



Virginia Coalition to Protect Women's Health

To: Dr. Norm Oliver; Virginia Board of Health
RE: Chapter 412. Regulations for Licensure of Abortion Facilities – NOIRA Recommendations
Attachments: Draft Language Changes to Chapter 412-10 to 412-370

Dear Dr. Oliver and Members of the Board of Health,

The following is a memorandum submitted by the Virginia Coalition to Protect Women's Health ("the Coalition") as public comment 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. The Board of Health issued this NOIRA to gather comments suggesting regulatory changes to aid in its review and assessment of all regulatory language in 12 VAC 5-412 and to ensure that it meets the Board's responsibilities under § 32.1-127. While we maintain that abortion clinics are already subject to the requisite regulatory, professional, and licensing standards as outpatient medical providers, we recommend the following in order to render the regulations more in line with evidence based medical practice. If that is the way the comment ends up being drafted, this framing will need to be weaved throughout the comment.

The members of this Coalition are health care providers and women's health advocates. In 2011, we came together in response to Senate Bill 924, which classified "facilities in which 5 or more first trimester abortions per month are performed" as a category of hospitals for a limited purpose. The bill became law in March of 2011 and, along with subsequently promulgated regulations, had the effect of limiting women's access to safe abortion care across the Commonwealth. We support proven and medically sound regulations that genuinely advance the public health.

Abortion providers in Virginia are already subject to a host of regulations and standards, like any other similarly situated medical provider. The Department of Health Professions' (VDHP) authority, separate from that of the Virginia Department of Health, regulates healthcare providers licensed by the boards within VDHP including the Boards of Medicine, Nursing and Pharmacy. This Department has its own inspection, investigative and enforcement authority and can refer violators to the Office of the Attorney General for criminal prosecution when necessary and impose monetary penalties.¹ Virginia's Board of Medicine also has enforcement and licensing authority over physicians and clinicians in the Commonwealth.²

The associated regulations further outline standards of practice, covering necessary details ranging from informed consent to discharge requirements.³ A special set of requirements governs the administration of anesthesia in office-based settings.⁴

¹ See VA Code Ann. Sec. 54.1-2400, -2505, -2506 et. seq.

² See VA Code Ann. Sec. 54.1-2400(7), - 2915(A)(6).

³ See 18 Va. Admin. Code Sec. 85-20 et seq.

⁴ See 18 Va. Admin. Code Sec. 85-20 et seq.

This regulatory scheme already ensures that reproductive healthcare is safe; there is no need for special targeted abortion facility regulations that are medically unnecessary and extremely burdensome, regulations that have forced some health care facilities to close and that make it difficult to open new facilities.

It is also important to remember that abortions are already an incredibly safe medical procedure.⁵ A 2014 ANSIRH issue brief notes that “less than a quarter of one percent of abortions result in a major complication”; “less than one percent of abortions result in a complication that is diagnosed and treated in an emergency room” and “the overall complication rate is lower than those for wisdom tooth removal and tonsillectomy.”⁶ Medication abortion is extremely safe, with serious adverse events occurring in less than one-third of one percent of medication abortions.⁷ In fact, “[s]erious complications are rare and occur far less frequently than during childbirth. Safety is enhanced when the abortion is performed as early in pregnancy as possible.”⁸

In this memorandum, we highlight the most important areas of concern that should be considered as this process begins. While we appreciate the regulatory changes that have already been made in 2016, it is important to note that many of the issues raised in previous rounds of regulatory review persist today. We would like to reiterate that we still stand by all of the changes and amendments suggested in the February 11, 2015 public comment submitted by this Coalition during the last regulatory review, and we would like to see each of the suggested changes that have not been implemented taken up by the Board of Health for consideration this time.

In Virginia, there is not, and never has been, a proven, medically justifiable reason for regulating abortion providers like hospitals. Until 2011, abortion providers and their practices were regulated like other physician groups and their practices.⁹ With the passage of TRAP (“targeted regulation of abortion providers”) laws in Virginia in 2011, abortion providers, and **only abortion providers**, were singled out for targeted, politicized regulations and restrictions by the state. These targeted restrictions had only one aim – to restrict and ultimately eliminate access to abortion in Virginia. These restrictions can do this by shutting down women’s health centers where abortion is performed, preventing physicians from performing abortions in their offices, and preventing new women’s health centers from opening. These restrictions also stigmatize abortion patients and providers, manifesting the State’s disapproval of the fundamental right to abortion at every entry-point in care. Meanwhile, there is no proven reason grounded in patient

⁵ “The Safety and Quality of Abortion Care in the United States” A Consensus Study Report, National Academies of Sciences, Engineering and Medicine, March 2018, at <http://nationalacademies.org/hmd/Reports/2018/the-safety-and-quality-of-abortion-care-in-the-united-states.aspx>. At 10.

⁶ Safety of abortion in the United States, Issue Brief #6, December 2014, Advancing New Standards in Reproductive Health. See also “the Safety and Quality of Abortion Care in the United States,” at 53.

⁷ Safety and effectiveness of first-trimester medication abortion in the United States, Issue Brief, August 2018, Advancing New Standards in Reproductive Health.

⁸ “The Safety and Quality of Abortion Care in the United States” A Consensus Study Report, National Academies of Sciences, Engineering and Medicine, March 2018, at <http://nationalacademies.org/hmd/Reports/2018/the-safety-and-quality-of-abortion-care-in-the-united-states.aspx>. At 11.

⁹ “Most abortions can be provided safely in office-based settings.” “The Safety and Quality of Abortion Care in the United States” A Consensus Study Report, National Academies of Sciences, Engineering and Medicine, March 2018, at <http://nationalacademies.org/hmd/Reports/2018/the-safety-and-quality-of-abortion-care-in-the-united-states.aspx>. At 10.

health and safety that the Virginia Department of Health should license only abortion providers and no other physician group or medical office, as a category of hospital. It is important to note that, while the authorizing statute requires that VDH regulate providers that perform five or more first trimester abortions per month as a category of hospitals, there is no requirement that VDH treat all categories of hospitals in the same way.

In the attached document, you will find a detailed (though not exhaustive) list of changes we would like to see in the current Chapter 412. This memorandum goes through the language changes, breaking them up into three main areas of concern: 1. **differentiating between medication and surgical abortion**; 2. **ensuring that patient and provider safety and confidentiality is prioritized in the regulations**; and 3. **reducing administrative burdens that do not confer a medical patient benefit**. At the end of the memorandum, you will find an annotated version of the abortion regulations with all of the proposed changes clearly marked.

We believe the licensing requirement and the TRAP statutes are unconstitutional, unduly burdensome and medically unnecessary.

1. Differentiate Between Medication Abortion and Surgical Abortion

We recommend that facilities that only provide medication abortion are entirely excluded from the regulations and that this exclusion is explicitly stated in the regulations.¹⁰

Medication abortion is a method of ending an early pregnancy with oral medications and is extremely safe, is associated with few complications or contraindications, and requires no anesthesia or sedation.¹¹ Medication abortion involves no surgery or even any medical procedure; it is simply the taking of pills. Serious complications after medication abortion occur only after the patient has left the clinic and are extremely rare; the rate of clinically significant adverse events is 0.16-31 percent, comparable to those of commonly prescribed antibiotics.¹² Importantly, these rates are far lower than those associated with pregnancy and childbirth.¹³ Given that medication abortion only involves the provision of an oral medication, the requirements in these licensing regulations are not medically necessary.

Reducing access by artificially lowering the availability of medication abortions and reducing access to legal abortions places an undue barrier in front of patients who want an early and safe termination of their pregnancy. Medication abortion allows for abortion very early in the

¹⁰ “No special equipment or emergency arrangements are required for medication abortions [...]” “The Safety and Quality of Abortion Care in the United States” A Consensus Study Report, National Academies of Sciences, Engineering and Medicine, March 2018, at <http://nationalacademies.org/hmd/Reports/2018/the-safety-and-quality-of-abortion-care-in-the-united-states.aspx>. At 14.

