Virginia Coalition to Protect Women's Health

February 11, 2015

Dear Dr. Levine and Board of Health Members,

The following is a memorandum submitted by the Virginia Coalition to Protect Women's Health ("the Coalition") as comments on the Virginia Board of Health's (the Board) rulemaking process to amend the regulations for the licensure of abortion facilities, 12 VAC 5–412. As a result of a periodic review of 12 VAC 5–412, the Virginia Department of Health (the Department) determined it was necessary to amend the regulations, and the Board approved a Notice of Intended Regulatory Action (NOIRA) to begin the rulemaking process.

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 health care in the Commonwealth, rather than arbitrarily forcing health care facilities to close through burdensome, medically unnecessary over-regulation.

The Department and the Board now have the opportunity to promulgate carefully considered amendments that are medically appropriate. We hope that the information provided herein will be useful to the Department and the Board as they consider amendments that will improve the current regulations. Accordingly, we set forth below a summary of the serious issues in the current regulations and specific recommendations for improvements that would preserve the high standards of patient safety and access to care that abortion facilities in the Commonwealth have provided for over forty years.

Proposed Amendments to 12VAC5-412-10. Definitions.

A medication abortion is when oral medications are used to end a pregnancy; no surgery is performed or even any medical procedure, simply the taking of a pill. Therefore, as discussed in greater detail below, it makes no sense to require facilities that provide only medication abortion care to meet the extensive physical plant requirements required by 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 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. Thus, amendments should be made to the definition of "Abortion Facility" and "Abortion" in 12

VAC 5-412-10 to clarify that these regulations are intended to apply only to facilities that provide surgical abortion care. The new definitions would read:

> "'Abortion Facility' means a facility in which five or more first trimester surgical abortions per month are performed."
>
> "'Abortion' means 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."

Proposed Amendments to 12VAC5-412-20. General.

Abortion providers are often the targets of violence by anti-abortion extremists, who seek out information about health center ownership and policies in order to harass and intimidate abortion providers and patients. The well-documented history of harassment and violence directed against the health care professionals who provide abortion care makes it clear that stringent confidentiality protections should be a part of the regulations, to ensure that sensitive information about the health care facility or its patients does not get into the wrong hands.

Thus, a new subsection should be included in 12VAC5-412-20, as follows:

> "Virginia Code 2.2-3705.2, related to disclosure of information to the public which would jeopardize the safety of any person, shall take precedence over any requirement in this Chapter."

Proposed Amendments to 12 VAC 5-412-80. Allowable variances.

We suggest that this provision be amended to reflect the standard for variances already in place for hospitals and outpatient surgical hospitals, in order to provide consistency across health care facility regulations. 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. There is no justification for removing the Commissioner's discretion as to only one type of health care facility. It is inappropriate and irrational to impose more stringent variance standards on abortion facilities than are applied to inpatient hospitals and other health care facilities in which more complex and invasive health care services are provided.

Thus, we recommend 12 VAC 5-412-80 be amended as follows:

> ~~"A. The commissioner may authorize a temporary variance only to a specific regulation of this Chapter. An abortion facility may request a temporary variance to a particular regulation or requirements contained in a particular regulation of this chapter when the standard or requirement poses an impractical hardship unique to the abortion facility and when a temporary~~

~~variance to it would not endanger the safety or well-being of patients. The request for a temporary variance shall describe how compliance with the current regulation constitutes an impractical hardship unique to the abortion facility. The request should include proposed alternatives, if any, to meet the purpose of the requirements that will ensure the protection and well-being of patients. At no time shall a temporary variance be extended to general applicability. The abortion facility may withdraw a request for a temporary variance at any time.~~
~~B. The commissioner may rescind or modify a temporary variance if: (i) conditions change; (ii) additional information becomes known which alters the basis for the original decision;(iii) the abortion facility fails to meet any conditions attached to the temporary variance; or (iv) results of the temporary variance jeopardize the safety or well being of patients.~~

~~C. Consideration of a temporary variance is initiated when a written request is submitted to the commissioner. The commissioner shall notify the abortion facility in writing of the receipt of the request for a temporary variance. The licensee shall be notified in writing of the commissioner's decision on the temporary variance request. If granted, the commissioner may attach conditions to a temporary variance to protect the safety and well-beingof patients.~~

~~D. If a temporary variance is denied, expires, or is rescinded, routine enforcement of the regulation or portion of the regulation to which the temporary variance was granted shall be resumed.~~

A. 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. Modification of any individual standard herein, for experimental or demonstrative purposes, or any other purposes, shall require advance written approval from the OLC."

