Virginia Coalition to Protect Women's Health

To: Board of Health member
Re: Comments concerning regulation of health care facilities that provide abortion care
Date: June 15, 2012

The Virginia Coalition to Protect Women's Health is a coalition of advocates, health care providers, and community members concerned about women's access to reproductive health care. We came together in 2011 out of a deep concern about Senate Bill 924, which required targeted regulation of health care facilities that provide abortion care. For almost forty years, reproductive health care facilities have provided safe, high quality health care to women seeking abortion care in Virginia. First-trimester abortion procedures are safely and appropriately performed in the office setting throughout the country. Outpatient abortions performed in the office or clinic setting have an excellent safety record and as a result, the applicable standards of care in the field do not require an outpatient surgical hospital or inpatient hospital setting for the performance of a first-trimester abortion. Therefore, it would be medically inappropriate, detrimental to patients, and a wasteful use of limited health care resources to require that a medical office providing abortion care be outfitted like an inpatient hospital or outpatient surgical hospital.

The proposed permanent regulations will have a significantly harmful impact on women's ability to access first-trimester abortion care in Virginia. Further, the regulations inappropriately single out health care facilities that provide abortion care from all other health care facilities for burdensome, impractical regulations that are not grounded in medical reality. This memorandum describes the five most serious issues contained in the regulations and offers recommendations for the Board to address those issues and maintain patient safety and access.

I. The Physical Plant Requirements Are Medically Unnecessary and Will Impose Serious Burdens on Health Care Providers (12 VAC 5-412-370).

Any physical plant requirements for health care facilities that provide first-trimester abortion care should reflect the medicine of first-trimester abortion services as well as the safety record of abortion care. However, the proposed permanent regulations apply extensive requirements from the Facility Guideline Institute's 2010 Guidelines for Design and Construction of Health Care Facilities ("Guidelines") to existing health care facilities. In this context, these requirements are extraordinarily burdensome, medically unnecessary and inappropriate to first-trimester abortion care, and imposing them on existing facilities will reduce or eliminate access to care for Virginia women.

Like the temporary regulations that are now in effect, the proposed permanent regulations inappropriately require abortion facilities to comply with standards that were "intended as

minimum standards for designing and constructing *new* health care facility projects."[1] The draft permanent regulation states that "abortion facilities *shall comply* with [three Parts of] the 2010 Guidelines for Design and Construction of Health Care Facilities of the Facilities Guidelines Institute, which shall take precedence over the Uniform Statewide Building Code."[2] The standards from the 2010 Guidelines for Design and Construction of Health Care Facilities ("the Guidelines") are inappropriate for two primary reasons: They are not medically related to the care provided and applying them to existing abortion care facilities is not consistent with the regulation of all other health care facilities.

First, health care facilities are generally regulated based on the nature of the procedures provided at that type of facility. Thus, inpatient hospitals, which are the setting for highly complex and invasive surgeries necessitating an overnight stay, are required to have the most sophisticated facilities. Outpatient surgical hospitals, which are the setting for a variety of complicated and invasive surgical procedures, are required to have more sophisticated facilities than medical offices, but less sophisticated than inpatient hospitals. First-trimester abortion, in contrast, is a simple surgical or medical procedure that is typically provided in office-based settings. Outpatient abortions performed in the office or clinic setting have an excellent safety record in this country. As a result, the applicable standards of care in the field do not require an outpatient surgical hospital or inpatient hospital setting for the performance of an uncomplicated abortion.

Second, requiring existing abortion care facilities to comply with the Guidelines is inconsistent with the regulation of every other type of health care facility in Virginia. In justifying imposing this requirement on existing abortion facilities, the Department of Health incorrectly asserts that "the regulatory provisions pertaining to facility design [and] construction are written based on Virginia § 32.1-127.001."[3] But this statute does not mandate that **existing facilities** meet the Guidelines standards, and clearly no other type of facility in the state has been forced to rebuild its existing building as a result of Virginia Code § 32.1-127.001.

Every single time the Board has adopted regulations implementing this code section, it has applied the regulations only to new construction and renovations of existing buildings. No other health care facility has been forced to rebuild its existing structure to comply with these Guidelines, even though Virginia Code § 32.1-127.001 applies to hospitals, nursing homes, hospice centers, and outpatient surgical facilities. Right after that code section was enacted, the

---

[1] Facility Guidelines Institute, *Guidelines for Design and Construction of Health Care Facilities* 4 (2010) (emphasis added). 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.

[2] 12 VAC 5-412-370 (emphasis added).

