Burgos, Alexander N

Subject: FW: DHHS rules

From: Dr Liz Deans, M.D. [mailto:elizabeth.i.deans@duke.edu]
Sent: Tuesday, September 08, 2015 4:06 PM
To: May, Amber Cronk <amber.may@oah.nc.gov>
Subject: DHHS rules

Rules Review Commission Members

Office of Administrative Hearings – Rules Division

Attn: Amber May, Commission Counsel

Amber.may@oah.nc.gov

Dear Chairman Dunklin and Members of the Commission,

Thank you for the opportunity to submit comments related to the proposed rules on certifications of clinics for abortion.

The rules proposed by the Department of Health and Human Services were written with extensive input from doctors, health care professionals and reproductive health experts and rely on evidence-based medicine. As a obstetrician/gynecologist I am committed to ensuring that the rules, as written, are clear and unambiguous for the providers to whom they apply. It is important for me to ensure that rules do not detract from care of patients or limit the care we as clinicians can provide.

We are specifically concerned that section 10A NCAC 14E .0311(a) of the proposed rules is unclear and ambiguous as currently written. The proposed rules change the language in section 10A NCAC 14E .0311(a) to read, "The procedure room shall be maintained exclusively for abortion procedures . . ." from the original language, which read "The operating room shall be maintained exclusively for surgical procedures . . . ." It is our understanding that this change was made merely to conform the terminology used here with that used throughout the regulation. Although it appears at first glance that these changes are slight, we believe that they result in significant ambiguity in the rule's interpretation. Should this section be read to mean that only

procedure rooms that are maintained exclusively for abortion procedures be subject to these rules? Or does it mean that procedure rooms in clinics that provide abortions must be maintained exclusively for abortion procedures, and can therefore no longer be used for other reproductive health care services, such as colposcopy, cyst drainage, endometrial biopsy, or management of spontaneous miscarriage?

We are concerned that this seemingly innocuous change in terminology will be confusing for those tasked with implementing these regulatory changes, and so we respectfully suggest a simple edit to this sentence to clarify its meaning.

Recommendation: Amend section 10A NCAC 14E .0311(a) to make it clear that the rule applies to all procedure rooms in clinics that provide abortions, regardless of whether those rooms are maintained exclusively for abortion procedures. Revised language should read as follows:

> "The procedure room shall be maintained exclusively for ~~abortion~~ surgical procedures . . ."

As this Commission recognizes, including on its website, "Words, terms or requirements that on their face may appear to be clear, start to become ambiguous when they must be put into practice." We hope that this information is helpful to the Commission as it finalizes these important regulations.

Thank you for your time and consideration of our concerns. If you have any questions or need any further information, please do not hesitate to contact me.

Sincerely,

Elizabeth Deans, MD MPH

Assistant Professor

Duke University

200 Trent Drive
244 Baker House
Durham, North Carolina, 27710

Elizabeth.i.deans@duke.edu

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Burgos, Alexander N

Subject: FW: Comments to Abortion Facility Regulations
Attachments: Rules Review Commission Comments.pdf

Hello,

Please see attached out comments regarding the proposed rules on certifications of clinics for abortion.

Respectfully,

Melissa Reed

--
Melissa L. Reed, Esq.
VP of Public Policy, Planned Parenthood South Atlantic
Executive Director, Planned Parenthood Votes! South Atlantic
Mobile: 919-924-1520

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www.ppsat.org

Planned Parenthood South Atlantic

September 8, 2015

Via electronic mail

Rules Review Commission Members
Office of Administrative Hearings – Rules Division
Attn: Amber May, Commission Counsel
Amber.may@oah.nc.gov

Dear Chairman Dunklin and Members of the Commission,

Thank you for the opportunity to submit comments related to the proposed rules on certifications of clinics for abortion. Planned Parenthood South Atlantic operates nine health centers in North Carolina, including four which provide medical and surgical abortion services since as early as 1974. Planned Parenthood South Atlantic supports the approval of the proposed amendments to 10A N.C. Admin. Code 14E, with one exception.

We are concerned that section 10A N.C. Admin. Code 14E .0311(a) of the proposed rules is unclear and ambiguous as written and, as such, fails to comply with the standard laid out in N.C. Gen. Stat. § 150B-21.9(a)(2). The proposed rules adjust the language in section 10A N.C. Admin. Code 14E .0311(a) to read, "The ~~operating~~ procedure room shall be maintained exclusively for ~~surgical~~ abortion procedures and shall be so designed and maintained to provide an atmosphere free of contamination by pathogenic organisms." We understand that this change may have been made to conform with the terminology used throughout the rest of the regulation, but the resulting language wipes the rule of its former clarity and leads to significant ambiguity in the rule's interpretation.

We are concerned that the proposed rule will be interpreted to require that procedure rooms in clinics where abortions are performed be maintained exclusively for that purpose and none other. Many abortion providing health centers currently use their procedure rooms for a variety of services, including colposcopies, endometrial biopsies, or management of spontaneous miscarriages. While we understand that it is not your job to consider questions relating to the "quality or efficacy of the rule," N.C. Gen. Stat. § 150B-21.9(a), we point this out to inform you of the impact this ambiguous rule could have on facilities which could be forced to either discontinue providing other reproductive healthcare services or build second procedure rooms at significant -- and medically unnecessary -- expense, to allow for the other services to be provided in alternative spaces.

It is possible that the Department of Health and Human Services intends the language in 10A N.C. Admin. Code 14E .0311(a) to mean that only procedure rooms that are maintained exclusively for abortion procedures are subject to these rules. We are concerned, however, that that interpretation is not at all clear from the face of the text.