Proposed Amendments to 12 VAC 5-412-90. Right of entry.

In order to protect the safety of women's health center staff and patients, 12 VAC 5-412-90 should be amended to clarify that the inspection should only be conducted when the facility is open for serving patients.

Thus, 12 VAC-412-90 should be amended as follows:

"~~Pursuant to 32.1-25 of the Code of Virginia,~~A licensed facility shall be open for inspection by a properly-identified OLC representative during any time the facility is serving patients. Any duly designated employee of the Virginia Department of Health shall have the right to enter upon and into the premises of any licensed abortion facility, or any entity the department has reason to believe is operated, or maintained as an abortion facility without a license, in order to determine the state of compliance with the provisions of this chapter and applicable laws. Any

such employee shall properly identify himself or herself as an inspector designated by OLC and may appear during any time the facility is open for inspection, as defined in this paragraph; the abortion facility may verify the identity of the inspector prior to his or her admission."

Proposed Amendments to 12 VAC 5-412-100. On-site inspection.

All patients have an expectation of privacy in their medical records, which is protected by both medical ethics[1] and law.[2] Further, confidentiality is of paramount importance to patients and abortion providers, in order to ensure patient and provider safety. Patients are targeted for harassment outside of abortion facilities and there is a history of anti-abortion activists seeking patient information in order to deter women from seeking abortion care. 12 VAC 5-412-100 does not provide appropriate protection for patient confidentiality. This provision should be amended to protect the confidentiality of patients in the facility, patient records, and facility information. Further, it is unreasonable 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.

12 VAC 5-412-100(B) should be modified to read:

"B. The abortion facility shall make available to the OLC's representative when the representative is on site at the facility any requested records, except that if the OLC representative requests patient medical records, the facility shall first redact any potentially identifying information before the OLC representative may review them. Records, including but not limited to patient medical records, shall not be removed from the premises. The facility shall allow access to interview the agents, employees, and contractors under the facility's control, direction or supervision. An OLC representative may not disclose any information obtained in compliance with this Section except as necessary for his or her job duties. Disclosure for any reason other than as necessary for his or her job duties may subject the representative to disciplinary action, including job termination. In addition, these requested records shall not be available through any open records or freedom of information requests."

12 VAC 5-412-100(C) should be amended as follows:

"C. A licensed facility shall be open for inspection by a properly-identified OLC representative during any time the facility is serving patients. If the OLC's representative arrives on the premises to conduct a survey during any time the facility is open for inspection, as defined in this paragraph, and the administrator, the nursing director, or a person authorized to give

[1] *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?.

[2] *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 U.S. 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).

access to patient records, is not available on the premises, such person or the designated alternate, shall be available on the premises within 2 hours of the surveyor's arrival. ~~A list of patients receiving services on the day of the survey as well as a list of all of the abortion facility's patients for the previous 12 months shall be provided to the surveyor within 2 hours of arrival if requested.~~ Failure to be available or to respond shall be grounds for penalties in accordance with Virginia Code § 32.1-27 and may lead to denial, suspension or revocation of the facility's license in accordance with 12VAC5-412-130."

Proposed Amendment to 12VAC5-412-110(B). Plan of correction.

In order to decrease unnecessary administrative burdens on abortion facilities and ensure patient health and safety, the following amendments should be made to 12VAC5-412-110:

In Subsection B change "15 working days" to "30 calendar days."

In Subsection B.2 change "30 working days" to "90 calendar days."

Proposed Amendment to 12 VAC 5-412-120(A). OLC complaint investigations.

It is within the purview of the Office of Licensure and Certification (OLC) to investigate credible complaints in order to ensure compliance with these regulations. However, it is a common tactic of anti-abortion extremists to file numerous complaints with no evidence or backing in order to harass abortion providers. OLC should only be required to investigate credible patient health and safety complaints.

We recommend that this provision be amended to read:

> "A. The OLC shall investigate any credible patient health and safety complaints regarding alleged violations of this chapter and applicable law."

Proposed Amendment to 12 VAC 5-412-130. Violation of this chapter or applicable law; Denial, revocation or suspension of license.

This provision of the regulations appears to require a women's health center to comply with the entire inpatient hospital code, and appears to condition their licensure on their compliance with each and every provision. Imposing the hospital code in this manner would make abortion facilities subject to many statutes that are either irrelevant or even nonsensical in the context of abortion. Not even hospitals themselves are required to comply with every statute in the hospital code in this manner as a condition of continued licensure.