¹¹ *Id.* At 51.

¹² Kelly Cleland et al., *Significant Adverse Events and Outcomes After Medical Abortion*, 121 *Obstetrics & Gynecology* 166, 169 (2013); Ushma Upadhyay et al., *Incidence of Emergency Department Visits and Complications After Abortion*, 125 *Obstetrics & Gynecology* 175, 178 (2015); see also Nadine Shehab et al., *Emergency Department Visits for Antibiotic-Associated Adverse Events*, 47 *Clinical Infectious Diseases* 735, 738 (2008).

¹³ Raymond & Grimes, *The Comparative Safety of Legal Induced Abortion and Childbirth in the United States*, 119 *Obstetrics & Gynecology* 215, 216 (Feb. 2012).

pregnancy, something that is both safer than later term abortions and preferred by many American women.¹⁴

Therefore, these regulations should be revised to ensure that facilities that provide only medication abortion services are subject only to more medically appropriate requirements, rather than being subjected to “one size fits all” regulations that are even unnecessary in the context of surgical abortion services.

We propose that the new definition should read as follows:

12VAC5-412-10. Definitions.

“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 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.”

The 2015 Coalition comment laid out other options for achieving a similar end within the regulations without amending the definitions, by adding a section excluding facilities that do not perform surgical abortions and only perform medical abortions from all sections inapplicable for medical abortions. However, simply amending the definition would ensure that medical abortion facilities are treated no differently than other similarly situated doctors’ offices in the most efficient, effective and clear way.

2. Ensure that Patient and Provider Safety is Prioritized in the Regulations

Abortion providers face harassment and violence, including death threats, not faced by other medical providers. Patients who receive care from abortion providers are not just subject to harassment, they also face repeated attempts by anti-abortion advocates and activists to breach their privacy. Organizations like Operation Rescue and other anti-abortion advocacy groups make it a habit to seek out patient records and at times even post those records online.¹⁵

More recently, this organization has made taking photos of patients and further invading patient privacy a part of a concerted campaign to smear abortion providers and their patients.¹⁶ Death threats and intimidation incidents against providers have doubled nationwide over the past year.¹⁷ Patients’ and Providers’ concerns about the possible exposure and misuse of their private information by anti-abortion activists and zealots is thus well-founded. Virginia’s regulatory scheme must ensure that patient records and personnel information are handled with the utmost care.

¹⁴ Abortion in the United States: The continuing controversy, Linda J Beckman, *Feminism & Psychology* 2016, Vol. 27(1) 101–113, 107.

¹⁵ Hippi Policy Becomes Focus of Abortion Debate, *Journal of Ahima*. <http://journal.ahima.org/2015/09/14/hipaa-policy-becomes-focus-of-abortion-debate/>

¹⁶ Anti-abortion activists vow to violate patients’ privacy in new tactic to stoke fear, August 22, 2018, *Think Progress*, <https://thinkprogress.org/abortion-911-anti-choice-activists-have-a-new-tactic-to-close-clinics-and-stoke-fear-684d49e41124/>

¹⁷ Death threats, intimidation double at U.S. abortion clinics, group says, *Routers*, May 7, 2018. <https://www.reuters.com/article/us-usa-abortion-violence/death-threats-intimidation-double-at-u-s-abortion-clinics-group-says-idUSKBN1I82K1>

In 2015, we proposed that a new subsection be included in 12VAC5-412-20 to address these concerns, 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.”

In addition to proposing the above language again, we also propose the addition of the following language to several sections of the regulations to ensure that any information obtained is used only for permitted purposes and treated with care: “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 duties may 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.”

Further, the following sections relating to personnel and staff structural and emergency preparedness, and patient and clinical records must include assurances that the information will be handled with the utmost care and will not be disclosed to the public for possible misuse¹⁸:

12VAC5-412-100B; 12VAC5-412-140B; 12VAC5-412-160B; 12VAC5-412-180I; 12VAC5-412-190E. (See below for the specific language changes proposed.)

3. Reduce Administrative Burdens That Do Not Confer a Medical Patient Benefit and Increase Access to Second-Trimester Services

While the law requires that VDH regulate providers that perform five or more first trimester abortions per month as a category of hospitals, it does not require that VDH treat all categories of hospitals in the same way. Many of the administrative burdens included in the regulations may be appropriate for large hospitals but are simply not appropriate for abortion providers, and ultimately, have an adverse impact on patient care. As a result of these burdens, for example, providers end up serving fewer patients.

For example, the current regulations include bloated formalities like a “quality improvement committee” responsible for oversight and supervision of the required “ongoing, comprehensive, integrated, self-assessment program of the quality and appropriateness of care or services provided,”¹⁹ useful for large hospitals but unnecessary for a small medical office. In a big hospital, where communication between large numbers of staff and between departments can be cumbersome, such detailed quality assurance provisions are imperative. On the other hand, in a physicians’ office with few staff, the same processes add unnecessary bureaucracy to a process that can be simplified and streamlined to fit the smaller practice.

¹⁸ 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).

¹⁹ Va. Admin. Code Sec. 5-412-210.

In reality, these requirements are medically-unnecessary and burden patient care. Beyond these burdens, the requirements are regularly used to cite abortion facilities for paperwork “irregularities” that have no impact on patient care in an effort to brand abortion facilities as unsafe and non-compliant with medical standards. For example, the 2016 Annandale Women and Family Center inspection report was 144-pages long. The report “alleged” 35 separate violations, despite the fact that multiple items in the report pointed out the same alleged deficiencies over and over again. These reports are used by anti-abortion advocates to paint abortion clinics as unsafe. AbortionDocs.org provides an example of how these reports are weaponized by anti-abortion advocates in misleading messaging.²⁰

Additionally, the current regulations severely hinder access to second trimester abortions by imposing the medically unnecessary requirement that they be provided in a hospital setting. The most common second trimester abortion procedures, aspiration and dilation and evacuation, are extremely safe, straightforward procedures that are completed in 5-10 minutes and require no surgical incision. In other states, these procedures are commonly and safely provided in outpatient, office-based settings. In Virginia, the regulation preventing this, 12 Va. Admin. Code § 5-412-230(A), has resulted in second trimester abortions being available in only two clinics throughout the state. The Board appears to be taking the position in related litigation, *Falls Church Med. Ctr., LLC v. Oliver*, No. 3:18-cv-428-HEH (E.D. Va. filed June 20, 2018), that—contrary to this provision--abortion clinics can and should be considered hospitals and therefore can legally provide second trimester abortions. Yet the Board has taken no steps to rescind 12 Va. Admin. Code § 5-412-230(A), which exposes clinics to the risk of criminal liability if they perform a single second trimester abortion.

To correct the fundamental problems in this area, we propose the following changes. As you will notice, we have requested many of these changes in the past.

12VAC5-412-10. Definitions

“Administrator” – In the context of abortion facilities, the job of an administrator need not be done by a single person. In fact, most doctors’ offices do not have an “administrator” in the same way that a hospital does. We suggest that this definition be amended to allow that the duties of the administrator can be performed by multiple people so long as there is a clear delineation of responsibilities and accountability ensuring that patient care and record-keeping are not compromised. Similarly, 12VAC5-412-170 should also be amended to allow this flexibility.

12VAC5-412-50. Request for issuance and 12VAC5-412-70 Return and/or reissuance of license

The change of ownership should not require a change of licensure, barring some extraordinary circumstance; providing notice is appropriate.

Further, in 12VAC5-412-70, it is unclear what 6. “Change of operator” is referring to. We recommend either discarding this requirement or clarify the definition.

12VAC5-412-60. License expiration and renewal

²⁰ A Tidewater Woman’s Clinic, Abortion Docs.org, http://abortiondocs.org/clinic/surgical/643/norfolk-a-tidewater-womens-health-clinic/?doing_wp_cron=1539714099.2630300521850585937500

Annual license renewal should not be conditioned on a determination by OLC that a medical facility is “in substantial compliance with [Chapter 412],” as this requirement leads to unnecessary and intrusive annual inspections that disrupt patient care. We recommend either discarding this requirement or modifying the language to limit the intrusion entailed in its enforcement.

