History Note. Please explain the relevance of this citation. **There's been no answer to this question.***

*Many of your rules cite only to G.S. 143B-10 and S.L. 2023-14, s. 2.4 as authority. I am not sure that Section 2.4 actually is an independent source of rulemaking authority; instead I see it more as a requirement to adopt rules—under other sources of authority—before October 1, 2023. Thus, to my reading, Section 2.4 isn't sufficient on its own as statutory authority; you need another statute that provides the Department with authority to regulate what's covered by the Rule. I don't see that specific authority in 143B-10. **Please add cites to each rule to whatever statute or statutes provide the Department with authority to make the specific regulatory act in each Rule.** As an example of what I'm looking for, see Rule .0106. The rule covers applications, and there's a cite to G.S. 131E-153.2, which requires clinic owners/sponsors to file an application, and directs the Department to define that application in rulemaking.*

Response:

The General Assembly stated in Section 2.4 of S.L. 2023-14 that “No later than October 1, 2023, the Department of Health and Human Services shall adopt the rules necessary to administer this Part.” (emphasis added). This mandate to adopt rules unambiguously refers to Part II of S.L. 2023-14, titled “Suitable Facilities for the Performance of Surgical Abortions.” In light of this mandate, as well as the repeal of the authority for then-existing rules, the Department adopted a first set of emergency rules on June 19, 2023 and a second set on July 6, 2023. The Department adopted all temporary rules on September 18 and submitted the temporary rules to the Rules Review Commission on September 29.

It is notable that the Department's authority to adopt rules only became effective on July 1, 2023, and the law required the adoption of rules to be completed prior to October 1, 2023. This rulemaking mandate is the only section of Part II that became effective prior to

October 1. The remainder of Part II became effective on October 1, 2023, which demonstrates a clear legislative intent that the Department adopt rules prior to October 1 pursuant to this S.L. 2023-14 to ensure that Part II could take effect within the timeframe provided by the General Assembly.

The mandate for the Department to promulgate rules necessary to administer Part II of Session Law 2023-14 replaced the prior authorization found under G.S. 14-45.1, which was repealed on July 1, 2023. This shift in authority from the prior law to the new Session Law was recognized by the Codifier of Rules' analysis of the statute in prior correspondence with the Department:

Part I, Sec. 1.1 of the Session Law repeals DHHS's current rulemaking authority. Part II, Section 2.4 of the Session Law does grant DHHS the authority to adopt rules by October 1, 2023...

Letter from Codifier of Rules to Secretary Kody Kinsley, re: Emergency Rule Filing, 10A NCAC 14E, June 22, 2023 (emphasis added).

Section 2.2 of Session Law 2023-14 amends Article 6 of Chapter 131E of the General Statutes by creating the Abortion Clinic Licensure Act (the Act). As stated in the session law, the purpose of the Act is to:

(b) ... provide for the development, establishment, and enforcement of basic standards:

- (1) For the care and treatment of individuals in abortion clinics;
- (2) For the maintenance and operation of abortion clinics so as to ensure safe and adequate treatment of such individuals in abortion clinics.

S.L. 2023-14, § 2.2. The temporary rules adopted by Department made minimum changes to the language necessary to comply with Part II of S.L. 2023-14 but otherwise retained the content of the previous 10A NCAC 14E permanent rules. The content of all the rules is directly supported by the purpose of the Act, which makes the adoption of these rules necessary to ensure that Part II of S.L. 2023-14 can be effectively administered by the Department. Consistent with Section 2.4 of S.L. 2023-14, the Department has determined that each of the proposed rules are necessary to implement the purpose as stated in G.S. § 131E-153(b). Additionally, the content of rules related to issuance of licenses, adverse action of licenses and inspections of abortion clinics is also explicitly indicated in the Act and further supports the adoption of these rules.

To clarify the source of authority, the Department has added S.L. 2023-14, s 2.2, to the authority in the history note of each of the proposed temporary rules.

See separate email.

Swap history note from G.S. 143B-10 to G.S. 131E-153, 153.2

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: October 6, 2023

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

AGENCY: North Carolina Department of Health and Human Services/DHSR

RULE CITATION: 10A NCAC 14E .0101

DEADLINE FOR RECEIPT: Friday, October 13, 2023.

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 is your statutory authority for this Rule? Neither 143B-10 nor S.L. 2023-14 s. 2.4 cover the content of the Rule. **Please see response provided on Page 2.***

*In (1), line 10, to be clear, you are defining “abortion” for the purpose of this subchapter to mean only “surgical abortion” as defined in G.S. 90-21.81(1c)? **Yes.***

*In (2), lines 11-13, please delete the parentheses and incorporate the parenthetical material into the body of the Rule. **Parentheses deleted.***

*In (3), lines 14-15, this is not a definition. Moreover, the term “Complication” is defined in G.S. 90-21.81(2a). Did you mean to adopt that definition? Each of the instances mentioned here is listed in the statutory definition. **Definition deleted.***

*In (6), line 22, the Rule references Rule .0302, which has been repealed. Please correct. **Reference corrected.***

*In (9), lines 29-30, is this necessary? “Qualifying Physician” is defined in G.S. 90-21.81(7a). **Definition deleted.***

*In (9), line 29, must the physician be licensed in any state, or in the State of North Carolina? **Definition deleted.***

*In (9), line 29, the statutory language defining abortion (G.S. 90-21.81A(a)) was amended in SL 2023-65 to remove the word “advise”. Was it your intent to leave that here? **Definition deleted. Please make sure you correct cross references to this Rule in your other Rules.***

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: October 6, 2023

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

AGENCY: North Carolina Department of Health and Human Services/DHSR

RULE CITATION: 10A NCAC 14E .0102

DEADLINE FOR RECEIPT: Friday, October 13, 2023.

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:

We are withdrawing this rule from consideration.

It appears that DHSR is requiring (“shall”) people who aren’t licensed and aren’t even applicants for licensure, but people merely considering the idea of establishing an abortion clinic, to do something. Where is your statutory authority to regulate those who aren’t licensed or applying to be licensed?

What is a discussion in this context? How would it be determined that someone has or has not complied with this Rule? Do they have to say something to DHSR staff, or passively listen? Would a 10 second conversation satisfy this Rule?

If a potential sponsor or owner does not comply with this Rule, and subsequently submits an otherwise acceptable application for licensure, would their application be denied for failure to “discuss” it first with DHSR staff?

On line 6, what “licensure requirements” are you referring to?

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

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

AGENCY: North Carolina Department of Health and Human Services/DHSR

RULE CITATION: 10A NCAC 14E .0104

DEADLINE FOR RECEIPT: Friday, October 13, 2023.

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 is your statutory authority for this Rule? Neither 143B-10 nor S.L. 2023-14 s. 2.4 cover the content of the Rule. **Please see response provided on Page 2.***

On lines 4-5, the Rule states that the “clinic” shall submit two copies of the building plans for “licensure purposes.”

*First, who at the “clinic” shall do this? **Language changed to “an applicant for a new clinic.”***

*Second, what are “licensure purposes”? What are the guidelines for this review? **Issue addressed in language change. No, I think this merely rephrases what was there already. What are the purposes? Review according to what standards? “for..... purposes of becoming-licensed”***

*On lines 7-8, there is no such code as the “North Carolina Administration and Enforcement Requirements Code.” **Issue addressed and incorrect language taken out. The URL goes to the NC Administrative Code. That technically is different than the State Building Code. It’s a building code, but the state Building Code is technically a different code. Just point to the specific part of the specific code you mean.***

*On line 7, the 2012 edition of the various state building codes have all been superseded by the 2018 versions. Your incorporation by reference does state “subsequent amendments and editions”, but it would be less ambiguous to update the reference. **Building code versions updated.***

*On line 9, the URL provided does not direct a user to any specific code, but redirects to the ICC website. **Website link 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: October 6, 2023

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

AGENCY: North Carolina Department of Health and Human Services/DHSR

RULE CITATION: 10A NCAC 14E .0106

DEADLINE FOR RECEIPT: Friday, October 13, 2023.

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), please consider revising in the active tense. Who shall submit the application?
(a) has been rewritten in the active tense.

In (b), line 6, where shall the applicant contact the Division? Do you have a contact rule? ***Address added.***

In (c), line 8, what is "general information that would be helpful"? Issue addressed. OK, but does this rule otherwise contain the contents or substantive requirements of the application form? If all that's necessary is the "ownership, staffing patterns, clinical services to be rendered, and professional staff in charge of services", then it's OK. But if you want more than that on the application, you need to say it here. Name of applicant, facility, ownership, building owner, building management, sanitation services, medical director, other medical staff, director of nursing, other nursing staff, consulting pathologist,

In (e), lines 14-15, are the contents or substantive requirements of the application form contained in another rule or in a statute? Are the same as in (c)? This is not clear. (e) deleted from this rule and merged into Rule .0109.

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

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

AGENCY: North Carolina Department of Health and Human Services/DHSR

RULE CITATION: 10A NCAC 14E .0107

DEADLINE FOR RECEIPT: Friday, October 13, 2023.

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)(2), line 6, what does it mean to “assure” that a physician is available? **Issue addressed.***

*In (a)(2), lines 6-7, what “board” is certifying the OB-GYN? **American Board of Obstetrics and Gynecology. Please say so in the rule. Will add.***

*In (a)(2), line 7, what board should the physician be eligible for? **Issue addressed. Not that I can see. American Board of Obstetrics and Gynecology.***

*In (d), line 13, add a comma following “explosions”. **Comma added.***

*In (d), line 13, what is a “disruption” in services? **Issue addressed. I’d prefer the active tense-prevents who from providing what services? Prevents the clinic from providing abortion services”***

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

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

AGENCY: North Carolina Department of Health and Human Services/DHSR

RULE CITATION: 10A NCAC 14E .0108

DEADLINE FOR RECEIPT: Friday, October 13, 2023.

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:

We are withdrawing this rule from consideration.

What is your statutory authority for this Rule? Neither 143B-10 nor S.L. 2023-14 s. 2.4 cover the content of the Rule.

On line 4, please define "conspicuous place".

In the absence of a definition of "conspicuous place", how is this rule necessary when it merely restates G.S. 131E-153.2(e)?

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

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

AGENCY: North Carolina Department of Health and Human Services/DHSR

RULE CITATION: 10A NCAC 14E .0109

DEADLINE FOR RECEIPT: Friday, October 13, 2023.

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:

*How does this Rule relate to .0106(e), which also covers renewal? Why is this topic separated into two rules? **We removed the renewal language of section .0106(e) and combined it with Rule .0109.***

*On line 4, what do you mean by “previously” suspended or revoked? Does this mean that the license is currently in that status? **Issue addressed.***

*On line 4, what “rules and statutes” are applicable? Be specific. **Issue addressed.***

*On line 5, what application? Is it the same form/contents as discussed in Rule .0106? **Issue addressed. No, it has not been addressed. Where are the contents or substantive requirements of this application form written down? In a rule or statute? In other words, because the statute gives the Department the authority to set the contents of the application, you need to state here exactly what you want on the application form for renewal. The rule will be updated with the contents of the application.***

*On line 6, under what circumstances is approval given? **Language deleted.***

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

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

AGENCY: North Carolina Department of Health and Human Services/DHSR

RULE CITATION: 10A NCAC 14E .0110

DEADLINE FOR RECEIPT: Friday, October 13, 2023.

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:

Withdrawn from consideration.

*On line 4, please define "substantial". **Issue addressed. I think by adding "may" instead of "shall" you've created a new issue. When may there be a failure to comply with the statutes and rules and the clinic not have its license revoked?***

To be honest, I wonder why this Rule is necessary, when it really just restates 131E-153.4.

*On line 5, what regulations are you referring to? **Issue addressed.***

*On line 5, please define "unsuitable". **Issue addressed.***

*Why is there a reference to G.S. 150B-23 in your History Note? **To provide a linkage to an individual's right to file a contested case upon the agency taking action on a clinic's license. But how does it give you authority to "deny, suspend, or revoke" a license? History Notes are for providing statutory authority, not letting people know what their rights are.***

*Should there not be a reference to G.S. 131E-153.4? **Issue addressed.***

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

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

AGENCY: North Carolina Department of Health and Human Services/DHSR

RULE CITATION: 10A NCAC 14E .0111

DEADLINE FOR RECEIPT: Friday, October 13, 2023.

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 is your statutory authority for this Rule? Neither 143B-10 nor S.L. 2023-14 s. 2.4 cover the content of the Rule. **Please see response provided on Page 2. Doesn't 131E-153.6 give you authority to conduct inspections?***

*In (a), lines 5-7, the sentence "An inspection . . . of this Subchapter" is confusingly written. Can it be simplified? In particular, what does it mean to say "An inspection shall be conducted whenever the purpose of the inspection is to determine" compliance? **Issue addressed and the sentence is simplified.***

*In (a), line 7, who should have "reason to believe" that the clinic isn't in compliance? **Issue addressed.***

*In (a), line 7, please simplify "some condition exists which is not in compliance". **Issue addressed.***

*In (b), line 9, what is the difference between "care" and "treatment"? **Issue addressed by deleted paragraph.***

*In (c), line 11, who would be the "person in charge"? **Issue addressed.***

*In (d), lines 14-15, what does "unless otherwise required by law" modify? Does it mean the Division can review records unless otherwise required by law, or that the Division shall maintain confidentiality unless otherwise required by law? **Addressed by breaking up sentences.***

*In (f), lines 18-19, the division's response must be in writing, but the clinic's plan of correction is not explicitly required to be in writing. Is this intentional? **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: October 6, 2023

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

AGENCY: North Carolina Department of Health and Human Services/DHSR

RULE CITATION: 10A NCAC 14E .0112

DEADLINE FOR RECEIPT: Friday, October 13, 2023.

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 is your statutory authority for this Rule? Neither 143B-10 nor S.L. 2023-14 s. 2.4 cover the content of the Rule. **Please see response provided on Page 2.***

*On line 4, what "specified types" of alterations are you referring to? **Issue addressed.***

*On lines 6-7, the terms "therefor" and "herein" are to be avoided pursuant to our style guide. Consider revising. **Issue addressed.***

*On line 6, are these "recommendations" binding? **Issue addressed.***

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

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

AGENCY: North Carolina Department of Health and Human Services/DHSR

RULE CITATION: 10A NCAC 14E .0113

DEADLINE FOR RECEIPT: Friday, October 13, 2023.

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

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

We are withdrawing this rule from consideration.

What is your statutory authority for this Rule? Neither 143B-10 nor S.L. 2023-14 s. 2.4 cover the content of the Rule.

How is this rule different from Rule .0112?

On line 4, what are the plans to be “reviewed” for? Reviewed under what guidelines or standards?

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

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

AGENCY: North Carolina Department of Health and Human Services/DHSR

RULE CITATION: 10A NCAC 14E .0114

DEADLINE FOR RECEIPT: Friday, October 13, 2023.

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

*What is your statutory authority for this Rule? Neither 143B-10 nor S.L. 2023-14 s. 2.4 cover the content of the Rule. **Please see response provided on Page 2.***

*In (a), line 4, what are “construction documents and specifications”? **Language corrected to “building plans.”***

*Where is the statutory authority, specifically, for the review and approval required in (a), lines 5-7 by the Division of Public Health, the Environmental Health Section, and the Department of Insurance? **Language removed.***

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

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

AGENCY: North Carolina Department of Health and Human Services/DHSR

RULE CITATION: 10A NCAC 14E .0201

DEADLINE FOR RECEIPT: Friday, October 13, 2023.

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

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

*What is your statutory authority for this Rule? Neither 143B-10 nor S.L. 2023-14 s. 2.4 cover the content of the Rule. **Please see response provided on Page 2.***

*In (a), line 10, the URL for ecodes.biz just redirects back to the ICC website. Please correct. **Link replaced. As in Rule .0104, the URL only directs to the NC Administrative Code, which is a different code than the NC State Building Code. Please cite to the correct code, and provide a citation to the specific portion of the Building Code you're directing your regulated public to.***

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

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

AGENCY: North Carolina Department of Health and Human Services/DHSR

RULE CITATION: 10A NCAC 14E .0202

DEADLINE FOR RECEIPT: Friday, October 13, 2023.

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

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

*What is your statutory authority for this Rule? Neither 143B-10 nor S.L. 2023-14 s. 2.4 cover the content of the Rule. **Please see response provided on Page 2.***

*On line 9, please use a more direct URL to the NCAC. It should be <http://reports.oah.state.nc.us/ncac.asp>. **Link corrected.***

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

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

AGENCY: North Carolina Department of Health and Human Services/DHSR

RULE CITATION: 10A NCAC 14E .0207

DEADLINE FOR RECEIPT: Friday, October 13, 2023.

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 is your statutory authority for this Rule? Neither 143B-10 nor S.L. 2023-14 s. 2.4 cover the content of the Rule. **Please see response provided on Page 2.***

*On line 4, please correct the reference to Rule .0206, which has been repealed. I assume, but am not sure, that this should now say Rule .0212, based on the rule titles. **Issue addressed.***

*Do the requirements here and in Rule .0212 conflict in any way with the requirements of the Building Code and with the requirements of 15A NCAC 18A .1300? **No.***

*What is the purpose of (9)? This list is of areas that have to comply with Rule .0212, and here we've got a semi-definition of "medicine room". Does the cabinet in the clean workroom also have to comply with Rule .0212? What if it isn't a cabinet, and it is a separate room? **Wording changed to avoid confusion. Wording is still off. As edited, it says "a clean area for self contained secure medical storage complying with security requirements of state and federal laws is provided". I think the "as provided" needs to be deleted, and maybe say "also complying with security requirements..."***

*In (10), line 16, add "of" between "handling" and "clean". **Issue addressed.***

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

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

AGENCY: North Carolina Department of Health and Human Services/DHSR

RULE CITATION: 10A NCAC 14E .0209

DEADLINE FOR RECEIPT: Friday, October 13, 2023.

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

*What is your statutory authority for this Rule? Neither 143B-10 nor S.L. 2023-14 s. 2.4 cover the content of the Rule. **Please see response provided on Page 2.***

*In (a), consider rewriting in the active tense. Who shall provide the elevator? **Issue addressed.***

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

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

AGENCY: North Carolina Department of Health and Human Services/DHSR

RULE CITATION: 10A NCAC 14E .0210

DEADLINE FOR RECEIPT: Friday, October 13, 2023.

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

*What is your statutory authority for this Rule? S.L. 2023-14 s. 2.4 does not cover the content of the Rule. **Please see response provided on Page 2.***

*This rule seems potentially self-contradictory. Can a corridor be greater than 60 inches wide but insufficient to allow for patient evacuation by stretcher? **Issue addressed.***

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

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

AGENCY: North Carolina Department of Health and Human Services/DHSR

RULE CITATION: 10A NCAC 14E .0211

DEADLINE FOR RECEIPT: Friday, October 13, 2023.

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 is your statutory authority for this Rule? S.L. 2023-14 s. 2.4 does not cover the content of the Rule. **Please see response provided on Page 2.***

*On line 6, please define "small closet". **Issue addressed by deleting "small closets."***

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

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

AGENCY: North Carolina Department of Health and Human Services/DHSR

RULE CITATION: 10A NCAC 14E .0212

DEADLINE FOR RECEIPT: Friday, October 13, 2023.

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

*What is your statutory authority for this Rule? Neither 143B-10 nor S.L. 2023-14 s. 2.4 cover the content of the Rule. **Please see response provided on Page 2.***

*Does this Rule conflict in any way with the Building Code or with 15A NCAC 18A .1300? **No.***

*In (1)(b)(ii), the Rule requires air delivered “at or near” the ceiling, but removed “not less than three inches” from the floor. Is the lack of specificity for the ceiling intended? **Yes.***

*In (1)(b)(v), line 27, add a comma following “closets”. **Issue addressed.***

*With respect to both instances of the NFPA you’re incorporating, do the portions of the Building Code, which you’ve also incorporated, contain any contradictory NC Fire Code provisions? **No.***

*Also with respect to both instances of the NFPA, please provide more specific URLs to where these documents can be found free of charge. I went on NFPA.org and was unable to access them for free. **www.NFPA.org is the correct URL. The documents are available for free if one creates a profile.***

*In (2)(a)(i), p.2, line 9, does the reference to NFPA-99-2012 mean the 2012 version? The current NFPA version is 2024. The incorporation says “including subsequent amendments and editions”. Same question for NFPA 70-2011 in (2)(a)(ii). **Version corrected.***

*With respect to NFPA-70-2011, NFPA-70 is the National Electric Code. North Carolina has already adopted the 2018 National Electric Code with state specific amendments. Would NFPA-70-2011 still be in effect, or has it been superseded by provisions in the 2018 code? **Version corrected.***

Brian Lieberman
Commission Counsel

Date submitted to agency: October 6, 2023

*In (2)(a)(ii), lines 15-16, what does “current editions relating to inhalation anesthesia” mean? Does this mean only portions of these documents are incorporated by reference? If so, please specifically state which portions are incorporated by reference. **Issue addressed.***

*In (3)(a), line 32, what does “listed batter backup lighting units” mean? Specifically, I’m asking about “listed”. **The list is found at <https://www.ncosfm.gov/third-party-testing-agencies/open>. Beyond seeing that this is a document from the Fire Marshal, I have no idea what this document does. Moreover, it’s still not clear in the Rule what you mean by “listed”.***

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

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

AGENCY: North Carolina Department of Health and Human Services/DHSR

RULE CITATION: 10A NCAC 14E .0213

DEADLINE FOR RECEIPT: Friday, October 13, 2023.

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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:

We are withdrawing this rule from consideration.