The Department itself explicitly acknowledged the problems with this provision by providing abortion facilities with a list of the statutes in the hospital code they expect to enforce against abortion providers in a guidance document. That guidance document instructs clinics to "check back periodically," as it will be updated "as needed." Abortion facilities should not be at risk of losing their licenses because they are relying on official Department guidance that is outdated or incomplete when the Department can simply incorporate that guidance into the text of the regulations. Abortion facilities should be able to rely on

the plain text of the regulations to know what is required of them in order to obtain and keep their licenses.

We suggest that 12 VAC 5-412-130(A) be amended so that abortion facilities are clearly informed as to which sections of Virginia law apply to them:

> "A. When the department determines that an abortion facility is (i) in violation of ~~any provision of Article 1 (§ 32.1-123 et seq.)of Chapter 5 of Title 32.1 of the Code of Virginia~~ §§ 32.1-125.01, 32.1-125.4, 32.1-132, 32.1-135.2, or 32.1-137.01 of the Code of Virginia or of any ~~applicable regulation~~ regulation in Title 12, Chapter 412 of the Virginia Administrative Code, if such violation constitutes a threat to patient health and safety or (ii) is permitting, aiding, or abetting the commission of any illegal act in the abortion facility, the department may deny, suspend or revoke the license to operate an abortion facility in accordance with § 32.1-135 of the Code of Virginia."

Incorporation of all of the provisions of Article 1 of Chapter 5 of Title 32.1 of the Code of Virginia should be removed from 12 VAC 5-412-130(B). That section should read:

> "B. If a license or certification is revoked as herein provided, a new license or certification ~~may~~shall be issued by the commissioner after satisfactory evidence is submitted to him that the conditions upon which revocation was based have been corrected and after proper inspection has been made and compliance with all provisions of ~~Article 1 of Chapter 5 of Title 32.1 of the Code of Virginia and~~ applicable state and federal law and regulations hereunder has been obtained."

Proposed Amendments to 12 VAC 5-412-140(B). Management and administration.

In order to protect the safety of women's health center staff and patients, this provision should be amended to ensure the confidentiality of information that is reported to the OLC.

12 VAC 5-412-140(B) should be amended as follows:

> "B. The abortion facility shall submit or make available reports and information necessary to establish compliance with this chapter and applicable law. OLC representatives may not disclose any information obtained in compliance with this Section except as necessary for his or her job duties. Disclosure for any reason other than as necessary for his or her job dutiesmay subject the representative to disciplinary action, including job termination. In addition, these documents shall not be available through any open records or freedom of information requests."

Proposed Amendment to 12VAC5-412-160(B). Policies and procedures.

In order to protect the safety of women's health center staff and patients, this provision should be amended to ensure the confidentiality of information that is reported to the OLC.

12 VAC 5-412-160(B) should be amended as follows:

> "B. These policies and procedures shall be based on recognized standards and guidelines. A copy of the policies and procedures approved by the governing body and revisions thereto shall be made available to the OLC upon request. OLC representatives may not disclose any policies, procedures or plans obtained in compliance with this Section except as necessary for his or her job duties, and may not reveal such information to the public. Disclosure for any reason other than as necessary for his or her job duties may subject the representative to disciplinary action, including job termination."

Proposed Amendments to 12VAC5-412-180. Personnel.

In order to protect the safety of women's health center staff and patients, this provision should be amended to ensure the confidentiality of information that is reported to the OLC.

12 VAC 5-412-180 should be amended to include a new Subsection I, as follows:

> "I. Nothing in these regulations shall authorize any employee or agent of the OLC or the department to copy or disclose to any party by any means information regarding facility personnel unless such employee or agent is in violation of the law or regulations governing abortion clinics. Violation of this provision shall be grounds for disciplinary action including termination of employment."

Proposed Amendments to 12VAC5-412-190. Clinical staff.

In order to ensure consistency with the rules of any supervisory agency with respect to clinical staff and the practice of medicine by physicians, and to protect the safety of abortion facility staff and patients, this provision should be amended.

12 VAC 5-412-190 should be amended to include a new Subsection E, as follows:

> "E. Nothing in these regulations shall be interpreted to overlap or conflict with the rules of any supervisory agency with respect to clinical staff and the practice of medicine by physicians. Further, notwithstanding anything to the contrary in these regulations, no employee or agent of the OLC or the department may disclose the names or other identifying information of any medical practitioners or other staff employed by or providing services at an abortion facility. Violation of this provision shall be grounds for disciplinary action including termination of employment."

