

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.*

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

7. Why is adherence to notice and hearing requirements contrary to the public interest and the immediate adoption of the rule is required? The rules governing the licensing of abortion clinics are found in Subchapter 14E of Title 10A of the Administrative Code. The authority for these rules derived from N.C.G.S. § 14-45.1 that was repealed by Session Law 2023-14, Part 1, Section 1.1, effective July 1, 2023. The General Assembly stated in S.L. 2023-14 that:

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.

These newly enacted provisions provided a mandate for the Department to adopt rules necessary to regulate abortion clinics between July 1, 2023 and October 1, 2023, at which time additional authority for the rulemaking, including those rules governing the licensure of abortion clinics, is granted to the Medical Care Commission, as required by Section 2.2 of S.L. 2023-14. Given the changes to the law that became effective July 1, the Department acted with urgency to make certain amendments to the existing rules to conform with those provisions in S.L. 2023-14 that became effective on July 1st and emergency rules became effective on June 30, 2023. Further, the repeal of existing laws governing abortions in North Carolina, which also was effective July 1, 2023, required the Department to act swiftly in making conforming changes to these rules. The adoption of this temporary rule amendment will ensure continuity of care for patients, resolve any uncertainty about the rule's applicable to impacted providers until the Department is able to promulgate permanent rules, and critically, will protect the health and safety of women in obtaining lawful abortions in a clinic regulated by the Department. Adherence to notice and hearing requirements is contrary to the public interest for the immediate and critical near term because it is not possible to complete notice and comment rulemaking for permanent rulemaking by October 1, 2023.

8. Rule establishes or increases a fee? (See G.S. 12-3.1)

Yes

Agency submitted request for consultation on:
Consultation not required. Cite authority:

No

9. Rule-making Coordinator: Nadine Pfeiffer

Phone: 919-855-3811

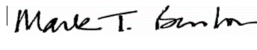
E-Mail: Nadine.pfeiffer@dhhs.nc.gov

Agency contact, if any: Rajeev Premakumar

Phone: 984-800-1117

E-Mail: raj.premakumar@dhhs.nc.gov

10. Signature of Agency Head*:

DocuSigned by:


* If this function has been delegated (reassigned) pursuant to G.S. 143B-10(a), submit a copy of the delegation with this form.

Typed Name: Mark T. Benton

Title: Chief Deputy Secretary, N.C. DHHS

E-Mail: mark.benton@dhhs.nc.gov

RULES REVIEW COMMISSION USE ONLY

Action taken:

Submitted for RRC Review:

Date returned to agency:

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.

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)?

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

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.

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

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

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

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?

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

1 10A NCAC 14E .0101 is amended under temporary procedures as follows:

2
3 **SUBCHAPTER 14E - CERTIFICATIONS OF CLINICS FOR ABORTION LICENSURE OF SUITABLE**
4 **FACILITIES FOR THE PERFORMANCE OF SURGICAL ABORTIONS**

5
6 **SECTION .0100 – CERTIFICATION LICENSURE PROCEDURE**

7
8 **10A NCAC 14E .0101 DEFINITIONS**

9 The following definitions will apply throughout this Subchapter:

- 10 (1) "Abortion" means the termination of a pregnancy as defined in G.S. ~~90-21.81(1)~~, 90-21.81(1c).
- 11 (2) "Clinic" means a freestanding facility (a facility neither physically attached nor operated by a
12 licensed hospital) for the performance of abortions completed during the first ~~20~~ 12 weeks of
13 pregnancy.
- 14 (3) "Complication" includes but is not limited to hemorrhage, infection, uterine perforation, cervical
15 laceration, or retained products of conception.
- 16 (4) "Division" means the Division of Health Service Regulation of the North Carolina Department of
17 Health and Human Services.
- 18 (5) "Gestational age" means the length of pregnancy as indicated by the date of the first day of the last
19 normal monthly menstrual period, if known, or as determined by ultrasound.
- 20 (6) "Governing authority" means the individual, agency, group, or corporation appointed, elected or
21 otherwise designated, in which the ultimate responsibility and authority for the conduct of the
22 abortion clinic is vested pursuant to Rule .0302 of this Subchapter.
- 23 (7) "Health Screening" means an evaluation of an employee or contractual employee, including
24 tuberculosis testing, to identify any underlying conditions that may affect the person's ability to
25 work in the clinic.
- 26 (8) "New clinic" means one that is not certified as an abortion clinic by the Division as of July 1, ~~2014~~,
27 2023, and has not been certified or licensed within the previous six months of the application for
28 ~~certification~~, licensure.
- 29 (9) "Qualified Physician" means a licensed physician who advises, procures, or causes a miscarriage or
30 abortion as defined in G.S. ~~14-45.1(g)~~, 90-21.81(7a).
- 31 (10) "Registered Nurse" means a person who holds a valid license issued by the North Carolina Board
32 of Nursing to practice professional nursing in accordance with the Nursing Practice Act, G.S. 90,
33 Article 9A.

34
35 *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. 2.4;*
36 *Eff. February 1, 1976;*
37 *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.*



TEMPORARY RULE-MAKING FINDINGS OF NEED

[Authority G.S. 150B-21.1]

OAH USE ONLY

VOLUME:

ISSUE:

1. Rule-Making Agency: N.C. Department of Health and Human Services/Director, DHHSR
2. Rule citation & name: 10A NCAC 14E .0102 CONFERENCE
3. Action: <input type="checkbox"/> Adoption <input checked="" type="checkbox"/> Amendment <input type="checkbox"/> Repeal
4. Was this an Emergency Rule: <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No Effective date: 06/30/23
5. Provide dates for the following actions as applicable: <ul style="list-style-type: none"> a. Proposed Temporary Rule submitted to OAH: 06/20/23 b. Proposed Temporary Rule published on the OAH website: 06/22/23 c. Public Hearing date: 07/19/23 d. Comment Period: 06/28/23 – 07/20/23 e. Notice pursuant to G.S. 150B-21.1(a3)(2): 06/20/23 f. Adoption by agency on: 09/18/23 g. Proposed effective date of temporary rule [if other than effective date established by G.S. 150B- 21.1(b) and G.S. 150B-21.3]: 10/27/23 h. Rule approved by RRC as a permanent rule [See G.S. 150B-21.3(b2)]: n/a
6. Reason for Temporary Action. Attach a copy of any cited law, regulation, or document necessary for the review. <ul style="list-style-type: none"> <input type="checkbox"/> A serious and unforeseen threat to the public health, safety or welfare. <input checked="" type="checkbox"/> The effective date of a recent act of the General Assembly or of the U.S. Congress. Cite: N.C.G.A. SL 2023-14, Part I, s. 1.1 and Part II, s. 2.4 (SB 20) “An Act to Make Various Changes to Health Care Laws and to Appropriate Funds for Health Care Programs” Effective date: 7/1/23 <input type="checkbox"/> A recent change in federal or state budgetary policy. Effective date of change: <input type="checkbox"/> A recent federal regulation. Cite: Effective date: <input type="checkbox"/> A recent court order. Cite order: <input type="checkbox"/> State Medical Facilities Plan. <input type="checkbox"/> Other: <p>Explain: On May 16, 2023, Senate Bill 20 became law as SL 2023-14. This new law entitled “An Act to Make Various Changes to Health Care Laws and to Appropriate Funds for Health Care Programs” revised various state laws governing abortions in North Carolina. The Department was made aware of the proposed changes on May 2, 2023, when a Proposed Conference Committee Substitute was issued that made the changes to the State’s abortion laws. The revisions in Part I and Part 2.4 of the law went into effect on July 1, 2023, less than 2 months after the Department became aware of the proposed changes. Among other changes, S.L. 2023-14 makes significant changes to defining when an abortion is lawful. Current rules governing the certification of abortion clinics are found in Subchapter 14E of Title 10A of the Administrative Code. Given the changes to the law that became effective July 1, emergency rules became effective June 30, 2023. Adoption of temporary rules to amend the existing rules to conform with the provisions of S.L. 2023-14 will ensure continuity of care for patients and resolve any uncertainty about the rules applicable to impacted providers while being critical to protect the health and safety of women in obtaining lawful abortions in a certified abortion clinic. Therefore, the N.C. DHHS is amending Rule 10A NCAC 14E .0102 under temporary procedures.</p>

7. Why is adherence to notice and hearing requirements contrary to the public interest and the immediate adoption of the rule is required? The rules governing the licensing of abortion clinics are found in Subchapter 14E of Title 10A of the Administrative Code. The authority for these rules derived from N.C.G.S. § 14-45.1 that was repealed by Session Law 2023-14, Part 1, Section 1.1, effective July 1, 2023. The General Assembly stated in S.L. 2023-14 that:

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.

These newly enacted provisions provided a mandate for the Department to adopt rules necessary to regulate abortion clinics between July 1, 2023 and October 1, 2023, at which time additional authority for the rulemaking, including those rules governing the licensure of abortion clinics, is granted to the Medical Care Commission, as required by Section 2.2 of S.L. 2023-14. Given the changes to the law that became effective July 1, the Department acted with urgency to make certain amendments to the existing rules to conform with those provisions in S.L. 2023-14 that became effective on July 1st and emergency rules became effective on June 30, 2023. Further, the repeal of existing laws governing abortions in North Carolina, which also was effective July 1, 2023, required the Department to act swiftly in making conforming changes to these rules. The adoption of this temporary rule amendment will ensure continuity of care for patients, resolve any uncertainty about the rule's applicable to impacted providers until the Department is able to promulgate permanent rules, and critically, will protect the health and safety of women in obtaining lawful abortions in a clinic regulated by the Department. Adherence to notice and hearing requirements is contrary to the public interest for the immediate and critical near term because it is not possible to complete notice and comment rulemaking for permanent rulemaking by October 1, 2023.

8. Rule establishes or increases a fee? (See G.S. 12-3.1)

Yes

Agency submitted request for consultation on:
Consultation not required. Cite authority:

No

9. Rule-making Coordinator: Nadine Pfeiffer

Phone: 919-855-3811

E-Mail: Nadine.pfeiffer@dhhs.nc.gov

Agency contact, if any: Rajeev Premakumar

Phone: 984-800-1117

E-Mail: raj.premakumar@dhhs.nc.gov

10. Signature of Agency Head*:

DocuSigned by:

Mark T. Benton

* If this function has been delegated (reassigned) pursuant to G.S. 143B-10(a), submit a copy of the delegation with this form.

Typed Name: Mark T. Benton

Title: Chief Deputy Secretary, N.C. DHHS

E-Mail: mark.benton@dhhs.nc.gov

RULES REVIEW COMMISSION USE ONLY

Action taken:

Submitted for RRC Review:

Date returned to agency:

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:

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.

Brian Liebman
Commission Counsel
Date submitted to agency: October 6, 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.*



TEMPORARY RULE-MAKING FINDINGS OF NEED

[Authority G.S. 150B-21.1]

OAH USE ONLY

VOLUME:

ISSUE:

1. Rule-Making Agency: N.C. Department of Health and Human Services/Director, DHHSR
2. Rule citation & name: 10A NCAC 14E .0104 PLANS
3. Action: <input type="checkbox"/> Adoption <input checked="" type="checkbox"/> Amendment <input type="checkbox"/> Repeal
4. Was this an Emergency Rule: <input checked="" type="checkbox"/> Yes Effective date: 06/30/23 <input type="checkbox"/> No
5. Provide dates for the following actions as applicable: a. Proposed Temporary Rule submitted to OAH: 06/20/23 b. Proposed Temporary Rule published on the OAH website: 06/22/23 c. Public Hearing date: 07/19/23 d. Comment Period: 06/28/23 – 07/20/23 e. Notice pursuant to G.S. 150B-21.1(a3)(2): 06/20/23 f. Adoption by agency on: 09/18/23 g. Proposed effective date of temporary rule [if other than effective date established by G.S. 150B- 21.1(b) and G.S. 150B-21.3]: 10/27/23 h. Rule approved by RRC as a permanent rule [See G.S. 150B-21.3(b2)]: n/a
6. Reason for Temporary Action. Attach a copy of any cited law, regulation, or document necessary for the review. <input type="checkbox"/> A serious and unforeseen threat to the public health, safety or welfare. <input checked="" type="checkbox"/> The effective date of a recent act of the General Assembly or of the U.S. Congress. Cite: N.C.G.A. SL 2023-14, Part I, s. 1.1 and Part II, s. 2.4 (SB 20) “An Act to Make Various Changes to Health Care Laws and to Appropriate Funds for Health Care Programs” Effective date: 7/1/23 <input type="checkbox"/> A recent change in federal or state budgetary policy. Effective date of change: <input type="checkbox"/> A recent federal regulation. Cite: Effective date: <input type="checkbox"/> A recent court order. Cite order: <input type="checkbox"/> State Medical Facilities Plan. <input type="checkbox"/> Other:
Explain: On May 16, 2023, Senate Bill 20 became law as SL 2023-14. This new law entitled “An Act to Make Various Changes to Health Care Laws and to Appropriate Funds for Health Care Programs” revised various state laws governing abortions in North Carolina. The Department was made aware of the proposed changes on May 2, 2023, when a Proposed Conference Committee Substitute was issued that made the changes to the State’s abortion laws. The revisions in Part I and Part 2.4 of the law went into effect on July 1, 2023, less than 2 months after the Department became aware of the proposed changes. Among other changes, S.L. 2023-14 makes significant changes to defining when an abortion is lawful. Current rules governing the certification of abortion clinics are found in Subchapter 14E of Title 10A of the Administrative Code. Given the changes to the law that became effective July 1, emergency rules became effective June 30, 2023. Adoption of temporary rules to amend the existing rules to conform with the provisions of S.L. 2023-14 will ensure continuity of care for patients and resolve any uncertainty about the rules applicable to impacted providers while being critical to protect the health and safety of women in obtaining lawful abortions in a certified abortion clinic. Therefore, the N.C. DHHS is amending Rule 10A NCAC 14E .0104 under temporary procedures.

7. Why is adherence to notice and hearing requirements contrary to the public interest and the immediate adoption of the rule is required? The rules governing the licensing of abortion clinics are found in Subchapter 14E of Title 10A of the Administrative Code. The authority for these rules derived from N.C.G.S. § 14-45.1 that was repealed by Session Law 2023-14, Part 1, Section 1.1, effective July 1, 2023. The General Assembly stated in S.L. 2023-14 that:

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.

These newly enacted provisions provided a mandate for the Department to adopt rules necessary to regulate abortion clinics between July 1, 2023 and October 1, 2023, at which time additional authority for the rulemaking, including those rules governing the licensure of abortion clinics, is granted to the Medical Care Commission, as required by Section 2.2 of S.L. 2023-14. Given the changes to the law that became effective July 1, the Department acted with urgency to make certain amendments to the existing rules to conform with those provisions in S.L. 2023-14 that became effective on July 1st and emergency rules became effective on June 30, 2023. Further, the repeal of existing laws governing abortions in North Carolina, which also was effective July 1, 2023, required the Department to act swiftly in making conforming changes to these rules. The adoption of this temporary rule amendment will ensure continuity of care for patients, resolve any uncertainty about the rule's applicable to impacted providers until the Department is able to promulgate permanent rules, and critically, will protect the health and safety of women in obtaining lawful abortions in a clinic regulated by the Department. Adherence to notice and hearing requirements is contrary to the public interest for the immediate and critical near term because it is not possible to complete notice and comment rulemaking for permanent rulemaking by October 1, 2023.

8. Rule establishes or increases a fee? (See G.S. 12-3.1)

Yes

Agency submitted request for consultation on:
Consultation not required. Cite authority:

No

9. Rule-making Coordinator: Nadine Pfeiffer

Phone: 919-855-3811

E-Mail: Nadine.pfeiffer@dhhs.nc.gov

Agency contact, if any: Rajeev Premakumar

Phone: 984-800-1117

E-Mail: raj.premakumar@dhhs.nc.gov

10. Signature of Agency Head*:

DocuSigned by:



* If this function has been delegated (reassigned) pursuant to G.S. 143B-10(a), submit a copy of the delegation with this form.

Typed Name: Mark T. Benton

Title: Chief Deputy Secretary, N.C. DHHS

E-Mail: mark.benton@dhhs.nc.gov

RULES REVIEW COMMISSION USE ONLY

Action taken:

Submitted for RRC Review:

Date returned to agency:

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.

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?

Second, what are “licensure purposes”? What are the guidelines for this review?

On lines 7-8, there is no such code as the “North Carolina Administration and Enforcement Requirements Code.”

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.

On line 9, the URL provided does not direct a user to any specific code, but redirects to the ICC website.

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

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

2

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

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

13

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

15 *Eff. February 1, 1976;*

16 *Readopted Eff. December 19, 1977;*

17 *Amended Eff. October 1, 2015;*

18 *Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. August 24,*
 19 *2019;*

20 *Codifier determined that agency's findings of need did not meet criteria for emergency rule on June*
 21 *22, 2023;*

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

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

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



TEMPORARY RULE-MAKING FINDINGS OF NEED

[Authority G.S. 150B-21.1]

OAH USE ONLY

VOLUME:

ISSUE:

1. Rule-Making Agency: N.C. Department of Health and Human Services/Director, DHHSR
2. Rule citation & name: 10A NCAC 14E .0106 APPLICATION
3. Action: <input type="checkbox"/> Adoption <input checked="" type="checkbox"/> Amendment <input type="checkbox"/> Repeal
4. Was this an Emergency Rule: <input checked="" type="checkbox"/> Yes Effective date: 06/30/23 <input type="checkbox"/> No
5. Provide dates for the following actions as applicable: a. Proposed Temporary Rule submitted to OAH: 06/20/23 b. Proposed Temporary Rule published on the OAH website: 06/22/23 c. Public Hearing date: 07/19/23 d. Comment Period: 06/28/23 – 07/20/23 e. Notice pursuant to G.S. 150B-21.1(a3)(2): 06/20/23 f. Adoption by agency on: 09/18/23 g. Proposed effective date of temporary rule [if other than effective date established by G.S. 150B- 21.1(b) and G.S. 150B-21.3]: 10/27/23 h. Rule approved by RRC as a permanent rule [See G.S. 150B-21.3(b2)]: n/a
6. Reason for Temporary Action. Attach a copy of any cited law, regulation, or document necessary for the review. <input type="checkbox"/> A serious and unforeseen threat to the public health, safety or welfare. <input checked="" type="checkbox"/> The effective date of a recent act of the General Assembly or of the U.S. Congress. Cite: N.C.G.A. SL 2023-14, Part I, s. 1.1 and Part II, s. 2.4 (SB 20) “An Act to Make Various Changes to Health Care Laws and to Appropriate Funds for Health Care Programs” Effective date: 7/1/23 <input type="checkbox"/> A recent change in federal or state budgetary policy. Effective date of change: <input type="checkbox"/> A recent federal regulation. Cite: Effective date: <input type="checkbox"/> A recent court order. Cite order: <input type="checkbox"/> State Medical Facilities Plan. <input type="checkbox"/> Other:
Explain: On May 16, 2023, Senate Bill 20 became law as SL 2023-14. This new law entitled “An Act to Make Various Changes to Health Care Laws and to Appropriate Funds for Health Care Programs” revised various state laws governing abortions in North Carolina. The Department was made aware of the proposed changes on May 2, 2023, when a Proposed Conference Committee Substitute was issued that made the changes to the State’s abortion laws. The revisions in Part I and Part 2.4 of the law went into effect on July 1, 2023, less than 2 months after the Department became aware of the proposed changes. Among other changes, S.L. 2023-14 makes significant changes to defining when an abortion is lawful. Current rules governing the certification of abortion clinics are found in Subchapter 14E of Title 10A of the Administrative Code. Given the changes to the law that became effective July 1, emergency rules became effective June 30, 2023. Adoption of temporary rules to amend the existing rules to conform with the provisions of S.L. 2023-14 will ensure continuity of care for patients and resolve any uncertainty about the rules applicable to impacted providers while being critical to protect the health and safety of women in obtaining lawful abortions in a certified abortion clinic. Therefore, the N.C. DHHS is amending Rule 10A NCAC 14E .0106 under temporary procedures.

