Virginia Coalition to Protect Women's Health

February 15, 2012

Dear Board of Health Member,

Enclosed please find a packet of information submitted by the Virginia Coalition to Protect Women's Health as comments on the Board's rulemaking process pursuant to Senate Bill 924. As a result of the mandate for "emergency" regulations in Senate Bill 924, the Virginia Department of Health crafted temporary regulations for women's health centers in the Commonwealth. The temporary regulations contain some significant problems that would pose threats to patient access to health care and confidentiality. The Board of Health now enters the critical period in which it has the opportunity to create carefully considered permanent regulations for women's clinics that are medically appropriate. We hope that the information provided herein will be useful to the Board as it considers the promulgation of permanent regulations, and in particular, as the Board considers how the permanent regulations can and should improve upon the emergency regulations currently in force.

The members of the Coalition are health care providers and women's health advocates. We came together in response to Senate Bill 924, which classifies "facilities in which 5 or more first trimester abortions per month are performed" as a category of hospitals for a limited purpose, and which became law in March 2011. We support proven and medically sound regulations that *genuinely* advance the public health. Regulations that meet these standards can help to ensure women's continued access to reproductive healthcare in the Commonwealth, rather than arbitrarily forcing health care facilities to close through burdensome, unnecessary over-regulation.

Please find attached:

- A memo regarding serious issues contained in the temporary regulations, which includes general recommendations for improvements that would preserve the high standards of patient safety and access to care that women's health centers in the Commonwealth have provided for nearly forty years. Regulations that make it more difficult for health centers to provide high quality reproductive health care do not improve patient safety. Instead, they make it harder for women and their families to access critical reproductive health care services, including life-saving cancer screenings, family planning, STI testing and treatment, and continued safe, legal abortion care. Medically unnecessary, burdensome regulations may drive up health care costs or drive health care providers out of practice, making comprehensive, preventive reproductive health care even less accessible to women across the state.

- A letter from Dr. James Kenley, former Virginia Commissioner of Health under four Governors, providing comments on the temporary regulations based on his forty years of expertise as a medical professional.

- A fact sheet explaining the safety and high standards of abortion care practiced by women's health centers in the Commonwealth. First-trimester abortion care remains one of the safest and most common of all office-based procedures. Women's health centers in the state are proud to uphold high standards of patient care and safety, including by following regulations already governing the health care professionals who provide care to women. Moreover, women's health centers that provide first-trimester abortion care are subject to the same regulations as physician's offices providing services like dentistry, oral surgery, and colonoscopies, including federal and state regulations related to laboratory and office safety, patient confidentiality, and proper disposal of medical waste.

We support the highest standards of care that genuinely protects the health and safety of patients and ensures their access to needed reproductive health care. Unnecessary regulations put the health of women and their families at risk. We hope that the Board of Health will be persuaded by proven medical practices and science and will change the onerous provisions that threaten to close or limit services at safe women's health centers that serve tens of thousands of women in Virginia.

Please do not hesitate to contact us if we can be of assistance or provide further information. Thank you for considering these comments.

Respectfully,

The Virginia Coalition to Protect Women's Health

Virginia Coalition to Protect Women's Health

To: Board Member, Virginia Board of Health

Re: Comments concerning regulation of health care facilities that provide abortion care

Date: February 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 the effects of Senate Bill 924 and related regulation of health care facilities that provide abortion care on women's health and safety. 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 care is extremely safe, and health care professionals safely provide it to women in office-based practices throughout the country.

The emergency regulations currently in effect will have a significantly harmful impact on women's ability to access first-trimester abortion care in Virginia. Further, the emergency 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 four most serious issues contained in the regulations and offers recommendations for the Board to address those issues and maintain patient safety and access.

1. The Physical Plant Requirements Are Medically Unnecessary and Will Impose Serious Burdens on Health Care Providers (12 VAC 5-412-380).

Any physical plant requirements for health care facilities that provide first-trimester abortion care should reflect the medical reality regarding the safety of first-trimester abortion services. In stark contrast, the current temporary regulations incorporate extensive, burdensome requirements from the Facility Guideline Institute's *2010 Guidelines for Design and Construction of Health Care Facilities* ("Guidelines"). These requirements are 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.

The Guidelines are not intended to apply 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). Further, the Guidelines clearly provide 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.* 6 (2010). It simply makes no sense to require existing health care facilities to comply with standards that were never intended to apply to them.[1] In addition, there is no medical reason for imposing these burdens on health care facilities. Thus, by establishing physical plant requirements that fail to distinguish between existing facilities and new construction, the emergency regulations unjustifiably create the risk that existing health care facilities will be forced to undertake extremely expensive renovations, move, or shut down.