Additionally, we are concerned that the ambiguous language proposed for section 10A N.C. Admin. Code 14E.0311(a) could be read to regulate procedures that fall outside of the Department's authority and, as such, fails to comply with the standard laid out in N.C. Gen. Stat. § 150B-21.9(a)(1).

The proposed amendments to Chapter 10A N.C. Admin. Code 14E, Certifications of Clinics for Abortion, are in response to enactment of Session Law 2013-366 s.4(c), Part IV. Amend Women's Right to Know Act, which became effective on July 29, 2013. This act requires the Department to amend rules pertaining to clinics certified by the Department to be suitable facilities for the performance of abortions under N.C. Gen. Stat. § 14-45.1.

As noted above, many health centers that provide abortions also provide a range of other reproductive healthcare services. How a clinic provides these services is outside the scope of these rules. However, the lack of clarity in the proposed 10A N.C. Admin. Code 14E .0311(a) could mean that the rule is interpreted to go outside the authority delegated to the Department by the General Assembly.

As the text on the Rules Review Commission's website states, "Words, terms or requirements that on their face may appear to be clear, start to become ambiguous when they must be put into practice." We are concerned that this seemingly innocuous change in terminology will be confusing to both interpret and implement, and therefore respectfully suggest a simple edit to this sentence to clarify its meaning. "The procedure room shall be maintained exclusively for surgical procedures . . ." would make it clear that the rule applies to all procedure rooms in clinics that provide abortions, regardless of whether those rooms are maintained exclusively for abortion procedures.

Again, we appreciate the opportunity to comment.

Respectfully,

Jenny Black

Jenny Black
President and CEO
Planned Parenthood South Atlantic

Burgos, Alexander N

From: Heather Shumaker <hshumaker@prochoice.org>
Sent: Tuesday, September 08, 2015 5:00 PM
Subject: Comments on the Proposed Amendments Regarding the Licensing of Abortion Facilities
Attachments: RRC comments 2015 FINAL.pdf

Follow Up Flag: Follow up
Flag Status: Flagged

Dear Rules Review Commission Staff,

Please find attached written comments on the proposed amendments regarding the licensing of abortion facilities. Please feel free to contact me with any questions.

Best Regards,

Heather D. Shumaker, JD *
State Policy Director
National Abortion Federation
1660 L Street, NW, Suite 450
Washington, DC 20036
hshumaker@prochoice.org
202.667.5881 ext 220
www.prochoice.org

*Admitted to the New York Bar

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NATIONAL ABORTION FEDERATION

1660 L Street, NW, Suite 450 ▪ Washington, DC 20036 ▪ p: 202.667.5881 ▪ f: 202.667.5890
www.prochoice.org

September 8, 2015

Rules Review Commission
Office of Administrative Hearings
6714 Mail Service Center
Raleigh, NC 27699-6700

Re: Proposed Rules for Abortion Facilities

Dear Rules Review Commission Members,

Thank you for the opportunity to submit written comments on the proposed amendments regarding the licensing of abortion facilities.[1]

The National Abortion Federation (NAF) is the professional association of abortion providers in North America. Our mission is to ensure safe, legal, and accessible abortion care, which promotes health and justice for women. Our member facilities care for half of the women who choose abortion in the United States and Canada each year, including women in North Carolina.

NAF member facilities, including our members in North Carolina, adhere to our evidence-based *Clinical Policy Guidelines* (CPGs), which set the standards for quality abortion care in North America.[2] NAF's CPGs establish clinical guidelines, which are developed by consensus of medical professionals, based on rigorous review of the relevant medical literature and known patient outcomes. In addition, NAF is the leading organization offering accredited continuing medical education to health care professionals in all aspects of abortion care.

Abortion care is one of the safest and most commonly provided medical procedures in the United States. Serious complications are extremely rare.[3] Credit for the outstanding safety record of abortion care is attributed to the specialized care given and received in

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[1] Certifications of Clinics for Abortion, 29 N.C. Reg. 11 (Dec. 1, 2014) (to be codified at 10A NC ADMIN. CODE § 14E). The submission of written comments concerning permanent rules to the Rules Review Commission is permitted, provided that they "specify how a rule either complies with or fails to comply with the statutory grounds for RRC's review" including that a rule "is clear and unambiguous." 26 NC ADMIN. CODE § 05.0103; N.C. GEN. STAT. 150B-21.9.

[2] NATIONAL ABORTION FEDERATION, *CLINICAL POLICY GUIDELINES* (2015), *available at* http://prochoice.org/education-and-advocacy/2015-clinical-policy-guidelines/.

[3] *Facts on Induced Abortion in the United States*, GUTTMACHER INSTITUTE, http://www.guttmacher.org/pubs/fb_induced_abortion.html (last updated Feb. 2014).

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Cristina Villarreal Velásquez ▪ Lori Williams, MSN/APN ▪ Beverly Winikoff, MD, MPH

outpatient facilities, which currently provide 95% of the abortion care in the United States.[4] In North Carolina, these facilities are already subject to extensive state regulations, above and beyond those that apply to other outpatient facilities offering other medical procedures with a comparable safety record. North Carolina abortion facilities are licensed under current regulations and have an excellent safety record.

Given the safety of abortion care and substantial existing regulations, NAF believes that increased regulation is unnecessary. However, we commend the Department of Health and Human Services (DHHS) on the process thus far, which has focused on medicine and science. DHHS also appropriately convened a workgroup of medical experts that could accurately advise DHHS as to the standard of care in abortion and on appropriate evidence-based medical regulations.