What is your statutory authority for this Rule? Neither 143B-10 nor S.L. 2023-14 s. 2.4 cover the content of the Rule.

What does this sentence mean? It's facially vague and ambiguous.

On line 4, what does "written indication" mean?

On line 4, what's the significance of "shared or purchased"?

On line 4, what are "appropriate" modifications? Please delete or define.

On line 5, "space requirements" for what? What requirements are you referring to?

On line 5, "may be anticipated" by whom?

On lines 4-5, what effect would be caused by modifying the space requirements?

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

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

AGENCY: North Carolina Department of Health and Human Services/DHSR

RULE CITATION: 10A NCAC 14E .0315

DEADLINE FOR RECEIPT: Friday, October 13, 2023.

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

*What is your statutory authority for this Rule? Neither 143B-10 nor S.L. 2023-14 s. 2.4 cover the content of the Rule. **Please see response provided on Page 2.***

*How is this rule any different than Rule .0202? Both require adherence to the sanitation standards in 15A NCAC 18A .1300. **This Rule addresses standards beyond the sanitation standards in Rule .0202. You deleted the reference to 15A NCAC 18A .1300 but left it on the last line of the rule.***

*In (1), line 8, add a comma following "woodwork". **Done.***

*In (1), line 8, what is "waste material"? **Language removed.***

*In (3), line 11, please define "clean and sanitary condition". **Term defined consistent with 15A NCAC 18A .1312. That term is not defined in 15A NCAC 18A .1312. And even if it was, you have not incorporated it by reference here.***

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

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

AGENCY: North Carolina Department of Health and Human Services/DHSR

RULE CITATION: 10A NCAC 14E .0317

DEADLINE FOR RECEIPT: Friday, October 13, 2023.

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

We are withdrawing this rule from consideration.

What is your statutory authority for this Rule? Neither 143B-10 nor S.L. 2023-14 s. 2.4 cover the content of the Rule.

On line 4, what does "fully disclosed" mean?

Does this Rule require anything not already required in Section .0100? Ownership must be disclosed on the application form.

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

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

AGENCY: North Carolina Department of Health and Human Services/DHSR

RULE CITATION: 10A NCAC 14E .0318

DEADLINE FOR RECEIPT: Friday, October 13, 2023.

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

*What is your statutory authority for this Rule? Neither 143B-10 nor S.L. 2023-14 s. 2.4 cover the content of the Rule. **Please see response provided on Page 2.***

*Specifically to statutory authority here, where is your authority to require the governing authority to appoint a CEO? I don't see anything in the Session Law that would give you authority to regulate the organizational structure and personnel practices of any private entity, or to require a the CEO to delegate his or her authority. **Please see response provided on Page 2. The Department has the authority to adopt rules on clinic operations to ensure safe and adequate treatment pursuant to Section 2.2 of Session Law 2023-14.***

*Again, to statutory authority, where is your authority to require a governing authority to adopt policies and procedures? **Please see response provided on Page 2. The Department has the authority to adopt rules on clinic operations to ensure safe and adequate treatment pursuant to Section 2.2 of Session Law 2023-14.***

*In (a), line 5, to whom would the CEO/designee represent the governing authority? **To individuals and entities outside of the clinic.***

*In (d)(3), line 20, define "professional and safe". **Language changed. OK, not trying to be difficult, but now you need to define "safe and adequate". The point is that when you're telling the regulated public to do something, you have to be clear about the standards by which their efforts to comply will be judged. How is a clinic to know if their policy and procedure manual ensures safe and adequate care unless you tell them what that means?***

In (e), what do you mean by "shall be responsible to assure" that the supplier meets the local or state standards? Do you have authority to require a 3rd party to conform to state and local standards? Do you have statutory authority to require a clinic to enter into a contract? Do you have statutory authority to essentially specify the terms of that

Brian Lieberman
Commission Counsel

Date submitted to agency: October 6, 2023

*contract? **Please see response provided on Page 2. The Department has the authority to adopt rules on clinic operations to ensure safe and adequate treatment pursuant to Section 2.2 of Session Law 2023-14.***

*In (e), line 24, omit the comma following “laundry”. **Done.***

*In (e), line 25, capitalize “state” if referring only to the State of North Carolina. **Done.***

*In (g), line 29-30, who are “supporting personnel”? **Clinic staff.***

*In (g), line 30, please define “safe patient care.” **Issue revised.***

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

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

AGENCY: North Carolina Department of Health and Human Services/DHSR

RULE CITATION: 10A NCAC 14E .0319

DEADLINE FOR RECEIPT: Friday, October 13, 2023.

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

*What is your statutory authority for this Rule? Neither 143B-10 nor S.L. 2023-14 s. 2.4 cover the content of the Rule. **Please see response provided on Page 2.***

*Specifically, do you have statutory authority to require documents to be kept on file on the clinic's premises? **Please see response provided on Page 2. The Department has the authority to adopt rules on clinic operations to ensure safe and adequate treatment pursuant to Section 2.2 of Session Law 2023-14.***

*In (a)(7), line 12, please define "related to licensure". **Issue addressed by changing the language.***

*In (b), line 13, is this requirement not redundant with Rule .0108? **No, Rule .0108 has been withdrawn.***

*In (c), line 14, what policies and procedures are you requiring? Is this other than the policies and procedures required elsewhere in these rules? **This rule pertains to the manual requiring specified policies and procedures. So is this is a separate manual than the one referenced in .0318?***

*In (c)(1), line 17, consider making "clinical discharge criteria" an independent item. **Correction made.***

*In (c)(3), line 19, to be clear, do you mean medical policies and procedures? For instance, a description of the steps the doctor would take in performing each procedure? **Issue addressed by changing the language. Do you have statutory authority to require a manual with policy and procedure that governs the steps of a medical procedure? Aren't medical procedures up to the discretion of the doctor, and governed by the standard of care?***

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: October 6, 2023

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

AGENCY: North Carolina Department of Health and Human Services/DHSR

RULE CITATION: 10A NCAC 14E .0320

DEADLINE FOR RECEIPT: Friday, October 13, 2023.

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

*What is your statutory authority for this Rule? Neither 143B-10 nor S.L. 2023-14 s. 2.4 cover the content of the Rule. **Please see response provided on Page 2.***

*In (a), line 5, what do you mean by “administrative decisions on their disposition”? **Issue addressed. Still not clear what an “administrative decision” is. Do you mean whether to admit or discharge?***

*In (c), line 8, what is a “general” hospital? Is this different than the definition of “hospital” in the statute? “acute care hospital” **Issue addressed by clarifying the language.***

*In (d)(2), line 13, delete the “(s)” and make “physician(s)” either plural or “physician or physicians”. **Done.***

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

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

AGENCY: North Carolina Department of Health and Human Services/DHSR

RULE CITATION: 10A NCAC 14E .0321

DEADLINE FOR RECEIPT: Friday, October 13, 2023.

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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:

*What is your statutory authority for this Rule? Neither 143B-10 nor S.L. 2023-14 s. 2.4 cover the content of the Rule. **Please see response provided on Page 2.***

*Throughout, please use the active tense and specify the subject of sentences where you're directing someone to take some action. I've tried to call out below where this is particularly problematic, but please review the entire rule and make these changes. **Issue addressed.***

*In (a), line 4, who must maintain the record? Please use the active tense. **Changed to active tense.***

*In (a)(10), line 16, please define "have a bearing on". **Issue addressed by rephrasing language.***

*In (b), line 20, should "report" be plural? **Issue addressed by rephrasing.***

*In (b), line 22, who shall sign to authenticate? **Issue addressed by saying the clinic has the responsibility to authenticate. A clinic can't sign something. What person should do these acts? A doctor? A nurse? A staff member?***

*In (c), line 23, who shall explain the significance? **Addressed by clarifying language and specifying the clinic. A clinic can't speak. What person should explain the significance of the RH negative test result?***

*In (d), line 25, who shall perform the ultrasound? **Issue addressed.***

*In (e)(4), line 32, add the article before "physician". **Done.***

*In (e)(5), line 33, add the article before "Registered Nurse". **Done.***

In (e)(6), line 34, do you mean the time the procedure started, or the duration? Both? The start and end time of the procedure should be noted pursuant to the rule. The rule doesn't say this. Please edit accordingly.

In (f), line 35, do you have statutory authority to require that records be preserved in the state? Please see response provided on Page 2. The Department has the authority to adopt rules on clinic operations to ensure safe and adequate treatment pursuant to Section 2.2 of Session Law 2023-14.

In (f), p.2, line 2, would a patient's request for records be sufficient to remove the records? No.

In (h), line 5, arrangements shall be made by whom? Issue addressed by specifying the clinic. A clinic can't preserve something. What person should preserve the records?

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

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

AGENCY: North Carolina Department of Health and Human Services/DHSR

RULE CITATION: 10A NCAC 14E .0322

DEADLINE FOR RECEIPT: Friday, October 13, 2023.

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

*What is your statutory authority for this Rule? Neither 143B-10 nor S.L. 2023-14 s. 2.4 cover the content of the Rule. **Please see response provided on Page 2.***

In (a)(1)(A), (B), and (C), please add articles before the noun opening the sentence (“the employee’s...”) **Done**

In (a)(1)(D) and (E), what are you requiring by “verification”? **Issue addressed by changing language.**

*In (a)(3), line 13, do you have statutory authority for this provision? Are not personnel records otherwise confidential under the law? **Please see response provided on Page 2. The response on page 2 doesn’t specify anything about confidentiality of personnel records.***

In (a)(3), line 13, what do you mean by “notwithstanding the requirement found in Subparagraph (b)(2)”? *That language refers to a job description. **Issue addressed by simplifying the language.***

*In (f), line 29, are these health records not confidential under State and federal law? **No. Health records of employees aren’t confidential? Not under HIPAA? Are you sure about this? Also, change the reference to .0101(7) to conform with the edits to that 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: October 6, 2023

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

AGENCY: North Carolina Department of Health and Human Services/DHSR

RULE CITATION: 10A NCAC 14E .0323

DEADLINE FOR RECEIPT: Friday, October 13, 2023.

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 is your statutory authority for this Rule? Neither 143B-10 nor S.L. 2023-14 s. 2.4 cover the content of the Rule. **Please see response provided on Page 2.***

*Specifically, where is your authority to require the governing authority to designate a nursing supervisor? I don't see anything in the Session Law that would give you authority to regulate the organizational structure and personnel practices of any private entity. **Please see response provided on Page 2. The Department has the authority to adopt rules on clinic operations to ensure safe and adequate treatment pursuant to Section 2.2 of Session Law 2023-14.***

*In (a), line 5 and (b), line 6, please define "responsibility and accountability" and "responsible and accountable". **Issue addressed by rephrasing sentences and deleting language.***

*In (b)(2), line 8, what manual? Is this required in another rule? **The Nursing Policy and Procedure Manual, it is not required in another rule.***

*In (c), lines 10-11, who makes the judgment that there are sufficient personnel on staff? **The governing authority of the clinic. The Rule doesn't say that. Please amend accordingly.***

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

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

AGENCY: North Carolina Department of Health and Human Services/DHSR

RULE CITATION: 10A NCAC 14E .0324

DEADLINE FOR RECEIPT: Friday, October 13, 2023.

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 is your statutory authority for this Rule? Neither 143B-10 nor S.L. 2023-14 s. 2.4 cover the content of the Rule. **Please see response provided on Page 2.***

*Specifically, where is your authority to require the governing authority to establish a quality assurance program and a compliance committee? Where is your authority to require the governing authority to set staffing requirements for the committee? Where is your authority to set the committee's functions? **Please see response provided on Page 2. The Department has the authority to adopt rules on clinic operations to ensure safe and adequate treatment pursuant to Section 2.2 of Session Law 2023-14.***

*In (b), line 7, "corrective action" for what? **Issue addressed by specifying rule. The text of the Rule does not specify another rule.***

*In (c), lines 8-9, are these members of the committee to also be members of the governing authority? Employees of the clinic? Or must they be independent and unaffiliated with the clinic at all? **They can be employees of the clinic. I'm not sure this answers the question. I assumed they could be employees, but must they be employees? Either way, the rule doesn't say this, so please amend accordingly.***

*In (c), line 9, what are "other health professionals"? **Health professionals that are not physicians such as nurse practitioners, pharmacists, registered nurses, and physician's assistants.***

*In (f), line 19, who shall conduct these programs? Please use the active tense. **Rewritten in active tense.***

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: October 6, 2023

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

AGENCY: North Carolina Department of Health and Human Services/DHSR

RULE CITATION: 10A NCAC 14E .0325

DEADLINE FOR RECEIPT: Friday, October 13, 2023.

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 is your statutory authority for this Rule? Neither 143B-10 nor S.L. 2023-14 s. 2.4 cover the content of the Rule. **Please see response provided on Page 2.***

*In (a), line 4, what do you mean by “have the capability to . . . obtain” lab tests? Does this mean an agreement with a 3^d party? **A clinic needs to either have a clinical laboratory certificate, which would allow them to provide lab tests on their own, or they would need to contract with a reference lab. This makes sense, but isn’t clear in the rule. Please amend accordingly.***

*In (b), this is written in a roundabout way. Did you mean to say that the governing authority must establish a written policy stating which “surgical samples” must be examined by a pathologist? **Issue addressed by rephrasing the statement.***

*In (b), line 7, what do you mean by “those types of specimens”? What specimens? **Issue addressed by deleting language.***

*In (e), lines 15-16, are you allowing that the lab tests may be performed by any “employee” who has access to the manual? **No, the Rule is only specific to the requirement for a manual. Only employees that are authorized and qualified may perform the tests.***

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

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

AGENCY: North Carolina Department of Health and Human Services/DHSR

RULE CITATION: 10A NCAC 14E .0326

DEADLINE FOR RECEIPT: Friday, October 13, 2023.

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 is your statutory authority for this Rule? Neither 143B-10 nor S.L. 2023-14 s. 2.4 cover the content of the Rule. **Please see response provided on Page 2.***

*In (a), line 4, what is the definition of an “emergency case”? **Issue addressed. In the new language, “could reasonably be expected to result” by whom? Also, what is “serious jeopardy”, “serious impairment to bodily functions”, and “serious dysfunction of bodily organs”? What’s the difference between “impairment” and “dysfunction”? What level of dysfunction or impairment is “serious”?***

*In (a), line 4, define “nearby”. **Issue addressed.***

*In (a), line 5, when is hospitalization necessary? **When the clinic can no longer provide treatment or services due to the patient’s condition.***

*In (b), line 6, how can a clinic “have” a procedure? Consider rephrasing. **Issue addressed by specifying “written protocols”***

*In (b), line 6, define “suitable equipment”. **Issue addressed.***

*In (b), line 6, again, please define “medical emergencies”. **Issue addressed.***

*In (c), line 9, what kind of “documentation” are you requiring? **A letter or email or other written acknowledgement that the hospital will facilitate the transfer of patients that are in need of emergency care. The “documentation” required is that the clinic has not been unable to secure such an agreement. Again, what documentation are you requiring?***

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: October 6, 2023

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

AGENCY: North Carolina Department of Health and Human Services/DHSR

RULE CITATION: 10A NCAC 14E .0327

DEADLINE FOR RECEIPT: Friday, October 13, 2023.

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 is your statutory authority for this Rule? Neither 143B-10 nor S.L. 2023-14 s. 2.4 cover the content of the Rule. **Please see response provided on Page 2.***

*In (a), line 5, please define an “atmosphere free of contamination”. **Issue addressed by changing the wording. Changing “atmosphere” to “environment” doesn’t fix this issue. Are you requiring the procedure room to be sterile? If so, say that. Also, is a procedure room different than an “operating room” in G.S. 131E-153.1(3)?***

*In (a), line 6, are there not standard procedures for infection control and universal precautions? **There are standards, but they may originate from different sources. The Rule is intended to require the clinic to choose one of the generally accepted standard procedures. The rule doesn’t say this. It say the clinic shall establish procedures, full stop. I’d read that to mean the clinic can come up with its own procedures.***

*In (b)(2), line 12, add a comma following “pregnancy”. **Done.***

*In (b)(2), line 12-13, the grammar of the sentence seems off, particularly on line 13. Please consider revising. **Issue addressed by restructuring sentence. Still not sure about the last part of the sentence. I assume you mean that the physician will evaluate the patient for an ectopic pregnancy or for whether she has already undergone another surgical abortion that is incomplete? If so, please make that clearer.***

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: October 6, 2023

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

AGENCY: North Carolina Department of Health and Human Services/DHSR

RULE CITATION: 10A NCAC 14E .0328

DEADLINE FOR RECEIPT: Friday, October 13, 2023.

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 is your statutory authority for this Rule? Neither 143B-10 nor S.L. 2023-14 s. 2.4 cover the content of the Rule. **Please see response provided on Page 2.***

*In (b), line 5, may a physician administer medications directly, or must he or she allow an RN to do it? **Issue addressed.***

*In (c), line 7, please define "direct supervision"? **Issue addressed.***

*In (c), line 7, may anesthesia be administered by any licensed physician, or an anesthesiologist? **Yes, so long as they are qualified within their scope of practice and under the direct supervision of a licensed physician. This wasn't a yes or no question, and I don't really understand the answer. Are you saying that in an abortion clinic, a patient may be anesthetized by someone other than an anesthesiologist?***

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

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

AGENCY: North Carolina Department of Health and Human Services/DHSR

RULE CITATION: 10A NCAC 14E .0329

DEADLINE FOR RECEIPT: Friday, October 13, 2023.

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

*What is your statutory authority for this Rule? Neither 143B-10 nor S.L. 2023-14 s. 2.4 cover the content of the Rule. **Please see response provided on Page 2.***

*In (a), line 4, and (c)(1), line 10, please define “ambulatory basis” and “ambulatory”. **“Ambulatory basis” and “ambulatory” deleted.***

*In (b), line 7, please define “adverse condition”. **Issue addressed by taking language out.***

*In (c)(2), line 11, what do you mean by “controlled”? **Bleeding and pain are assessed to be stable and not a concern for discharge. This is a clinical determination. The rule doesn’t say this. Please amend accordingly. “Bleeding and pain are assessed to be stable and not a concern for discharge.”***

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

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

AGENCY: North Carolina Department of Health and Human Services/DHSR

RULE CITATION: 10A NCAC 14E .0330

DEADLINE FOR RECEIPT: Friday, October 13, 2023.

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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:

*What is your statutory authority for this Rule? Neither 143B-10 nor S.L. 2023-14 s. 2.4 cover the content of the Rule. **Please see response provided on Page 2.***

*In (a), line 4, please define or delete "properly". **Language deleted.***

*In (b), how is this to be determined, and by whom? **To be determined by the clinic through their governing authority and their policies and procedures adopted by the clinic. The rule doesn't say this. Also, which policies and procedures? You have several different rules that specify different manuals. Please amend the rule accordingly.***

"as determined by the clinic through their governing authority" Rule amended.

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

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

AGENCY: North Carolina Department of Health and Human Services/DHSR

RULE CITATION: 10A NCAC 14E .0331

DEADLINE FOR RECEIPT: Friday, October 13, 2023.

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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:

*What is your statutory authority for this Rule? Neither 143B-10 nor S.L. 2023-14 s. 2.4 cover the content of the Rule. **Please see response provided on Page 2.***

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

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

AGENCY: North Carolina Department of Health and Human Services/DHSR

RULE CITATION: 10A NCAC 14E .0403

DEADLINE FOR RECEIPT: Friday, October 13, 2023.

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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:

We are withdrawing this rule from consideration.

What is your statutory authority for this Rule? Neither 143B-10 nor S.L. 2023-14 s. 2.4 cover the content of the Rule.

How is this Rule different than what is required in Rule .0322?

On line 4, to whom must the person submit this application?

On line 4, what is the person applying for?

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

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

AGENCY: North Carolina Department of Health and Human Services/DHSR

RULE CITATION: 10A NCAC 14E .0404

DEADLINE FOR RECEIPT: Friday, October 13, 2023.

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:

We are withdrawing this rule from consideration.

What is your statutory authority for this Rule? Neither 143B-10 nor S.L. 2023-14 s. 2.4 cover the content of the Rule.

How is this Rule different from what is already required in Rule .0322?

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

10A NCAC 14E .0101 is amended under temporary procedures with changes as follows:

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

SECTION .0100 – CERTIFICATION LICENSURE PROCEDURE

10A NCAC 14E .0101 DEFINITIONS

The following definitions will apply throughout this Subchapter:

- (1) "Abortion" means the termination of a pregnancy as defined in G.S. ~~90-21.81(1)~~, 90-21.81(1c).
- (2) "Clinic" means a freestanding facility ~~(a~~ facility neither physically attached nor operated by a licensed ~~hospital)~~ hospital for the performance of abortions completed during the first ~~20~~ 12 weeks of pregnancy.
- ~~(3) "Complication" includes but is not limited to hemorrhage, infection, uterine perforation, cervical laceration, or retained products of conception.~~
- ~~(4)~~(3) "Division" means the Division of Health Service Regulation of the North Carolina Department of Health and Human Services.
- ~~(5)~~(4) "Gestational age" means the length of pregnancy as indicated by the date of the first day of the last normal monthly menstrual period, if known, or as determined by ultrasound.
- ~~(6)~~(5) "Governing authority" means the individual, agency, group, or corporation appointed, elected or otherwise designated, in which the ultimate responsibility and authority for the conduct of the abortion clinic is vested pursuant to Rule ~~.0302~~ .0318 of this Subchapter.
- ~~(7)~~(6) "Health Screening" means an evaluation of an employee or contractual employee, including tuberculosis testing, to identify any underlying conditions that may affect the person's ability to work in the clinic.
- ~~(8)~~(7) "New clinic" means one that is not certified as an abortion clinic by the Division as of July 1, ~~2014~~, 2023, and has not been certified or licensed within the previous six months of the application for ~~certification~~, licensure.
- ~~(9) "Qualified Physician" means a licensed physician who advises, procures, or causes a miscarriage or abortion as defined in G.S. 14-45.1(g); [143B-10; 131E-153; S.L. 2013-366, s. 4(e); S.L. 2023-14,~~
- ~~(10)~~(8) "Registered Nurse" means a person who holds a valid license issued by the North Carolina Board of Nursing to practice professional nursing in accordance with the Nursing Practice Act, G.S. 90, Article 9A.