Proposed Amendment to 12VAC5-412-290(C). Emergency services.

This provision must be amended to remove the medically unnecessary transfer agreement requirement. These types of arrangements are subject to business interests and political influence; therefore, a hospital could deny a transfer agreement for variety of reasons that have nothing to do with the safety of abortion or the quality of care provided at a women's health center. In the rare event of a

complication, federal law (EMTALA) requires that any patient have access to hospital care.[3] Thus, *no* patient requiring emergency care—regardless of the medical procedure giving rise to the emergency—can be denied access to a hospital in Virginia. The transfer agreement is nothing but a restriction designed to place medically unnecessary obstacles between abortion providers and patients seeking their services.

12VAC5-412-290(C) must be amended as follows:

> "C. ~~A written agreement shall be executed with a licensed general hospital to ensure that any patient of the abortion facility shall receive needed emergency treatment. The agreement shall be with a licensed general hospital capable of providing full surgical, anesthesia, clinical laboratory, and diagnostic radiology service on 30 minutes notice and which has a physician in the hospital and available for emergency service at all times.~~ When emergency transfer is necessary, the responsible physician at the abortion facility must provide direct communication to the emergency department staff regarding the status of the patient, the procedure details, and the suspected complication. All patients must be provided with contact information for a representative of the abortion facility, so that an emergency department physician or treating provider may make contact with a provider of the facility if late complications arise."

Proposed Amendments to 12VAC5-412-320. Required Reporting.

In order to protect the safety of abortion facility staff and patients, this provision should be amended to ensure the confidentiality of information that is reported to the OLC.

12 VAC 5-412-320 should be amended to include a new subsection, as follows:

> "The VDH Report of Induced Termination of Pregnancy for any individual abortion whether surgical or medical shall not be disclosed to the public by any means."

Proposed Amendments to 12VAC5-412-340. Disaster preparedness.

In order to protect the safety of abortion facility staff and patients, this provision should be amended to ensure the confidentiality of information that is reported to the OLC.

12 VAC 5-412-340 should be amended to include a new Subsection, as follows:

> "These plans, policies, and procedures shall not be available through any open records or freedom of information requests."

[3] 42 U.S.C.A. §§1395dd(a),(b)(1),(e)(1) (EMTALA) (requiring hospitals with an emergency department to provide appropriate treatment or transfer to another medical facility for individuals presenting with an emergency medical condition).

Proposed Amendment to 12 VAC 5-412-370. Local and state codes and standards.

As a preliminary matter, the application of any new facility construction guidelines, including the 2014 Guidelines for Design and Construction of Hospital and Outpatient Facilities of the Facility Guidelines Institute (commonly known as the "FGI Guidelines" or "Guidelines"), to existing facilities, as was done with the application of the 2010 Guidelines for Design and Construction of Health Care Facilities ("the 2010 FGI Guidelines"), is inappropriate for two main reasons.

First, all other regulated health care facilities in Virginia*, including inpatient hospitals*, have grandfathering provisions that both protect patient safety while allowing health facilities to operate without having to renovate or rebuild every time new regulations are adopted. In each and every case, the Guidelines apply 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. *See* 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).

Second, failing to grandfather in existing facilities is contrary to the plain language of the Guidelines themselves, which make clear that its provisions are only intended to apply to new construction or major renovations. For example, Section 1.1-1.1 of the 2014 FGI Guidelines state that"[t]he provisions of this [general] chapter shall apply to all *new* construction and *major* renovation projects in hospitals and outpatient facilities." 2014 FGI GUIDELINES § 1.1-1.1 (emphasis added). The Guidelines go on to state that "[i]n renovation projects and additions to existing facilities, *only that portion of the total facility affected by the project* shall be required to comply with applicable sections of the Guidelines." 2014 FGI GUIDELINES § 1.1-3.2.1 (emphasis added).

I. The FGI Guidelines are Inappropriate for Health Facilities Providing Abortion.

The standards from the 2014 FGI Guidelines are not appropriate for health facilities providing abortion services because they are not medically appropriate for the care provided.

Many of the Guidelines' requirements are clearly intended to address issues that are only present in the context of surgical procedures requiring a sterile environment. In contrast to more complicated, invasive surgical procedures, first trimester abortion is a simple, non-invasive surgical or medical procedure that is typically provided in office-based settings. Indeed, "surgical" abortion is not what one typically thinks of as surgery, as it is performed by passing sterile instruments through the vagina, an orifice normally colonized with bacteria, to gently remove the contents of the uterus, and is not an invasive procedure. 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 the application of guidelines specifically geared toward the performance of more complicated, sterile procedures.

