

1 10A NCAC 14E .0101 is amended with changes as published in NCR 29:11, pp. 1290-1298 as follows:

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3 **10A NCAC 14E .0101 DEFINITIONS**

4 The following definitions will apply throughout this Subchapter:

5 (1) "Abortion" means the termination of a pregnancy as defined in G.S. ~~90-21.6.~~ 90-21.81(1).

6 ~~(+)~~ (2) "Clinic" means a freestanding facility (a facility neither physically attached nor operated by a
7 licensed hospital) for the performance of abortions completed during the first 20 weeks of
8 pregnancy.

9 ~~(=)~~ (3) "Complication" includes but is not limited to hemorrhage, infection, uterine perforation, cervical
10 ~~laceration~~ laceration, or retained products of conception.

11 ~~(=)~~ (4) "Division" means the Division of Health Service Regulation of the North Carolina Department of
12 Health and Human Services.

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

16 ~~(=)~~ (6) "Governing authority" means the individual, ~~agency or group~~ agency, group, or corporation
17 appointed, elected or otherwise designated, in which the ultimate responsibility and authority for
18 the conduct of the abortion clinic is ~~vested.~~ vested pursuant to Rule .0302 of this Subchapter.

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

22 ~~(6)~~ (8) "New ~~facility~~ clinic" means one that is not certified as an abortion clinic by the Division as of
23 July 1, ~~1994,~~ 2014, and has not been certified within the previous six months of the application for
24 certification.

25 (9) "Qualified Physician" means a licensed physician who advises, procures, or causes a miscarriage
26 or abortion as defined in G.S. 14-45.1(g).

27 ~~{(9)}~~ (10) "Registered Nurse" means a person who holds a valid license issued by the North Carolina
28 Board of Nursing to practice professional nursing in accordance with the Nursing Practice Act,
29 Article 9A, Chapter 90 of the North Carolina General Statutes.

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31 *History Note:* Authority G.S. 14-45.1(a); 14-45.1(g); 143B-10; S.L. 2013-366 s.4(c);

32 Eff. February 1, 1976;

33 Readopted Eff. December 19, 1977;

34 Amended Eff. October 1, 2015; July 1, 1994; December 1, 1989; June 30, 1980.

1 10A NCAC 14E .0104 is amended with changes as published in NCR 29:11, pp. 1290-1298 as follows:

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

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

13

14 *History Note: Authority G.S. 14-45.1(a); 143B-10;*
15 *Eff. February 1, 1976;*
16 *Readopted Eff. December 19, 1977. 1977;*
17 *Amended Eff. October 1, 2015.*

1 10A NCAC 14E .0109 is amended with changes as published in NCR 29:11, pp. 1290-1298 as follows:

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

4 Each certificate, unless previously suspended or revoked, pursuant to the applicable rules and statutes shall be
5 renewable annually ~~without charge~~ upon the filing of an ~~application~~ application, payment of the non-refundable
6 renewal fee as defined in G.S. 131E-269, and its approval by the Division.

7

8 *History Note: Authority G.S. 14-45.1(a); 143B-10; G.S. 131E-269;*

9 *Eff. February 1, 1976;*

10 *Readopted Eff. December 19, 1977. 1977;*

11 *Amended Eff. October 1, 2015.*

1 10A NCAC 14E .0111 is amended with changes as published in NCR 29:11, pp. 1290-1298 as follows:

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

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

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

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

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

16 ~~[e) An inspection shall be considered whenever the purpose of the inspection is to determine whether the clinic~~
17 ~~complies with the rules of this Subchapter or whenever there is reason to believe that some condition exists which is~~
18 ~~not in compliance with the rules of this Subchapter.]~~

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

21 ~~(g)~~ (f) A clinic shall file a plan of correction for cited deficiencies within 10 business days of ~~[receipt.]~~ receipt of
22 the report of the survey. The Division shall review and respond to a written plan of correction within 10 business
23 days of ~~[receipt.]~~ receipt of the corrective action plan.