History Note: Authority G.S. ~~14-45.1(a); 14-45.1(g); [143B-10; 131E-153; S.L. 2013-366, s. 4(e); S.L. 2023-14,~~
~~s. [2.2; 2.4;~~
~~Eff. February 1, 1976;~~

1 *Readopted Eff. December 19, 1977;*

2 *Amended Eff. October 1, 2015; July 1, 1994; December 1, 1989; June 30, 1980;*

3 *Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. August 24,*
4 *2019;*

5 *Codifier determined that agency's findings of need did not meet criteria for emergency rule on June*
6 *22, 2023;*

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

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

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

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

10A NCAC 14E .0104 PLANS

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

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

10A NCAC 14E .0106 is amended under temporary procedures with changes as follows:

10A NCAC 14E .0106 APPLICATION

(a) Prior to the admission of patients, an application from the applicant for a new clinic for certification [licensure] shall be submitted to and approved by the Division. submit an application for licensure and receive approval from the Division.

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

(c) The application form shall set forth: the ownership, staffing patterns, clinical services to be rendered, [and] professional staff in charge of services, [services,] and general information that would be helpful to the Division's understanding of the clinic's operating program.

(1) Name of applicant;

(2) Name of facility;

(3) Ownership disclosure;

(4) Building owner;

(5) Building owner;

(6) Building management;

(7) Sanitation services;

(8) Medical director;

(9) Other medical staff;

(10) Director of nursing;

(11) Other nursing staff; and

(12) Consulting pathologist.

(d) After construction requirements in Section .0200 of this Subchapter have been met and the application for certification licensure has been received and approved, the Division shall conduct an on-site, certification licensure survey.

(e) Each certificate [license] must be renewed at the beginning of each calendar year. The governing authority shall file an application for renewal of certification [licensure] with the Division at least 30 days prior to the date of expiration on forms furnished by the Division. Failure to file a renewal application shall result in expiration of the certificate [license] to operate.

History Note: Authority G.S. 14-45.1(a); 131E-153; 131E-153.2; S.L. 2023-14, s. [2.2]; 2.4;

Eff. February 1, 1976;

Readopted Eff. December 19, 1977;

Amended Eff. July 1, 1994;

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

1 *Codifier determined that agency's findings of need did not meet criteria for emergency rule on June*
2 *22, 2023;*
3 *Emergency Rule Eff. June 30, 2023;*
4 *Repealed Eff. July 1, 2023 pursuant to G.S. ~~150B-21.7~~ 150B-21.7;*
5 *Temporary Amendment Eff. October 27, 2023.*

10A NCAC 14E .0107 is amended under temporary procedures with changes as follows:

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

(a) The Division shall issue a ~~certificate~~ license if it finds the facility can:

(1) Comply with all requirements described in this Subchapter; and

(2) ~~Assure that, in the event that complications arise from the abortion procedure, an OB-GYN board certified~~ Have a board certified OB-GYN or board eligible physician by the American Board of Obstetrics and Gynecology shall be ~~available.~~ available in the event that complications arise from an abortion procedure.

(b) Each ~~certificate~~ license shall be issued only for the premises and persons or organizations named in the application and shall not be transferable.

(c) The governing authority shall notify the Division in writing, within 10 working days, of any change in the name of the facility or change in the name of the administrator.

(d) The facility shall report to the Division all incidents, within 10 working days, of vandalism to the facility such as fires, ~~explosions~~ explosions, or other action ~~causing disruption of that prevents~~ services ~~from [being provided.]~~ providing abortion services.

History Note: Authority ~~G.S. 14-45.1(a);~~ 131E-153; 131E-153.2; S.L. 2023-14, s. ~~2.2~~; 2.4;

Eff. February 1, 1976;

Readopted Eff. December 19, 1977;

Amended Eff. July 1, 1994;

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

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

Emergency Rule Eff. June 30, 2023;

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

Temporary Amendment Eff. October 27, 2023.

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

10A NCAC 14E .0109 RENEWAL

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

(b) The renewal application form shall set forth:

(1) Name of applicant;

(2) Name of facility;

(3) Ownership disclosure;

(4) Building owner;

(5) Building owner;

(6) Building management;

(7) Sanitation services;

(8) Medical director;

(9) Other medical staff;

(10) Director of nursing;

(11) Other nursing staff;

(12) Consulting pathologist;

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

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

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

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

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

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

- 1 *Temporary Amendment Eff. October 27, 2023.*
- 2
- 3

10A NCAC 14E .0111 is amended under temporary procedures with changes as follows:

10A NCAC 14E .0111 INSPECTIONS

(a) Any clinic ~~certified~~ licensed by the Division to perform abortions shall be inspected by representatives of the Division annually and as it may deem necessary as a condition of holding such license. An inspection ~~shall~~ may be conducted whenever the Division receives a complaint alleging the clinic is not in compliance with the rules of the Subchapter. ~~purpose of the inspection is to determine whether the clinic complies with the rules of this Subchapter Subchapter. or whenever there is reason to believe that some condition exists which is not in compliance with the rules of this Subchapter.~~

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

~~(e)~~(b) Representatives of the Division shall make their identities known to the person in charge- clinic staff prior to inspection of the clinic.

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

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

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

History Note: Authority G.S. 14-45.1(a); 14-45.1(a1); 143B-10; 131E-153; 131E-153.6; S.L. 2013-366, s. 4(e); S.L. 2023-14, s. 2.2; 2.4;
Eff. February 1, 1976;
Readopted Eff. December 19, 1977;
Amended Eff. October 1, 2015; July 1, 1994;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. August 24, 2019;
Codifier determined that agency's findings of need did not meet criteria for emergency rule on June 22, 2023;
Emergency Rule Eff. June 30, 2023;
Repealed Eff. July 1, 2023 pursuant to G.S. 150B-21.7; 150B-21.7;
Temporary Amendment Eff. October 27, 2023.

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

2
3 **10A NCAC 14E .0112 ALTERATIONS**

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

8
9 *History Note: Authority G.S. ~~14-45.1(a); 143B-10; 131E-153~~; S.L. 2023-14, s. ~~2.2;~~ 2.4;*

10 *Eff. February 1, 1976;*

11 *Readopted Eff. December 19, 1977;*

12 *Amended Eff. December 1, 1989;*

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

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

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

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

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

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

2
3 **10A NCAC 14E .0114 APPROVAL**

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

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

11
12 *History Note:* Authority G.S. ~~[143B-10; 131E-153; S.L. 2013-366, s. 4(e); S.L. 2023-14, s. 2.2; 2.4;~~
13 ~~Emergency Adoption Eff. July 18, 2023; 2023;~~
14 Temporary Adoption Eff. October 27, 2023.

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

SECTION .0200 - MINIMUM STANDARDS FOR CONSTRUCTION AND EQUIPMENT

10A NCAC 14E .0201 BUILDING CODE REQUIREMENTS

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

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

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

*History Note: Authority G.S. ~~14-45-1(a)~~; ~~[143B-10;]~~ 131E-153; S.L. 2013-366, s. 4(e); S.L. 2023-14, s. ~~[2.2;]~~ 2.4; Eff. February 1, 1976;
Readopted Eff. December 19, 1977;
Amended Eff. October 1, 2015; July 1, 1994; December 1, 1989;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. August 24, 2019;
Codifier determined that agency's findings of need did not meet criteria for emergency rule on June 22, 2023;
Emergency Rule Eff. June 30, 2023;
Repealed Eff. July 1, 2023 pursuant to G.S. ~~150B-21.7~~. 150B-21.7;
Temporary Amendment Eff. October 27, 2023.*

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

2
3 **10A NCAC 14E .0202 SANITATION**

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

10
11 *History Note:* Authority ~~G.S. 14-45.1(a); 143B-10;~~ [131E-153](#); ~~S.L. 2013-366, s. 4(e); S.L. 2023-14, s. 2.2;~~ [12.4](#);
12 *Eff. February 1, 1976;*
13 *Readopted Eff. December 19, 1977;*
14 *Amended Eff. August 1, 2019; October 1, 2015; July 1, 1994;*
15 *Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. August 24,*
16 *2019;*
17 *Codifier determined that agency's findings of need did not meet criteria for emergency rule on June*
18 *22, 2023;*
19 *Emergency Rule Eff. June 30, 2023;*
20 *Repealed Eff. July 1, 2023 pursuant to G.S. ~~150B-21.7~~; 150B-21.7;*
21 *Temporary Amendment Eff. October 27, 2023.*

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

10A NCAC 14E .0207 AREA REQUIREMENTS

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

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

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

1

Temporary Amendment Eff. October 27, 2023.

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

2
3 **10A NCAC 14E .0209 ELEVATOR**

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

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

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

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

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

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

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

2
3 **10A NCAC 14E .0210 CORRIDORS**

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

6
7 *History Note: Authority [~~143B-10;~~ 131E-153; S.L. 2013-366, s. 4(e); S.L. 2023-14, s. ~~2.2;~~ 2.4;*

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

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

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

2
3 **10A NCAC 14E .0211 DOORS**

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

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

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

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

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

10A NCAC 14E .0212 ELEMENTS AND EQUIPMENT

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

(1) Mechanical requirements.

(a) Temperatures and humidities:

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

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

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

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

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

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

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

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

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

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

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

Toilets,

Soiled holding N 10

Clean work or

Clean holding P 4

(P = positive pressure N = negative pressure)

(2) Plumbing And Other Piping Systems.

(a) Medical Gas and Vacuum Systems

(i) Piped-in medical gas and vacuum systems, if installed, shall meet the requirements of NFPA-99-2012, ~~type one system~~ category 1 system, which is hereby incorporated by reference including subsequent amendments and editions. Copies of NFPA-99-2012 may be purchased from the National Fire Protection Association, 1 Batterymarch Park, P.O. Box 9101, Quincy, MA 02269-9101, or accessed electronically free of charge at <http://www.nfpa.org>.

(ii) [If inhalation anesthesia is used in any concentration, the] The facility must meet the ~~inhalation anesthesia~~ requirements of NFPA ~~[70-2011]~~70-2020 and NFPA ~~[99-2012,] 99-2021, current editions relating to inhalation anesthesia,~~ which are hereby incorporated by reference including subsequent amendments and editions. Copies of NFPA 70-2011 and NFPA 99-2012 may be purchased from the National Fire Protection Association, 1 Batterymarch Park, P.O. Box 9101, Quincy, MA 02269-9101, or accessed electronically free of charge at <http://www.nfpa.org>.

(b) Lavatories and sinks for use by medical personnel shall have the water supply spout mounted so that its discharge point is a minimum distance of five inches above the rim of the fixture with mixing type fixture valves that can be operated without the use of the hands.

(c) Hot water distribution systems shall provide hot water at hand washing and bathing facilities at a minimum temperature of 100 degrees F. and a maximum temperature of 116 degrees F.

(d) Floor drains shall not be installed in procedure rooms.

(e) Building drainage and waste systems shall be designed to avoid installations in the ceiling directly above procedure rooms.

(3) Electrical Requirements.

(a) Procedure and recovery rooms, and paths of egress from these rooms to the outside shall have at a minimum, listed battery backup lighting units of one and one-half hour capability that will automatically provide at least five foot candles 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.

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

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

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

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

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

10 Temporary Adoption Eff. October 27, 2023.

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

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

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

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

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

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

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

10A NCAC 14E .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 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 ~~professional and safe~~ 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, and services offered.

(e) When the clinic contracts with outside vendors to provide services such as ~~laundry,~~ laundry or therapy services, the governing authority shall be responsible to assure the supplier meets the same local and ~~state~~ 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 ~~patient care,~~ and adequate treatment.

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

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

10A NCAC 14E .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 licensure care and services provided by the clinic is a party.

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

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

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

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

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

2
3 **10A NCAC 14E .0320 ADMISSION AND DISCHARGE**

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

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

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

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

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

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

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

10A NCAC 14E .0321 MEDICAL RECORDS

(a) The clinic shall maintain ~~[A]~~ a complete and permanent record ~~[shall be maintained]~~ 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 surgery or procedure and signature of the physician performing the procedure witnessed by a family member, other patient representative, or facility staff member;
- (10) the patient's history and physical examination including identification of pre-existing or current illnesses, drug sensitivities or other idiosyncrasies ~~[having a bearing on]~~ that may impact the procedure or anesthetic to be administered; and
- (11) 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] all other pertinent information such as pre- and post-procedure instructions, laboratory ~~[report,]~~ reports, drugs administered, report of abortion procedure, and follow-up instruction, including family planning ~~[advice, shall be recorded and authenticated by signature, date, and time,]-~~ advice.

(c) If Rh is negative, the clinic shall explain the significance ~~[shall be explained]~~ to the patient and ~~[so recorded,]~~ 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 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.

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

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

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

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

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

10A NCAC 14E .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 for employment that includes education, training, experience and references;

(C) a resume of education and work experience;

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

(E) [verification] a list of references.

(2) Personnel records shall be confidential.

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

(b) Job Descriptions:

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

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

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

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

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

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

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

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

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

10A NCAC 14E .0323 NURSING SERVICE

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

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

(1) provision of nursing services to patients; and

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

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

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

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

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

10A NCAC 14E .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,~~ necessary to achieve and maintain compliance with clinic procedures and policies.

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

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

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

(1) reports made to the governing authority;

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

(3) information on any corrective action taken.

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

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

Emergency Adoption Eff. July 18, 2023; 2023;

Temporary Adoption Eff. October 27, 2023.

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

10A NCAC 14E .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.

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

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

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

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

(3) Rh factor testing.

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

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

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

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

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

History Note: Authority G.S. ~~[43B-10;]~~ [131E-153; S.L. 2013-366, s. 4(e); S.L. 2023-14, s. ~~[2.2;]~~ 2.4;
Emergency Adoption Eff. July 18, 2023. 2023;
Temporary Adoption Eff. October 27, 2023.

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

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

(a) Each clinic shall have a written plan for the transfer of emergency cases from the clinic to [a nearby] 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, [procedures], personnel, and [suitable] equipment to handle medical emergencies as defined above which may arise in connection with services provided by the clinic.

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

(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;

(E) utilizing a suction machine; and

(F) 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. ~~[143B-10]; [131E-153]~~; S.L. 2013-366, s. 4(e); S.L. 2023-14, s. ~~[2.2];~~ 2.4;
Emergency Adoption Eff. July 18, 2023. 2023;
Temporary Adoption Eff. October 27, 2023.

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

10A NCAC 14E .0327 SURGICAL SERVICES

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

(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 ~~[pregnaney]~~ pregnancy, or an incomplete ~~[procedure shall be considered and evaluated by the physician performing the]~~ procedure.

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

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

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

2
3 **10A NCAC 14E .0328 MEDICATIONS AND ANESTHESIA**

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

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

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

11
12 *History Note: Authority G.S. [143B-10; 131E-153; S.L. 2013-366, s. 4(e); S.L. 2023-14, s. 2.2; 2.4;*
13 *Emergency Adoption Eff. July 18, 2023. 2023;*
14 *Temporary Adoption Eff. October 27, 2023.*

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

2
3 **10A NCAC 14E .0329 POST-OPERATIVE CARE**

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

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

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

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

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

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

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

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

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

21
22 *History Note: Authority G.S. ~~[43B-10;]~~ [131E-153; S.L. 2013-366, s. 4(e); S.L. 2023-14, s. ~~[2.2;]~~ 2.4;*
23 *Emergency Adoption Eff. July 18, 2023. 2023;*
24 *Temporary Adoption Eff. October 27, 2023.*

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

2
3 **10A NCAC 14E .0330 CLEANING OF MATERIALS AND EQUIPMENT**

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

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

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

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

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

Burgos, Alexander N

Subject: FW: Temporary Rules 10A NCAC 14E - Requests for Changes - October 2023 RRC
Attachments: Response Request for Technical Changes Temp Rules 10A NCAC 14E 10-13-23 (BL responses).docx

From: Liebman, Brian R <brian.liebman@oah.nc.gov>
Sent: Monday, October 16, 2023 4:57 PM
To: Corpening, Taylor <taylor.corpening@dhhs.nc.gov>
Cc: Burgos, Alexander N <alexander.burgos@oah.nc.gov>; Premakumar, Rajeev K <raj.premakumar@dhhs.nc.gov>
Subject: RE: Temporary Rules 10A NCAC 14E - Requests for Changes - October 2023 RRC

Hi Taylor,

Attached, please find additional responses regarding these rules. My responses are in red.

Right now, the only rule that I don't see grounds for objection on is .0101. I think the general requirement to adopt rules implementing Part II would give you authority to adopt a definitions rule. So my statutory authority question on that rule is withdrawn.

I have statutory authority concerns for Rules .0111, .0112, .0114, .0201-.0212, and .0315-.0328.

I think you likely have statutory authority for .0111 – it's in 131E-153.6—but you haven't cited it in your History Note. That's easily fixed. For the others, as I suggested earlier, it does not appear to me that the four corners of Section 2.2 of the SL gives you authority to regulate in this manner. To be clear, for the Section .0200 and .0300 rules, there are also plenty of areas where I have continued issues with clarity, but the statutory authority issues are paramount there.

I think there are clarity issues in Rules .0104, .0107, and .0109, but they can be fixed fairly easily.

For Rule .0110, I am questioning the necessity of the rule under 150B-21.9(a)(3). The rule seems to restate what's in 131E-153.4, and as such it would "repeat the content of a law, a rule, or a federal regulation" as barred by 150B-19.1.

Rules .0106 and .0109 both have a potential issue with failure to comply with the APA, to the extent that the contents of the application forms referenced in those rules are not contained in any rule or statute.

Please get any edits back to me no later than 12 PM tomorrow, Tuesday, October 17.

Thanks,
Brian

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

E-mail correspondence to and from this address may be subject to the North Carolina Public Records Law N.C.G.S. Chapter 132 and may be disclosed to third parties.

te all records of this email.

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

AGENCY: North Carolina Department of Health and Human Services/DHSR

RULE CITATION: All Rules

DEADLINE FOR RECEIPT: Friday, October 13, 2023.

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:

*Each of your rules cites G.S. 143B-10 in the History Note. Please explain the relevance of this citation. **There's been no answer to this question.***

*Many of your rules cite only to G.S. 143B-10 and S.L. 2023-14, s. 2.4 as authority. I am not sure that Section 2.4 actually is an independent source of rulemaking authority; instead I see it more as a requirement to adopt rules—under other sources of authority—before October 1, 2023. Thus, to my reading, Section 2.4 isn't sufficient on its own as statutory authority; you need another statute that provides the Department with authority to regulate what's covered by the Rule. I don't see that specific authority in 143B-10. **Please add cites to each rule to whatever statute or statutes provide the Department with authority to make the specific regulatory act in each Rule.** As an example of what I'm looking for, see Rule .0106. The rule covers applications, and there's a cite to G.S. 131E-153.2, which requires clinic owners/sponsors to file an application, and directs the Department to define that application in rulemaking.*

Response:

The General Assembly stated in Section 2.4 of S.L. 2023-14 that “No later than October 1, 2023, the Department of Health and Human Services shall adopt the rules necessary to administer this Part.” (emphasis added). This mandate to adopt rules unambiguously refers to Part II of S.L. 2023-14, titled “Suitable Facilities for the Performance of Surgical Abortions.” In light of this mandate, as well as the repeal of the authority for then-existing rules, the Department adopted a first set of emergency rules on June 19, 2023 and a second set on July 6, 2023. The Department adopted all temporary rules on September 18 and submitted the temporary rules to the Rules Review Commission on September 29.

It is notable that the Department's authority to adopt rules only became effective on July 1, 2023, and the law required the adoption of rules to be completed prior to October 1, 2023. This rulemaking mandate is the only section of Part II that became effective prior to

October 1. The remainder of Part II became effective on October 1, 2023, which demonstrates a clear legislative intent that the Department adopt rules prior to October 1 pursuant to this S.L. 2023-14 to ensure that Part II could take effect within the timeframe provided by the General Assembly.

The mandate for the Department to promulgate rules necessary to administer Part II of Session Law 2023-14 replaced the prior authorization found under G.S. 14-45.1, which was repealed on July 1, 2023. This shift in authority from the prior law to the new Session Law was recognized by the Codifier of Rules' analysis of the statute in prior correspondence with the Department:

Part I, Sec. 1.1 of the Session Law repeals DHHS's current rulemaking authority. Part II, Section 2.4 of the Session Law does grant DHHS the authority to adopt rules by October 1, 2023...

Letter from Codifier of Rules to Secretary Kody Kinsley, re: Emergency Rule Filing, 10A NCAC 14E, June 22, 2023 (emphasis added).