7. Why is adherence to notice and hearing requirements contrary to the public interest and the immediate adoption of the rule is required? The rules governing the licensing of abortion clinics are found in Subchapter 14E of Title 10A of the Administrative Code. The authority for these rules derived from N.C.G.S. § 14-45.1 that was repealed by Session Law 2023-14, Part 1, Section 1.1, effective July 1, 2023. The General Assembly stated in S.L. 2023-14 that:

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.

These newly enacted provisions provided a mandate for the Department to adopt rules necessary to regulate abortion clinics between July 1, 2023 and October 1, 2023, at which time additional authority for the rulemaking, including those rules governing the licensure of abortion clinics, is granted to the Medical Care Commission, as required by Section 2.2 of S.L. 2023-14. Given the changes to the law that became effective July 1, the Department acted with urgency to make certain amendments to the existing rules to conform with those provisions in S.L. 2023-14 that became effective on July 1st and emergency rules became effective on June 30, 2023. Further, the repeal of existing laws governing abortions in North Carolina, which also was effective July 1, 2023, required the Department to act swiftly in making conforming changes to these rules. The adoption of this temporary rule amendment will ensure continuity of care for patients, resolve any uncertainty about the rule's applicable to impacted providers until the Department is able to promulgate permanent rules, and critically, will protect the health and safety of women in obtaining lawful abortions in a clinic regulated by the Department. Adherence to notice and hearing requirements is contrary to the public interest for the immediate and critical near term because it is not possible to complete notice and comment rulemaking for permanent rulemaking by October 1, 2023.

8. Rule establishes or increases a fee? (See G.S. 12-3.1)

Yes

Agency submitted request for consultation on:
Consultation not required. Cite authority:

No

9. Rule-making Coordinator: Nadine Pfeiffer

Phone: 919-855-3811

E-Mail: Nadine.pfeiffer@dhhs.nc.gov

Agency contact, if any: Rajeev Premakumar

Phone: 984-800-1117

E-Mail: raj.premakumar@dhhs.nc.gov

10. Signature of Agency Head*:

DocuSigned by:

Mark T. Benton

* If this function has been delegated (reassigned) pursuant to G.S. 143B-10(a), submit a copy of the delegation with this form.

Typed Name: Mark T. Benton

Title: Chief Deputy Secretary, N.C. DHHS

E-Mail: mark.benton@dhhs.nc.gov

RULES REVIEW COMMISSION USE ONLY

Action taken:

Submitted for RRC Review:

Date returned to agency:

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?

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

In (c), line 8, what is "general information that would be helpful"?

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.

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

1 10A NCAC 14E .0106 is amended under temporary procedures as follows:

2

3 **10A NCAC 14E .0106 APPLICATION**

4 (a) Prior to the admission of patients, an application from the clinic for ~~certification~~ licensure shall be submitted to
5 and approved by the Division.

6 (b) Application forms may be obtained by contacting the Division.

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

10 (d) After construction requirements in Section .0200 of this Subchapter have been met and the application for
11 ~~certification~~ licensure has been received and approved, the Division shall conduct an on-site, ~~certification~~ licensure
12 survey.

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

17

18 *History Note: Authority G.S. ~~14-45.1(a)~~; 131E-153.2; S.L. 2023-14, s. 2.4;*

19 *Eff. February 1, 1976;*

20 *Readopted Eff. December 19, 1977;*

21 *Amended Eff. July 1, 1994;*

22 *Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. August 24,*
23 *2019;*

24 *Codifier determined that agency's findings of need did not meet criteria for emergency rule on June*
25 *22, 2023;*

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

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

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



TEMPORARY RULE-MAKING FINDINGS OF NEED

[Authority G.S. 150B-21.1]

OAH USE ONLY

VOLUME:

ISSUE:

1. Rule-Making Agency: N.C. Department of Health and Human Services/Director, DHHSR
2. Rule citation & name: 10A NCAC 14E .0107 ISSUANCE OF LICENSE
3. Action: <input type="checkbox"/> Adoption <input checked="" type="checkbox"/> Amendment <input type="checkbox"/> Repeal
4. Was this an Emergency Rule: <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No Effective date: 06/30/23
5. Provide dates for the following actions as applicable: <ul style="list-style-type: none"> a. Proposed Temporary Rule submitted to OAH: 06/20/23 b. Proposed Temporary Rule published on the OAH website: 06/22/23 c. Public Hearing date: 07/19/23 d. Comment Period: 06/28/23 – 07/20/23 e. Notice pursuant to G.S. 150B-21.1(a3)(2): 06/20/23 f. Adoption by agency on: 09/18/23 g. Proposed effective date of temporary rule [if other than effective date established by G.S. 150B- 21.1(b) and G.S. 150B-21.3]: 10/27/23 h. Rule approved by RRC as a permanent rule [See G.S. 150B-21.3(b2)]: n/a
6. Reason for Temporary Action. Attach a copy of any cited law, regulation, or document necessary for the review. <ul style="list-style-type: none"> <input type="checkbox"/> A serious and unforeseen threat to the public health, safety or welfare. <input checked="" type="checkbox"/> The effective date of a recent act of the General Assembly or of the U.S. Congress. Cite: N.C.G.A. SL 2023-14, Part I, s. 1.1 and Part II, s. 2.4 (SB 20) “An Act to Make Various Changes to Health Care Laws and to Appropriate Funds for Health Care Programs” Effective date: 7/1/23 <input type="checkbox"/> A recent change in federal or state budgetary policy. Effective date of change: <input type="checkbox"/> A recent federal regulation. Cite: Effective date: <input type="checkbox"/> A recent court order. Cite order: <input type="checkbox"/> State Medical Facilities Plan. <input type="checkbox"/> Other: <p>Explain: On May 16, 2023, Senate Bill 20 became law as SL 2023-14. This new law entitled “An Act to Make Various Changes to Health Care Laws and to Appropriate Funds for Health Care Programs” revised various state laws governing abortions in North Carolina. The Department was made aware of the proposed changes on May 2, 2023, when a Proposed Conference Committee Substitute was issued that made the changes to the State’s abortion laws. The revisions in Part I and Part 2.4 of the law went into effect on July 1, 2023, less than 2 months after the Department became aware of the proposed changes. Among other changes, S.L. 2023-14 makes significant changes to defining when an abortion is lawful. Current rules governing the certification of abortion clinics are found in Subchapter 14E of Title 10A of the Administrative Code. Given the changes to the law that became effective July 1, emergency rules became effective June 30, 2023. Adoption of temporary rules to amend the existing rules to conform with the provisions of S.L. 2023-14 will ensure continuity of care for patients and resolve any uncertainty about the rules applicable to impacted providers while being critical to protect the health and safety of women in obtaining lawful abortions in a certified abortion clinic. Therefore, the N.C. DHHS is amending Rule 10A NCAC 14E .0107 under temporary procedures.</p>

7. Why is adherence to notice and hearing requirements contrary to the public interest and the immediate adoption of the rule is required? The rules governing the licensing of abortion clinics are found in Subchapter 14E of Title 10A of the Administrative Code. The authority for these rules derived from N.C.G.S. § 14-45.1 that was repealed by Session Law 2023-14, Part 1, Section 1.1, effective July 1, 2023. The General Assembly stated in S.L. 2023-14 that:

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.

These newly enacted provisions provided a mandate for the Department to adopt rules necessary to regulate abortion clinics between July 1, 2023 and October 1, 2023, at which time additional authority for the rulemaking, including those rules governing the licensure of abortion clinics, is granted to the Medical Care Commission, as required by Section 2.2 of S.L. 2023-14. Given the changes to the law that became effective July 1, the Department acted with urgency to make certain amendments to the existing rules to conform with those provisions in S.L. 2023-14 that became effective on July 1st and emergency rules became effective on June 30, 2023. Further, the repeal of existing laws governing abortions in North Carolina, which also was effective July 1, 2023, required the Department to act swiftly in making conforming changes to these rules. The adoption of this temporary rule amendment will ensure continuity of care for patients, resolve any uncertainty about the rule's applicable to impacted providers until the Department is able to promulgate permanent rules, and critically, will protect the health and safety of women in obtaining lawful abortions in a clinic regulated by the Department. Adherence to notice and hearing requirements is contrary to the public interest for the immediate and critical near term because it is not possible to complete notice and comment rulemaking for permanent rulemaking by October 1, 2023.

8. Rule establishes or increases a fee? (See G.S. 12-3.1)

Yes

Agency submitted request for consultation on:
Consultation not required. Cite authority:

No

9. Rule-making Coordinator: Nadine Pfeiffer

Phone: 919-855-3811

E-Mail: Nadine.pfeiffer@dhhs.nc.gov

Agency contact, if any: Rajeev Premakumar

Phone: 984-800-1117

E-Mail: raj.premakumar@dhhs.nc.gov

10. Signature of Agency Head*:

DocuSigned by:

Mark T. Benton

* If this function has been delegated (reassigned) pursuant to G.S. 143B-10(a), submit a copy of the delegation with this form.

Typed Name: Mark T. Benton

Title: Chief Deputy Secretary, N.C. DHHS

E-Mail: mark.benton@dhhs.nc.gov

RULES REVIEW COMMISSION USE ONLY

Action taken:

Submitted for RRC Review:

Date returned to agency:

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?

In (a)(2), lines 6-7, what “board” is certifying the OB-GYN?

In (a)(2), line 7, what board should the physician be eligible for?

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

In (d), line 13, what is a “disruption” in services?

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

1 10A NCAC 14E .0107 is amended under temporary procedures 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 or board eligible physician shall be available.

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

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

12 (d) The facility shall report to the Division all incidents, within 10 working days, of vandalism to the facility such as
13 fires, explosions or other action causing disruption of services.

14

15 *History Note: Authority G.S. ~~14-45-1(a)~~; 131E-153.2; S.L. 2023-14, s. 2.4;*

16 *Eff. February 1, 1976;*

17 *Readopted Eff. December 19, 1977;*

18 *Amended Eff. July 1, 1994;*

19 *Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. August 24,*
20 *2019;*

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

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

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

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



TEMPORARY RULE-MAKING FINDINGS OF NEED

[Authority G.S. 150B-21.1]

OAH USE ONLY

VOLUME:

ISSUE:

1. Rule-Making Agency: N.C. Department of Health and Human Services/Director, DHHSR
2. Rule citation & name: 10A NCAC 14E .0108 POSTING
3. Action: <input type="checkbox"/> Adoption <input checked="" type="checkbox"/> Amendment <input type="checkbox"/> Repeal
4. Was this an Emergency Rule: <input checked="" type="checkbox"/> Yes Effective date: 06/30/23 <input type="checkbox"/> No
5. Provide dates for the following actions as applicable: a. Proposed Temporary Rule submitted to OAH: 06/20/23 b. Proposed Temporary Rule published on the OAH website: 06/22/23 c. Public Hearing date: 07/19/23 d. Comment Period: 06/28/23 – 07/20/23 e. Notice pursuant to G.S. 150B-21.1(a3)(2): 06/20/23 f. Adoption by agency on: 09/18/23 g. Proposed effective date of temporary rule [if other than effective date established by G.S. 150B- 21.1(b) and G.S. 150B-21.3]: 10/27/23 h. Rule approved by RRC as a permanent rule [See G.S. 150B-21.3(b2)]: n/a
6. Reason for Temporary Action. Attach a copy of any cited law, regulation, or document necessary for the review. <input type="checkbox"/> A serious and unforeseen threat to the public health, safety or welfare. <input checked="" type="checkbox"/> The effective date of a recent act of the General Assembly or of the U.S. Congress. Cite: N.C.G.A. SL 2023-14, Part I, s. 1.1 and Part II, s. 2.4 (SB 20) “An Act to Make Various Changes to Health Care Laws and to Appropriate Funds for Health Care Programs” Effective date: 7/1/23 <input type="checkbox"/> A recent change in federal or state budgetary policy. Effective date of change: <input type="checkbox"/> A recent federal regulation. Cite: Effective date: <input type="checkbox"/> A recent court order. Cite order: <input type="checkbox"/> State Medical Facilities Plan. <input type="checkbox"/> Other:
<p>Explain: On May 16, 2023, Senate Bill 20 became law as SL 2023-14. This new law entitled “An Act to Make Various Changes to Health Care Laws and to Appropriate Funds for Health Care Programs” revised various state laws governing abortions in North Carolina. The Department was made aware of the proposed changes on May 2, 2023, when a Proposed Conference Committee Substitute was issued that made the changes to the State’s abortion laws. The revisions in Part I and Part 2.4 of the law went into effect on July 1, 2023, less than 2 months after the Department became aware of the proposed changes. Among other changes, S.L. 2023-14 makes significant changes to defining when an abortion is lawful. Current rules governing the certification of abortion clinics are found in Subchapter 14E of Title 10A of the Administrative Code. Given the changes to the law that became effective July 1, emergency rules became effective June 30, 2023. Adoption of temporary rules to amend the existing rules to conform with the provisions of S.L. 2023-14 will ensure continuity of care for patients and resolve any uncertainty about the rules applicable to impacted providers while being critical to protect the health and safety of women in obtaining lawful abortions in a certified abortion clinic. Therefore, the N.C. DHHS is amending Rule 10A NCAC 14E .0108 under temporary procedures.</p>

7. Why is adherence to notice and hearing requirements contrary to the public interest and the immediate adoption of the rule is required? The rules governing the licensing of abortion clinics are found in Subchapter 14E of Title 10A of the Administrative Code. The authority for these rules derived from N.C.G.S. § 14-45.1 that was repealed by Session Law 2023-14, Part 1, Section 1.1, effective July 1, 2023. The General Assembly stated in S.L. 2023-14 that:

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.

These newly enacted provisions provided a mandate for the Department to adopt rules necessary to regulate abortion clinics between July 1, 2023 and October 1, 2023, at which time additional authority for the rulemaking, including those rules governing the licensure of abortion clinics, is granted to the Medical Care Commission, as required by Section 2.2 of S.L. 2023-14. Given the changes to the law that became effective July 1, the Department acted with urgency to make certain amendments to the existing rules to conform with those provisions in S.L. 2023-14 that became effective on July 1st and emergency rules became effective on June 30, 2023. Further, the repeal of existing laws governing abortions in North Carolina, which also was effective July 1, 2023, required the Department to act swiftly in making conforming changes to these rules. The adoption of this temporary rule amendment will ensure continuity of care for patients, resolve any uncertainty about the rule's applicable to impacted providers until the Department is able to promulgate permanent rules, and critically, will protect the health and safety of women in obtaining lawful abortions in a clinic regulated by the Department. Adherence to notice and hearing requirements is contrary to the public interest for the immediate and critical near term because it is not possible to complete notice and comment rulemaking for permanent rulemaking by October 1, 2023.

8. Rule establishes or increases a fee? (See G.S. 12-3.1)

Yes

Agency submitted request for consultation on:
Consultation not required. Cite authority:

No

9. Rule-making Coordinator: Nadine Pfeiffer

Phone: 919-855-3811

E-Mail: Nadine.pfeiffer@dhhs.nc.gov

Agency contact, if any: Rajeev Premakumar

Phone: 984-800-1117

E-Mail: raj.premakumar@dhhs.nc.gov

10. Signature of Agency Head*:

DocuSigned by:

Mark T. Benton

* If this function has been delegated (reassigned) pursuant to G.S. 143B-10(a), submit a copy of the delegation with this form.

Typed Name: Mark T. Benton

Title: Chief Deputy Secretary, N.C. DHHS

E-Mail: mark.benton@dhhs.nc.gov

RULES REVIEW COMMISSION USE ONLY

Action taken:

Submitted for RRC Review:

Date returned to agency:

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:

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.

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.*



TEMPORARY RULE-MAKING FINDINGS OF NEED

[Authority G.S. 150B-21.1]

OAH USE ONLY

VOLUME:

ISSUE:

1. Rule-Making Agency: N.C. Department of Health and Human Services/Director, DHHSR
2. Rule citation & name: 10A NCAC 14E .0109 RENEWAL
3. Action: <input type="checkbox"/> Adoption <input checked="" type="checkbox"/> Amendment <input type="checkbox"/> Repeal
4. Was this an Emergency Rule: <input checked="" type="checkbox"/> Yes Effective date: 06/30/23 <input type="checkbox"/> No
5. Provide dates for the following actions as applicable: a. Proposed Temporary Rule submitted to OAH: 06/20/23 b. Proposed Temporary Rule published on the OAH website: 06/22/23 c. Public Hearing date: 07/19/23 d. Comment Period: 06/28/23 – 07/20/23 e. Notice pursuant to G.S. 150B-21.1(a3)(2): 06/20/23 f. Adoption by agency on: 09/18/23 g. Proposed effective date of temporary rule [if other than effective date established by G.S. 150B- 21.1(b) and G.S. 150B-21.3]: 10/27/23 h. Rule approved by RRC as a permanent rule [See G.S. 150B-21.3(b2)]: n/a
6. Reason for Temporary Action. Attach a copy of any cited law, regulation, or document necessary for the review. <input type="checkbox"/> A serious and unforeseen threat to the public health, safety or welfare. <input checked="" type="checkbox"/> The effective date of a recent act of the General Assembly or of the U.S. Congress. Cite: N.C.G.A. SL 2023-14, Part I, s. 1.1 and Part II, s. 2.4 (SB 20) “An Act to Make Various Changes to Health Care Laws and to Appropriate Funds for Health Care Programs” Effective date: 7/1/23 <input type="checkbox"/> A recent change in federal or state budgetary policy. Effective date of change: <input type="checkbox"/> A recent federal regulation. Cite: Effective date: <input type="checkbox"/> A recent court order. Cite order: <input type="checkbox"/> State Medical Facilities Plan. <input type="checkbox"/> Other:
<p>Explain: On May 16, 2023, Senate Bill 20 became law as SL 2023-14. This new law entitled “An Act to Make Various Changes to Health Care Laws and to Appropriate Funds for Health Care Programs” revised various state laws governing abortions in North Carolina. The Department was made aware of the proposed changes on May 2, 2023, when a Proposed Conference Committee Substitute was issued that made the changes to the State’s abortion laws. The revisions in Part I and Part 2.4 of the law went into effect on July 1, 2023, less than 2 months after the Department became aware of the proposed changes. Among other changes, S.L. 2023-14 makes significant changes to defining when an abortion is lawful. Current rules governing the certification of abortion clinics are found in Subchapter 14E of Title 10A of the Administrative Code. Given the changes to the law that became effective July 1, emergency rules became effective June 30, 2023. Adoption of temporary rules to amend the existing rules to conform with the provisions of S.L. 2023-14 will ensure continuity of care for patients and resolve any uncertainty about the rules applicable to impacted providers while being critical to protect the health and safety of women in obtaining lawful abortions in a certified abortion clinic. Therefore, the N.C. DHHS is amending Rule 10A NCAC 14E .0109 under temporary procedures.</p>

7. Why is adherence to notice and hearing requirements contrary to the public interest and the immediate adoption of the rule is required? The rules governing the licensing of abortion clinics are found in Subchapter 14E of Title 10A of the Administrative Code. The authority for these rules derived from N.C.G.S. § 14-45.1 that was repealed by Session Law 2023-14, Part 1, Section 1.1, effective July 1, 2023. The General Assembly stated in S.L. 2023-14 that:

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.