[3] Virginia Code Ann. § 32.1-127.001, enacted in 2005, states:

Notwithstanding any law or regulation to the contrary, the Board of Health shall promulgate regulations pursuant to § 32.1-127 for the licensure of hospitals and nursing homes that shall include minimum standards for the design and construction of hospitals, nursing homes, and certified nursing facilities consistent with the current edition of the Guidelines for Design and Construction of Hospital and Health Care Facilities issued by the American Institute of Architects Academy of Architecture for Health.

Board of Health adopted new "design and construction" regulations, based on the then-new law, for hospitals, nursing homes, hospice facilities and outpatient surgical facilities. In **each and every case**, the Board applied the Guidelines *only* to "all construction of *new* buildings and additions, alterations or repairs to existing buildings," **not** to existing facilities that are not undergoing significant construction.[4] In fact, guidance issued by the Department of Health in 2006, when hospitals, nursing homes and outpatient surgical facility regulations were amended to include reference to the Guidelines, makes it absolutely clear that those facilities were only to follow the Guidelines when they engaged in new construction or alteration to their existing facilities.[5]

It is clear from the language of this proposed regulation that abortion facilities are being treated differently than all other health care facilities. We believe that this is inconsistent with current law and with appropriate medical standards, and urge adoption of an amendment that brings this regulation in line with all other such regulations.

II. The Regulations Should Mandate Compliance With Only the Portions of the Hospital Code that VDH Will Enforce (12 VAC 5-412-130).

12 VAC 5-412-130 allows for denial, suspension or revocation of a license for any violation of "any provision of Article 1 of Chapter 5 of Title 32.1 of the Code of Virginia (§ 32.1-123 *et seq*.) or of any applicable regulation." This provision appears to mean that abortion facilities' licenses will be conditioned on compliance with each and every provision of the Virginia Code governing hospitals and nursing homes ("the hospital code"). This Code section incorporates more than thirty-five different statutes, many of which are irrelevant or nonsensical in the context of health care facilities providing abortions. Moreover, not even *hospitals themselves* are required to comply with every provision of the hospital code as a condition of continued licensure. Conditioning an abortion facility's initial and continued licensure on compliance with the entire hospital code is not only outside of the scope of the enabling legislation, it is inconsistent with every other regulation imposed on health care facilities in Virginia.

First, the enabling legislation for this regulation, Senate Bill 924, explicitly amended only a single subsection of the statute governing rulemaking with respect to hospitals, *see* Va. Code

[4] Moreover, in each and every case, the regulations state that the facility type in question shall be "designed and constructed according to [several Parts of] the 2010 Guidelines for Design and Construction of Health Care Facilities of the Facilities Guidelines Institute" but that "the requirements of the Uniform Statewide Building Code and local zoning and building ordinances shall take precedence." 12 VAC 5-410-650 (hospitals); 12 VAC 5-410-1350 (outpatient surgical centers); 12 VAC 5-371-410 (nursing homes); 12 VAC 5-391-440 (hospices). In contrast, the draft permanent regulations state that "abortion facilities shall comply with [three Parts of] the 2010 Guidelines for Design and Construction of Health Care Facilities of the Facilities Guidelines Institute, which shall take precedence over the Uniform Statewide Building Code." 12 VAC 5-412-370.

[5] Virginia Department of Health, Office of Licensure and Certification, *Design and Construction of Health Care Facilities*, July 1, 2006, *available at* http://townhall.virginia.gov/l/GetFile.cfm?File=E:\townhall\docroot\GuidanceDocs\601\GDoc_VDH_2991_v1.pdf.

Ann. § 32.1-127(B)(1), to apply to facilities providing more than five first-trimester abortions. Therefore, applying the provisions of all of Article 1 (or any additional Articles) to health care facilities that provide first-trimester abortion care is outside the scope of these regulations. SB 924 gave the Board of Health only the authority to create regulations governing " minimum standards for (i) the construction and maintenance . . . to assure the environmental protection and the life safety of its patients, and employees, and the public;(ii) the operation, staffing and equipping . . . [of abortion facilities]; (iii) qualifications and training of staff of [abortion facilities], . . . except those professionals licensed or certified by the Department of Health Professions; and (iv) conditions under which a[n abortion facility] . . . may provide medical and nursing services to patients in their places of residence; and (v) policies related to infection prevention, disaster preparedness, and facility security of [abortion facilities]." It is simply not true that the enabling legislation gives the Commissioner the authority to impose the entire hospital code on abortion facilities.

Second, this regulation is inconsistent with the regulations imposed on all other forms of health care facilities. For example, for inpatient hospitals, the standard for license suspension or revocation is as follows: "The commissioner may revoke or suspend the license to operate a hospital in accordance with § 32.1-135 of the Code of Virginia for the following reasons: 1. Violation of any provision of these rules and regulations. Violations which in the judgment of the commissioner jeopardize the health or safety of patients shall be sufficient cause for immediate revocation or suspension; or 2. Willfully permitting, aiding, or abetting the commission of any illegal act in the hospital."[6] This regulation is completely inconsistent with Virginia health care facility regulations. **Even hospitals themselves** are not required to comply with each and every provision of the hospital code as a condition of continued licensure.

