STATE OF NORTH CAROLINA
DEPARTMENT OF HEALTH AND HUMAN SERVICES

MEDICAL CARE COMMISSION QUARTERLY MEETING
DIVISION OF HEALTH SERVICE REGULATION
809 RUGGLES DRIVE, RALEIGH NC 27603
EDGERTON BUILDING
CONFERENCE ROOM – 026A
OR
TEAMS Video Conference: Click here to join the meeting
OR
Dial-IN: 1-984-204-1487 / Passcode: 675 543 670#

January 23, 2024 (Tuesday)
11:30 a.m.

Agenda

I. Meeting Opens – Roll Call

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

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

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

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

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

V. New Business

A. Rules for Adoption (Discuss rules)

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

Emergency rulemaking to consider adopting the emergency abortion rules as temporary abortion rules (13S) before they expire on January 30, 2024.

- **Rules:** 10A NCAC 13S .0101, .0104, .0111, .0112, .0114, .0201, .0202, .0207, .0209, .0210, .0211, .0212, .0315, .0318, .0319, .0320, .0321, .0322, .0323, .0324, .0325, .0326, .0327, .0328, .0329, .0330, & .0331.

  (27 Rules)

  (See Exhibits A thru G)

VI. Meeting Adjournment

1 10A NCAC 13S .0101 is proposed for adoption under temporary procedures as follows:
2
3 **SUBCHAPTER 13S - LICENSURE OF SUITABLE FACILITIES FOR THE PERFORMANCE OF**
4 **SURGICAL ABORTIONS**
5
6 **SECTION .0100 – LICENSURE PROCEDURE**
7
8 **10A NCAC 13S .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(1c).
11 (2) "Clinic" means a freestanding facility neither physically attached nor operated by a licensed hospital
12 for the performance of abortions completed during the first 12 weeks of pregnancy.
13 (3) "Division" means the Division of Health Service Regulation of the North Carolina Department of
14 Health and Human Services.
15 (4) "Gestational age" means the length of pregnancy as indicated by the date of the first day of the last
16 normal monthly menstrual period, if known, or as determined by ultrasound.
17 (5) "Governing authority" means the individual, agency, group, or corporation appointed, elected or
18 otherwise designated, in which the ultimate responsibility and authority for the conduct of the
19 abortion clinic is vested pursuant to Rule .0318 of this Subchapter.
20 (6) "Health Screening" means an evaluation of an employee or contractual employee, including
21 tuberculosis testing, to identify any underlying conditions that may affect the person's ability to
22 work in the clinic.
23 (7) "New clinic" means one that is not certified as an abortion clinic by the Division as of July 1, 2023,
24 and has not been certified or licensed within the previous six months of the application for licensure.
25 (8) "Registered Nurse" means a person who holds a valid license issued by the North Carolina Board
26 of Nursing to practice professional nursing in accordance with the Nursing Practice Act, G.S. 90,
27 Article 9A.
28
29 *History Note: Authority G.S. 131E-153; 131E-153.5; 143B-165.*

1 10A NCAC 13S .0104 is proposed for adoption under temporary procedures as follows:

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3 **10A NCAC 13S .0104 PLANS**

4 Prior to issuance of a license pursuant to Rule .0107 of this Section, an applicant for a new clinic shall submit two
5 copies of the building plans to the Division. When the clinic requires a review by the Division and the Department of
6 Insurance, according to the North Carolina State Building Code, 2018 edition, including subsequent amendments and
7 editions. Copies of the Code are available from the International Code Council at
8 https://codes.iccsafe.org/content/NCAPC2018/chapter-1-administrative-code at no cost. When the local jurisdiction
9 has authority from the North Carolina Building Code Council to review the plans, the clinic shall submit only one
10 copy of the plans to the Division. In that case, the clinic shall submit an additional set of plans directly to the local
11 jurisdiction.

12

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

14

1 10A NCAC 13S .0111 is proposed for adoption under temporary procedures as follows:

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3 **10A NCAC 13S .0111 INSPECTIONS**

4 (a) Any clinic licensed by the Division to perform abortions shall be inspected by representatives of the Division
5 annually and as it may deem necessary as a condition of holding such license. An inspection may be conducted
6 whenever the Division receives a complaint alleging the clinic is not in compliance with the rules of the Subchapter.
7 (b) Representatives of the Division shall make their identities known to the clinic staff prior to inspection of the clinic.
8 (c) Representatives of the Division may review any records in any medium necessary to determine compliance with
9 the rules of this Subchapter. The Department shall maintain the confidentiality of the complainant and the patient,
10 unless otherwise required by law.
11 (d) The clinic shall allow the Division to have immediate access to its premises and the records necessary to conduct
12 an inspection and determine compliance with the rules of this Subchapter.
13 (e) A clinic shall file a written plan of correction for cited deficiencies within 10 business days of receipt of the report
14 of the survey. The Division shall review and respond to a written plan of correction within 10 business days of receipt
15 of the corrective action plan.

16

17 *History Note: Authority G.S. 131E-153; 131E-153.2; 131E-153.5; 131E-153.6; 143B-165.*

1 10A NCAC 13S .0112 is proposed for adoption under temporary procedures as follows:

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3 **10A NCAC 13S .0112 ALTERATIONS**

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

8

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

1 10A NCAC 13S .0114 is proposed for adoption under temporary procedures as follows:

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3 **10A NCAC 13S .0114 APPROVAL**

4 (a) Approval of building plans shall be obtained from the Division of Health Service Regulation, in accordance with

5 the rules in Section .0200 of this Subchapter.

6 (b) Approval of building plans shall expire one year after the date of approval unless a building permit for the

7 construction has been obtained prior to the expiration date of the approval of building plans.

8

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

1 10A NCAC 13S .0201 is proposed for adoption under temporary procedures as follows:
2
3 **SECTION .0200 - MINIMUM STANDARDS FOR CONSTRUCTION AND EQUIPMENT**
4
5 **10A NCAC 13S .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 https://codes.iccsafe.org/content/NCAPC2018/chapter-1-
11 administrative-code.
12 (b) The requirements contained in this Section shall apply to new clinics and to any alterations, repairs, rehabilitation
13 work, or additions which are made to a previously licensed facility.
14
15 *History Note: Authority G.S. 131E-153; 131E-153.5; 143B-165.*

1 10A NCAC 13S .0202 is proposed for adoption under temporary procedures as follows:

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3 **10A NCAC 13S .0202 SANITATION**

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

10

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

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

10A NCAC 13S .0207 AREA REQUIREMENTS

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

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

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

1 10A NCAC 13S .0209 is proposed for adoption under temporary procedures as follows:

2

3 **10A NCAC 13S .0209 ELEVATOR**

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

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

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

7

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

9

1 10A NCAC 13S .0210 is proposed for adoption under temporary procedures as follows:

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3 **10A NCAC 13S .0210 CORRIDORS**

4 The width of patient use corridors shall be no less than 60 inches.

5

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

1 10A NCAC 13S .0211 is proposed for adoption under temporary procedures as follows:

2

3 **10A NCAC 13S .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 not
6 subject to occupancy.

7

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

9

1 10A NCAC 13S .0212 is proposed for adoption under temporary procedures as follows:
2
3 **10A NCAC 13S .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:

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

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:

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

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

6 (2) Plumbing And Other Piping Systems.
7 (a) Medical Gas and Vacuum Systems
8 (i) Piped-in medical gas and vacuum systems, if installed, shall meet the
9 requirements of NFPA-99-2012, category 1 system, which is hereby incorporated
10 by reference including subsequent amendments and editions. Copies of NFPA-
11 99-2012 may be purchased from the National Fire Protection Association, 1
12 Batterymarch Park, P.O. Box 9101, Quincy, MA 02269-9101, or accessed
13 electronically free of charge at http://www.nfpa.org.
14 (ii) The facility must meet the inhalation anesthesia requirements of NFPA 70-2020
15 and NFPA 99-2021, which are hereby incorporated by reference including
16 subsequent amendments and editions. Copies of NFPA 70-2011 and NFPA 99-
17 2012 may be purchased from the National Fire Protection Association, 1
18 Batterymarch Park, P.O. Box 9101, Quincy, MA 02269-9101, or accessed
19 electronically free of charge at http://www.nfpa.org.
20 (b) Lavatories and sinks for use by medical personnel shall have the water supply spout
21 mounted so that its discharge point is a minimum distance of five inches above the rim of
22 the fixture with mixing type fixture valves that can be operated without the use of the hands.
23 (c) Hot water distribution systems shall provide hot water at hand washing and bathing
24 facilities at a minimum temperature of 100 degrees F. and a maximum temperature of 116
25 degrees F.
26 (d) Floor drains shall not be installed in procedure rooms.
27 (e) Building drainage and waste systems shall be designed to avoid installations in the ceiling
28 directly above procedure rooms.
29 (3) Electrical Requirements.
30 (a) Procedure and recovery rooms, and paths of egress from these rooms to the outside shall
31 have at a minimum, listed battery backup lighting units of one and one-half hour capability
32 that will automatically provide at least five foot candles of illumination at the floor in the
33 event needed for a utility or local lighting circuit failure.
34 (b) Electrically operated medical equipment necessary for the safety of the patient shall have,
35 at a minimum, battery backup.
36 (c) Receptacles located within six feet of sinks or lavatories shall be ground-fault protected.

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. 131E-153; 131E-153.5; 143B-165.*

10A NCAC 13S .0315 is proposed for adoption under temporary procedures as follows:

SECTION .0300 – SERVICES

10A NCAC 13S .0315 HOUSEKEEPING

In addition to the standards set forth in Rule .0202 of this Subchapter, clinics that are licensed by the Division to perform abortions shall meet the following standards:

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

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

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

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

2

3 **10A NCAC 13S .0318 GOVERNING AUTHORITY**

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

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

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

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

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

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

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

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

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

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

31

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

1 10A NCAC 13S .0319 is proposed for adoption under temporary procedures as follows:
2
3 **10A NCAC 13S .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 care and services provided by 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;
18 (2) clinical discharge criteria;
19 (3) policy and procedure for validating the full and true name of the patient;
20 (4) policy and procedure for abortion procedures performed at the clinic;
21 (5) policy and procedure for the provision of patient privacy in the recovery area of the clinic;
22 (6) protocol for determining gestational age as defined in Rule .0101(5) of this Subchapter;
23 (7) protocol for referral of patients for whom services have been declined; and
24 (8) protocol for discharge instructions that informs patients who to contact for post-procedural problems
25 and questions.
26
27 *History Note: Authority G.S. 131E-153; 131E-153.5; 143B-165.*

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

2

3 **10A NCAC 13S .0320 ADMISSION AND DISCHARGE**

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

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

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

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

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

13 (2) the name of the attending physician or physicians and hospital admitting privileges, if any. In the
14 absence of admitting privileges a statement to that effect shall be included;

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

16 (4) grievance procedures a patient may follow if dissatisfied with the care and services rendered; and

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

18

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

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

2

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

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

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

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

7 (3) the patient's address;

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

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

10 (6) the patient's diagnoses;

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

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

13 (9) a voluntarily-signed consent for each surgery or procedure and signature of the physician performing

14 the procedure witnessed by a family member, other patient representative, or facility staff member;

15 (10) the patient's history and physical examination including identification of pre-existing or current

16 illnesses, drug sensitivities or other idiosyncrasies that may impact the procedure or anesthetic to be

17 administered; and

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

19 patient.

20 (b) The clinic shall record and authenticate by signature, date, and time all other pertinent information such as pre-

21 and post-procedure instructions, laboratory reports, drugs administered, report of abortion procedure, and follow-up

22 instruction, including family planning advice.

23 (c) If Rh is negative, the clinic shall explain the significance to the patient and shall record the explanation. The

24 patient in writing may reject Rh immunoglobulin. A written record of the patient's decision shall be a permanent part

25 of her medical record.

26 (d) An ultrasound examination shall be performed by a technician qualified in ultrasonography and the results,

27 including gestational age, placed in the patient's medical record for any patient who is scheduled for an abortion

28 procedure.

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

30 least the following:

31 (1) the patient name;

32 (2) the estimated length of gestation;

33 (3) the type of procedure;

34 (4) the name of the physician:

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

36 (6) the date and time of procedure.

1 (f) Medical records shall be the property of the clinic and shall be preserved or retained in the State of North Carolina
2 for a period of not less than 10 years from the date of the most recent discharge, unless the client is a minor, in which
3 case the record must be retained until three years after the client's 18th birthday, regardless of change of clinic
4 ownership or administration. Such medical records shall be made available to the Division upon request and shall not
5 be removed from the premises where they are retained except by subpoena or court order.
6 (g) The clinic shall have a written plan for destruction of medical records to identify information to be retained and
7 the manner of destruction to ensure confidentiality of all material.
8 (h) Should a clinic cease operation, the clinic shall arrange for preservation of records for at least 10 years. The clinic
9 shall send written notification to the Division of these arrangements.
10
11 *History Note: Authority G.S. 131E-153; 131E-153.5; 143B-165.*

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

10A NCAC 13S .0322 PERSONNEL RECORDS

(a) Personnel Records:

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

(A) the employee's identification;

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

(C) a resume of education and work experience;

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

(E) a list of references.

(2) Personnel records shall be confidential.

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

(b) Job Descriptions:

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

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

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

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

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

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

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

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

1 10A NCAC 13S .0323 is proposed for adoption under temporary procedures as follows:

2

3 **10A NCAC 13S .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 for all nursing services.

6 (b) The nursing supervisor shall report to the chief executive officer or designee and shall be responsible 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. 131E-153; 131E-153.5; 143B-165.*

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

2

3 **10A NCAC 13S .0324 QUALITY ASSURANCE**

4 (a) The governing authority shall establish a quality assurance program for the purpose of providing standards of care
5 for the clinic. The program shall include the establishment of a committee that shall evaluate compliance with clinic
6 procedures and policies.
7 (b) The committee shall determine corrective action, if necessary to achieve and maintain compliance with clinic
8 procedures and policies.
9 (c) The committee shall consist of at least one physician who is not an owner, the chief executive officer or designee,
10 and other health professionals. The committee shall meet at least once per quarter.
11 (d) The functions of the committee shall include development of policies for selection of patients, approval for
12 adoption of policies, review of credentials for staff privileges, peer review, tissue inspection, establishment of infection
13 control procedures, and approval of additional procedures to be performed in the clinic.
14 (e) Records shall be kept of the activities of the committee for a period not less than 10 years. These records shall
15 include:
16 (1) reports made to the governing authority;
17 (2) minutes of committee meetings including date, time, persons attending, description and results of
18 cases reviewed, and recommendations made by the committee; and
19 (3) information on any corrective action taken.
20 (f) The clinic shall conduct orientation, training, or education programs to correct deficiencies that are uncovered as
21 a result of the quality assurance program.
22

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

10A NCAC 13S .0325 is proposed for adoption under temporary procedures as follows:

10A NCAC 13S .0325 LABORATORY SERVICES

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

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

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

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

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

(3) Rh factor testing.

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

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

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

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

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

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

10A NCAC 13S .0326 is proposed for adoption under temporary procedures as follows:

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

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

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

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

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

- (1) basic cardio-pulmonary life support;
- (2) emergency protocols for:
  - (A) administration of intravenous fluids;
  - (B) establishing and maintaining airway support;
  - (C) oxygen administration;
  - (D) utilizing a bag-valve-mask resuscitator with oxygen reservoir;
  - (E) utilizing a suction machine; and
  - (F) utilizing an automated external defibrillator;
- (3) emergency lighting available in the procedure room as set forth in Rule .0212 of this Subchapter; and
- (4) ultrasound equipment.