The same holds even truer in the context of medication abortion, which is a method of ending an early pregnancy by taking pills that cause the woman to miscarry within a short and predictable period of time. It is commonly provided out of doctors' offices and clinics nationwide. Medication abortion is

extremely safe and is associated with few complications or contraindications. In a medication abortion, the patient takes a mifepristone pill at the health center. That day, she is given misoprostol pills and instructed to take them herself twenty-four to forty-eight hours later. She then passes the products of conception at home, or another location of her choosing, usually approximately four or five hours after she takes misoprostol. Medication abortion requires no anesthesia or sedation. There is nothing about the safety of mifepristone that requires it to be taken in a health center. Rather, it is taken in a health center or health professional's office in order to enable the provider to confirm that the patient takes the mifepristone, and at what time, for purposes of monitoring the safety and efficacy of the process. Because medication abortion involves the provision of an oral medication, rather than any surgery, it is obviously unnecessary – and would provide no medical benefit – for facilities that provide only medication abortion to meet any of the extensive facility requirements imposed by the FGI Guidelines.

Instead of applying the FGI Guidelines to health centers providing abortions, the Department and the Board should promulgate new regulations, with the participation and input of all stakeholders including abortion providers, that are evidence-based and include only provisions that will improve patient safety and public health. Should the Department and the Board determine that they must apply any provisions from the FGI Guidelines to abortion providers, they should, at a minimum, ensure that "the requirements of the Uniform Statewide Building Code and local zoning and building ordinances shall take precedence." In doing so, the Department and the Board would be aligning the regulations applicable to health centers providing abortion with those regulations governing most, if not all, medical facilities in Virginia. *See* 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).

II. Requirements from Chapter 3.8 are the Least Inappropriate for Abortion Providers.

While the FGI Guidelines should not be applied to health facilities providing abortion, should the Department and the Board determine that the enabling statute requires it to apply the FGI Guidelines, some of the more relevant provisions from Chapter 3.8, Specific Requirements for Office-Based Procedure and Operating Rooms, would be the least inappropriate of the available requirements. Additionally, as discussed below, the Department and the Board should treat health centers providing only medication abortion and not surgical abortion differently from those health centers providing surgical abortion.

Health care facilities are generally regulated based on the nature of the procedures provided at the facility. First trimester surgical abortion is a simple procedure that is typically provided in office-based settings, which have an excellent safety record of providing abortion in this country. As such, the health centers providing abortion would be more similar to the office-based surgical facilities addressed in Chapter 3.8, due to their typical size, the services they typically offer, and their typical locations in the community, rather than facilities governed by other chapters.

III. The Department and the Board Should Not Apply the Provisions of Chapter 3.8 that are Medically Inappropriate.

While Chapter 3.8 is the least inappropriate chapter of the 2014 FGI Guidelines to apply to abortion providers, it still contains many provisions that would be medically inappropriate in the context of providing abortion. As discussed separately below, these provisions are even more inappropriate in the context of facilities only providing medication abortion and not surgical abortion.

The 2014 FGI Guidelines state that its recommendations may not be appropriate for all facilities, noting that its contents describe "elements that are common to most types of outpatient facilities," and that "[c]onsideration shall be given to the special needs of the anticipated patient population as described in the functional program." 2014 FGI GUIDELINES § 3.1-1.1.1. Moreover, the enabling statute states that the Department should promulgate regulations "consistent with the current edition of" the FGI Guidelines, which means that at the very least, the Department and the Board have the flexibility to create regulations that are appropriate for the health care facilities at issue. As such, there are several provisions from Chapter 3.8 that the Department and the Board should *not* apply to health centers providing abortion services. Those provisions are detailed below.

3.8-3.1: Office-Based Procedure Room. We urge the Department and the Board to make explicit that first trimester surgical abortion may be provided in an office-based procedure room. Procedure rooms are appropriate for the provision of first trimester abortion because, as stated, first trimester abortion is a non-invasive procedure that does not require a sterile environment.[4]

This is supported by the language of the 2014 Guidelines itself, in which the definition of "invasive procedure" makes clear that surgical abortion, which is performed by passing sterile instruments through the vagina, an orifice normally colonized with bacteria, to gently remove the contents of the uterus is not an invasive procedure, and, as such, would be appropriately performed in a procedure room or, in the case of medication abortion and surgical abortion using only local anesthetics, an examination room or treatment room.[5]

[4] The Department has previously found that abortion procedures using only local anesthetics could be safely provided in a treatment room, as defined in Section 3.1-3.2.4.2 of the 2010 FGI Guidelines. Though this treatment room category does not appear in the 2014 FGI Guidelines, it remains appropriate for the provision of these first trimester surgical abortion services.