NAF offers the below comments to members of the Rules Review Commission on the sections of the proposed amendments that we believe to be unclear and ambiguous. Our comments are based on our experience and expertise in developing evidence-based standards, drafting medically-appropriate regulations for abortion facilities with state health departments, and in the delivery of high-quality abortion care. We are confident that our suggestions will not only help ensure that the proposed regulations are consistent with evidence-based practices, which have proven most effective in ensuring patient safety, but provide for rules that are clear and unambiguous.

I. The proposed amendments do not contain a definition for "patient."

The definitions section of the proposed amendments provides several new definitions and changes to existing definitions.[5] The existing code and proposed amendments reference "patient" several times, for example within the sections on admission and discharge,[6] medical records,[7] and nursing services.[8] However, no definition of "patient" is provided. We would suggest a clarification of the definition of "patient" to mean a "patient receiving abortion care" or an amendment to the word "patient" throughout the code to say "abortion patient" in order to clarify that the code references abortion patients, and not patients receiving other services.

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[4] Rachel K. Jones and Kathryn Kooistra, GUTTMACHER INSTITUTE, *Abortion Incidence and Access to Services in the United States*, 2008, 43 PERSPECTIVES ON SEXUAL AND REPRODUCTIVE HEALTH, no. 1, at 42 (March 2011).
[5] *See* 10A NC ADMIN. CODE § 14E.0101.
[6] *See id.* at § 14E.0304.
[7] *See id.* at § 14E.0305.
[8] *See id.* at § 14E.0307.

II. The proposed amendments on medical record retention should be clarified.

The proposed amendments require a ten year retention of medical records, in place of the previous twenty year retention requirement.[9] We do not dispute this change, but rather seek clarification as to whether the ten year retention requirement – or the twenty year retention requirement – applies to medical records that contain a discharge date preceding the implementation of the proposed amendments.

III. The proposed "Surgical Services" amendment should be changed to reflect "medical procedures" rather than "abortion procedures."

The proposed amendments require that "[t]he procedure room shall be maintained exclusively for abortion procedures and shall be so designed and maintained to provide an atmosphere free of contamination by pathogenic organisms."[10] While it appears that the change in the language of this section was intended to expand the uses of the procedure room, it would instead restrict the usage of the procedure rooms for other medical reasons. For example, other medical procedures such as biopsies, colposcopies, and cyst drainage would no longer be able to be provided in a room utilized for abortion care. Likewise, medical abortion, under the current language, would have to be provided in a room that was intended for a surgical abortion procedure. We do not think this was the intent of DHHS and request that the language be modified to reflect the true intention.

Conclusion

We appreciate the opportunity to provide you with these comments. Thank you for your time in reviewing our comments.

Sincerely,

Lisa M Brown

Lisa M. Brown
General Counsel & Senior Policy Director

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[9] *See id.* at § 14E.0305(f).
[10] *See id.* at § 14E.0311(a).

Burgos, Alexander N

Subject: FW: Comments on Rules for abortion clinics
Attachments: Provider Comments for Rules Commission- Bryant.docx

From: Bryant, Amy [mailto:amy_bryant@med.unc.edu]
Sent: Tuesday, September 08, 2015 4:36 PM
To: May, Amber Cronk <amber.may@oah.nc.gov>
Subject: Comments on Rules for abortion clinics

Dear Ms. May,

Please see below my concerns regarding proposed rules on certifications of clinics for abortion. These comments are also attached here.

Thank you very much.

Sincerely,

Amy Bryant

Amy Bryant, MD, MSCR | Assistant Professor
Division of Family Planning, Department of Obstetrics & Gynecology
University of North Carolina School of Medicine

3020 Old Clinic Building, CB 7570
Chapel Hill, NC 27599-7570

Office: 919-962-4880 | Fax: 919-843-6691
Appointments: 919-843-5633

amy_bryant@med.unc.edu

http://www.med.unc.edu/obgyn/

September 8, 2015

Via electronic mail
Rules Review Commission Members
Office of Administrative Hearings – Rules Division
Attn: Amber May, Commission Counsel
Amber.may@oah.nc.gov

Dear Chairman Dunklin and Members of the Commission,

Thank you for the opportunity to submit comments related to the proposed rules on certifications of clinics for abortion.

The rules proposed by the Department of Health and Human Services were written with extensive input from doctors, health care professionals and reproductive health experts and rely on evidence-based medicine. As an obstetrician/gynecologist, I am committed to ensuring that the rules, as written, are clear and unambiguous for the providers to whom they apply. Misunderstandings about rules could make it difficult to care for patients in the safest and most appropriate ways.

I am specifically concerned that section 10A NCAC 14E .0311(a) of the proposed rules is unclear and ambiguous as currently written. The proposed rules change the language in section 10A NCAC 14E .0311(a) to read, "The procedure room shall be maintained exclusively for abortion procedures . . ." from the original language, which read "The operating room shall be maintained exclusively for surgical procedures . . . ." It is my understanding that this change was made merely to conform the terminology used here with that used throughout the regulation. Although it appears at first glance that these changes are slight, I believe that they result in significant ambiguity in the rule's interpretation. Should this section be read to mean that only procedure rooms that are maintained exclusively for abortion procedures be subject to these rules? Or does it mean that procedure rooms in clinics that provide abortions must be maintained exclusively for abortion procedures, and can therefore no longer be used for other reproductive health care services, such as colposcopy, cyst drainage, endometrial biopsy, or management of spontaneous miscarriage?

I am concerned that this seemingly innocuous change in terminology will be confusing for those tasked with implementing these regulatory changes, and so I respectfully suggest a simple edit to this sentence to clarify its meaning.

