Virginia Department of Health
Office of Licensure and Certification

Revised

Frequently Asked Questions (FAQs) about Abortion Facility Licensure

The VDH Office of Licensure and Certification (OLC) has received questions from licensees concerning licensure and the *Regulations for Licensure of Abortion Facilities*, 12 VAC 5-412. This document provides responses to those questions. New entries are dated when added.

INFORMED WRITTEN CONSENT

Q: What is meant by "informed consent" for an abortion and how will compliance with informed consent be assessed?

A.: A separate guidance document regarding informed written consent is available at: http://www.vdh.virginia.gov/OLC/AcuteCare/documents/2012/pdf/Guidance%20Document%20Informed%20Consent%20final%20approved%2007%2020%2012.pdf

APPLICATION FOR LICENSURE

Q: Where can I find information about being licensed as an abortion facility?

A: Information regarding licensure of abortion facilities can be found on the Office of Licensure and Certification (OLC) web site at: www.vdh.virginia.gov/olc/laws or http://www.vdh.virginia.gov/OLC/AcuteCare/abortionfacilities.htm

Q: Where is the application to be licensed found?

A: The application for licensure can be downloaded from OLC's website.

Q: What supporting documentation needs be submitted to VDH with the application for licensure?

A: The following information is required to be submitted with the application:

1. Proposed organizational chart;
2. Facility's disaster preparedness plan (12 VAC 5-412-340);
3. Facility's patient rights policies and procedures (12 VAC 5-412-200); and
4. Job description, qualifications and specific responsibilities of the administrator (12 VAC5-412-

180F).

Q: What is the application fee?

A: The application fee is $75.00 and must accompany the application for licensure.

VDH ACCESS TO ABORTION FACILITIES

Q: Does a VDH representative have the right to enter the abortion facility at any time?

A: Yes. Virginia Code § 32.1-25 states: "Upon presentation of appropriate credentials and upon consent of the owner or custodian, the [State Health] Commissioner or his designee shall have the right to enter at any reasonable time onto the property to inspect, investigate, evaluate, conduct tests or take samples for testing as he reasonably deems necessary in order to determine compliance with…any regulations of the Board…." Appropriate credentials means a Commonwealth of Virginia authorized photo ID that is clearly visible upon entering the facility.

Q: Are there specific procedures to enable a facility administrator to verify the identity of a VDH representative seeking to obtain access to a facility and its patient records?

A: The administrator can call the VDH Office of Licensure and Certification at (804)367-2102 to verify the identification of its employees seeking to obtain access to the facility or patient records.

THE PLAN OF CORRECTION (POC)

Q. If the initial licensure on-site survey finds deficiencies; will the facility be able to submit a POC (Plan of Correction) for review?

A. If the on-site survey identifies deficiencies, the licensure application may be denied. However, at the discretion of the State Health Commissioner, OLC may offer the facility the opportunity to submit a plan of correction.

Q: If deficiencies are identified during the on-site survey, may a facility continue providing abortion services if a plan of correction has been submitted?

A: VDH will not initiate enforcement action while it determines whether the POC submitted by the facility is approved or denied. If the POC is denied, the facility's license may be effected depending on the scope and severity of the deficiency(ies) and enforcement action may be taken.

Q: How will VDH evaluate the POC?

A: The POC will be carefully reviewed by VDH for compliance with the regulations. An on-site survey may be conducted before VDH determines if the POC can be approved or denied.

PATIENT CARE

Q: Our facility includes a separate non-medical wing for use by our educators, development/ fundraising staff and public policy staff. Do the personnel requirements of 12 VAC 5-412-180 pertain only to medical personnel that work in the medical area and that have direct involvement with patients?

A: This regulation is applicable to all employees of the abortion facility.

Q: 12 VAC 5-412-180 requires that personnel records shall be "readily available" for review by a VDH representative during inspection. Does electronic availability meet these regulatory requirements if personnel records are maintained off site?

A: Yes – electronic availability is acceptable for meeting the intent of this regulation, provided VDH representatives are given direct access to the records. System security or system failures cannot be used as reasons to delay immediate access to requested records.

COMPLAINT FILING

Q: Can VDH provide some parameters for complying with 12 VAC 5-412-200(A)?

A: It is important that any facility providing medical services, regardless of the type or category of those services, have the ability to communicate effectively with its patients who may not understand English and are not accompanied or represented by an interpreter or a sign language interpreter. Bilingual print media and electronic translation services are acceptable methods for meeting the regulatory provisions.