Section 2.2 of Session Law 2023-14 amends Article 6 of Chapter 131E of the General Statutes by creating the Abortion Clinic Licensure Act (the Act). As stated in the session law, the purpose of the Act is to:

(b) ... provide for the development, establishment, and enforcement of basic standards:

- (1) For the care and treatment of individuals in abortion clinics;**
- (2) For the maintenance and operation of abortion clinics so as to ensure safe and adequate treatment of such individuals in abortion clinics.**

S.L. 2023-14, § 2.2. The temporary rules adopted by Department made minimum changes to the language necessary to comply with Part II of S.L. 2023-14 but otherwise retained the content of the previous 10A NCAC 14E permanent rules. The content of all the rules is directly supported by the purpose of the Act, which makes the adoption of these rules necessary to ensure that Part II of S.L. 2023-14 can be effectively administered by the Department. Consistent with Section 2.4 of S.L. 2023-14, the Department has determined that each of the proposed rules are necessary to implement the purpose as stated in G.S. § 131E-153(b). Additionally, the content of rules related to issuance of licenses, adverse action of licenses and inspections of abortion clinics is also explicitly indicated in the Act and further supports the adoption of these rules.

To clarify the source of authority, the Department has added S.L. 2023-14, s 2.2, to the authority in the history note of each of the proposed temporary rules.

See separate email.

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: October 6, 2023

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

AGENCY: North Carolina Department of Health and Human Services/DHSR

RULE CITATION: 10A NCAC 14E .0101

DEADLINE FOR RECEIPT: Friday, October 13, 2023.

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 is your statutory authority for this Rule? Neither 143B-10 nor S.L. 2023-14 s. 2.4 cover the content of the Rule. **Please see response provided on Page 2.***

*In (1), line 10, to be clear, you are defining “abortion” for the purpose of this subchapter to mean only “surgical abortion” as defined in G.S. 90-21.81(1c)? **Yes.***

*In (2), lines 11-13, please delete the parentheses and incorporate the parenthetical material into the body of the Rule. **Parentheses deleted.***

*In (3), lines 14-15, this is not a definition. Moreover, the term “Complication” is defined in G.S. 90-21.81(2a). Did you mean to adopt that definition? Each of the instances mentioned here is listed in the statutory definition. **Definition deleted.***

*In (6), line 22, the Rule references Rule .0302, which has been repealed. Please correct. **Reference corrected.***

*In (9), lines 29-30, is this necessary? “Qualifying Physician” is defined in G.S. 90-21.81(7a). **Definition deleted.***

*In (9), line 29, must the physician be licensed in any state, or in the State of North Carolina? **Definition deleted.***

*In (9), line 29, the statutory language defining abortion (G.S. 90-21.81A(a)) was amended in SL 2023-65 to remove the word “advise”. Was it your intent to leave that here? **Definition deleted. Please make sure you correct cross references to this Rule in your other Rules.***

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: October 6, 2023

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

AGENCY: North Carolina Department of Health and Human Services/DHSR

RULE CITATION: 10A NCAC 14E .0102

DEADLINE FOR RECEIPT: Friday, October 13, 2023.

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:

We are withdrawing this rule from consideration.

It appears that DHSR is requiring ("shall") people who aren't licensed and aren't even applicants for licensure, but people merely considering the idea of establishing an abortion clinic, to do something. Where is your statutory authority to regulate those who aren't licensed or applying to be licensed?

What is a discussion in this context? How would it be determined that someone has or has not complied with this Rule? Do they have to say something to DHSR staff, or passively listen? Would a 10 second conversation satisfy this Rule?

If a potential sponsor or owner does not comply with this Rule, and subsequently submits an otherwise acceptable application for licensure, would their application be denied for failure to "discuss" it first with DHSR staff?

On line 6, what "licensure requirements" are you referring to?

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

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

AGENCY: North Carolina Department of Health and Human Services/DHSR

RULE CITATION: 10A NCAC 14E .0104

DEADLINE FOR RECEIPT: Friday, October 13, 2023.

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 is your statutory authority for this Rule? Neither 143B-10 nor S.L. 2023-14 s. 2.4 cover the content of the Rule. **Please see response provided on Page 2.***

On lines 4-5, the Rule states that the “clinic” shall submit two copies of the building plans for “licensure purposes.”

*First, who at the “clinic” shall do this? **Language changed to “an applicant for a new clinic.”***

*Second, what are “licensure purposes”? What are the guidelines for this review? **Issue addressed in language change. No, I think this merely rephrases what was there already. What are the purposes? Review according to what standards?***

*On lines 7-8, there is no such code as the “North Carolina Administration and Enforcement Requirements Code.” **Issue addressed and incorrect language taken out. The URL goes to the NC Administrative Code. That technically is different than the State Building Code. It’s a building code, but the state Building Code is technically a different code. Just point to the specific part of the specific code you mean.***

*On line 7, the 2012 edition of the various state building codes have all been superseded by the 2018 versions. Your incorporation by reference does state “subsequent amendments and editions”, but it would be less ambiguous to update the reference. **Building code versions updated.***

*On line 9, the URL provided does not direct a user to any specific code, but redirects to the ICC website. **Website link 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: October 6, 2023

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

AGENCY: North Carolina Department of Health and Human Services/DHSR

RULE CITATION: 10A NCAC 14E .0106

DEADLINE FOR RECEIPT: Friday, October 13, 2023.

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), please consider revising in the active tense. Who shall submit the application?
(a) has been rewritten in the active tense.

In (b), line 6, where shall the applicant contact the Division? Do you have a contact rule? ***Address added.***

In (c), line 8, what is "general information that would be helpful"? Issue addressed. OK, but does this rule otherwise contain the contents or substantive requirements of the application form? If all that's necessary is the "ownership, staffing patterns, clinical services to be rendered, and professional staff in charge of services", then it's OK. But if you want more than that on the application, you need to say it here.

In (e), lines 14-15, are the contents or substantive requirements of the application form contained in another rule or in a statute? Are the same as in (c)? This is not clear. (e) deleted from this rule and merged into Rule .0109.

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

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

AGENCY: North Carolina Department of Health and Human Services/DHSR

RULE CITATION: 10A NCAC 14E .0107

DEADLINE FOR RECEIPT: Friday, October 13, 2023.

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)(2), line 6, what does it mean to “assure” that a physician is available? **Issue addressed.***

*In (a)(2), lines 6-7, what “board” is certifying the OB-GYN? **American Board of Obstetrics and Gynecology. Please say so in the rule.***

*In (a)(2), line 7, what board should the physician be eligible for? **Issue addressed. Not that I can see.***

*In (d), line 13, add a comma following “explosions”. **Comma added.***

*In (d), line 13, what is a “disruption” in services? **Issue addressed. I'd prefer the active tense-prevents who from providing what services?***

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

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

AGENCY: North Carolina Department of Health and Human Services/DHSR

RULE CITATION: 10A NCAC 14E .0108

DEADLINE FOR RECEIPT: Friday, October 13, 2023.

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:

We are withdrawing this rule from consideration.

What is your statutory authority for this Rule? Neither 143B-10 nor S.L. 2023-14 s. 2.4 cover the content of the Rule.

On line 4, please define "conspicuous place".

In the absence of a definition of "conspicuous place", how is this rule necessary when it merely restates G.S. 131E-153.2(e)?

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

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

AGENCY: North Carolina Department of Health and Human Services/DHSR

RULE CITATION: 10A NCAC 14E .0109

DEADLINE FOR RECEIPT: Friday, October 13, 2023.

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:

*How does this Rule relate to .0106(e), which also covers renewal? Why is this topic separated into two rules? **We removed the renewal language of section .0106(e) and combined it with Rule .0109.***

*On line 4, what do you mean by “previously” suspended or revoked? Does this mean that the license is currently in that status? **Issue addressed.***

*On line 4, what “rules and statutes” are applicable? Be specific. **Issue addressed.***

*On line 5, what application? Is it the same form/contents as discussed in Rule .0106? **Issue addressed. No, it has not been addressed. Where are the contents or substantive requirements of this application form written down? In a rule or statute? In other words, because the statute gives the Department the authority to set the contents of the application, you need to state here exactly what you want on the application form for renewal.***

*On line 6, under what circumstances is approval given? **Language deleted.***

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

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

AGENCY: North Carolina Department of Health and Human Services/DHSR

RULE CITATION: 10A NCAC 14E .0110

DEADLINE FOR RECEIPT: Friday, October 13, 2023.

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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:

*On line 4, please define “substantial”. **Issue addressed. I think by adding “may” instead of “shall” you’ve created a new issue. When may there be a failure to comply with the statutes and rules and the clinic not have its license revoked?***

To be honest, I wonder why this Rule is necessary, when it really just restates 131E-153.4.

*On line 5, what regulations are you referring to? **Issue addressed.***

*On line 5, please define “unsuitable”. **Issue addressed.***

*Why is there a reference to G.S. 150B-23 in your History Note? **To provide a linkage to an individual’s right to file a contested case upon the agency taking action on a clinic’s license. But how does it give you authority to “deny, suspend, or revoke” a license? History Notes are for providing statutory authority, not letting people know what their rights are.***

*Should there not be a reference to G.S. 131E-153.4? **Issue addressed.***

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

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

AGENCY: North Carolina Department of Health and Human Services/DHSR

RULE CITATION: 10A NCAC 14E .0111

DEADLINE FOR RECEIPT: Friday, October 13, 2023.

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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:

*What is your statutory authority for this Rule? Neither 143B-10 nor S.L. 2023-14 s. 2.4 cover the content of the Rule. **Please see response provided on Page 2. Doesn't 131E-153.6 give you authority to conduct inspections?***

*In (a), lines 5-7, the sentence "An inspection . . . of this Subchapter" is confusingly written. Can it be simplified? In particular, what does it mean to say "An inspection shall be conducted whenever the purpose of the inspection is to determine" compliance? **Issue addressed and the sentence is simplified.***

*In (a), line 7, who should have "reason to believe" that the clinic isn't in compliance? **Issue addressed.***

*In (a), line 7, please simplify "some condition exists which is not in compliance". **Issue addressed.***

*In (b), line 9, what is the difference between "care" and "treatment"? **Issue addressed by deleted paragraph.***

*In (c), line 11, who would be the "person in charge"? **Issue addressed.***

*In (d), lines 14-15, what does "unless otherwise required by law" modify? Does it mean the Division can review records unless otherwise required by law, or that the Division shall maintain confidentiality unless otherwise required by law? **Addressed by breaking up sentences.***

*In (f), lines 18-19, the division's response must be in writing, but the clinic's plan of correction is not explicitly required to be in writing. Is this intentional? **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: October 6, 2023

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

AGENCY: North Carolina Department of Health and Human Services/DHSR

RULE CITATION: 10A NCAC 14E .0112

DEADLINE FOR RECEIPT: Friday, October 13, 2023.

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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:

*What is your statutory authority for this Rule? Neither 143B-10 nor S.L. 2023-14 s. 2.4 cover the content of the Rule. **Please see response provided on Page 2.***

*On line 4, what "specified types" of alterations are you referring to? **Issue addressed.***

*On lines 6-7, the terms "therefor" and "herein" are to be avoided pursuant to our style guide. Consider revising. **Issue addressed.***

*On line 6, are these "recommendations" binding? **Issue addressed.***

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

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

AGENCY: North Carolina Department of Health and Human Services/DHSR

RULE CITATION: 10A NCAC 14E .0113

DEADLINE FOR RECEIPT: Friday, October 13, 2023.

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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:

We are withdrawing this rule from consideration.

What is your statutory authority for this Rule? Neither 143B-10 nor S.L. 2023-14 s. 2.4 cover the content of the Rule.

How is this rule different from Rule .0112?

On line 4, what are the plans to be “reviewed” for? Reviewed under what guidelines or standards?

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

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

AGENCY: North Carolina Department of Health and Human Services/DHSR

RULE CITATION: 10A NCAC 14E .0114

DEADLINE FOR RECEIPT: Friday, October 13, 2023.

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

*What is your statutory authority for this Rule? Neither 143B-10 nor S.L. 2023-14 s. 2.4 cover the content of the Rule. **Please see response provided on Page 2.***

*In (a), line 4, what are “construction documents and specifications”? **Language corrected to “building plans.”***

*Where is the statutory authority, specifically, for the review and approval required in (a), lines 5-7 by the Division of Public Health, the Environmental Health Section, and the Department of Insurance? **Language removed.***

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

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

AGENCY: North Carolina Department of Health and Human Services/DHSR

RULE CITATION: 10A NCAC 14E .0201

DEADLINE FOR RECEIPT: Friday, October 13, 2023.

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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:

*What is your statutory authority for this Rule? Neither 143B-10 nor S.L. 2023-14 s. 2.4 cover the content of the Rule. **Please see response provided on Page 2.***

*In (a), line 10, the URL for ecodes.biz just redirects back to the ICC website. Please correct. **Link replaced. As in Rule .0104, the URL only directs to the NC Administrative Code, which is a different code than the NC State Building Code. Please cite to the correct code, and provide a citation to the specific portion of the Building Code you're directing your regulated public to.***

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

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

AGENCY: North Carolina Department of Health and Human Services/DHSR

RULE CITATION: 10A NCAC 14E .0202

DEADLINE FOR RECEIPT: Friday, October 13, 2023.

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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:

*What is your statutory authority for this Rule? Neither 143B-10 nor S.L. 2023-14 s. 2.4 cover the content of the Rule. **Please see response provided on Page 2.***

*On line 9, please use a more direct URL to the NCAC. It should be <http://reports.oah.state.nc.us/ncac.asp>. **Link corrected.***

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

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

AGENCY: North Carolina Department of Health and Human Services/DHSR

RULE CITATION: 10A NCAC 14E .0207

DEADLINE FOR RECEIPT: Friday, October 13, 2023.

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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:

*What is your statutory authority for this Rule? Neither 143B-10 nor S.L. 2023-14 s. 2.4 cover the content of the Rule. **Please see response provided on Page 2.***

*On line 4, please correct the reference to Rule .0206, which has been repealed. I assume, but am not sure, that this should now say Rule .0212, based on the rule titles. **Issue addressed.***

*Do the requirements here and in Rule .0212 conflict in any way with the requirements of the Building Code and with the requirements of 15A NCAC 18A .1300? **No.***

*What is the purpose of (9)? This list is of areas that have to comply with Rule .0212, and here we've got a semi-definition of "medicine room". Does the cabinet in the clean workroom also have to comply with Rule .0212? What if it isn't a cabinet, and it is a separate room? **Wording changed to avoid confusion. Wording is still off. As edited, it says "a clean area for self contained secure medical storage complying with security requirements of state and federal laws is provided". I think the "as provided" needs to be deleted, and maybe say "also complying with security requirements..."***

*In (10), line 16, add "of" between "handling" and "clean". **Issue addressed.***

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

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

AGENCY: North Carolina Department of Health and Human Services/DHSR

RULE CITATION: 10A NCAC 14E .0209

DEADLINE FOR RECEIPT: Friday, October 13, 2023.

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

*What is your statutory authority for this Rule? Neither 143B-10 nor S.L. 2023-14 s. 2.4 cover the content of the Rule. **Please see response provided on Page 2.***

*In (a), consider rewriting in the active tense. Who shall provide the elevator? **Issue addressed.***

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

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

AGENCY: North Carolina Department of Health and Human Services/DHSR

RULE CITATION: 10A NCAC 14E .0210

DEADLINE FOR RECEIPT: Friday, October 13, 2023.

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

*What is your statutory authority for this Rule? S.L. 2023-14 s. 2.4 does not cover the content of the Rule. **Please see response provided on Page 2.***

*This rule seems potentially self-contradictory. Can a corridor be greater than 60 inches wide but insufficient to allow for patient evacuation by stretcher? **Issue addressed.***

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

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

AGENCY: North Carolina Department of Health and Human Services/DHSR

RULE CITATION: 10A NCAC 14E .0211

DEADLINE FOR RECEIPT: Friday, October 13, 2023.

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

*What is your statutory authority for this Rule? S.L. 2023-14 s. 2.4 does not cover the content of the Rule. **Please see response provided on Page 2.***

*On line 6, please define "small closet". **Issue addressed by deleting "small closets."***

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

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

AGENCY: North Carolina Department of Health and Human Services/DHSR

RULE CITATION: 10A NCAC 14E .0212

DEADLINE FOR RECEIPT: Friday, October 13, 2023.

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

*What is your statutory authority for this Rule? Neither 143B-10 nor S.L. 2023-14 s. 2.4 cover the content of the Rule. **Please see response provided on Page 2.***

*Does this Rule conflict in any way with the Building Code or with 15A NCAC 18A .1300? **No.***

*In (1)(b)(ii), the Rule requires air delivered “at or near” the ceiling, but removed “not less than three inches” from the floor. Is the lack of specificity for the ceiling intended? **Yes.***

*In (1)(b)(v), line 27, add a comma following “closets”. **Issue addressed.***

*With respect to both instances of the NFPA you’re incorporating, do the portions of the Building Code, which you’ve also incorporated, contain any contradictory NC Fire Code provisions? **No.***

*Also with respect to both instances of the NFPA, please provide more specific URLs to where these documents can be found free of charge. I went on NFPA.org and was unable to access them for free. **www.NFPA.org is the correct URL. The documents are available for free if one creates a profile.***

*In (2)(a)(i), p.2, line 9, does the reference to NFPA-99-2012 mean the 2012 version? The current NFPA version is 2024. The incorporation says “including subsequent amendments and editions”. Same question for NFPA 70-2011 in (2)(a)(ii). **Version corrected.***

*With respect to NFPA-70-2011, NFPA-70 is the National Electric Code. North Carolina has already adopted the 2018 National Electric Code with state specific amendments. Would NFPA-70-2011 still be in effect, or has it been superseded by provisions in the 2018 code? **Version corrected.***

Brian Liebman
Commission Counsel

Date submitted to agency: October 6, 2023

*In (2)(a)(ii), lines 15-16, what does “current editions relating to inhalation anesthesia” mean? Does this mean only portions of these documents are incorporated by reference? If so, please specifically state which portions are incorporated by reference. **Issue addressed.***

*In (3)(a), line 32, what does “listed batter backup lighting units” mean? Specifically, I’m asking about “listed”. **The list is found at <https://www.ncosfm.gov/third-party-testing-agencies/open>. Beyond seeing that this is a document from the Fire Marshal, I have no idea what this document does. Moreover, it’s still not clear in the Rule what you mean by “listed”.***

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

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

AGENCY: North Carolina Department of Health and Human Services/DHSR

RULE CITATION: 10A NCAC 14E .0213

DEADLINE FOR RECEIPT: Friday, October 13, 2023.

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

We are withdrawing this rule from consideration.

What is your statutory authority for this Rule? Neither 143B-10 nor S.L. 2023-14 s. 2.4 cover the content of the Rule.

What does this sentence mean? It's facially vague and ambiguous.

On line 4, what does "written indication" mean?

On line 4, what's the significance of "shared or purchased"?

On line 4, what are "appropriate" modifications? Please delete or define.

On line 5, "space requirements" for what? What requirements are you referring to?

On line 5, "may be anticipated" by whom?

On lines 4-5, what effect would be caused by modifying the space requirements?

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

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

AGENCY: North Carolina Department of Health and Human Services/DHSR

RULE CITATION: 10A NCAC 14E .0315

DEADLINE FOR RECEIPT: Friday, October 13, 2023.

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

*What is your statutory authority for this Rule? Neither 143B-10 nor S.L. 2023-14 s. 2.4 cover the content of the Rule. **Please see response provided on Page 2.***

*How is this rule any different than Rule .0202? Both require adherence to the sanitation standards in 15A NCAC 18A .1300. **This Rule addresses standards beyond the sanitation standards in Rule .0202. You deleted the reference to 15A NCAC 18A .1300 but left it on the last line of the rule.***

*In (1), line 8, add a comma following "woodwork". **Done.***

*In (1), line 8, what is "waste material"? **Language removed.***

*In (3), line 11, please define "clean and sanitary condition". **Term defined consistent with 15A NCAC 18A .1312. That term is not defined in 15A NCAC 18A .1312. And even if it was, you have not incorporated it by reference here.***

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

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

AGENCY: North Carolina Department of Health and Human Services/DHSR

RULE CITATION: 10A NCAC 14E .0317

DEADLINE FOR RECEIPT: Friday, October 13, 2023.

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

We are withdrawing this rule from consideration.

What is your statutory authority for this Rule? Neither 143B-10 nor S.L. 2023-14 s. 2.4 cover the content of the Rule.

On line 4, what does "fully disclosed" mean?

Does this Rule require anything not already required in Section .0100? Ownership must be disclosed on the application form.

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

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

AGENCY: North Carolina Department of Health and Human Services/DHSR

RULE CITATION: 10A NCAC 14E .0318

DEADLINE FOR RECEIPT: Friday, October 13, 2023.

