PRO-LIFE ACTION LEAGUE
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January 29, 2015

Ms. Nadine Pfeiffer
Division of Health Service Regulation
2701 Mail Service Center
Raleigh, NC 27699

Dear Ms. Pfeiffer,

The Pro-Life Action League is pleased to provide comments and objections to the Proposed Rules governing abortion clinics. While best known for our vigorous defense of the lives of the unborn, we also have extensive experience with regard to the level of safety (or lack thereof) in abortion clinics with respect to the protection of the mother of the aborted child.

While to truly "do no harm" abortion would need to be banned entirely, we hope that we can contribute to a greater protection for the lives and health of women and somewhat reduce the harm done.

We are pleased that the North Carolina legislature took up the task of revising abortion clinic regulations. Informed consent is an important tool to prevent coercion, either by the relatives or friends of the mother or by the personnel in the clinic itself.

We are also pleased that the governing authority is more specifically spelled out, that the policies and procedures are to be documented and executed, and that inspections will be annual and as needed.

Before getting into greater detail, we would like to state **three major objections** to the Proposed Rules as currently constituted:

1. We object to the drastic reduction in the retention of medical records by the clinics, particularly as concerns minors.

2. We object to the removal of the rule that medical or nursing staff must accompany a transferred patient. This proposed change, combined with the provision of (a) not requiring a transfer agreement with a local hospital merely if an effort has been made

to secure one, and (b) no requirement that the physician be on staff of the local hospital, endangers women's health by providing them with no continuity of care.

3. We object to the "grandfathering" of clinics that don't meet the physical requirements.

Each of these objections will be explained in detail below, along with additional suggestions, comments, and complaints, in the order in which relevant sections appear in the Proposed Rules.

We would suggest additional definitions in .0101. "Physician" and "qualified person" are used in the body, but left undefined, along with other terms that require further definition. We would suggest amending 10A NCAC 14E.0111 (a) to read: "Any clinic certified by the Division to perform abortions shall be subject to <u>unannounced</u> inspections by authorized representatives of the Division annually and as it may deem necessary as a condition of holding such license."

While we believe that was the intention of this rule, spelling it out specifically would provide clarity. This is also important because of documented instances in recent years in which clinics in other states were tipped off that an inspection would be occurring the next day and clinic practice was modified specifically because inspectors would be present.

It is good that a plan of correction must be filed within 10 days of receipt of cited deficiencies, but we are greatly concerned that there are no consequences for failing to file a plan. In our experience, numerous clinics have "dragged their feet" for years simply because there were no legal consequences for doing so. The prospect of temporary closure would surely deter clinics from flouting this requirement.

We strongly object to the "grandfather" clause in 10A NCAC 14E .0201: Building Code Requirements. Applying the building code requirements only to "new clinics and to any alteration, repairs, rehabilitation work, or additions which are made to a previously certified facility" will not improve safety at all. In fact, it may actually *worsen* safety because a clinic may put off a needed repair or other work specifically to avoid having the section become applicable. Our experience has taught us that many abortion clinics do not desire to put any money toward the improvement of their building than they have to.

On July 1, 1994 the requirement for corridor width for clinic facilities was amended to be a minimum of 60 inches. But this was never enforced because a "new facility" was defined as one that was not certified as an abortion clinic as of that date. That means that many, perhaps most, clinics have been exempt from meeting the standard for over 20 years.

With this new definition of "new facility," they will be grandfathered in again. When will the clinics be safe? Twenty years is far too long for a sensible medical standard to be ignored.

We further recommend that all of the ASF requirements be incorporated, including the provision that clinics must comply within one year. There are many types of ASFs, and they are all held to the same standards. From the state's point of view, why should women seeking abortion be treated in facilities with lower standards than, for instance, a person seeking eye surgery or a colonoscopy? Given the number of ambulance transfers we observe at abortion clinics, our experience suggests that abortion clinics need to be held to the same high standards that all ASFs are.

Some building modifications need to be applicable immediately—for example, corridor width and emergency exiting. These can be critical in saving the life of a hemorrhaging patient. This section should be modified to meet the expectations of the legislature, not lowered to meet the demands of the abortion clinic owners.

We have several objections to the proposed changes in 10A NCAC 14E .0305: Medical Records. Paragraph (a) currently refers to "physician's authenticated history and physical examination," but in the proposed rules, it refers to "the patient's history and physical examination." Authentication should still be required. Patients deserve to know that their physicians have looked over their history and have personally examined them. This is not something less qualified persons should be allowed to do.

We can only charitably believe that paragraph (f) was misprinted. First, reducing the period that medical records must be retained from 20 years to10 years is not in the interests of women. Often long-term consequences of undergoing an abortion procedure are not discovered until more than 10 years have passed. The woman who had an abortion at age 19 and then decided to wait until 30 to start her family, may not realize until then that her fertility was lost due to an abortionist's negligence. But her records will have been destroyed. We urge you to restore the rule requiring 20 years retention.

More troubling, though, is the proposed rule regarding minors' medical records. According to the proposed rules, her records may be destroyed when she turns 21. A minor girl could get an abortion at 17 and then have her records destroyed only four years later—even fewer than the already inadequate 10 years the Proposed Rules require for adult women. We believe the DHSR meant to say that the 10 year period would *start* when a woman turns 21, but that is not how the proposed rules read. We suggest that the language be changed to require that medical records be retained for 20 years after a minor turns 21. That would give a woman ample time to look into her medical records, should she so choose. There is no good reason for shortening the period unless the purpose of the rule change is to lessen abortion clinics' liability. We doubt that was the intent of the legislation.