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25 *History Note:* Authority G.S. 14-45.1(a); 14-45.1(a1); ~~[G.S. 90-21.83;]~~ 143B-10; S.L. 2013-366 s.4(c);
26 Eff. February 1, 1976;
27 Readopted Eff. December 19, 1977;
28 Amended Eff. October 1, 2015, July 1, 1994.

1 10A NCAC 14E .0201 is amended with changes as published in NCR 29:11, pp. 1290-1298 as follows:

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3 **10A NCAC 14E .0201 BUILDING CODE REQUIREMENTS**

4 (a) The physical plant for a ~~facility clinic~~ clinic ~~must~~ shall meet or exceed minimum requirements of the North Carolina
5 State Building Code for Group B occupancy (business office facilities) which is incorporated herein by reference
6 including subsequent ~~amendments.~~ amendments and editions. Copies of ~~The North Carolina Building Code,~~
7 ~~Volume One, General Construction,~~ may be obtained for thirty dollars (\$30.00) from the N.C. Department of
8 ~~Insurance, P.O. 26387, Raleigh, NC 27611.~~ the Code can be obtained from the International Code Council online at
9 <http://www.iccsafe.org>, <http://shop.iccsafe.org/north-carolina-doi.discounts?ref=NC> for a cost of five hundred
10 twenty-seven dollars (\$527.00), or accessed electronically free of charge at <http://www.ecodes.biz>.

11 (b) The requirements contained in this Section shall apply to new ~~facilities~~ clinics and to any alterations, repairs,
12 rehabilitation work, or additions which are made to a previously certified facility.

13

14 *History Note: Authority G.S. 14-45.1(a); 143B-10;*
15 *Eff. February 1, 1976;*
16 *Readopted Eff. December 19, 1977;*
17 *Amended Eff. October 1, 2015; July 1, 1994; December 1, 1989.*

1 10A NCAC 14E .0202 is amended with changes as published in NCR 29:11, pp. 1290-1298 as follows:

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3 **10A NCAC 14E .0202 SANITATION**

4 ~~Abortion clinics~~ Clinics that are certified by the Division to perform abortions ~~must~~ shall comply with the ~~rules~~
5 Rules governing the sanitation of hospitals, nursing homes, ~~and rest homes, sanitariums, sanatoriums and~~
6 ~~educational~~ adult care homes, and other institutions, contained in 15A NCAC 18A .1300 which is hereby
7 incorporated by reference including subsequent amendments and editions. Copies of 15A NCAC 18A .1300 may be
8 obtained at no charge from the Division of Public Health, Environmental Health Section ~~Environmental Health~~
9 ~~Services, Division of Environmental Health, N.C. Department of Environment and Natural Resources, 1630 1632~~
10 Mail Service Center, Raleigh, NC 27699-1630. 27699-1632, or accessed electronically free of charge from the
11 Office of Administrative Hearings at <http://www.ncoah.com>.

12

13 *History Note: Authority G.S. 14-45.1(a); 143B-10;*
14 *Eff. February 1, 1976;*
15 *Readopted Eff. December 19, 1977;*
16 *Amended Eff. October 1, 2015; July 1, 1994.*

1 10A NCAC 14E .0206 is amended with changes as published in NCR 29:11, pp. 1290-1298 as follows:

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3 **10A NCAC 14E .0206 ELEMENTS AND EQUIPMENT**

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

6 (1) Mechanical ~~requirements~~ requirements.

7 (a) Temperatures and humidities:

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

10
11

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

12
13
14

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

19 (i) The ventilation system shall be designed and balanced to provide the pressure
20 relationships ~~shown herein.~~ detailed in Subparagraph (b)(vii) of this Rule.

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

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

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

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

31 (vi) Air handling duct systems shall not have duct ~~linings in ducts serving procedure~~
32 ~~or recovery rooms.~~ linings.

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

35
36

Area	Pressure Relationship	Minimum Air Changes/Hour
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37

1	Procedure	P	6
2	Recovery	P	6
3	Soiled work,		
4	janitor's Janitor's closet,		
5	toilets, Toilets,		
6	Soiled holding	N	10
7	Clean work or		
8	Clean holding	P	4

(P = positive pressure N = negative pressure)

(2) Plumbing And Other Piping ~~Systems~~ Systems.