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

*What is your statutory authority for this Rule? Neither 143B-10 nor S.L. 2023-14 s. 2.4 cover the content of the Rule. **Please see response provided on Page 2.***

*Specifically to statutory authority here, where is your authority to require the governing authority to appoint a CEO? I don't see anything in the Session Law that would give you authority to regulate the organizational structure and personnel practices of any private entity, or to require a the CEO to delegate his or her authority. **Please see response provided on Page 2. The Department has the authority to adopt rules on clinic operations to ensure safe and adequate treatment pursuant to Section 2.2 of Session Law 2023-14.***

*Again, to statutory authority, where is your authority to require a governing authority to adopt policies and procedures? **Please see response provided on Page 2. The Department has the authority to adopt rules on clinic operations to ensure safe and adequate treatment pursuant to Section 2.2 of Session Law 2023-14.***

*In (a), line 5, to whom would the CEO/designee represent the governing authority? **To individuals and entities outside of the clinic.***

*In (d)(3), line 20, define "professional and safe". **Language changed. OK, not trying to be difficult, but now you need to define "safe and adequate". The point is that when you're telling the regulated public to do something, you have to be clear about the standards by which their efforts to comply will be judged. How is a clinic to know if their policy and procedure manual ensures safe and adequate care unless you tell them what that means?***

In (e), what do you mean by "shall be responsible to assure" that the supplier meets the local or state standards? Do you have authority to require a 3rd party to conform to state and local standards? Do you have statutory authority to require a clinic to enter into a contract? Do you have statutory authority to essentially specify the terms of that

Brian Lieberman
Commission Counsel

Date submitted to agency: October 6, 2023

*contract? **Please see response provided on Page 2. The Department has the authority to adopt rules on clinic operations to ensure safe and adequate treatment pursuant to Section 2.2 of Session Law 2023-14.***

*In (e), line 24, omit the comma following “laundry”. **Done.***

*In (e), line 25, capitalize “state” if referring only to the State of North Carolina. **Done.***

*In (g), line 29-30, who are “supporting personnel”? **Clinic staff.***

*In (g), line 30, please define “safe patient care.” **Issue revised.***

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

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

AGENCY: North Carolina Department of Health and Human Services/DHSR

RULE CITATION: 10A NCAC 14E .0319

DEADLINE FOR RECEIPT: Friday, October 13, 2023.

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

*What is your statutory authority for this Rule? Neither 143B-10 nor S.L. 2023-14 s. 2.4 cover the content of the Rule. **Please see response provided on Page 2.***

*Specifically, do you have statutory authority to require documents to be kept on file on the clinic's premises? **Please see response provided on Page 2. The Department has the authority to adopt rules on clinic operations to ensure safe and adequate treatment pursuant to Section 2.2 of Session Law 2023-14.***

*In (a)(7), line 12, please define "related to licensure". **Issue addressed by changing the language.***

*In (b), line 13, is this requirement not redundant with Rule .0108? **No, Rule .0108 has been withdrawn.***

*In (c), line 14, what policies and procedures are you requiring? Is this other than the policies and procedures required elsewhere in these rules? **This rule pertains to the manual requiring specified policies and procedures. So is this is a separate manual than the one referenced in .0318?***

*In (c)(1), line 17, consider making "clinical discharge criteria" an independent item. **Correction made.***

*In (c)(3), line 19, to be clear, do you mean medical policies and procedures? For instance, a description of the steps the doctor would take in performing each procedure? **Issue addressed by changing the language. Do you have statutory authority to require a manual with policy and procedure that governs the steps of a medical procedure? Aren't medical procedures up to the discretion of the doctor, and governed by the standard of care?***

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: October 6, 2023

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

AGENCY: North Carolina Department of Health and Human Services/DHSR

RULE CITATION: 10A NCAC 14E .0320

DEADLINE FOR RECEIPT: Friday, October 13, 2023.

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

*What is your statutory authority for this Rule? Neither 143B-10 nor S.L. 2023-14 s. 2.4 cover the content of the Rule. **Please see response provided on Page 2.***

*In (a), line 5, what do you mean by “administrative decisions on their disposition”? **Issue addressed. Still not clear what an “administrative decision” is. Do you mean whether to admit or discharge?***

*In (c), line 8, what is a “general” hospital? Is this different than the definition of “hospital” in the statute? “acute care hospital” **Issue addressed by clarifying the language.***

*In (d)(2), line 13, delete the “(s)” and make “physician(s)” either plural or “physician or physicians”. **Done.***

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

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

AGENCY: North Carolina Department of Health and Human Services/DHSR

RULE CITATION: 10A NCAC 14E .0321

DEADLINE FOR RECEIPT: Friday, October 13, 2023.

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 is your statutory authority for this Rule? Neither 143B-10 nor S.L. 2023-14 s. 2.4 cover the content of the Rule. **Please see response provided on Page 2.***

*Throughout, please use the active tense and specify the subject of sentences where you're directing someone to take some action. I've tried to call out below where this is particularly problematic, but please review the entire rule and make these changes. **Issue addressed.***

*In (a), line 4, who must maintain the record? Please use the active tense. **Changed to active tense.***

*In (a)(10), line 16, please define "have a bearing on". **Issue addressed by rephrasing language.***

*In (b), line 20, should "report" be plural? **Issue addressed by rephrasing.***

*In (b), line 22, who shall sign to authenticate? **Issue addressed by saying the clinic has the responsibility to authenticate. A clinic can't sign something. What person should do these acts? A doctor? A nurse? A staff member?***

*In (c), line 23, who shall explain the significance? **Addressed by clarifying language and specifying the clinic. A clinic can't speak. What person should explain the significance of the RH negative test result?***

*In (d), line 25, who shall perform the ultrasound? **Issue addressed.***

*In (e)(4), line 32, add the article before "physician". **Done.***

*In (e)(5), line 33, add the article before "Registered Nurse". **Done.***

In (e)(6), line 34, do you mean the time the procedure started, or the duration? Both? The start and end time of the procedure should be noted pursuant to the rule. The rule doesn't say this. Please edit accordingly.

In (f), line 35, do you have statutory authority to require that records be preserved in the state? Please see response provided on Page 2. The Department has the authority to adopt rules on clinic operations to ensure safe and adequate treatment pursuant to Section 2.2 of Session Law 2023-14.

In (f), p.2, line 2, would a patient's request for records be sufficient to remove the records? No.

In (h), line 5, arrangements shall be made by whom? Issue addressed by specifying the clinic. A clinic can't preserve something. What person should preserve the records?

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

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

AGENCY: North Carolina Department of Health and Human Services/DHSR

RULE CITATION: 10A NCAC 14E .0322

DEADLINE FOR RECEIPT: Friday, October 13, 2023.

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

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

*What is your statutory authority for this Rule? Neither 143B-10 nor S.L. 2023-14 s. 2.4 cover the content of the Rule. **Please see response provided on Page 2.***

In (a)(1)(A), (B), and (C), please add articles before the noun opening the sentence (“the employee’s...”) **Done**

In (a)(1)(D) and (E), what are you requiring by “verification”? **Issue addressed by changing language.**

*In (a)(3), line 13, do you have statutory authority for this provision? Are not personnel records otherwise confidential under the law? **Please see response provided on Page 2. The response on page 2 doesn’t specify anything about confidentiality of personnel records.***

In (a)(3), line 13, what do you mean by “notwithstanding the requirement found in Subparagraph (b)(2)”? *That language refers to a job description. **Issue addressed by simplifying the language.***

*In (f), line 29, are these health records not confidential under State and federal law? **No. Health records of employees aren’t confidential? Not under HIPAA? Are you sure about this? Also, change the reference to .0101(7) to conform with the edits to that Rule.***

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

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

AGENCY: North Carolina Department of Health and Human Services/DHSR

RULE CITATION: 10A NCAC 14E .0323

DEADLINE FOR RECEIPT: Friday, October 13, 2023.

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 is your statutory authority for this Rule? Neither 143B-10 nor S.L. 2023-14 s. 2.4 cover the content of the Rule. **Please see response provided on Page 2.***

*Specifically, where is your authority to require the governing authority to designate a nursing supervisor? I don't see anything in the Session Law that would give you authority to regulate the organizational structure and personnel practices of any private entity. **Please see response provided on Page 2. The Department has the authority to adopt rules on clinic operations to ensure safe and adequate treatment pursuant to Section 2.2 of Session Law 2023-14.***

*In (a), line 5 and (b), line 6, please define "responsibility and accountability" and "responsible and accountable". **Issue addressed by rephrasing sentences and deleting language.***

*In (b)(2), line 8, what manual? Is this required in another rule? **The Nursing Policy and Procedure Manual, it is not required in another rule.***

*In (c), lines 10-11, who makes the judgment that there are sufficient personnel on staff? **The governing authority of the clinic. The Rule doesn't say that. Please amend accordingly.***

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

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

AGENCY: North Carolina Department of Health and Human Services/DHSR

RULE CITATION: 10A NCAC 14E .0324

DEADLINE FOR RECEIPT: Friday, October 13, 2023.

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 is your statutory authority for this Rule? Neither 143B-10 nor S.L. 2023-14 s. 2.4 cover the content of the Rule. **Please see response provided on Page 2.***

*Specifically, where is your authority to require the governing authority to establish a quality assurance program and a compliance committee? Where is your authority to require the governing authority to set staffing requirements for the committee? Where is your authority to set the committee's functions? **Please see response provided on Page 2. The Department has the authority to adopt rules on clinic operations to ensure safe and adequate treatment pursuant to Section 2.2 of Session Law 2023-14.***

*In (b), line 7, "corrective action" for what? **Issue addressed by specifying rule. The text of the Rule does not specify another rule.***

*In (c), lines 8-9, are these members of the committee to also be members of the governing authority? Employees of the clinic? Or must they be independent and unaffiliated with the clinic at all? **They can be employees of the clinic. I'm not sure this answers the question. I assumed they could be employees, but must they be employees? Either way, the rule doesn't say this, so please amend accordingly.***

*In (c), line 9, what are "other health professionals"? **Health professionals that are not physicians such as nurse practitioners, pharmacists, registered nurses, and physician's assistants.***

*In (f), line 19, who shall conduct these programs? Please use the active tense. **Rewritten in active tense.***

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: October 6, 2023

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

AGENCY: North Carolina Department of Health and Human Services/DHSR

RULE CITATION: 10A NCAC 14E .0325

DEADLINE FOR RECEIPT: Friday, October 13, 2023.

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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:

*What is your statutory authority for this Rule? Neither 143B-10 nor S.L. 2023-14 s. 2.4 cover the content of the Rule. **Please see response provided on Page 2.***

*In (a), line 4, what do you mean by “have the capability to . . . obtain” lab tests? Does this mean an agreement with a 3^d party? **A clinic needs to either have a clinical laboratory certificate, which would allow them to provide lab tests on their own, or they would need to contract with a reference lab. This makes sense, but isn’t clear in the rule. Please amend accordingly.***

*In (b), this is written in a roundabout way. Did you mean to say that the governing authority must establish a written policy stating which “surgical samples” must be examined by a pathologist? **Issue addressed by rephrasing the statement.***

*In (b), line 7, what do you mean by “those types of specimens”? What specimens? **Issue addressed by deleting language.***

*In (e), lines 15-16, are you allowing that the lab tests may be performed by any “employee” who has access to the manual? **No, the Rule is only specific to the requirement for a manual. Only employees that are authorized and qualified may perform the tests.***

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

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

AGENCY: North Carolina Department of Health and Human Services/DHSR

RULE CITATION: 10A NCAC 14E .0326

DEADLINE FOR RECEIPT: Friday, October 13, 2023.

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 is your statutory authority for this Rule? Neither 143B-10 nor S.L. 2023-14 s. 2.4 cover the content of the Rule. **Please see response provided on Page 2.***

*In (a), line 4, what is the definition of an “emergency case”? **Issue addressed. In the new language, “could reasonably be expected to result” by whom? Also, what is “serious jeopardy”, “serious impairment to bodily functions”, and “serious dysfunction of bodily organs”? What’s the difference between “impairment” and “dysfunction”? What level of dysfunction or impairment is “serious”?***

*In (a), line 4, define “nearby”. **Issue addressed.***

*In (a), line 5, when is hospitalization necessary? **When the clinic can no longer provide treatment or services due to the patient’s condition.***

*In (b), line 6, how can a clinic “have” a procedure? Consider rephrasing. **Issue addressed by specifying “written protocols”***

*In (b), line 6, define “suitable equipment”. **Issue addressed.***

*In (b), line 6, again, please define “medical emergencies”. **Issue addressed.***

*In (c), line 9, what kind of “documentation” are you requiring? **A letter or email or other written acknowledgement that the hospital will facilitate the transfer of patients that are in need of emergency care. The “documentation” required is that the clinic has not been unable to secure such an agreement. Again, what documentation are you requiring?***

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: October 6, 2023

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

AGENCY: North Carolina Department of Health and Human Services/DHSR

RULE CITATION: 10A NCAC 14E .0327

DEADLINE FOR RECEIPT: Friday, October 13, 2023.

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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:

*What is your statutory authority for this Rule? Neither 143B-10 nor S.L. 2023-14 s. 2.4 cover the content of the Rule. **Please see response provided on Page 2.***

*In (a), line 5, please define an “atmosphere free of contamination”. **Issue addressed by changing the wording. Changing “atmosphere” to “environment” doesn’t fix this issue. Are you requiring the procedure room to be sterile? If so, say that. Also, is a procedure room different than an “operating room” in G.S. 131E-153.1(3)?***

*In (a), line 6, are there not standard procedures for infection control and universal precautions? **There are standards, but they may originate from different sources. The Rule is intended to require the clinic to choose one of the generally accepted standard procedures. The rule doesn’t say this. It say the clinic shall establish procedures, full stop. I’d read that to mean the clinic can come up with its own procedures.***

*In (b)(2), line 12, add a comma following “pregnancy”. **Done.***

*In (b)(2), line 12-13, the grammar of the sentence seems off, particularly on line 13. Please consider revising. **Issue addressed by restructuring sentence. Still not sure about the last part of the sentence. I assume you mean that the physician will evaluate the patient for an ectopic pregnancy or for whether she has already undergone another surgical abortion that is incomplete? If so, please make that clearer.***

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: October 6, 2023

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

AGENCY: North Carolina Department of Health and Human Services/DHSR

RULE CITATION: 10A NCAC 14E .0328

DEADLINE FOR RECEIPT: Friday, October 13, 2023.

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

*What is your statutory authority for this Rule? Neither 143B-10 nor S.L. 2023-14 s. 2.4 cover the content of the Rule. **Please see response provided on Page 2.***

*In (b), line 5, may a physician administer medications directly, or must he or she allow an RN to do it? **Issue addressed.***

*In (c), line 7, please define "direct supervision"? **Issue addressed.***

*In (c), line 7, may anesthesia be administered by any licensed physician, or an anesthesiologist? **Yes, so long as they are qualified within their scope of practice and under the direct supervision of a licensed physician. This wasn't a yes or no question, and I don't really understand the answer. Are you saying that in an abortion clinic, a patient may be anesthetized by someone other than an anesthesiologist?***

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

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

AGENCY: North Carolina Department of Health and Human Services/DHSR

RULE CITATION: 10A NCAC 14E .0329

DEADLINE FOR RECEIPT: Friday, October 13, 2023.

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

*What is your statutory authority for this Rule? Neither 143B-10 nor S.L. 2023-14 s. 2.4 cover the content of the Rule. **Please see response provided on Page 2.***

*In (a), line 4, and (c)(1), line 10, please define “ambulatory basis” and “ambulatory”. **“Ambulatory basis” and “ambulatory” deleted.***

*In (b), line 7, please define “adverse condition”. **Issue addressed by taking language out.***

*In (c)(2), line 11, what do you mean by “controlled”? **Bleeding and pain are assessed to be stable and not a concern for discharge. This is a clinical determination. The rule doesn’t say this. Please amend accordingly.***

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

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

AGENCY: North Carolina Department of Health and Human Services/DHSR

RULE CITATION: 10A NCAC 14E .0330

DEADLINE FOR RECEIPT: Friday, October 13, 2023.

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

*What is your statutory authority for this Rule? Neither 143B-10 nor S.L. 2023-14 s. 2.4 cover the content of the Rule. **Please see response provided on Page 2.***

*In (a), line 4, please define or delete "properly". **Language deleted.***

*In (b), how is this to be determined, and by whom? **To be determined by the clinic through their governing authority and their policies and procedures adopted by the clinic. The rule doesn't say this. Also, which policies and procedures? You have several different rules that specify different manuals. Please amend the rule accordingly.***

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

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

AGENCY: North Carolina Department of Health and Human Services/DHSR

RULE CITATION: 10A NCAC 14E .0331

DEADLINE FOR RECEIPT: Friday, October 13, 2023.

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

AGENCY: North Carolina Department of Health and Human Services/DHSR

RULE CITATION: 10A NCAC 14E .0403

DEADLINE FOR RECEIPT: Friday, October 13, 2023.

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

We are withdrawing this rule from consideration.

What is your statutory authority for this Rule? Neither 143B-10 nor S.L. 2023-14 s. 2.4 cover the content of the Rule.

How is this Rule different than what is required in Rule .0322?

On line 4, to whom must the person submit this application?

On line 4, what is the person applying for?

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

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

AGENCY: North Carolina Department of Health and Human Services/DHSR

RULE CITATION: 10A NCAC 14E .0404

DEADLINE FOR RECEIPT: Friday, October 13, 2023.

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

We are withdrawing this rule from consideration.

What is your statutory authority for this Rule? Neither 143B-10 nor S.L. 2023-14 s. 2.4 cover the content of the Rule.

How is this Rule different from what is already required in Rule .0322?

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

Burgos, Alexander N

Subject: FW: Temporary Rules 10A NCAC 14E - Requests for Changes - October 2023 RRC

From: Liebman, Brian R <brian.liebman@oah.nc.gov>
Sent: Monday, October 16, 2023 1:04 PM
To: Corpening, Taylor <taylor.corpening@dhhs.nc.gov>
Cc: Burgos, Alexander N <alexander.burgos@oah.nc.gov>
Subject: RE: Temporary Rules 10A NCAC 14E - Requests for Changes - October 2023 RRC

Hi Taylor,

Thanks for the heads up. If there is a further response forthcoming, I would need to hear from you no later than tomorrow at 12:00. I need time to draft a staff opinion and for the Commission to review it prior to the meeting.

I will have another email coming your way with additional comments on other rules within the next few hours. It'll have to be same deadline on those.

Best,
Brian

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

E-mail correspondence to and from this address may be subject to the North Carolina Public Records Law N.C.G.S. Chapter 132 and may be disclosed to third parties.

From: Corpening, Taylor <taylor.corpening@dhhs.nc.gov>
Sent: Monday, October 16, 2023 1:02 PM
To: Liebman, Brian R <brian.liebman@oah.nc.gov>
Subject: RE: Temporary Rules 10A NCAC 14E - Requests for Changes - October 2023 RRC

Hi Brian,

I have forwarded your response to the necessary people. I also wanted to inform you that Eric Hunt will be speaking on behalf of the Division at Thursday's meeting.

Best,
Taylor Corpening
Rule-making Coordinator
Division of Health Service Regulation
[NC Department of Health and Human Services](#)

Office: 919-855-4619
Fax: 919-733-2757
taylor.corpening@dhhs.nc.gov

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

Burgos, Alexander N

Subject: FW: Temporary Rules 10A NCAC 14E - Requests for Changes - October 2023 RRC

From: Liebman, Brian R <brian.liebman@oah.nc.gov>

Sent: Monday, October 16, 2023 11:05 AM

To: Corpening, Taylor <taylor.corpening@dhhs.nc.gov>; Rules, Oah <oah.rules@oah.nc.gov>

Cc: Premakumar, Rajeev K <raj.premakumar@dhhs.nc.gov>; Burgos, Alexander N <alexander.burgos@oah.nc.gov>

Subject: RE: Temporary Rules 10A NCAC 14E - Requests for Changes - October 2023 RRC

Hi all,

I am writing just to address the statutory authority issue, which I think is the most serious issue facing these rules. I will address any individual rule changes that need further work in a separate email.

I've reviewed your response, and I do not agree with the analysis you've laid out here. First, the citation to Section 2.2 of the Session Law is facially ambiguous and fails to meet the agency's burden of showing statutory authority. Section 2.2 codifies a new Part in Article 6 of Chapter 131E. Within that part, there are 9 sections. Just as it would be inappropriate to cite to "Chapter 131E, Part 4E" in the History Note, it is inappropriate to cite to Section 2.2 of the Session Law, because it is not a direct cite to your authority. Unlike the citation to Section 2.4, which contains a single and discrete direction, the citation to Section 2.2 leaves the reader to sort through an entire Part in order to guess at your authority.

Getting back to Section 2.4, it does provide the Department with authority to adopt rules. However, as noted, this is not an open-ended grant of authority—the statute states that the Department “shall adopt the rules necessary to administer this Part” referring to Part II of the Session Law, not Part 4A of Article 6 of G.S. 131E. Thus, that particular grant of authority requires that the rules pertain to something within Part II.

To that end, you point to G.S. 131-153(b), which is, for lack of a better term, the “purpose” statute in Part 4A as authority for all of these rules. I can tell you that the Commission explicitly rejected an identical argument in August 2022, when considering changes to the hospital licensure rules in 10A NCAC 13B. There, MCC had authority under 131E-79 to “promulgate rules necessary to implement this Article”, referring to Article 5. However, nowhere in Article 5 was the Commission given any authority to regulate the topics that were covered by the rules in Chapter 13B. MCC argued that the “purpose” statute of 131E-75 gave them the authority to, for instance, require hospitals to hire certain staff and give them particular duties. The Commission rejected that argument and objected to many of the 13B rules for lack of statutory authority. I believe they would likely do the same here in response to the same argument. If you have other sources of authority, I would urge you to cite them here.

With that in mind, I have to caution you on something I noticed in the Session Law. The language of Section 2.4 instructs the “Department of Health and Human Services to adopt the rules necessary to administer this Part” by October 1. However, the language in G.S. 131E-153.5 states that the Medical Care Commission shall adopt, amend, and repeal all rules necessary for this part. Similarly, MCC has authority under 143B-165 to adopt rules related to Article 6, which contains 131E-153, et seq. Thus, to the extent that *the Department* has drafted and adopted these rules, they may not cite to that authority. If you can show that MCC met, drafted, and adopted these rules, then the authority in 131E-153.5 and 143B-165 would apply. However, the rules would have to be re-filed with new findings of need forms and proof that MCC, rather than the Department, complied with all steps of temporary rulemaking under the APA.