Again in paragraph (h), record preservation for closed abortion clinics has been reduced from 20 to 10 years. We would ask you to retain the 20 years requirement. Again, the rule as currently proposed does nothing to enhance the rights of women, but only reduces the time the clinics have to worry about facing liability. The purpose of these rule modifications is not to protect the abortion clinics, but to reasonably protect women.

Consider ASF rule 10A NCAC 13C .1002(d), which states, "For licensing purposes the length of time that medical records are to be retained is dependent upon the need for their use in continuing patient care and for legal, research, or educational purposes. The length of time shall not be less than 20 years." We would suggest that women undergoing abortion need a longer time than most patients due to their situation, not a shortened time. Because of the abortion, a woman may decide to put off childbearing for years—easily 10 years or more—and would not be aware of fertility problems directly attributable to the abortion until some time later when she failed to achieve a pregnancy.

Retaining records until a woman is at least 38 poses little inconvenience for the abortion clinic, but provides necessary information for those women injured in the process. Again, we find no evidence in the legislation that the intent was to strip these women of this vital information.

We have some concern about the lack of consumer protections that are found in ASF rules 10A NCAC 13C .0205, but have no particular suggestions and acknowledge that this may lie outside the scope of the legislation.

We commend you for Section .0302 outlining the Governing Authority. It follows the ASF rules. However, we suggest that .0303(a)(3) be amended by removing "if applicable" since in .0302 (d)(2), minutes of the annual meetings are maintained even in the event that the governing authority is an individual. This diverges from the ASF rule, and could lead to problems. For example, the former Femcare abortion facility in Asheville, an ASF, did not review its policy and procedure manual for *23 years*. Thus, we suggest maintaining the requirement of minutes for all governing authority meetings, even in the event that the governing authority is an individual. We also recommend that the governing authority be responsible for building and equipment maintenance and maintenance logs.

We are pleased with the Personnel Records (.0306) and the Nursing Services (.0307) rules changes.

The addition of the Quality Assurance requirements in 10A NCAC 14E .0308 is also commendable. This is important for any abortion clinic where procedures are done without regard to evaluating results, complications, or improvement. Rigorous enforcement is

necessary, since in our experience it is difficult to foster the attitude changes required on the part of abortion clinic staff to engage in critical self-assessment.

Regarding 10A NCAC 14E .0309 (b), there is essentially no requirement for a pathological examination of tissue because it is left up to the governing body to determine whether an exam is necessary. This is a clear example of allowing the fox to guard the hen house, particularly since in the original language in 10A NCAC 14E .0311 (b)(2), equipment for microscopic examination was required—but that language has been deleted. Without microscopic examination, detection of ectopic pregnancies, incomplete abortions, and other complications is compromised, to the detriment of women's safety.

As mentioned above, in 10A NCAC 14E .0310 (c) Emergency Back-Up Services, the good rule of a written transfer agreement with a nearby hospital is totally undone by the provision that mere "documentation of its efforts to establish such a transfer agreement with a hospital" counts as compliance. In speaking with representatives of the Department, we have not received the name of a single ASF that does not have a transfer agreement. While this exception is found in the ASF rules, it apparently has never been utilized. If this exception is allowed for abortion clinics, we fear that it will be utilized widely, possibly by every clinic, thus completely undermining the goal of protecting women's health.

Women's safety is further undone with 10A NCAC 14E .0313(c), which was deleted in the proposed rules. If adopted, North Carolina law would no longer require an attending medical or nursing staff member to accompany a non-ambulatory patient during any transfer. Taken together with the previous proposed rule, this provision would allow for a hemorrhaging patient to be sent unaccompanied to a hospital that has no formal relationship with the clinic. This is dangerous. It is not what anyone would desire for their loved one.

Perhaps the reason that Paragraph .0310(c) was deleted can be found in the deficiency report dated December 11, 2012 for A Preferred Women's Health Center in Charlotte. That deficiency report referred to two patient transfers in the previous four months, both of which were sent unaccompanied by ambulance. The response of the RN on duty was, "I can not leave, I am the only nurse here." Neither did the physician accompany the patient.

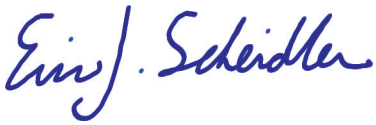
With the proposed rules changes, instead of being cited for a deficiency, the clinic would be in compliance—to the detriment of patient care. Again, this rule change serves only the abortion clinic, not the safety of patients. Therefore, we urge you to restore the rule for requiring accompanied transfers, and that you require transfer agreements. If the abortion clinics have insufficient professional staff, they should hire more staff to ensure they have qualified personnel available to accompany patients being transferred by ambulance. This lack of qualified personnel would not be tolerated in any other medical setting. If a clinic

cannot make an agreement with a nearby hospital, then abortions, or any surgeries, should not be performed there.

Regarding .0310(d), we would like to see more specific provisions for emergencies—specifically, requiring a laryngoscope, an appropriate selection of endotracheal tubes, and pulse oximeters in addition to the other interventions.

I hope that these comments submitted on behalf of the Pro-Life Action League are well received. If you have any questions or would like any supporting materials regarding our experience in other states with abortion clinic inspections and regulations, please feel free to contact me.

Sincerely,



Eric J. Scheidler
Executive Director

Submitted by Email