[5] The 2014 FGI Guidelines' Glossary defines an "invasive procedure" in relevant part as a procedure that "[p]enetrates the protective surfaces of a patient's body (e.g., skin, mucous membranes, cornea)[,]" "[i]s performed in an aseptic surgical field (i.e., a procedure site)[,]" and "[g]enerally requires entry into a body cavity." 2014 FGI GUIDELINES, Glossary, at xxxiv. The definition goes on to state that "[a]ccepted standards of patient care are used to determine where an invasive procedure is performed[,]" and that "[t]he intent [of the definition] is to differentiate those procedures that carry a high risk of infection, either by exposure of a usually sterile body cavity to the external environment or by implantation of a foreign object(s) into *a normally sterile site*. Procedures performed *through orifices normally colonized with bacteria* and percutaneous procedures that do not involve an incision deeper than skin would not be included in this definition." *Id*. (emphasis added).

The more restrictive Chapter 3.7 then makes clear that procedure rooms, identical in space requirements to those in 3.8-3.1, are "designated for the performance of procedures that are *not defined as an invasive procedure* and do not require location in the restricted area of a surgical suite but may use sterile instruments or equipment." 2014 FGI GUIDELINES § 3.7-3.2.1 (emphasis added).

3.8-7.2.3: Surfaces. The surface requirements incorporated by Chapter 3.8 are not medically necessary in the context of abortion as it does not require a sterile environment to adequately protect patient health and safety.

3.8-8.2: Heating Ventilation, and Air-Conditioning (HVAC) Systems. Section 3.8-8.2's recommendations for heating, ventilation, and air-conditioning (HVAC) systems are unduly burdensome for health centers providing abortion. The Department and the Board should eliminate these requirements and instead require compliance with the Uniform Statewide Building Code and local zoning and building ordinances.

IV. To the Extent that Chapter 3.1 is Incorporated into the Regulations, the Department and the Board Should Eliminate Certain Provisions That Are Medically Unnecessary.

By applying the more relevant and appropriate provisions of 3.8, the Department and the Board have more than adequately satisfied the statutory requirements, and we do not believe there is any basis for additionally requiring compliance with requirements from Chapter 3.1. However, should the Department and the Board decide to incorporate provisions from 3.1, we would urge them to exempt abortion providers from the medically inappropriate provisions in Sections 3.1-7 (Design and Construction Requirements) and 3.1-8 (Building Systems).[6] Again, as discussed below, the Department and the Board should treat health centers providing only medication abortion and not surgical abortion differently from those health centers providing surgical abortion.

3.1-7: Design and Construction Requirements. Section 3.1-7 goes well beyond what is medically appropriate or necessary for the provision of abortion services and, as such, should not be applied to abortion providers. Many of the requirements in Section 3.1-7 are clearly intended to address issues that are only present in the context of surgical procedures requiring a sterile environment. As discussed, surgical abortion is a simple, non-invasive surgical or medical procedure that is typically provided in a non-sterile, office-based setting.

To the extent that the Department and the Board do not exempt all abortion providers from Section 3.1-7 in its entirety, they should exclude from the requirements the following provisions: Section 3.1-7.2.2.2

[6] Chapter 3.1 states that it "contains elements that are common to most types of outpatient facilities[,]" but notes that they are only "required when referenced in a specific outpatient facility chapter in Part 3[,]" and that "[c]onsideration shall be given to the special needs of the anticipated patient population as described in the functional program." 2014 FGI GUIDELINES § 3.1-1.1.1.

(ceiling height requirements), 3.1-7.2.2.8 (hand-washing station specifications), 3.1-7.2.3 (surfaces, as discussed above), and 3.1-7.2.3.2 (restrictions on walls and wall protections). These provisions go beyond that which is required for the provision of a non-sterile, non-invasive procedure such as surgical abortion.

3.1-8: Building Systems. Section 3.1-7 also imposes requirements that are medically unnecessary and onerous for health centers providing abortion as they are all are more suitable for procedures requiring a sterile environment.

To the extent that the Department and the Board do not exempt all abortion providers from Section 3.1-8 in its entirety, they should exclude from the requirements the following provisions: Sections 3.1-8.2 (requirements for heating, ventilation, and air-conditioning (HVAC) systems), 3.1-8.7.2 (requiring elevators for health centers with more than one floor), and any other provisions that were not explicitly incorporated by Chapter 3.8.