These newly enacted provisions provided a mandate for the Department to adopt rules necessary to regulate abortion clinics between July 1, 2023 and October 1, 2023, at which time additional authority for the rulemaking, including those rules governing the licensure of abortion clinics, is granted to the Medical Care Commission, as required by Section 2.2 of S.L. 2023-14. Given the changes to the law that became effective July 1, the Department acted with urgency to make certain amendments to the existing rules to conform with those provisions in S.L. 2023-14 that became effective on July 1st and emergency rules became effective on June 30, 2023. Further, the repeal of existing laws governing abortions in North Carolina, which also was effective July 1, 2023, required the Department to act swiftly in making conforming changes to these rules. The adoption of this temporary rule amendment will ensure continuity of care for patients, resolve any uncertainty about the rule's applicable to impacted providers until the Department is able to promulgate permanent rules, and critically, will protect the health and safety of women in obtaining lawful abortions in a clinic regulated by the Department. Adherence to notice and hearing requirements is contrary to the public interest for the immediate and critical near term because it is not possible to complete notice and comment rulemaking for permanent rulemaking by October 1, 2023.

8. Rule establishes or increases a fee? (See G.S. 12-3.1)

Yes

Agency submitted request for consultation on:
Consultation not required. Cite authority:

No

9. Rule-making Coordinator: Nadine Pfeiffer

Phone: 919-855-3811

E-Mail: Nadine.pfeiffer@dhhs.nc.gov

Agency contact, if any: Rajeev Premakumar

Phone: 984-800-1117

E-Mail: raj.premakumar@dhhs.nc.gov

10. Signature of Agency Head*:

DocuSigned by:

Mark T. Benton

* If this function has been delegated (reassigned) pursuant to G.S. 143B-10(a), submit a copy of the delegation with this form.

Typed Name: Mark T. Benton

Title: Chief Deputy Secretary, N.C. DHHS

E-Mail: mark.benton@dhhs.nc.gov

RULES REVIEW COMMISSION USE ONLY

Action taken:

Submitted for RRC Review:

Date returned to agency:

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?

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

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

On line 5, what application? Is it the same form / contents as discussed in Rule .0106?

On line 6, under what circumstances is approval given?

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

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

2

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

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

7

8 *History Note: Authority G.S. ~~14-45.1(a)~~; ~~131E-269~~; 131E-153.2; 143B-10; S.L. 2023-14, s. 2.4;*

9 *Eff. February 1, 1976;*

10 *Readopted Eff. December 19, 1977;*

11 *Amended Eff. October 1, 2015;*

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

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

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

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

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



TEMPORARY RULE-MAKING FINDINGS OF NEED

[Authority G.S. 150B-21.1]

OAH USE ONLY

VOLUME:

ISSUE:

1. Rule-Making Agency: N.C. Department of Health and Human Services/Director, DHHSR
2. Rule citation & name: 10A NCAC 14E .0110 REVOCATION
3. Action: <input type="checkbox"/> Adoption <input checked="" type="checkbox"/> Amendment <input type="checkbox"/> Repeal
4. Was this an Emergency Rule: <input checked="" type="checkbox"/> Yes Effective date: 06/30/23 <input type="checkbox"/> No
5. Provide dates for the following actions as applicable: a. Proposed Temporary Rule submitted to OAH: 06/20/23 b. Proposed Temporary Rule published on the OAH website: 06/22/23 c. Public Hearing date: 07/19/23 d. Comment Period: 06/28/23 – 07/20/23 e. Notice pursuant to G.S. 150B-21.1(a3)(2): 06/20/23 f. Adoption by agency on: 09/18/23 g. Proposed effective date of temporary rule [if other than effective date established by G.S. 150B- 21.1(b) and G.S. 150B-21.3]: 10/27/23 h. Rule approved by RRC as a permanent rule [See G.S. 150B-21.3(b2)]: n/a
6. Reason for Temporary Action. Attach a copy of any cited law, regulation, or document necessary for the review. <input type="checkbox"/> A serious and unforeseen threat to the public health, safety or welfare. <input checked="" type="checkbox"/> The effective date of a recent act of the General Assembly or of the U.S. Congress. Cite: N.C.G.A. SL 2023-14, Part I, s. 1.1 and Part II, s. 2.4 (SB 20) “An Act to Make Various Changes to Health Care Laws and to Appropriate Funds for Health Care Programs” Effective date: 7/1/23 <input type="checkbox"/> A recent change in federal or state budgetary policy. Effective date of change: <input type="checkbox"/> A recent federal regulation. Cite: Effective date: <input type="checkbox"/> A recent court order. Cite order: <input type="checkbox"/> State Medical Facilities Plan. <input type="checkbox"/> Other:
Explain: On May 16, 2023, Senate Bill 20 became law as SL 2023-14. This new law entitled “An Act to Make Various Changes to Health Care Laws and to Appropriate Funds for Health Care Programs” revised various state laws governing abortions in North Carolina. The Department was made aware of the proposed changes on May 2, 2023, when a Proposed Conference Committee Substitute was issued that made the changes to the State’s abortion laws. The revisions in Part I and Part 2.4 of the law went into effect on July 1, 2023, less than 2 months after the Department became aware of the proposed changes. Among other changes, S.L. 2023-14 makes significant changes to defining when an abortion is lawful. Current rules governing the certification of abortion clinics are found in Subchapter 14E of Title 10A of the Administrative Code. Given the changes to the law that became effective July 1, emergency rules became effective June 30, 2023. Adoption of temporary rules to amend the existing rules to conform with the provisions of S.L. 2023-14 will ensure continuity of care for patients and resolve any uncertainty about the rules applicable to impacted providers while being critical to protect the health and safety of women in obtaining lawful abortions in a certified abortion clinic. Therefore, the N.C. DHHS is amending Rule 10A NCAC 14E .0110 under temporary procedures.

7. Why is adherence to notice and hearing requirements contrary to the public interest and the immediate adoption of the rule is required? The rules governing the licensing of abortion clinics are found in Subchapter 14E of Title 10A of the Administrative Code. The authority for these rules derived from N.C.G.S. § 14-45.1 that was repealed by Session Law 2023-14, Part 1, Section 1.1, effective July 1, 2023. The General Assembly stated in S.L. 2023-14 that:

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.

These newly enacted provisions provided a mandate for the Department to adopt rules necessary to regulate abortion clinics between July 1, 2023 and October 1, 2023, at which time additional authority for the rulemaking, including those rules governing the licensure of abortion clinics, is granted to the Medical Care Commission, as required by Section 2.2 of S.L. 2023-14. Given the changes to the law that became effective July 1, the Department acted with urgency to make certain amendments to the existing rules to conform with those provisions in S.L. 2023-14 that became effective on July 1st and emergency rules became effective on June 30, 2023. Further, the repeal of existing laws governing abortions in North Carolina, which also was effective July 1, 2023, required the Department to act swiftly in making conforming changes to these rules. The adoption of this temporary rule amendment will ensure continuity of care for patients, resolve any uncertainty about the rule's applicable to impacted providers until the Department is able to promulgate permanent rules, and critically, will protect the health and safety of women in obtaining lawful abortions in a clinic regulated by the Department. Adherence to notice and hearing requirements is contrary to the public interest for the immediate and critical near term because it is not possible to complete notice and comment rulemaking for permanent rulemaking by October 1, 2023.

8. Rule establishes or increases a fee? (See G.S. 12-3.1)

Yes

Agency submitted request for consultation on:
Consultation not required. Cite authority:

No

9. Rule-making Coordinator: Nadine Pfeiffer

Phone: 919-855-3811

E-Mail: Nadine.pfeiffer@dhhs.nc.gov

Agency contact, if any: Rajeev Premakumar

Phone: 984-800-1117

E-Mail: raj.premakumar@dhhs.nc.gov

10. Signature of Agency Head*:

DocuSigned by:

Mark T. Benton

* If this function has been delegated (reassigned) pursuant to G.S. 143B-10(a), submit a copy of the delegation with this form.

Typed Name: Mark T. Benton

Title: Chief Deputy Secretary, N.C. DHHS

E-Mail: mark.benton@dhhs.nc.gov

RULES REVIEW COMMISSION USE ONLY

Action taken:

Submitted for RRC Review:

Date returned to agency:

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:

On line 4, please define "substantial".

On line 5, what regulations are you referring to?

On line 5, please define "unsuitable".

Why is there a reference to G.S. 150B-23 in your History Note?

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

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

1 10A NCAC 14E .0110 is amended under temporary procedures as follows:

2

3 **10A NCAC 14E .0110 REVOCATION**

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

6

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

8 *Eff. February 1, 1976;*

9 *Amended Eff. December 1, 1989;*

10 *Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. August 24,*
11 *2019;*

12 *Codifier determined that agency's findings of need did not meet criteria for emergency rule on June*
13 *22, 2023;*

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

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

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



TEMPORARY RULE-MAKING FINDINGS OF NEED

[Authority G.S. 150B-21.1]

OAH USE ONLY

VOLUME:

ISSUE:

1. Rule-Making Agency: N.C. Department of Health and Human Services/Director, DHHSR
2. Rule citation & name: 10A NCAC 14E .0111 INSPECTIONS
3. Action: <input type="checkbox"/> Adoption <input checked="" type="checkbox"/> Amendment <input type="checkbox"/> Repeal
4. Was this an Emergency Rule: <input checked="" type="checkbox"/> Yes Effective date: 06/30/23 <input type="checkbox"/> No
5. Provide dates for the following actions as applicable: a. Proposed Temporary Rule submitted to OAH: 06/20/23 b. Proposed Temporary Rule published on the OAH website: 06/22/23 c. Public Hearing date: 07/19/23 d. Comment Period: 06/28/23 – 07/20/23 e. Notice pursuant to G.S. 150B-21.1(a3)(2): 06/20/23 f. Adoption by agency on: 09/18/23 g. Proposed effective date of temporary rule [if other than effective date established by G.S. 150B- 21.1(b) and G.S. 150B-21.3]: 10/27/23 h. Rule approved by RRC as a permanent rule [See G.S. 150B-21.3(b2)]: n/a
6. Reason for Temporary Action. Attach a copy of any cited law, regulation, or document necessary for the review. <input type="checkbox"/> A serious and unforeseen threat to the public health, safety or welfare. <input checked="" type="checkbox"/> The effective date of a recent act of the General Assembly or of the U.S. Congress. Cite: N.C.G.A. SL 2023-14, Part I, s. 1.1 and Part II, s. 2.4 (SB 20) “An Act to Make Various Changes to Health Care Laws and to Appropriate Funds for Health Care Programs” Effective date: 7/1/23 <input type="checkbox"/> A recent change in federal or state budgetary policy. Effective date of change: <input type="checkbox"/> A recent federal regulation. Cite: Effective date: <input type="checkbox"/> A recent court order. Cite order: <input type="checkbox"/> State Medical Facilities Plan. <input type="checkbox"/> Other:
<p>Explain: On May 16, 2023, Senate Bill 20 became law as SL 2023-14. This new law entitled “An Act to Make Various Changes to Health Care Laws and to Appropriate Funds for Health Care Programs” revised various state laws governing abortions in North Carolina. The Department was made aware of the proposed changes on May 2, 2023, when a Proposed Conference Committee Substitute was issued that made the changes to the State’s abortion laws. The revisions in Part I and Part 2.4 of the law went into effect on July 1, 2023, less than 2 months after the Department became aware of the proposed changes. Among other changes, S.L. 2023-14 makes significant changes to defining when an abortion is lawful. Current rules governing the certification of abortion clinics are found in Subchapter 14E of Title 10A of the Administrative Code. Given the changes to the law that became effective July 1, emergency rules became effective June 30, 2023. Adoption of temporary rules to amend the existing rules to conform with the provisions of S.L. 2023-14 will ensure continuity of care for patients and resolve any uncertainty about the rules applicable to impacted providers while being critical to protect the health and safety of women in obtaining lawful abortions in a certified abortion clinic. Therefore, the N.C. DHHS is amending Rule 10A NCAC 14E .0111 under temporary procedures.</p>

7. Why is adherence to notice and hearing requirements contrary to the public interest and the immediate adoption of the rule is required? The rules governing the licensing of abortion clinics are found in Subchapter 14E of Title 10A of the Administrative Code. The authority for these rules derived from N.C.G.S. § 14-45.1 that was repealed by Session Law 2023-14, Part 1, Section 1.1, effective July 1, 2023. The General Assembly stated in S.L. 2023-14 that:

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.

These newly enacted provisions provided a mandate for the Department to adopt rules necessary to regulate abortion clinics between July 1, 2023 and October 1, 2023, at which time additional authority for the rulemaking, including those rules governing the licensure of abortion clinics, is granted to the Medical Care Commission, as required by Section 2.2 of S.L. 2023-14. Given the changes to the law that became effective July 1, the Department acted with urgency to make certain amendments to the existing rules to conform with those provisions in S.L. 2023-14 that became effective on July 1st and emergency rules became effective on June 30, 2023. Further, the repeal of existing laws governing abortions in North Carolina, which also was effective July 1, 2023, required the Department to act swiftly in making conforming changes to these rules. The adoption of this temporary rule amendment will ensure continuity of care for patients, resolve any uncertainty about the rule's applicable to impacted providers until the Department is able to promulgate permanent rules, and critically, will protect the health and safety of women in obtaining lawful abortions in a clinic regulated by the Department. Adherence to notice and hearing requirements is contrary to the public interest for the immediate and critical near term because it is not possible to complete notice and comment rulemaking for permanent rulemaking by October 1, 2023.

8. Rule establishes or increases a fee? (See G.S. 12-3.1)

Yes

Agency submitted request for consultation on:
Consultation not required. Cite authority:

No

9. Rule-making Coordinator: Nadine Pfeiffer

Phone: 919-855-3811

E-Mail: Nadine.pfeiffer@dhhs.nc.gov

Agency contact, if any: Rajeev Premakumar

Phone: 984-800-1117

E-Mail: raj.premakumar@dhhs.nc.gov

10. Signature of Agency Head*:

DocuSigned by:

Mark T. Benton

* If this function has been delegated (reassigned) pursuant to G.S. 143B-10(a), submit a copy of the delegation with this form.

Typed Name: Mark T. Benton

Title: Chief Deputy Secretary, N.C. DHHS

E-Mail: mark.benton@dhhs.nc.gov

RULES REVIEW COMMISSION USE ONLY

Action taken:

Submitted for RRC Review:

Date returned to agency:

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.

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?

In (a), line 7, who should have “reason to believe” that the clinic isn’t in compliance?

In (a), line 7, please simplify “some condition exists which is not in compliance”.

In (b), line 9, what is the difference between “care” and “treatment”?

In (c), line 11, who would be the “person in charge”?

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?

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?

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

1 10A NCAC 14E .0111 is amended under temporary procedures as follows:

2

3 **10A NCAC 14E .0111 INSPECTIONS**

4 (a) Any clinic ~~certified~~ licensed by the Division to perform abortions shall be inspected by representatives of the
5 Division annually and as it may deem necessary as a condition of holding such license. An inspection shall be
6 conducted whenever the purpose of the inspection is to determine whether the clinic complies with the rules of this
7 Subchapter or whenever there is reason to believe that some condition exists which is not in compliance with the rules
8 of this Subchapter.

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

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

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

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

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

21

22 *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. 2.4;*
23 *Eff. February 1, 1976;*

24 *Readopted Eff. December 19, 1977;*

25 *Amended Eff. October 1, 2015; July 1, 1994;*

26 *Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. August 24,*
27 *2019;*

28 *Codifier determined that agency's findings of need did not meet criteria for emergency rule on June*
29 *22, 2023;*

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

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

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



TEMPORARY RULE-MAKING FINDINGS OF NEED

[Authority G.S. 150B-21.1]

OAH USE ONLY

VOLUME:

ISSUE:

1. Rule-Making Agency: N.C. Department of Health and Human Services/Director, DHHSR
2. Rule citation & name: 10A NCAC 14E .0112 ALTERATIONS
3. Action: <input type="checkbox"/> Adoption <input checked="" type="checkbox"/> Amendment <input type="checkbox"/> Repeal
4. Was this an Emergency Rule: <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No Effective date: 06/30/23
5. Provide dates for the following actions as applicable: <ul style="list-style-type: none"> a. Proposed Temporary Rule submitted to OAH: 06/20/23 b. Proposed Temporary Rule published on the OAH website: 06/22/23 c. Public Hearing date: 07/19/23 d. Comment Period: 06/28/23 – 07/20/23 e. Notice pursuant to G.S. 150B-21.1(a3)(2): 06/20/23 f. Adoption by agency on: 09/18/23 g. Proposed effective date of temporary rule [if other than effective date established by G.S. 150B- 21.1(b) and G.S. 150B-21.3]: 10/27/23 h. Rule approved by RRC as a permanent rule [See G.S. 150B-21.3(b2)]: n/a
6. Reason for Temporary Action. Attach a copy of any cited law, regulation, or document necessary for the review. <ul style="list-style-type: none"> <input type="checkbox"/> A serious and unforeseen threat to the public health, safety or welfare. <input checked="" type="checkbox"/> The effective date of a recent act of the General Assembly or of the U.S. Congress. Cite: N.C.G.A. SL 2023-14, Part I, s. 1.1 and Part II, s. 2.4 (SB 20) “An Act to Make Various Changes to Health Care Laws and to Appropriate Funds for Health Care Programs” Effective date: 7/1/23 <input type="checkbox"/> A recent change in federal or state budgetary policy. Effective date of change: <input type="checkbox"/> A recent federal regulation. Cite: Effective date: <input type="checkbox"/> A recent court order. Cite order: <input type="checkbox"/> State Medical Facilities Plan. <input type="checkbox"/> Other: <p>Explain: On May 16, 2023, Senate Bill 20 became law as SL 2023-14. This new law entitled “An Act to Make Various Changes to Health Care Laws and to Appropriate Funds for Health Care Programs” revised various state laws governing abortions in North Carolina. The Department was made aware of the proposed changes on May 2, 2023, when a Proposed Conference Committee Substitute was issued that made the changes to the State’s abortion laws. The revisions in Part I and Part 2.4 of the law went into effect on July 1, 2023, less than 2 months after the Department became aware of the proposed changes. Among other changes, S.L. 2023-14 makes significant changes to defining when an abortion is lawful. Current rules governing the certification of abortion clinics are found in Subchapter 14E of Title 10A of the Administrative Code. Given the changes to the law that became effective July 1, emergency rules became effective June 30, 2023. Adoption of temporary rules to amend the existing rules to conform with the provisions of S.L. 2023-14 will ensure continuity of care for patients and resolve any uncertainty about the rules applicable to impacted providers while being critical to protect the health and safety of women in obtaining lawful abortions in a certified abortion clinic. Therefore, the N.C. DHHS is amending Rule 10A NCAC 14E .0112 under temporary procedures.</p>

7. Why is adherence to notice and hearing requirements contrary to the public interest and the immediate adoption of the rule is required? The rules governing the licensing of abortion clinics are found in Subchapter 14E of Title 10A of the Administrative Code. The authority for these rules derived from N.C.G.S. § 14-45.1 that was repealed by Session Law 2023-14, Part 1, Section 1.1, effective July 1, 2023. The General Assembly stated in S.L. 2023-14 that:

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.