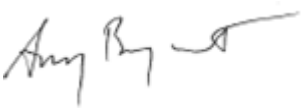
Recommendation: Amend section 10A NCAC 14E .0311(a) to make it clear that the rule applies to all procedure rooms in clinics that provide abortions, regardless of whether those rooms are maintained exclusively for abortion procedures. Revised language should read as follows:

"The procedure room shall be maintained exclusively for surgical procedures . . ."

As this Commission recognizes, including on its website, "Words, terms or requirements that on their face may appear to be clear, start to become ambiguous when they must be put into practice." We hope that this information is helpful to the Commission as it finalizes these important regulations.

Thank you for your time and consideration of our concerns. If you have any questions or need any further information, please do not hesitate to contact me.

Sincerely,



Amy Bryant, MD, MSCR | Assistant Professor
University of North Carolina School of Medicine

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DIVISION OF FAMILY PLANNING
DEPARTMENT OF OBSTETRICS AND GYNECOLOGY
3006 OLD CLINIC BLDG
CAMPUS BOX 7570
CHAPEL HILL, NC 27599-7570

T 919-843-5633
F 919-843-6691
www.uncfamplan.org

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Director, Ryan Resident Training Program
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Clinical Professor
DAVID GRIMES, MD, FACOG, FACPM

Fellows
SHANTI RAMESH, MD
JAMIE KRASHIN, MD

Division Manager
KRISHNA FOUST

Administrative Associate
ERIN COMPTON

September 8, 2015

Via electronic mail
Rules Review Commission Members
Office of Administrative Hearings – Rules Division
Attn: Amber May, Commission Counsel
Amber.may@oah.nc.gov

Dear Chairman Dunklin and Members of the Commission,

Thank you for the opportunity to submit comments related to the proposed rules on certifications of clinics for abortion.

The rules proposed by the Department of Health and Human Services were written with extensive input from doctors, health care professionals and reproductive health experts and rely on evidence-based medicine. As an obstetrician/gynecologist, I am committed to ensuring that the rules, as written, are clear and unambiguous for the providers to whom they apply. Misunderstandings about rules could make it difficult to care for patients in the safest and most appropriate ways.

I am specifically concerned that section 10A NCAC 14E .0311(a) of the proposed rules is unclear and ambiguous as currently written. The proposed rules change the language in section 10A NCAC 14E .0311(a) to read, "The procedure room shall be maintained exclusively for abortion procedures . . ." from the original language, which read "The operating room shall be maintained exclusively for surgical procedures . . . ." It is my understanding that this change was made merely to conform the terminology used here with that used throughout the regulation. Although it appears at first glance that these changes are slight, I believe that they result in significant ambiguity in the rule's interpretation. Should this section be read to mean that only procedure rooms that are maintained exclusively for abortion procedures be subject to these rules? Or does it mean that procedure rooms in clinics that provide abortions must be maintained exclusively for abortion procedures, and can therefore no longer be used for other reproductive health care services, such as colposcopy, cyst drainage, endometrial biopsy, or management of spontaneous miscarriage?

I am concerned that this seemingly innocuous change in terminology will be confusing for those tasked with implementing these regulatory changes, and so I respectfully suggest a simple edit to this sentence to clarify its meaning.

Recommendation: Amend section 10A NCAC 14E .0311(a) to make it clear that the rule applies to all procedure rooms in clinics that provide abortions, regardless of whether those rooms are maintained exclusively for abortion procedures. Revised language should read as follows:

"The procedure room shall be maintained exclusively for surgical procedures . . ."

As this Commission recognizes, including on its website, "Words, terms or requirements that on their face may appear to be clear, start to become ambiguous when they must be put into practice." We hope that this information is helpful to the Commission as it finalizes these important regulations.

Thank you for your time and consideration of our concerns. If you have any questions or need any further information, please do not hesitate to contact me.

Sincerely,

Amy Bryant, MD, MSCR | Assistant Professor
University of North Carolina School of Medicine

Burgos, Alexander N

Subject: FW: Rules Review Commission Review of Amendments to 10A NCAC 14E
Attachments: Center for Reproductive Rights Comments Re Amendments to 10A NCAC 14E.pdf

---

From: Genevieve Scott <gscott@reprorights.org>
Sent: Tuesday, September 8, 2015 2:00:47 PM
To: May, Amber Cronk
Cc: Rulescoordinator, Dhsr
Subject: Rules Review Commission Review of Amendments to 10A NCAC 14E

Dear Ms. May,

The Center for Reproductive Rights submits the attached comments to the Rules Review Commission in response to the proposed amendments to 10A NCAC 14E, Certifications of Clinics for Abortion, pursuant to 26 NCAC 05.0103. Thank you for the opportunity to comment.

Best regards,

Genevieve Scott

CENTER FOR REPRODUCTIVE RIGHTS

GENEVIEVE E. SCOTT *
Staff Attorney, U.S. Legal Program
gscott@reprorights.org

199 Water Street, 22nd Floor
New York NY 10038
Tel 917 637 3605 **Fax** 917 637 3666

Website | Facebook | Twitter

*admitted in New York

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CENTER FOR REPRODUCTIVE RIGHTS

Rules Review Commission Members
North Carolina Office of Administrative Hearings – Rules Division
Attn: Amber May, Commission Counsel
Amber.may@oah.nc.gov

September 8, 2015

VIA E-MAIL

Dear Chairman Dunklin and Members of the Commission,

The Center for Reproductive Rights submits these comments in response to the proposed amendments to 10A NCAC 14E, Certifications of Clinics for Abortion ("the Proposed Rules"), authorized by Session Law 2013-366 § 4(c), Part IV. The Center for Reproductive Rights is a global legal advocacy organization that has successfully litigated cases for over 20 years, protecting the rights of women to access safe and legal abortion and other reproductive health care, including in North Carolina. We support proven and medically sound regulations that genuinely advance the public health and do not impose regulations on abortion providers not imposed on those providing similar health care. We support the approval of the proposed amendments to 10A NCAC 14E, with one exception.