For at least two reasons, requiring health care facilities that provide abortion care to comply with the 2010 Guidelines is inconsistent with the laws governing the Board's rulemaking. First, such a requirement is beyond the scope of the Board's authority. Senate Bill 924 amends only one subsection within VA. CODE ANN. § 32.1-127, classifying abortion facilities as a category of hospital only "for purposes of *this paragraph*." *Id*. (emphasis added). Accordingly, while a different provision of state law mandates that the Board promulgate regulations for "hospitals" that include design and construction standards "consistent with the current edition of the [Guidelines]," VA. CODE ANN. § 32.1-127.001, that provision of law is not modified in any way by Senate Bill 924—the bill's reach is on its face confined to § 32.1-127(B)(1) alone. Second, the legislation requiring the Board to promulgate regulations does not require the Board to use any specific documents or standards. *See* S.B. 924, 2011 Leg., Reg. Sess. (Va. 2011), codified as amended at VA. CODE ANN. § 32.1-127(B)(1) (requiring the Board to promulgate regulations that include, *inter alia*, "minimum standards" for the construction and maintenance of abortion facilities). Therefore, neither Senate Bill 924 nor any provision of existing state law requires the Board to incorporate the current version of the Guidelines.

Finally, independently, even if the state law mandating that the Board promulgate regulations that include design and construction standards consistent with the current editions of the Guidelines *did* apply to abortion facilities, the Guidelines on their face apply only to new construction and significant renovations or additions, as discussed above. Thus, to be "consistent" with the Guidelines, the regulations would have to apply the Guidelines requirements only to new construction and significant renovations or additions – not to existing

[1] 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. (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 the 2010 Guidelines to existing facilities, or to require facilities to undergo extensive construction every time the Guidelines are updated.

facilities that are not undergoing renovations or additions, and are providing the same services they have safely provided for years.

Notably, every other Virginia regulation of health care facilities or buildings treats existing facilities and new construction differently. For example, the regulations that apply to hospitals in Virginia contain requirements for "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. The requirements for existing facilities, however, 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 services and newborn services impose physical plant requirements only 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. Indeed, we are aware of *no other instance* in which Virginia has forced existing healthcare facilities to satisfy standards designed for new construction.

If the Board decides to include physical plant requirements in the permanent regulations, we urge it to do so in a way that is consistent with the requirements applicable to health care facilities that provide all other forms of care in the Commonwealth.

2. The Permanent Regulations Concerning Variances, Inspections, and Licensure Penalties for Abortion Facilities Should Be Consistent With Comparable Regulations For All Other Health Care Facilities.

It is inappropriate to single out health care facilities that provide abortion care from all other health care facilities with respect to their ability to obtain variances from burdensome and impractical regulations or with respect to the standards that govern inspections for compliance and consequences for non-compliance with regulations. We urge the Board to bring these regulations and standards into harmony with those applied to other health care facilities.

a. Variances (12 VAC 5-412-90).

Regulation 12 VAC 5-412-90 allows only a *temporary* variance from regulations applicable to abortion facilities. In addition, it appears to only allow such a variance 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 allows the commissioner to issue a *permanent* waiver if the enforcement of a regulation would be "clearly impractical." 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.").

b. Inspection Procedures and Licensure Penalties (12 VAC 5-412-130).

Regulation 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 … or of any applicable regulation," however minor and unrelated to patient care and safety. But 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 § 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. Furthermore, doing so would make abortion facilities subject to many statutes that are either irrelevant or even nonsensical in the context of abortion care. As a minimum, the regulations are unclear about which statutes and regulations abortion facilities must comply with in order to obtain a license and remain licensed. We urge the Board to eliminate from the permanent regulations the incorporation of "Article 1 of Chapter 5 of Title 32.1 of the Code of Virginia (§32.1-123 et seq.)" along with any reference to §32.1-135. Moreover, the regulations cover a broad range of topics, many of which are not related to patient safety. Clinics should be encouraged to submit plans of correction or compliance for violations of applicable regulations, but should not risk revocation or suspension of their license based on minor infractions unrelated to patient care and safety. We urge the Board to exercise its discretion under VA. CODE ANN. § 32.1-135(A) to establish standards for licensure penalties that reference the immediate safety of patients and/or to provide for license revocation in the event of a *substantial* violation.

3. The Permanent Regulations Must Protect Patient and Provider Confidentiality.

The permanent regulations should ensure that the confidentiality of patients seeking care from health care facilities that provide abortion care is explicitly protected in accordance with the requirements of medical ethics and relevant law. In addition, the permanent regulations should ensure that the confidentiality of health care providers who care for abortion patients is safeguarded.

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

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.