V. Health Centers Providing Only Medication Abortion Should Be Separately Regulated.

As noted in our proposed amendment to 12VAC5-412-10, above, facilities that only provide medication abortion should be entirely excluded from the regulations. As discussed above, medication abortion is a method of ending an early pregnancy with oral medications. Medication abortion is extremely safe, is associated with few complications or contraindications, and requires no anesthesia or sedation. Given that medication abortion involves the provision of an oral medication, the requirements of Title 12, Agency 5, Chapter 412, and in particular the extensive facility requirements detailed in the FGI Guidelines would serve no medical benefit whatsoever and, as such, should not be applied to facilities only providing medication abortion and not surgical abortion.

Should the Department and the Board also choose to apply the FGI Guidelines to health centers only providing medication abortion and not surgical abortion, it should only apply those provisions in a way that is consistent with the intent of the Guidelines and with a level of flexibility that would reflect the non-surgical nature of the medication abortion procedure. Given that Chapter 3.8 of the Guidelines states that "[t]his chapter applies to procedure and operating rooms in physicians' offices…*where surgical procedures are performed*[,]" the Department and the Board must modify these requirements so as to eliminate those provisions that are the least medically appropriate in the context of providing abortion. 2014 FGI GUIDELINES § 3.8-1.1 (emphasis added). As such, we request that the Department and the Board exempt facilities that are only providing medication abortion and not surgical abortion from Sections 3.8-3.1 (procedure room requirements) and 3.8-3.2 (operating room requirements) and allow for the oral medication to be dispensed in an examination room. We also request that these facilities be exempted from other provisions designed for sites providing surgical procedures, such as Section 3.8-7.2.3 (surface requirements) and Section 3.8-8.2 (heating, ventilation, and air conditioning requirements).

Moreover, should the Department and the Board choose to apply Chapter 3.1 to facilities only providing

medication abortion and not surgical abortion, it should exempt these facilities from having to comply with its most medically inappropriate provisions, Sections 3.1-7 (Design and Construction Requirements) and 3.1-8 (Building Systems) in their entirety, and instead allow compliance with the Uniform Statewide Building Code and local zoning and building ordinances.

VI. Conclusion.

To summarize, the Department and the Board should not apply the FGI Guidelines to health centers providing abortion, particularly not to those health centers only providing medication abortion and not surgical abortion, but should instead require compliance with the Uniform Statewide Building Code and local zoning and building ordinances. At the very least, if the Department and the Board should apply some portions of the FGI Guidelines to abortion providers, they should ensure that the Uniform Statewide Building Code and local zoning and building ordinances take precedence, as they do for other medical facilities in the state.

If the Department and the Board do apply the FGI Guidelines, they should apply Chapter 3.8 (Specific Requirements for Office-Based Procedure and Operating Rooms), but amend those requirements as detailed above. Should the Department and the Board also determine that it must also apply Chapter 3.1 of the Guidelines, they should also amend those requirements as detailed above. In all cases, the Department and the Board should tailor the Guidelines' requirements so as to not be unduly burdensome to those health centers only providing medication abortion and not surgical abortion.

Accordingly, we recommend several options for amending 12 VAC 5-412-370:

Facilities that provide surgical abortion:

Option #1:

> "All construction of new buildings and major additions, renovations, alterations or repairs of buildings for occupancy as abortion facilities shall comply with state and local codes, zoning and building ordinances, and the Uniform Statewide Building Code and shall ~~comply~~ be designed and constructed according to ~~with~~ Part 3.8, excluding §§ 3.8-7.2.3 and 3.8-8.2, of the 2014 edition of the Guidelines for Design and Construction of Hospitals and Outpatient Facilities of the Facilities Guidelines Institute~~,~~. Abortion procedures may take place in a procedure room, as detailed in 3.8-3.1. Rooms designed in accordance with 3.8-3.2 are not required. The requirements of ~~which shall take precedence over~~ the Uniform Statewide Building Code and local zoning and building ordinances shall take precedence. ~~pursuant to Virginia Code §32.1-127.001. –~~.
>
> ~~Entities operating as of the effective date of these regulations as identified by the department through submission of Reports of Induced Termination of Pregnancy pursuant to 12VAC5-550-120 or other means and that are now subject to licensure may be licensed in their current buildings if such entities submit a plan with the application for licensure that will bring them into full compliance with this provision within two years from the date of licensure.~~

In order to determine whether the abortion facility is in compliance with this provision, the commissioner may obtain additional information from the facility or its architect concerning the design and construction of the facility."