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

10A NCAC 13S .0327 is proposed for adoption under temporary procedures as follows:

10A NCAC 13S .0327 SURGICAL SERVICES

(a) The procedure room shall be maintained exclusively for surgical procedures and shall be so designed and maintained to provide an environment free of contamination. The clinic shall establish procedures for infection control and universal precautions.

(b) Tissue Examination:

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

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

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

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

1 10A NCAC 13S .0328 is proposed for adoption under temporary procedures as follows:
2
3 **10A NCAC 13S .0328 MEDICATIONS AND ANESTHESIA**
4 (a) No medication or treatment shall be given except on written order of a physician.
5 (b) Any medications shall be administered by a physician or Registered Nurse and shall be recorded in the patient's
6 permanent record.
7 (c) The anesthesia shall be administered only under the direct supervision of a licensed physician. Direct supervision
8 means the physician must be present in the clinic and immediately available to furnish assistance and direction
9 throughout the administration of the anesthesia. It does not mean the physician must be present in the room when the
10 anesthesia is administered.
11
12 *History Note: Authority G.S. 131E-153; 131E-153.5; 143B-165.*

1 10A NCAC 13S .0329 is proposed for adoption under temporary procedures as follows:
2
3 **10A NCAC 13S .0329 POST-OPERATIVE CARE**
4 (a) A patient whose pregnancy is terminated shall be observed in the clinic to ensure that no post-operative
5 complications are present. Thereafter, patients may be discharged according to a physician's order and the clinic's
6 protocols.
7 (b) Any patient having a complication known or suspected to have occurred during or after the performance of the
8 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 able to move independently with a stable blood pressure and pulse; and
11 (2) bleeding and pain are assessed to be stable and not a concern for discharge.
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. 131E-153; 131E-153.5; 143B-165.*

1 10A NCAC 13S .0330 is proposed for adoption under temporary procedures as follows:

2

3 **10A NCAC 13S .0330 CLEANING OF MATERIALS AND EQUIPMENT**

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

5 (b) Methods of cleaning, handling, and storing all supplies and equipment shall be such as to prevent the transmission

6 of infection through their use as determined by the clinic through their governing authority.

7

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

1 10A NCAC 13S .0331 is proposed for adoption under temporary procedures as follows:

2

3 **10A NCAC 13S .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. 131E-153;131E-153.2; 131E-153.5; 143B-165.*

The American College of
Obstetricians and Gynecologists
WOMEN'S HEALTH CARE PHYSICIANS

VIA ELECTRONIC TRANSMISSION

Taylor Corpening
Rule Review Manager
Health and Human Services
Taylor Corpening
809 Ruggles Drive
2701 Mail Service Center
Raleigh, NC 27699

Kody Kinsley
Secretary
Health and Human Services
2501 Mail Service Center
Raleigh, NC 27699

RE: Request for Comments for North Carolina Proposed Regulations Concerning Abortion Clinics

The North Carolina Section of the American College of Obstetricians and Gynecologists (ACOG) is pleased to submit these comments in response to the North Carolina Department of Health and Human Services proposed rules for the licensure of abortion clinics.[1]

The American College of Obstetricians and Gynecologists is the nation's leading group of physicians providing evidence-based obstetric and gynecologic care. With more than 62,000 members, ACOG maintains the highest standards of clinical practice and continuing education of its members; strongly advocates for equitable, exceptional, and respectful care for all women and people in need of obstetric and gynecologic care; promotes patient education; and increases awareness among its members and the public of critical issues facing patients and their families and communities.

I. Abortion Is a Safe and Essential Component of Women's Health Care

As the leading medical organization dedicated to the health of individuals in need of gynecologic and obstetric care, the American College of Obstetricians and Gynecologists (ACOG) supports the availability of high-quality reproductive health services for all people and is committed to protecting and increasing access to abortion. Abortion is a common medical intervention that improves the lives, health, and well-being of those who need it.

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[1] See NC Health and Human Services *Medical Care Commission - 10A NCAC 13S .0101, .0104, .0106-.0107, .0109, .0111-.0112, .0114, .0201-.0202, .0207, .0209-.0212, .0315, .0318-.0331.* NCDHHS. Accessed on 12/4/2023: https://www.oah.nc.gov/documents/rules/10a-ncac-13s-proposed-temporary-rules/download?attachment.

Abortion is an extremely safe medical procedure.[2] The risk of maternal death associated with childbirth is approximately 14 times higher than the risk associated with abortion.[3] Decades of clinical evidence clearly show that the various methods of abortion care, medication or procedural care, are safe and effective.[4] In the United States, 88% of abortions occur within the first trimester, when abortion is safest.[5]

Serious complications from abortions are rare at all gestational ages.[6] Only about 2% of women who undergo abortion experience a complication associated with the abortion, and most complications are minor and easily treatable with follow-up procedures or antibiotics.[7] The risk of complication or mortality from abortion is less than the same risk from common procedures like wisdom tooth removal, cancer-screening colonoscopy, and plastic surgery.[8]

With roughly one-quarter of women in the United States accessing abortion care in their lifetime,[9] this essential medical care must be provided according to the best available medical evidence, not restricted based on political ideology.

II. The Proposed Rules Constitute Legislative Interference in Patient Medical Care

Sound health policy is best based on scientific fact and evidence-based medicine. The best health care is provided free of political interference in the patient-physician relationship. Personal decision-making by women and their doctors should not be replaced by political ideology. ACOG opposes facility and staffing requirements like those found in the proposed rules because they improperly regulate medical care and do not improve patient safety or quality of care.[10]

This type of restriction on abortion is a Targeted Restriction of Abortion Providers (TRAP). Facility and staffing requirements are often enacted under the guise of promoting patient safety but single out abortion from other outpatient procedures and imposed medically unnecessary requirements designed

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[2] Increasing access to abortion. ACOG Committee Opinion No. 815. American College of Obstetricians and Gynecologists. Obstet Gyne-col 2020; 136:e107-15, at e108.

[3] Raymond EG, Grimes DA. The comparative safety of legal induced abortion and childbirth in the United States. Obstet Gynecol. 2012 Feb;119(2 Pt 1):215-9. doi: 10.1097/AOG.0b013e31823fe923. PMID: 22270271.

[4] National Academies of Sciences, Engineering, and Medicine. 2018. The Safety and Quality of Abortion Care in the United States. Washington, DC: The National Academies Press. https://doi.org/10.17226/24950. Pg 10.

[5] Increasing access to abortion. ACOG Committee Opinion No. 815. American College of Obstetricians and Gynecologists. Obstet Gyne-col 2020; 136:e107-15, at e108.

[6] *Id*.

[7] Upadhyay UD, Desai S, Zlidar V, Weitz TA, Grossman D, Anderson P, Taylor D. Incidence of emergency department visits and complications after abortion. Obstet Gynecol. 2015 Jan;125(1):175-183. doi: 10.1097/AOG.0000000000000603. PMID: 25560122.

[8] *ACOG.* (n.d.) Accessed on 12/4/2023: https://www.acog.org/advocacy/abortion-is-essential/come-prepared/abortion-access-fact-sheet.

[9] R. K. Jones and J. Jerman "Population Group Abortion Rates and Lifetime Incidence of Abortion: United States, 2008–2014", American Journal of Public Health 112, no. 9 (September 1, 2022): pp. 1284-1296.

[10] Increasing access to abortion. ACOG Committee Opinion No. 815. American College of Obstetricians and Gynecologists. Obstet Gyne-col 2020; 136:e107-15, at e109.

to reduce access to abortion.[11] Restrictions like those in the proposed rules make abortion more difficult and expensive to obtain by imposing additional costs on the patients who can least afford them.[12] Barriers limiting abortion access most profoundly affect communities that already face health care and social inequities. Limiting access to abortion forces people to carry pregnancies to term and face these risks. For example, Black women face a maternal mortality rate that is three times higher than that of white women.[13]

Government serves a valuable role in the protection of public health and safety and the provision of essential health services; however, laws and regulations that veer from these functions and unduly interfere with patient-physician relationships are not appropriate. Absent a substantial public health justification, government should not interfere with individual patient-physician encounters.[14] ACOG welcomes evidence-based safety regulations and creates a number of best practice recommendations to improve patient safety for office-based procedures.

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The North Carolina Section of ACOG appreciates the opportunity to comment on the proposed rules to regulate the licensure of abortion clinics in the state. ACOG welcomes working with government officials and safety experts on ways to ensure our patients receive safe, high-quality care. If you require additional information about the issues raised in this letter, please contact Elizabeth Livingston at elizabeth.livingston@duke.edu.

Respectfully Submitted,

Elizabeth Livingston, MD
Section Chair
North Carolina Section – American College of Obstetricians and Gynecologists

Clayton Alfonso, MD
Section Vice-Chair
North Carolina Section – American College of Obstetricians and Gynecologists

Jamila Wade, MD
Section Secretary Treasurer
North Carolina Section – American College of Obstetricians and Gynecologists

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[11] *Id.*
[12] *Id*.
[13] Hoyert DL. Maternal mortality rates in the United States, 2020. NCHS Health E-Stats. 2022. DOI: https://dx.doi.org/10.15620/cdc:113967.
[14] *ACOG*. (n.d.). Accessed on 12/4/2023: https://www.acog.org/clinical-information/policy-and-position-statements/statements-of-policy/2019/legislative-interference-with-patient-care-medical-decisions-and-the-patient-physician-relationship.

Exhibit C

December 6, 2023

VIA ELECTRONIC TRANSMISSION

Taylor Corpening
DHSR Rules Coordinator
809 Ruggles Drive
2701 Mail Service Center, Raleigh, NC 27699
dhsr.rulescoordinator@dhhs.nc.gov

Re: Request for Comments for North Carolina Medical Care Commission Proposed Temporary Rules for Abortion Clinics

Thank you for the opportunity to submit comments on the proposed temporary rules for the Licensure of Suitable Facilities for the Performance of Surgical Abortions. Surgical, or procedural, abortion has a demonstrated history of safety.[1] The types of abortions that occur in a clinic setting are not what is commonly understood to be surgery at all – they involve no incision, do not require general anesthesia, and do not require a sterile field because the procedure occurs in a natural body orifice. Abortion has a far lower complication rate (less than 1%) than other procedures that occur in outpatient clinic settings.[2] Moreover, the mortality risk for abortion is lower than that of many other common procedures that are performed in outpatient clinics. For example, one recent and robust analysis found that in the United States, the mortality rate for colonoscopy is 2.9 per 100,000 procedures; the mortality rate for tonsillectomy ranges from 2.9 to 6.3 per 100,000 procedures; and the mortality rate for plastic surgery is 0.8 to 1.7 per 100,000 procedures.[3] By contrast, the mortality rate for legal induced abortion is 0.7 per 100,000 procedures.[4] These procedures of greater risk are routinely provided on an outpatient basis in a clinic setting.

Despite the safety of abortion care, especially when compared to other clinic-based procedures, the regulation of abortion clinics far outpaces the requirements or recommendations for other

[1] Ushma D. Upadhyay et al., Incidence of Emergency Department Visits and Complications After Abortion, 125 Obstetrics & Gynecology 175, 181 (2015).
[2] *Id.*
[3] Nat'l Acads. of Scis., Eng'g, & Med., *The Safety and Quality of Abortion Care in the United States*, Nat'l Acads. Press 1, 74–75 (2018).
[4] *Id.*

office-based procedures. For the next several pages, we are providing a chart that directly compares requirements included in the proposed temporary regulations (which mirror abortion clinic regulations that have been in place for many years) with the North Carolina Medical Board's Guidelines for Office Based Procedures.[5] The Medical Board sets guidelines for such office-based procedures, which they differentiate into Level I,[6] II,[7] and III[8] procedures based on, for example, the type of sedation used and risk of complications for a particular procedure. As you can see from the comparison, abortion clinics are required to meet standards far above those considered appropriate, best practice guidelines for other office-based procedures – even those where deep sedation is provided. An especially striking example is that clinics providing care for miscarriage are not required to meet guidelines specific to abortion clinics, even though the personnel and procedures are often identical.

As experienced healthcare providers familiar with outpatient procedures as well as the practice of abortion in North Carolina, we would suggest that abortion is a Level II office-based procedure as defined by the Medical Board Guidelines and should be regulated accordingly. "Level II office-based procedures are defined as "any surgical or special procedures" that (1) "require the administration of local or peripheral nerve block, minor conduction blockade, Bier block, minimal sedation, or conscious sedation"; and (2) "where there is only a moderate risk of surgical and/or anesthetic complications and the need for hospitalization as a result of these complications is unlikely."[9] Currently, none of the free

[5] N.C. Med. Bd., Position Statements: Office-Based Procedures (last amended Sept. 2021), https://www.ncmedboard.org/resources-information/professionalresources/laws-rules-position-statements/position-statements/office-based_procedures.

[6] Level I office-based procedures are defined as "any surgical or special procedures" that (1) "do not involve drug-induced alteration of consciousness"; (2) "where preoperative medications are not required or used other than minimal preoperative tranquilization of the patient (anxiolysis of the patient)"; (3) "where the anesthesia required or used is local, topical, digital block, or none"; and (4) "where the probability of complications requiring hospitalization is remote." *Id.*

[7] Level II office-based procedures are defined as "any surgical or special procedures" that (1) "require the administration of local or peripheral nerve block, minor conduction blockade, Bier block, minimal sedation, or conscious sedation"; and (2) "where there is only a moderate risk of surgical and/or anesthetic complications and the need for hospitalization as a result of these complications is unlikely." *Id.*

[8] Level III office-based procedures are defined as "any surgical or special procedures" that (1) "require, or reasonably should require, the use of major conduction blockade, deep sedation/analgesia, or general anesthesia"; and (2) have "only a moderate risk of surgical and/or anesthetic complications and the need for hospitalization as a result of these complications is unlikely." *Id.*

[9] *Id.*

standing clinics providing abortion in the state use deep sedation or general anesthesia for abortion procedures. Should a clinic wish to introduce deep sedation or general anesthesia, it could be required to meet requirements for Level III office-based procedures.

Thank you for considering these recommendations which would improve consistency in regulation of medical care in this state.

Respectfully submitted,

R. Phillips Heine, MD
Ob/Gyn, Maternal Fetal Medicine, Winston Salem, NC

Brenna Hughes, MD
Ob/Gyn, Maternal Fetal Medicine, Durham, NC

Abigail Melnick, MD
Obstetric Anesthesiologist, Durham, NC

Jessica Morse, MD, MPH
Ob/Gyn, Complex Family Planning, Durham, NC

Erica Pettigrew, MD, JD, MPH
Family Medicine and Public Health, Orange County, NC

Geeta K. Swamy, MD
Haywood Brown, MD Distinguished Professor of Women's Health, Durham, NC

Jonas Swartz, MD, MPH
Ob/Gyn, Complex Family Planning, Durham, NC

Anne West Honart, MD, MPhil
Ob/Gyn, Maternal Fetal Medicine, Durham, NC

Adam Zolotor, MD, DrPH
Family Medicine, NC

Comparison of North Carolina regulations for Abortion Clinics and other Procedural Clinics[10]

	Proposed Abortion Clinic Regulations	**Medical Board Guidelines for Level I Procedures**	**Medical Board Guidelines for Level II Procedures**	**Medical Board Guidelines for Level III Procedures**
Physical Requirements	"(a) The physical plant for a clinic shall meet or exceed minimum requirements of the North Carolina State Building Code for Group B occupancy (business office facilities) which is incorporated herein by reference including subsequent amendments and editions. (b) The requirements contained in this Section shall apply to new clinics and to any alterations, repairs, rehabilitation work, or additions which are made to a previously certified facility." 10A NCAC 13S .0201. "Clinics that are licensed by the Division to perform abortions shall comply with the Rules governing the sanitation of hospitals, nursing homes, adult care homes, and other institutions, contained in 15A N.C. Admin. Code 18A.1300 which is hereby incorporated by reference including subsequent amendments and editions." 10A NCAC 13S .0202 Clinic must have receiving area; examining room; preoperative preparation and holding room; individual patient locker facilities or equivalent; procedure room; recovery room; clean workroom; soiled workroom; medicine room (which may be part of the clean workroom if certain requirements are met); separate and distinct areas for storage and handling clean and soiled linen; patient toilet; separate and distinct areas for storage and handling clean	None.	None.	None.