12VAC5-412-90. Right of entry

There should be a distinction between complaint driven inspections and routine inspections. In addition, all inspections should be undertaken only during business hours in order to protect the safety of women’s health center staff and patients and should be announced prior to the inspection. And complaint-driven inspections should occur only for “credible” complaints. Inspections must not interfere with patient services.

Additionally, denying entry to an inspector should not constitute sufficient cause for “immediate” license revocation or suspension, without the opportunity for notice and hearing established by the Virginia Administrative Process Act (APA). We recommend either removing this sentence or modifying it so that denial of entry constitutes cause for initiating the standard license revocation or suspension process consistent with the Virginia APA.

12VAC5-412-100. On-site inspection

It would be helpful if for routine inspections, the OLC could develop a system of scheduled inspections, and provide short notice of inspection so that the inspection would cause the least disruption to patient care.

12VAC5-412-110. Plan of correction.

We would request that an additional 15 days be given to the administrator to submit an acceptable plan of correction and an additional 60 days for the expected correction date to reduce the administrative burden on small abortion providers. The requirement that the plan of corrections show the expected correction date “not to exceed 30 working days from the exit date of the survey,” is an unreasonable one given the recent experience of abortion providers when they do not receive an inspection report until well past that deadline or only within a few days of that deadline, if one is to understand the “end of the survey” to mean the date on which the actual inspection was over and not the date on which the abortion facility received the inspection report.

12VAC5-412-120 OLC Complaint investigation

The OLC currently investigates all complaints against abortion providers, most of which come from outside the abortion clinics by people who have not set foot in the clinic and are made for purely political or ideological reasons. This creates a record of non-compliance and increases the burden on abortion providers. We request that the words “credible patient health and safety” be added before “complaint” to eliminate the investigation of patently frivolous calls.

Various states’ statutes and regulations support requiring that only credible complaints against clinics be investigated, in addition to routine inspections that are already required. For example, Iowa requires their Department of Inspection and Appeals to conduct a preliminary review of complaints to weed out the credible from those meant to harass. Similarly, Maryland’s Department of Health must consider a variety of factors, including “whether the complainant has

first-hand knowledge of the alleged incident” and “the nature of the complaint,” to determine whether a complaint should spark an on-site investigation. Even Indiana, a state known for its hostility towards providing women with the reproductive healthcare they want and need, requires non-routine clinic investigations to be driven by “credible complaints.”

We suggest the following non-exhaustive list of factors for considerations before deciding whether the complaint is credible: “i. whether the complainant has first-hand knowledge of the alleged incident; ii. the facility's regulatory history, including the number of verified prior complaints; iii. whether there has been a recent inspection of the facility, and whether the incident would have been observed during this prior review.”

12VAC5-412-130. Violation of this chapter or applicable law; denial, revocation, or suspension of license.

Violations of any section in this regulation does not on its own constitute a threat to patient health and safety. Clinics already have to comply with other applicable statutes and regulations which already ensure patient health and safety. Insisting that abortion facilities face the denial, revocation or suspension of their licenses for violations of sections that are not even remotely applicable to them and do not endanger patient health and safety, for example those that should not apply to facilities that only perform medication abortions. We suggest section A be amended to read as follows:

A. When the department determines that an abortion facility is (i) in violation of § 32.1-125.01, 32.1-125.4, or 32.1-135.2 of the Code of Virginia or ~~of any applicable regulation~~ any 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.

Section B. and C. make the re-issue of a license optional even if satisfactory evidence if submitted by the provider that the reason for the suspension or revocation had been corrected and the public will not be jeopardized by the resumption of operation. The reissue should be mandatory when all conditions are met.

12VAC5-412-150. Governing Body

Strike 12 VAC5-412-150 in its entirety because it confers no medical benefit on patients. There is no medical reason to mandate this manner of governance for abortion providers, as opposed to any other equally efficacious organizational structure. Providers should have the flexibility to determine their internal organization based on resources and needs.

12VAC5-412-160. Policies and procedures.

In this section, the regulations require abortion facilities to include admission and discharge criteria in their written policies. This requirement is inappropriate for abortion facilities, as they are not hospitals and do not admit and discharge patients in this manner. We request that this portion of the regulations along with all like sections be stricken from the regulations. To make the correction: Strike A.4 “Admission and discharge, including criteria for evaluating the patient before admission and before discharge.”.

12VAC5-412-170. Administrator.

See comment above re – role of administrator. In this section, we urge the Board to amend section A. to read: “The governing body shall select an administrator who shall be responsible for appropriately staffing the facility with personnel to cover the managerial, operational, financial, and reporting components of the abortion facility, including but not limited to [omitted].”

12VAC5-412-180. Personnel.

Abortion providers should not be burdened with regulations regarding their staffing decisions greater than those applicable to any other similarly situated medical provider and are already subject to a plethora of regulations. The additional layers included here are not necessary and merely create additional compliance paperwork. Therefore, we recommend that the Board strike B, C, E, F and G as none of these sections confer a direct medical benefit on patients.

12VAC5-412-190. Clinical Staff.

We recommend the Board strike the first sentence of C. This requirement is unnecessary because this section also requires that a licensed health care practitioner trained in post-procedure assessment remain on the premises until the last patient is discharged, patient health and safety is already adequately protected.

We recommend that the Board add Section. E, acknowledging that regulations in this section should be interpreted in a manner that does not conflict with any other applicable regulations or rules.

12VAC5-412-210 Quality Management

We recommend that the Board strike Section C. This provision is overly burdensome for abortion facilities and is particularly unnecessary for those where only medication abortions are performed.

12 Va. Admin. Code § 5-412-230(A) Patient Services; Patient Counseling

We recommend that the Board withdraw this provision to clarify that licensed abortion clinics can provide second trimester abortions.

12VAC5-412-240 Medical Testing and Laboratory Services.

We recommend that the Board Strike A.3. This provision singles out abortion providers and imposes a medically unnecessary requirement. Health care providers already follow the CDC guidelines regarding STI screening and an additional requirement is unnecessary.

12VAC5-412-340 Disaster Preparedness

We recommend that the Board strike the entire section. Facilities already have disaster preparedness plans. It is unnecessary to include this in the regulation and will only serve to make these plans FOIABLE, which could mean that they are used by individuals or anti-abortion groups to jeopardize the safety and security of health centers and patients.

Below, please find the annotated regulations with all of the suggested language changes incorporated throughout the regulations and marked in **RED**.

For a full list of the Coalition’s organizational partners, see this link:

https://www.womenshealthcoalitionva.org/?page_id=32

Chapter 412. Regulations for Licensure of Abortion Facilities

PART I

DEFINITIONS AND REQUIREMENTS FOR LICENSURE

12VAC5-412-10. Definitions.

The following words and terms when used in this regulation shall have the following meanings unless the context clearly indicates otherwise:

"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.

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

"Administrator" means the person appointed by the governing body as having responsibility for the overall management of the abortion facility. **The duties of the "administrator" may be performed by multiple people so long as there is a clear delineation of responsibilities and accountability ensuring that patient care and record-keeping are not compromised.** Job titles may include director, executive director, office manager, or business manager.

"Commissioner" means the State Health Commissioner.

"Department" means the Virginia Department of Health.

"Informed written consent" means the knowing and voluntary written consent to abortion by a pregnant woman of any age in accordance with § 18.2-76 of the Code of Virginia.

"Licensee" means the person, partnership, corporation, association, organization, or professional entity that owns or on whom rests the ultimate responsibility and authority for the conduct of the abortion facility.

"Minor" means a patient under the age of 18.

"Patient" means any person seeking or obtaining services at an abortion facility.

"Physician" means a person licensed to practice medicine in Virginia.

"Spontaneous miscarriage" means the expulsion or extraction of a product of human conception resulting in other than a live birth and which is not an abortion.

Statutory Authority

§ 32.1-127 of the Code of Virginia.

