To: Board Member, Virginia Board of Health

Re: Draft regulations issued August 26, 2011

Date: September 1, 2011

Abortion facilities in Virginia have been providing safe care for more than thirty years. The clinics regulated by these draft regulations provide first-trimester abortion care, one of the safest surgical procedures available in the United States today. They also provide medication abortion, a non-surgical method of terminating a pregnancy by using oral medications to induce a miscarriage. First-trimester surgical and medication abortions are extremely safe and are consistently and safely provided in office-based practices throughout the country.

The draft regulations contain some significant problems that would pose threats to patient access to care and confidentiality. This memorandum describes the most serious issues contained in the draft regulations and some general recommendations for how the Board could address those issues and maintain patient safety and access.

1. Physical Plant Requirements -- 12 VAC 5-412-380

The physical plant requirements for first-trimester abortions should reflect the medical reality and safety of first-trimester abortion services, rather than incorporating extensive, burdensome requirements that are not related to the service and that will reduce or eliminate access to care.

a. Temporary Regulations and Physical Plant Requirements

The draft regulations issued on Friday, August 26th are intended to be temporary regulations. They have been promulgated through the "emergency" rulemaking process and will be in effect for one year, although there is the potential for them to be in effect for an additional six months. As currently drafted, clinics would have to come into compliance with physical plant requirements temporarily and then be forced to comply with potentially different physical plant requirements shortly thereafter. This not only would cost the providers a significant amount of time and money, but it will delay or prevent patients from accessing care over the course of that time. Our recommendation would be to omit any physical plant requirements from regulations that are only temporary and to note that appropriate requirements will be included in the permanent regulations.

b. Existing Facilities versus New Construction

The draft regulations appear to require existing abortion facilities to come into compliance with several sections of the Facility Guideline Institute's *2010 Guidelines for Design and Construction of Health Care Facilities* ("Guidelines") within the next two years, and to be ready to propose a plan for that compliance in order to become licensed. However, these Guidelines clearly state that they are intended to apply only to new construction, not to existing facilities.

Specifically, the Guidelines state that they are "intended as minimum standards for designing and constructing *new* health care facility projects." Facility Guidelines Institute, *Guidelines for Design and Construction of Health Care Facilities* 4 (2010) (emphasis added).[1]

If the Board chooses to adopt physical plant requirements in these temporary regulations, they should clarify that existing facilities would not be required to meet these new construction requirements and instead would be permitted to operate in their current facilities. As existing facilities have been providing safe care for many years, there is no need to require them to entirely rebuild their facilities under new construction requirements.

Notably, other regulations of health care facilities or of buildings take into account the differences between existing and new construction. For example, the regulations that currently apply to hospitals in Virginia include regulations for all hospitals, and then a separate section that applies to "construction of new buildings and additions, renovations, alterations or repairs of existing buildings for occupancy as a hospital." 12 VAC 5-410-650. These new construction requirements incorporate the Guidelines, but the requirements for existing facilities do not. The same is true for the regulations governing outpatient surgical hospitals, which apply certain physical plant requirements to "construction of new buildings and additions alterations or repairs to existing buildings for occupancy," and apply the guidelines to the "design[] and construct[ion]" of hospitals. 12 VAC 5-410-1350. And similarly, regulations concerning obstetric service and newborn service impose physical plant requirements for "[r]enovation or construction of a hospital's obstetric unit" or "[c]onstruction and renovation of a hospital's nursery…." *See* 12 VAC 5-410-442; 12 VAC 5-410-445. Another example is the sections of the Americans with Disabilities Act (ADA) that address construction, which include several different types of grandfathering for existing facilities. *See* 42 U.S.C. § 12183. Indeed, we are aware of *no other instance* in which Virginia has required existing healthcare facilities to comply with regulations or guidelines designed for new construction.

It is worth noting that some recently built abortion facilities that will now be governed by these regulations were built to comply with the versions of the Guidelines in existence at the time they were constructed, for example the 2006 Guidelines, or the 2001 Guidelines. (This was done not because these guidelines are medically appropriate for first-trimester abortion care, but based on other strategic concerns, including a climate of increasingly strict regulation.) It would be profoundly unfair – and entirely contrary to the intent of the Guidelines – to apply these

[1] That the Guidelines are not intended to apply to existing facilities is further clarified by their provision that if existing facilities undertake significant renovations or additions, "only that portion of the total facility affected by the project shall be required to comply with the applicable section of these Guidelines." *Id.* at 6.

guidelines to existing facilities, or to require facilities to undergo extensive construction every time the Guidelines are updated.