[10] Unless otherwise noted, all information in the columns regarding Medical Board guidelines for office- based procedures can be found in N.C. Med. Bd., *Position Statements: Office-Based Procedures* (last amended Sept. 2021), https://www.ncmedboard.org/resources-information/professional-resources/laws-rules-position-statements/position-statements/office-based_procedures.

	Proposed Abortion Clinic Regulations	Medical Board Guidelines for Level I Procedures	Medical Board Guidelines for Level II Procedures	Medical Board Guidelines for Level III Procedures
	and soiled linen; patient toilet; personnel lockers and toilet facilities; laboratory; nourishment station with storage and preparation area for serving meals or in-between meal snacks; janitor's closets; adequate space and equipment for assembling, sterilizing, and storing medical and surgical supplies; storage space for medical records; and office space for nurses' charting, doctors' charting, communications, counseling, and business functions. *See* 10A NCAC 13S .0207. Any facility that provides abortions that has more than one floor must have at least one elevator that can accommodate a stretcher (six-and-one-half feet with an opening of no less than three feet in width). *See* 10A NCAC 13S .0209. Patient-use corridors in any facility that provides abortions must be no less than 60 inches wide. *See* 10A NCAC 13S .0210. The minimum width of doors to all rooms needing access for stretchers must be three feet. *See* 10A NCAC 13S .0211. A facility that provides abortion must comply with strict ventilation and air supply requirements. *See* 10A NCAC 13S .0212.			

	Proposed Abortion Clinic Regulations	Medical Board Guidelines for Level I Procedures	Medical Board Guidelines for Level II Procedures	Medical Board Guidelines for Level III Procedures
License & Fee Requirements	"Any license holder or prospective applicant desiring to make alterations or additions to a clinic or to construct a new clinic, before commencing such alteration, addition or new construction shall submit plans and specifications to the Division for preliminary inspection and approval or recommendations with respect to compliance with this Subchapter" 10A NCAC 13S .0112 "(a) Approval of building plans shall be obtained from the Division of Health Service Regulation, in accordance with the rules in Section .0200 of this Subchapter. (b) Approval of building plans shall expire one year after the date of approval unless a building permit for the construction has been obtained prior to the expiration date of the approval of building plans." 10A NCAC 13S .0114 "(a) Prior to the admission of patients, an applicant for a new clinic shall submit an application for licensure and receive approval from the Division. (b) Application forms may be obtained by contacting the Division (c) The application form shall set forth: (1) Name of applicant; (2) Name of facility; (3) Ownership disclosure; (4) Building owner; (5) Building owner; (6) Building management; (7) Sanitation services; (8) Medical director; (9) Other medical staff; (10) Director of nursing; (11) Other nursing staff; and (12) Consulting pathologist.	None.	Physician performing Level II procedures in an office "should be able to demonstrate, upon request by the Board, substantial compliance with these guidelines, or should obtain accreditation of the office setting by an approved accreditation agency or organization."	Physician performing Level III procedures in an office "should be able to demonstrate, upon request by the Board, substantial compliance with these guidelines, or should obtain accreditation of the office setting by an approved accreditation agency or organization."

	Proposed Abortion Clinic Regulations	**Medical Board Guidelines for Level I Procedures**	**Medical Board Guidelines for Level II Procedures**	**Medical Board Guidelines for Level III Procedures**
	(d) After construction requirements in Section .0200 of this Subchapter have been met and the application for licensure has been received and approved, the Division shall conduct an on-site, licensure survey. 10A NCAC 13S .0106 "(a) The Division shall issue a license if it finds the facility can: (1) Comply with all requirements described in this Subchapter; and (2) Have a board certified OB-GYN or board eligible physician by the American Board of Obstetrics and Gynecology shall be available in the event that complications arise from an abortion procedure. (b) Each license shall be issued only for the premises and persons or organizations named in the application and shall not be transferable. (c) The governing authority shall notify the Division in writing, within 10 working days, of any change in the name of the facility or change in the name of the administrator. (d) The facility shall report to the Division all incidents, within 10 working days, of vandalism to the facility such as fires, explosions, or other action that prevents services from providing abortion services." 10A NCAC 13S .0107 "(a) Each license, renewed at the beginning of each calendar year. (b) The renewal application form shall set forth: (1) Name of applicant; (2) Name of facility; (3) Ownership disclosure; (4) Building owner; (5) Building owner; (6) Building management; (7) Sanitation services; (8) Medical director;			

	Proposed Abortion Clinic Regulations	Medical Board Guidelines for Level I Procedures	Medical Board Guidelines for Level II Procedures	Medical Board Guidelines for Level III Procedures
	(9) Other medical staff; (10) Director of nursing; (11) Other nursing staff; (12) Consulting pathologist; (13) The number of procedures performed during the reporting period; and (14) The number of patients that were transferred to a hospital during a reporting period. (c) Upon the filing of a renewal application, the clinic must pay a non-refundable renewal fee as defined in G.S. 131E-153.2. (d) An application for renewal of licensure must be filed with the Division at least 30 days prior to the date of expiration. Renewal application forms shall be furnished by the Division. (e) Failure to file a renewal application shall result in expiration of the license to operate." 10A NCAC 13S .0109			
Inspection & Investigation Authority	"(a) Any clinic licensed by the Division to perform abortions shall be inspected by representatives of the Division annually and as it may deem necessary as a condition of holding such license. An inspection may be conducted whenever the Division receives a complaint alleging the clinic is not in compliance with the rules of the Subchapter. (b) Representatives of the Division shall make their identities known to the clinic staff prior to inspection of the clinic. (c) Representatives of the Division may review any records in any medium necessary to determine compliance with the rules of this Subchapter. The Department shall maintain the confidentiality of the complainant and the patient, unless otherwise required by law.			

	Proposed Abortion Clinic Regulations	Medical Board Guidelines for Level I Procedures	Medical Board Guidelines for Level II Procedures	Medical Board Guidelines for Level III Procedures
	(d) The clinic shall allow the Division to have immediate access to its premises and the records necessary to conduct an inspection and determine compliance with the rules of this Subchapter. (e) A clinic shall file a written plan of correction for cited deficiencies within 10 business days of receipt of the report of the survey. The Division shall review and respond to a written plan of correction within 10 business days of receipt of the corrective action plan" 10A NCAC 13S .0111			
Medical Staff Organization & Personnel Requirements	(c) All persons having direct responsibility for patient care shall be at least 18 years of age. (d) The clinic shall provide an orientation program to familiarize each new employee or contractual employee with the clinic, its policies, and the employee's job responsibilities. (e) The governing authority shall be responsible for implementing health standards for employees, as well as contractual employees, which are consistent with recognized professional practices for the prevention and transmission of communicable diseases. (f) Employee and contractual employee records for health screening as defined in Rule .0101(7) of this Subchapter, education, training, and verification of professional certification shall be available for review by the Division. 10A NCAC 13S .0322 (c)-(f). --- (b) The nursing supervisor shall report to the chief executive officer or designee and shall be responsible for: (1) provision of nursing services to patients; and (2) developing a nursing policy and procedure manual and	None.	Physician performing procedure or other health care professional present *should* be ACLS certified, and at least one other health care professional *should* be BCLS certified. "Recovery *should* be monitored by a registered nurse *or other health care professional* practicing within the scope of his or her license or certification who is BCLS certified and has the capability of administering medications as required for analgesia, nausea/vomiting, or other indications." (emphases added).	An anesthesiologist or a CRNA supervised by a physician *should* administer anesthesia. The physician cannot administer the anesthesia. Physician performing procedure or the anesthesia provider *should* be ACLS certified, and *at least one other health care professional should* be BCLS certified. "Recovery from a Level III procedure *should* be monitored by an ACLS certified (PALS or APLS certified when appropriate) health care professional using appropriate criteria for the level of anesthesia. *At least one health care professional* who is ACLS certified *should* be immediately available during postoperative monitoring and until the patient meets

	Proposed Abortion Clinic Regulations	Medical Board Guidelines for Level I Procedures	Medical Board Guidelines for Level II Procedures	Medical Board Guidelines for Level III Procedures
	written job descriptions for nursing personnel. (c) The clinic shall have the number of licensed and ancillary nursing personnel on duty to assure that staffing levels meet the total nursing needs of patients based on the number of patients in the clinic and their individual nursing care needs. 10A NCAC 13S .0323 (b)-(c)			discharge criteria." (emphases added).
Patient Transfer Agreement	"(a) Each clinic shall have a written plan for the transfer of emergency cases from the clinic to a nearby hospital when hospitalization becomes necessary. [...] (c) The clinic shall have a written agreement between the clinic and a hospital to facilitate the transfer of patients who are in need of emergency care. A clinic that has documentation of its efforts to establish such a transfer agreement with a hospital that provides emergency services and has been unable to secure such an agreement shall be considered to be in compliance with this Rule." 10A N.C. Admin Code 13S .0326(a),(c) "Any patient not discharged within 12 hours following the abortion procedure shall be transferred to a ~~general~~ hospital licensed pursuant to Chapter 131E, Article 5 of the General Statutes."-10A N.C. Admin Code 13S .0320(c) "`Any patient having a complication known or suspected to have occurred	None.	No written agreement required; physician should assure that a transfer protocol is in place, preferably with a hospital licensed in the same jurisdiction and within reasonable proximity.	No written agreement required; physician should assure that a transfer protocol is in place, preferably with a hospital licensed in the same jurisdiction and within reasonable proximity.

	Proposed Abortion Clinic Regulations	Medical Board Guidelines for Level I Procedures	Medical Board Guidelines for Level II Procedures	Medical Board Guidelines for Level III Procedures
	during or after the performance of the abortion shall be transferred to a hospital for evaluation or admission."-10A N.C. Admin Code 13S .0329(b)			
Requirements for Medical Records	Shall maintain complete and permanent record containing: ● Date/time of admission and discharge; ● Patient's full and true name, address, date of birth, emergency contact information, diagnoses, duration of pregnancy, and condition on admission and discharge; ● Signed consent form; ● "[P]atient's history and physical examination including identification of pre-existing or current illnesses, drug sensitivities or other idiosyncrasies having a bearing on the procedure or anesthetic to be administered, and documentation that indicates all items listed in Rule .0320(d) of this Section were provided to the patient." 10A N.C. Admin Code 13S .0321(a) Must maintain daily procedure log containing patients' name, length of gestation, type of procedure, name of physician, name of Registered Nurse on duty, and date/time of procedure. 10A N.C. Admin Code 13S .0321(e) Clinics must preserve or retain medical records in North Carolina for at least 10 years	None.	Medical record should include: procedure code or narrative description of procedure; "sufficient information to identify the patient, support the diagnosis, justify the treatment, and document the outcome and required follow-up care"; "Medical history, physical examination, lab studies obtained within 30 days of the	Medical record should include: procedure code or narrative description of procedure; "sufficient information to identify the patient, support the diagnosis, justify the treatment, and document the outcome and required follow-up care"; "Medical history, physical examination, lab studies obtained within 30 days of the

	Proposed Abortion Clinic Regulations	Medical Board Guidelines for Level I Procedures	Medical Board Guidelines for Level II Procedures	Medical Board Guidelines for Level III Procedures
	from the date of the most recent discharge. For minors, clinics must maintain such records until three years after the patient turns eighteen. 10A N.C. Admin Code 13S .0321(f)			
Requirements for Personnel Records	"(a) Personnel Records: (1) A record of each employee shall be maintained that includes the following: (A) employee's identification; (B) application for employment that includes education, training, experience and references; (C) resume of education and work experience; (D) copy of valid license (if required), education, training, and prior employment experience; and (E) list of references. (2) Personnel records shall be confidential. (3) representatives of the Division conducting an inspection of the clinic shall have the right to inspect personnel records. (b) Job Descriptions: (1) The clinic shall have a written description that describes the duties of every position. (2) Each job description shall include position title, authority, specific responsibilities, and minimum qualifications. Qualifications shall include education, training, experience, special abilities, and valid license or certification required. (3) The clinic shall review annually and, if needed, update all job descriptions. The clinic shall provide the updated job	None.	None.	None.

	Proposed Abortion Clinic Regulations	**Medical Board Guidelines for Level I Procedures**	**Medical Board Guidelines for Level II Procedures**	**Medical Board Guidelines for Level III Procedures**
	description to each employee or contractual employee assigned to the position. [...] (f) Employee and contractual employee records for health screening as defined in Rule .0101(7) of this Subchapter, education, training, and verification of professional certification shall be available for review by the Division." 10A N.C. Admin Code 13S .0322(a)(b)(f)			
Governing Authority Requirements	"When there is a planned change in ownership or in the chief executive officer, the governing authority of the clinic shall notify the Division in writing of the change." 10A N.C. Admin Code 13S .0318(c) "(a) The governing authority, as defined in Rule .0101(6) of this	None.	None.	None.

	Proposed Abortion Clinic Regulations	Medical Board Guidelines for Level I Procedures	Medical Board Guidelines for Level II Procedures	Medical Board Guidelines for Level III Procedures
Governing Authority Requirements	"When there is a planned change in ownership or in the chief executive officer, the governing authority of the clinic shall notify the Division in writing of the change." 10A N.C. Admin Code 13S .0318(c) "(a) The governing authority, as defined in Rule .0101(6) of this Subchapter, shall appoint a chief executive officer or a designee of the clinic to represent the governing authority and shall define his or her authority and duties in writing. This person shall be responsible for the management of the clinic, implementation of the policies of the governing authority and authorized and empowered to carry out the provisions of these Rules. (b) The chief executive officer or designee shall designate, in writing, a person to act on his or her behalf during his or her absence. In the absence of the chief executive officer or designee, the person on the grounds of the clinic who is designated by the chief executive officer or designee to be in charge of the clinic shall have access to all areas in the clinic related to patient care and to the operation of the physical plant. (c) When there is a planned change in ownership or in the chief executive officer, the governing authority of the clinic shall notify the Division in writing of the change. (d) The clinic's governing authority shall adopt operating policies and procedures that shall: (1) specify the individual to whom responsibility for	None.	None.	None.