(a) Medical Gas and Vacuum Systems

(i) Piped-in medical gas and vacuum systems, if installed, shall meet the requirements of ~~NFPA 99-1990,~~ NFPA-99-2012, type one system, which is hereby incorporated by reference including subsequent amendments and editions. Copies of ~~NFPA 99-1990~~ NFPA-99-2012 may be purchased from the National Fire Protection Association, 1 Batterymarch Park, P.O. Box 9101, Quincy, MA 02269-9101, ~~for twenty eight dollars and fifty cents (\$28.50).~~ or accessed electronically free of charge at <http://www.nfpa.org>.

(ii) If inhalation anesthesia is used in any concentration, the facility must meet the requirements of ~~NFPA 70-1993~~ NFPA 70-2011 and ~~NFPA 99-1990,~~ NFPA 99-2012, current editions relating to inhalation anesthesia, which are hereby incorporated by reference including subsequent amendments and editions. Copies of ~~NFPA 70-1993~~ NFPA 70-2011 and ~~NFPA 99-1990~~ NFPA 99-2012 may be purchased from the National Fire Protection Association, 1 Batterymarch Park, P.O. Box 9101, Quincy, MA 02269-9101, ~~for thirty two dollars and fifty cents (\$32.50) and twenty eight dollars and fifty cents (\$28.50) respectively.~~ or accessed electronically free of charge at <http://www.nfpa.org>.

(b) Lavatories and sinks for use by medical personnel shall have the water supply spout mounted so that its discharge point is a minimum distance of five inches above the rim of the fixture with mixing type fixture valves ~~which~~ that can be operated without the use of the hands.

(c) Hot water distribution systems shall provide hot water at hand washing and bathing facilities at a minimum temperature of 100 degrees F. and a maximum temperature of 116 degrees F.

(d) Floor drains shall not be installed in procedure rooms.

1 (e) Building drainage and waste systems shall be designed to avoid installations in the
2 ceiling directly above procedure rooms.

3 (3) ~~Electrical Requirements~~ Requirements.

4 (a) Procedure and recovery rooms, and paths of egress from these rooms to the outside shall
5 have at a minimum, listed battery backup lighting units of one and one-half hour
6 capability that will automatically provide at least five foot candles of illumination at the
7 floor in the event of ~~needed for~~ a utility or local lighting circuit failure.

8 (b) ~~Essential electrically~~ Electrically operated medical equipment necessary for the safety of
9 the patient shall have, at a minimum, battery backup.

10 (c) Receptacles located within six feet of sinks or lavatories shall be ground-fault protected.

11 (d) ~~Provide at~~ At least one wired-in, ionization-type smoke detector shall be within 15 feet of
12 each procedure or recovery room entrance.

13 (4) ~~Each facility and its grounds shall be maintained to minimize hazards and enhance safety for staff~~
14 ~~and patients.~~ Buildings systems and medical equipment ~~must~~ shall have preventative maintenance
15 conducted as recommended by the equipment manufacturers' or installers' literature to assure
16 ~~satisfactory operation.~~ operation in compliance with manufacturer's instructions.

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18 *History Note:* Authority G.S. 14-45.1(a); 143B-10;
19 Eff. February 1, 1976;
20 Readopted Eff. December 19, 1977;
21 Amended Eff. October 1, 2015; July 1, 1994; December 1, 1989.

1 10A NCAC 14E .0207 is amended with changes as published in NCR 29:11, pp. 1290-1298 as follows:

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

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

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

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31 *History Note: Authority G.S. 14-45.1(a); 143B-10;*
32 *Eff. February 1, 1976;*
33 *Readopted Eff. December 19, 1977;*
34 *Amended Eff. October 1, 2015; December 24, 1979.*

1 10A NCAC 14E .0302 is amended with changes as published in NCR 29:11, pp. 1290-1298 as follows:

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3 **SECTION .0300 – ADMINISTRATION GOVERNING AUTHORITY**

4
5
6 **10A NCAC 14E .0302 PERSON IN AUTHORITY GOVERNING AUTHORITY**

7 ~~The governing authority shall designate a person to have authority and responsibility for the administrative and~~
8 ~~professional functions of the clinic.~~