Historical Notes

Derived from Virginia Register Volume 29, Issue 19, eff. June 20, 2013; amended, Virginia Register Volume 33, Issue 13, eff. March 22, 2017.

12VAC5-412-20. General.

A license to establish or operate an abortion facility shall be issued only (i) when the abortion facility is in compliance with all applicable federal, state, and local statutes and regulations and the provisions of this chapter and (ii) when the application fee has been received by the department.

No person or entity shall establish, conduct, maintain, or operate in this state, any abortion facility without having obtained a license. Any person establishing, conducting, maintaining, or operating an abortion facility without a license shall be subject to penalties and other actions pursuant to § 32.1-27 of the Code of Virginia.

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.

Statutory Authority

§§ 32.1-12 and 32.1-127 of the Code of Virginia.

Historical Notes

Derived from Virginia Register Volume 29, Issue 19, eff. June 20, 2013.

12VAC5-412-30. (Repealed.)

Historical Notes

Derived from Virginia Register Volume 29, Issue 19, eff. June 20, 2013; repealed, Virginia Register Volume 33, Issue 13, eff. March 22, 2017.

12VAC5-412-40. Separate license.

An abortion facility operating at more than one location shall be required to obtain separate licenses for each location in which abortion services are provided.

Abortion facilities which have separate organized sections, units, or buildings to provide services of a classification covered by provisions of other state statutes or regulations shall be required to have any additional applicable license required for that type or classification of service.

Facilities licensed as either a general hospital or an outpatient surgical hospital by the department are not subject to the provisions of this chapter.

Statutory Authority

§§ 32.1-12 and 32.1-127 of the Code of Virginia.

Historical Notes

Derived from Virginia Register Volume 29, Issue 19, eff. June 20, 2013.

12VAC5-412-50. Request for issuance.

- A. Abortion facility licenses shall be issued by the commissioner. All applications for licensure shall be submitted initially to the department's Office of Licensure and Certification (OLC).
- B. Each abortion facility shall be designated by a distinct identifying name which shall appear on the application for licensure. Any change of name shall be reported to the OLC within 30 days.
- C. Application for initial licensure of an abortion facility shall be accompanied by a copy of the abortion facility's certificate of use and occupancy or a statement from the facility's certified architect or engineer that the facility is substantially complete and eligible for a certificate of occupancy.
- D. The OLC shall consider an application complete when all requested information and the appropriate nonrefundable application fee are submitted.
- E. Written notification from the applicant to OLC that it is ready for the on-site survey must be received 30 days prior to OLC scheduling of the initial licensure survey. Applicants for initial licensure shall be notified of the time and date of the initial licensure survey, after the notice of readiness is received by the OLC.
- F. ~~A license shall not be assigned or transferred. A new application for licensure shall be made at least 30 days in advance of a change of ownership or location. In the case of a license assignment or transfer, the OLC shall be notified at least 30 days in advance of the change of ownership.~~

Statutory Authority

§§ 32.1-12 and 32.1-127 of the Code of Virginia.

Historical Notes

Derived from Virginia Register Volume 29, Issue 19, eff. June 20, 2013.

12VAC5-412-60. License expiration and renewal.

- A. Licenses shall expire at midnight April 30 following the date of issue and shall be renewable annually, upon filing of a renewal application and payment of the appropriate nonrefundable renewal application fee. ~~Renewal applications shall only be granted after a determination by the OLC that the applicant is in substantial compliance with this chapter. If an abortion facility was subject to an on-site OLC inspection within the immediately preceding twelve months, OLC shall not conduct an additional on-site inspection for purposes of determining compliance as required by this provision.~~
- B. The annual license renewal application shall be submitted to the OLC at least 60 days prior to the expiration date of the current license. A renewal application submitted more than 60 days past the expiration of the current license shall not be accepted.
- C. An abortion facility failing to submit an acceptable plan of correction as required in 12VAC5-412-110 shall not be eligible for license renewal until an acceptable plan of corrections has been filed and an inspection has demonstrated that the corrections have been implemented. .

Statutory Authority

§§ 32.1-12 and 32.1-127 of the Code of Virginia.

Historical Notes

Derived from Virginia Register Volume 29, Issue 19, eff. June 20, 2013.

12VAC5-412-70. Return and/or reissuance of license.

A. It is the responsibility of the abortion facility's governing body to maintain a current and accurate license at all times.

B. An abortion facility shall give written notification 30 calendar days in advance of implementing any of the following planned changes:

1. Change of location.
2. Change of ownership.
3. Change of name.
4. Voluntary closure.
5. Change of administrator.
6. Change of operator. [please clearly define operator]

Notices shall be sent to the attention of the director of the OLC.

C. The license issued by the commissioner shall be returned to the OLC when ~~any of the changes listed in subsection~~ changes 1, 3 or 4 of subsection B of this section occur. In addition, if the abortion facility is no longer operational, or the license has been suspended or revoked, the license shall be returned to the OLC within five calendar days of the abortion facility closing. The abortion facility's patients and the OLC shall be notified where all patient records will be located.

D. The OLC shall determine if any changes affect the terms of the license or the continuing eligibility for a license. A licensing representative may perform an announced inspection of the abortion facility during the process of evaluating a change.

E. The abortion facility will be notified in writing by the OLC whether a license can be reissued or a new application is needed.

Statutory Authority

§§ 32.1-12 and 32.1-127 of the Code of Virginia.

Historical Notes

Derived from Virginia Register Volume 29, Issue 19, eff. June 20, 2013.

12VAC5-412-80. Allowable variances.

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 any purpose shall require advance written approval from the OLC.

Statutory Authority

§ 32.1-127 of the Code of Virginia.

Historical Notes

Derived from Virginia Register Volume 29, Issue 19, eff. June 20, 2013; amended, Virginia Register Volume 33, Issue 13, eff. March 22, 2017.

12VAC5-412-90. Right of entry.

~~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. ~~A~~ 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. ~~These inspections shall be announced within a reasonable time prior to the inspection.~~ Any such employee shall properly identify himself 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 admission. Such entries and inspections shall be made with the permission of the owner or person in charge, unless an inspection warrant is obtained after denial of entry from an appropriate circuit court. ~~If the owner, or person in charge, refuses entry, this shall be sufficient cause for immediate revocation or suspension of the license initiating license revocation or suspension in accordance with the provisions of the Administrative Process Act (§ 2.2-4000 et seq. of the Code of Virginia).~~ If the entity is unlicensed, the owner or person in charge shall be subject to penalties and other actions pursuant to § 32.1-27 of the Code of Virginia.

Statutory Authority

§§ 32.1-12 and 32.1-127 of the Code of Virginia.

Historical Notes

Derived from Virginia Register Volume 29, Issue 19, eff. June 20, 2013.

12VAC5-412-100. On-site inspection.

A. An OLC representative shall make periodic ~~unannounced~~ **scheduled** on-site inspections of each abortion facility as necessary, but not less often than biennially. If the department finds, after inspection, noncompliance with any provision of this chapter, the abortion facility shall receive a written licensing report of such findings. The abortion facility shall submit a written plan of correction in accordance with provisions of 12VAC5-412-110.

~~B. The abortion facility shall make available to the OLC's representative any requested records and shall allow access to interview the agents, employees, contractors, and any person under the abortion facility's control, direction, or supervision. 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.~~ 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.

Statutory Authority

§ 32.1-127 of the Code of Virginia.

Historical Notes

Derived from Virginia Register Volume 29, Issue 19, eff. June 20, 2013; amended, Virginia Register Volume 33, Issue 13, eff. March 22, 2017.

12VAC5-412-110. Plan of correction.

A. Upon receipt of a written licensing report, each abortion facility shall prepare a written plan of correction addressing each licensing violation cited at the time of inspection.

B. The administrator shall submit, within ~~15~~ **30** working days of receipt of the inspection report, an acceptable plan of correction as determined by the OLC. The plan of correction shall contain for each violation cited:

1. A description of the corrective action or actions to be taken and the personnel to implement the corrective action;
2. The expected correction date, not to exceed ~~30~~ **90** working days from the exit date of the survey;

3. A description of the measures implemented to prevent a recurrence of the violation; and
4. The signature of the person responsible for the validity of the report.