These newly enacted provisions provided a mandate for the Department to adopt rules necessary to regulate abortion clinics between July 1, 2023 and October 1, 2023, at which time additional authority for the rulemaking, including those rules governing the licensure of abortion clinics, is granted to the Medical Care Commission, as required by Section 2.2 of S.L. 2023-14. Given the changes to the law that became effective July 1, the Department acted with urgency to make certain amendments to the existing rules to conform with those provisions in S.L. 2023-14 that became effective on July 1st and emergency rules became effective on June 30, 2023. Further, the repeal of existing laws governing abortions in North Carolina, which also was effective July 1, 2023, required the Department to act swiftly in making conforming changes to these rules. The adoption of this temporary rule amendment will ensure continuity of care for patients, resolve any uncertainty about the rule's applicable to impacted providers until the Department is able to promulgate permanent rules, and critically, will protect the health and safety of women in obtaining lawful abortions in a clinic regulated by the Department. Adherence to notice and hearing requirements is contrary to the public interest for the immediate and critical near term because it is not possible to complete notice and comment rulemaking for permanent rulemaking by October 1, 2023.

8. Rule establishes or increases a fee? (See G.S. 12-3.1)

Yes

Agency submitted request for consultation on:
Consultation not required. Cite authority:

No

9. Rule-making Coordinator: Nadine Pfeiffer

Phone: 919-855-3811


E-Mail: Nadine.pfeiffer@dhhs.nc.gov

Agency contact, if any: Rajeev Premakumar

Phone: 984-800-1117

E-Mail: raj.premakumar@dhhs.nc.gov

10. Signature of Agency Head*:

DocuSigned by:


* If this function has been delegated (reassigned) pursuant to G.S. 143B-10(a), submit a copy of the delegation with this form.

Typed Name: Mark T. Benton

Title: Chief Deputy Secretary, N.C. DHHS

E-Mail: mark.benton@dhhs.nc.gov

RULES REVIEW COMMISSION USE ONLY

Action taken:

Submitted for RRC Review:

Date returned to agency:

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.

On line 4, what "specified types" of alterations are you referring to?

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

On line 6, are these "recommendations" binding?

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

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

2

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

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

8

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

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.*



TEMPORARY RULE-MAKING FINDINGS OF NEED

[Authority G.S. 150B-21.1]

OAH USE ONLY

VOLUME:

ISSUE:

1. Rule-Making Agency: N.C. Department of Health and Human Services/Director, DHHSR
2. Rule citation & name: 10A NCAC 14E .0113 CHANGES
3. Action: <input checked="" type="checkbox"/> Adoption <input type="checkbox"/> Amendment <input type="checkbox"/> Repeal
4. Was this an Emergency Rule: <input checked="" type="checkbox"/> Yes Effective date: 07/18/23 <input type="checkbox"/> No
5. Provide dates for the following actions as applicable: a. Proposed Temporary Rule submitted to OAH: 07/06/23 b. Proposed Temporary Rule published on the OAH website: 07/12/23 c. Public Hearing date: 07/27/23 d. Comment Period: 07/14/23 – 08/04/23 e. Notice pursuant to G.S. 150B-21.1(a3)(2): 07/06/23 f. Adoption by agency on: 09/18/23 g. Proposed effective date of temporary rule [if other than effective date established by G.S. 150B- 21.1(b) and G.S. 150B-21.3]: 10/27/23 h. Rule approved by RRC as a permanent rule [See G.S. 150B-21.3(b2)]: n/a
6. Reason for Temporary Action. Attach a copy of any cited law, regulation, or document necessary for the review. <input checked="" type="checkbox"/> A serious and unforeseen threat to the public health, safety or welfare. <input checked="" type="checkbox"/> The effective date of a recent act of the General Assembly or of the U.S. Congress. Cite: N.C.G.A. SL 2023-14, Part I, s. 1.1 and Part II, s. 2.4 (SB 20) “An Act to Make Various Changes to Health Care Laws and to Appropriate Funds for Health Care Programs” Effective date: 7/1/23 <input type="checkbox"/> A recent change in federal or state budgetary policy. Effective date of change: <input type="checkbox"/> A recent federal regulation. Cite: Effective date: <input type="checkbox"/> A recent court order. Cite order: <input type="checkbox"/> State Medical Facilities Plan. <input type="checkbox"/> Other:
Explain: On June 30, 2023, the Codifier of Rules notified N.C. DHHS that, “Pursuant to G.S. 150B-21.7, all permanent rules in 10A NCAC 14E are repealed effective July 1, 2023 following the repeal of G.S. 14-45.1 in Session Law 2023-14.” The repeal of these rules occurred following a submission by the Department requesting the Codifier amend the history note of the rules to reflect the change in statutory authority from G.S. 14-45.1 to Session Law 2023-14, Part II, Section 2.4. The Department’s rulemaking authority under both laws directs the Department to regulate facilities suitable for the performance of abortions through ensuring that minimum health and safety standards are implemented and adhered to by the facilities performing abortions and providing other reproductive health services. Specifically, the General Assembly states that enforcement of these basic standards are to ensure safe and adequate treatment of individuals in abortion clinics. The rules repealed effective July 1, 2023 contain current minimum standards for nursing services, laboratory services, emergency back-up services, surgical services, medications and anesthesia, post-operative care, staff qualifications and basic standards for building codes, sanitation, and record keeping. Following the repeal of the rules, emergency rule adoptions became effective July 18, 2023. The rule repeals represent a serious and unforeseen threat to public health and safety of those seeking reproductive health care and to the operation of facilities providing this care, and therefore, the N.C. DHHS is adopting Rule 10A NCAC 14E .0113 under temporary procedures.

7. Why is adherence to notice and hearing requirements contrary to the public interest and the immediate adoption of the rule is required?

Notice would be contrary to public interest given the repeal of this rule for minimum standards in the regulated clinics. The providers have been operating for years based upon this rule and have not received notice that the rule would be repealed. Unless a temporary rule is adopted, there will be uncertainty about the minimum standards applicable to a clinic and how to operate. The adoption of a temporary rule will ensure continuity of care for patients and resolve uncertainty about the rules applicable to impacted providers beginning July 1st until the Department is able to promulgate permanent rules. The temporary rule will allow the Department to regulate the clinics and hold the clinics to basic standards that are in place to protect the health and safety of women in obtaining lawful abortions. Adherence to notice and hearing requirements is contrary to the public interest for the immediate and critical near term because the timeframe for notice and comment rulemaking create a months' long threat to the public health and safety of women and providers due to the elimination of these established minimum standards.

8. Rule establishes or increases a fee? (See G.S. 12-3.1)

- Yes
 Agency submitted request for consultation on:
 Consultation not required. Cite authority:
- No

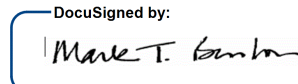
9. Rule-making Coordinator: Nadine Pfeiffer

Phone: 919-855-3811
 E-Mail: Nadine.pfeiffer@dhhs.nc.gov

Agency contact, if any: Rajeev Premakumar

Phone: 984-800-1117
 E-Mail: raj.premakumar@dhhs.nc.gov

10. Signature of Agency Head*:

DocuSigned by:


* If this function has been delegated (reassigned) pursuant to G.S. 143B-10(a), submit a copy of the delegation with this form.

Typed Name: Mark T. Benton
 Title: Chief Deputy Secretary, N.C. DHHS
 E-Mail: mark.benton@dhhs.nc.gov

RULES REVIEW COMMISSION USE ONLY

Action taken:

Submitted for RRC Review:

Date returned to agency:

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.

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.

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.

Brian Liebman
Commission Counsel
Date submitted to agency: October 6, 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.*

7. Why is adherence to notice and hearing requirements contrary to the public interest and the immediate adoption of the rule is required?

Notice would be contrary to public interest given the repeal of this rule for minimum standards in the regulated clinics. The providers have been operating for years based upon this rule and have not received notice that the rule would be repealed. Unless a temporary rule is adopted, there will be uncertainty about the minimum standards applicable to a clinic and how to operate. The adoption of a temporary rule will ensure continuity of care for patients and resolve uncertainty about the rules applicable to impacted providers beginning July 1st until the Department is able to promulgate permanent rules. The temporary rule will allow the Department to regulate the clinics and hold the clinics to basic standards that are in place to protect the health and safety of women in obtaining lawful abortions. Adherence to notice and hearing requirements is contrary to the public interest for the immediate and critical near term because the timeframe for notice and comment rulemaking create a months' long threat to the public health and safety of women and providers due to the elimination of these established minimum standards.

8. Rule establishes or increases a fee? (See G.S. 12-3.1)
 Yes

Agency submitted request for consultation on:
 Consultation not required. Cite authority:

 No
9. Rule-making Coordinator: Nadine Pfeiffer

Phone: 919-855-3811

E-Mail: Nadine.pfeiffer@dhhs.nc.gov

Agency contact, if any: Rajeev Premakumar

Phone: 984-800-1117

E-Mail: raj.premakumar@dhhs.nc.gov

10. Signature of Agency Head*:

DocuSigned by:

Mark T. Benton

* If this function has been delegated (reassigned) pursuant to G.S. 143B-10(a), submit a copy of the delegation with this form.

Typed Name: Mark T. Benton

Title: Chief Deputy Secretary, N.C. DHHS

E-Mail: mark.benton@dhhs.nc.gov

RULES REVIEW COMMISSION USE ONLY

Action taken:

Submitted for RRC Review:

 Date returned to agency:

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.

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.

In (a), line 4, what are "construction documents and specifications"?

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?

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

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

2

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

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

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

11

12 *History Note: Authority G.S. 143B-10; S.L. 2023-14, s. 2.4;*
13 *Emergency Adoption Eff. July 18, ~~2023~~ 2023;*
14 *Temporary Adoption Eff. October 27, 2023.*



TEMPORARY RULE-MAKING FINDINGS OF NEED

[Authority G.S. 150B-21.1]

OAH USE ONLY

VOLUME:

ISSUE:

1. Rule-Making Agency: N.C. Department of Health and Human Services/Director, DHHSR
2. Rule citation & name: 10A NCAC 14E .0201 BUILDING CODE REQUIREMENTS
3. Action: <input type="checkbox"/> Adoption <input checked="" type="checkbox"/> Amendment <input type="checkbox"/> Repeal
4. Was this an Emergency Rule: <input checked="" type="checkbox"/> Yes Effective date: 06/30/23 <input type="checkbox"/> No
5. Provide dates for the following actions as applicable: a. Proposed Temporary Rule submitted to OAH: 06/20/23 b. Proposed Temporary Rule published on the OAH website: 06/22/23 c. Public Hearing date: 07/19/23 d. Comment Period: 06/28/23 – 07/20/23 e. Notice pursuant to G.S. 150B-21.1(a3)(2): 06/20/23 f. Adoption by agency on: 09/18/23 g. Proposed effective date of temporary rule [if other than effective date established by G.S. 150B- 21.1(b) and G.S. 150B-21.3]: 10/27/23 h. Rule approved by RRC as a permanent rule [See G.S. 150B-21.3(b2)]: n/a
6. Reason for Temporary Action. Attach a copy of any cited law, regulation, or document necessary for the review. <input type="checkbox"/> A serious and unforeseen threat to the public health, safety or welfare. <input checked="" type="checkbox"/> The effective date of a recent act of the General Assembly or of the U.S. Congress. Cite: N.C.G.A. SL 2023-14, Part I, s. 1.1 and Part II, s. 2.4 (SB 20) “An Act to Make Various Changes to Health Care Laws and to Appropriate Funds for Health Care Programs” Effective date: 7/1/23 <input type="checkbox"/> A recent change in federal or state budgetary policy. Effective date of change: <input type="checkbox"/> A recent federal regulation. Cite: Effective date: <input type="checkbox"/> A recent court order. Cite order: <input type="checkbox"/> State Medical Facilities Plan. <input type="checkbox"/> Other:
Explain: On May 16, 2023, Senate Bill 20 became law as SL 2023-14. This new law entitled “An Act to Make Various Changes to Health Care Laws and to Appropriate Funds for Health Care Programs” revised various state laws governing abortions in North Carolina. The Department was made aware of the proposed changes on May 2, 2023, when a Proposed Conference Committee Substitute was issued that made the changes to the State’s abortion laws. The revisions in Part I and Part 2.4 of the law went into effect on July 1, 2023, less than 2 months after the Department became aware of the proposed changes. Among other changes, S.L. 2023-14 makes significant changes to defining when an abortion is lawful. Current rules governing the certification of abortion clinics are found in Subchapter 14E of Title 10A of the Administrative Code. Given the changes to the law that became effective July 1, emergency rules became effective June 30, 2023. Adoption of temporary rules to amend the existing rules to conform with the provisions of S.L. 2023-14 will ensure continuity of care for patients and resolve any uncertainty about the rules applicable to impacted providers while being critical to protect the health and safety of women in obtaining lawful abortions in a certified abortion clinic. Therefore, the N.C. DHHS is amending Rule 10A NCAC 14E .0201 under temporary procedures.

7. Why is adherence to notice and hearing requirements contrary to the public interest and the immediate adoption of the rule is required? The rules governing the licensing of abortion clinics are found in Subchapter 14E of Title 10A of the Administrative Code. The authority for these rules derived from N.C.G.S. § 14-45.1 that was repealed by Session Law 2023-14, Part 1, Section 1.1, effective July 1, 2023. The General Assembly stated in S.L. 2023-14 that:

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.

These newly enacted provisions provided a mandate for the Department to adopt rules necessary to regulate abortion clinics between July 1, 2023 and October 1, 2023, at which time additional authority for the rulemaking, including those rules governing the licensure of abortion clinics, is granted to the Medical Care Commission, as required by Section 2.2 of S.L. 2023-14. Given the changes to the law that became effective July 1, the Department acted with urgency to make certain amendments to the existing rules to conform with those provisions in S.L. 2023-14 that became effective on July 1st and emergency rules became effective on June 30, 2023. Further, the repeal of existing laws governing abortions in North Carolina, which also was effective July 1, 2023, required the Department to act swiftly in making conforming changes to these rules. The adoption of this temporary rule amendment will ensure continuity of care for patients, resolve any uncertainty about the rule's applicable to impacted providers until the Department is able to promulgate permanent rules, and critically, will protect the health and safety of women in obtaining lawful abortions in a clinic regulated by the Department. Adherence to notice and hearing requirements is contrary to the public interest for the immediate and critical near term because it is not possible to complete notice and comment rulemaking for permanent rulemaking by October 1, 2023.

8. Rule establishes or increases a fee? (See G.S. 12-3.1)

Yes

Agency submitted request for consultation on:
Consultation not required. Cite authority:

No

9. Rule-making Coordinator: Nadine Pfeiffer

Phone: 919-855-3811

E-Mail: Nadine.pfeiffer@dhhs.nc.gov

Agency contact, if any: Rajeev Premakumar

Phone: 984-800-1117

E-Mail: raj.premakumar@dhhs.nc.gov

10. Signature of Agency Head*:

DocuSigned by:



* If this function has been delegated (reassigned) pursuant to G.S. 143B-10(a), submit a copy of the delegation with this form.

Typed Name: Mark T. Benton

Title: Chief Deputy Secretary, N.C. DHHS

E-Mail: mark.benton@dhhs.nc.gov

RULES REVIEW COMMISSION USE ONLY

Action taken:

Submitted for RRC Review:

Date returned to agency:

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.

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.

In (a), line 10, the URL for ecodes.biz just redirects back to the ICC website. Please correct.

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

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

2

3

SECTION .0200 - MINIMUM STANDARDS FOR CONSTRUCTION AND EQUIPMENT

4

10A NCAC 14E .0201 BUILDING CODE REQUIREMENTS

6 (a) The physical plant for a clinic shall meet or exceed minimum requirements of the North Carolina State Building

7 Code for Group B occupancy (business office facilities) which is incorporated herein by reference including

8 subsequent amendments and editions. Copies of the Code can be obtained from the International Code Council online

9 at <http://shop.iccsafe.org/north-carolina-doi.discounts?ref=NC> for a cost of five hundred twenty-seven dollars

10 (\$527.00), or accessed electronically free of charge at <http://www.ecodes.biz>.

11 (b) The requirements contained in this Section shall apply to new clinics and to any alterations, repairs, rehabilitation

12 work, or additions which are made to a previously ~~certified~~ licensed facility.

13

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

15 *Eff. February 1, 1976;*

16 *Readopted Eff. December 19, 1977;*

17 *Amended Eff. October 1, 2015; July 1, 1994; December 1, 1989;*

18 *Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. August 24,*
19 *2019;*

20 *Codifier determined that agency's findings of need did not meet criteria for emergency rule on June*
21 *22, 2023;*

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

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

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



TEMPORARY RULE-MAKING FINDINGS OF NEED

[Authority G.S. 150B-21.1]

OAH USE ONLY

VOLUME:

ISSUE:

1. Rule-Making Agency: N.C. Department of Health and Human Services/Director, DHHSR
2. Rule citation & name: 10A NCAC 14E .0202 SANITATION
3. Action: <input type="checkbox"/> Adoption <input checked="" type="checkbox"/> Amendment <input type="checkbox"/> Repeal
4. Was this an Emergency Rule: <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No Effective date: 06/30/23
5. Provide dates for the following actions as applicable: <ul style="list-style-type: none"> a. Proposed Temporary Rule submitted to OAH: 06/20/23 b. Proposed Temporary Rule published on the OAH website: 06/22/23 c. Public Hearing date: 07/19/23 d. Comment Period: 06/28/23 – 07/20/23 e. Notice pursuant to G.S. 150B-21.1(a3)(2): 06/20/23 f. Adoption by agency on: 09/18/23 g. Proposed effective date of temporary rule [if other than effective date established by G.S. 150B- 21.1(b) and G.S. 150B-21.3]: 10/27/23 h. Rule approved by RRC as a permanent rule [See G.S. 150B-21.3(b2)]: n/a
6. Reason for Temporary Action. Attach a copy of any cited law, regulation, or document necessary for the review. <ul style="list-style-type: none"> <input type="checkbox"/> A serious and unforeseen threat to the public health, safety or welfare. <input checked="" type="checkbox"/> The effective date of a recent act of the General Assembly or of the U.S. Congress. Cite: N.C.G.A. SL 2023-14, Part I, s. 1.1 and Part II, s. 2.4 (SB 20) “An Act to Make Various Changes to Health Care Laws and to Appropriate Funds for Health Care Programs” Effective date: 7/1/23 <input type="checkbox"/> A recent change in federal or state budgetary policy. Effective date of change: <input type="checkbox"/> A recent federal regulation. Cite: Effective date: <input type="checkbox"/> A recent court order. Cite order: <input type="checkbox"/> State Medical Facilities Plan. <input type="checkbox"/> Other: <p>Explain: On May 16, 2023, Senate Bill 20 became law as SL 2023-14. This new law entitled “An Act to Make Various Changes to Health Care Laws and to Appropriate Funds for Health Care Programs” revised various state laws governing abortions in North Carolina. The Department was made aware of the proposed changes on May 2, 2023, when a Proposed Conference Committee Substitute was issued that made the changes to the State’s abortion laws. The revisions in Part I and Part 2.4 of the law went into effect on July 1, 2023, less than 2 months after the Department became aware of the proposed changes. Among other changes, S.L. 2023-14 makes significant changes to defining when an abortion is lawful. Current rules governing the certification of abortion clinics are found in Subchapter 14E of Title 10A of the Administrative Code. Given the changes to the law that became effective July 1, emergency rules became effective June 30, 2023. Adoption of temporary rules to amend the existing rules to conform with the provisions of S.L. 2023-14 will ensure continuity of care for patients and resolve any uncertainty about the rules applicable to impacted providers while being critical to protect the health and safety of women in obtaining lawful abortions in a certified abortion clinic. Therefore, the N.C. DHHS is amending Rule 10A NCAC 14E .0202 under temporary procedures.</p>

7. Why is adherence to notice and hearing requirements contrary to the public interest and the immediate adoption of the rule is required? The rules governing the licensing of abortion clinics are found in Subchapter 14E of Title 10A of the Administrative Code. The authority for these rules derived from N.C.G.S. § 14-45.1 that was repealed by Session Law 2023-14, Part 1, Section 1.1, effective July 1, 2023. The General Assembly stated in S.L. 2023-14 that:

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.