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

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

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

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

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

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

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

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

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

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

1 *History Note:* Authority G.S. 14-45.1(a); 143B-10; [~~G.S. 90-21.83;~~] S.L. 2013-366 s.4(c);
2 *Eff. February 1, 1976;*
3 *Readopted Eff. December 19, 1977;*
4 *Amended Eff. October 1, 2015; December 1, 1989.*

1 10A NCAC 14E .0303 is amended with changes as published in NCR 29:11, pp. 1290-1298 as follows:

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3 **10A NCAC 14E .0303 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
6 partnership papers;
7 (2) policies and procedures of the governing authority, as required by Rule .0302 of this Section;
8 (3) minutes of the governing authority [~~meetings, if applicable;~~ meetings;
9 (4) minutes of the clinic's professional and administrative staff meetings;
10 (5) a current copy of the rules of this Subchapter;
11 (6) reports of inspections, reviews, and corrective actions taken related to licensure; and
12 (7) contracts and agreements related to licensure to which the clinic is a party.

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

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

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

26
27 *History Note:* Authority G.S. 14-45.1(a); [~~G.S. 90-21.83;~~] 143B-10; S.L. 2013-366 s.4(c);
28 Eff. February 1, 1976;
29 Readopted Eff. December 19, 1977;
30 Amended Eff. October 1, 2015; July 1, 1994.

1 10A NCAC 14E .0305 is amended with changes as published in NCR 29:11, pp. 1290-1298 as follows:

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3 **10A NCAC 14E .0305 MEDICAL RECORDS**

4 (a) A complete and permanent record shall be maintained for all patients ~~including; including the date and time of~~
5 ~~admission and discharge; the full and true name; address; date of birth; nearest of kin; diagnoses; duration of~~
6 ~~pregnancy; condition on admission and discharge; referring and attending physician; a witnessed, voluntarily signed~~
7 ~~consent for each surgery or procedure and signature of the physician performing the procedure; and the physician's~~
8 ~~authenticated history and physical examination including identification of pre-existing or current illnesses, drug~~
9 ~~sensitivities or other idiosyncrasies having a bearing on the operative procedure or anesthetic to be administered.~~

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

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

12 (3) the patient's address;

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

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

15 (6) the patient's diagnoses;

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

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

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

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

24 (11) documentation that indicates all items listed in Rule .0304(d) of this Section were provided to the
25 patient.

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

29 (c) If Rh is negative, the significance shall be explained to the patient and so recorded. The patient in writing may
30 reject Rh immunoglobulin, ~~or accept the appropriate desensitization material.~~ A written record of the patient's
31 decision shall be a permanent part of her medical record.

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

34 (e) The ~~facility~~ clinic shall maintain a daily procedure log of all patients receiving abortion services. This log shall
35 contain at least the following: patient name, estimated length of gestation, type of procedure, name of physician,
36 name of RN on duty, and date and time of procedure.

37 (1) the patient name;

- 1 (2) the estimated length of gestation;
- 2 (3) the type of procedure;
- 3 (4) the name of physician;
- 4 (5) the name of Registered Nurse on duty; and
- 5 (6) the date and time of procedure.

6 (f) Medical records shall be the property of the facility clinic and shall be preserved or retained in the State of North
7 Carolina for a period of not less than at least 20 10 years from the date of the most recent discharge, unless the client
8 is a minor, in which case the record must be retained until three years after the client's 18th birthday, regardless of
9 change of facility clinic ownership or administration. Such medical records shall be made available to the Division
10 upon request and shall not be removed from the premises where they are retained except by subpoena or court order.

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

13 (h) Should a facility clinic cease operation, arrangements shall be made for preservation of records for at least 20 10
14 years. The facility clinic shall notify the Division, in writing, concerning the arrangements. send written notification
15 to the Division of these arrangements.