Q: How does the OLC investigate complaints that it receives concerning abortion facilities?

A: As with all health care entities licensed by VDH, all complaints are reviewed and investigated for regulatory compliance. An investigation may include an on-site survey. At the conclusion of the investigation, findings are documented and the allegations determined to be either substantiated or unsubstantiated. If the allegations are substantiated, the facility is required to submit a POC.

COMPLIANCE WITH BUILDING DESIGN AND CONSTRUCTION REQUIREMENTS

Q: How will VDH interpret the Guidelines for Design and Construction of Health Care Facilities, 2010 edition in order to determine compliance with 12 VAC 5-412-370?

A: VDH OLC Surveyors will assess the facilities for compliance with the relevant sections of Part 1 and sections 3.1-1 through 3.1-8 and section 3.7 of Part 3 of the Guidelines. Pursuant to sections 1.2-2 and 3.1-1.2.1of the Guidelines, each abortion facility will be required to have a functional program. In accordance with section 3.7-1.2.1, the extent of the diagnostic, clinical, and administrative facilities to be

provided will be determined by the services contemplated and the estimated patient load as described in the functional program. Key compliance requirements are listed below:

- Abortion procedure room space requirements must meet the provisions of the Guidelines pertaining to either a treatment room or class A operating room depending upon the level of anesthesia provided (see below)
- Air handling provisions of the Guidelines pertaining to treatment rooms are generally relevant and applicable to all abortion facilities subject to the Regulations for Licensure of Abortion Facilities.
    - Abortion procedure rooms shall be provided a minimum of two air changes per hour of outside air.
    - Air supplied to all abortion procedure rooms shall be filtered through filters of at least 30 percent efficiency rating.
- All public corridors shall be at least 5 feet wide.
- All staff only corridors shall be at least 44 inches wide.

Facilities that administer no or only minimal sedation (as defined at 18VAC85-20-310) shall demonstrate compliance with the following minimum standards for design and construction:

- Abortion procedure rooms must meet the space requirements of treatment rooms as per Guidelines section 3.1-3.2.4.
- Each such room shall have a minimum clear floor area of 120 square feet and a minimum clearance of 3 feet at each side and at the foot of the procedure table.

Facilities that administer moderate sedation (as defined at 18VAC85-20-310) will have to demonstrate compliance with the following minimum standards for design and construction:

- Abortion procedure rooms must meet the space requirements of class A operating room as per Guidelines section 3.7-3.3.2.
- Each such room shall have a minimum clear floor area of 150 square feet and a minimum clearance of 3 feet 6 inches at each side and at the foot of the procedure table.

Q: The design guidelines in Sections 1.2-2 and 3.7 of the Guidelines for Design and Construction of Health Care Facilities, 2010 edition, call for a detailed functional program. How does VDH intend to interpret this guideline?

A: The functional program is intended to assist the providers in determining their compliance with the applicable design and construction requirements for the service they provide. Facilities are not required to submit, as part of their application for licensure, a written document describing their functional program. However, the facility may be required to supply supporting evidence of how the facility meets the Guidelines. Developing a functional program will assist the administrator in evaluating the applicability of the Guidelines, as well as assisting the surveyor during the on-site survey.

Q: Section 3.7 of the Guidelines identifies three classifications of operating rooms. Are facilities required to have operating rooms even for non-sterile procedures? If so which classification

will be required?

A: Each provider will be reviewed for compliance with 12 VAC 5-412-370 based on the services and procedures they are performing.

REQUESTS FOR VARIANCES

Q: What is meant by "temporary variance" for an abortion facility and what are the requirements/process for obtaining one?

A.: The OLC has produced a Guidance Document regarding temporary variances for abortion facilities which is available at: http://www.vdh.virginia.gov/OLC/AcuteCare/documents/2012/pdf/Abortion%20Facility%20Variance%20Guidance.pdf

Q: Can facilities seek variances to certain regulatory requirements, and under what circumstances?

A: The Regulations authorize the State Health Commissioner to issue temporary variances. An abortion facility can request a variance to a particular standard when the requirement poses an impractical hardship unique to the facility and when a variance would not endanger the safety or well-being of patients, employees, or the public. Consideration of a variance is initiated when a written request is submitted to the Director of the Office of Licensure and Certification. Temporary variances may be granted for up to the duration of the remaining licensure period.