	Proposed Abortion Clinic Regulations	**Medical Board Guidelines for Level I Procedures**	**Medical Board Guidelines for Level II Procedures**	**Medical Board Guidelines for Level III Procedures**
	operation and maintenance of the clinic is delegated and methods established by the governing authority for holding such individuals responsible; (2) provide for at least annual meetings of the governing authority, for which minutes shall be maintained; and (3) maintain a policies and procedures manual designed to ensure professional and safe care for the patients which shall be reviewed, and revised when necessary, at least annually, and shall include provisions for administration and use of the clinic, compliance, personnel quality assurance, procurement of outside services and consultations, patient care policies, and services offered. (e) When the clinic contracts with outside vendors to provide services such as laundry, or therapy services, the governing authority shall be responsible to assure the supplier meets the same local and state standards the clinic would have to meet if it were providing those services itself using its own staff. (f) The governing authority shall provide for the selection and appointment of the professional staff and the granting of clinical privileges and shall be responsible for the professional conduct of these persons. (g) The governing authority shall be responsible for ensuring the availability of supporting personnel to meet patient needs and to provide safe and adequate treatment." 10A N.C. Admin Code 13S .0318(a)(b)(c)(d)(f)(g)			

	Proposed Abortion Clinic Regulations	**Medical Board Guidelines for Level I Procedures**	**Medical Board Guidelines for Level II Procedures**	**Medical Board Guidelines for Level III Procedures**
	"(a) The following essential documents and references shall be on file in the administrative office of the clinic: (1) documents evidencing control and ownerships, such as deeds, leases, or incorporation or partnership papers; (2) policies and procedures of the governing authority, asrequired by Rule .0318 ~~.0302~~ of this Section; (3) minutes of the governing authority meetings; (4) minutes of the clinic's professional and administrative staff meetings; (5) a current copy of the rules of this Subchapter; (6) reports of inspections, reviews, and corrective actions taken related to licensure; and (7) contracts and agreements related to licensure to which the clinic is a party. (b) All operating licenses, permits, and certificates shall be displayed on the licensed premises. (c) The governing authority shall prepare a manual of clinic policies and procedures for use by employees, medical staff, and contractual physicians to assist them in understanding their responsibilities within the organizational framework of the clinic. These shall include: (1) patient selection and exclusion criteria;~~ and~~ (2) clinical discharge criteria; (3) policy and procedure for validating the full and true name of the patient; (4) policy and procedure for abortion procedures performed at the clinic; (5) policy and procedure for the provision of patient privacy in			

	Proposed Abortion Clinic Regulations	Medical Board Guidelines for Level I Procedures	Medical Board Guidelines for Level II Procedures	Medical Board Guidelines for Level III Procedures
	the recovery area of the clinic; (6) protocol for determining gestational age as defined in Rule .0101(5) of this Subchapter; (7) protocol for referral of patients for whom services have been declined; and (8) protocol for discharge instructions that informs patients who to contact for post-procedural problems and questions." 10A N.C. Admin Code 13S .0319(a)(b)(c)			
Required Information to Patient	"(d) Following admission and prior to obtaining the consent for the procedure, representatives of the clinic's management shall provide to each patient the following information: (1) a fee schedule and any extra charges routinely applied; (2) the name of the attending physician(s) and hospital admitting privileges, if any. In the absence of admitting privileges a statement to that effect shall be included; (3) instructions for post- procedure problems and questions as outlined in Rule .0329(d) of this Section; (4) grievance procedures a patient may follow if dissatisfied with the care and services rendered; and (5) the telephone number for Complaint Intake of the Division." 10A N.C. Admin Code 13S .0320(d) "(d) Written instructions shall be issued to all patients in accordance with the orders of the physician in charge of the abortion procedure and shall include the following: (1) symptoms and	None.	"The patient should receive verbal instruction understandable to the patient or guardian, confirmed by written post-operative instructions and emergency contact numbers. The instructions should include: ● the procedure performed; ● information about potential complications; ● telephone numbers to be used by the patient to discuss complications or should questions arise; ● instructions for medications prescribed and pain management; ● information regarding the follow-up visit date, time and location; and ● designated treatment hospital in the event of	"The patient should receive verbal instruction understandable to the patient or guardian, confirmed by written post-operative instructions and emergency contact numbers. The instructions should include: ● the procedure performed; ● information about potential complications; ● telephone numbers to be used by the patient to discuss complications or should questions arise; ● instructions for medications prescribed and pain management; ● information regarding the follow-up visit date, time and location; and ● designated treatment hospital in the event of

	Proposed Abortion Clinic Regulations	Medical Board Guidelines for Level I Procedures	Medical Board Guidelines for Level II Procedures	Medical Board Guidelines for Level III Procedures
	complications to be looked for; and (2) a dedicated telephone number to be used by the patients should any complication occur or question arise. This number shall be answered by a person 24 hours a day, seven days a week." 10A N.C. Admin Code 13S .0329(d)		emergency." "If the licensee is not going to be available after hours, the licensee must provide clear instructions to the patient for securing after-hours care. It is the responsibility of the licensee to ensure that the patient has sufficient information regarding how to secure after-hours care."[11]	emergency." "If the licensee is not going to be available after hours, the licensee must provide clear instructions to the patient for securing after-hours care. It is the responsibility of the licensee to ensure that the patient has sufficient information regarding how to secure after-hours care."[12]
Quality Assurance	"(a) The governing authority shall establish a quality assurance program for the purpose of providing standards of care for the clinic. The program shall include the establishment of a committee that shall evaluate compliance with clinic procedures and policies. (b) The committee shall determine corrective action, if necessary to achieve and maintain compliance with clinic procedures and policies. (c) The committee shall consist of at least one physician who is not an owner, the chief executive officer or designee, and other health professionals. The committee shall meet at least once per quarter. (d) The functions of the committee shall include development of policies for selection of patients, approval for adoption of policies, review of credentials for staff	None.	"A performance improvement program should be implemented to provide a mechanism to review yearly the current practice activities and quality of care provided to patients." "Performance improvement activities should include, but are not limited to, review of mortalities; the appropriateness and necessity of procedures performed; emergency transfers; reportable complications, and resultant outcomes (including all postoperative infections); analysis of patient satisfaction	"A performance improvement program should be implemented to provide a mechanism to review yearly the current practice activities and quality of care provided to patients." "Performance improvement activities should include, but are not limited to, review of mortalities; the appropriateness and necessity of procedures performed; emergency transfers; reportable complications, and resultant outcomes (including all postoperative infections); analysis of patient satisfaction

[11] N.C. Med. Bd., *Availability of Licensees to Their Patients* (last amended May 2012), https://www.ncmedboard.org/resources-information/professional-resources/laws-rules-position-statements/position-statements/availability_of_licensees_to_their_patients.
[12] *Id*.

	Proposed Abortion Clinic Regulations	Medical Board Guidelines for Level I Procedures	Medical Board Guidelines for Level II Procedures	Medical Board Guidelines for Level III Procedures
	privileges, peer review, tissue inspection, establishment of infection control procedures, and approval of additional procedures to be performed in the clinic. (e) Records shall be kept of the activities of the committee for a period not less than 10 years. These records shall include: (1) reports made to the governing authority; (2) minutes of committee meetings including date, time, persons attending, description and results of cases reviewed, and recommendations made by the committee; and (3) information on any corrective action taken. (f) The clinic shall conduct orientation, training, or education programs to correct deficiencies that are uncovered as a result of the quality assurance program." 10A N.C. Admin Code 13S .0324		surveys and complaints; and identification of undesirable trends (such as diagnostic errors, unacceptable results, follow-up of abnormal test results, medication errors, and system problems). Findings of the performance improvement program should be incorporated into the practice's educational activity."	surveys and complaints; and identification of undesirable trends (such as diagnostic errors, unacceptable results, follow-up of abnormal test results, medication errors, and system problems). Findings of the performance improvement program should be incorporated into the practice's educational activity."
Laboratory Services Requirement	"(a) Each clinic shall have the capability to provide or obtain laboratory tests required in connection with the procedure to be performed. (b) The governing authority shall establish written policies regarding which surgical specimens require examination by a pathologist. requiring examination by a pathologist of all surgical specimens except for those types of specimens that the governing authority has determined do not require examination. (c) Each patient shall have the following performed and a record of the results placed in the patient's medical record prior	None.	"Appropriate laboratory studies should be obtained within 30 days of the planned surgical procedure."	"Appropriate laboratory studies should be obtained within 30 days of the planned surgical procedure."

	Proposed Abortion Clinic Regulations	Medical Board Guidelines for Level I Procedures	Medical Board Guidelines for Level II Procedures	Medical Board Guidelines for Level III Procedures
	to the abortion: (1) pregnancy testing, except when a positive diagnosis of pregnancy has been established by ultrasound; (2) anemia testing (hemoglobin or hematocrit); and (3) Rh factor testing. (d) Patients requiring the administration of blood shall be transferred to a local hospital having blood bank facilities. (e) The clinic shall maintain a manual in a location accessible by employees, that includes the procedures, instructions, and manufacturer's instructions for each test procedure performed, including: (1) sources of reagents, standard and calibration procedures, and quality control procedures; and (2) information concerning the basis for the listed 'normal' ranges. (f) The clinic shall perform and document, at least quarterly, calibration of equipment and validation of test results." 10A N.C. Admin Code 13S .0325			
Medical Requirements	"(b) The clinic shall have written protocols,; personnel, and-equipment to handle medical emergencies[...]which may arise in connection with services provided by the clinic. [...] (d) The clinic shall provide intervention for emergency situations. These provisions shall include: (1) basic cardio-pulmonary life support; (2) emergency protocols for: (A) administrati on of intravenous fluids; (B) establishing and maintaining airway support;	None.	"All office personnel should be familiar with and capable of carrying out written emergency instructions. The instructions should be followed in the event of an emergency, any untoward anesthetic, medical or surgical complications, or other conditions making hospitalization of a patient necessary. The instructions should include	"All office personnel should be familiar with and capable of carrying out written emergency instructions. The instructions should be followed in the event of an emergency, any untoward anesthetic, medical or surgical complications, or other conditions making hospitalization of a patient necessary. The instructions should include arrangements

	Proposed Abortion Clinic Regulations	Medical Board Guidelines for Level I Procedures	Medical Board Guidelines for Level II Procedures	Medical Board Guidelines for Level III Procedures
	(C) oxygen administration; (D) utilizing a bag-valve-mask resuscitator with oxygen reservoir; (E) utilizing a suction machine; and (F) utilizing an automated external defibrillator; (3) emergency lighting available in the procedure room as set forth in Rule- .2012 of this Subchapter; and (4) ultrasound equipment." 10A N.C. Admin Code 13S .0326(b)(d) "(a) The procedure room shall be maintained exclusively for surgical procedures and shall be so designed and maintained to provide an environment free of contamination. The clinic shall establish procedures for infection control and universal precautions. (b) Tissue Examination: (1) The physician performing the abortion is responsible for examination of all products of conception (P.O.C.) prior to patient discharge. Such examination shall note specifically the presence or absence of chorionic villi and fetal parts, or the amniotic sac. The results of the examination shall be recorded in the patient's medical record. (2) If adequate tissue is not obtained based on the gestational age, the physician performing the procedure shall evaluate for ectopic pregnancy, or an incomplete procedure. 10A N.C. Admin Code 13S .0328		arrangements for immediate contact of emergency medical services when indicated and when advanced cardiac life support is needed. When emergency medical services are not indicated, the instructions should include procedures for timely escort of the patient to the hospital or to an appropriate practitioner." "A physician who performs surgical or special procedures in an office requiring the administration of anesthesia services should be credentialed to perform that surgical or special procedure by a hospital, an ambulatory surgical facility, or substantially comply with criteria established by the Board." "If the physician administers the anesthetic as part of a surgical or special procedure (Level II only), he or she also should have documented competence to deliver the level of anesthesia administered."	for immediate contact of emergency medical services when indicated and when advanced cardiac life support is needed. When emergency medical services are not indicated, the instructions should include procedures for timely escort of the patient to the hospital or to an appropriate practitioner." "A physician who performs surgical or special procedures in an office requiring the administration of anesthesia services should be credentialed to perform that surgical or special procedure by a hospital, an ambulatory surgical facility, or substantially comply with criteria established by the Board."

	Proposed Abortion Clinic Regulations	Medical Board Guidelines for Level I Procedures	Medical Board Guidelines for Level II Procedures	Medical Board Guidelines for Level III Procedures
Post-Operative Discharge Requirements	"(a) A patient whose pregnancy is terminated on an ambulatory basis shall be observed in the clinic to ensure that no post-operative complications are present. Thereafter, patients may be discharged according to a physician's order and the clinic's protocols. [...] (c) The following criteria shall be documented prior to discharge: (1) the patient shall be ambulatory with a stable blood pressure and pulse; and (2) bleeding and pain are assessed to be stable and not a concern for discharge. [...] (e) The clinic shall have a defined protocol for triaging post-operative calls and complications. This protocol shall establish a pathway for physician contact to ensure ongoing care of complications that the operating physician is incapable of managing." 10A N.C. Admin Code 13S .0329(a)(c)(e)	None.	"Criteria for discharge for all patients who have received anesthesia should include the following: ● confirmation of stable vital signs; ● stable oxygen saturation levels; ● return to pre-procedure mental status; ● adequate pain control; ● minimal bleeding, nausea and vomiting; ● resolving neural blockade, resolution of the neuraxial blockade; and ● eligible to be discharged in the company of a competent adult."	"Criteria for discharge for all patients who have received anesthesia should include the following: ● confirmation of stable vital signs; ● stable oxygen saturation levels; ● return to pre-procedure mental status; ● adequate pain control; ● minimal bleeding, nausea and vomiting; ● resolving neural blockade, resolution of the neuraxial blockade; and ● eligible to be discharged in the company of a competent adult."
Sanitation and Housekeeping Requirements	"(a) All supplies and equipment used in patient care shall be cleaned or sterilized between use for different patients. (b) Methods of cleaning, handling, and storing all supplies and equipment shall be such as to prevent the transmission of infection through their use as determined by the clinic through their governing authority." 10A N.C. Admin Code 13S .0330 "Clinics that are licensed by the Division to perform abortions	None.	"The practice should comply with state and federal regulations regarding infection control. For all surgical and special procedures, the level of sterilization should meet applicable industry and occupational safety requirements. There should be a procedure and schedule for cleaning, disinfecting and sterilizing equipment and patient care items. Personnel	The practice should comply with state and federal regulations regarding infection control. For all surgical and special procedures, the level of sterilization should meet applicable industry and occupational safety requirements. There should be a procedure and schedule for cleaning, disinfecting and sterilizing equipment and patient care items. Personnel

	Proposed Abortion Clinic Regulations	Medical Board Guidelines for Level I Procedures	Medical Board Guidelines for Level II Procedures	Medical Board Guidelines for Level III Procedures
	shall comply with the Rules governing the sanitation of hospitals, nursing homes, adult care homes, and other institutions, contained in 15A NCAC 18A .1300 which is hereby incorporated by reference including subsequent amendments and editions. 10A N.C. Admin Code 13S .0202 "In addition to the standards set forth in Rule .0202 of this Subchapter, clinics that are licensed by the Division to perform abortions shall meet the following standards: (1) the floors, walls, woodwork, and windows must be cleaned at least daily; (2) the premises must be kept free from rodents and insect infestation; (3) bath and toilet facilities must be maintained in a clean and sanitary condition consistent with 15A NCAC 18A .1312; and (4) linen that comes directly in contact with the patient shall be provided for each individual patient. No such linen shall be interchangeable from one patient to another before being cleaned, sterilized, or laundered." 10A N.C. Admin Code 13S .0315		should be trained in infection control practices, implementation of universal precautions, and disposal of hazardous waste products. Protective clothing and equipment should be readily available."	should be trained in infection control practices, implementation of universal precautions, and disposal of hazardous waste products. Protective clothing and equipment should be readily available."