16
17 *History Note:* Authority G.S. 14-45.1(a); [G.S. 90-21.83;] 143B-10; S.L. 2013-366 s.4(c);
18 *Eff. February 1, 1976;*
19 *Readopted Eff. December 19, 1977;*
20 *Amended Eff. October 1, 2015; July 1, 1994; December 1, 1989.*

1 10A NCAC 14E .0306 is amended with changes as published in NCR 29:11, pp. 1290-1298 as follows:

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3 **10A NCAC 14E .0306 PERSONNEL RECORDS**

4 ~~(a) Application. Each prospective employee or contractual employee must submit an application for employment~~
5 ~~which includes education, training, experience, and references.~~

6 ~~(b)~~ (a) Personnel Records:

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

8 (A) employee's identification;

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

10 ~~(B)~~ (C) resume of education and work experience;

11 ~~(C)~~ (D) verification of valid license (if required), education, training, and prior employment
12 experience; and

13 ~~(D)~~ (E) verification of references.

14 (2) Personnel records shall be confidential.

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

17 ~~(b)~~ ~~(c)~~ (c) Job Descriptions:

18 (1) The ~~facility~~ clinic shall have a written description ~~which~~ that describes the duties of every
19 position.

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

23 (3) The ~~facility~~ clinic shall review annually ~~and~~ and, if needed, update all job ~~descriptions, and~~
24 descriptions. The clinic shall provide a ~~current copy~~ the updated job description to each employee
25 or contractual employee assigned to the position.

26 ~~(d)~~ (c) All persons having direct responsibility for patient care shall be at least 18 years of age. ~~[All other~~
27 personnel, paid or unpaid, working in the clinic shall be at least 16 years of age.]

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

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

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

36
37 *History Note: Authority G.S. 14-45.1(a); ~~14-45.1(a1)~~; ~~[G.S. 90-21.83;]~~ 143B-10; S.L. 2013-366 s.4(c);*

- 1 *Eff. February 1, 1976;*
- 2 *Readopted Eff. December 19, 1977;*
- 3 *Amended Eff. October 1, 2015; July 1, 1994.*

1 10A NCAC 14E .0307 is amended with changes as published in NCR 29:11, pp. 1290-1298 as follows:

2

3 **10A NCAC 14E .0307 NURSING SERVICE**

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

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

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

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

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

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

16 ~~(b) There shall be supporting personnel sufficient to meet patient needs and to provide safe patient care.~~

17

18 *History Note: Authority G.S. 14-45.1(a); 143B-10; ~~[G.S. 90-21.83;]~~ S.L. 2013-366 s.4(c);*

19 *Eff. February 1, 1976;*

20 *Readopted Eff. December 19, 1977;*

21 *Amended Eff. October 1, 2015; December 1, 1989.*

1 10A NCAC 14E .0308 is adopted with changes as published in NCR 29:11, pp. 1290-1298 as follows:

2

3 **10A NCAC 14E .0308 ~~RESERVED FOR FUTURE CODIFICATION~~ QUALITY ASSURANCE**

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

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

8 (c) The committee shall consist of at least one physician who is not an owner, the chief executive officer or
9 designee, and other health ~~professionals as indicated.~~ professionals. The committee shall meet at least once per
10 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
13 infection 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) Orientation, ~~training~~ training, or education programs shall be conducted to correct deficiencies that are
21 uncovered as a result of the quality assurance program.

22

23 *History Note: Authority G.S. 14-45.1(a); ~~G.S. 90-21.83;~~ 143B-10; S.L.2013-366 s.4(c);*

24 *Eff. October 1, 2015.*

1 10A NCAC 14E .0309 is amended with changes as published in NCR 29:11, pp. 1290-1298 as follows:

2
3 **10A NCAC 14E .0309 LABORATORY SERVICES**

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

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

9 ~~(a) (c) Pre-operative Tests. As a minimum, there shall be performed for each patient the following laboratory tests~~
10 ~~which must be recorded~~ Each patient shall have the following performed and a record of the results placed in the
11 patient's medical record prior to the abortion:

- 12 (1) ~~Pregnancy~~ pregnancy testing, except when a positive diagnosis of pregnancy has been established
13 by ultrasound;
- 14 (2) ~~Anemia~~ anemia testing (hemoglobin or hematocrit); and
- 15 (3) Rh factor testing.