VDH has essentially acknowledged that it would not be appropriate to require abortion facilities to comply with all of these statutes by stating that it will only "take enforcement action against abortion facilities" for violating certain sub-parts of the Code as identified in a January 18, 2012 VDH document about the temporary regulations containing frequently asked questions and answers ("FAQ document"). Clearly, VDH recognizes that it would not be appropriate to apply the entire hospital code to abortion facilities. Nonetheless, these proposed permanent regulations incorporate the entire Code and refer to the FAQ document as if it were the only way to limit that incorporation.[7]

The hospital code should not be incorporated into these regulations at all. However, if the Board would prefer to follow VDH's guidance on this matter, there is a simple solution: The permanent regulations should reference only those statutes within the hospital code that VDH actually intends abortion facilities to comply with. Health care centers should not be at risk of losing their licenses because they are relying on official Department guidance when that guidance can easily be incorporated into the text of the regulations.

---

[6] 12 VAC 5-410-160.

[7] Note that the FAQ document is not permanent or exhaustive: It instructs clinics to "check back periodically," as it will be updated "as needed." Health care centers should not be at risk of losing their licenses because they are relying on official Department guidance that is outdated when that guidance could be incorporated directly into the regulations.

III. The Regulations Should Ensure Patient and Provider Confidentiality and Security.

A. Patient Confidentiality -- 12 VAC 5-412-100

12 VAC 5-412-100, 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 patient lists, without appropriate protection for patient confidentiality. It is in the best interests of VDH to protect this information from any potential disclosure. Due to the unique confidentiality needs of abortion patients, provisions should be added to protect the confidentiality of patients in the facility, patient records, and facility information.

All patients have an expectation of privacy in their medical records, which is protected by both medical ethics[8] and law.[9] 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. Despite the statement by VDH that their staff are bound by confidentiality laws and agency policy, a unique audience exists whose sole purpose is to collect information about abortion providers and their patients.

The temporary regulations included a requirement that the abortion facility provide the surveyor with a list of current patients. This provision unnecessarily infringed on the confidentiality of the patients seeking medical care at the time that an inspector chooses to arrive on the premises. Despite receiving comments on the draft regulations encouraging VDH to strengthen the confidentiality protections, VDH chose to make the permanent regulations substantially worse by requiring a list of all patients for the previous 12 months, as well as a list of patients receiving services on the day of the survey, to be provided to the surveyor. The requested list of all patients from the past 12 months is an unprecedented intrusion on patient privacy which does not exist anywhere else in the Virginia Code and is completely unnecessary for a licensing inspection. In its responses to the comments on this provision, VDH states that this change is designed as a "clarification of the meaning of current patients." The new language goes far beyond that and should be removed.

VDH cites to Section 32.1-25 of the Code of Virginia in their response to public comments asking for increased patient and provider protections. However, as discussed in the above section on the hospital code, the Department of Health is not permitted to apply this code

---

[8] *See* AMA, Code of Medical Ethics, Opinion 5.05 Confidentiality (2010), *available at* http://www.ama-assn.org/ama/pub/physician-resources/medical-ethics/code-medical-ethics/opinion505.page?.

[9] *See* HIPAA, 42 U.S.C. §§ 1320d et seq. In addition, this particular issue of state health department access to patient records has come up in at least one other state, when Arizona regulations were drafted to give the Arizona Department of Health broad access to patient records. The federal Court of Appeals for the Ninth Circuit struck down that regulation, holding that "giving [the state department of health] unbounded access to unredacted patient records violates the informational privacy rights of patients." *Tucson Woman's Clinic v. Eden*, 379 F.3d 531, 553 (9th Cir. 2004).

section to abortion facilities under SB 924. Furthermore, the Department has already said it sees no need to enforce more than a handful of the statutes in the hospital code, and the Code sections they mention do not include Section 32.1-25.

The regulations should protect patient confidentiality by ensuring that the facility has the opportunity to redact all patient identifying information from records before any routine inspection, and stipulating that records may only be inspected, and not removed, from the premises. The request for a patient list should be deleted in its entirety, as there is no medical justification for seeking this information during a licensure inspection. 12 VAC 5-412-100(B) should make explicit that while the Office of Licensure and Certification's (OLC) representatives may access patient records and other 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. 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.

B. Provider Safety -- 12 VAC 5-412-90; 12 VAC 5-412-140

Abortion facilities 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, and seek entry into abortion facilities under false pretenses. In 2010-2011 alone, there were 158 incidents of harassment at NAF abortion facilities in Virginia. This includes picketing, hate mail, harassing phone calls and suspicious packages.