Thanks,
Brian

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

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Burgos, Alexander N

Subject: FW: Temporary Rules 10A NCAC 14E - Requests for Changes - October 2023 RRC

From: Liebman, Brian R <brian.liebman@oah.nc.gov>

Sent: Friday, October 13, 2023 5:03 PM

To: Corpening, Taylor <taylor.corpening@dhhs.nc.gov>; Rules, Oah <oah.rules@oah.nc.gov>

Cc: Premakumar, Rajeev K <raj.premakumar@dhhs.nc.gov>; Burgos, Alexander N <alexander.burgos@oah.nc.gov>

Subject: RE: Temporary Rules 10A NCAC 14E - Requests for Changes - October 2023 RRC

Thanks, Taylor. I will look at the responses and will be back to you as soon as I can.

Brian Liebman

Counsel to the North Carolina Rules Review Commission

Office of Administrative Hearings

(984)236-1948

brian.liebman@oah.nc.gov

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Burgos, Alexander N

Subject: FW: Temporary Rules 10A NCAC 14E - Requests for Changes - October 2023 RRC
Attachments: Response Request for Technical Changes Temp Rules 10A NCAC 14E 10-13-23.docx; 10A NCAC 14E .0101.docx; 10A NCAC 14E .0104.docx; 10A NCAC 14E .0106.docx; 10A NCAC 14E .0107.docx; 10A NCAC 14E .0109.docx; 10A NCAC 14E .0110.docx; 10A NCAC 14E .0111.docx; 10A NCAC 14E .0112.docx; 10A NCAC 14E .0201.docx; 10A NCAC 14E .0202.docx; 10A NCAC 14E .0207.docx; 10A NCAC 14E .0315.docx; 10A NCAC 14E .0114.docx; 10A NCAC 14E .0209.docx; 10A NCAC 14E .0210.docx; 10A NCAC 14E .0211.docx; 10A NCAC 14E .0212.docx; 10A NCAC 14E .0318.docx; 10A NCAC 14E .0319.docx; 10A NCAC 14E .0320.docx; 10A NCAC 14E .0321.docx; 10A NCAC 14E .0322.docx; 10A NCAC 14E .0323.docx; 10A NCAC 14E .0324.docx; 10A NCAC 14E .0325.docx; 10A NCAC 14E .0326.docx; 10A NCAC 14E .0327.docx; 10A NCAC 14E .0328.docx; 10A NCAC 14E .0329.docx; 10A NCAC 14E .0330.docx; 10A NCAC 14E .0113.docx; 10A NCAC 14E .0213.docx; 10A NCAC 14E .0317.docx; 10A NCAC 14E .0403.docx; 10A NCAC 14E .0404.docx; 10A NCAC 14E .0102.docx; 10A NCAC 14E .0108.docx

From: Corpening, Taylor <taylor.corpening@dhhs.nc.gov>
Sent: Friday, October 13, 2023 4:59 PM
To: Liebman, Brian R <brian.liebman@oah.nc.gov>; Rules, Oah <oah.rules@oah.nc.gov>
Cc: Premakumar, Rajeev K <raj.premakumar@dhhs.nc.gov>; Burgos, Alexander N <alexander.burgos@oah.nc.gov>
Subject: RE: Temporary Rules 10A NCAC 14E - Requests for Changes - October 2023 RRC

Hi Brian,

Attached are the responses to your requests for changes and the updated rules. Please note that Rules .0102, .0108, .0113, .0213, .0317, .0403, and .0404 have been withdrawn from consideration.

Taylor Corpening
Rule-making Coordinator
Division of Health Service Regulation
[NC Department of Health and Human Services](#)

Office: 919-855-4619
Fax: 919-733-2757
taylor.corpening@dhhs.nc.gov

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.

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

AGENCY: North Carolina Department of Health and Human Services/DHSR

RULE CITATION: All Rules

DEADLINE FOR RECEIPT: Friday, October 13, 2023.

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:

Each of your rules cites G.S. 143B-10 in the History Note. Please explain the relevance of this citation.

*Many of your rules cite only to G.S. 143B-10 and S.L. 2023-14, s. 2.4 as authority. I am not sure that Section 2.4 actually is an independent source of rulemaking authority; instead I see it more as a requirement to adopt rules—under other sources of authority—before October 1, 2023. Thus, to my reading, Section 2.4 isn't sufficient on its own as statutory authority; you need another statute that provides the Department with authority to regulate what's covered by the Rule. I don't see that specific authority in 143B-10. **Please add cites to each rule to whatever statute or statutes provide the Department with authority to make the specific regulatory act in each Rule.** As an example of what I'm looking for, see Rule .0106. The rule covers applications, and there's a cite to G.S. 131E-153.2, which requires clinic owners/sponsors to file an application, and directs the Department to define that application in rulemaking.*

Response:

The General Assembly stated in Section 2.4 of S.L. 2023-14 that “No later than October 1, 2023, the Department of Health and Human Services shall adopt the rules necessary to administer this Part.” (emphasis added). This mandate to adopt rules unambiguously refers to Part II of S.L. 2023-14, titled “Suitable Facilities for the Performance of Surgical Abortions.” In light of this mandate, as well as the repeal of the authority for then-existing rules, the Department adopted a first set of emergency rules on June 19, 2023 and a second set on July 6, 2023. The Department adopted all temporary rules on September 18 and submitted the temporary rules to the Rules Review Commission on September 29.

It is notable that the Department's authority to adopt rules only became effective on July 1, 2023, and the law required the adoption of rules to be completed prior to October 1, 2023. This rulemaking mandate is the only section of Part II that became effective prior to

Brian Liebman
Commission Counsel
Date submitted to agency: October 6, 2023

October 1. The remainder of Part II became effective on October 1, 2023, which demonstrates a clear legislative intent that the Department adopt rules prior to October 1 pursuant to this S.L. 2023-14 to ensure that Part II could take effect within the timeframe provided by the General Assembly.

The mandate for the Department to promulgate rules necessary to administer Part II of Session Law 2023-14 replaced the prior authorization found under G.S. 14-45.1, which was repealed on July 1, 2023. This shift in authority from the prior law to the new Session Law was recognized by the Codifier of Rules' analysis of the statute in prior correspondence with the Department:

Part I, Sec. 1.1 of the Session Law repeals DHHS's current rulemaking authority. Part II, Section 2.4 of the Session Law does grant DHHS the authority to adopt rules by October 1, 2023...

Letter from Codifier of Rules to Secretary Kody Kinsley, re: Emergency Rule Filing, 10A NCAC 14E, June 22, 2023 (emphasis added).

Section 2.2 of Session Law 2023-14 amends Article 6 of Chapter 131E of the General Statutes by creating the Abortion Clinic Licensure Act (the Act). As stated in the session law, the purpose of the Act is to:

(b) ... provide for the development, establishment, and enforcement of basic standards:

- (1) For the care and treatment of individuals in abortion clinics;**
- (2) For the maintenance and operation of abortion clinics so as to ensure safe and adequate treatment of such individuals in abortion clinics.**

S.L. 2023-14, § 2.2. The temporary rules adopted by Department made minimum changes to the language necessary to comply with Part II of S.L. 2023-14 but otherwise retained the content of the previous 10A NCAC 14E permanent rules. The content of all the rules is directly supported by the purpose of the Act, which makes the adoption of these rules necessary to ensure that Part II of S.L. 2023-14 can be effectively administered by the Department. Consistent with Section 2.4 of S.L. 2023-14, the Department has determined that each of the proposed rules are necessary to implement the purpose as stated in G.S. § 131E-153(b). Additionally, the content of rules related to issuance of licenses, adverse action of licenses and inspections of abortion clinics is also explicitly indicated in the Act and further supports the adoption of these rules.

To clarify the source of authority, the Department has added S.L. 2023-14, s 2.2, to the authority in the history note of each of the proposed temporary rules.

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: October 6, 2023

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

AGENCY: North Carolina Department of Health and Human Services/DHSR

RULE CITATION: 10A NCAC 14E .0101

DEADLINE FOR RECEIPT: Friday, October 13, 2023.

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 is your statutory authority for this Rule? Neither 143B-10 nor S.L. 2023-14 s. 2.4 cover the content of the Rule. **Please see response provided on Page 2.***

*In (1), line 10, to be clear, you are defining “abortion” for the purpose of this subchapter to mean only “surgical abortion” as defined in G.S. 90-21.81(1c)? **Yes.***

*In (2), lines 11-13, please delete the parentheses and incorporate the parenthetical material into the body of the Rule. **Parentheses deleted.***

*In (3), lines 14-15, this is not a definition. Moreover, the term “Complication” is defined in G.S. 90-21.81(2a). Did you mean to adopt that definition? Each of the instances mentioned here is listed in the statutory definition. **Definition deleted.***

*In (6), line 22, the Rule references Rule .0302, which has been repealed. Please correct. **Reference corrected.***

*In (9), lines 29-30, is this necessary? “Qualifying Physician” is defined in G.S. 90-21.81(7a). **Definition deleted.***

*In (9), line 29, must the physician be licensed in any state, or in the State of North Carolina? **Definition deleted.***

*In (9), line 29, the statutory language defining abortion (G.S. 90-21.81A(a)) was amended in SL 2023-65 to remove the word “advise”. Was it your intent to leave that here? **Definition deleted.***

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: October 6, 2023

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

AGENCY: North Carolina Department of Health and Human Services/DHSR

RULE CITATION: 10A NCAC 14E .0102

DEADLINE FOR RECEIPT: Friday, October 13, 2023.

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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:

We are withdrawing this rule from consideration.

It appears that DHSR is requiring (“shall”) people who aren’t licensed and aren’t even applicants for licensure, but people merely considering the idea of establishing an abortion clinic, to do something. Where is your statutory authority to regulate those who aren’t licensed or applying to be licensed?

What is a discussion in this context? How would it be determined that someone has or has not complied with this Rule? Do they have to say something to DHSR staff, or passively listen? Would a 10 second conversation satisfy this Rule?

If a potential sponsor or owner does not comply with this Rule, and subsequently submits an otherwise acceptable application for licensure, would their application be denied for failure to “discuss” it first with DHSR staff?

On line 6, what “licensure requirements” are you referring to?

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

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

AGENCY: North Carolina Department of Health and Human Services/DHSR

RULE CITATION: 10A NCAC 14E .0104

DEADLINE FOR RECEIPT: Friday, October 13, 2023.

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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:

*What is your statutory authority for this Rule? Neither 143B-10 nor S.L. 2023-14 s. 2.4 cover the content of the Rule. **Please see response provided on Page 2.***

On lines 4-5, the Rule states that the “clinic” shall submit two copies of the building plans for “licensure purposes.”

*First, who at the “clinic” shall do this? **Language changed to “an applicant for a new clinic.”***

*Second, what are “licensure purposes”? What are the guidelines for this review? **Issue addressed in language change.***

*On lines 7-8, there is no such code as the “North Carolina Administration and Enforcement Requirements Code.” **Issue addressed and incorrect language taken out.***

*On line 7, the 2012 edition of the various state building codes have all been superseded by the 2018 versions. Your incorporation by reference does state “subsequent amendments and editions”, but it would be less ambiguous to update the reference. **Building code versions updated.***

*On line 9, the URL provided does not direct a user to any specific code, but redirects to the ICC website. **Website link corrected.***

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

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

AGENCY: North Carolina Department of Health and Human Services/DHSR

RULE CITATION: 10A NCAC 14E .0106

DEADLINE FOR RECEIPT: Friday, October 13, 2023.

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), please consider revising in the active tense. Who shall submit the application?
(a) has been rewritten in the active tense.

In (b), line 6, where shall the applicant contact the Division? Do you have a contact rule? ***Address added.***

In (c), line 8, what is "general information that would be helpful"? ***Issue addressed.***

In (e), lines 14-15, are the contents or substantive requirements of the application form contained in another rule or in a statute? Are the same as in (c)? This is not clear. (e)
deleted from this rule and merged into Rule .0109.

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

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

AGENCY: North Carolina Department of Health and Human Services/DHSR

RULE CITATION: 10A NCAC 14E .0107

DEADLINE FOR RECEIPT: Friday, October 13, 2023.

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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)(2), line 6, what does it mean to “assure” that a physician is available? **Issue addressed.***

*In (a)(2), lines 6-7, what “board” is certifying the OB-GYN? **American Board of Obstetrics and Gynecology.***

*In (a)(2), line 7, what board should the physician be eligible for? **Issue addressed.***

*In (d), line 13, add a comma following “explosions”. **Comma added.***

*In (d), line 13, what is a “disruption” in services? **Issue addressed.***

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

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

AGENCY: North Carolina Department of Health and Human Services/DHSR

RULE CITATION: 10A NCAC 14E .0108

DEADLINE FOR RECEIPT: Friday, October 13, 2023.

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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:

We are withdrawing this rule from consideration.

What is your statutory authority for this Rule? Neither 143B-10 nor S.L. 2023-14 s. 2.4 cover the content of the Rule.

On line 4, please define "conspicuous place".

In the absence of a definition of "conspicuous place", how is this rule necessary when it merely restates G.S. 131E-153.2(e)?

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

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

AGENCY: North Carolina Department of Health and Human Services/DHSR

RULE CITATION: 10A NCAC 14E .0109

DEADLINE FOR RECEIPT: Friday, October 13, 2023.

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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:

*How does this Rule relate to .0106(e), which also covers renewal? Why is this topic separated into two rules? **We removed the renewal language of section .0106(e) and combined it with Rule .0109.***

*On line 4, what do you mean by “previously” suspended or revoked? Does this mean that the license is currently in that status? **Issue addressed.***

*On line 4, what “rules and statutes” are applicable? Be specific. **Issue addressed.***

*On line 5, what application? Is it the same form/contents as discussed in Rule .0106? **Issue addressed.***

*On line 6, under what circumstances is approval given? **Language deleted.***

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

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

AGENCY: North Carolina Department of Health and Human Services/DHSR

RULE CITATION: 10A NCAC 14E .0110

DEADLINE FOR RECEIPT: Friday, October 13, 2023.

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

*On line 4, please define “substantial”. **Issue addressed.***

*On line 5, what regulations are you referring to? **Issue addressed.***

*On line 5, please define “unsuitable”. **Issue addressed.***

*Why is there a reference to G.S. 150B-23 in your History Note? **To provide a linkage to an individual’s right to file a contested case upon the agency taking action on a clinic’s license.***

*Should there not be a reference to G.S. 131E-153.4? **Issue addressed.***

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

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

AGENCY: North Carolina Department of Health and Human Services/DHSR

RULE CITATION: 10A NCAC 14E .0111

DEADLINE FOR RECEIPT: Friday, October 13, 2023.

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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:

*What is your statutory authority for this Rule? Neither 143B-10 nor S.L. 2023-14 s. 2.4 cover the content of the Rule. **Please see response provided on Page 2.***

*In (a), lines 5-7, the sentence “An inspection . . . of this Subchapter” is confusingly written. Can it be simplified? In particular, what does it mean to say “An inspection shall be conducted whenever the purpose of the inspection is to determine” compliance? **Issue addressed and the sentence is simplified.***

*In (a), line 7, who should have “reason to believe” that the clinic isn’t in compliance? **Issue addressed.***

*In (a), line 7, please simplify “some condition exists which is not in compliance”. **Issue addressed.***

*In (b), line 9, what is the difference between “care” and “treatment”? **Issue addressed by deleted paragraph.***

*In (c), line 11, who would be the “person in charge”? **Issue addressed.***

*In (d), lines 14-15, what does “unless otherwise required by law” modify? Does it mean the Division can review records unless otherwise required by law, or that the Division shall maintain confidentiality unless otherwise required by law? **Addressed by breaking up sentences.***

*In (f), lines 18-19, the division’s response must be in writing, but the clinic’s plan of correction is not explicitly required to be in writing. Is this intentional? **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: October 6, 2023

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

AGENCY: North Carolina Department of Health and Human Services/DHSR

RULE CITATION: 10A NCAC 14E .0112

DEADLINE FOR RECEIPT: Friday, October 13, 2023.

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

*What is your statutory authority for this Rule? Neither 143B-10 nor S.L. 2023-14 s. 2.4 cover the content of the Rule. **Please see response provided on Page 2.***

*On line 4, what "specified types" of alterations are you referring to? **Issue addressed.***

*On lines 6-7, the terms "therefor" and "herein" are to be avoided pursuant to our style guide. Consider revising. **Issue addressed.***

*On line 6, are these "recommendations" binding? **Issue addressed.***

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

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

AGENCY: North Carolina Department of Health and Human Services/DHSR

RULE CITATION: 10A NCAC 14E .0113

DEADLINE FOR RECEIPT: Friday, October 13, 2023.

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

We are withdrawing this rule from consideration.

What is your statutory authority for this Rule? Neither 143B-10 nor S.L. 2023-14 s. 2.4 cover the content of the Rule.

How is this rule different from Rule .0112?

On line 4, what are the plans to be “reviewed” for? Reviewed under what guidelines or standards?

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

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

AGENCY: North Carolina Department of Health and Human Services/DHSR

RULE CITATION: 10A NCAC 14E .0114

DEADLINE FOR RECEIPT: Friday, October 13, 2023.

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

*What is your statutory authority for this Rule? Neither 143B-10 nor S.L. 2023-14 s. 2.4 cover the content of the Rule. **Please see response provided on Page 2.***

*In (a), line 4, what are “construction documents and specifications”? **Language corrected to “building plans.”***

*Where is the statutory authority, specifically, for the review and approval required in (a), lines 5-7 by the Division of Public Health, the Environmental Health Section, and the Department of Insurance? **Language removed.***

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

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

AGENCY: North Carolina Department of Health and Human Services/DHSR

RULE CITATION: 10A NCAC 14E .0201

DEADLINE FOR RECEIPT: Friday, October 13, 2023.

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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:

*What is your statutory authority for this Rule? Neither 143B-10 nor S.L. 2023-14 s. 2.4 cover the content of the Rule. **Please see response provided on Page 2.***

*In (a), line 10, the URL for ecodes.biz just redirects back to the ICC website. Please correct. **Link replaced.***

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

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

AGENCY: North Carolina Department of Health and Human Services/DHSR

RULE CITATION: 10A NCAC 14E .0202

DEADLINE FOR RECEIPT: Friday, October 13, 2023.

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

*What is your statutory authority for this Rule? Neither 143B-10 nor S.L. 2023-14 s. 2.4 cover the content of the Rule. **Please see response provided on Page 2.***

*On line 9, please use a more direct URL to the NCAC. It should be <http://reports.oah.state.nc.us/ncac.asp>. **Link corrected.***

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

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

AGENCY: North Carolina Department of Health and Human Services/DHSR

RULE CITATION: 10A NCAC 14E .0207

DEADLINE FOR RECEIPT: Friday, October 13, 2023.

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 is your statutory authority for this Rule? Neither 143B-10 nor S.L. 2023-14 s. 2.4 cover the content of the Rule. **Please see response provided on Page 2.***

*On line 4, please correct the reference to Rule .0206, which has been repealed. I assume, but am not sure, that this should now say Rule .0212, based on the rule titles. **Issue addressed.***

*Do the requirements here and in Rule .0212 conflict in any way with the requirements of the Building Code and with the requirements of 15A NCAC 18A .1300? **No.***

*What is the purpose of (9)? This list is of areas that have to comply with Rule .0212, and here we've got a semi-definition of "medicine room". Does the cabinet in the clean workroom also have to comply with Rule .0212? What if it isn't a cabinet, and it is a separate room? **Wording changed to avoid confusion.***

*In (10), line 16, add "of" between "handling" and "clean". **Issue addressed.***

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

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

AGENCY: North Carolina Department of Health and Human Services/DHSR

RULE CITATION: 10A NCAC 14E .0209

DEADLINE FOR RECEIPT: Friday, October 13, 2023.

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 is your statutory authority for this Rule? Neither 143B-10 nor S.L. 2023-14 s. 2.4 cover the content of the Rule. **Please see response provided on Page 2.***

*In (a), consider rewriting in the active tense. Who shall provide the elevator? **Issue addressed.***

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

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

AGENCY: North Carolina Department of Health and Human Services/DHSR

RULE CITATION: 10A NCAC 14E .0210

DEADLINE FOR RECEIPT: Friday, October 13, 2023.

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 is your statutory authority for this Rule? S.L. 2023-14 s. 2.4 does not cover the content of the Rule. **Please see response provided on Page 2.***

*This rule seems potentially self-contradictory. Can a corridor be greater than 60 inches wide but insufficient to allow for patient evacuation by stretcher? **Issue addressed.***

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

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

AGENCY: North Carolina Department of Health and Human Services/DHSR

RULE CITATION: 10A NCAC 14E .0211

DEADLINE FOR RECEIPT: Friday, October 13, 2023.

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 is your statutory authority for this Rule? S.L. 2023-14 s. 2.4 does not cover the content of the Rule. **Please see response provided on Page 2.***

*On line 6, please define "small closet". **Issue addressed by deleting "small closets."***

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

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

AGENCY: North Carolina Department of Health and Human Services/DHSR

RULE CITATION: 10A NCAC 14E .0212

DEADLINE FOR RECEIPT: Friday, October 13, 2023.