16 ~~(b) (d) Blood and Blood Products. Those patients~~ Patients requiring the administration of blood shall be transferred
17 ~~immediately~~ to a local hospital having blood bank facilities.

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

- 20 (1) ~~Sources~~ sources of reagents, standard and calibration procedures, and quality control procedures;
21 and
- 22 (2) ~~Information~~ information concerning the basis for the listed "normal" ranges.

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

25
26 *History Note:* Authority G.S. 14-45.1(a); [~~G.S. 90-21.83;~~] 143B-10; S.L. 2013-366 s.4(c);
27 Eff. February 1, 1976;
28 Readopted Eff. December 19, 1977;
29 Amended Eff. October 1, 2015; July 1, 1994; December 1, 1989; October 28, 1981.

1 10A NCAC 14E .0310 is amended with changes as published in NCR 29:11, pp. 1290-1298 as follows:

2
3 **10A NCAC 14E .0310 EMERGENCY BACK-UP SERVICES**

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

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

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

12 (d) The ~~facility~~ clinic shall provide intervention for emergency situations. These provisions shall include: ~~include~~
13 but are not limited to:

14 (1) ~~Basic~~ basic cardio-pulmonary life support;

15 (2) ~~Emergency~~ emergency protocols for:

16 ~~(a) (A) Venous access supplies, administration of intravenous fluids;~~

17 ~~(b) (B) Air way support and oxygen, establishing and maintaining airway support;~~

18 (C) oxygen administration;

19 ~~(c) (D) utilizing a bag-valve-mask resuscitator Bag valve mask unit with oxygen reservoir,~~
20 ~~reservoir; and~~

21 ~~(d) (E) utilizing a Suction suction machine; and~~

22 (F) utilizing an automated external defibrillator;

23 (3) ~~Emergency~~ emergency lighting available in the ~~operating room;~~ procedure room as set forth in
24 Rule .0206 of this Subchapter; and

25 (4) ~~Ultrasound~~ ultrasound equipment.

26
27 *History Note:* Authority G.S. 14-45.1(a); ~~[G.S. 90-21.83;]~~ 143B-10; S.L. 2013-366 s.4(c);

28 *Eff. February 1, 1976;*

29 *Readopted Eff. December 19, 1977;*

30 *Amended Eff. October 1, 2015; July 1, 1994; December 24, 1979.*

1 10A NCAC 14E .0311 is amended with changes as published in NCR 29:11, pp. 1290-1298 as follows:

2
3 **10A NCAC 14E .0311 SURGICAL SERVICES**

4 (a) ~~Facilities.~~ ~~[Clinics.]~~ The ~~operating procedure~~ room shall be maintained exclusively for ~~[surgical]~~ ~~[abortion]~~
5 procedures and shall be so designed and maintained to provide an atmosphere free of contamination by pathogenic
6 organisms. The ~~facility clinic~~ shall establish procedures for infection control and universal precautions.

7 (b) Tissue Examination:

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

12 ~~(2) The facility shall have written procedures, supplies and equipment available for gross and~~
13 ~~microscopic evaluation of abortion specimens. If placental or fetal tissue is not identified by gross~~
14 ~~examination, a microscopic examination must be done on the P.O.C. In cases where the~~
15 ~~microscopic evaluation is negative for chorionic villi and fetal parts, or the weight of the P.O.C.~~
16 ~~falls substantially below the appropriate weight range for the fetal age, a microscopic examination~~
17 ~~by a board certified or board eligible pathologist shall be done on the P.O.C.~~

18 ~~(3) The results of this examination, the findings of further patient evaluation and any subsequent~~
19 ~~treatment must be recorded in the patient's medical record.~~

20 (2) ~~[Based on gestational age, if]~~ If adequate tissue is not [obtained,] obtained based on the gestational
21 age, ectopic pregnancy or an incomplete procedure shall be considered and evaluated by the
22 physician performing the procedure.

23 (4) (3) The ~~facility clinic~~ shall establish procedures for obtaining, identifying, ~~storing~~ storing, and
24 transporting specimens.

