



North Carolina Department of Health and Human Services
Division of Health Service Regulation
Office of the Director

Pat McCrory
Governor

Richard O. Brajer
Secretary DHHS

Drexdal Pratt
Division Director

September 16, 2015

Via Email Only

Members of the N.C. Rules Review Commission and
Ms. Amber Cronk May, Commission Counsel

Re: Response to Comments to 10A NCAC 14E

Dear Commissioners and Ms. May:

This correspondence serves as the Department of Health and Human Services, Division of Health Service Regulation's response to comments received by the N.C. Rules Review Commission regarding proposed revisions to 10A NCAC 14E, Certifications of Clinics for Abortion. In the written comments concerning the permanent rules, several commenters proposed changes to 10A NCAC 14 .0311(a). In addition, one commenter asserted that the term "patient" should be defined for purposes of the Subchapter and also sought clarification regarding the 10-year retention requirement contained in 10A NCAC 14E .0305(f).

With respect to 10A NCAC 14. 0311(a), multiple commenters were concerned with the following proposed language: "The procedure room shall be maintained exclusively for abortion procedures...." Primarily, commenters were concerned that this rule would be interpreted to require procedure rooms in clinics that provide abortions to be maintained exclusively for abortion procedures to the exclusion of other types of reproductive health care services.

The Agency understands the concerns of the commenters and has thus revised the proposed language to state the following: "The procedure room shall be maintained exclusively for surgical procedures...." This change maintains the purpose of the rule while not restricting the use of the procedure room by limiting the room only to the performance of abortions.

One commenter suggested that the term "patient" be defined for purposes of this Subchapter or alternatively proposed that the term "abortion patient" be used in place of the term "patient." The Agency sees no reason to further define the term "patient" or otherwise change the language. 10A NCAC 14E is entitled "Certifications of Clinics for Abortion" and "clinic" is defined in 10A NCAC 14E .0101 as "a freestanding facility...for the performance of abortions completed during the first 20 weeks of pregnancy." Given this context of abortion-specific rules, there is no



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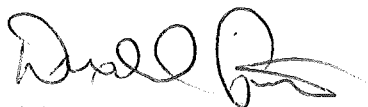
ambiguity in the term "patient." In the context of these rules, "patient" is clearly any woman presenting for the performance of an abortion completed during the first 20 weeks of pregnancy.

Regarding the 10-year retention requirement in 10A NCAC 14E .0305(f), the commenter did not dispute the proposed change but wanted to "seek clarification" as to whether the 10-year retention requirement applies to medical records that contain a discharge date preceding the implementation of the proposed amendments. There does not appear to be any ambiguity in the rule. On the effective date of the proposed change, the retention requirement will no longer be 20 years. Clinics will simply be subject to the rules as they exist on and after the effective date.

Please find the attached proposed rule 10A NCAC .0311, addressing the submitted comments with the Agency's technical change. As set forth above, the Agency believes the proposed rules meet the standards contained in N.C. Gen. Stat. § 150B-21.9.

Thank you for your consideration in the matter. Do not hesitate to call me if you have any questions.

Sincerely,

A handwritten signature in black ink, appearing to read "Drexal Pratt", with a stylized flourish at the end.

Drexal Pratt

Attachment

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 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.*