The provision on Surgical Services (14E.0311) fails to comply with the statutory grounds for the Rules Review Commission's review because it is not "clear and unambiguous." *See* N.C. Gen. Stat. Ann. § 150B-21.9 (West). The provision may be interpreted to unnecessarily restrict the use of procedure rooms. The provision states that: "The procedure room shall be maintained exclusively for abortion procedures. . . ." The term "abortion procedure" replaced the term "surgical procedure." *See* 10A NCAC § 14E.0311. Though the Department may intend this language to mean that only procedure rooms that are maintained exclusively for abortion procedures are subject to these rules, the meaning is not clear. It may instead be interpreted to mean that only abortion procedures may be performed in the procedure rooms. There is no medical advantage to preventing clinics from performing other medical procedures in procedure rooms. In contrast to the complicated, invasive surgical procedures generally performed in outpatient surgical facilities, first-trimester abortion is a simple, non-invasive surgical or medical procedure that is typically provided in office-based settings. The same holds even more true in the context of medication abortion, where an oral medication is dispensed to the patient in the health center. Many clinics have only one procedure room available for surgical procedures, and this provision could operate to prevent use of any room used for abortion procedures for other gynecological services that the clinic provides as a service to its patients.

Our understanding is that the rule was changed merely to conform to terminology used in other parts of the regulation, but it has resulted in ambiguity and confusion about the meaning of the rule. As the text on the Rules Review Commission's website states, "Words, terms or

requirements that on their face may appear to be clear, start to become ambiguous when they must be put into practice." In an effort to clarify the meaning of the rule, and because the provision of safe abortion services will not be implicated by allowing other procedures to also be performed in the procedure rooms, we respectfully suggest that the rule be edited to clarify that other medical procedures may be performed. We recommend that the Rules Review Commission clarify the meaning of the statute by replacing the phrase: "The procedure room shall be maintained exclusively for abortion procedures . . ." with the phrase that previously appeared in the statute: "The procedure room shall be maintained exclusively for surgical procedures . . . ."

Our suggested revisions are based on our experience working with local health departments to craft reasonable and medically sound regulations for abortion care providers, as well as the expertise of physicians and clinics in North Carolina, who have provided women with safe abortion services for decades. We appreciate the opportunity to comment and look forward to working with the Rules Review Commission to ensure that women seeking abortion care in North Carolina receive high quality service, without the imposition of ambiguous and unduly restrictive requirements. Please do not hesitate to contact us if you would like further information.

Sincerely,

Janet Crepps*
Senior Counsel, U.S. Legal Program
Center for Reproductive Rights
199 Water Street, 22nd Floor
New York, NY 10038
(917) 637-3697
jcrepps@reprorights.org
**Admitted in Alaska and South Carolina*

Genevieve Scott**
Staff Attorney, U.S. Legal Program
Center for Reproductive Rights
199 Water Street, 22nd Floor
New York, NY 10038
(917) 637-3697
gscott@reprorights.org
***Admitted in New York*

Burgos, Alexander N

Subject: FW: Office of Administrative Hearings – Rules Division -- proposed rules for abortion providers

From: Dr Beverly Gray, M.D. [mailto:beverly.gray@duke.edu]
Sent: Tuesday, September 08, 2015 1:11 PM
To: May, Amber Cronk <amber.may@oah.nc.gov>
Subject: Office of Administrative Hearings – Rules Division -- proposed rules for abortion providers

Rules Review Commission Members

Office of Administrative Hearings – Rules Division
Attn: Amber May, Commission Counsel
Amber.may@oah.nc.gov

Dear Chairman Dunklin and Members of the Commission,

Thank you for the opportunity to submit comments related to the proposed rules on certifications of clinics for abortion.

The rules proposed by the Department of Health and Human Services were written with extensive input from doctors, health care professionals and reproductive health experts and rely on evidence-based medicine. As an obstetrician/gynecologist at Duke University Medical Center, I am committed to ensuring that the rules, as written, are clear and unambiguous for the providers to whom they apply. As an obstetrician/gynecologist at Duke University Medical Center, I provide care for patients who experience pregnancy loss and also seek care for abortion. In our facility we provide an excellent standard of care for all of our patients.

We are specifically concerned that section 10A NCAC 14E .0311(a) of the proposed rules is unclear and ambiguous as currently written. The proposed rules change the language in section 10A NCAC 14E .0311(a) to read, "The procedure room shall be maintained exclusively for abortion procedures . . ." from the original language, which read "The operating room shall be maintained exclusively for surgical procedures . . . ." It is our understanding that this change was made merely to conform the terminology used here with that used throughout the regulation. Although it appears at first glance that these changes are slight, we believe that they result in significant ambiguity in the rule's interpretation. Should this section be read to mean that only procedure rooms that are maintained exclusively for abortion procedures be subject to these rules? Or does it mean that procedure rooms in clinics that provide abortions must be maintained exclusively for abortion procedures, and can therefore no longer be used for other reproductive health care services, such as colposcopy, cyst drainage, endometrial biopsy, or management of spontaneous miscarriage? The ambiguity of this rule could have a significant impact on patients who are seeking both miscarriage and abortion care, as the procedure and the equipment are identical. For patients cared for in our operating rooms, it would be an unreasonable request to maintain only one operating suite for abortion care, as operating space is limited, even at a major medical institution.