	Proposed Abortion Clinic Regulations	**Medical Board Guidelines for Level I Procedures**	**Medical Board Guidelines for Level II Procedures**	**Medical Board Guidelines for Level III Procedures**
Food Service	"Nourishments, such as crackers and soft drinks, shall be available and offered to all patients." 10A N.C. Admin Code 13S .0331	None.	None.	None.

December 6, 2023

VIA ELECTRONIC SUBMISSION

Taylor Corpening
DSHR Rule-making Coordinator
Raleigh, NC 27699
dhsr.rulescoordinator@dhhs.nc.gov

Re: Request for Comments for Subchapter 13S Licensure of Suitable Facilities for the Performance of Surgical Abortions.

To North Carolina Medical Care Commission:

On behalf of Ipas, a non-profit, international non-governmental organization in Chapel Hill, I am pleased to submit the following evidence in response to the North Carolina Medical Care Commission's proposal to adopt rules cited as *10A NCAC 13S .0101, .0104, .0106, .0107, .0109, .0111, .0112, .0114, .0210, .0202, .0207, .0209-.0212, .0315 and .0318-.033* posted on November 6, 2023.

Ipas began its work on safe abortion in 1973 with the provision of life-saving manual vacuum aspiration (MVA) technology to health systems in several countries. Over the ensuing 50 years, Ipas has garnered enormous experience through its continued singular commitment to expanding access to and improving the quality and safety of abortion globally. Much of our work has been in countries with restrictive abortion laws and with low resources. Even in these settings with few clinical regulations and resources, abortion and miscarriage management with vacuum aspiration has proven to be safe, simple, and effective (Huber et al., 2016; Grimes et al., 2006; Henkel & Shaw, 2021).

Abortion is essential health care to which everyone has a right. However, in this state, the imposition of needless restrictions on abortion care, which are in direct conflict with the abundant, robust evidence on the safety of abortion provided with vacuum aspiration, make the delivery of abortion care unnecessarily difficult for clinics and providers and limits access for patients.

For your consideration, we offer the following summary of the evidence supporting the safety of abortion with manual vacuum aspiration.

Recommendations from leading international organizations

Vacuum aspiration is recommended for abortion care and miscarriage management by the World Health Organization (WHO) and the world's leading gynecological and obstetric organizations, including the American College of Obstetricians and Gynecologists (ACOG), the Royal College of Obstetricians and Gynaecologists (RCOG) and the International Federation of Gynecology and Obstetrics (FIGO).

"Abortion, using medication or a simple outpatient surgical procedure, is a safe health-care intervention, when carried out with a method appropriate to the gestational age of pregnancy and – in the case of a

P.O. Box 9990 Chapel Hill, NC 27515 USA
+1-919-967-7052 /1-800-334-8446
ContactUs@ipas.org

ipas.org

facility-based procedure – by a person with the necessary skills. In these circumstances, complications or serious adverse effects are rare." (WHO, 2022).

"*Abortion is safer than many common medical procedures. The risk of complication or mortality from abortion is less than the same risk from common procedures like wisdom tooth removal, cancer-screening colonoscopy, and plastic surgery.*" (ACOG, 2023).

Safety

A 2015 systematic review analyzed 57 studies reporting data for 337,460 aspiration abortions performed before 14 weeks gestation in North America, Western Europe, Scandinavia and Australia/New Zealand (White, Carroll, & Grossman, 2015). Major complications requiring intervention (such as hemorrhage requiring transfusion or perforation necessitating repair) occurred in ≤ 0.1% of procedures; hospitalization was necessary in ≤ 0.5% of cases.

Studies looking at different cadres of providers (physician assistants, nurses, nurse midwives, etc.) in other settings have had similar results (Hakim-Elahi, Tovell, & Burnhill, 1990; Jejeebhoy et al., 2011; Warriner et al., 2006; Weitz et al., 2013). In two studies that compared newly trained midlevel providers to experienced physician providers (Jejeebhoy et al., 2011; Weitz et al., 2013), there were no observed differences in aspiration abortion success or complication rates.

A retrospective cohort study conducted in the United States compared rates of procedural complications during outpatient aspiration abortion through 13 weeks and six days gestation in women with at least one medical comorbidity (diabetes, hypertension, obesity, HIV, epilepsy, asthma, thyroid disease and bleeding/clotting disorders) to women without comorbidities. The overall rate of complications—which included uterine perforation, blood loss greater than 100mL, cervical laceration and retained products of conception that required re-aspiration— was 2.9%; there was no difference between the two groups (Guiahi et al., 2015). Two later retrospective cohort studies, that together included 5,288 aspiration abortion procedures performed before 13 weeks gestation, found no differences in complication rates between obese, overweight, and normal weight women (Benson et al., 2016; Mark et al., 2017).

Abortion safety compared to other outpatient procedures

The overall risk of having a complication at the time of an abortion is like that incurred during outpatient dental procedures (Jung et al, 2023). "The major incident rate for abortion (0.1%) is lower than the published rates for pregnancy (1.4%), as well as other common procedures such as colonoscopy (0.2%), wisdom tooth removal (1.0%), and tonsillectomy (1.4%). Abortion care is, thus, safer than many other unregulated outpatient procedures" (Upadhyay et al., 2018).

Mortality

In the United States, the mortality rate from all legal induced abortion between 2013-2020 was 0.45 deaths per 100,000 reported abortions; mortality rates disaggregated by abortion type or length of pregnancy are not available. "Since 1978, all rates for the preceding 5-year periods have been fewer than 1 death per 100,000 abortions, demonstrating the low risk for death associated with legal induced abortion" (Kortsmit et al., 2023). In comparison, during the period from 2007-2016 the mortality rate from live birth in the United States was 17 deaths per 100,000 live births (Creanga et al., 2017; Petersen

et al., 2019). A secondary data analysis that compared mortality rates associated with live birth to those from legal induced abortion in the United States found that the risk of death from childbirth was 14-fold higher than the risk of death from abortion (Raymond & Grimes, 2012). In the 2015 systematic review about the safety of vacuum aspiration in multiple countries referenced above, no deaths were reported (White et al., 2015).

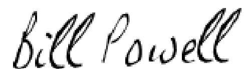
Effects of facility type on abortion safety

A retrospective cohort study of women who underwent induced abortions in ambulatory surgical centers (ASCs) versus office-based settings found that rates of abortion-related morbidities and adverse events did not differ significantly regardless of where the procedures were performed (Roberts et al, 2018). A systematic review found that the existing evidence, while limited, does not indicate a difference in patient safety for outpatient procedures performed in ASCs versus physician offices. Additionally, laws that have singled out abortion facilities with specific facility requirements appear to be associated with decreased availability of services (Berglas et al., 2018).

We ask the Committee to reconsider the proposed regulations and to adopt regulations that are in keeping with this evidence underscoring the profound safety of abortion with vacuum aspiration performed as a simple, office-based procedure.

Should you have questions about any of the cited evidence or have other questions, I welcome you to contact me at the address or email below.

Respectfully,



Bill Powell, PhD, RN, FNP
Senior Medical Scientist
Ipas
P.O. Box 9990
Chapel Hill, NC 27515
powellb@ipas.org

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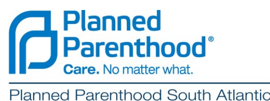

December 6, 2023

VIA ELECTRONIC TRANSMISSION

Taylor Corpening
DSHR Rules Coordinator
809 Ruggles Drive
2701 Mail Service Center
Raleigh, NC 27699
dhsr.rulescoordinator@dhhs.nc.gov

Re: Request for Comments for North Carolina Medical Care Commission Proposed Temporary Rules for Abortion Clinics

Planned Parenthood South Atlantic (Planned Parenthood) submits these comments in response to the North Carolina Medical Care Commission proposal to adopt temporary rules for licensure of suitable facilities for the performance of surgical abortions, cited as 10A NCAC 13S .0101, .0104, .0106, .0107, .0109, .0111, .0112, .0114, .0201, .0202, .0207, .0209-.0212, .0315, and .0318-.0331. As a trusted health care provider, educator, and advocate, Planned Parenthood appreciates the opportunity to weigh in on policy recommendations that impact our health care clinics, and by extension our patients all across the state.

Planned Parenthood is a safety net provider for the populations in North Carolina most in need of health services. The majority of our clinics in North Carolina provide abortion care in addition to other types of health care, including birth control services, STI testing and treatment, preventive screenings, and other essential services. People across our state trust Planned Parenthood to provide them with quality, expert care in a confidential and non-judgmental setting, and we have done that in North Carolina for decades.

"Surgical"[1] — or procedural — abortion care is extremely safe.[2] It has a far lower complication rate (less than 1%) than many other procedures performed in outpatient clinic settings, such as colonoscopies, liposuction, and wisdom teeth extraction.[3] Abortions are routinely provided in

[1] Although certain outpatient abortion methods are sometimes referred to as "surgical abortion," that is a misnomer, as they do not entail the typical characteristics of surgery, such as an incision into bodily structures. According to the American College of Obstetricians and Gynecologists (ACOG), the leading professional organization for obstetrician-gynecologists, these methods are more appropriately characterized as a procedure, which is defined as a "short interventional technique that includes the following general categories . . . non-incisional diagnostic or therapeutic intervention through a natural body cavity or orifice" and is "generally associated with lower risk of complications."

[2] Nat'l Acads. of Scis., Eng'g, & Med., The Safety and Quality of Abortion Care in the United States, Nat'l Acads. Press 1, 74–75 (2018). The mortality risk for abortion is lower than that of many other common procedures that are not required to be performed in a hospital. For example, one recent and robust analysis found that in the United States, the mortality rate for colonoscopy is 2.9 per 100,000 procedures and the mortality rate for plastic surgery is 0.8 to 1.7 per 100,000 procedures. By contrast, the mortality rate for legal induced abortion is 0.7 per 100,000 procedures.

[3] Ushma D. Upadhyay et al., Incidence of Emergency Department Visits and Complications After Abortion, 125 Obstetrics & Gynecology 175, 181 (2015); Nat'l Acads. of Scis., Eng'g & Med., The Safety & Quality of Abortion Care in the United States 10 (2018) at 74–75. *See* Am. Soc'y for Gastrointestinal

office-based settings, with no effect on safety.[4] Despite this fact, the facilities requirements for abortion clinics in North Carolina are much more onerous than the facilities guidelines promulgated by the North Carolina Medical Board for the provision of safe and effective outpatient procedures — the standard for other similarly situated providers.[5] As a result of this medically unnecessary and costly regulation of abortion clinics, over time, the number of abortion clinics has decreased and stagnated — reducing access to these services.[6] Today, there are only fourteen freestanding abortion clinics in the entire state.

During this rulemaking process, the Medical Care Commission has the opportunity to reevaluate the regulation of abortion clinics in our state, and make additional changes to its proposed temporary rules that would protect patient health and safety without impeding access to health care. We do not ask for special treatment, but rather that abortion clinic regulations be right-sized to reflect the safety of the procedures occurring within them, and that abortion clinics be held to the same or similar standards that apply to other providers of comparable outpatient procedures.

Methods and Safety of Procedural Abortion Care

First, it may be helpful to understand the methods of procedural abortion care — what it is, and what it is not.

Up to approximately 14 to 15 weeks after a person's last menstrual period (LMP), procedural abortions typically involve the use of gentle suction to empty the contents of the uterus. This procedure, which is also referred to as an aspiration abortion, is the same procedure that is used to treat miscarriage. Aspiration abortion typically takes between five to ten minutes to

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Endoscopy, Complications of Colonoscopy, 74 Gastrointestinal Endoscopy 745, 747 (2011); Grazer & de Jong, Fatal Outcomes from Liposuction: Census Survey of Cosmetic Surgeons, 105 Plastic & Reconstructive Surgery 436, 441 (2000); Francois Blondeau & Nach G. Daniel, Extraction of Impacted Mandibular Third Molars: Postoperative Complications and their Risk Factors, 73 J. Canadian Dental Ass'n 325 (2007).

[4] In a study of more than 50,000 abortions, there was no statistically significant difference in morbidities and adverse events between abortions performed in an ambulatory surgical setting versus those performed in an office-based setting. Sarah C.M. Roberts, Ushma Upadhyay & Guodong Liu, Association of Facility Type with Procedural-Related Morbidities and Adverse Events Among Patients Undergoing Induced Abortions , 319(24) JAMA 2497-2504 (2018), https://jamanetwork.com/journals/jama/fullarticle/2685987.

[5] North Carolina Medical Board Position Statement 5.1.1, Office Based Procedures, (Sept. 2021), https://www.ncmedboard.org/resources-information/professional-resources/laws-rules-position-statements/position-statements/office-based_procedures. The Facility Guidelines Institute – an independent not-for-profit organization that sets guidelines for the design and construction of health care facilities – notes that "a procedure that does not entail penetration of the protective surfaces [of the patient's body] is by definition not invasive and therefore not required . . . to be performed in an ASC." Brief for Amicus Curiae Facility Guidelines Institute in Support of Neither Party at 3, Whole Woman's Health v. Hellerstedt, 136 S. Ct. 2292 (2016), https://www.scotusblog.com/wp-content/uploads/2016/01/15-274-ac-Facility-Guidelines-Institute.pdf (hereinafter, "FGI Amicus Brief").

[6] The costs associated with abortions performed at ambulatory surgical centers are significantly higher than the costs associated with abortions performed in office-based settings, without any difference in safety. Douglas L. Leslie et al., Healthcare Costs for Abortions Performed in Ambulatory Surgery Centers vs. Office-Based Settings, 222 Obstetrics & Gynecology, 348 (2020).

complete. It can be done in a medical office under a local anesthetic — indeed, aspiration is routinely done in medical offices to treat miscarriage.[7]

Starting around 14 to 15 weeks LMP, and depending on specific patient needs, procedural abortions are generally performed using a method called dilation and evacuation ("D&E"), in which clinicians dilate the cervix and use a combination of suction and instruments to empty the uterus. This procedure can also be used to treat miscarriage.

Depending on the patient and method of cervical dilation, D&E can be performed as a one- or two-day procedure. As with aspiration abortions, D&E abortions are routinely and safely provided in outpatient, office-based settings. D&E generally involves no more than moderate sedation, though clinicians use different levels of sedation depending on the setting and patient preference. In North Carolina, this type of procedural abortion is now only utilized for abortions provided under the exceptions to the 12-week abortion ban — namely, in cases of rape, incest, "life-limiting" fetal anomaly, or if there is a medical emergency.

While sometimes referred to as "surgical" abortions, aspiration and D&E abortions are not what is commonly understood to be "surgery." For example, they involve no incision, do not require general anesthesia, and do not require a sterile field, because the vagina naturally contains bacteria.[8]

Procedural abortion care — whether aspiration or D&E — is safely provided on an outpatient basis, with extremely low complication rates. When complications do occur, they are usually minor and managed in an outpatient setting, either during the same visit as the abortion or in a follow-up visit. Major complications, which are defined as complications requiring hospital admission, surgery, or blood transfusion, occur in less than one-quarter of one percent (0.23%) of all abortions.[9] Abortion-related emergency room visits constitute just 0.01% of all emergency room visits among women aged 15–49 in the United States.[10] The risk of complications from an abortion in the first trimester of pregnancy — after which point abortion is banned in North Carolina except in very narrow circumstances — is even lower.[11]

[7] Courtney A. Schreiber et al., Treatment Decisions at the Time of Miscarriage Diagnosis, 128 Obstetrics & Gynecology 1347, 1347 (2016).