Option #2:

"All construction of new buildings and major additions, renovations, alterations or repairs of buildings for occupancy as abortion facilities shall comply with state and local codes, zoning and building ordinances, and the Uniform Statewide Building Code and shall ~~comply~~ be designed and constructed according to ~~with~~ Part 1, Part 3.1-1 to 3.1-6, and Part 3.8, excluding §§ 3.8-7.2.3 and 3.8-8.2, of the 2014 edition of the Guidelines for Design and Construction of Hospitals and Outpatient Facilities of the Facilities Guidelines Institute~~,~~ Abortion procedures may take place in a procedure room, as detailed in 3.8-3.1. Rooms designed in accordance with 3.8-3.2 are not required. The requirements of ~~which shall take precedence over~~ the Uniform Statewide Building Code and local zoning and building ordinances shall take precedence.

~~Entities operating as of the effective date of these regulations as identified by the department through submission of Reports of Induced Termination of Pregnancy pursuant to 12VAC5-550-120 or other means and that are now subject to licensure may be licensed in their current buildings if such entities submit a plan with the application for licensure that will bring them into full compliance with this provision within two years from the date of licensure.~~

In order to determine whether the abortion facility is in compliance with this provision, the commissioner may obtain additional information from the facility or its architect concerning the design and construction of the facility."

Option #3:

"All construction of new buildings and major additions, renovations, alterations or repairs of buildings for occupancy as abortion facilities shall comply with state and local codes, zoning and building ordinances, and the Uniform Statewide Building Code and shall ~~comply~~ be designed and constructed according to ~~with~~ Part 1, Part 3.1, excluding §§ 3.1-7.2.2.2, 3.1-7.2.2.8, 3.1-7.2.3, 3.1-7.2.3.2, 3.1-8.2, and 3.1-8.7.2, and Part 3.8, excluding §§ 3.8-7.2.3 and 3.8-8.2, of the 2014 edition of the Guidelines for Design and Construction of Hospitals and Outpatient Facilities of the Facilities Guidelines Institute~~,~~. Abortion procedures may take place in a procedure room, as detailed in 3.8-3.1. Rooms designed in accordance with 3.8-3.2 are not required. The requirements of ~~which shall take precedence over~~ the Uniform Statewide Building Code and local zoning and building ordinances shall take precedence.

~~Entities operating as of the effective date of these regulations as identified by the department through submission of Reports of Induced Termination of Pregnancy pursuant to 12VAC5-550-120 or other means and that are now subject to licensure may be licensed in their current buildings if such entities submit a plan with the application for~~

~~licensure that will bring them into full compliance with this provision within two years from the date of licensure.~~

In order to determine whether the abortion facility is in compliance with this provision, the commissioner may obtain additional information from the facility or its architect concerning the design and construction of the facility."

Facilities that only provide medication abortion:

Option #1

As discussed above, in "*Proposed amendments to 12VAC5-412-10. Definitions."* exclude facilities that only provide medication abortion from the regulations entirely based on the amended definitions.

Option #2

"Abortion facilities providing only medication abortion and not surgical abortion shall comply with state and local codes, zoning and building ordinances, and the Uniform Statewide Building Code. Abortion facilities providing only medication abortion and not surgical abortion shall be exempt from compliance with 12 VAC5-412-240(D); 12 VAC5-412-250; 12 VAC5-412-270; 12 VAC5-412-280; and 12 VAC5-412-290 or any other provision that is medically inappropriate for facilities that only provide medication, and not surgical, abortion."

Option #3

"All construction of new buildings and major additions, renovations, alterations or repairs of buildings for occupancy as abortion facilities which provide only medication and not surgical abortion shall comply with state and local codes, zoning and building ordinances, and the Uniform Statewide Building Code. These facilities must also comply with Part 3.8, excluding §§ 3.8-3.1, 3.8-3.2, 3.8-7.2.3 and 3.8-8.2, of the 2014 edition of the Guidelines for Design and Construction of Hospitals and Outpatient Facilities of the Facilities Guidelines Institute. Abortion facilities providing only medication abortion and not surgical abortion shall be exempt from compliance with 12 VAC5-412-240(D); 12 VAC5-412-250; 12 VAC5-412-270; 12 VAC5-412-280; and 12 VAC5-412-290 or any other provision that is medically inappropriate for facilities that only provide medication, and not surgical, abortion."