We are concerned that this seemingly innocuous change in terminology will be confusing for those tasked with implementing these regulatory changes, and so we respectfully suggest a simple edit to this sentence to clarify its meaning.

Recommendation: Amend section 10A NCAC 14E .0311(a) to make it clear that the rule applies to all procedure rooms in clinics that provide abortions, regardless of whether those rooms are maintained exclusively for abortion procedures. Revised language should read as follows:

> "The procedure room shall be maintained exclusively for ~~abortion~~ surgical procedures . . ."

As this Commission recognizes, including on its website, "Words, terms or requirements that on their face may appear to be clear, start to become ambiguous when they must be put into practice." We hope that this information is helpful to the Commission as it finalizes these important regulations.

Thank you for your time and consideration of our concerns. If you have any questions or need any further information, please do not hesitate to contact me.

Take care,

Bev Gray, MD
Associate Residency Director
Director Ryan Family Planning Program
Duke University Medical Center
Department of Obstetrics & Gynecology

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Burgos, Alexander N

Subject: FW: Comment on Rules Filed by DHHS
Attachments: NARAL Comment on DHHS Rules.pdf

From: Chavi Koneru [mailto:chavi@prochoicenc.org]
Sent: Tuesday, September 08, 2015 11:02 AM
To: May, Amber Cronk <amber.may@oah.nc.gov>
Subject: Comment on Rules Filed by DHHS

Hi Amber,

I got your contact information from Susanna Birdsong at the ACLU.

I am attaching a comment letter that I would like to submit, on behalf of NARAL, relating to the rules filed by DHHS. There are a couple of others who are also submitting letters (or may have already). I just wanted to make sure that it was alright to send you our comments and that you would be willing to share them with all the Commissioners. Please let me know if we should be sending this information to someone else.

Thanks for your help,

Chavi

--
Chavi Khanna Koneru
Policy Analyst and Operations Coordinator
NARAL Pro-Choice North Carolina
Office phone: (919) 908-8930
Messages: (919) 908-9321

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NARAL
Pro-Choice North Carolina Foundation

September 8, 2015
Via electronic mail
Rules Review Commission Members
Office of Administrative Hearings – Rules Division
Attn: Amber May, Commission Counsel
Amber.may@oah.nc.gov

Dear Chairman Dunklin and Members of the Commission,

Thank you for the opportunity to submit comments related to the proposed rules on certifications of clinics for abortion.

The rules proposed by the Department of Health and Human Services were written with extensive input from doctors, health care professionals and reproductive health experts and rely on evidence-based medicine. As a statewide advocate for women's reproductive rights, NARAL Pro-Choice North Carolina is committed to ensuring that the rules, as written, are clear and unambiguous for the providers to whom they apply.

We are specifically concerned that section 10A NCAC 14E .0311(a) of the proposed rules is unclear and ambiguous as currently written. The proposed rules change the language in section 10A NCAC 14E .0311(a) to read, "The procedure room shall be maintained exclusively for abortion procedures . . ." from the original language, which read "The operating room shall be maintained exclusively for surgical procedures . . . ." It is our understanding that this change was made merely to conform the terminology used here with that used throughout the regulation. Although it appears at first glance that these changes are slight, we believe that they result in significant ambiguity in the rule's interpretation. Should this section be read to mean that only procedure rooms that are maintained exclusively for abortion procedures be subject to these rules? Or does it mean that procedure rooms in clinics that provide abortions must be maintained exclusively for abortion procedures, and can therefore no longer be used for other reproductive health care services, such as colposcopy, cyst drainage, endometrial biopsy, or management of spontaneous miscarriage?

NARAL
Pro-Choice North Carolina Foundation

We are concerned that this seemingly innocuous change in terminology will be confusing for those tasked with implementing these regulatory changes, and so we respectfully suggest a simple edit to this sentence to clarify its meaning.

Recommendation: Amend section 10A NCAC 14E .0311(a) to make it clear that the rule applies to all procedure rooms in clinics that provide abortions, regardless of whether those rooms are maintained exclusively for abortion procedures. Revised language should read as follows:

> "The procedure room shall be maintained exclusively for ~~abortion~~ surgical procedures . . ."

As this Commission recognizes, including on its website, "Words, terms or requirements that on their face may appear to be clear, start to become ambiguous when they must be put into practice." We hope that this information is helpful to the Commission as it finalizes these important regulations.

Thank you for your time and consideration of our concerns. If you have any questions or need any further information, please do not hesitate to contact me.

Sincerely,

Chavi K. Koneru

Chavi Koneru
NARAL Pro-Choice North Carolina
Policy Analyst and Operations Coordinator
chavi@prochoicenc.org
919-908-9321

Burgos, Alexander N

Subject: FW: Regulations for abortion clinics

From: amy alspaugh [mailto:amyalspaugh@gmail.com]
Sent: Tuesday, September 08, 2015 10:33 AM
To: May, Amber Cronk <amber.may@oah.nc.gov>
Subject: Regulations for abortion clinics

09/08/2015

Rules Review Commission Members

Office of Administrative Hearings – Rules Division

Attn: Amber May, Commission Counsel

Amber.may@oah.nc.gov

Dear Chairman Dunklin and Members of the Commission,

Thank you for the opportunity to submit comments related to the proposed rules on certifications of clinics for abortion.