[8] See, e.g., Bonnie S. Jones, Sara Daniel & Lindsay K. Cloud, State Law Approaches to Facility Regulation of Abortion and Other Office Interventions , 108(4) Am. J. of Pub. Health 486, 486 (2018), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5844403/pdf/AJPH.2017.304278.pdf ("Like other procedures performed through an orifice naturally colonized with bacteria, procedural abortions need to be performed in 'clean,' but not 'sterile,' physical environments."); FGI Amicus Brief at 4-5.

[9] Ushma Upadhyay et al., Incidence of Emergency Department Visits and Complications After Abortion, 125 Obstetrics & Gynecology 175 (2015).

[10] Ushma Upadhyay et al., Abortion-Related Emergency Room Visits in the United States: An Analysis of a National Emergency Room Sample, 16 BMC Med. 1, 1 (2018).

[11] *Id.*

Comparison to Other Outpatient Procedures

Despite the extremely low complication rate associated with abortion care, the proposed temporary regulations require abortion clinics to comply with a thicket of rules that are administratively onerous and medically unnecessary. The regulations mirror others that have been in place for many years in this state.[12] They are outdated and based on misperceptions about the health care that is being provided.

In North Carolina, many other types of outpatient procedures with higher complication rates than abortion are performed in office-based settings (i.e., one that is not an ambulatory surgical center ("ASC") or other specialized facility). Among these procedures are invasive procedures and those where general anesthesia is used.[13] These office-based settings are not regulated by the State; rather, the Medical Board sets guidelines for such office-based procedures, which they differentiate into Level I, II, and III procedures based on, for example, the type of sedation used and risk of complications for a particular procedure.[14] This evidence-based guidance applies to various types of office-based gynecological procedures, including diagnostic procedures that remove tissue from the uterus for testing, which are substantially similar in technique and risk to procedural abortion. It also applies to office-based procedures used to manage incomplete miscarriages — care that is identical in technique and, in some cases, carries more risk of complication than procedural abortion.

In contrast to evidence-based guidance, the abortion clinic regulations mandate that any facility that provides procedural abortions must comply with myriad restrictions completely unrelated to patient health and safety. For example, a clinic that provides any procedural abortions and has more than one floor must have at least one elevator that can accommodate a stretcher, 10A N.C. Admin. Code 13S.0209, even though stretchers are not used in abortion care and the rate of serious complications that would require a hospital transfer, as noted above, are exceedingly rare. Likewise, patient-use corridors in any facility that provides abortions must be no less than 60 inches wide, again to facilitate stretcher use, 10A N.C. Admin. Code 13S.0210, and the minimum width of doors to all rooms needing access for stretchers must be three feet, 10A N.C. Admin. Code 13S.0211.

The proposed regulations also impose strict ventilation and air supply requirements. See 10A N.C. Admin. Code 13S.0212 Specifically, the ventilation and air supply requirements are

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[12] Previously contained in Subchapter 14E of 10A NC Admin. Code; repealed effective July 1, 2023 following the repeal of G.S. 14-45.1 in Session Law 2023-14.

[13] These procedures include liposuction (5% complication rate), breast augmentation (10.6% complication rate for most common complication), and abdominoplasty (10–20% complication rate). Hannah Headon et al., Capsular Contracture after Breast Augmentation: An Update for Clinical Practice, 42 Archives Plastic Surgery 532 (2015); Pedro Vidal et al., Abdominoplasty: Risk Factors, Complication Rates, and Safety of Combined Procedures, 44 Archives Plastic Surgery 457 (2017). All of these procedures are currently performed in office-based, non-ASC facilities in North Carolina.

[14] Health centers providing abortion care are also appropriately regulated in the same manner as other medical offices through state and local building and fire safety codes, CLIA, OSHA, clinician licensure requirements, and other regulations of general applicability.

targeted at ensuring a sterile field for surgeries, which is unnecessary for the provision of abortion care.[15] While abortion providers of course sterilize equipment and maintain clean environments, procedural abortion, like other similar outpatient procedures, differs from surgery because it does not require a sterile field. This is because procedural abortion does not entail an incision into the body, but rather insertion of instruments into a body cavity through a natural orifice.[16]

Further, the proposed temporary regulations require non-hospital-affiliated facilities that provide abortions to have a multitude of separate, specially designated spaces — including a receiving area, examining room, preoperative preparation and holding room, procedure room, recovery room, clean workroom, soiled workroom, a space with patient lockers, and "nourishment station with storage and preparation area for serving meals or in-between meal snacks." 10A N.C. Admin. Code 13S .0207. There is no medical reason why these would need to all be separate spaces, but it makes finding adequate space for an abortion clinic more difficult and more costly. Notably, the Board of Medicine does not impose any such mandate on other providers of comparable office-based medical procedures.

Additionally, the proposed temporary regulations require health care facilities that provide abortions to have a licensed RN supervise and organize nursing staff, and there must be at least one licensed RN with experience in post-operative or post-partum care on duty at all times that procedural abortion patients are in the clinic. 10A N.C. Admin. Code 13S .0323. A health facility that provides abortion care is not exempt from this requirement even if one or more clinicians of comparable or even higher-level training (e.g., a physician or a PA) are present, as contemplated in the Medical Board's office-based procedures guidance. This means that regardless of who else is available, if there is no RN on duty, or if the RN has to leave suddenly, patients cannot receive an abortion. This blanket RN requirement serves no medical purpose, limits clinics' ability to provide care, and is out of line with the regulation of other similar office-based providers.

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[15] The ACOG Consensus Guidelines on outpatient abortion care clearly state that no heightened environmental controls are required for the safe provision of in-clinic abortion: "Facilities should use adequate heating, ventilation, and cooling systems. Systems typical for offices are adequate in this context; no special heating, ventilation, or cooling systems are needed." ACOG, Consensus Guidelines for Facilities Performing Outpatient Procedures Evidence Over Ideology, 133 Obstetrics & Gynecology 255, 259 (2019), DOI: 10.1097/AOG.0000000000003058. These Consensus Guidelines were endorsed by a number of additional prominent national organizations and associations, including the American Public Health Association, American Academy of Family Physicians, American College of Nurse-Midwives, American College of Physicians, and the Society of Family Planning. *See* ACOG, Press Statements: New Guidelines for Facilities Performing Office-Based Procedures Including Abortion (Jan. 24, 2019), https://www.acog.org/news/news-releases/2019/01/new-guidelines-for-facilities-performing-office-based-procedures-including-abortion.

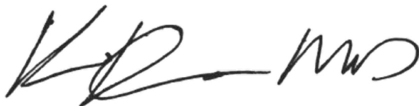
[16] *See, e.g.,* Bonnie S. Jones, Sara Daniel & Lindsay K. Cloud, State Law Approaches to Facility Regulation of Abortion and Other Office Interventions , 108(4) Am. J. of Pub. Health 486, 486 (2018), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5844403/pdf/AJPH.2017.304278.pdf ("Like other procedures performed through an orifice naturally colonized with bacteria, procedural abortions need to be performed in 'clean,' but not 'sterile,' physical environments."); FGI Amicus Brief at 4-5.

There is no medical reason or justification for requiring facilities that provide procedural abortions, which have lower complication rates than comparable office-based procedures[17] to accommodate stretchers, maintain specific temperatures or air flow and myriad unnecessary separate spaces, and adhere to rigid staffing structures while other medical offices do not face the same requirements. This arbitrary regulation of facilities where abortions are provided is without medical basis and at odds with statements from professional standard-setting bodies, including the American Medical Association and the American College of Obstetricians and Gynecologists.[18]

We urge you to take the opportunity to "adopt, amend, and repeal" regulations to ensure that the regulations applicable to licensed abortion clinics are actually suitable for facilities that provide procedural abortions. Using your judgment of the medical evidence, as medical providers and professionals, you can encourage a new and different standard that aligns more appropriately with the type and complexity of the care that is occurring in abortion clinics in our state.

If you require additional information about the issues raised in this letter, please contact me at katherine.farris@ppsat.org.

Respectfully submitted,



Katherine Farris
Chief Medical Officer
Planned Parenthood South Atlantic
100 South Boylan Ave., Raleigh, NC 27603

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[17] *See, e.g.*, Nat'l Acads. of Scis., Eng'g & Med., The Safety & Quality of Abortion Care in the United States 10 (2018) at 74–75 ("Abortion-related mortality is also lower than that for colonoscopies (2.9 per 100,000), plastic surgery (0.8 to 1.7 per 100,000), dental procedures (0.0 to 1.7 per 100,000), and adult tonsillectomies (2.9 to 6.3 per 100,000).").

[18] Brief of Amici Curiae American College of Obstetricians and Gynecologists, American Medical Association, et al. in Support of June Medical Services, L.L.C., et al. at 20, June Med. Servs. LLC v. Russo, 140 S.Ct. 2103 (2020) (Nos. 18-1323, 18-1460); ACOG, New Guidelines for Facilities Performing OfficeBased Procedures Including Abortion (Jan. 24, 2019), https://www.acog.org/news/news-releases/2019/01/new-guidelines-for-facilities-performing-office-based-procedures-including-abortion; ACOG, Consensus Guidelines for Facilities Performing Outpatient Procedures Evidence Over Ideology, 133 Obstetrics & Gynecology 255, 255–60 (2019), DOI: 10.1097/AOG.0000000000003058.

Exhibit F

Licensing of Abortion Clinic Rules Readoption
10A NCAC 13S – Public Comments
Comment Period 11/7/23-12/6/23

Introduction:

There were 4 written comments received during the public comment period on the readoption and amendment of Rules 10A NCAC 13S .0101, .0104, .0106, .0107, .0109, .0111, .0112, .0114, .0201, .0202, .0207, .0209-.0212, .0315, and .0318-.0331. These comments were submitted by representatives from Planned Parenthood, The American College of Obstetricians and Gynecologists, Ipas Partners for Reproductive Justice and Jonas Swartz.

1) Listing of Comments Received and Agency's Consideration of Comments:

Commenter	Comment Summary
1) Planned Parenthood	The rules are too strict and have restrictions completely unrelated to patient health and safety. Specifically for rules .0209, .0210, and .0211, which restrict the size of patient-use corridors to facilitate stretcher use. Stretchers are not used in abortion care and it is highly unlikely that patients requires a hospital transfer. Rule .0212 deals with ensuring sterile fields for surgeries, but procedural abortion, being an outpatient procedure, does not requires a sterile field because it is not surgery. Rule .0207 requires non-hospital-affiliated facilities that provide abortions to have a multitude of separate, specially designed spaces. This makes finding adequate space for an abortion clinic more difficult and costly. Rule .0323's blanket RN requirement serves no medical purpose, limits a clinic's ability to provide care, and is out of line with the regulation of other similar office-based providers. Take away: The rules are too strict and do not align with the industry standards set by entities like the American Medical Association and the American College of Obstetricians and Gynecologists.

Agency Response to Comments Above:

DHSR acknowledges receipt of comments and will be discussed with internal and external stakeholders in meetings for the adoption of rules.

2) Listing of Comments Received and Agency's Consideration of Comments:

Commenter	Comment Summary
2.) The American College of Obstetricians and Gynecologists	ACOG opposes facility and staffing requirements like those found in the proposed rules because they improperly regulate medical care and do not improve patient safety or quality of care. The restrictions in the proposed rules make it more difficult and expensive to obtain abortions by imposing additional costs on the patients who can least afford them.

Agency Response to Comments Above:

DHSR acknowledges receipt of comments and will be discussed with internal and external stakeholders in meetings for the adoption of rules.

3) Listing of Comments Received and Agency's Consideration of Comments:

Commenter	Comment Summary
3.) Ipas Partners for Reproductive Justice	Ipas provided a summary of evidence supporting the safety of abortion with manual vacuum aspiration. The evidence discussed overall safety, abortion safety compared to other outpatient procedures, mortality, and the effects of facility type on abortion safety. Ipas did not cite specific concerns with specific rules. Take away: Reconsider the proposed regulations and adopt regulations that are in keeping with the evidencing provided, underscoring the profound safety of abortion with vacuum aspiration performed as a simple, office-based procedure.

Agency Response to Comments Above:

DHSR acknowledges receipt of comments and will be discussed with internal and external stakeholders in meetings for the adoption of rules.

4) Listing of Comments Received and Agency's Consideration of Comments:

Commenter	Comment Summary				
4.) Jonas Swartz		Proposed Rule(s) that are inconsistent with Medical Board Guidelines.	Medical Board Guidelines for Level I Procedures	Medical Board Guidelines for Level II Procedures	Medical Board Guidelines for Level III Procedures
	Physical Requirements	10A NCAC 13S .0201, .0202, .0207,	None	None	None

Commenter	Comment Summary				
		.0209, .0210, .0211, .0212			
	License & Fees Requirements	10A NCAC 13S .0112, .0114, .0106, .0107, .0109	None	Physician performing Level II procedures in an office “should be able to demonstrate, upon request by the Board, substantial compliance with these guidelines, or should obtain accreditation of the office setting by an approved accreditation agency or organization.”	Physician performing Level III procedures in an office “should be able to demonstrate, upon request by the Board, substantial compliance with these guidelines, or should obtain accreditation of the office setting by an approved accreditation agency or organization.”
	Inspection and Investigation Authority	10A NCAC 13S .0111	None	None	None
	Medical Staff Organization & Personnel Requirements	10A NCAC 13S .0322, .0323	None	Physician performing procedure or other health care professional present SHOULD be ACLS certified, and at least on other health care professional SHOULD be BCLS certified.	An anesthesiologist or a CRNA supervised by a physician should administer anesthesia. The physician cannot administer the anesthesia. Physician

Commenter	Comment Summary				
					performing procedure or the anesthesia provider should be ACLS certified, and at least one other health care professional should be BCLS certified.
	Patient Transfer Agreement	10A NCAC 13S .0326(a),(c), .0320(c), .0329(c)	None	No written agreement required	No written agreement required
	Requirements for Medical Records	10A NCAC 13S .0321(a), .0321(e), .0321(f)	None	Medical record should include: procedure code or narrative description of procedure; "sufficient information to identify the patient, support the diagnosis, justify the treatment, and document the outcome and required follow-up care"; "Medical history, physical examination, lab studies obtained within 30 days	Medical record should include: procedure code or narrative description of procedure; "sufficient information to identify the patient, support the diagnosis, justify the treatment, and document the outcome and required follow-up care"; "Medical history, physical examination, lab studies obtained within 30 days
	Requirements for Personnel Records	10A NCAC 13S .0322(a)(b)(c)	None	None	none

Commenter	Comment Summary				
	Governing Authority Requirements	10A NCAC 13S .0318(a)(b)(c)(d)(f)(g), .0319(a)(b)(c)	None	None	None
	Required Information to Patient	10A NCAC 13S .0320(d)	None	"The patient should receive verbal instruction understandable to the patient or guardian, confirmed by written post-operative instructions and emergency contact numbers. The instructions should include: ● the procedure performed; ● information about potential complications; ● telephone numbers to be used by the patient to discuss complications or should questions arise; ● instructions for medications prescribed and pain management; ● information regarding the follow-up visit date, time and location; and ● designated treatment hospital in the event of emergency." "If the licensee is not going to be available after hours, the licensee must provide clear instructions to the patient for securing after-hours care. It is the responsibility of the licensee to ensure that the patient has sufficient information regarding how to secure after-hours care."[11]	
	Quality Assurance	10A NCAC .0324	None	"A performance improvement program should be implemented to provide a mechanism to review yearly the current practice activities and quality of care provided to patients." "Performance improvement activities should include, but are not limited to,	

Commenter	Comment Summary				
				review of mortalities; the appropriateness and necessity of procedures performed; emergency transfers; reportable complications, and resultant outcomes (including all postoperative infections); analysis of patient satisfaction surveys and complaints; and identification of undesirable trends (such as diagnostic errors, unacceptable results, follow-up of abnormal test results, medication errors, and system problems). Findings of the performance improvement program should be incorporated into the practice's educational activity."	
	Laboratory Services Requirement	10A NCAC 13S .0325	None	"Appropriate laboratory studies should be obtained within 30 days of the planned surgical procedure."	
	Medical Requirements	10A NCAC 13S .0326(b)(d), .0328	None	"All office personnel should be familiar with and capable of carrying out written emergency instructions. The instructions should be followed in the event of an emergency, any untoward anesthetic, medical or surgical complications, or other conditions making hospitalization of a patient necessary. The instructions should include arrangements for immediate contact of emergency medical services when indicated and	"All office personnel should be familiar with and capable of carrying out written emergency instructions. The instructions should be followed in the event of an emergency, any untoward anesthetic, medical or surgical complications, or other conditions making hospitalization of a patient necessary. The instructions should include arrangements for immediate contact of emergency medical services when indicated and

Commenter	Comment Summary				
				when advanced cardiac life support is needed. When emergency medical services are not indicated, the instructions should include procedures for timely escort of the patient to the hospital or to an appropriate practitioner." "A physician who performs surgical or special procedures in an office requiring the administration of anesthesia services should be credentialed to perform that surgical or special procedure by a hospital, an ambulatory surgical facility, or substantially comply with criteria established by the Board." "If the physician administers the anesthetic as part of a surgical or special procedure (Level II only), he or she also should have documented competence to deliver the level of anesthesia administered."	when advanced cardiac life support is needed. When emergency medical services are not indicated, the instructions should include procedures for timely escort of the patient to the hospital or to an appropriate practitioner." "A physician who performs surgical or special procedures in an office requiring the administration of anesthesia services should be credentialed to perform that surgical or special procedure by a hospital, an ambulatory surgical facility, or substantially comply with criteria established by the Board."