C. The administrator shall be notified whenever any item in the plan of correction is determined to be unacceptable. Failure to submit an acceptable plan of correction may result in a penalty in accordance with § 32.1-27 of the Code of Virginia or in denial, revocation, or suspension of a license in accordance with 12VAC5-412-130.

D. The administrator shall be responsible for assuring the plan of correction is implemented and monitored so that compliance is maintained.

Statutory Authority

§§ 32.1-12 and 32.1-127 of the Code of Virginia.

Historical Notes

Derived from Virginia Register Volume 29, Issue 19, eff. June 20, 2013.

12VAC5-412-120. OLC complaint investigations.

A. The OLC shall investigate any **credible patient health and safety** complaints regarding alleged violations of this chapter and applicable law. When the investigation is complete, the abortion facility and the complainant, if known, will be notified of the findings of the investigation.

When determining whether the complaint is credible, the factors to be considered will include, but are not limited to: i. whether the complainant has first-hand knowledge of the alleged incident; ii. the facility's regulatory history, including the number of verified prior complaints; iii. whether there has been a recent inspection of the facility, and whether the incident would have been observed during this prior review.

B. As required by the OLC, the administrator shall submit a plan of correction for any deficiencies found during a complaint investigation in accordance with 12VAC5-412-110 and shall be responsible for assuring the plan of correction is implemented and monitored so that compliance is maintained.

Statutory Authority

§§ 32.1-12 and 32.1-127 of the Code of Virginia.

Historical Notes

Derived from Virginia Register Volume 29, Issue 19, eff. June 20, 2013.

12VAC5-412-130. Violation of this chapter or applicable law; denial, revocation, or suspension of license.

A. When the department determines that an abortion facility is (i) in violation of § 32.1-125.01, 32.1-125.4, or 32.1-135.2 of the Code of Virginia or ~~of any applicable regulation~~ **any 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.

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 §§ 32.1-125.01, 32.1-125.4, and 32.1-135.2 of the Code of Virginia and applicable state and federal law and regulations hereunder has been obtained.

C. Suspension of a license shall in all cases be for an indefinite time. The commissioner ~~may~~ shall restore a suspended license when he determines that the conditions upon which suspension was based have been corrected and that the interests of the public will not be jeopardized by resumption of operation. No additional fee shall be required for restoring such license.

D. The abortion facility has the right to contest the denial, revocation, or suspension of a license in accordance with the provisions of the Administrative Process Act (§ 2.2-4000 et seq. of the Code of Virginia).

Statutory Authority

§ 32.1-127 of the Code of Virginia.

Historical Notes

Derived from Virginia Register Volume 29, Issue 19, eff. June 20, 2013; amended, Virginia Register Volume 33, Issue 13, eff. March 22, 2017.

PART II

ORGANIZATION AND MANAGEMENT

12VAC5-412-140. Management and administration.

A. The abortion facility shall comply with:

1. This chapter (12VAC5-412);
2. Other applicable federal, state, or local laws and regulations; and
3. The abortion facility's policies and procedures.

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 duties may 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.**

C. The abortion facility shall permit OLC inspectors to conduct inspections to:

1. Verify application information;
2. Determine compliance with this chapter and applicable law;
3. Review necessary records and documents; and
4. Investigate complaints.

D. An abortion facility shall give written notification 30 calendar days in advance of implementing any of the following planned changes:

1. Change of location.
2. Change of ownership.
3. Change of name.
4. Voluntary closure.
5. Change of administrator.
6. Change of operator.

Notices shall be sent to the attention of the director of the OLC.

E. The current license from the department shall be posted at all times in a place readily visible and accessible to the public.

Statutory Authority

§§ 32.1-12 and 32.1-127 of the Code of Virginia.

Historical Notes

Derived from Virginia Register Volume 29, Issue 19, eff. June 20, 2013.

~~12VAC5-412-150. Governing body.~~

~~A. Each abortion facility shall have a governing body responsible for the management and control of the operation of the abortion facility.~~

~~B. There shall be disclosure of abortion facility ownership. Ownership interest shall be reported to the OLC and in the case of corporations, all individuals or entities holding 5.0% or more of total ownership shall be identified by name and address. The OLC shall be notified of any changes in ownership.~~

~~C. The governing body shall provide facilities, personnel, and other resources necessary to meet patient and program needs.~~

~~D. The governing body shall have a formal organizational plan with written bylaws. These shall clearly set forth organization, duties and responsibilities, accountability, and relationships of professional staff and other personnel. The bylaws shall identify the person or organizational body responsible for formulating policies.~~

~~E. The bylaws shall include at a minimum the following:~~

- ~~1. A statement of purpose;~~
- ~~2. Description of the functions and duties of the governing body or other legal authority;~~
- ~~3. A statement of authority and responsibility delegated to the administrator and to the clinical staff;~~
- ~~4. Provision for selection and appointment of clinical staff and granting of clinical privileges; and~~
- ~~5. Provision of guidelines for relationships among the governing body, the administrator, and the clinical staff.~~

~~Statutory Authority~~

~~§§ 32.1-12 and 32.1-127 of the Code of Virginia.~~

~~Historical Notes~~

~~Derived from Virginia Register Volume 29, Issue 19, eff. June 20, 2013.~~

12VAC5-412-160. Policies and procedures.

A. Each abortion facility shall develop, implement, and maintain documented policies and procedures, which shall be readily available on the premises and shall be reviewed annually and updated as necessary by the governing body. The policies and procedures shall include but shall not be limited to the following topics:

1. Personnel;
2. Types of elective services performed in the abortion facility;
3. Types of anesthesia that may be used;
- ~~4. Admissions and discharges, including criteria for evaluating the patient before admission and before discharge;~~
5. Obtaining informed written consent of the patient pursuant to § 18.2-76 of the Code of Virginia prior to the initiation of any procedures;
6. When to use sonography to assess patient risk;
7. Infection prevention;

8. Quality and risk management;
9. Management and effective response to medical and/or surgical emergency;
10. Management and effective response to fire;
11. Ensuring compliance with all applicable federal, state, and local laws;
12. Abortion facility security;
13. Disaster preparedness;
14. Patient rights;
15. Functional safety and abortion facility maintenance; and
16. Identification of the administrator and methods established by the governing body for holding the administrator responsible and accountable.

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 representatives to disciplinary action, including job termination.**

Statutory Authority

§§ 32.1-12 and 32.1-127 of the Code of Virginia.

Historical Notes

Derived from Virginia Register Volume 29, Issue 19, eff. June 20, 2013.

12VAC5-412-170. Administrator.

A. The governing body shall select an administrator who shall be responsible **for appropriately staffing the facility with personnel to cover** the managerial, operational, financial, and reporting components of the abortion facility, including but not limited to:

1. Ensuring the development, implementation, and enforcement of all policies and procedures, including patient rights;
2. Employing qualified personnel and ensuring appropriate personnel orientation, training, education, and evaluation;
3. Ensuring the accuracy of public information materials and activities;
4. Ensuring an effective budgeting and accounting system is implemented; and

5. Maintaining compliance with applicable laws and regulations and implementing corrective action.

B. Any change in the position of the administrator shall be reported immediately by the governing body to the department in writing.

C. A qualified individual shall be appointed in writing to act in the absence of the administrator.

Statutory Authority

§§ 32.1-12 and 32.1-127 of the Code of Virginia.

Historical Notes

Derived from Virginia Register Volume 29, Issue 19, eff. June 20, 2013.

12VAC5-412-180. Personnel.

A. Each abortion facility shall have a staff that is adequately trained and capable of providing appropriate service and supervision to patients. The abortion facility shall develop, implement, and maintain policies and procedures to ensure and document appropriate staffing by licensed clinicians based on the level, intensity, and scope of services provided.