The request for variance must describe the impractical hardship unique to the facility caused by the enforcement of the requirements. When possible, the request should include proposed alternatives to meet the purpose of the requirements which will ensure the protection and well-being of patients, employees and the public.

The State Health Commissioner can only authorize variances to the agency's own licensing requirements, not to regulations of another agency or to any requirements in federal, state, or local laws.

The facility shall develop procedures for monitoring the implementation of any approved variances to assure the ongoing collection of any data relevant to the variance and the presentation of any later report concerning the variance as requested by OLC. At no time shall a variance for one facility be extended to general applicability.

Q: Can a variance be rescinded or modified?

A: Yes, a variance may be rescinded or modified at the discretion of the Commissioner.

GENERAL

Q: Will abortion facilities be required to meet all the inpatient hospital requirements contained in Article 1 of Chapter 5 of Title 32.1 of the Code of Virginia (§ 32.1-123 et seq.)?

A: VDH intends to only take enforcement action for violations of Virginia Code §§ 32.1-125.01, 32.1-125.4, 32.1-132, 32.1-135.2, and 32.1-137.01 or the Regulations for Licensure of Abortion Facilities.

Q. How will VDH surveyors protect patient confidentially while reviewing patient records?

A: VDH staff are bound by confidentiality laws and agency policy. No record that contains personal health information will be released publically. If deficiencies are found during review of patient records, documentation which supports the deficiency citation may be copied and retained in the surveyor's working papers. However, the regulations at 12 VAC 5-412-100(B) state "If copies of records are removed from the premises, patient names and addresses contained in such records shall be redacted by the abortion facility before removal."

Q: If we submit our facility disaster preparedness plans with the licensure application as required, will they be treated as confidential information and not be released in response to a Freedom of Information Act (FOIA) request?

A: When responding to FOIA requests VDH will withhold records from mandatory disclosure in accordance with FOIA and other laws. Section 2.2-3705.2(16) exempts from disclosure, pursuant to FOIA, certain records "to the extent such records reveal the disaster plans or the evacuation plans for [hospital and nursing facilities] in the event of fire, explosions, natural disaster, or other catastrophic event." Licensed as a type of hospital, abortion facilities are included in this FOIA exemption. However, such protection does not extend to disclosure of records relating to the effectiveness of executed evacuation plans after the occurrence of fire, explosion, natural disaster, or other catastrophic event. (See §2.2-3705.2(16) of the Code of Virginia, effective July 1, 2013)

Q: Will review of facility policies and procedures be restricted to the facility?

A: VDH surveyors will be reviewing policies that are necessary to determine whether an abortion facility is in compliance with the Regulations.

Q: If I am the sole owner of an abortion facility must there be a Board of Directors or separate governing body?

A: No, a sole owner can be the governing body of an abortion facility.

Q: If an abortion facility performs four or less first trimester abortions per month, is it subject to any state legal requirements?

A: Yes. All abortions performed in the Commonwealth are required (pursuant to 12VAC5-550-120(B)) to be reported to the VDH Division of Vital Records using the Report of Induced Termination of

Pregnancy form.

VDH will provide abortion facilities with these forms. Additional forms can be obtained from the VDH Division of Vital Records:

Telephone: (804) 662-6233 (Donna Owens)
(804) 482-7936 (Janice Gardner)

Mail: Division of Vital Records Attn:
Cashier Office
P. O. Box 1000
Richmond, Virginia 23218

Email: vitalrec.supplies@vdh.virginia.gov

In addition, prior to performing any abortion, physicians are required (pursuant to §18.2-76 of the Code of Virginia) to obtain the informed written consent of the pregnant woman. In obtaining the informed written consent, the physician is required to offer the pregnant woman the opportunity to review the following printed materials published by VDH:

- Abortion: Making An Informed Decision
- Fetal Development: Understanding the Stages
- A Virginia Guide to Family Planning, Genetics and Social Services

VDH will provide abortion facilities with these materials. Additional copies are available upon request from:

VDH Division of Child and Family Health Attn:
Ardriene Stuart
109 Governor Street, 8th Floor West
Richmond, VA 23219

Phone: (804) 864-7755 Fax: (804) 864-7771 Email: Ardriene.stuart@vdh.virginia.gov

NOTE: Please check back periodically as this FAQ document will be updated as needed.