These newly enacted provisions provided a mandate for the Department to adopt rules necessary to regulate abortion clinics between July 1, 2023 and October 1, 2023, at which time additional authority for the rulemaking, including those rules governing the licensure of abortion clinics, is granted to the Medical Care Commission, as required by Section 2.2 of S.L. 2023-14. Given the changes to the law that became effective July 1, the Department acted with urgency to make certain amendments to the existing rules to conform with those provisions in S.L. 2023-14 that became effective on July 1st and emergency rules became effective on June 30, 2023. Further, the repeal of existing laws governing abortions in North Carolina, which also was effective July 1, 2023, required the Department to act swiftly in making conforming changes to these rules. The adoption of this temporary rule amendment will ensure continuity of care for patients, resolve any uncertainty about the rule's applicable to impacted providers until the Department is able to promulgate permanent rules, and critically, will protect the health and safety of women in obtaining lawful abortions in a clinic regulated by the Department. Adherence to notice and hearing requirements is contrary to the public interest for the immediate and critical near term because it is not possible to complete notice and comment rulemaking for permanent rulemaking by October 1, 2023.

8. Rule establishes or increases a fee? (See G.S. 12-3.1)

Yes

Agency submitted request for consultation on:
Consultation not required. Cite authority:

No

9. Rule-making Coordinator: Nadine Pfeiffer

Phone: 919-855-3811

E-Mail: Nadine.pfeiffer@dhhs.nc.gov

Agency contact, if any: Rajeev Premakumar

Phone: 984-800-1117

E-Mail: raj.premakumar@dhhs.nc.gov

10. Signature of Agency Head*:

DocuSigned by:

Mark T. Benton

* If this function has been delegated (reassigned) pursuant to G.S. 143B-10(a), submit a copy of the delegation with this form.

Typed Name: Mark T. Benton

Title: Chief Deputy Secretary, N.C. DHHS

E-Mail: mark.benton@dhhs.nc.gov

RULES REVIEW COMMISSION USE ONLY

Action taken:

Submitted for RRC Review:

Date returned to agency:

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.

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.

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

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

1 10A NCAC 14E .0202 is amended under temporary procedures 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/>.

10

11 *History Note: Authority G.S. ~~14-45.1(a)~~; 143B-10; S.L. 2023-14, s. 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.*



TEMPORARY RULE-MAKING FINDINGS OF NEED

[Authority G.S. 150B-21.1]

OAH USE ONLY

VOLUME:

ISSUE:

1. Rule-Making Agency: N.C. Department of Health and Human Services/Director, DHHSR
2. Rule citation & name: 10A NCAC 14E .0207 AREA REQUIREMENTS
3. Action: <input type="checkbox"/> Adoption <input checked="" type="checkbox"/> Amendment <input type="checkbox"/> Repeal
4. Was this an Emergency Rule: <input checked="" type="checkbox"/> Yes Effective date: 06/30/23 <input type="checkbox"/> No
5. Provide dates for the following actions as applicable: a. Proposed Temporary Rule submitted to OAH: 06/20/23 b. Proposed Temporary Rule published on the OAH website: 06/22/23 c. Public Hearing date: 07/19/23 d. Comment Period: 06/28/23 – 07/20/23 e. Notice pursuant to G.S. 150B-21.1(a3)(2): 06/20/23 f. Adoption by agency on: 09/18/23 g. Proposed effective date of temporary rule [if other than effective date established by G.S. 150B- 21.1(b) and G.S. 150B-21.3]: 10/27/23 h. Rule approved by RRC as a permanent rule [See G.S. 150B-21.3(b2)]: n/a
6. Reason for Temporary Action. Attach a copy of any cited law, regulation, or document necessary for the review. <input type="checkbox"/> A serious and unforeseen threat to the public health, safety or welfare. <input checked="" type="checkbox"/> The effective date of a recent act of the General Assembly or of the U.S. Congress. Cite: N.C.G.A. SL 2023-14, Part I, s. 1.1 and Part II, s. 2.4 (SB 20) “An Act to Make Various Changes to Health Care Laws and to Appropriate Funds for Health Care Programs” Effective date: 7/1/23 <input type="checkbox"/> A recent change in federal or state budgetary policy. Effective date of change: <input type="checkbox"/> A recent federal regulation. Cite: Effective date: <input type="checkbox"/> A recent court order. Cite order: <input type="checkbox"/> State Medical Facilities Plan. <input type="checkbox"/> Other:
<p>Explain: On May 16, 2023, Senate Bill 20 became law as SL 2023-14. This new law entitled “An Act to Make Various Changes to Health Care Laws and to Appropriate Funds for Health Care Programs” revised various state laws governing abortions in North Carolina. The Department was made aware of the proposed changes on May 2, 2023, when a Proposed Conference Committee Substitute was issued that made the changes to the State’s abortion laws. The revisions in Part I and Part 2.4 of the law went into effect on July 1, 2023, less than 2 months after the Department became aware of the proposed changes. Among other changes, S.L. 2023-14 makes significant changes to defining when an abortion is lawful. Current rules governing the certification of abortion clinics are found in Subchapter 14E of Title 10A of the Administrative Code. Given the changes to the law that became effective July 1, emergency rules became effective June 30, 2023. Adoption of temporary rules to amend the existing rules to conform with the provisions of S.L. 2023-14 will ensure continuity of care for patients and resolve any uncertainty about the rules applicable to impacted providers while being critical to protect the health and safety of women in obtaining lawful abortions in a certified abortion clinic. Therefore, the N.C. DHHS is amending Rule 10A NCAC 14E .0207 under temporary procedures.</p>

7. Why is adherence to notice and hearing requirements contrary to the public interest and the immediate adoption of the rule is required? The rules governing the licensing of abortion clinics are found in Subchapter 14E of Title 10A of the Administrative Code. The authority for these rules derived from N.C.G.S. § 14-45.1 that was repealed by Session Law 2023-14, Part 1, Section 1.1, effective July 1, 2023. The General Assembly stated in S.L. 2023-14 that:

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.

These newly enacted provisions provided a mandate for the Department to adopt rules necessary to regulate abortion clinics between July 1, 2023 and October 1, 2023, at which time additional authority for the rulemaking, including those rules governing the licensure of abortion clinics, is granted to the Medical Care Commission, as required by Section 2.2 of S.L. 2023-14. Given the changes to the law that became effective July 1, the Department acted with urgency to make certain amendments to the existing rules to conform with those provisions in S.L. 2023-14 that became effective on July 1st and emergency rules became effective on June 30, 2023. Further, the repeal of existing laws governing abortions in North Carolina, which also was effective July 1, 2023, required the Department to act swiftly in making conforming changes to these rules. The adoption of this temporary rule amendment will ensure continuity of care for patients, resolve any uncertainty about the rule's applicable to impacted providers until the Department is able to promulgate permanent rules, and critically, will protect the health and safety of women in obtaining lawful abortions in a clinic regulated by the Department. Adherence to notice and hearing requirements is contrary to the public interest for the immediate and critical near term because it is not possible to complete notice and comment rulemaking for permanent rulemaking by October 1, 2023.

8. Rule establishes or increases a fee? (See G.S. 12-3.1)

Yes

Agency submitted request for consultation on:
Consultation not required. Cite authority:

No

9. Rule-making Coordinator: Nadine Pfeiffer

Phone: 919-855-3811

E-Mail: Nadine.pfeiffer@dhhs.nc.gov

Agency contact, if any: Rajeev Premakumar

Phone: 984-800-1117

E-Mail: raj.premakumar@dhhs.nc.gov

10. Signature of Agency Head*:

DocuSigned by:

Mark T. Benton

* If this function has been delegated (reassigned) pursuant to G.S. 143B-10(a), submit a copy of the delegation with this form.

Typed Name: Mark T. Benton

Title: Chief Deputy Secretary, N.C. DHHS

E-Mail: mark.benton@dhhs.nc.gov

RULES REVIEW COMMISSION USE ONLY

Action taken:

Submitted for RRC Review:

Date returned to agency:

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.

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.

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?

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?

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

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

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

2

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

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

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

26

27 *History Note: Authority G.S. 14-45.1(a); 143B-10; S.L. 2023-14, s. 2.4;*

28 *Eff. February 1, 1976;*

29 *Readopted Eff. December 19, 1977;*

30 *Amended Eff. October 1, 2015; December 24, 1979;*

31 *Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. August 24,*
32 *2019;*

33 *Codifier determined that agency's findings of need did not meet criteria for emergency rule on June*
34 *22, 2023;*

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

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

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

7. Why is adherence to notice and hearing requirements contrary to the public interest and the immediate adoption of the rule is required?

Notice would be contrary to public interest given the repeal of this rule for minimum standards in the regulated clinics. The providers have been operating for years based upon this rule and have not received notice that the rule would be repealed. Unless a temporary rule is adopted, there will be uncertainty about the minimum standards applicable to a clinic and how to operate. The adoption of a temporary rule will ensure continuity of care for patients and resolve uncertainty about the rules applicable to impacted providers beginning July 1st until the Department is able to promulgate permanent rules. The temporary rule will allow the Department to regulate the clinics and hold the clinics to basic standards that are in place to protect the health and safety of women in obtaining lawful abortions. Adherence to notice and hearing requirements is contrary to the public interest for the immediate and critical near term because the timeframe for notice and comment rulemaking create a months' long threat to the public health and safety of women and providers due to the elimination of these established minimum standards.

8. Rule establishes or increases a fee? (See G.S. 12-3.1)

- Yes
 Agency submitted request for consultation on:
 Consultation not required. Cite authority:
- No


9. Rule-making Coordinator: Nadine Pfeiffer

Phone: 919-855-3811
 E-Mail: Nadine.pfeiffer@dhhs.nc.gov

Agency contact, if any: Rajeev Premakumar

Phone: 984-800-1117
 E-Mail: raj.premakumar@dhhs.nc.gov

10. Signature of Agency Head*:

DocuSigned by:


* If this function has been delegated (reassigned) pursuant to G.S. 143B-10(a), submit a copy of the delegation with this form.

Typed Name: Mark T. Benton
 Title: Chief Deputy Secretary, N.C. DHHS
 E-Mail: mark.benton@dhhs.nc.gov

RULES REVIEW COMMISSION USE ONLY

Action taken:

Submitted for RRC Review:

Date returned to agency:

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.

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

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

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

2

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

4 (a) In multi-story buildings, at least one elevator for patient use shall be provided.

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. 2.4;*

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

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

7. Why is adherence to notice and hearing requirements contrary to the public interest and the immediate adoption of the rule is required?

Notice would be contrary to public interest given the repeal of this rule for minimum standards in the regulated clinics. The providers have been operating for years based upon this rule and have not received notice that the rule would be repealed. Unless a temporary rule is adopted, there will be uncertainty about the minimum standards applicable to a clinic and how to operate. The adoption of a temporary rule will ensure continuity of care for patients and resolve uncertainty about the rules applicable to impacted providers beginning July 1st until the Department is able to promulgate permanent rules. The temporary rule will allow the Department to regulate the clinics and hold the clinics to basic standards that are in place to protect the health and safety of women in obtaining lawful abortions. Adherence to notice and hearing requirements is contrary to the public interest for the immediate and critical near term because the timeframe for notice and comment rulemaking create a months' long threat to the public health and safety of women and providers due to the elimination of these established minimum standards.

8. Rule establishes or increases a fee? (See G.S. 12-3.1) Yes

Agency submitted request for consultation on:
 Consultation not required. Cite authority:

 No**9. Rule-making Coordinator: Nadine Pfeiffer**

Phone: 919-855-3811

E-Mail: Nadine.pfeiffer@dhhs.nc.gov

Agency contact, if any: Rajeev Premakumar

Phone: 984-800-1117

E-Mail: raj.premakumar@dhhs.nc.gov

10. Signature of Agency Head*:

DocuSigned by:



* If this function has been delegated (reassigned) pursuant to G.S. 143B-10(a), submit a copy of the delegation with this form.

Typed Name: Mark T. Benton

Title: Chief Deputy Secretary, N.C. DHHS

E-Mail: mark.benton@dhhs.nc.gov

RULES REVIEW COMMISSION USE ONLY

Action taken:

Submitted for RRC Review:

 Date returned to agency:

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.

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

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

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

2

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

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

6

7 *History Note: Authority S.L. 2023-14, s. 2.4;*

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

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

7. Why is adherence to notice and hearing requirements contrary to the public interest and the immediate adoption of the rule is required?

Notice would be contrary to public interest given the repeal of this rule for minimum standards in the regulated clinics. The providers have been operating for years based upon this rule and have not received notice that the rule would be repealed. Unless a temporary rule is adopted, there will be uncertainty about the minimum standards applicable to a clinic and how to operate. The adoption of a temporary rule will ensure continuity of care for patients and resolve uncertainty about the rules applicable to impacted providers beginning July 1st until the Department is able to promulgate permanent rules. The temporary rule will allow the Department to regulate the clinics and hold the clinics to basic standards that are in place to protect the health and safety of women in obtaining lawful abortions. Adherence to notice and hearing requirements is contrary to the public interest for the immediate and critical near term because the timeframe for notice and comment rulemaking create a months' long threat to the public health and safety of women and providers due to the elimination of these established minimum standards.

8. Rule establishes or increases a fee? (See G.S. 12-3.1) Yes

Agency submitted request for consultation on:
 Consultation not required. Cite authority:

 No**9. Rule-making Coordinator: Nadine Pfeiffer**

Phone: 919-855-3811


E-Mail: Nadine.pfeiffer@dhhs.nc.gov

Agency contact, if any: Rajeev Premakumar

Phone: 984-800-1117

E-Mail: raj.premakumar@dhhs.nc.gov

10. Signature of Agency Head*:

DocuSigned by:


* If this function has been delegated (reassigned) pursuant to G.S. 143B-10(a), submit a copy of the delegation with this form.

Typed Name: Mark T. Benton

Title: Chief Deputy Secretary, N.C. DHHS

E-Mail: mark.benton@dhhs.nc.gov

RULES REVIEW COMMISSION USE ONLY

Action taken:

Submitted for RRC Review:

 Date returned to agency:

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.

On line 6, please define "small closet".

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

1 10A NCAC 14E .0211 is adopted under temporary procedures 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. 2.4;*
9 *Emergency Adoption Eff. July 18, ~~2023~~ 2023;*
10 *Temporary Adoption Eff. October 27, 2023.*

7. Why is adherence to notice and hearing requirements contrary to the public interest and the immediate adoption of the rule is required?

Notice would be contrary to public interest given the repeal of this rule for minimum standards in the regulated clinics. The providers have been operating for years based upon this rule and have not received notice that the rule would be repealed. Unless a temporary rule is adopted, there will be uncertainty about the minimum standards applicable to a clinic and how to operate. The adoption of a temporary rule will ensure continuity of care for patients and resolve uncertainty about the rules applicable to impacted providers beginning July 1st until the Department is able to promulgate permanent rules. The temporary rule will allow the Department to regulate the clinics and hold the clinics to basic standards that are in place to protect the health and safety of women in obtaining lawful abortions. Adherence to notice and hearing requirements is contrary to the public interest for the immediate and critical near term because the timeframe for notice and comment rulemaking create a months' long threat to the public health and safety of women and providers due to the elimination of these established minimum standards.

8. Rule establishes or increases a fee? (See G.S. 12-3.1)

- Yes
 Agency submitted request for consultation on:
 Consultation not required. Cite authority:
- No

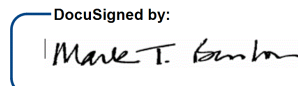
9. Rule-making Coordinator: Nadine Pfeiffer

Phone: 919-855-3811
 E-Mail: Nadine.pfeiffer@dhhs.nc.gov

Agency contact, if any: Rajeev Premakumar

Phone: 984-800-1117
 E-Mail: raj.premakumar@dhhs.nc.gov

10. Signature of Agency Head*:

DocuSigned by:


* If this function has been delegated (reassigned) pursuant to G.S. 143B-10(a), submit a copy of the delegation with this form.

Typed Name: Mark T. Benton
 Title: Chief Deputy Secretary, N.C. DHHS
 E-Mail: mark.benton@dhhs.nc.gov

RULES REVIEW COMMISSION USE ONLY

Action taken:

Submitted for RRC Review:

Date returned to agency:

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.

Does this Rule conflict in any way with the Building Code or with 15A NCAC 18A .1300?

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?

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

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?

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.

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).

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?

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.

In (3)(a), line 32, what does “listed batter backup lighting units” mean? Specifically, I’m asking about “listed”.

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

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

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

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

6 (1) Mechanical requirements.

7 (a) Temperatures and humidities:

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

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

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

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

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

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

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

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

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

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

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

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

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

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.*

7. Why is adherence to notice and hearing requirements contrary to the public interest and the immediate adoption of the rule is required?

Notice would be contrary to public interest given the repeal of this rule for minimum standards in the regulated clinics. The providers have been operating for years based upon this rule and have not received notice that the rule would be repealed. Unless a temporary rule is adopted, there will be uncertainty about the minimum standards applicable to a clinic and how to operate. The adoption of a temporary rule will ensure continuity of care for patients and resolve uncertainty about the rules applicable to impacted providers beginning July 1st until the Department is able to promulgate permanent rules. The temporary rule will allow the Department to regulate the clinics and hold the clinics to basic standards that are in place to protect the health and safety of women in obtaining lawful abortions. Adherence to notice and hearing requirements is contrary to the public interest for the immediate and critical near term because the timeframe for notice and comment rulemaking create a months' long threat to the public health and safety of women and providers due to the elimination of these established minimum standards.

8. Rule establishes or increases a fee? (See G.S. 12-3.1)

- Yes
 Agency submitted request for consultation on:
 Consultation not required. Cite authority:
- No


9. Rule-making Coordinator: Nadine Pfeiffer

Phone: 919-855-3811
 E-Mail: Nadine.pfeiffer@dhhs.nc.gov

Agency contact, if any: Rajeev Premakumar

Phone: 984-800-1117
 E-Mail: raj.premakumar@dhhs.nc.gov

10. Signature of Agency Head*:

DocuSigned by:


* If this function has been delegated (reassigned) pursuant to G.S. 143B-10(a), submit a copy of the delegation with this form.

Typed Name: Mark T. Benton
 Title: Chief Deputy Secretary, N.C. DHHS
 E-Mail: mark.benton@dhhs.nc.gov

RULES REVIEW COMMISSION USE ONLY

Action taken:

Submitted for RRC Review:

Date returned to agency:

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:

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.