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 is your statutory authority for this Rule? Neither 143B-10 nor S.L. 2023-14 s. 2.4 cover the content of the Rule. **Please see response provided on Page 2.***

*Does this Rule conflict in any way with the Building Code or with 15A NCAC 18A .1300? **No.***

*In (1)(b)(ii), the Rule requires air delivered “at or near” the ceiling, but removed “not less than three inches” from the floor. Is the lack of specificity for the ceiling intended? **Yes.***

*In (1)(b)(v), line 27, add a comma following “closets”. **Issue addressed.***

*With respect to both instances of the NFPA you’re incorporating, do the portions of the Building Code, which you’ve also incorporated, contain any contradictory NC Fire Code provisions? **No.***

*Also with respect to both instances of the NFPA, please provide more specific URLs to where these documents can be found free of charge. I went on NFPA.org and was unable to access them for free. **www.NFPA.org is the correct URL. The documents are available for free if one creates a profile.***

*In (2)(a)(i), p.2, line 9, does the reference to NFPA-99-2012 mean the 2012 version? The current NFPA version is 2024. The incorporation says “including subsequent amendments and editions”. Same question for NFPA 70-2011 in (2)(a)(ii). **Version corrected.***

*With respect to NFPA-70-2011, NFPA-70 is the National Electric Code. North Carolina has already adopted the 2018 National Electric Code with state specific amendments. Would NFPA-70-2011 still be in effect, or has it been superseded by provisions in the 2018 code? **Version corrected.***

Brian Lieberman
Commission Counsel

Date submitted to agency: October 6, 2023

*In (2)(a)(ii), lines 15-16, what does “current editions relating to inhalation anesthesia” mean? Does this mean only portions of these documents are incorporated by reference? If so, please specifically state which portions are incorporated by reference. **Issue addressed.***

*In (3)(a), line 32, what does “listed batter backup lighting units” mean? Specifically, I’m asking about “listed”. **The list is found at <https://www.ncosfm.gov/third-party-testing-agencies/open>.***

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

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

AGENCY: North Carolina Department of Health and Human Services/DHSR

RULE CITATION: 10A NCAC 14E .0213

DEADLINE FOR RECEIPT: Friday, October 13, 2023.

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:

We are withdrawing this rule from consideration.

What is your statutory authority for this Rule? Neither 143B-10 nor S.L. 2023-14 s. 2.4 cover the content of the Rule.

What does this sentence mean? It's facially vague and ambiguous.

On line 4, what does "written indication" mean?

On line 4, what's the significance of "shared or purchased"?

On line 4, what are "appropriate" modifications? Please delete or define.

On line 5, "space requirements" for what? What requirements are you referring to?

On line 5, "may be anticipated" by whom?

On lines 4-5, what effect would be caused by modifying the space requirements?

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

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

AGENCY: North Carolina Department of Health and Human Services/DHSR

RULE CITATION: 10A NCAC 14E .0315

DEADLINE FOR RECEIPT: Friday, October 13, 2023.

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 is your statutory authority for this Rule? Neither 143B-10 nor S.L. 2023-14 s. 2.4 cover the content of the Rule. **Please see response provided on Page 2.***

*How is this rule any different than Rule .0202? Both require adherence to the sanitation standards in 15A NCAC 18A .1300. **This Rule addresses standards beyond the sanitation standards in Rule .0202.***

*In (1), line 8, add a comma following "woodwork". **Done.***

*In (1), line 8, what is "waste material"? **Language removed.***

*In (3), line 11, please define "clean and sanitary condition". **Term defined consistent with 15A NCAC 18A .1312.***

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

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

AGENCY: North Carolina Department of Health and Human Services/DHSR

RULE CITATION: 10A NCAC 14E .0317

DEADLINE FOR RECEIPT: Friday, October 13, 2023.

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:

We are withdrawing this rule from consideration.

What is your statutory authority for this Rule? Neither 143B-10 nor S.L. 2023-14 s. 2.4 cover the content of the Rule.

On line 4, what does "fully disclosed" mean?

Does this Rule require anything not already required in Section .0100? Ownership must be disclosed on the application form.

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

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

AGENCY: North Carolina Department of Health and Human Services/DHSR

RULE CITATION: 10A NCAC 14E .0318

DEADLINE FOR RECEIPT: Friday, October 13, 2023.

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 is your statutory authority for this Rule? Neither 143B-10 nor S.L. 2023-14 s. 2.4 cover the content of the Rule. **Please see response provided on Page 2.***

*Specifically to statutory authority here, where is your authority to require the governing authority to appoint a CEO? I don't see anything in the Session Law that would give you authority to regulate the organizational structure and personnel practices of any private entity, or to require a the CEO to delegate his or her authority. **Please see response provided on Page 2. The Department has the authority to adopt rules on clinic operations to ensure safe and adequate treatment pursuant to Section 2.2 of Session Law 2023-14.***

*Again, to statutory authority, where is your authority to require a governing authority to adopt policies and procedures? **Please see response provided on Page 2. The Department has the authority to adopt rules on clinic operations to ensure safe and adequate treatment pursuant to Section 2.2 of Session Law 2023-14.***

*In (a), line 5, to whom would the CEO/designee represent the governing authority? **To individuals and entities outside of the clinic.***

*In (d)(3), line 20, define "professional and safe". **Language changed.***

*In (e), what do you mean by "shall be responsible to assure" that the supplier meets the local or state standards? Do you have authority to require a 3rd party to conform to state and local standards? Do you have statutory authority to require a clinic to enter into a contract? Do you have statutory authority to essentially specify the terms of that contract? **Please see response provided on Page 2. The Department has the authority to adopt rules on clinic operations to ensure safe and adequate treatment pursuant to Section 2.2 of Session Law 2023-14.***

*In (e), line 24, omit the comma following "laundry". **Done.***

*In (e), line 25, capitalize “state” if referring only to the State of North Carolina. **Done.***

*In (g), line 29-30, who are “supporting personnel”? **Clinic staff.***

*In (g), line 30, please define “safe patient care.” **Issue revised.***

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

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

AGENCY: North Carolina Department of Health and Human Services/DHSR

RULE CITATION: 10A NCAC 14E .0319

DEADLINE FOR RECEIPT: Friday, October 13, 2023.

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 is your statutory authority for this Rule? Neither 143B-10 nor S.L. 2023-14 s. 2.4 cover the content of the Rule. **Please see response provided on Page 2.***

*Specifically, do you have statutory authority to require documents to be kept on file on the clinic's premises? **Please see response provided on Page 2. The Department has the authority to adopt rules on clinic operations to ensure safe and adequate treatment pursuant to Section 2.2 of Session Law 2023-14.***

*In (a)(7), line 12, please define "related to licensure". **Issue addressed by changing the language.***

*In (b), line 13, is this requirement not redundant with Rule .0108? **No, Rule .0108 has been withdrawn.***

*In (c), line 14, what policies and procedures are you requiring? Is this other than the policies and procedures required elsewhere in these rules? **This rule pertains to the manual requiring specified policies and procedures.***

*In (c)(1), line 17, consider making "clinical discharge criteria" an independent item. **Correction made.***

*In (c)(3), line 19, to be clear, do you mean medical policies and procedures? For instance, a description of the steps the doctor would take in performing each procedure? **Issue addressed by changing the language.***

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

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

AGENCY: North Carolina Department of Health and Human Services/DHSR

RULE CITATION: 10A NCAC 14E .0320

DEADLINE FOR RECEIPT: Friday, October 13, 2023.

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 is your statutory authority for this Rule? Neither 143B-10 nor S.L. 2023-14 s. 2.4 cover the content of the Rule. **Please see response provided on Page 2.***

*In (a), line 5, what do you mean by “administrative decisions on their disposition”? **Issue addressed.***

*In (c), line 8, what is a “general” hospital? Is this different than the definition of “hospital” in the statute? “acute care hospital” **Issue addressed by clarifying the language.***

*In (d)(2), line 13, delete the “(s)” and make “physician(s)” either plural or “physician or physicians”. **Done.***

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

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

AGENCY: North Carolina Department of Health and Human Services/DHSR

RULE CITATION: 10A NCAC 14E .0321

DEADLINE FOR RECEIPT: Friday, October 13, 2023.

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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:

*What is your statutory authority for this Rule? Neither 143B-10 nor S.L. 2023-14 s. 2.4 cover the content of the Rule. **Please see response provided on Page 2.***

*Throughout, please use the active tense and specify the subject of sentences where you're directing someone to take some action. I've tried to call out below where this is particularly problematic, but please review the entire rule and make these changes. **Issue addressed.***

*In (a), line 4, who must maintain the record? Please use the active tense. **Changed to active tense.***

*In (a)(10), line 16, please define "have a bearing on". **Issue addressed by rephrasing language.***

*In (b), line 20, should "report" be plural? **Issue addressed by rephrasing.***

*In (b), line 22, who shall sign to authenticate? **Issue addressed by saying the clinic has the responsibility to authenticate.***

*In (c), line 23, who shall explain the significance? **Addressed by clarifying language and specifying the clinic.***

*In (d), line 25, who shall perform the ultrasound? **Issue addressed.***

*In (e)(4), line 32, add the article before "physician". **Done.***

*In (e)(5), line 33, add the article before "Registered Nurse". **Done.***

*In (e)(6), line 34, do you mean the time the procedure started, or the duration? Both? **The start and end time of the procedure should be noted pursuant to the rule.***

Brian Liebman
Commission Counsel
Date submitted to agency: October 6, 2023

*In (f), line 35, do you have statutory authority to require that records be preserved in the state? **Please see response provided on Page 2. The Department has the authority to adopt rules on clinic operations to ensure safe and adequate treatment pursuant to Section 2.2 of Session Law 2023-14.***

*In (f), p.2, line 2, would a patient's request for records be sufficient to remove the records? **No.***

*In (h), line 5, arrangements shall be made by whom? **Issue addressed by specifying the clinic.***

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

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

AGENCY: North Carolina Department of Health and Human Services/DHSR

RULE CITATION: 10A NCAC 14E .0322

DEADLINE FOR RECEIPT: Friday, October 13, 2023.

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 is your statutory authority for this Rule? Neither 143B-10 nor S.L. 2023-14 s. 2.4 cover the content of the Rule. **Please see response provided on Page 2.***

In (a)(1)(A), (B), and (C), please add articles before the noun opening the sentence (“the employee’s...”) **Done**

In (a)(1)(D) and (E), what are you requiring by “verification”? **Issue addressed by changing language.**

In (a)(3), line 13, do you have statutory authority for this provision? Are not personnel records otherwise confidential under the law? **Please see response provided on Page 2.**

In (a)(3), line 13, what do you mean by “notwithstanding the requirement found in Subparagraph (b)(2)”? That language refers to a job description. **Issue addressed by simplifying the language.**

In (f), line 29, are these health records not confidential under State and federal law? **No.**

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

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

AGENCY: North Carolina Department of Health and Human Services/DHSR

RULE CITATION: 10A NCAC 14E .0323

DEADLINE FOR RECEIPT: Friday, October 13, 2023.

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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:

*What is your statutory authority for this Rule? Neither 143B-10 nor S.L. 2023-14 s. 2.4 cover the content of the Rule. **Please see response provided on Page 2.***

*Specifically, where is your authority to require the governing authority to designate a nursing supervisor? I don't see anything in the Session Law that would give you authority to regulate the organizational structure and personnel practices of any private entity. **Please see response provided on Page 2. The Department has the authority to adopt rules on clinic operations to ensure safe and adequate treatment pursuant to Section 2.2 of Session Law 2023-14.***

*In (a), line 5 and (b), line 6, please define "responsibility and accountability" and "responsible and accountable". **Issue addressed by rephrasing sentences and deleting language.***

*In (b)(2), line 8, what manual? Is this required in another rule? **The Nursing Policy and Procedure Manual, it is not required in another rule.***

*In (c), lines 10-11, who makes the judgment that there are sufficient personnel on staff? **The governing authority of the clinic.***

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

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

AGENCY: North Carolina Department of Health and Human Services/DHSR

RULE CITATION: 10A NCAC 14E .0324

DEADLINE FOR RECEIPT: Friday, October 13, 2023.

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 is your statutory authority for this Rule? Neither 143B-10 nor S.L. 2023-14 s. 2.4 cover the content of the Rule. **Please see response provided on Page 2.***

*Specifically, where is your authority to require the governing authority to establish a quality assurance program and a compliance committee? Where is your authority to require the governing authority to set staffing requirements for the committee? Where is your authority to set the committee's functions? **Please see response provided on Page 2. The Department has the authority to adopt rules on clinic operations to ensure safe and adequate treatment pursuant to Section 2.2 of Session Law 2023-14.***

*In (b), line 7, "corrective action" for what? **Issue addressed by specifying rule.***

In (c), lines 8-9, are these members of the committee to also be members of the governing authority? Employees of the clinic? Or must they be independent and unaffiliated with the clinic at all? They can be employees of the clinic.

*In (c), line 9, what are "other health professionals"? **Health professionals that are not physicians such as nurse practitioners, pharmacists, registered nurses, and physician's assistants.***

*In (f), line 19, who shall conduct these programs? Please use the active tense. **Rewritten in active tense.***

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

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

AGENCY: North Carolina Department of Health and Human Services/DHSR

RULE CITATION: 10A NCAC 14E .0325

DEADLINE FOR RECEIPT: Friday, October 13, 2023.

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 is your statutory authority for this Rule? Neither 143B-10 nor S.L. 2023-14 s. 2.4 cover the content of the Rule. **Please see response provided on Page 2.***

*In (a), line 4, what do you mean by “have the capability to . . . obtain” lab tests? Does this mean an agreement with a 3rd party? **A clinic needs to either have a clinical laboratory certificate, which would allow them to provide lab tests on their own, or they would need to contract with a reference lab.***

*In (b), this is written in a roundabout way. Did you mean to say that the governing authority must establish a written policy stating which “surgical samples” must be examined by a pathologist? **Issue addressed by rephrasing the statement.***

*In (b), line 7, what do you mean by “those types of specimens”? What specimens? **Issue addressed by deleting language.***

*In (e), lines 15-16, are you allowing that the lab tests may be performed by any “employee” who has access to the manual? **No, the Rule is only specific to the requirement for a manual. Only employees that are authorized and qualified may perform the tests.***

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

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

AGENCY: North Carolina Department of Health and Human Services/DHSR

RULE CITATION: 10A NCAC 14E .0326

DEADLINE FOR RECEIPT: Friday, October 13, 2023.

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 is your statutory authority for this Rule? Neither 143B-10 nor S.L. 2023-14 s. 2.4 cover the content of the Rule. **Please see response provided on Page 2.***

*In (a), line 4, what is the definition of an “emergency case”? **Issue addressed.***

*In (a), line 4, define “nearby”. **Issue addressed.***

*In (a), line 5, when is hospitalization necessary? **When the clinic can no longer provide treatment or services due to the patient’s condition.***

*In (b), line 6, how can a clinic “have” a procedure? Consider rephrasing. **Issue addressed by specifying “written protocols”***

*In (b), line 6, define “suitable equipment”. **Issue addressed.***

*In (b), line 6, again, please define “medical emergencies”. **Issue addressed.***

*In (c), line 9, what kind of “documentation” are you requiring? A letter or email or other written acknowledgement **that the hospital will facilitate the transfer of patients that are in need of emergency care.***

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

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

AGENCY: North Carolina Department of Health and Human Services/DHSR

RULE CITATION: 10A NCAC 14E .0327

DEADLINE FOR RECEIPT: Friday, October 13, 2023.

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 is your statutory authority for this Rule? Neither 143B-10 nor S.L. 2023-14 s. 2.4 cover the content of the Rule. **Please see response provided on Page 2.***

*In (a), line 5, please define an "atmosphere free of contamination". **Issue addressed by changing the wording.***

*In (a), line 6, are there not standard procedures for infection control and universal precautions? **There are standards, but they may originate from different sources. The Rule is intended to require the clinic to choose one of the generally accepted standard procedures.***

*In (b)(2), line 12, add a comma following "pregnancy". **Done.***

*In (b)(2), line 12-13, the grammar of the sentence seems off, particularly on line 13. Please consider revising. **Issue addressed by restructuring sentence.***

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

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

AGENCY: North Carolina Department of Health and Human Services/DHSR

RULE CITATION: 10A NCAC 14E .0328

DEADLINE FOR RECEIPT: Friday, October 13, 2023.

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 is your statutory authority for this Rule? Neither 143B-10 nor S.L. 2023-14 s. 2.4 cover the content of the Rule. **Please see response provided on Page 2.***

*In (b), line 5, may a physician administer medications directly, or must he or she allow an RN to do it? **Issue addressed.***

*In (c), line 7, please define "direct supervision"? **Issue addressed.***

*In (c), line 7, may anesthesia be administered by any licensed physician, or an anesthesiologist? **Yes, so long as they are qualified within their scope of practice and under the direct supervision of a licensed physician.***

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

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

AGENCY: North Carolina Department of Health and Human Services/DHSR

RULE CITATION: 10A NCAC 14E .0329

DEADLINE FOR RECEIPT: Friday, October 13, 2023.

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 is your statutory authority for this Rule? Neither 143B-10 nor S.L. 2023-14 s. 2.4 cover the content of the Rule. **Please see response provided on Page 2.***

*In (a), line 4, and (c)(1), line 10, please define “ambulatory basis” and “ambulatory”. **“Ambulatory basis” and “ambulatory” deleted.***

*In (b), line 7, please define “adverse condition”. **Issue addressed by taking language out.***

*In (c)(2), line 11, what do you mean by “controlled”? **Bleeding and pain are assessed to be stable and not a concern for discharge. This is a clinical determination.***

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

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

AGENCY: North Carolina Department of Health and Human Services/DHSR

RULE CITATION: 10A NCAC 14E .0330

DEADLINE FOR RECEIPT: Friday, October 13, 2023.

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 is your statutory authority for this Rule? Neither 143B-10 nor S.L. 2023-14 s. 2.4 cover the content of the Rule. **Please see response provided on Page 2.***

*In (a), line 4, please define or delete "properly". **Language deleted.***

*In (b), how is this to be determined, and by whom? **To be determined by the clinic through their governing authority and their policies and procedures adopted by the clinic.***

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

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

AGENCY: North Carolina Department of Health and Human Services/DHSR

RULE CITATION: 10A NCAC 14E .0331

DEADLINE FOR RECEIPT: Friday, October 13, 2023.

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 is your statutory authority for this Rule? Neither 143B-10 nor S.L. 2023-14 s. 2.4 cover the content of the Rule. **Please see response provided on Page 2.***

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

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

AGENCY: North Carolina Department of Health and Human Services/DHSR

RULE CITATION: 10A NCAC 14E .0403

DEADLINE FOR RECEIPT: Friday, October 13, 2023.

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:

We are withdrawing this rule from consideration.

What is your statutory authority for this Rule? Neither 143B-10 nor S.L. 2023-14 s. 2.4 cover the content of the Rule.

How is this Rule different than what is required in Rule .0322?

On line 4, to whom must the person submit this application?

On line 4, what is the person applying for?

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

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

AGENCY: North Carolina Department of Health and Human Services/DHSR

RULE CITATION: 10A NCAC 14E .0404

DEADLINE FOR RECEIPT: Friday, October 13, 2023.

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:

We are withdrawing this rule from consideration.

What is your statutory authority for this Rule? Neither 143B-10 nor S.L. 2023-14 s. 2.4 cover the content of the Rule.

How is this Rule different from what is already required in Rule .0322?

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

10A NCAC 14E .0101 is amended under temporary procedures with changes as follows:

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

SECTION .0100 – CERTIFICATION LICENSURE PROCEDURE

10A NCAC 14E .0101 DEFINITIONS

The following definitions will apply throughout this Subchapter:

- (1) "Abortion" means the termination of a pregnancy as defined in G.S. ~~90-21.81(1)~~, 90-21.81(1c).
- (2) "Clinic" means a freestanding facility ~~(a~~ facility neither physically attached nor operated by a licensed ~~hospital)~~ hospital for the performance of abortions completed during the first ~~20~~ 12 weeks of pregnancy.
- ~~(3) "Complication" includes but is not limited to hemorrhage, infection, uterine perforation, cervical laceration, or retained products of conception.~~
- ~~(4)~~(3) "Division" means the Division of Health Service Regulation of the North Carolina Department of Health and Human Services.
- ~~(5)~~(4) "Gestational age" means the length of pregnancy as indicated by the date of the first day of the last normal monthly menstrual period, if known, or as determined by ultrasound.
- ~~(6)~~(5) "Governing authority" means the individual, agency, group, or corporation appointed, elected or otherwise designated, in which the ultimate responsibility and authority for the conduct of the abortion clinic is vested pursuant to Rule ~~.0302~~ .0318 of this Subchapter.
- ~~(7)~~(6) "Health Screening" means an evaluation of an employee or contractual employee, including tuberculosis testing, to identify any underlying conditions that may affect the person's ability to work in the clinic.
- ~~(8)~~(7) "New clinic" means one that is not certified as an abortion clinic by the Division as of July 1, ~~2014~~, 2023, and has not been certified or licensed within the previous six months of the application for ~~certification~~, licensure.
- ~~(9) "Qualified Physician" means a licensed physician who advises, procures, or causes a miscarriage or abortion as defined in G.S. 14-45.1(g). [90-21.81(7a).]~~
- ~~(10)~~(8) "Registered Nurse" means a person who holds a valid license issued by the North Carolina Board of Nursing to practice professional nursing in accordance with the Nursing Practice Act, G.S. 90, Article 9A.