The rules proposed by the Department of Health and Human Services were written with extensive input from doctors, health care professionals and reproductive health experts and rely on evidence-based medicine. As a Certified Nurse-Midwife, I am committed to ensuring that the rules, as written, are clear and unambiguous for the providers to whom they apply. Ensuring my patients have access to the full range of reproductive health is essential, and improving upon the clarity of these rules will help ensure that.

We are specifically concerned that section 10A NCAC 14E .0311(a) of the proposed rules is unclear and ambiguous as currently written. The proposed rules change the language in section 10A NCAC 14E .0311(a) to read, “The procedure room shall be maintained exclusively for abortion procedures . . .” from the original language, which read “Theoperating room shall be maintained exclusively for surgical procedures . . . .” It is our understanding that this change was made merely to conform the terminology used here with that used throughout the regulation. Although it appears at first glance that these changes are slight, we believe that they

result in significant ambiguity in the rule's interpretation. Should this section be read to mean that only procedure rooms that are maintained exclusively for abortion procedures be subject to these rules? Or does it mean that procedure rooms in clinics that provide abortions must be maintained exclusively for abortion procedures, and can therefore no longer be used for other reproductive health care services, such as colposcopy, cyst drainage, endometrial biopsy, or management of spontaneous miscarriage?

We are concerned that this seemingly innocuous change in terminology will be confusing for those tasked with implementing these regulatory changes, and so we respectfully suggest a simple edit to this sentence to clarify its meaning.

Recommendation: Amend section 10A NCAC 14E .0311(a) to make it clear that the rule applies to all procedure rooms in clinics that provide abortions, regardless of whether those rooms are maintained exclusively for abortion procedures. Revised language should read as follows:

> "The procedure room shall be maintained exclusively for ~~abortion~~ surgical procedures . . ."

As this Commission recognizes, including on its website, "Words, terms or requirements that on their face may appear to be clear, start to become ambiguous when they must be put into practice." We hope that this information is helpful to the Commission as it finalizes these important regulations.

Thank you for your time and consideration of our concerns. If you have any questions or need any further information, please do not hesitate to contact me.

Sincerely,

Amy Alspaugh, CNM

Durham County Department of Public Health

865-310-1693

amyalspaugh@gmail.com

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Burgos, Alexander N

Subject: FW: Abortion clinic certification rules

_____
From: David Grimes <dagrimes@mindspring.com>
Sent: Tuesday, September 8, 2015 8:39:21 AM
To: May, Amber Cronk
Subject: Abortion clinic certification rules

September 7, 2015
Via electronic mail
Rules Review Commission Members
Office of Administrative Hearings – Rules Division
Attn: Amber May, Commission Counsel
Amber.may@oah.nc.gov

Dear Chairman Dunklin and Members of the Commission,

I write to comment on one point in the proposed rules change. As background, I have been a gynecologist for more than 4 decades, and I was a member of the advisory committee that met with Ms. Conley and other staff of DHHS when these rule changes were being considered. One ambiguity needs to be resolved before the proposed rules go forward.

Section 10A NCAC 14E .0311(a) of the proposed rules is unclear and ambiguous as currently written. The proposed rules change the language in section 10A NCAC 14E .0311(a) to read, "The procedure room shall be maintained exclusively for abortion procedures . . ." from the original language, which read "The operating room shall be maintained exclusively for surgical procedures . . . ." I believe this change was made merely to conform the terminology used here with that used throughout the regulation. Although it appears at first glance that these changes are slight, this may result in significant ambiguity in the rule's interpretation. I believe the sentence should be deleted altogether.

On days of the week when a clinic procedure room is not being used for abortion, it should be able to be used for other medical purposes. These could include performing vaginal ultrasound examinations, doing IUD and Nexplanon insertions, and endometrial biopsies. There is no valid medical reason to leave a room vacant and unused for other gynecological procedures. This restriction has no medical justification. Moreover, this is not the standard of care in hospital operating rooms, which are used for many types of procedures.

If you have any questions about my comments, please let me know. Thank you for your consideration.

Sincerely,

David A. Grimes, MD, FACOG, FACPM
PO Box 1972
Carolina Beach, NC28428

ACLU 50
AMERICAN CIVIL LIBERTIES UNION of NORTH CAROLINA
50 YEARS OF PROTECTING YOUR LIBERTY

P.O. Box 28004 • Raleigh, North Carolina 27611-8004
Phone (919) 834-3466 • Fax (866) 511-1344
www.acluofnc.org

September 3, 2015

Via electronic mail

Rules Review Commission Members
Office of Administrative Hearings – Rules Division
Attn: Amber May, Commission Counsel
Amber.may@oah.nc.gov

Dear Chairman Dunklin and Members of the Commission,

Thank you for the opportunity to submit comments related to the proposed rules on certifications of clinics for abortion. As an organization dedicated to protecting the constitutional right of women to access complete reproductive health care, including safe and legal abortion, the American Civil Liberties Union of North Carolina (ACLU-NC) supports the approval of the proposed amendments to 10A NCAC 14E, with one exception.