~~B. The abortion facility shall obtain written applications for employment from all staff. The abortion facility shall obtain and verify information on the application as to education, training, experience, and appropriate professional licensure, if applicable.~~

~~C. Each abortion facility shall obtain a criminal history record check pursuant to § 32.1-126.02 of the Code of Virginia on any compensated employee not licensed by the Board of Pharmacy, whose job duties provide access to controlled substances within the abortion facility.~~

D. The abortion facility shall develop, implement, and maintain policies and procedures to document that its staff participate in initial and ongoing training and education that is directly related to staff duties and appropriate to the level, intensity, and scope of services provided. This shall include documentation of annual participation in fire safety and infection prevention in-service training.

~~E. Job descriptions:~~

~~1. Written job descriptions that adequately describe the duties of every position shall be maintained.~~

~~2. Each job description shall include position title, authority, specific responsibilities, and minimum qualifications.~~

~~3. Job descriptions shall be reviewed at least annually, kept current, and given to each employee and volunteer when assigned to the position and when revised.~~

~~F. A personnel file shall be maintained for each staff member. The records shall be completely and accurately documented, readily available, including by electronic means and systematically~~

~~organized to facilitate the compilation and retrieval of information. The file shall contain a current job description that reflects the individual's responsibilities and work assignments, and documentation of the person's in-service education, and professional licensure, if applicable.~~

~~G. Personnel policies and procedures shall include, but not be limited to:~~

- ~~1. Written job descriptions that specify authority, responsibility, and qualifications for each job classification;~~
- ~~2. Process for verifying current professional licensing or certification and training of employees or independent contractors;~~
- ~~3. Process for annually evaluating employee performance and competency;~~
- ~~4. Process for verifying that contractors and their employees meet the personnel qualifications of the abortion facility; and~~
- ~~5. Process for reporting licensed and certified health care practitioners for violations of their licensing or certification standards to the appropriate board within the Department of Health Professions.~~

H. A personnel file shall be maintained for each staff member. Personnel record information shall be safeguarded against loss and unauthorized use. Employee health related information shall be maintained separately within the employee's personnel file. ~~Unless redacted, copies of personnel files shall not be removed from the premises.~~ Copies of personnel files shall not be removed from the premises.

I. Nothing in these regulations shall authorize any employee or agent of the OLC or the department to copy 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.

Statutory Authority

§ 32.1-127 of the Code of Virginia.

Historical Notes

Derived from Virginia Register Volume 29, Issue 19, eff. June 20, 2013; amended, Virginia Register Volume 33, Issue 13, eff. March 22, 2017.

12VAC5-412-190. Clinical staff.

A. Physicians and nonphysician health care practitioners shall constitute the clinical staff. Clinical privileges of physician and nonphysician health care practitioners shall be clearly defined.

B. Abortions shall be performed by physicians who are licensed to practice medicine in Virginia and who are qualified by training and experience to perform abortions. The abortion facility shall

develop, implement, and maintain policies and procedures to ensure and document that abortions that occur in the abortion facility are only performed by physicians who are qualified by training and experience.²¹

C. ~~A physician shall remain on the premises until all patients are medically stable.~~ Licensed health care practitioners trained in post-procedure assessment shall remain on the premises until the last patient has been discharged. The abortion facility shall develop, implement, and maintain policies and procedures that ensure there is an appropriate evaluation of medical stability prior to discharge of the patient and that adequately trained health care practitioners remain with the patient until she is discharged from the abortion facility.

D. Licensed practical nurses, working under direct supervision and direction of a physician or a registered nurse, may be employed as components of the clinical staff.

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.

Statutory Authority

§ 32.1-127 of the Code of Virginia.

Historical Notes

Derived from Virginia Register Volume 29, Issue 19, eff. June 20, 2013; amended, Virginia Register Volume 33, Issue 13, eff. March 22, 2017.

12VAC5-412-200. Patients' rights.

A. Each abortion facility shall establish a protocol relating to the rights and responsibilities of patients. The protocol shall include a process reasonably designed to inform patients of their rights and responsibilities, in a language or manner they understand. Patients shall be given a copy of their rights and responsibilities upon admission.

B. The abortion facility shall establish and maintain complaint handling procedures which specify the:

1. System for logging receipt, investigation, and resolution of complaints; and

²¹ We believe that Advanced Medical Practitioners like nurse practitioners and trained physicians assistants can perform certain abortions as safely as a physician. See “The Safety and Quality of Abortion Care in the United States” A Consensus Study Report, National Academies of Sciences, Engineering and Medicine, March 2018, at <http://nationalacademies.org/hmd/Reports/2018/the-safety-and-quality-of-abortion-care-in-the-united-states.aspx>. At 14.

2. Format of the written record of the findings of each complaint investigated.
- C. The abortion facility shall designate staff responsible for complaint resolution, including:
1. Complaint intake, including acknowledgment of complaints;
 2. Investigation of the complaint;
 3. Review of the investigation findings and resolution for the complaint; and
 4. Notification to the complainant of the proposed resolution within 30 days from the date of receipt of the complaint.
- D. Any patient seeking an abortion shall be given a copy of the complaint procedures, in a language or manner ~~she understands they understand~~, at the time of admission to service.
- E. The abortion facility shall provide each patient or ~~her~~ ~~their~~ designee with the name, mailing address, and telephone number of the:
1. Abortion facility contact person; and
 2. OLC Complaint Unit, including the toll-free complaint hotline number. Patients may submit complaints anonymously to the OLC. The abortion facility shall display a copy of this information in a conspicuous place.
- F. The abortion facility shall maintain documentation of all complaints received and the status of each complaint from date of receipt through its final resolution. Records shall be maintained for no less than three years.

Statutory Authority

§ 32.1-127 of the Code of Virginia.

Historical Notes

Derived from Virginia Register Volume 29, Issue 19, eff. June 20, 2013; amended, Virginia Register Volume 33, Issue 13, eff. March 22, 2017.

PART III

QUALITY MANAGEMENT AND INFECTION PREVENTION

12VAC5-412-210. Quality management.

A. The abortion facility shall implement an ongoing, comprehensive, integrated, self-assessment program of the quality and appropriateness of care or services provided, including services provided under contract or agreement. The program shall include process design, data collection/analysis, assessment and improvement, and evaluation. The findings shall be used to correct identified problems and revise policies and practices, as necessary.

B. The following shall be evaluated to assure adequacy and appropriateness of services, and to identify unacceptable or unexpected trends or occurrences:

1. Staffing patterns and performance;
2. Supervision appropriate to the level of service;
3. Patient records;
4. Patient satisfaction;
5. Complaint resolution;
6. Infections, complications, and other adverse events; and
7. Staff concerns regarding patient care.

~~C. A quality improvement committee responsible for the oversight and supervision of the program shall be established and at a minimum shall consist of:~~

- ~~1. A physician;~~
- ~~2. A nonphysician health care practitioner;~~
- ~~3. A member of the administrative staff; and~~
- ~~4. An individual with demonstrated ability to represent the rights and concerns of patients. The individual may be a member of the facility's staff.~~

~~In selecting members of this committee, consideration shall be given to the candidate's abilities and sensitivity to issues relating to quality of care and services provided to patients.~~

D. Measures shall be implemented to resolve problems or concerns that have been identified.

E. Results of the quality improvement program shall be reported to the licensee at least annually and shall include the deficiencies identified and recommendations for corrections and improvements. The report shall be acted upon by the governing body and the facility. All corrective actions shall be documented. Identified deficiencies that jeopardize patient safety shall be reported immediately in writing to the licensee by the quality improvement committee.

Statutory Authority

§§ 32.1-12 and 32.1-127 of the Code of Virginia.

Historical Notes

Derived from Virginia Register Volume 29, Issue 19, eff. June 20, 2013.

12VAC5-412-220. Infection prevention.

A. The abortion facility shall have an infection prevention plan that encompasses the entire abortion facility and all services provided. An individual with training and expertise in infection

prevention shall participate in the development of infection prevention policies and procedures and shall review them to assure they comply with applicable regulations and standards.