Commenter	Comment Summary			
	Post-Operative Discharge Requirements	10A NCAC 13S .0329(a)(c)(e)	None	"Criteria for discharge for all patients who have received anesthesia should include the following: ● confirmation of stable vital signs; ● stable oxygen saturation levels; ● return to preprocedure mental status; ● adequate pain control; ● minimal bleeding, nausea and vomiting; ● resolving neural blockade, resolution of the neuraxial blockade; and ● eligible to be discharged in the company of a competent adult."
	Sanitation and Housekeeping Requirements	10A NCAC 13S .0330, .0202, .0315	None	"The practice should comply with state and federal regulations regarding infection control. For all surgical and special procedures, the level of sterilization should meet applicable industry and occupational safety requirements. There should be a procedure and schedule for cleaning, disinfecting and sterilizing equipment and patient care items. Personnel should be trained in infection control practices, implementation of universal precautions, and disposal of hazardous waste products. Protective clothing and equipment should be readily available."
	Food Service	10A NCAC 13S .0331	None	None
	Take away: The rules should be changed to reflect/ be consistent with the regulation of medical care in the state and be less restrictive.			

Agency Response to Comments Above:

DHSR acknowledges receipt of comments and will be discussed with internal and external stakeholders in meetings for the adoption of rules.

CENTER *for*
REPRODUCTIVE
RIGHTS

NEW YORK
199 Water Street, Fl. 22
New York, NY 10038
TEL. (917) 637-3600

reproductiverights.org

December 6, 2023

Submitted via electronic mail
Taylor Corpening
Rulemaking Coordinator, North Carolina Division of Health Service Regulation
809 Ruggles Drive
2701 Mail Service Center
Raleigh, NC 27699

Re: Request for Comments for Subchapter 13S Licensure of Suitable Facilities for the Performance of Surgical Abortions.

Dear Ms. Corpening and members of the North Carolina Medical Care Commission,

The Center for Reproductive Rights ("Center") is pleased to submit these comments in response to the Medical Care Commission's ("Commission") proposal to adopt temporary rules cited as 10A NCAC 13S .0101, .0104 .0106, .0107, .0109, .0111, .0112, and .0114 (imposing licensure, inspection, and building plan requirements); 0210, .0202, .0207, and .0209-.0212 (imposing construction and equipment requirements); and .0315 and .0318-.033 (regulating how services are provided, including emergency transfer and staffing requirements) posted on November 6, 2023.[1]

We urge the Commission to reconsider the proposed regulations. As a threshold matter, we object to the new licensing scheme and accompanying regulations as arbitrarily singling out non-hospital facilities offering procedural abortion care, subjecting them to onerous and medically unjustified requirements that no other providers of office-based medical care must meet. This interference with the provision of abortion services will harm patients. Clinics that provide procedural abortion care should be subject to the same generally applicable rules that govern other outpatient, office-based care.[2]

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[1] Dept. of Health and Hum. Serv., Proposed Rule Changes Governing Abortion Clinics (proposed Oct. 30, 2023), https://www.oah.nc.gov/documents/rules/10a-ncac-13s-proposed-temporary-rules/download?attachment. [hereinafter "Proposed Temporary Rule"].
[2] See N.C. Medical Bd., Position Statement, 5.1.1 Office-Based Procedures, (Amended Sep. 2021), https://www.ncmedboard.org/resources-information/professional-

In addition, the proposed regulations go much further than required by S.B. 20, imposing a host of medically unnecessary restrictions that clinics must navigate in order to provide essential healthcare. While S.B. 20 authorizes the Commission to create regulations to implement its licensing scheme, the statutory text by no means requires the thicket created by the proposed regulations.

The history of the targeted regulation of abortion providers ("TRAP") nationally and in North Carolina makes clear that these regulations are part of a national effort to make abortion inaccessible.[3] State legislatures have enacted TRAP restrictions under the guise of protecting patient health and safety, but they undermine those stated interests. We strongly urge the Commission to reconsider the proposed regulations and instead draft regulations that are factually aligned with the stated reason for this regulatory action: "protecting the health and safety of people obtaining reproductive health care."[4]

The Center is a legal advocacy organization that uses the power of the law to advance reproductive rights as human rights around the world. Since 1992, the Center has worked to protect the right to abortion and other reproductive health care services, including maternal health and assisted reproduction. As part of our mission, we aim to ensure that all people have meaningful access to abortion care. The Center has successfully challenged restrictive abortion laws, including TRAP restrictions, before state and federal courts, including U.S. Supreme Court cases *Whole Woman's Health v. Hellerstedt* and *June Medical Service*s *v. Russo*, discussed in more detail below. As an organization that works to expand access to abortion care, we value the opportunity to contribute to the regulatory process.

This comment provides an overview of how TRAP laws emerged and their demonstrated purpose of shuttering abortion clinics. Section I illustrates North Carolina's TRAP scheme as part of a coordinated national effort to hinder abortion access. Section II reviews Supreme Court cases demonstrating that TRAP restrictions are not rooted in patient safety. Section III demonstrates that the proposed regulations

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resources/laws-rules-position-statements/position-statements/office-based_procedures. [hereinafter "Medical Board Guidelines for Office-Based Procedures"].
[3] *Targeted Regulations of Abortion Providers*, CENTER FOR REPRODUCTIVE RIGHTS (2015), https://reproductiverights.org/targeted-regulation-of-abortion-providers-trap/.
[4] Proposed Temporary Rule, *supra* note 1.

undermine patient health and safety and requests that the Commission reconsider the proposed regulations.

I. North Carolina's TRAP scheme is part of a nationwide effort to regulate abortion out of existence.

TRAP restrictions chip away at the right to abortion and, while this incrementalist approach reached its zenith in the 2010s, these efforts continue in states where abortion remains legal, even if not always accessible.

After *Roe* protected the right to abortion at the national level, the anti-abortion movement pivoted to a strategy of passing restrictions under the guise of "protecting women's health." This approach was informed by market research conducted by the National Right to Life Committee(NRLC), which found the public believed the anti-abortion movement's fetus-centered strategy[5] failed to take the health of the pregnant person into account.[6] A shift in the focus to justifying restrictions under the purported interest of "protecting women's health" emerged.[7] This shift is exemplified by the anti-abortion model legislation that has permeated state legislatures across the country. Since 2005, Americans United for Life (AUL) has released annual guides commonly referred to as a "playbook" of model anti-abortion legislation.[8]
The timing of the introduction of TRAP restrictions in North Carolina is noteworthy given the context of these national efforts. North Carolina was one of five states in 2013 that implemented new TRAP restrictions

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[5] Daniel Mansbach & Alisa Von Hagel, *The Changing Strategies of the Anti-Abortion Movement*, POLITICAL RESEARCH ASSOCIATES (Jan. 7, 2021), https://politicalresearch.org/2021/01/07/changing-strategies-anti-abortion-movement#_ftn1. *See also Woman vs. Fetus: Frame Transformation and Intramovement Dynamics in the Pro-Life Movement*, Sociological Spectrum 34(2), 163, 184 (2014), https://www.tandfonline.com/doi/full/10.1080/02732173.2014.878624. ("[T]his strategy is based on the claims that the fetus, from the moment of conception, is a human being deserving equal protection under the law.").
[6] *Id.*
[7] David Cohen et. al., *Rethinking Strategy After Dobbs*, Stanford Law Review (Aug. 2022), https://www.stanfordlawreview.org/online/rethinking-strategy-after-dobbs/. *See also* Reva B. Siegel, Brainerd Currie Lecture, *The Right's Reasons: Constitutional Conflict and the Spread of the Woman-Protective Antiabortion Argument*, 57 DUKE L.J. 1641 (2008) (describing the rise of the woman-protective antiabortion argument).
[8] Jacqueline Y. Ma, "Undue" Delegation: Private Delegation and Other Strategies to Challenge Admitting-Privileges Laws, 30 Colum. J. Gender & L. 549, 555–57 (2016), https://journals.library.columbia.edu/index.php/cjgl/article/view/2737/1242.

for abortion providers, including requirements that abortion clinics meet standards similar to ASCs.[9] Importantly, there was no medical justification for these restrictions in North Carolina but what did change was a shift in the makeup of the North Carolina General Assembly and the election of an anti-abortion Governor in 2012.[10] In fact, then-Speaker of the House, Thom Tillis, infamously added numerous abortion restrictions, including a licensing scheme like the one created by S.B. 20, to a motorcycle safety bill as a backdoor attempt to quietly erode reproductive rights on the final day of the 2013 legislative session.[11] Following the enactment of the state's TRAP laws, reproductive rights advocates began bringing attention to the proliferation of TRAP in the United States, highlighting North Carolina in explaining how such restrictions do not align with patient safety.[12]

Requiring clinics offering procedural abortion to comply with burdensome licensure, inspection, and building requirements is unnecessary and undermines patient health by requiring abortion providers to expend time and resources that clinic staff would otherwise use to serve patients. For instance, the proposed regulations include licensure and inspection requirements that exceptionalize abortion providers, as other office-based providers are not subject to such requirements.[13] Failure to meet and comply with arduous administrative processes to maintain licensure includes harsh penalties including

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[9] Elizabeth Nash & Rachel Benson Gold,, GUTTMACHER INSTITUTE, LAWS AFFECTING REPRODUCTIVE HEALTH AND RIGHTS: 2013 STATE POLICY REVIEW (Dec. 2013), https://www.guttmacher.org/laws-affecting-reproductive-health-and-rights-2013-state-policy-review.

[10] *See* Election 2012: North Carolina, N.Y. TIMES (2012), https://www.nytimes.com/elections/2012/results/states/north-carolina.html.

[11] Tim Murphy, *Mr. Motorcycle Abortion Bill Goes to Washington,* MOTHER JONES (July 29, 2013), https://www.motherjones.com/politics/2013/07/kay-hagan-thom-tillis-abortion-race/.

[12] ELIZABETH NASH & RACHEL BENSON GOLD, GUTTMACHER INSTITUTE, LAWS AFFECTING REPRODUCTIVE HEALTH AND RIGHTS: 2013 STATE POLICY REVIEW (Dec. 2013), https://www.guttmacher.org/laws-affecting-reproductive-health-and-rights-2013-state-policy-review. *See* RACHEL BENSON GOLD & ELIZABETH NASH, GUTTMACHER INSTITUTE, TRAP LAWS GAIN POLITICAL TRACTION WHILE ABORTION CLINICS— AND THE WOMEN THEY SERVE—PAY THE PRICE GUTTMACHER INSTITUTE, (2013), https://www.guttmacher.org/sites/default/files/pdfs/pubs/gpr/16/2/gpr160207.pdf.

[13] Medical Board Guidelines for Office-Based Procedures, *supra* note 2.

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cessation of operation.[14] Further, the proposed rule regarding inspections places abortion clinics under constant burden of having to divert time and resources from patient care to comply with the inspection process as "[a]n inspection may be conducted whenever the Division receives a complaint alleging the clinic is not in compliance with the rules of the subchapter" with no safeguard to substantiate complaints.[15]

Construction and equipment requirements subjecting abortion clinics to physical plant requirements resembling those of ASCs,[16] are unnecessary and threatens patient access. Compliance with such burdensome requirements is insurmountable for many clinics due to cost alone.[17] Although North Carolina has sixteen clinics offering abortion care, 91% of counties do not have an abortion provider. Subjecting clinics to such requirements undermine the Department of Health and Human Service's objective to maintain continuity of care as such prohibitive requirements has resulted in fewer clinics being able to provide procedural abortion care. These requirements provide no added patient health or safety benefit, as there is no significant difference in rates of complications between abortions provided in an ASC compared to office-based settings.[18] For instance, the proposed regulations mandate that abortion facilities have door widths to fit a stretcher.[19] Such a requirement is not necessary to advance patient health and safety as abortion is a far safer procedure than those provided at ASCs and the state does not require other outpatient facilities to meet such stringent plant requirements.

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[14] Proposed Temporary Rule, *supra* note 1. Medical Board Guidelines for Office-Based Procedures, *supra* note 2.
[15] Proposed Temporary Rule, *supra* note 1.
[16] North Carolina Subchapter 13C – Licensing of Ambulatory Surgical Facilities, http://reports.oah.state.nc.us/ncac/title%2010a%20-%20health%20and%20human%20services/chapter%2013%20-%20nc%20medical%20care%20commission/subchapter%20c/subchapter%20c%20rules.pdf.
[17] Medical Board Guidelines for Office-Based Procedures, *supra* note 2.
[18] *Safety of Abortion in Ambulatory Surgical Centers v. Office-base settings*, NEW STANDARDS IN REPRODUCTIVE HEALTH (June 2018), https://www.ansirh.org/sites/default/files/publications/files/safety_of_abortion_in_ascs_fact_sheet.pdf.
[19] Proposed Temporary Rule, *supra* note 1 (10A NCAC 13S.0211"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 not subject to occupancy.").

The proposed regulations also impose strict ventilation and air supply requirements. Specifically, the ventilation and air supply requirements are targeted at ensuring a sterile field for surgeries, which is unnecessary for the provision of abortion care. While the state's abortion providers of course sterilize equipment and maintain clean environments, the sterile field required for surgery is unnecessary for a procedural abortion as it does not entail an incision into the body, but rather insertion of instruments into a body cavity through a natural orifice.[20] Conversely, these requirements align with the model legislation promoted by AUL,[21] and the unnecessarily burdensome plant requirements at issue in *Whole Woman's Health* which resulted in 80% of clinics closing when the Texas law took effect.[22] In fact, the purpose is not to further patient safety at all. Instead, the intent of such restrictions, as outlined above, is to regulate abortion providers out of existence.