Brian Liebman
Commission Counsel
Date submitted to agency: October 6, 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.*



TEMPORARY RULE-MAKING FINDINGS OF NEED

[Authority G.S. 150B-21.1]

OAH USE ONLY

VOLUME:

ISSUE:

1. Rule-Making Agency: N.C. Department of Health and Human Services/Director, DHHSR
2. Rule citation & name: 10A NCAC 14E .0315 HOUSEKEEPING
3. Action: <input type="checkbox"/> Adoption <input checked="" type="checkbox"/> Amendment <input type="checkbox"/> Repeal
4. Was this an Emergency Rule: <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No Effective date: 06/30/23
5. Provide dates for the following actions as applicable: <ul style="list-style-type: none"> a. Proposed Temporary Rule submitted to OAH: 06/20/23 b. Proposed Temporary Rule published on the OAH website: 06/22/23 c. Public Hearing date: 07/19/23 d. Comment Period: 06/28/23 – 07/20/23 e. Notice pursuant to G.S. 150B-21.1(a3)(2): 06/20/23 f. Adoption by agency on: 09/18/23 g. Proposed effective date of temporary rule [if other than effective date established by G.S. 150B- 21.1(b) and G.S. 150B-21.3]: 10/27/23 h. Rule approved by RRC as a permanent rule [See G.S. 150B-21.3(b2)]: n/a
6. Reason for Temporary Action. Attach a copy of any cited law, regulation, or document necessary for the review. <ul style="list-style-type: none"> <input type="checkbox"/> A serious and unforeseen threat to the public health, safety or welfare. <input checked="" type="checkbox"/> The effective date of a recent act of the General Assembly or of the U.S. Congress. Cite: N.C.G.A. SL 2023-14, Part I, s. 1.1 and Part II, s. 2.4 (SB 20) “An Act to Make Various Changes to Health Care Laws and to Appropriate Funds for Health Care Programs” Effective date: 7/1/23 <input type="checkbox"/> A recent change in federal or state budgetary policy. Effective date of change: <input type="checkbox"/> A recent federal regulation. Cite: Effective date: <input type="checkbox"/> A recent court order. Cite order: <input type="checkbox"/> State Medical Facilities Plan. <input type="checkbox"/> Other: <p>Explain: On May 16, 2023, Senate Bill 20 became law as SL 2023-14. This new law entitled “An Act to Make Various Changes to Health Care Laws and to Appropriate Funds for Health Care Programs” revised various state laws governing abortions in North Carolina. The Department was made aware of the proposed changes on May 2, 2023, when a Proposed Conference Committee Substitute was issued that made the changes to the State’s abortion laws. The revisions in Part I and Part 2.4 of the law went into effect on July 1, 2023, less than 2 months after the Department became aware of the proposed changes. Among other changes, S.L. 2023-14 makes significant changes to defining when an abortion is lawful. Current rules governing the certification of abortion clinics are found in Subchapter 14E of Title 10A of the Administrative Code. Given the changes to the law that became effective July 1, emergency rules became effective June 30, 2023. Adoption of temporary rules to amend the existing rules to conform with the provisions of S.L. 2023-14 will ensure continuity of care for patients and resolve any uncertainty about the rules applicable to impacted providers while being critical to protect the health and safety of women in obtaining lawful abortions in a certified abortion clinic. Therefore, the N.C. DHHS is amending Rule 10A NCAC 14E .0315 under temporary procedures.</p>

7. Why is adherence to notice and hearing requirements contrary to the public interest and the immediate adoption of the rule is required? The rules governing the licensing of abortion clinics are found in Subchapter 14E of Title 10A of the Administrative Code. The authority for these rules derived from N.C.G.S. § 14-45.1 that was repealed by Session Law 2023-14, Part 1, Section 1.1, effective July 1, 2023. The General Assembly stated in S.L. 2023-14 that:

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.

These newly enacted provisions provided a mandate for the Department to adopt rules necessary to regulate abortion clinics between July 1, 2023 and October 1, 2023, at which time additional authority for the rulemaking, including those rules governing the licensure of abortion clinics, is granted to the Medical Care Commission, as required by Section 2.2 of S.L. 2023-14. Given the changes to the law that became effective July 1, the Department acted with urgency to make certain amendments to the existing rules to conform with those provisions in S.L. 2023-14 that became effective on July 1st and emergency rules became effective on June 30, 2023. Further, the repeal of existing laws governing abortions in North Carolina, which also was effective July 1, 2023, required the Department to act swiftly in making conforming changes to these rules. The adoption of this temporary rule amendment will ensure continuity of care for patients, resolve any uncertainty about the rule's applicable to impacted providers until the Department is able to promulgate permanent rules, and critically, will protect the health and safety of women in obtaining lawful abortions in a clinic regulated by the Department. Adherence to notice and hearing requirements is contrary to the public interest for the immediate and critical near term because it is not possible to complete notice and comment rulemaking for permanent rulemaking by October 1, 2023.

8. Rule establishes or increases a fee? (See G.S. 12-3.1)

Yes

Agency submitted request for consultation on:
Consultation not required. Cite authority:

No

9. Rule-making Coordinator: Nadine Pfeiffer

Phone: 919-855-3811

E-Mail: Nadine.pfeiffer@dhhs.nc.gov

Agency contact, if any: Rajeev Premakumar

Phone: 984-800-1117

E-Mail: raj.premakumar@dhhs.nc.gov

10. Signature of Agency Head*:

DocuSigned by:

Mark T. Benton

* If this function has been delegated (reassigned) pursuant to G.S. 143B-10(a), submit a copy of the delegation with this form.

Typed Name: Mark T. Benton

Title: Chief Deputy Secretary, N.C. DHHS

E-Mail: mark.benton@dhhs.nc.gov

RULES REVIEW COMMISSION USE ONLY

Action taken:

Submitted for RRC Review:

Date returned to agency:

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.

How is this rule any different than Rule .0202? Both require adherence to the sanitation standards in 15A NCAC 18A .1300.

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

In (1), line 8, what is "waste material"?

In (3), line 11, please define "clean and sanitary condition".

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

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

2

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

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

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

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

18

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

20 *Eff. February 1, 1976;*

21 *Readopted Eff. December 19, 1977;*

22 *Amended Eff. August 1, 2019; October 1, 2015; December 1, 1989;*

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

25 *Codifier determined that agency's findings of need did not meet criteria for emergency rule on June*
26 *22, 2023;*

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

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

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

7. Why is adherence to notice and hearing requirements contrary to the public interest and the immediate adoption of the rule is required?

Notice would be contrary to public interest given the repeal of this rule for minimum standards in the regulated clinics. The providers have been operating for years based upon this rule and have not received notice that the rule would be repealed. Unless a temporary rule is adopted, there will be uncertainty about the minimum standards applicable to a clinic and how to operate. The adoption of a temporary rule will ensure continuity of care for patients and resolve uncertainty about the rules applicable to impacted providers beginning July 1st until the Department is able to promulgate permanent rules. The temporary rule will allow the Department to regulate the clinics and hold the clinics to basic standards that are in place to protect the health and safety of women in obtaining lawful abortions. Adherence to notice and hearing requirements is contrary to the public interest for the immediate and critical near term because the timeframe for notice and comment rulemaking create a months' long threat to the public health and safety of women and providers due to the elimination of these established minimum standards.

8. Rule establishes or increases a fee? (See G.S. 12-3.1)

- Yes
 Agency submitted request for consultation on:
 Consultation not required. Cite authority:
- No


9. Rule-making Coordinator: Nadine Pfeiffer

Phone: 919-855-3811
 E-Mail: Nadine.pfeiffer@dhhs.nc.gov

Agency contact, if any: Rajeev Premakumar

Phone: 984-800-1117
 E-Mail: raj.premakumar@dhhs.nc.gov

10. Signature of Agency Head*:

DocuSigned by:


* If this function has been delegated (reassigned) pursuant to G.S. 143B-10(a), submit a copy of the delegation with this form.

Typed Name: Mark T. Benton
 Title: Chief Deputy Secretary, N.C. DHHS
 E-Mail: mark.benton@dhhs.nc.gov

RULES REVIEW COMMISSION USE ONLY

Action taken:

Submitted for RRC Review:

Date returned to agency:

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:

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.

Brian Liebman
Commission Counsel
Date submitted to agency: October 6, 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.*

7. Why is adherence to notice and hearing requirements contrary to the public interest and the immediate adoption of the rule is required?

Notice would be contrary to public interest given the repeal of this rule for minimum standards in the regulated clinics. The providers have been operating for years based upon this rule and have not received notice that the rule would be repealed. Unless a temporary rule is adopted, there will be uncertainty about the minimum standards applicable to a clinic and how to operate. The adoption of a temporary rule will ensure continuity of care for patients and resolve uncertainty about the rules applicable to impacted providers beginning July 1st until the Department is able to promulgate permanent rules. The temporary rule will allow the Department to regulate the clinics and hold the clinics to basic standards that are in place to protect the health and safety of women in obtaining lawful abortions. Adherence to notice and hearing requirements is contrary to the public interest for the immediate and critical near term because the timeframe for notice and comment rulemaking create a months' long threat to the public health and safety of women and providers due to the elimination of these established minimum standards.

8. Rule establishes or increases a fee? (See G.S. 12-3.1)

- Yes
 Agency submitted request for consultation on:
 Consultation not required. Cite authority:
- No


9. Rule-making Coordinator: Nadine Pfeiffer

Phone: 919-855-3811
 E-Mail: Nadine.pfeiffer@dhhs.nc.gov

Agency contact, if any: Rajeev Premakumar

Phone: 984-800-1117
 E-Mail: raj.premakumar@dhhs.nc.gov

10. Signature of Agency Head*:

DocuSigned by:


* If this function has been delegated (reassigned) pursuant to G.S. 143B-10(a), submit a copy of the delegation with this form.

Typed Name: Mark T. Benton
 Title: Chief Deputy Secretary, N.C. DHHS
 E-Mail: mark.benton@dhhs.nc.gov

RULES REVIEW COMMISSION USE ONLY

Action taken:

Submitted for RRC Review:

Date returned to agency:

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.

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.

Again, to statutory authority, where is your authority to require a governing authority to adopt policies and procedures?

In (a), line 5, to whom would the CEO/designee represent the governing authority?

In (d)(3), line 20, define "professional and safe".

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?

In (e), line 24, omit the comma following "laundry".

In (e), line 25, capitalize "state" if referring only to the State of North Carolina.

In (g), line 29-30, who are "supporting personnel"?

In (g), line 30, please define "safe patient care."

Brian Liebman
Commission Counsel
Date submitted to agency: October 6, 2023

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

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

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

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

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

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

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

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

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

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

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

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

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

31
32 *History Note: Authority G.S. 143B-10; S.L. 2023-14, s. 2.4;*
33 *Emergency Adoption Eff. July 18, 2023. 2023;*
34 *Temporary Adoption Eff. October 27, 2023.*

7. Why is adherence to notice and hearing requirements contrary to the public interest and the immediate adoption of the rule is required?

Notice would be contrary to public interest given the repeal of this rule for minimum standards in the regulated clinics. The providers have been operating for years based upon this rule and have not received notice that the rule would be repealed. Unless a temporary rule is adopted, there will be uncertainty about the minimum standards applicable to a clinic and how to operate. The adoption of a temporary rule will ensure continuity of care for patients and resolve uncertainty about the rules applicable to impacted providers beginning July 1st until the Department is able to promulgate permanent rules. The temporary rule will allow the Department to regulate the clinics and hold the clinics to basic standards that are in place to protect the health and safety of women in obtaining lawful abortions. Adherence to notice and hearing requirements is contrary to the public interest for the immediate and critical near term because the timeframe for notice and comment rulemaking create a months' long threat to the public health and safety of women and providers due to the elimination of these established minimum standards.

8. Rule establishes or increases a fee? (See G.S. 12-3.1) Yes

Agency submitted request for consultation on:
 Consultation not required. Cite authority:

 No**9. Rule-making Coordinator: Nadine Pfeiffer**

Phone: 919-855-3811

E-Mail: Nadine.pfeiffer@dhhs.nc.gov

Agency contact, if any: Rajeev Premakumar

Phone: 984-800-1117

E-Mail: raj.premakumar@dhhs.nc.gov

10. Signature of Agency Head*:

DocuSigned by:



* If this function has been delegated (reassigned) pursuant to G.S. 143B-10(a), submit a copy of the delegation with this form.

Typed Name: Mark T. Benton

Title: Chief Deputy Secretary, N.C. DHHS

E-Mail: mark.benton@dhhs.nc.gov

RULES REVIEW COMMISSION USE ONLY

Action taken:

Submitted for RRC Review:

 Date returned to agency:

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.

Specifically, do you have statutory authority to require documents to be kept on file on the clinic's premises?

In (a)(7), line 12, please define "related to licensure".

In (b), line 13, is this requirement not redundant with Rule .0108?

In (c), line 14, what policies and procedures are you requiring? Is this other than the policies and procedures required elsewhere in these rules?

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

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?

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

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

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

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

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

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

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

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

25
26 *History Note: Authority G.S. 143B-10; S.L. 2023-14, s. 2.4;*
27 *Emergency Adoption Eff. July 18, 2023- 2023;*
28 *Temporary Adoption Eff. October 27, 2023.*

7. Why is adherence to notice and hearing requirements contrary to the public interest and the immediate adoption of the rule is required?

Notice would be contrary to public interest given the repeal of this rule for minimum standards in the regulated clinics. The providers have been operating for years based upon this rule and have not received notice that the rule would be repealed. Unless a temporary rule is adopted, there will be uncertainty about the minimum standards applicable to a clinic and how to operate. The adoption of a temporary rule will ensure continuity of care for patients and resolve uncertainty about the rules applicable to impacted providers beginning July 1st until the Department is able to promulgate permanent rules. The temporary rule will allow the Department to regulate the clinics and hold the clinics to basic standards that are in place to protect the health and safety of women in obtaining lawful abortions. Adherence to notice and hearing requirements is contrary to the public interest for the immediate and critical near term because the timeframe for notice and comment rulemaking create a months' long threat to the public health and safety of women and providers due to the elimination of these established minimum standards.

8. Rule establishes or increases a fee? (See G.S. 12-3.1) Yes

Agency submitted request for consultation on:
 Consultation not required. Cite authority:

 No**9. Rule-making Coordinator: Nadine Pfeiffer**

Phone: 919-855-3811

E-Mail: Nadine.pfeiffer@dhhs.nc.gov

Agency contact, if any: Rajeev Premakumar

Phone: 984-800-1117

E-Mail: raj.premakumar@dhhs.nc.gov

10. Signature of Agency Head*:

DocuSigned by:

Mark T. Benton

6E41EF320AD6440...

* If this function has been delegated (reassigned) pursuant to G.S. 143B-10(a), submit a copy of the delegation with this form.

Typed Name: Mark T. Benton

Title: Chief Deputy Secretary, N.C. DHHS

E-Mail: mark.benton@dhhs.nc.gov

RULES REVIEW COMMISSION USE ONLY

Action taken:

Submitted for RRC Review:

 Date returned to agency:

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.

In (a), line 5, what do you mean by “administrative decisions on their disposition”?

In (c), line 8, what is a “general” hospital? Is this different than the definition of “hospital” in the statute?

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

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

1 10A NCAC 14E .0320 is adopted under temporary procedures 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.

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.

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) and hospital admitting privileges, if any. In the absence of
14 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. 2.4;*

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

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

7. Why is adherence to notice and hearing requirements contrary to the public interest and the immediate adoption of the rule is required?

Notice would be contrary to public interest given the repeal of this rule for minimum standards in the regulated clinics. The providers have been operating for years based upon this rule and have not received notice that the rule would be repealed. Unless a temporary rule is adopted, there will be uncertainty about the minimum standards applicable to a clinic and how to operate. The adoption of a temporary rule will ensure continuity of care for patients and resolve uncertainty about the rules applicable to impacted providers beginning July 1st until the Department is able to promulgate permanent rules. The temporary rule will allow the Department to regulate the clinics and hold the clinics to basic standards that are in place to protect the health and safety of women in obtaining lawful abortions. Adherence to notice and hearing requirements is contrary to the public interest for the immediate and critical near term because the timeframe for notice and comment rulemaking create a months' long threat to the public health and safety of women and providers due to the elimination of these established minimum standards.

8. Rule establishes or increases a fee? (See G.S. 12-3.1) Yes

Agency submitted request for consultation on:
 Consultation not required. Cite authority:

 No**9. Rule-making Coordinator: Nadine Pfeiffer**

Phone: 919-855-3811

E-Mail: Nadine.pfeiffer@dhhs.nc.gov


Agency contact, if any: Rajeev Premakumar

Phone: 984-800-1117

E-Mail: raj.premakumar@dhhs.nc.gov

10. Signature of Agency Head*:

DocuSigned by:



* If this function has been delegated (reassigned) pursuant to G.S. 143B-10(a), submit a copy of the delegation with this form.

Typed Name: Mark T. Benton

Title: Chief Deputy Secretary, N.C. DHHS

E-Mail: mark.benton@dhhs.nc.gov

RULES REVIEW COMMISSION USE ONLY

Action taken:

Submitted for RRC Review:

 Date returned to agency:

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.

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.

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

In (a)(10), line 16, please define "have a bearing on".

In (b), line 20, should "report" be plural?

In (b), line 22, who shall sign to authenticate?

In (c), line 23, who shall explain the significance?

In (d), line 25, who shall perform the ultrasound?

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

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

In (e)(6), line 34, do you mean the time the procedure started, or the duration? Both?

In (f), line 35, do you have statutory authority to require that records be preserved in the state?

In (f), p.2, line 2, would a patient's request for records be sufficient to remove the records?

Brian Liebman
Commission Counsel
Date submitted to agency: October 6, 2023

In (h), line 5, arrangements shall be made by whom?

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

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

2

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

4 (a) A complete and permanent record shall be maintained for all patients including:

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

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

7 (3) the patient's address;

8 (4) the patient's date of birth;

9 (5) the patient's emergency contact information;

10 (6) the patient's diagnoses;

11 (7) the patient's duration of pregnancy;

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

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

15 (10) the patient's history and physical examination including identification of pre-existing or current
 16 illnesses, drug sensitivities or other idiosyncrasies having a bearing on the procedure or anesthetic
 17 to be administered; and

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

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

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

25 (d) An ultrasound examination shall be performed and the results, including gestational age, placed in the patient's
 26 medical record for any patient who is scheduled for an abortion procedure.

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

29 (1) the patient name;

30 (2) the estimated length of gestation;

31 (3) the type of procedure;

32 (4) the name of physician;

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

34 (6) the date and time of procedure.

35 (f) Medical records shall be the property of the clinic and shall be preserved or retained in the State of North Carolina
 36 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
 37 case the record must be retained until three years after the client's 18th birthday, regardless of change of clinic

1 ownership or administration. Such medical records shall be made available to the Division upon request and shall not
2 be removed from the premises where they are retained except by subpoena or court order.