If the physical plant requirements are not eliminated in the temporary regulations, we recommend that the regulations distinguish between existing facilities and new construction, and apply the physical plant requirements of the Guidelines only to new construction.

c. Variance Provisions -- 12 VAC 5-412-90

Draft regulation 12 VAC 5-412.90 allows for variances to be granted from particular requirements of the regulations, but appears to allow only a temporary variance and only upon a showing that the requirement "would be an impractical hardship unique to the abortion facility." This provision should be changed to adopt the standard for variances already in place for hospitals and outpatient surgical hospitals, which is contained at 12 VAC 5-410-30 ("Upon the finding that the enforcement of one or more of these regulations would be clearly impractical, the commissioner shall have the authority to waive, either temporarily or permanently, the enforcement of one or more of these regulations, provided safety and patient care and services are not adversely affected.").

2. Inspection Procedures and Licensure Penalties -- 12 VAC 5-412-130

Draft regulation 12 VAC 5-412-130 allows for revocation of a license for any violation of any applicable regulation, however minor and unrelated to patient care and safety. These regulations are extensive and cover a variety of areas of facility policy, many of which are not related to patient safety. Clinics should be encouraged to submit plans of correction or compliance, but should not risk revocation or suspension of their license based on minor infractions unrelated to patient care and safety. This provision should be changed to reference the immediate safety of patients, or require a substantial violation for the revocation of the license.

3. Patient and Provider Confidentiality and Safety

a. Patient Confidentiality -- 12 VAC 5-412-110

Draft regulation 12 VAC 5-412-110, dealing with on-site inspection, permits Department of Health employees to arrive on the premises at any time and requires the facility to give them access to the facility and to patient medical records and a list of current patients, without appropriate protection for patient confidentiality. Provisions should be added to protect the confidentiality of patients in the facility and patient records.

Confidentiality is of paramount importance to patients and abortion providers. Patients are targeted for harassment outside of clinics and there is a history of anti-abortion activists seeking patient information in order to deter women from seeking abortion care. These regulations should make explicit that while OLC's representatives may access these documents at the facility

as part of the inspection (in order to ensure compliance with the regulations), these documents may not be removed from the premises. If OLC is given the ability to remove any records or documents from the premises, the regulations should be clarified to require that any document containing identifying information about patients must be redacted, and that only redacted copies may be removed. In addition, the regulations should make clear that all Department representatives who have access to identifying patient information must keep that information in the strictest of confidence and that failure to do so will subject them to disciplinary action. In addition, the regulations should clarify that state employees may not interview current patients without their explicit permission.

Provisions should also be added to clarify that the inspection provisions apply only during normal business hours. This is especially important in light of the fact that the regulations allow for license revocation if a staff member is not available to provide access to patient records within an hour of an inspector's arrival.

b. Provider Confidentiality -- 12 VAC 5-412-140 and 12 VAC 5-412-150

Draft regulations 12 VAC 5-412-140 and 12 VAC 5-412-150 give the Department of Health the right to request all ownership information and many types of facility policies and procedures, such as facility security and disaster preparedness plans, without any requirement that these documents be kept confidential. Provisions should be included to ensure the confidentiality of facility information that is reported to the OLC. As stated above, confidentiality is of utmost importance and abortion providers are often the targets of violence by anti-abortion extremists, who seek out information about facility ownership and policies in order to harass and intimidate abortion providers.

c. Patient and Provider Safety -- 12 VAC 5-412-100

Draft regulation 12 VAC 5-412-100, dealing with the right of entry, allows Department of Health employees to enter the facility at any time, without notice. The regulation does not require that the state employee provide identification to assure the facility that they are in fact associated with the Department. It is essential that Department of Health employees properly identify themselves when seeking entry to an abortion facility, due to the sensitive nature of the provision of abortion care, and the targeting of abortion providers and patients for violence and harassment by anti-abortion extremists.