Requiring abortion providers to comply with stringent emergency transfer and staffing regulations when abortion is safer than other procedures offered at outpatient facilities is arbitrary and does not further patient health and safety. For instance, the proposed regulations require abortion clinics have a written plan for the transfer of emergency cases to the closest hospital.[23] Such a requirement is similar to the regulatory burden at issue in both *Whole Woman's Health* and *June Medical Services*,[24] requiring providers to obtain admitting privileges. In contrast, other office-based providers are not required to maintain such a written plan. Instead, the Medical Board has outlined guidelines for level II and level III procedures in which individual providers should "assure that a transfer protocol is in place, preferably with a hospital licensed in the same jurisdiction and within reasonable proximity."[25]

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[20] Proposed Temporary Rule, *supra* note 1 (10A NCAC 13S .0212 Elements and Equipment "All air supply and exhaust systems for the procedure suite and recovery area shall be mechanically operated. All fans serving exhaust systems shall be located at the discharge end of the system. The ventilation rates shown herein shall be considered as minimum acceptable rates. (i-vii).").
[21] AMERICANS UNITED FOR LIFE, *see* supra note 17. (https://aul.org/wp-content/uploads/2022/12/Womens-Health-Protection-Act-11-2022.pdf.).
[22] See *infra* text accompanying note 38. Miriam Berg, *New Map: 80% of Abortion Providers in Texas Close Overnight,* PLANNED PARENTHOOD (Oct. 9, 2014), New Map: 80% of Abortion Providers in Texas Close Overnight (plannedparenthoodaction.org)
[23] Proposed Temporary Rule, *supra* note 1.
[24] See *infra* text accompanying note 37-44
[25] Medical Board Guidelines for Office-Based Procedures, *supra* note 2.

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The way abortion providers are arbitrarily targeted by the proposed regulations can be further demonstrated by the requirements in .0323(d).[26] This regulation requires procedural abortion clinics to always have a nurse on duty when patients are in the clinic. A health facility that provides abortion care is not exempt from this requirement even if one or more clinicians of comparable or even higher-level training (e.g., a physician or an advanced practice clinician) are present. This requirement means that regardless of who else is available, if there is no registered nurse on duty, or if the nurse has to leave suddenly, patients cannot have an abortion. Subjecting procedural abortion providers to such a requirement appears arbitrary as compared to the NCMB guidelines for outpatient procedures, which specify that recovery "should be monitored by a registered nurse or other health care professional within the scope of his or her license or certification…"[27]

Further, the TRAP licensing scheme enacted by S.B. 20 mirrors the model language in the most recent AUL playbook.[28] Specifically, AUL's "Women's Health Protection Act" includes model legislation and policy guidance, boilerplate bill text, legislative intent, definitions, and regulations mirroring ASC requirements and directs the Department of Health to promulgate rules.

II. Courts have recognized that TRAP schemes undermine patient health and safety.

TRAP laws regulate abortion facilities without medical justification and more stringently than other similar outpatient medical facilities, including those providing riskier procedures. Abortion is incredibly safe and is far safer than carrying a pregnancy to term.[29] Abortion is also safer than

[26] Proposed Temporary Rule, *supra* note 1.
[27] Medical Board Guidelines for Office-Based Procedures, *supr*a note 2.
[28] Women's Health Protection Act (Abortion Clinic Regulations), Model Legislation & Policy Guide, Americans united for Life (2022), https://aul.org/wp-content/uploads/2022/12/Womens-Health-Protection-Act-11-2022.pdf.

[29] Elizabeth G. Raymond & David A. Grimes, The Comparative Safety of Legal Induced Abortion and Childbirth in the United States, 119 Obstetrics & Gynecology 215, 216 (2012)

other common procedures such as colonoscopy, wisdom tooth removal, and tonsillectomy."[30]

Yet, the true intent of this tactic is not to improve health and safety of patients, but instead to regulate abortion clinics out of existence. Following the Court's decisions in *Roe v. Wade*, [31] *Planned Parenthood of Southeastern Pennsylvania v. Casey*, [32] and *Gonzales v. Carhart*, [33] which refined the parameters of the abortion right, anti-abortion groups responded with model legislation testing the limits of these judgments. This model legislation gave rise to two cases in which the U.S. Supreme Court struck down TRAP restrictions, *Whole Woman's Health v. Hellerstedt*[34] and *June Medical Services v. Russo*.[35] Although abrogated on other grounds by the 2022 Supreme Court decision *Dobbs v. Jackson Women's Health Organization*,[36] *Whole Woman's Health* and *June Medical* both shed light on the actual intent and effect of TRAP restrictions.

Whole Woman's Health challenged two Texas laws: (1) a requirement that doctors who provide abortion services obtain admitting privileges at a local hospital and (2) a requirement that abortion facilities meet the same requirements as ambulatory surgical centers. Texas enacted these laws to shut down abortion clinics, and they did just that, forcing more than half of Texas' clinics to close their doors. In striking down these laws, the Court observed that "abortions taking place in an abortion facility are safe—indeed, safer than numerous procedures that take place outside hospitals" and yet are not subject to similar facility requirements.[37]

Organizations of healthcare providers, such as the National Physicians Alliance, American Academy of Nursing, and Doctors for America "who

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[30] National Academies Report, *supra* note 12, at 74–75 ("Abortion-related mortality is also lower than that for colonoscopies (2.9 per 100,000), plastic surgery (0.8 to 1.7 per 100,000), dental procedures (0.0 to 1.7 per 100,000), and adult tonsillectomies (2.9 to 6.3 per 100,000).")
[31] Roe v. Wade, 410 U.S. 113 (1973).
[32] Pa. V. Casey, 505 U.S. 833 (1992).
[33] Gonzales v. Carhart, 550 U.S. 124 (2007).
[34] Whole Woman's Health v. Hellerstedt, 579, U.S. 582 (2016).
[35] June Medical Services L.L.C. v. Russo, 591 U.S. __ (2020).
[36] Acknowledging the U.S. Supreme Court's June 2022 ruling which declared no federal constitutional right to abortion., Dobbs v. Jackson Women's Health Org., 597 U.S. __ (2022).
[37] Whole Woman's Health v. Hellerstedt, 136 S. Ct. 2292, 2315 (2016)

share a profound concern that the increasing political interference with – and pretextual regulation of —their professions will harm patients" submitted a brief in the case analyzing the law's intent.[38] These organizations acknowledged the legitimate role of states in regulating the provision of healthcare and examined how Texas used "health and safety" as mere pretext to make it difficult, and at times impossible, to provide abortion. The brief includes statements by leading national health organizations explaining that the Texas law would not promote patient health and safety. We encourage the Commission to review these.[39] *June Medical* challenged a Louisiana law that would have similarly prevented doctors from providing abortion services in the state unless they secured admitting privileges at a local hospital. Again, this law was designed to close clinics and undermine access to abortion—and was identical to the Texas admitting privileges law struck down in *Whole Woman's Health.*[40]

The Court struck down the challenged admitting privileges requirement, once again calling out the state for using deceptive medical regulations to shut down clinics. The ruling cited a brief led by the American College of Obstetricians and Gynecologists, and other American medical associations which underscored that "local admitting-privileges requirements for abortion providers offer no medical benefit and do not meaningfully advance continuity of care."[41]Another brief submitted by State Attorneys General outlined that the state failed to provide credible evidence to justify the need for the law to protect patient health. The brief highlights the lower court's finding that "'abortion in Louisiana has been extremely safe, with particularly low rates of serious complications" And just as in *Whole Woman's Health*, "[t]he state introduced no evidence

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[38]Brief for National Physicians Alliance, et al. as Amici Curiae Supporting Petitioners, Whole Woman's Health v. Hellerstedt, 579 U.S 582 (2016),https://www.reproductiverights.org/sites/default/files/documents/National%20Physicians%20Alliance%20Skadden.pdf,
[39] *Id.* at 11-12.
[40] *June Medical Services*, 591 U.S. at 1 ("Louisiana's Act 620, which is almost word-for-word identical to the Texas "admitting privileges" law at issue in Whole Woman's Health v. Hellerstedt…").
[41] *Id.* at 38 (citing Brief for American College of Obstetrics and Gynecologists, et al. as Amici Curiae Supporting Respondents, June Medical Services L.L.C. v. Russo, 591 U.S. __ (2020), https://www.acog.org/-/media/project/acog/acogorg/files/advocacy/amicus-briefs/2019/120219-june-medical-services-llcvrusso.pdf).

showing that patients have better outcomes when their physicians have admitting privileges" or "of any instance in which an admitting privileges requirement would have helped even one woman obtain better treatment.""[42]

Further, the State Attorneys General highlight ways the Louisiana law actually would worsen patient health. "The district court found on the basis of the record before it that Louisiana's admitting-privileges requirement would affirmatively undermine the State's interest in women's health by drastically reducing the availability of safe and legal abortions in Louisiana."[43] Despite the outcome of *Dobbs*, these cases illuminate how TRAP restrictions, such as the proposed regulations, actually undermine the stated objectives of protecting patient health and safety.

III. The proposed regulations undermine patient health and safety.

Repealing North Carolina's TRAP scheme would further the Department of Health and Human Services' stated objectives to protect patient health and safety while maintaining continuity of care,[44] as the North Carolina Medical Board sets guidelines for such office-based procedures, which

[42] Brief for States of New York et al. as Amici Curiae Supporting Petitioners, June Medical Services L.L.C. v. Gee, No. 17-30391 (5th Cir. 2019). *June Medical Services* 591 U.S. at 4-6.
[43] Brief for States of New York et al., June Medical Services L.L.C. v. Gee, No. 17-30391 (5th Cir. 2019) at 15.
[44] Proposed Temporary Rule, *supra* note 1.

they differentiate into Level I,[45] II,[46] and III[47] procedures, based on, for example, the type of sedation used and risk of complications for a particular procedure. In North Carolina, non-abortion procedures performed in the office-based setting (i.e., one that is not an ASC or other specialized facility)[48] include invasive procedures and include procedures where general anesthesia is used. Such procedures are more invasive than abortion and have higher complication rates than abortion, including liposuction (5% complication rate); breast augmentation (10.6% complication rate for most common complication[49]); abdominoplasty (10–20% complication rate[50]); gluteal fat grafting (mortality rate of one in 3,000,96 compared to 0.58 in 100,000 for abortion[51]). All of these

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[45] Level I office-based procedures are defined as "any surgical or special procedures" that (1) "do not involve drug-induced alteration of consciousness"; (2) "where preoperative medications are not required or used other than minimal preoperative tranquilization of the patient (anxiolysis of the patient)"; (3) "where the anesthesia required or used is local, topical, digital block, or none"; and (4) "Where there is only a moderate risk of surgical and/or anesthetic complications and the need for hospitalization as a result of these complications is unlikely." N.C. Med. Bd., Position Statements: Office-Based Procedures (last amended Sept. 2021), https://www.ncmedboard.org/resources-information/professional-resources/laws-rules-position-statements/position-statements/office-based_procedures.

[46] Level II office-based procedures are defined as "any surgical or special procedures" that (1) "require, or reasonably should require, the use of a major conduction blockade, deep sedation/analgesia, or general anesthesia;" and (2) "where there is only a moderate risk of surgical and/or anesthetic complications and the need for hospitalization as a result of these complications is unlikely." *Id.*

[47] Level III office-based procedures are defined as "any surgical or special procedures" that (1) "require,
or reasonably should require, the use of major conduction blockade, deep sedation/analgesia, or general
anesthesia"; and (2) "where there is only a moderate risk of surgical and/or anesthetic complications and the need
for hospitalization as a result of these complications is unlikely." *Id.*

[48] Such settings include dialysis facilities, cancer treatment facilities, and plastic surgery practices.

[49] Hannah Headon et al., Capsular Contracture after Breast Augmentation: An Update for Clinical
Practice, 42 Archives Plastic Surgery 532 (2015).

[50] Pedro Vidal et al., Abdominoplasty: Risk Factors, Complication Rates, and Safety of Combined
Procedures, 44 Archives Plastic Surgery 457 (2017).

[51] Am. Soc'y of Plastic Surgeons, Plastic Surgery Societies Issue Urgent Warning About the Risks
Associated with Brazilian Butt Lifts (Aug. 6, 2018), https://www.plasticsurgery.org/news/press-releases/plastic-surgery-societies-issue-urgent-warning-about-the-risks-associated-with-brazilian-butt-lifts.

procedures are currently performed in office-based, non-ASC facilities in North Carolina.

Further, doctors, nurses, and medical professionals who provide or assist in the provision of abortion care are already subject to North Carolina's generally applicable professional licensure, health, and tort laws and regulations. For instance, the Medical Board has the power to place physicians and physicians assistants on probation, impose other sanctions, or suspend or revoke their licenses for a variety of acts or conduct.[52]

In the year and a half following the overturning of *Roe*, public health experts, medical associations, and legal scholars have worked to educate government officials and the public about the dire effects of abortion bans and the related public health consequences, including an increase in maternal and infant mortality.[53] North Carolina's twelve-week ban has demonstrably hindered patient care as abortion has decreased by 31% since the law took effect in July.[54] In addition to the ban, the state's TRAP restrictions further exacerbate this public health crisis as compliance with such burdensome restrictions depletes resources, especially time, that providers would otherwise use to serve patients.[55] As a long-standing body comprised of healthcare providers responsible for licensing and regulating healthcare facilities in furtherance of the Department of Health and Human Services objectives to ensure patient health and safety,[56] the Commission is well poised to put forth regulations that are based on medical evidence as opposed to those put forth by state legislators seeking to undermine abortion access in the state.

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[52] N.C. Gen. Stat. § 90-14.
[53] THE U.S. MATERNAL HEALTH DIVIDE: THE LIMITED MATERNAL HEALTH SERVICES AND WORSE OUTCOMES OF STATES PROPOSING NEW ABORTION RESTRICTIONS, COMMONWEALTH FUND (Dec. 2022), U.S. Maternal Health Divide: Limited Services and Worse Outcomes | Commonwealth Fund.
[54] *New Data Show a 31% Decrease in Abortion in North Carolina After Recent Implementation of 12-Week Ban and In-Person Counseling Requirement*, GUTTMACHER INST. (Oct. 11, 2023), https://www.guttmacher.org/news-release/2023/new-data-show-31-decrease-abortions-north-carolina-after-recent-implementation-12.
[55] MERCIER ET AL., *TRAP laws and the invisible labor of US abortion providers*, CRIT PUBLIC HEALTH. 26(1),77-87 (2016), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4999072/.
[56] HEALTH CARE FACILITIES FINANCE ACT ANNUAL REPORT, N.C. MEDICAL CARE COMM'N, 4-5 (June 30, 2022), https://info.ncdhhs.gov/dhsr/ncmcc/pdf/2022/HealthCareFacilitiesFinanceActAnnualReport-June302022.pdf.

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For the reasons outlined above, we request that the Commission reconsider promulgating regulations that would undermine the health and safety of North Carolinians and instead craft rules that are more aligned with those asserted interests.

Thank you for the opportunity to submit these comments.

Respectfully Submitted,

Jennifer Mahan

Jennifer N. Mahan
State Legislative Fellow