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

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

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.*



TEMPORARY RULE-MAKING FINDINGS OF NEED

[Authority G.S. 150B-21.1]

OAH USE ONLY

VOLUME:

ISSUE:

1. Rule-Making Agency: N.C. Department of Health and Human Services/Director, DHHSR
2. Rule citation & name: 10A NCAC 14E .0322 PERSONNEL RECORDS
3. Action: <input checked="" type="checkbox"/> Adoption <input type="checkbox"/> Amendment <input type="checkbox"/> Repeal
4. Was this an Emergency Rule: <input checked="" type="checkbox"/> Yes Effective date: 07/18/23 <input type="checkbox"/> No
5. Provide dates for the following actions as applicable: a. Proposed Temporary Rule submitted to OAH: 07/06/23 b. Proposed Temporary Rule published on the OAH website: 07/12/23 c. Public Hearing date: 07/27/23 d. Comment Period: 07/14/23 – 08/04/23 e. Notice pursuant to G.S. 150B-21.1(a3)(2): 07/06/23 f. Adoption by agency on: 09/18/23 g. Proposed effective date of temporary rule [if other than effective date established by G.S. 150B- 21.1(b) and G.S. 150B-21.3]: 10/27/23 h. Rule approved by RRC as a permanent rule [See G.S. 150B-21.3(b2)]: n/a
6. Reason for Temporary Action. Attach a copy of any cited law, regulation, or document necessary for the review. <input checked="" type="checkbox"/> A serious and unforeseen threat to the public health, safety or welfare. <input checked="" type="checkbox"/> The effective date of a recent act of the General Assembly or of the U.S. Congress. Cite: N.C.G.A. SL 2023-14, Part I, s. 1.1 and Part II, s. 2.4 (SB 20) “An Act to Make Various Changes to Health Care Laws and to Appropriate Funds for Health Care Programs” Effective date: 7/1/23 <input type="checkbox"/> A recent change in federal or state budgetary policy. Effective date of change: <input type="checkbox"/> A recent federal regulation. Cite: Effective date: <input type="checkbox"/> A recent court order. Cite order: <input type="checkbox"/> State Medical Facilities Plan. <input type="checkbox"/> Other:
Explain: On June 30, 2023, the Codifier of Rules notified N.C. DHHS that, “Pursuant to G.S. 150B-21.7, all permanent rules in 10A NCAC 14E are repealed effective July 1, 2023 following the repeal of G.S. 14-45.1 in Session Law 2023-14.” The repeal of these rules occurred following a submission by the Department requesting the Codifier amend the history note of the rules to reflect the change in statutory authority from G.S. 14-45.1 to Session Law 2023-14, Part II, Section 2.4. The Department’s rulemaking authority under both laws directs the Department to regulate facilities suitable for the performance of abortions through ensuring that minimum health and safety standards are implemented and adhered to by the facilities performing abortions and providing other reproductive health services. Specifically, the General Assembly states that enforcement of these basic standards are to ensure safe and adequate treatment of individuals in abortion clinics. The rules repealed effective July 1, 2023 contain current minimum standards for nursing services, laboratory services, emergency back-up services, surgical services, medications and anesthesia, post-operative care, staff qualifications and basic standards for building codes, sanitation, and record keeping. Following the repeal of the rules, emergency rule adoptions became effective July 18, 2023. The rule repeals represent a serious and unforeseen threat to public health and safety of those seeking reproductive health care and to the operation of facilities providing this care, and therefore, the N.C. DHHS is adopting Rule 10A NCAC 14E .0322 under temporary procedures.

7. Why is adherence to notice and hearing requirements contrary to the public interest and the immediate adoption of the rule is required?

Notice would be contrary to public interest given the repeal of this rule for minimum standards in the regulated clinics. The providers have been operating for years based upon this rule and have not received notice that the rule would be repealed. Unless a temporary rule is adopted, there will be uncertainty about the minimum standards applicable to a clinic and how to operate. The adoption of a temporary rule will ensure continuity of care for patients and resolve uncertainty about the rules applicable to impacted providers beginning July 1st until the Department is able to promulgate permanent rules. The temporary rule will allow the Department to regulate the clinics and hold the clinics to basic standards that are in place to protect the health and safety of women in obtaining lawful abortions. Adherence to notice and hearing requirements is contrary to the public interest for the immediate and critical near term because the timeframe for notice and comment rulemaking create a months' long threat to the public health and safety of women and providers due to the elimination of these established minimum standards.

8. Rule establishes or increases a fee? (See G.S. 12-3.1)

- Yes
Agency submitted request for consultation on:
Consultation not required. Cite authority:
- No

9. Rule-making Coordinator: Nadine Pfeiffer

Phone: 919-855-3811


E-Mail: Nadine.pfeiffer@dhhs.nc.gov

Agency contact, if any: Rajeev Premakumar

Phone: 984-800-1117

E-Mail: raj.premakumar@dhhs.nc.gov

10. Signature of Agency Head*:

DocuSigned by:


* If this function has been delegated (reassigned) pursuant to G.S. 143B-10(a), submit a copy of the delegation with this form.

Typed Name: Mark T. Benton

Title: Chief Deputy Secretary, N.C. DHHS

E-Mail: mark.benton@dhhs.nc.gov

RULES REVIEW COMMISSION USE ONLY

Action taken:

Submitted for RRC Review:

 Date returned to agency:

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.

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

In (a)(1)(D) and (E), what are you requiring by “verification”?

In (a)(3), line 13, do you have statutory authority for this provision? Are not personnel records otherwise confidential under the law?

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.

In (f), line 29, are these health records not confidential under State and federal law?

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

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

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

4 (a) Personnel Records:

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

6 (A) employee's identification;

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

8 (C) resume of education and work experience;

9 (D) verification of valid license (if required), education, training, and prior employment
10 experience; and

11 (E) verification of references.

12 (2) Personnel records shall be confidential.

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

15 (b) Job Descriptions:

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

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

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

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

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

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

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

30
31 *History Note: Authority G.S. 143B-10; S.L. 2023-14, s. 2.4;*

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

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



TEMPORARY RULE-MAKING FINDINGS OF NEED

[Authority G.S. 150B-21.1]

OAH USE ONLY

VOLUME:

ISSUE:

1. Rule-Making Agency: N.C. Department of Health and Human Services/Director, DHHSR
2. Rule citation & name: 10A NCAC 14E .0323 NURSING SERVICE
3. Action: <input checked="" type="checkbox"/> Adoption <input type="checkbox"/> Amendment <input type="checkbox"/> Repeal
4. Was this an Emergency Rule: <input checked="" type="checkbox"/> Yes Effective date: 07/18/23 <input type="checkbox"/> No
5. Provide dates for the following actions as applicable: a. Proposed Temporary Rule submitted to OAH: 07/06/23 b. Proposed Temporary Rule published on the OAH website: 07/12/23 c. Public Hearing date: 07/27/23 d. Comment Period: 07/14/23 – 08/04/23 e. Notice pursuant to G.S. 150B-21.1(a3)(2): 07/06/23 f. Adoption by agency on: 09/18/23 g. Proposed effective date of temporary rule [if other than effective date established by G.S. 150B- 21.1(b) and G.S. 150B-21.3]: 10/27/23 h. Rule approved by RRC as a permanent rule [See G.S. 150B-21.3(b2)]: n/a
6. Reason for Temporary Action. Attach a copy of any cited law, regulation, or document necessary for the review. <input checked="" type="checkbox"/> A serious and unforeseen threat to the public health, safety or welfare. <input checked="" type="checkbox"/> The effective date of a recent act of the General Assembly or of the U.S. Congress. Cite: N.C.G.A. SL 2023-14, Part I, s. 1.1 and Part II, s. 2.4 (SB 20) “An Act to Make Various Changes to Health Care Laws and to Appropriate Funds for Health Care Programs” Effective date: 7/1/23 <input type="checkbox"/> A recent change in federal or state budgetary policy. Effective date of change: <input type="checkbox"/> A recent federal regulation. Cite: Effective date: <input type="checkbox"/> A recent court order. Cite order: <input type="checkbox"/> State Medical Facilities Plan. <input type="checkbox"/> Other:
Explain: On June 30, 2023, the Codifier of Rules notified N.C. DHHS that, “Pursuant to G.S. 150B-21.7, all permanent rules in 10A NCAC 14E are repealed effective July 1, 2023 following the repeal of G.S. 14-45.1 in Session Law 2023-14.” The repeal of these rules occurred following a submission by the Department requesting the Codifier amend the history note of the rules to reflect the change in statutory authority from G.S. 14-45.1 to Session Law 2023-14, Part II, Section 2.4. The Department’s rulemaking authority under both laws directs the Department to regulate facilities suitable for the performance of abortions through ensuring that minimum health and safety standards are implemented and adhered to by the facilities performing abortions and providing other reproductive health services. Specifically, the General Assembly states that enforcement of these basic standards are to ensure safe and adequate treatment of individuals in abortion clinics. The rules repealed effective July 1, 2023 contain current minimum standards for nursing services, laboratory services, emergency back-up services, surgical services, medications and anesthesia, post-operative care, staff qualifications and basic standards for building codes, sanitation, and record keeping. Following the repeal of the rules, emergency rule adoptions became effective July 18, 2023. The rule repeals represent a serious and unforeseen threat to public health and safety of those seeking reproductive health care and to the operation of facilities providing this care, and therefore, the N.C. DHHS is adopting Rule 10A NCAC 14E .0323 under temporary procedures.

7. Why is adherence to notice and hearing requirements contrary to the public interest and the immediate adoption of the rule is required?

Notice would be contrary to public interest given the repeal of this rule for minimum standards in the regulated clinics. The providers have been operating for years based upon this rule and have not received notice that the rule would be repealed. Unless a temporary rule is adopted, there will be uncertainty about the minimum standards applicable to a clinic and how to operate. The adoption of a temporary rule will ensure continuity of care for patients and resolve uncertainty about the rules applicable to impacted providers beginning July 1st until the Department is able to promulgate permanent rules. The temporary rule will allow the Department to regulate the clinics and hold the clinics to basic standards that are in place to protect the health and safety of women in obtaining lawful abortions. Adherence to notice and hearing requirements is contrary to the public interest for the immediate and critical near term because the timeframe for notice and comment rulemaking create a months' long threat to the public health and safety of women and providers due to the elimination of these established minimum standards.

8. Rule establishes or increases a fee? (See G.S. 12-3.1) Yes

Agency submitted request for consultation on:
 Consultation not required. Cite authority:

 No**9. Rule-making Coordinator: Nadine Pfeiffer**

Phone: 919-855-3811


E-Mail: Nadine.pfeiffer@dhhs.nc.gov

Agency contact, if any: Rajeev Premakumar

Phone: 984-800-1117

E-Mail: raj.premakumar@dhhs.nc.gov

10. Signature of Agency Head*:

DocuSigned by:


* If this function has been delegated (reassigned) pursuant to G.S. 143B-10(a), submit a copy of the delegation with this form.

Typed Name: Mark T. Benton

Title: Chief Deputy Secretary, N.C. DHHS

E-Mail: mark.benton@dhhs.nc.gov

RULES REVIEW COMMISSION USE ONLY

Action taken:

Submitted for RRC Review:

 Date returned to agency:

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.

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.

In (a), line 5 and (b), line 6, please define "responsibility and accountability" and "responsible and accountable".

In (b)(2), line 8, what manual? Is this required in another rule?

In (c), lines 10-11, who makes the judgment that there are sufficient personnel on staff?

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

1 10A NCAC 14E .0323 is adopted under temporary procedures 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 be responsible and accountable to the chief executive officer or designee for:

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

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

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

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

15

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

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

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

7. Why is adherence to notice and hearing requirements contrary to the public interest and the immediate adoption of the rule is required?

Notice would be contrary to public interest given the repeal of this rule for minimum standards in the regulated clinics. The providers have been operating for years based upon this rule and have not received notice that the rule would be repealed. Unless a temporary rule is adopted, there will be uncertainty about the minimum standards applicable to a clinic and how to operate. The adoption of a temporary rule will ensure continuity of care for patients and resolve uncertainty about the rules applicable to impacted providers beginning July 1st until the Department is able to promulgate permanent rules. The temporary rule will allow the Department to regulate the clinics and hold the clinics to basic standards that are in place to protect the health and safety of women in obtaining lawful abortions. Adherence to notice and hearing requirements is contrary to the public interest for the immediate and critical near term because the timeframe for notice and comment rulemaking create a months' long threat to the public health and safety of women and providers due to the elimination of these established minimum standards.

8. Rule establishes or increases a fee? (See G.S. 12-3.1) Yes

Agency submitted request for consultation on:
 Consultation not required. Cite authority:

 No**9. Rule-making Coordinator: Nadine Pfeiffer**

Phone: 919-855-3811

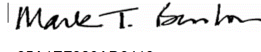
E-Mail: Nadine.pfeiffer@dhhs.nc.gov

Agency contact, if any: Rajeev Premakumar

Phone: 984-800-1117

E-Mail: raj.premakumar@dhhs.nc.gov

10. Signature of Agency Head*:

DocuSigned by:


* If this function has been delegated (reassigned) pursuant to G.S. 143B-10(a), submit a copy of the delegation with this form.

Typed Name: Mark T. Benton

Title: Chief Deputy Secretary, N.C. DHHS

E-Mail: mark.benton@dhhs.nc.gov

RULES REVIEW COMMISSION USE ONLY

Action taken:

Submitted for RRC Review:

 Date returned to agency:

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.

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?

In (b), line 7, "corrective action" for what?

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?

In (c), line 9, what are "other health professionals"?

In (f), line 19, who shall conduct these programs? Please use the 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

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

2

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

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

7 (b) The committee shall determine corrective action, if necessary.

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

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

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

15 (1) reports made to the governing authority;

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

18 (3) information on any corrective action taken.

19 (f) Orientation, training, or education programs shall be conducted to correct deficiencies that are uncovered as a
20 result of the quality assurance program.

21

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

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

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

7. Why is adherence to notice and hearing requirements contrary to the public interest and the immediate adoption of the rule is required?

Notice would be contrary to public interest given the repeal of this rule for minimum standards in the regulated clinics. The providers have been operating for years based upon this rule and have not received notice that the rule would be repealed. Unless a temporary rule is adopted, there will be uncertainty about the minimum standards applicable to a clinic and how to operate. The adoption of a temporary rule will ensure continuity of care for patients and resolve uncertainty about the rules applicable to impacted providers beginning July 1st until the Department is able to promulgate permanent rules. The temporary rule will allow the Department to regulate the clinics and hold the clinics to basic standards that are in place to protect the health and safety of women in obtaining lawful abortions. Adherence to notice and hearing requirements is contrary to the public interest for the immediate and critical near term because the timeframe for notice and comment rulemaking create a months' long threat to the public health and safety of women and providers due to the elimination of these established minimum standards.

8. Rule establishes or increases a fee? (See G.S. 12-3.1)

- Yes
 Agency submitted request for consultation on:
 Consultation not required. Cite authority:
- No

9. Rule-making Coordinator: Nadine Pfeiffer

Phone: 919-855-3811
 E-Mail: Nadine.pfeiffer@dhhs.nc.gov

Agency contact, if any: Rajeev Premakumar

Phone: 984-800-1117
 E-Mail: raj.premakumar@dhhs.nc.gov

10. Signature of Agency Head*:

DocuSigned by:


* If this function has been delegated (reassigned) pursuant to G.S. 143B-10(a), submit a copy of the delegation with this form.

Typed Name: Mark T. Benton
 Title: Chief Deputy Secretary, N.C. DHHS
 E-Mail: mark.benton@dhhs.nc.gov

RULES REVIEW COMMISSION USE ONLY

Action taken:

Submitted for RRC Review:

Date returned to agency:

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.

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?

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?

In (b), line 7, what do you mean by “those types of specimens”? What specimens?

In (e), lines 15-16, are you allowing that the lab tests may be performed by any “employee” who has access to the manual?

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

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

2

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

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

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

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

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

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

13 (3) Rh factor testing.

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

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

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

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

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

20

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

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

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

7. Why is adherence to notice and hearing requirements contrary to the public interest and the immediate adoption of the rule is required?

Notice would be contrary to public interest given the repeal of this rule for minimum standards in the regulated clinics. The providers have been operating for years based upon this rule and have not received notice that the rule would be repealed. Unless a temporary rule is adopted, there will be uncertainty about the minimum standards applicable to a clinic and how to operate. The adoption of a temporary rule will ensure continuity of care for patients and resolve uncertainty about the rules applicable to impacted providers beginning July 1st until the Department is able to promulgate permanent rules. The temporary rule will allow the Department to regulate the clinics and hold the clinics to basic standards that are in place to protect the health and safety of women in obtaining lawful abortions. Adherence to notice and hearing requirements is contrary to the public interest for the immediate and critical near term because the timeframe for notice and comment rulemaking create a months' long threat to the public health and safety of women and providers due to the elimination of these established minimum standards.

8. Rule establishes or increases a fee? (See G.S. 12-3.1) Yes

Agency submitted request for consultation on:
 Consultation not required. Cite authority:

 No**9. Rule-making Coordinator: Nadine Pfeiffer**

Phone: 919-855-3811

E-Mail: Nadine.pfeiffer@dhhs.nc.gov

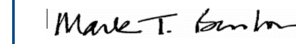
Agency contact, if any: Rajeev Premakumar

Phone: 984-800-1117

E-Mail: raj.premakumar@dhhs.nc.gov

10. Signature of Agency Head*:

DocuSigned by:



* If this function has been delegated (reassigned) pursuant to G.S. 143B-10(a), submit a copy of the delegation with this form.

Typed Name: Mark T. Benton

Title: Chief Deputy Secretary, N.C. DHHS

E-Mail: mark.benton@dhhs.nc.gov

RULES REVIEW COMMISSION USE ONLY

Action taken:

Submitted for RRC Review:

 Date returned to agency:

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.

In (a), line 4, what is the definition of an "emergency case"?

In (a), line 4, define "nearby".

In (a), line 5, when is hospitalization necessary?

In (b), line 6, how can a clinic "have" a procedure? Consider rephrasing.

In (b), line 6, define "suitable equipment".

In (b), line 6, again, please define "medical emergencies".

In (c), line 9, what kind of "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

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

2

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

4 (a) Each clinic shall have a written plan for the transfer of emergency cases from the clinic to a nearby hospital when
5 hospitalization becomes necessary.

6 (b) The clinic shall have procedures, personnel, and suitable equipment to handle medical emergencies which may
7 arise in connection with services provided by the clinic.

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

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

13 (1) basic cardio-pulmonary life support;

14 (2) emergency protocols for:

15 (A) administration of intravenous fluids;

16 (B) establishing and maintaining airway support;

17 (C) oxygen administration;

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

19 (E) utilizing a suction machine; and

20 (F) utilizing an automated external defibrillator;

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

23 (4) ultrasound equipment.

24

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

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

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



TEMPORARY RULE-MAKING FINDINGS OF NEED

[Authority G.S. 150B-21.1]

OAH USE ONLY

VOLUME:

ISSUE:

<p>1. Rule-Making Agency: N.C. Department of Health and Human Services/Director, DHSR</p>
<p>2. Rule citation & name: 10A NCAC 14E .0327 SURGICAL SERVICES</p>
<p>3. Action: <input checked="" type="checkbox"/> Adoption <input type="checkbox"/> Amendment <input type="checkbox"/> Repeal</p>
<p>4. Was this an Emergency Rule: <input checked="" type="checkbox"/> Yes Effective date: 07/18/23 <input type="checkbox"/> No</p>
<p>5. Provide dates for the following actions as applicable:</p> <p>a. Proposed Temporary Rule submitted to OAH: 07/06/23</p> <p>b. Proposed Temporary Rule published on the OAH website: 07/12/23</p> <p>c. Public Hearing date: 07/27/23</p> <p>d. Comment Period: 07/14/23 – 08/04/23</p> <p>e. Notice pursuant to G.S. 150B-21.1(a3)(2): 07/06/23</p> <p>f. Adoption by agency on: 09/18/23</p> <p>g. Proposed effective date of temporary rule [if other than effective date established by G.S. 150B- 21.1(b) and G.S. 150B-21.3]: 10/27/23</p> <p>h. Rule approved by RRC as a permanent rule [See G.S. 150B-21.3(b2)]: n/a</p>
<p>6. Reason for Temporary Action. Attach a copy of any cited law, regulation, or document necessary for the review.</p> <p><input checked="" type="checkbox"/> A serious and unforeseen threat to the public health, safety or welfare.</p> <p><input checked="" type="checkbox"/> The effective date of a recent act of the General Assembly or of the U.S. Congress. Cite: N.C.G.A. SL 2023-14, Part I, s. 1.1 and Part II, s. 2.4 (SB 20) “An Act to Make Various Changes to Health Care Laws and to Appropriate Funds for Health Care Programs” Effective date: 7/1/23</p> <p><input type="checkbox"/> A recent change in federal or state budgetary policy. Effective date of change:</p> <p><input type="checkbox"/> A recent federal regulation. Cite: Effective date:</p> <p><input type="checkbox"/> A recent court order. Cite order:</p> <p><input type="checkbox"/> State Medical Facilities Plan.</p> <p><input type="checkbox"/> Other:</p> <p>Explain: On June 30, 2023, the Codifier of Rules notified N.C. DHHS that, “Pursuant to G.S. 150B-21.7, all permanent rules in 10A NCAC 14E are repealed effective July 1, 2023 following the repeal of G.S. 14-45.1 in Session Law 2023-14.” The repeal of these rules occurred following a submission by the Department requesting the Codifier amend the history note of the rules to reflect the change in statutory authority from G.S. 14-45.1 to Session Law 2023-14, Part II, Section 2.4. The Department’s rulemaking authority under both laws directs the Department to regulate facilities suitable for the performance of abortions through ensuring that minimum health and safety standards are implemented and adhered to by the facilities performing abortions and providing other reproductive health services. Specifically, the General Assembly states that enforcement of these basic standards are to ensure safe and adequate treatment of individuals in abortion clinics. The rules repealed effective July 1, 2023 contain current minimum standards for nursing services, laboratory services, emergency back-up services, surgical services, medications and anesthesia, post-operative care, staff qualifications and basic standards for building codes, sanitation, and record keeping. Following the repeal of the rules, emergency rule adoptions became effective July 18, 2023. The rule repeals represent a serious and unforeseen threat to public health and safety of those seeking reproductive health care and to the operation of facilities providing this care, and therefore, the N.C. DHHS is adopting Rule 10A NCAC 14E .0327 under temporary procedures.</p>

7. Why is adherence to notice and hearing requirements contrary to the public interest and the immediate adoption of the rule is required?