History Note: Authority G.S. 14-45.1(a); 14-45.1(g); 143B-10; S.L. 2013-366, s. 4(e); S.L. 2023-14, s. 2.2; 2.4; Eff. February 1, 1976; Readopted Eff. December 19, 1977;

1 *Amended Eff. October 1, 2015; July 1, 1994; December 1, 1989; June 30, 1980;*
2 *Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. August 24,*
3 *2019;*
4 *Codifier determined that agency's findings of need did not meet criteria for emergency rule on June*
5 *22, 2023;*
6 *Emergency Rule Eff. June 30, 2023;*
7 *Repealed Eff. July 1, 2023 pursuant to G.S. ~~150B-21.7~~. 150B-21.7;*
8 *Temporary Amendment Eff. October 27, 2023.*

1 10A NCAC 14E .0102 is amended under temporary procedures as follows:

2
3 **10A NCAC 14E .0102 CONFERENCE**

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

7
8 *History Note: Authority G.S. ~~14-45.1(a)~~; 143B-10; S.L. 2023-14, s. 2.4;*

9 *Eff. February 1, 1976;*

10 *Readopted Eff. December 19, 1977;*

11 *Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. August 24,*
12 *2019;*

13 *Codifier determined that agency's findings of need did not meet criteria for emergency rule on June*
14 *22, 2023;*

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

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

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

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

10A NCAC 14E .0104 PLANS

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

History Note: Authority ~~G.S. 14-45.1(a); 143B-10; S.L. 2023-14, s. 2.2; 2.4;~~

Eff. February 1, 1976;

Readopted Eff. December 19, 1977;

Amended Eff. October 1, 2015;

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

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

Emergency Rule Eff. June 30, 2023;

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

Temporary Amendment Eff. October 27, 2023.

10A NCAC 14E .0106 is amended under temporary procedures with changes as follows:

10A NCAC 14E .0106 APPLICATION

(a) Prior to the admission of patients, an ~~application from the applicant for a new clinic for certification [licensure]~~ shall ~~be submitted to and approved by the Division.~~ submit an application for licensure and receive approval from the Division.

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

(c) The application form shall set forth the ownership, staffing patterns, clinical services to be rendered, and professional staff in charge of services, services, and general information that would be helpful to the Division's understanding of the clinic's operating program.

(d) After construction requirements in Section .0200 of this Subchapter have been met and the application for ~~certification~~ licensure has been received and approved, the Division shall conduct an on-site, ~~certification~~ licensure survey.

~~(e) Each certificate [license] must be renewed at the beginning of each calendar year. The governing authority shall file an application for renewal of certification [licensure] with the Division at least 30 days prior to the date of expiration on forms furnished by the Division. Failure to file a renewal application shall result in expiration of the certificate [license] to operate.~~

History Note: Authority G.S. ~~14-45.1(a)~~; 131E-153.2; S.L. 2023-14, s. 2.2; 2.4;

Eff. February 1, 1976;

Readopted Eff. December 19, 1977;

Amended Eff. July 1, 1994;

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

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

Emergency Rule Eff. June 30, 2023;

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

Temporary Amendment Eff. October 27, 2023.

1 10A NCAC 14E .0107 is amended under temporary procedures with changes as follows:

2
3 **10A NCAC 14E .0107 ISSUANCE OF ~~CERTIFICATE~~ LICENSE**

4 (a) The Division shall issue a ~~certificate~~ license if it finds the facility can:

5 (1) Comply with all requirements described in this Subchapter; and

6 (2) ~~Assure that, in the event that complications arise from the abortion procedure, an OB-GYN board~~
7 ~~certified~~ Have a board certified OB-GYN or board eligible physician shall be ~~available. available in~~
8 the event that complications arise from an abortion procedure.

9 (b) Each ~~certificate~~ license shall be issued only for the premises and persons or organizations named in the application
10 and shall not be transferable.

11 (c) The governing authority shall notify the Division in writing, within 10 working days, of any change in the name
12 of the facility or change in the name of the administrator.

13 (d) The facility shall report to the Division all incidents, within 10 working days, of vandalism to the facility such as
14 fires, ~~explosions~~ explosions, or other action ~~causing disruption of that prevents~~ services from being provided.

15
16 *History Note: Authority G.S. ~~14-45.1(a)~~; 131E-153.2; S.L. 2023-14, s. 2.2; 2.4;*

17 *Eff. February 1, 1976;*

18 *Readopted Eff. December 19, 1977;*

19 *Amended Eff. July 1, 1994;*

20 *Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. August 24,*
21 *2019;*

22 *Codifier determined that agency's findings of need did not meet criteria for emergency rule on June*
23 *22, 2023;*

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

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

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

1 10A NCAC 14E .0108 is amended under temporary procedures as follows:

2
3 **10A NCAC 14E .0108 POSTING**

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

5
6 *History Note: Authority G.S. ~~14-45.1(a)~~; 143B-10; S.L. 2023-14, s. 2.4;*

7 *Eff. February 1, 1976;*

8 *Readopted Eff. December 19, 1977;*

9 *Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. August 24,*
10 *2019;*

11 *Codifier determined that agency's findings of need did not meet criteria for emergency rule on June*
12 *22, 2023;*

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

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

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

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

10A NCAC 14E .0109 RENEWAL

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

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

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

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

History Note: Authority G.S. ~~14-45.1(a); 131E-269; 131E-153.2; 143B-10; S.L. 2023-14, s. 2.2; 2.4;~~

Eff. February 1, 1976;

Readopted Eff. December 19, 1977;

Amended Eff. October 1, 2015;

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

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

Emergency Rule Eff. June 30, 2023;

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

Temporary Amendment Eff. October 27, 2023.

1 10A NCAC 14E .0110 is amended under temporary procedures with changes as follows:

2
3 **10A NCAC 14E .0110 REVOCATION**

4 The Department ~~shall~~ may deny, suspend, or revoke a ~~certificate~~ license in any case where it finds ~~that a~~ substantial
5 failure to comply with ~~these regulations~~ Article 6 of Chapter 131E of the General Statutes and the rules adopted under
6 that law, renders the facility unsuitable for the performance of abortions.

7
8 *History Note:* Authority ~~G.S. 14-45.1(a); 131E-153.2; 131E-153.4;~~ 143B-10; 150B-23; S.L. 2023-14, s. 2.2; 2.4;

9 *Eff. February 1, 1976;*

10 *Amended Eff. December 1, 1989;*

11 *Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. August 24,*
12 *2019;*

13 *Codifier determined that agency's findings of need did not meet criteria for emergency rule on June*
14 *22, 2023;*

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

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

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

10A NCAC 14E .0111 is amended under temporary procedures with changes as follows:

10A NCAC 14E .0111 INSPECTIONS

(a) Any clinic ~~certified~~ licensed by the Division to perform abortions shall be inspected by representatives of the Division annually and as it may deem necessary as a condition of holding such license. An inspection ~~shall~~ may be conducted whenever the Division receives a complaint alleging the clinic is not in compliance with the rules of the Subchapter. ~~purpose of the inspection is to determine whether the clinic complies with the rules of this Subchapter Subchapter. or whenever there is reason to believe that some condition exists which is not in compliance with the rules of this Subchapter.~~

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

~~(e)(b)~~ Representatives of the Division shall make their identities known to the person in charge- clinic staff prior to inspection of the clinic.

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

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

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

*History Note: Authority G.S. ~~14-45.1(a); 14-45.1(a1); 143B-10; S.L. 2013-366, s. 4(e); S.L. 2023-14, s. 2.2; 2.4;~~
Eff. February 1, 1976;
Readopted Eff. December 19, 1977;
Amended Eff. October 1, 2015; July 1, 1994;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. August 24, 2019;
Codifier determined that agency's findings of need did not meet criteria for emergency rule on June 22, 2023;
Emergency Rule Eff. June 30, 2023;
Repealed Eff. July 1, 2023 pursuant to G.S. ~~150B-21.7; 150B-21.7;~~
Temporary Amendment Eff. October 27, 2023.*

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

2
3 **10A NCAC 14E .0112 ALTERATIONS**

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

8
9 *History Note: Authority G.S. ~~14-45.1(a)~~; 143B-10; S.L. 2023-14, s. 2.2; 2.4;*

10 *Eff. February 1, 1976;*

11 *Readopted Eff. December 19, 1977;*

12 *Amended Eff. December 1, 1989;*

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

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

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

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

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

1 10A NCAC 14E .0113 is adopted under temporary procedures as follows:

2
3 **10A NCAC 14E .0113 CHANGES**

4 All stages of the plans from schematics through working drawings shall be reviewed by the Division's staff each time
5 a change is made.

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

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

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

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

2
3 **10A NCAC 14E .0114 APPROVAL**

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

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

11
12 *History Note: Authority G.S. 143B-10; S.L. 2023-14, s. 2.2; 2.4;*

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

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

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

SECTION .0200 - MINIMUM STANDARDS FOR CONSTRUCTION AND EQUIPMENT

10A NCAC 14E .0201 BUILDING CODE REQUIREMENTS

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

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

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

History Note: Authority G.S. ~~14-45-1(a)~~; 143B-10; S.L. 2023-14, s. 2.2; 2.4;

Eff. February 1, 1976;

Readopted Eff. December 19, 1977;

Amended Eff. October 1, 2015; July 1, 1994; December 1, 1989;

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

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

Emergency Rule Eff. June 30, 2023;

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

Temporary Amendment Eff. October 27, 2023.

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

2
3 **10A NCAC 14E .0202 SANITATION**

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

10
11 *History Note: Authority G.S. ~~14-45.1(a)~~; 143B-10; S.L. 2023-14, s. 2.2; 2.4;*

12 *Eff. February 1, 1976;*

13 *Readopted Eff. December 19, 1977;*

14 *Amended Eff. August 1, 2019; October 1, 2015; July 1, 1994;*

15 *Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. August 24,*
16 *2019;*

17 *Codifier determined that agency's findings of need did not meet criteria for emergency rule on June*
18 *22, 2023;*

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

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

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

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

10A NCAC 14E .0207 AREA REQUIREMENTS

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

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

History Note: Authority G.S. ~~14-45.1(a)~~; 143B-10; S.L. 2023-14, s. 2.2; 2.4;

Eff. February 1, 1976;

Readopted Eff. December 19, 1977;

Amended Eff. October 1, 2015; December 24, 1979;

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

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

Emergency Rule Eff. June 30, 2023;

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

1

Temporary Amendment Eff. October 27, 2023.

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

2
3 **10A NCAC 14E .0209 ELEVATOR**

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

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

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

7
8 *History Note: Authority G.S. 143B-10; S.L. 2023-14, s. 2.2, 2.4;*

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

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

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

2
3 **10A NCAC 14E .0210 CORRIDORS**

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

6
7 *History Note: Authority S.L. 2023-14, s. 2.2; 2.4;*

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

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

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

2
3 **10A NCAC 14E .0211 DOORS**

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

7
8 *History Note: Authority S.L. 2023-14, s. 2.2; 2.4;*
9 *Emergency Adoption Eff. July 18, ~~2023~~, 2023;*
10 *Temporary Adoption Eff. October 27, 2023.*

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

10A NCAC 14E .0212 ELEMENTS AND EQUIPMENT

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

(1) Mechanical requirements.

(a) Temperatures and humidities:

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

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

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

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

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

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

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

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

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

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

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

Toilets,

Soiled holding N 10

Clean work or

Clean holding P 4

(P = positive pressure N = negative pressure)

(2) Plumbing And Other Piping Systems.

(a) Medical Gas and Vacuum Systems

(i) Piped-in medical gas and vacuum systems, if installed, shall meet the requirements of NFPA-99-2012, ~~type one system~~ category 1 system, which is hereby incorporated by reference including subsequent amendments and editions. Copies of NFPA-99-2012 may be purchased from the National Fire Protection Association, 1 Batterymarch Park, P.O. Box 9101, Quincy, MA 02269-9101, or accessed electronically free of charge at <http://www.nfpa.org>.

(ii) [If inhalation anesthesia is used in any concentration, the] The facility must meet the ~~inhalation anesthesia~~ requirements of NFPA ~~[70-2011]~~70-2020 and NFPA ~~[99-2012,] 99-2021, current editions relating to inhalation anesthesia,~~ which are hereby incorporated by reference including subsequent amendments and editions. Copies of NFPA 70-2011 and NFPA 99-2012 may be purchased from the National Fire Protection Association, 1 Batterymarch Park, P.O. Box 9101, Quincy, MA 02269-9101, or accessed electronically free of charge at <http://www.nfpa.org>.

(b) Lavatories and sinks for use by medical personnel shall have the water supply spout mounted so that its discharge point is a minimum distance of five inches above the rim of the fixture with mixing type fixture valves that can be operated without the use of the hands.

(c) Hot water distribution systems shall provide hot water at hand washing and bathing facilities at a minimum temperature of 100 degrees F. and a maximum temperature of 116 degrees F.

(d) Floor drains shall not be installed in procedure rooms.

(e) Building drainage and waste systems shall be designed to avoid installations in the ceiling directly above procedure rooms.

(3) Electrical Requirements.

(a) Procedure and recovery rooms, and paths of egress from these rooms to the outside shall have at a minimum, listed battery backup lighting units of one and one-half hour capability that will automatically provide at least five foot candles 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.

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

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

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

7
8 *History Note:* *Authority G.S. 143B-10; S.L. 2023-14, s. 2.2, 2.4;*

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

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

1 10A NCAC 14E .0213 is adopted under temporary procedures as follows:

2
3 **10A NCAC 14E .0213 SHARED SERVICES**

4 When there is written indication that services are to be shared or purchased, appropriate modifications or deletions in
5 space requirements may be anticipated.

6
7 *History Note: Authority G.S. 143B-10; S.L. 2023-14, s. 2.4;*
8 *Emergency Adoption Eff. July 18, ~~2023~~ 2023;*
9 *Temporary Adoption Eff. October 27, 2023.*

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

10A NCAC 14E .0315 HOUSEKEEPING

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

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

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

History Note: Authority G.S. ~~14-45.1(a)~~; 143B-10; S.L. 2023-14, s. 2.2; 2.4;

Eff. February 1, 1976;

Readopted Eff. December 19, 1977;

Amended Eff. August 1, 2019; October 1, 2015; December 1, 1989;

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

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

Emergency Rule Eff. June 30, 2023;

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

Temporary Amendment Eff. October 27, 2023.

1 10A NCAC 14E .0317 is adopted under temporary procedures as follows:

2
3 **10A NCAC 14E .0317 OWNERSHIP**

4 The ownership of the abortion clinic shall be fully disclosed to the Division.

5
6 *History Note: Authority G.S. 143B-10; S.L. 2023-14, s. 2.4;*
7 *Emergency Adoption Eff. July 18, ~~2023~~, 2023;*
8 *Temporary Adoption Eff. October 27, 2023.*

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

10A NCAC 14E .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 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 ~~[professional and safe]~~ 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, and services offered.

(e) When the clinic contracts with outside vendors to provide services such as ~~[laundry,]~~ laundry or therapy services, the governing authority shall be responsible to assure the supplier meets the same local and ~~[state]~~ 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 ~~[patient care,]~~ and adequate treatment.

*History Note: Authority G.S. 143B-10; S.L. 2023-14, s. 2.2; 2.4;
Emergency Adoption Eff. July 18, 2023- 2023;
Temporary Adoption Eff. October 27, 2023.*

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

10A NCAC 14E .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 [licensure] care and services [to which] provided by the clinic is a party.

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

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

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

History Note: Authority G.S. 143B-10; S.L. 2023-14, s. 2.2; 2.4;

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

Temporary Adoption Eff. October 27, 2023.

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

2
3 **10A NCAC 14E .0320 ADMISSION AND DISCHARGE**

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

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

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

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

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

13 (2) the name of the attending ~~[physician(s)]~~ physician or physicians and hospital admitting privileges,
14 if any. In the absence of admitting privileges a statement to that effect shall be included;

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

16 (4) grievance procedures a patient may follow if dissatisfied with the care and services rendered; and

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

18
19 *History Note: Authority G.S. 143B-10; S.L. 2023-14, s. 2.2; 2.4;*
20 *Emergency Adoption Eff. July 18, ~~2023~~ 2023;*
21 *Temporary Adoption Eff. October 27, 2023.*

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

10A NCAC 14E .0321 MEDICAL RECORDS

(a) The clinic shall maintain ~~[A]~~ a complete and permanent record ~~[shall be maintained]~~ 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 surgery or procedure and signature of the physician performing the procedure witnessed by a family member, other patient representative, or facility staff member;
- (10) the patient's history and physical examination including identification of pre-existing or current illnesses, drug sensitivities or other idiosyncrasies ~~[having a bearing on]~~ that may impact the procedure or anesthetic to be administered; and
- (11) 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] all other pertinent information such as pre- and post-procedure instructions, laboratory ~~[report,]~~ reports, drugs administered, report of abortion procedure, and follow-up instruction, including family planning ~~[advice, shall be recorded and authenticated by signature, date, and time,]-~~ advice.

(c) If Rh is negative, the clinic shall explain the significance ~~[shall be explained]~~ to the patient and ~~[so recorded,]~~ 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 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.

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

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

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

10
11 *History Note: Authority G.S. 143B-10; S.L. 2023-14, s ~~2.2~~; 2.4;*

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

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

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

10A NCAC 14E .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 for employment that includes education, training, experience and references;

(C) a resume of education and work experience;

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

(E) [verification] a list of references.

(2) Personnel records shall be confidential.

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

(b) Job Descriptions:

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

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

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

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

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

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

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

*History Note: Authority G.S. 143B-10; S.L. 2023-14, s. 2.2, 2.4;
Emergency Adoption Eff. July 18, 2023- 2023;
Temporary Adoption Eff. October 27, 2023.*

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

2
3 **10A NCAC 14E .0323 NURSING SERVICE**

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

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

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

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

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

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

16
17 *History Note: Authority G.S. 143B-10; S.L. 2023-14, s. 2.2, 2.4;*

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

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

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

10A NCAC 14E .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,~~ necessary to achieve and maintain compliance with clinic procedures and policies.

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

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

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

(1) reports made to the governing authority;

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

(3) information on any corrective action taken.

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

History Note: Authority G.S. 143B-10; S.L. 2023-14, s. 2.2; 2.4;

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

Temporary Adoption Eff. October 27, 2023.

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

10A NCAC 14E .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.

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

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

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

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

(3) Rh factor testing.

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

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

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

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

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

History Note: Authority G.S. 143B-10; S.L. 2023-14, s. 2.2; 2.4;

Emergency Adoption Eff. July 18, 2023; 2023;

Temporary Adoption Eff. October 27, 2023.

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

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

(a) Each clinic shall have a written plan for the transfer of emergency cases from the clinic to [a nearby] 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, [procedures], personnel, and [suitable] equipment to handle medical emergencies as defined above which may arise in connection with services provided by the clinic.

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

(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;

(E) utilizing a suction machine; and

(F) 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. 143B-10; S.L. 2023-14, s. 2.2; 2.4;

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

Temporary Adoption Eff. October 27, 2023.

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

2
3 **10A NCAC 14E .0327 SURGICAL SERVICES**

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

7 (b) Tissue Examination:

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

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

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

16
17 *History Note: Authority G.S. 143B-10; S.L. 2023-14, s. 2.2; 2.4;*

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

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

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

2
3 **10A NCAC 14E .0328 MEDICATIONS AND ANESTHESIA**

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

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

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

11
12 *History Note: Authority G.S. 143B-10; S.L. 2023-14, s. 2.2; 2.4;*

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

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

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

2
3 **10A NCAC 14E .0329 POST-OPERATIVE CARE**

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

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

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

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

12 (2) bleeding and pain shall be controlled.

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

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

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

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

21
22 *History Note: Authority G.S. 143B-10; S.L. 2023-14, s. 2.2; 2.4;*

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

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

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

2
3 **10A NCAC 14E .0330 CLEANING OF MATERIALS AND EQUIPMENT**

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

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

8
9 *History Note: Authority G.S. 143B-10; S.L. 2023-14, s. 2.2, 2.4;*

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

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

1 10A NCAC 14E .0403 is adopted under temporary procedures with changes as follows:

2
3 **10A NCAC 14E .0403 QUALIFICATIONS**

4 Every person admitted to practice in the clinic shall qualify by submitting a signed application in writing which shall
5 contain the following data: age, year and school of graduation, date of licensure, statement of postgraduate work, and
6 experience.

7
8 *History Note: Authority G.S. 143B-10; S.L. 2023-14, s. 2.4;*
9 *Emergency Adoption Eff. July 18, ~~2023~~, 2023;*
10 *Temporary Adoption Eff. October 27, 2023.*

1 10A NCAC 14E .0404 is adopted under temporary procedures as follows:

2
3 **10A NCAC 14E .0404 FILE**

4 An individual file for each physician practicing in the clinic shall be maintained. Each file shall contain the information
5 outlined in Rule .0403 of this Section.

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

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

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

Burgos, Alexander N

From: Liebman, Brian R
Sent: Monday, October 9, 2023 11:48 AM
To: Corpening, Taylor
Cc: Premakumar, Rajeev K; Burgos, Alexander N
Subject: Temporary Rules 10A NCAC 14E - Requests for Changes - October 2023 RRC
Attachments: 2023.10 - DHHS.DHSR Request for Technical Changes Temp Rules 10A NCAC 14E.docx

Good morning,

I'm the attorney who reviewed the temporary Rules submitted by DHHS for the October 2023 RRC meeting. The RRC will formally review these Rules at its meeting on Thursday, October 19, 2023, at 9:00 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 Friday, October 13, 2023.

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
Office of Administrative Hearings
(984)236-1948
brian.liebman@oah.nc.gov

E-mail correspondence to and from this address may be subject to the North Carolina Public Records Law N.C.G.S. Chapter 132 and may be disclosed to third parties.

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