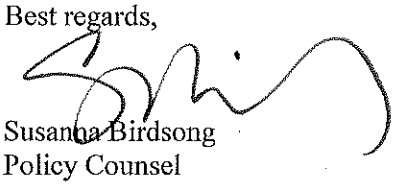
As we highlighted in our earlier comments regarding proposed rule 10A NCAC 14E, we are specifically concerned that section 10A NCAC 14E .0311(a) of the proposed rules is unclear as written. The proposed rules adjust the language in section 10A NCAC 14E .0311(a) to read, "The procedure room shall be maintained exclusively for abortion procedures . . ." from the original "The operating room shall be maintained exclusively for surgical procedures . . . ." It is our understanding that this change was made merely to conform the terminology used here with that used throughout the regulation. Although it appears at first glance that these changes are slight, we believe that they result in significant ambiguity in the rule's interpretation. We are concerned that the proposed rules will be interpreted to require that procedure rooms in clinics that provide abortions must be maintained exclusively for abortion procedures—and can therefore no longer be used for other reproductive health care services, such as colposcopy, cyst drainage, endometrial biopsy, or management of spontaneous miscarriage. These procedures often require the use of the same procedure room as that used to perform abortions, as many clinics only have one room for surgical procedures. If the language of the rule requiring that procedure rooms are maintained exclusively for abortion procedures remains, we are troubled that some clinics could be forced either to discontinue providing other gynecological services, or to build a second procedure room at a significant, and medically unnecessary, cost. In our earlier comments, we applauded the Department of Health and Human Services for consulting with doctors who provide reproductive health services and generally avoiding unnecessary and burdensome requirements that would not improve safety – with the exception of 10A NCAC 14E .0311(a). It is possible that the Department intends the language in 10A NCAC 14E .0311(a) to mean that only procedure rooms that are maintained exclusively for abortion procedures are subject to these rules, however we are concerned that that interpretation is not clear from the face of the text.

As the text on the Rules Review Commission's website states, "Words, terms or requirements that on their face may appear to be clear, start to become ambiguous when they must be put into practice." We are concerned that this seemingly innocuous change in terminology will be confusing for those tasked with implementing these regulatory changes, and so we respectfully suggest a simple edit to this sentence to clarify its meaning. "The procedure room shall be maintained exclusively for surgical procedures . . ."

would make it clear that the rule applies to all procedure rooms in clinics that provide abortions, regardless of whether those rooms are maintained exclusively for abortion procedures.

Again, we appreciate the opportunity to comment.

Best regards,



Susanna Birdsong
Policy Counsel
sbirdsong@acluofnc.org

WakeMed Health & Hospitals

September 7, 2015

Rules Review Commission Members
Office of Administrative Hearings – Rules Division
Attn: Amber May, Commission Counsel
Amber.may@oah.nc.gov

Dear Chairman Dunklin and Members of the Commission,

Thank you for the opportunity to submit comments related to the proposed rules on certifications of clinics for abortion.

The rules proposed by the Department of Health and Human Services were written with extensive input from doctors, health care professionals and reproductive health experts and rely on evidence-based medicine. As an OBGYN physician in North Carolina, I am committed to ensuring that the rules, as written, are clear and unambiguous for the providers to whom they apply. As an OBGYN physician that provides the full complement of reproductive health care services to the women of NC, including abortion, I see how this decision may directly and negatively impact the women of this state. Operating rooms in medicine are, by nature, multipurpose. Throughout my medical career, I have used operating rooms that had just been utilized for bowel surgery, brain/ spinal cord surgery, and orthopedic surgeries, and then were cleaned a gynecological procedure commenced. The notion that a surgical room should only be used for one procedure is wasteful and inefficient. In the clinics where I work that provide abortions, the other procedures that are performed in the operating room are those that specifically prevent pregnancy (and therefore abortion), such as hysteroscopic sterilization or intrauterine device (IUD) insertions. By requiring clinics to use these rooms to perform only abortions, this decision may have the unintended consequence of causing more unplanned pregnancies as clinics may not be able to provide those other, pregnancy prevention procedures. Surely, this committee is not interested in placing obstacles in the delivery of pregnancy prevention procedures.

We are specifically concerned that section 10A NCAC 14E .0311(a) of the proposed rules is unclear and ambiguous as currently written. The proposed rules change the language in section 10A NCAC 14E .0311(a) to read, “The procedure room shall be maintained exclusively for abortion procedures . . .” from the original language, which read “The operating room shall be

maintained exclusively for surgical procedures . . . .” It is our understanding that this change was made merely to conform the terminology used here with that used throughout the regulation. Although it appears at first glance that these changes are slight, we believe that they result in significant ambiguity in the rule’s interpretation. Should this section be read to mean that only procedure rooms that are maintained exclusively for abortion procedures be subject to these rules? Or does it mean that procedure rooms in clinics that provide abortions must be maintained exclusively for abortion procedures, and can therefore no longer be used for other reproductive health care services, such as colposcopy, cyst drainage, endometrial biopsy, or management of spontaneous miscarriage?

We are concerned that this seemingly innocuous change in terminology will be confusing for those tasked with implementing these regulatory changes, and so we respectfully suggest a simple edit to this sentence to clarify its meaning.

Recommendation: Amend section 10A NCAC 14E .0311(a) to make it clear that the rule applies to all procedure rooms in clinics that provide abortions, regardless of whether those rooms are maintained exclusively for abortion procedures. Revised language should read as follows:

> “The procedure room shall be maintained exclusively for ~~abortion~~ surgical procedures . . .”

As this Commission recognizes, including on its website, “Words, terms or requirements that on their face may appear to be clear, start to become ambiguous when they must be put into practice.” We hope that this information is helpful to the Commission as it finalizes these important regulations.

Thank you for your time and consideration of our concerns. If you have any questions or need any further information, please do not hesitate to contact me.

Sincerely,

Matthew L. Zerden, MD, MPH
OB Hospitalist,
WakeMed North Family Health & Women’s Hospital
Ph: (919) 350-8000
MZerden@WakeMed.Org

WakeMed
WakeMed Health & Hospitals