All patients have an expectation of privacy in their medical records, which is protected by both medical ethics[2] and law.[3] Confidentiality is of particularly pronounced importance to patients seeking reproductive health care services. At a minimum, the permanent regulations should provide at least as much protection for medical records of patients seeking abortion care as Virginia law affords to the records of patients receiving all other forms of care. *See* VA. CODE ANN. § 32.1-127.1:03(A)(2) (prohibiting removal of hospital health records from premises on which they are maintained without approval or court order). Patients seeking abortion care are targeted for harassment outside of clinics, and there is a history of anti-abortion groups seeking patient information in order to deter women from obtaining abortion care. These regulations should make explicit that Department representatives have access only to patient records that have been redacted of all patient identifying information. In addition, the regulations should make clear that while the Office of Licensure and Certification's (OLC) 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. In addition, the regulations should clarify that state employees may not interview current patients without their explicit permission.

Moreover, provisions should 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.

[2] *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?.

[3] *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).

b. Provider Safety (12 VAC 5-412-140 and 12 VAC 5-412-150).

Regulations 12 VAC 5-412-140 and 12 VAC 5-412-150 give the Department of Health the right to request all ownership information, facility policies and procedures, and personnel information without any requirement that these documents be kept confidential. Provisions should be included to ensure the confidentiality of facility information that is required by the OLC. As stated above, abortion providers are often the targets of violence by anti-abortion extremists, who seek out facility information and policies in order to harass and intimidate abortion providers. The permanent regulations should also include confidentiality protections for employee files and other personnel materials required by 12 VAC 5-412-170. The regulations contain no confidentiality protections for these documents, and do not purport to protect them from freedom of information requests by members of the public. The regulations should ensure that inspectors do not copy or disclose any personally identifying information regarding any staff member of an abortion facility. While inspectors are prohibited from disclosing personally identifying information regarding a *patient*, *see* VA. CODE ANN. § 32.1-127.1:03(A)(3), nothing in existing Virginia law or the emergency regulations prohibits an inspector from disclosing personally identifying or otherwise confidential information about *staff members* at an abortion facility. 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.

4. Distinguishing Between Facilities That Offer Medication Abortion And Those That Offer Medication and/or Surgical Abortion.

Senate Bill 924 requires the Board of Health to promulgate certain types of regulations, found in Va. Code §32-1.127(B)(1), for any facility "in which five or more first trimester abortions per month are performed." Abortion is defined in these regulations as "the use of an instrument, medicine, drug or other substance or device with the intent to terminate the pregnancy of a woman known to be pregnant, for reasons other than a live birth or to remove a dead fetus. Spontaneous miscarriage is excluded from this definition." Therefore, any facility in which either five or more medication or surgical abortions are performed are governed by these regulations.

Medication abortion involves the patient taking a medication that ends a pregnancy, usually mifepristone, followed by misoprostol to expel the contents of the uterus. The standard of care is for a provider to examine the woman to confirm that she is pregnant and to determine the gestational age of her pregnancy. If the woman is less than nine weeks pregnant, medication abortion may be an option. If she chooses that option, the provider gives the woman mifepristone to take in the clinic. She then takes misoprostol one to a few days later in her own home and experiences the loss of the pregnancy in the privacy of her home. Since the FDA approved RU-486, or mifepristone, for use in the United States in 2000, more than 1.5 million women in this country have experienced safe medication abortions.

Because medication abortion care involves the provision of oral medication, rather than any surgery, it is medically inappropriate to require facilities that provide only medication abortion care to meet the extensive physical plant requirements imposed on abortion facilities under these regulations. The same is true of the regulations' requirements for anesthesia services; examination of fetal tissue; and certain staffing, equipment, and emergency services requirements, none of which are medically appropriate in the context of medication abortion care. The regulations should be revised to ensure that facilities that provide only medication abortion care are subject only to medically appropriate requirements, rather than being subjected to "one size fits all" regulations that were developed in the very different medical context of surgical abortion services. .

5. The Permanent Regulations Should Not Derive Standards From External Sources.

The regulations require abortion facilities to comply with a number of outside statutes, guidelines and other materials. The incorporation of these materials poses at least three problems. First, the regulations require compliance with "current" versions, but some of these materials are updated so regularly as to make it difficult, if not wholly impossible, for facilities to ensure that they will always be in compliance with the most "current" version. Second, in some cases, the referenced material is difficult to find or does not seem to exist. Third, the materials referenced are not always the most medically appropriate for an abortion care setting or the only source of guidance on the particular issue. Abortion facilities should be encouraged to develop their policies and procedures based on the prevailing standards in the medical community, and not be limited to a particular set of guidelines.