Notice would be contrary to public interest given the repeal of this rule for minimum standards in the regulated clinics. The providers have been operating for years based upon this rule and have not received notice that the rule would be repealed. Unless a temporary rule is adopted, there will be uncertainty about the minimum standards applicable to a clinic and how to operate. The adoption of a temporary rule will ensure continuity of care for patients and resolve uncertainty about the rules applicable to impacted providers beginning July 1st until the Department is able to promulgate permanent rules. The temporary rule will allow the Department to regulate the clinics and hold the clinics to basic standards that are in place to protect the health and safety of women in obtaining lawful abortions. Adherence to notice and hearing requirements is contrary to the public interest for the immediate and critical near term because the timeframe for notice and comment rulemaking create a months' long threat to the public health and safety of women and providers due to the elimination of these established minimum standards.

8. Rule establishes or increases a fee? (See G.S. 12-3.1)

- Yes
 Agency submitted request for consultation on:
 Consultation not required. Cite authority:
- No

9. Rule-making Coordinator: Nadine Pfeiffer

Phone: 919-855-3811
 E-Mail: Nadine.pfeiffer@dhhs.nc.gov

Agency contact, if any: Rajeev Premakumar

Phone: 984-800-1117
 E-Mail: raj.premakumar@dhhs.nc.gov

10. Signature of Agency Head*:

DocuSigned by:


* If this function has been delegated (reassigned) pursuant to G.S. 143B-10(a), submit a copy of the delegation with this form.

Typed Name: Mark T. Benton
 Title: Chief Deputy Secretary, N.C. DHHS
 E-Mail: mark.benton@dhhs.nc.gov

RULES REVIEW COMMISSION USE ONLY

Action taken:

Submitted for RRC Review:

Date returned to agency:

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.

In (a), line 5, please define an "atmosphere free of contamination".

In (a), line 6, are there not standard procedures for infection control and universal precautions?

In (b)(2), line 12, add a comma following "pregnancy".

In (b)(2), line 12-13, the grammar of the sentence seems off, particularly on line 13. Please consider revising.

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

1 10A NCAC 14E .0327 is adopted under temporary procedures 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 atmosphere free of contamination by pathogenic organisms. The clinic shall establish
6 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, ectopic pregnancy or an incomplete
13 procedure shall be considered and evaluated by the physician performing the procedure.

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

15

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

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

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

7. Why is adherence to notice and hearing requirements contrary to the public interest and the immediate adoption of the rule is required?

Notice would be contrary to public interest given the repeal of this rule for minimum standards in the regulated clinics. The providers have been operating for years based upon this rule and have not received notice that the rule would be repealed. Unless a temporary rule is adopted, there will be uncertainty about the minimum standards applicable to a clinic and how to operate. The adoption of a temporary rule will ensure continuity of care for patients and resolve uncertainty about the rules applicable to impacted providers beginning July 1st until the Department is able to promulgate permanent rules. The temporary rule will allow the Department to regulate the clinics and hold the clinics to basic standards that are in place to protect the health and safety of women in obtaining lawful abortions. Adherence to notice and hearing requirements is contrary to the public interest for the immediate and critical near term because the timeframe for notice and comment rulemaking create a months' long threat to the public health and safety of women and providers due to the elimination of these established minimum standards.

8. Rule establishes or increases a fee? (See G.S. 12-3.1)

Yes
Agency submitted request for consultation on:
Consultation not required. Cite authority:

No

9. Rule-making Coordinator: Nadine Pfeiffer

Phone: 919-855-3811

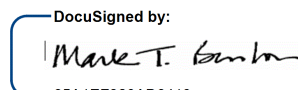
E-Mail: Nadine.pfeiffer@dhhs.nc.gov

Agency contact, if any: Rajeev Premakumar

Phone: 984-800-1117

E-Mail: raj.premakumar@dhhs.nc.gov

10. Signature of Agency Head*:

DocuSigned by:


* If this function has been delegated (reassigned) pursuant to G.S. 143B-10(a), submit a copy of the delegation with this form.

Typed Name: Mark T. Benton

Title: Chief Deputy Secretary, N.C. DHHS

E-Mail: mark.benton@dhhs.nc.gov

RULES REVIEW COMMISSION USE ONLY

Action taken:

Submitted for RRC Review:

Date returned to agency:

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.

In (b), line 5, may a physician administer medications directly, or must he or she allow an RN to do it?

In (c), line 7, please define "direct supervision"?

In (c), line 7, may anesthesia be administered by any licensed physician, or an anesthesiologist?

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

1 10A NCAC 14E .0328 is adopted under temporary procedures 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 Registered Nurse licensed in accordance with G.S. 90-171.30 or G.S.
6 90-171.32 and must be recorded in the patient's permanent record.

7 (c) The anesthesia shall be administered only under the direct supervision of a licensed physician.

8

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

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

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



TEMPORARY RULE-MAKING FINDINGS OF NEED

[Authority G.S. 150B-21.1]

OAH USE ONLY

VOLUME:

ISSUE:

1. Rule-Making Agency: N.C. Department of Health and Human Services/Director, DHHSR
2. Rule citation & name: 10A NCAC 14E .0329 POST-OPERATIVE CARE
3. Action: <input checked="" type="checkbox"/> Adoption <input type="checkbox"/> Amendment <input type="checkbox"/> Repeal
4. Was this an Emergency Rule: <input checked="" type="checkbox"/> Yes Effective date: 07/18/23 <input type="checkbox"/> No
5. Provide dates for the following actions as applicable: a. Proposed Temporary Rule submitted to OAH: 07/06/23 b. Proposed Temporary Rule published on the OAH website: 07/12/23 c. Public Hearing date: 07/27/23 d. Comment Period: 07/14/23 – 08/04/23 e. Notice pursuant to G.S. 150B-21.1(a3)(2): 07/06/23 f. Adoption by agency on: 09/18/23 g. Proposed effective date of temporary rule [if other than effective date established by G.S. 150B- 21.1(b) and G.S. 150B-21.3]: 10/27/23 h. Rule approved by RRC as a permanent rule [See G.S. 150B-21.3(b2)]: n/a
6. Reason for Temporary Action. Attach a copy of any cited law, regulation, or document necessary for the review. <input checked="" type="checkbox"/> A serious and unforeseen threat to the public health, safety or welfare. <input checked="" type="checkbox"/> The effective date of a recent act of the General Assembly or of the U.S. Congress. Cite: N.C.G.A. SL 2023-14, Part I, s. 1.1 and Part II, s. 2.4 (SB 20) "An Act to Make Various Changes to Health Care Laws and to Appropriate Funds for Health Care Programs" Effective date: 7/1/23 <input type="checkbox"/> A recent change in federal or state budgetary policy. Effective date of change: <input type="checkbox"/> A recent federal regulation. Cite: Effective date: <input type="checkbox"/> A recent court order. Cite order: <input type="checkbox"/> State Medical Facilities Plan. <input type="checkbox"/> Other:
Explain: On June 30, 2023, the Codifier of Rules notified N.C. DHHS that, "Pursuant to G.S. 150B-21.7, all permanent rules in 10A NCAC 14E are repealed effective July 1, 2023 following the repeal of G.S. 14-45.1 in Session Law 2023-14." The repeal of these rules occurred following a submission by the Department requesting the Codifier amend the history note of the rules to reflect the change in statutory authority from G.S. 14-45.1 to Session Law 2023-14, Part II, Section 2.4. The Department's rulemaking authority under both laws directs the Department to regulate facilities suitable for the performance of abortions through ensuring that minimum health and safety standards are implemented and adhered to by the facilities performing abortions and providing other reproductive health services. Specifically, the General Assembly states that enforcement of these basic standards are to ensure safe and adequate treatment of individuals in abortion clinics. The rules repealed effective July 1, 2023 contain current minimum standards for nursing services, laboratory services, emergency back-up services, surgical services, medications and anesthesia, post-operative care, staff qualifications and basic standards for building codes, sanitation, and record keeping. Following the repeal of the rules, emergency rule adoptions became effective July 18, 2023. The rule repeals represent a serious and unforeseen threat to public health and safety of those seeking reproductive health care and to the operation of facilities providing this care, and therefore, the N.C. DHHS is adopting Rule 10A NCAC 14E .0329 under temporary procedures.

7. Why is adherence to notice and hearing requirements contrary to the public interest and the immediate adoption of the rule is required?

Notice would be contrary to public interest given the repeal of this rule for minimum standards in the regulated clinics. The providers have been operating for years based upon this rule and have not received notice that the rule would be repealed. Unless a temporary rule is adopted, there will be uncertainty about the minimum standards applicable to a clinic and how to operate. The adoption of a temporary rule will ensure continuity of care for patients and resolve uncertainty about the rules applicable to impacted providers beginning July 1st until the Department is able to promulgate permanent rules. The temporary rule will allow the Department to regulate the clinics and hold the clinics to basic standards that are in place to protect the health and safety of women in obtaining lawful abortions. Adherence to notice and hearing requirements is contrary to the public interest for the immediate and critical near term because the timeframe for notice and comment rulemaking create a months' long threat to the public health and safety of women and providers due to the elimination of these established minimum standards.

8. Rule establishes or increases a fee? (See G.S. 12-3.1) Yes

Agency submitted request for consultation on:
 Consultation not required. Cite authority:

 No**9. Rule-making Coordinator: Nadine Pfeiffer**

Phone: 919-855-3811

E-Mail: Nadine.pfeiffer@dhhs.nc.gov

Agency contact, if any: Rajeev Premakumar

Phone: 984-800-1117

E-Mail: raj.premakumar@dhhs.nc.gov

10. Signature of Agency Head*:

DocuSigned by:

Mark T. Benton

* If this function has been delegated (reassigned) pursuant to G.S. 143B-10(a), submit a copy of the delegation with this form.

Typed Name: Mark T. Benton

Title: Chief Deputy Secretary, N.C. DHHS

E-Mail: mark.benton@dhhs.nc.gov

RULES REVIEW COMMISSION USE ONLY

Action taken:

Submitted for RRC Review:

 Date returned to agency:

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.

In (a), line 4, and (c)(1), line 10, please define “ambulatory basis” and “ambulatory”.

In (b), line 7, please define “adverse condition”.

In (c)(2), line 11, what do you mean by “controlled”?

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

1 10A NCAC 14E .0329 is adopted under temporary procedures 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 complication known or suspected to have occurred during or after the
8 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 with a stable blood pressure and pulse; and

11 (2) bleeding and pain shall be controlled.

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

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

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

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

20

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

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

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

7. Why is adherence to notice and hearing requirements contrary to the public interest and the immediate adoption of the rule is required?

Notice would be contrary to public interest given the repeal of this rule for minimum standards in the regulated clinics. The providers have been operating for years based upon this rule and have not received notice that the rule would be repealed. Unless a temporary rule is adopted, there will be uncertainty about the minimum standards applicable to a clinic and how to operate. The adoption of a temporary rule will ensure continuity of care for patients and resolve uncertainty about the rules applicable to impacted providers beginning July 1st until the Department is able to promulgate permanent rules. The temporary rule will allow the Department to regulate the clinics and hold the clinics to basic standards that are in place to protect the health and safety of women in obtaining lawful abortions. Adherence to notice and hearing requirements is contrary to the public interest for the immediate and critical near term because the timeframe for notice and comment rulemaking create a months' long threat to the public health and safety of women and providers due to the elimination of these established minimum standards.

8. Rule establishes or increases a fee? (See G.S. 12-3.1)

- Yes
 Agency submitted request for consultation on:
 Consultation not required. Cite authority:
- No

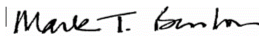
9. Rule-making Coordinator: Nadine Pfeiffer

Phone: 919-855-3811
 E-Mail: Nadine.pfeiffer@dhhs.nc.gov

Agency contact, if any: Rajeev Premakumar

Phone: 984-800-1117
 E-Mail: raj.premakumar@dhhs.nc.gov

10. Signature of Agency Head*:

DocuSigned by:


* If this function has been delegated (reassigned) pursuant to G.S. 143B-10(a), submit a copy of the delegation with this form.

Typed Name: Mark T. Benton
 Title: Chief Deputy Secretary, N.C. DHHS
 E-Mail: mark.benton@dhhs.nc.gov

RULES REVIEW COMMISSION USE ONLY

Action taken:

Submitted for RRC Review:

Date returned to agency:

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.

In (a), line 4, please define or delete "properly".

In (b), how is this to be determined, and by whom?

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

1 10A NCAC 14E .0330 is adopted under temporary procedures 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. 2.4;*

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

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

7. Why is adherence to notice and hearing requirements contrary to the public interest and the immediate adoption of the rule is required?

Notice would be contrary to public interest given the repeal of this rule for minimum standards in the regulated clinics. The providers have been operating for years based upon this rule and have not received notice that the rule would be repealed. Unless a temporary rule is adopted, there will be uncertainty about the minimum standards applicable to a clinic and how to operate. The adoption of a temporary rule will ensure continuity of care for patients and resolve uncertainty about the rules applicable to impacted providers beginning July 1st until the Department is able to promulgate permanent rules. The temporary rule will allow the Department to regulate the clinics and hold the clinics to basic standards that are in place to protect the health and safety of women in obtaining lawful abortions. Adherence to notice and hearing requirements is contrary to the public interest for the immediate and critical near term because the timeframe for notice and comment rulemaking create a months' long threat to the public health and safety of women and providers due to the elimination of these established minimum standards.

8. Rule establishes or increases a fee? (See G.S. 12-3.1)

Yes
Agency submitted request for consultation on:
Consultation not required. Cite authority:

No

9. Rule-making Coordinator: Nadine Pfeiffer

Phone: 919-855-3811

E-Mail: Nadine.pfeiffer@dhhs.nc.gov

Agency contact, if any: Rajeev Premakumar

Phone: 984-800-1117

E-Mail: raj.premakumar@dhhs.nc.gov

10. Signature of Agency Head*:

DocuSigned by:

Mark T. Benton

6E41EF320AD6440...

* If this function has been delegated (reassigned) pursuant to G.S. 143B-10(a), submit a copy of the delegation with this form.

Typed Name: Mark T. Benton

Title: Chief Deputy Secretary, N.C. DHHS

E-Mail: mark.benton@dhhs.nc.gov

RULES REVIEW COMMISSION USE ONLY

Action taken:

Submitted for RRC Review:

Date returned to agency:

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

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

2

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

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

5

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

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

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

7. Why is adherence to notice and hearing requirements contrary to the public interest and the immediate adoption of the rule is required?

Notice would be contrary to public interest given the repeal of this rule for minimum standards in the regulated clinics. The providers have been operating for years based upon this rule and have not received notice that the rule would be repealed. Unless a temporary rule is adopted, there will be uncertainty about the minimum standards applicable to a clinic and how to operate. The adoption of a temporary rule will ensure continuity of care for patients and resolve uncertainty about the rules applicable to impacted providers beginning July 1st until the Department is able to promulgate permanent rules. The temporary rule will allow the Department to regulate the clinics and hold the clinics to basic standards that are in place to protect the health and safety of women in obtaining lawful abortions. Adherence to notice and hearing requirements is contrary to the public interest for the immediate and critical near term because the timeframe for notice and comment rulemaking create a months' long threat to the public health and safety of women and providers due to the elimination of these established minimum standards.

8. Rule establishes or increases a fee? (See G.S. 12-3.1) Yes

Agency submitted request for consultation on:
 Consultation not required. Cite authority:

 No**9. Rule-making Coordinator: Nadine Pfeiffer**

Phone: 919-855-3811

E-Mail: Nadine.pfeiffer@dhhs.nc.gov

Agency contact, if any: Rajeev Premakumar

Phone: 984-800-1117

E-Mail: raj.premakumar@dhhs.nc.gov

10. Signature of Agency Head*:

DocuSigned by:

Mark T. Benton

* If this function has been delegated (reassigned) pursuant to G.S. 143B-10(a), submit a copy of the delegation with this form.

Typed Name: Mark T. Benton

Title: Chief Deputy Secretary, N.C. DHHS

E-Mail: mark.benton@dhhs.nc.gov

RULES REVIEW COMMISSION USE ONLY

Action taken:

Submitted for RRC Review:

 Date returned to agency:

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:

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.

1 10A NCAC 14E .0403 is adopted under temporary procedures 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.*

7. Why is adherence to notice and hearing requirements contrary to the public interest and the immediate adoption of the rule is required?

Notice would be contrary to public interest given the repeal of this rule for minimum standards in the regulated clinics. The providers have been operating for years based upon this rule and have not received notice that the rule would be repealed. Unless a temporary rule is adopted, there will be uncertainty about the minimum standards applicable to a clinic and how to operate. The adoption of a temporary rule will ensure continuity of care for patients and resolve uncertainty about the rules applicable to impacted providers beginning July 1st until the Department is able to promulgate permanent rules. The temporary rule will allow the Department to regulate the clinics and hold the clinics to basic standards that are in place to protect the health and safety of women in obtaining lawful abortions. Adherence to notice and hearing requirements is contrary to the public interest for the immediate and critical near term because the timeframe for notice and comment rulemaking create a months' long threat to the public health and safety of women and providers due to the elimination of these established minimum standards.

8. Rule establishes or increases a fee? (See G.S. 12-3.1)

- Yes
 Agency submitted request for consultation on:
 Consultation not required. Cite authority:
- No


9. Rule-making Coordinator: Nadine Pfeiffer

Phone: 919-855-3811
 E-Mail: Nadine.pfeiffer@dhhs.nc.gov

Agency contact, if any: Rajeev Premakumar

Phone: 984-800-1117
 E-Mail: raj.premakumar@dhhs.nc.gov

10. Signature of Agency Head*:

DocuSigned by:


* If this function has been delegated (reassigned) pursuant to G.S. 143B-10(a), submit a copy of the delegation with this form.

Typed Name: Mark T. Benton
 Title: Chief Deputy Secretary, N.C. DHHS
 E-Mail: mark.benton@dhhs.nc.gov

RULES REVIEW COMMISSION USE ONLY

Action taken:

Submitted for RRC Review:

Date returned to agency:

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:

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.

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.*