1. The process for development, implementation, and maintenance of infection prevention policies and procedures and the regulations or guidance documents on which they are based shall be documented.

2. All infection prevention policies and procedures shall be reviewed at least annually by the administrator and appropriate members of the clinical staff. The annual review process and recommendations for changes/updates shall be documented in writing.

3. A designated person in the abortion facility shall have received training in basic infection prevention, and shall also be involved in the annual review.

B. Written infection prevention policies and procedures shall include, but not be limited to:

1. Procedures for screening incoming patients and visitors for acute infectious illnesses and applying appropriate measures to prevent transmission of community-acquired infection within the abortion facility;

2. Training of all personnel in proper infection prevention techniques;

3. Correct hand-washing technique, including indications for use of soap and water and use of alcohol-based hand rubs;

4. Use of standard precautions;

5. Compliance with bloodborne pathogen requirements of the U.S. Occupational Safety and Health Administration;

6. Use of personal protective equipment;

7. Use of safe injection practices;

8. Plans for annual retraining of all personnel in infection prevention methods;

9. Procedures for monitoring staff adherence to recommended infection prevention practices; and

10. Procedures for documenting annual retraining of all staff in recommended infection prevention practices.

C. Written policies and procedures for the management of the abortion facility, equipment, and supplies shall address the following:

1. Access to hand-washing equipment and adequate supplies (e.g., soap, alcohol-based hand rubs, disposable towels or hot air driers);

2. Availability of utility sinks, cleaning supplies, and other materials for cleaning, disposal, storage, and transport of equipment and supplies;

3. Appropriate storage for cleaning agents (e.g., locked cabinets or rooms for chemicals used for cleaning) and product-specific instructions for use of cleaning agents (e.g., dilution, contact time, management of accidental exposures);
4. Procedures for handling, storing, and transporting clean linens, clean/sterile supplies, and equipment;
5. Procedures for handling/temporary storage/transport of soiled linens;
6. Procedures for handling, storing, processing, and transporting regulated medical waste in accordance with applicable regulations;
7. Procedures for the processing of each type of reusable medical equipment between uses on different patients. The procedure shall address: (i) the level of cleaning/disinfection/sterilization to be used for each type of equipment; (ii) the process (e.g., cleaning, chemical disinfection, heat sterilization); and (iii) the method for verifying that the recommended level of disinfection/sterilization has been achieved. The procedure shall reference the manufacturer's recommendations and any applicable state or national infection control guidelines;
8. Procedures for appropriate disposal of nonreusable equipment;
9. Policies and procedures for maintenance/repair of equipment in accordance with manufacturer recommendations;
10. Procedures for cleaning of environmental surfaces with appropriate cleaning products;
11. An effective pest control program, managed in accordance with local health and environmental regulations; and
12. Other infection prevention procedures necessary to prevent/control transmission of an infectious agent in the abortion facility as recommended or required by the department.

D. The abortion facility shall have an employee health program that includes:

1. Access to recommended vaccines;
2. Procedures for assuring that employees with communicable diseases are identified and prevented from work activities that could result in transmission to other personnel or patients;
3. An exposure control plan for bloodborne pathogens;
4. Documentation of screening and immunizations offered/received by employees in accordance with statute, regulation, or recommendations of public health authorities, including documentation of screening for tuberculosis and access to hepatitis B vaccine; and
5. Compliance with requirements of the U.S. Occupational Safety and Health Administration for reporting of workplace-associated injuries or exposure to infection.

E. The abortion facility shall develop, implement, and maintain policies and procedures for the following patient education, follow up, and reporting activities:

1. A procedure for surveillance, documentation, and tracking of reported infections; and
2. Policies and procedures for reporting conditions to the local health department in accordance with the Regulations for Disease Reporting and Control (12VAC5-90), including outbreaks of disease.

Statutory Authority

§ 32.1-127 of the Code of Virginia.

Historical Notes

Derived from Virginia Register Volume 29, Issue 19, eff. June 20, 2013; amended, Virginia Register Volume 33, Issue 13, eff. March 22, 2017.

PART IV

PATIENT CARE MANAGEMENT

12VAC5-412-230. Patient services; patient counseling.

A. Abortions performed in abortion facilities shall be performed only on patients who are within the first trimester of pregnancy meaning 13 weeks and 6 days after last menstrual period or based on an appropriate clinical estimate by a licensed health care provider. Redline this

B. No person may perform an abortion upon an unemancipated minor unless informed written consent is obtained from the minor and the minor's parent, guardian, or other authorized person. If the unemancipated minor elects not to seek the informed written consent of an authorized person, a copy of the court order authorizing the abortion entered pursuant to § 16.1-241 of the Code of Virginia shall be obtained prior to the performance of the abortion.

C. A physician shall not perform an abortion without first obtaining the informed written consent of the patient pursuant to the provisions of § 18.2-76 of the Code of Virginia.

D. When abortions are being performed, a staff member currently certified to perform cardiopulmonary resuscitation shall be available on site for emergency care.

E. The abortion facility shall offer each patient seeking an abortion, in a language or manner she understands, appropriate counseling and instruction in the abortion procedure and shall develop, implement, and maintain policies and procedures for the provision of or referral for family planning services to its patients.

F. There shall be an organized discharge planning process that includes an assessment of a patient's safety for discharge and discharge instructions for patients to include instructions to call or return if signs of infection develop.

Statutory Authority

§ 32.1-127 of the Code of Virginia.

Historical Notes

Derived from Virginia Register Volume 29, Issue 19, eff. June 20, 2013; amended, Virginia Register Volume 33, Issue 13, eff. March 22, 2017.

12VAC5-412-240. Medical testing and laboratory services.

A. Prior to the initiation of any abortion, a medical history and physical examination, including a confirmation of pregnancy, and completion of all the requirements of informed written consent pursuant to § 18.2-76 of the Code of Virginia, shall be completed for each patient.

1. Medical testing shall include a recognized method to confirm pregnancy and determination or documentation of Rh factor.

2. Use of any additional medical testing shall be based on an assessment of patient risk.

~~3. The abortion facility shall develop, implement, and maintain policies and procedures for offering screening of sexually transmitted diseases consistent with current guidelines issued by the U.S. Centers for Disease Control and Prevention or at a minimum referring patients to clinics that provide such testing.~~

4. A written report of each laboratory test and examination shall be a part of the patient's record.

B. Laboratory services shall be provided on site or through arrangement with a laboratory certified to provide the required procedures under the Clinical Laboratory Improvement Amendments of 1988 (CLIA-88) (42 CFR Part 493).

1. Facilities for collecting specimens shall be available on site.

2. If laboratory services are provided on site they shall be directed by a person who qualifies as a director under CLIA-88 and shall be performed in compliance with CLIA-88 standards.

3. All laboratory supplies shall be monitored for expiration dates, if applicable, and disposed of properly.

C. The abortion facility shall have policies and procedures for evaluation of all tissues removed during the abortion and for reevaluation of the patient in the event the evaluation of tissue is insufficient to confirm termination of the pregnancy. The facility shall track and log any specimens sent for further pathologic examination.

D. All tissues removed resulting from the abortion procedure shall be managed in accordance with requirements for medical waste pursuant to the Regulated Medical Waste Management Regulations (9VAC20-120).

Statutory Authority

§ 32.1-127 of the Code of Virginia.

Historical Notes

Derived from Virginia Register Volume 29, Issue 19, eff. June 20, 2013; amended, Virginia Register Volume 33, Issue 13, eff. March 22, 2017.

12VAC5-412-250. Anesthesia service.

A. The anesthesia service shall comply with the office-based anesthesia provisions of the Regulations Governing the Practice of Medicine, Osteopathic Medicine, Podiatry, and Chiropractic (18VAC85-20-310 et seq.).

B. The anesthesia service shall be directed by and under the supervision of a physician licensed in Virginia who is certified in advanced resuscitative techniques and has met the continuing education requirements.