Conclusion

We urge the Board to consider carefully the above issues, the medical reality of the safety of first-trimester abortion care, and the importance of women's access to health care in Virginia, in promulgating the permanent regulations. We appreciate your consideration of these comments. The Coalition looks forward to working with the Board to ensure that the permanent regulations reflect medically appropriate standards for abortion facilities. In addition, we hereby request a public hearing after permanent regulations have been proposed.

February 15, 2012

Dear Board of Health Member,

As a retired doctor and former health commissioner for the Commonwealth of Virginia, I am deeply concerned about the emergency regulations created by the Department of Health for women's health centers in the Commonwealth that are now in effect.

For almost forty years, women's health care centers in the Commonwealth have been trusted health care providers, serving tens of thousands of women and their families each year. Women in Virginia turn to the Commonwealth's health care centers for a wide-range of preventive and reproductive services, including life-saving cancer screenings, sex education and options counseling, birth control, and abortion care.

When I was a young physician in Cincinnati and Atlanta in the 1950s, I helped women who needed emergency medical care following either self-induced or "back alley" abortions. Later, in practice, one of the most memorable patients that I treated was a mature, educated mother of two whose spouse had recently survived a brain hemorrhage. Pregnant some 20 years before the Supreme Court legalized abortion care and with nowhere to turn, she desperately tried to self-abort with a hat pin.

In the middle of the night, I was called to her house where I found her in excruciating pain suffering from severe chills and a fever of 105 degrees. After telling me what she had done, I rushed her to the hospital where she received emergency medical treatment that thankfully saved her life.

Health care centers in the Commonwealth provide essential services to women, keeping them safe from the consequences that come from lack of access to needed reproductive health care. Women's health centers in the Commonwealth are comprised of highly trained doctors and nurses who insist on the highest standards of patient care. They proudly follow rigorous safety guidelines and evidence-based medical standards already in place.

As currently written, the temporary regulations, specifically the time and resources required to physically alter health centers for no medical reason, are likely to increase financial barriers for patients as well as reduce women's ability to find a health care provider. The current temporary regulations require extensive, medically unnecessary and inappropriate renovations to meet building standards intended only for the design and construction of new outpatient surgical hospitals, not existing health centers. Even existing hospitals are not expected to meet new building requirements during the regulation process, and yet abortion providers are being singled out for no medical reason.

Abortion is a safe and legal procedure. Studies show that the vast majority of women seeking abortion care are in the first trimester, and 97% report no medical complications. The proposed regulations would likely require every women's health center in the Commonwealth to make extensive structural modifications that have no proven medical benefit to patients.

As the former Commissioner of Health under four governors, I urge the members of the Virginia Department of Health and the Board of Health to adhere to their charge - to protect the public health and safety of the people of the Commonwealth by adopting only those regulations that are medically appropriate, and based in science.

Sincerely,

Dr. James B. Kenley M.D., MPH

The Facts of First-Trimester Abortion Care

There are two common types of first-trimester abortion procedures: medical abortion and surgical abortion. A medical abortion is one that is brought about by taking medications that will end a pregnancy. Either of two medications, mifepristone or methotrexate, can be used for medical abortion. Each of these medications is taken together with another medication, misoprostol, to induce an abortion. Medical abortion is effective generally up to nine weeks gestation, and allows a woman to have a safe, effective abortion without a surgical procedure.

Surgical abortion ends a pregnancy by emptying the uterus with special instruments. Virtually all first-trimester surgical abortions are accomplished by vacuum aspiration, which involves very light suction applied to the contents of the uterus. A routine first-trimester surgical abortion takes approximately 5-15 minutes to complete, and is one of the safest types of medical procedures.

Complications from having a first-trimester surgical abortion are considerably less frequent and less serious than those associated with giving birth. Medical abortions have a similarly excellent safety profile, with serious complications occurring in less than 0.5% of cases.

Serious complications arising from surgical abortions provided before 13 weeks are quite unusual. About 88% of the women who obtain abortion care are less than 13 weeks pregnant. Of these women, 97% report no complications; 2.5% have minor complications that can be handled at the medical office or abortion facility; and less than 0.5% have more serious complications that require some additional surgical procedure and/or hospitalization.[4]

In addition, first-trimester abortions pose virtually no long-term risk of such problems as infertility, ectopic pregnancy, spontaneous abortion (miscarriage) or birth defect, and little or no risk of preterm or low-birth-weight deliveries.[5]

[4] National Abortion Federation, *Safety of Abortion*, available at http://www.prochoice.org/about_abortion/facts/safety_of_abortion.html

[5] Guttmacher Institute, Facts on Induced Abortion in the United States, August 2011, available at http://www.guttmacher.org/pubs/fb_induced_abortion.html