25 ~~(5) The facility shall establish a method for follow up of patients on whom no villi are seen.~~

26
27 *History Note: Authority G.S. 14-45.1(a); 143B-10;*

28 *Eff. February 1, 1976;*

29 *Readopted Eff. December 19, 1977;*

30 *Amended Eff. October 1, 2015; July 1, 1994; December 1, 1989; November 1, 1984; September 1,*
31 *1984.*

1 10A NCAC 14E .0313 is amended with changes as published in NCR 29:11, pp. 1290-1298 as follows:

2
3 **10A NCAC 14E .0313 POST-OPERATIVE CARE**

4 (a) ~~Patients~~ A patient whose pregnancy is terminated on an ambulatory basis ~~should~~ shall be observed in the
5 ~~abortion clinic for a reasonable number of hours, not less than one, to insure~~ to ensure that no ~~immediate~~
6 ~~post-operative complications are present. Thereafter, patients may be discharged according to a physician's order~~
7 ~~and the clinic's protocols. such patients may be discharged if their course has been uneventful.~~

8 (b) Any patient having an adverse condition or complication known or suspected to have occurred during or after
9 the performance of the abortion shall be transferred to ~~the back-up~~ a hospital for evaluation or admission.

10 (c) The following criteria [must] shall be documented prior to discharge:

11 (1) the patient [must] shall be ambulatory with a stable blood pressure and pulse; and

12 (2) bleeding and pain [must] shall be controlled.

13 ~~(c) Any non-ambulatory patient shall be accompanied by an attending medical or nursing staff member during any~~
14 ~~transfer within or outside the facility.~~

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

17 (1) symptoms and complications to be looked ~~for,~~ for; and

18 ~~(2) activities to be avoided;~~

19 ~~(3) (2) specify a dedicated~~ specific a dedicated telephone number to be used by the patients should any complication occur or
20 question arise. This number [must] shall be answered by a person 24 hours a day, seven days a
21 week. [A recorded phone message only is unacceptable.]

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

25
26 *History Note: Authority G.S. 14-45.1(a); 143B-10;*

27 *Eff. February 1, 1976;*

28 *Readopted Eff. December 19, 1977;*

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

1 10A NCAC 14E .0315 is amended with changes as published in NCR 29:11, pp. 1290-1298 as follows:

2
3 **10A NCAC 14E .0315 HOUSEKEEPING**

4 ~~Abortion clinics~~ Clinics that are certified by the Division to perform abortions shall meet the standards for sanitation
5 as required by the Division of ~~Environmental Health~~ Public Health, Environmental Health Section, in the rules and
6 regulations governing the sanitation of ~~private~~ hospitals, nursing homes, and rest homes, sanitariums, sanatoriums,
7 ~~and educational~~ adult care homes, and other institutions, ~~10 NCAC 10A,~~ set forth in 15A NCAC 18A .1300,
8 including subsequent amendments and editions, with special emphasis on the following:

- 9 (1) ~~There must be cleaning of such a frequency as to maintain~~ the floors, walls, woodwork and
10 windows ~~in a manner to minimize the spread of dust particles in the atmosphere. Accumulated~~
11 must be cleaned, and accumulated waste material must be removed at least ~~daily.~~ daily;
- 12 (2) ~~The~~ the premises must be kept free from rodents and insect ~~infestation.~~ infestation;
- 13 (3) ~~Bath~~ bath and toilet facilities must be maintained in a clean and sanitary condition at all ~~times.~~
14 times; and
- 15 (4) ~~Linen which~~ linen that comes directly in contact with the patient shall be provided ~~as needed~~ for
16 each individual patient. No such linen shall be interchangeable from one patient to another before
17 being ~~properly~~ cleaned, sterilized, or laundered.

18 Copies of 15A NCAC 18A .1300 may be obtained at no charge from the Division of Public Health, Environmental
19 Health Section, 1632 Mail Service Center, Raleigh, NC, 27699-1632, or accessed electronically free of charge from
20 the Office of Administrative Hearings at <http://www.ncoah.com>.

21
22 *History Note: Authority G.S. 14-45.1(a); 143B-10;*
23 *Eff. February 1, 1976;*
24 *Readopted Eff. December 19, 1977;*
25 *Amended Eff. October 1, 2015; December 1, 1989.*