Several different sections of the draft permanent regulations give VDH 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. VDH states in its responses to public comment that they have an agency confidentiality policy that addresses these concerns. However, there is a unique market for information about abortion providers and patients, and it is in the best interests of VDH, the OLC, and the abortion facilities to institute strong protections for confidentiality to ensure the safety of abortion providers and patients. Indeed, VDH has already stated in the FAQ document that the facility disaster preparedness plans submitted with the licensure applications may be subject to a FOIA request, and that the discretion to disclose or withhold is ultimately that of VDH. This clearly shows that additional confidentiality provisions are needed.

In light of these serious concerns, provisions should be included to ensure the confidentiality of facility information that is reported to the OLC. In order to protect the safety of abortion facility staff and patients, provisions should be added to clarify that the inspection should only be conducted 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. The regulations should include confidentiality protections for employee files and other personnel materials required by 12 VAC 5-412-170. The regulations should also ensure that inspectors do not copy or disclose any personally identifying information regarding any staff member of an abortion facility.

Finally, the regulations should ensure that these documents are not available through open records or freedom of information requests. Again, given the long history of attacks on abortion providers, it is essential that confidentiality of information about staff members is protected in the permanent regulations.

IV. Variance Provisions Should Be Consistent With Regulations of Other Health Care Facilities (12 VAC 5-412-80).

The Commissioner of the Department of Health has the authority to grant variances for all other existing health care facilities. The variance provisions in the proposed permanent regulations are more limited and onerous than those contained in much more highly regulated facilities like inpatient hospitals. The variance provisions in regulations of all other health care facilities are virtually identical, giving the Commissioner of the Department of Health broad authority to grant a variance—including a *permanent* variance—as long as patient health, safety and services are not compromised. For example, for outpatient surgical hospitals, "[u]pon 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."[10] In stark contrast to regulations of all other health care facilities, the draft permanent regulation only permits the commissioner to grant a *temporary* variance in a narrower and more rigidly structured set of circumstances, following a completely different standard than those adopted in other regulations.[11] There is no justification for removing the Commissioner's discretion as to only one type of health care facility.

VDH has variously stated that changes were made to the variance section of the draft permanent regulations "in order to be consistent with other VDH health care facility regulations"[12] and that it "will *work to* develop a consistent approach to the issuance of variances."[13] Clearly, if the changes were necessary to make these regulations consistent with previous regulations, there would be no need for VDH to "work to develop a consistent approach" in implementation. There is in fact no need for VDH to develop such an approach – instead, the regulations themselves should be consistent with existing regulations of all other health care facilities, so that VDH need not "work to" reconcile conflicting standards.

This section of the regulations should be consistent with all other variance provisions in Virginia health law, and, among other things, allow abortion facilities to obtain a permanent variance so long as safety and patient care are not adversely affected, consistent with the

---

[10] 12 VAC 5-410-30.

[11] Indeed, the variance provisions in the abortion facility regulations are far more onerous than those contained in regulations governing both inpatient hospitals and outpatient surgical facilities in a number of ways, including that they may only be granted "temporary" variances, they must meet a different and more stringent burden, must propose alternatives, and the Commissioner may attach special conditions to any variance granted. None of these provisions applies to any other type of health care facilities.

[12] Virginia Department of Health, *Proposed Regulation Agency Background Document*, *Regulations for Licensure of Abortion Facilities*, May 1, 2012, at 42.

[13] *Id*. at 12 (emphasis added).

variance procedures for much more highly regulated health care facilities such as inpatient hospitals and outpatient surgical facilities.

V. The Regulations Regarding Complaint Investigations Should Be Consistent with Other Health Care Facility Regulations (12 VAC 412-120).

The draft permanent regulations include a new section, 12 VAC 5-412-120, addressing OLC complaint investigations. It is within the purview of OLC to investigate substantiated complaints in order to ensure compliance with these regulations. However, it is a common tactic of anti-choice extremists and career protestors to file numerous complaints with no evidence or backing in order to harass abortion providers. If OLC is required to investigate every complaint, regardless of whether it is substantiated or entirely fabricated, this may quickly become an unwieldy process for both OLC and the licensed facility.

The reason stated by VDH for this change is to make these regulations consistent with other health facility licensing. The wording of this new section does not actually reflect the complaint investigation language already contained in the Regulations for Licensure of Home Care Organizations, Nursing Facilities or Hospice.[14] If VDH intends to be consistent with other regulations, we recommend that this sentence be appropriately amended.

[14] *See* 12 VAC 5-381-100(A), Regulations for the Licensure of Home Care Organizations; 12 VAC 5-371-70(A), Regulations for the Licensure of Nursing Facilities; and 12 VAC 5-391-100(A), Regulations for the Licensure of Hospice.