C. When moderate sedation or conscious sedation is administered, the licensed health care practitioner who administers the anesthesia shall routinely monitor the patient according to procedures consistent with such administration. The administration of sedation and monitoring of the patient shall be documented in the patient's medical record.

D. An abortion facility administering moderate sedation/conscious sedation shall maintain the following equipment, supplies, and pharmacological agents as required by 18VAC85-20-360 B:

1. Appropriate equipment to manage airways;
2. Drugs and equipment to treat shock and anaphylactic reactions;
3. Precordial stethoscope;
4. Pulse oximeter with appropriate alarms or an equivalent method of measuring oxygen saturation;
5. Continuous electrocardiograph;
6. Devices for measuring blood pressure, heart rate, and respiratory rate;
7. Defibrillator; and
8. Accepted method of identifying and preventing the interchangeability of gases.

E. Elective general anesthesia shall not be used.

F. If deep sedation or a major conductive block is administered or if general anesthesia is administered in an emergent situation, the licensed health care practitioner who administers the anesthesia service shall remain present and available in the facility to monitor the patient until the patient meets the discharge criteria.

G. In addition to the requirements of subsection D of this section, an abortion facility administering deep sedation or a major conductive block, or administering general anesthesia in an emergent situation, shall maintain the following equipment, supplies, and pharmacological agents as required by 18VAC85-20-360 C:

1. Drugs to treat malignant hyperthermia, when triggering agents are used;

2. Peripheral nerve stimulator, if a muscle relaxant is used; and
3. If using an anesthesia machine, the following shall be included:
 - a. End-tidal carbon dioxide monitor (capnograph);
 - b. In-circuit oxygen analyzer designed to monitor oxygen concentration within breathing circuit by displaying oxygen percent of the total respiratory mixture;
 - c. Oxygen failure-protection devices (fail-safe system) that have the capacity to announce a reduction in oxygen pressure and, at lower levels of oxygen pressure, to discontinue other gases when the pressure of the supply of oxygen is reduced;
 - d. Vaporizer exclusion (interlock) system, which ensures that only one vaporizer, and therefore only a single anesthetic agent can be actualized on any anesthesia machine at one time;
 - e. Pressure-compensated anesthesia vaporizers, designed to administer a constant nonpulsatile output, which shall not be placed in the circuit downstream of the oxygen flush valve;
 - f. Flow meters and controllers, which can accurately gauge concentration of oxygen relative to the anesthetic agent being administered and prevent oxygen mixtures of less than 21% from being administered;
 - g. Alarm systems for high (disconnect), low (subatmospheric), and minimum ventilatory pressures in the breathing circuit for each patient under general anesthesia; and
 - h. A gas evacuation system.

H. The abortion facility shall develop, implement, and maintain policies and procedures outlining criteria for discharge from anesthesia care. Such criteria shall include stable vital signs, responsiveness and orientation, ability to move voluntarily, controlled pain, and minimal nausea and vomiting. Discharge from anesthesia care is the responsibility of the health care practitioner providing the anesthesia care and shall occur only when the patient has met specific physician-defined criteria, and those criteria have been documented within the patient's medical record.

Statutory Authority

§ 32.1-127 of the Code of Virginia.

Historical Notes

Derived from Virginia Register Volume 29, Issue 19, eff. June 20, 2013; amended, Virginia Register Volume 33, Issue 13, eff. March 22, 2017.

12VAC5-412-260. Administration, storage and dispensing of drugs.

A. Controlled substances, as defined in § 54.1-3401 of the Code of Virginia, shall be stored, administered, and dispensed in accordance with federal and state laws. The dispensing of drugs,

excluding manufacturers' samples, shall be in accordance with Chapter 33 (§ 54.1-3300 et seq.) of Title 54.1 of the Code of Virginia, Regulations Governing the Practice of Pharmacy (18VAC110-20), and Regulations for Practitioners of the Healing Arts to Sell Controlled Substances (18VAC110-30).

B. Drugs, as defined in § 54.1-3401 of the Code of Virginia, whose intended use is to induce a termination of pregnancy shall only be prescribed, dispensed, or administered by a physician.

C. Drugs maintained in the abortion facility for daily administration shall not be expired and shall be properly stored in enclosures of sufficient size with restricted access to authorized personnel only. Drugs shall be maintained at appropriate temperatures in accordance with definitions in 18VAC110-20-10.

D. The mixing, diluting, or reconstituting of drugs for administration shall be in accordance with regulations of the Board of Medicine (18VAC85-20-400 et seq.).

E. Records of all drugs in Schedules I-V received, sold, administered, dispensed, or otherwise disposed of shall be maintained in accordance with federal and state laws, to include the inventory and reporting requirements of a theft or loss of drugs found in § 54.1-3404 of the Code of Virginia.

Statutory Authority

§§ 32.1-12 and 32.1-127 of the Code of Virginia.

Historical Notes

Derived from Virginia Register Volume 29, Issue 19, eff. June 20, 2013.

12VAC5-412-270. Equipment and supplies.

An abortion facility shall maintain medical equipment and supplies appropriate and adequate to care for patients based on the level, scope, and intensity of services provided, to include:

1. A bed or recliner suitable for recovery;
2. Oxygen with flow meters and masks or equivalent;
3. Mechanical suction;
4. Resuscitation equipment to include, as a minimum, resuscitation bags and oral airways;
5. Emergency medications, intravenous fluids, and related supplies and equipment;
6. Sterile suturing equipment and supplies;
7. Adjustable examination light;
8. Containers for soiled linen and waste materials with covers; and
9. Refrigerator.

Statutory Authority

§§ 32.1-12 and 32.1-127 of the Code of Virginia.

Historical Notes

Derived from Virginia Register Volume 29, Issue 19, eff. June 20, 2013.

12VAC5-412-280. Emergency equipment and supplies.

An abortion facility shall maintain medical equipment, supplies, and drugs appropriate and adequate to manage potential emergencies based on the level, scope, and intensity of services provided. Such medical equipment, supplies, and drugs shall be determined by the physician and shall be consistent with the current edition of the American Heart Association's Guidelines for Cardiopulmonary Resuscitation and Emergency Cardiovascular Care.

Statutory Authority

§ 32.1-127 of the Code of Virginia.

Historical Notes

Derived from Virginia Register Volume 29, Issue 19, eff. June 20, 2013; amended, Virginia Register Volume 33, Issue 13, eff. March 22, 2017.

12VAC5-412-290. Emergency services.

A. An abortion facility shall provide ongoing urgent or emergent care and maintain on the premises adequate monitoring equipment, suction apparatus, oxygen, and related items for resuscitation and control of hemorrhage and other complications.

B. An abortion facility that performs abortions using intravenous sedation shall provide equipment and services to render emergency resuscitative and life-support procedures pending transfer of the patient to a hospital. Such medical equipment and services shall be consistent with the current edition of the American Heart Association's Guidelines for Cardiopulmonary Resuscitation and Emergency Cardiovascular Care.

C. When emergency transfer is necessary, the responsible physician at the abortion facility must provide direct communication to the appropriate receiving facility 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.

Statutory Authority

§ 32.1-127 of the Code of Virginia.

Historical Notes

Derived from Virginia Register Volume 29, Issue 19, eff. June 20, 2013; amended, Virginia Register Volume 33, Issue 13, eff. March 22, 2017.

PART V

SUPPORT SERVICES - HEALTH INFORMATION RECORDS AND REPORTS

12VAC5-412-300. Health information records.

An accurate and complete clinical record or chart shall be maintained on each patient. The record or chart shall contain sufficient information to satisfy the diagnosis or need for the medical or surgical service. If medically indicated, it shall include, but not be limited to the following:

1. Patient identification;
2. Admitting information, including patient history and physical examination;
3. Signed consent;
4. Confirmation of pregnancy;
5. Procedure report to include:
 - a. Physician orders;
 - b. Laboratory tests, pathologist's report of tissue, and radiologist's report of x-rays;
 - c. Anesthesia record;
 - d. Operative record;
 - e. Surgical medication and medical treatments;
 - f. Recovery room notes;
 - g. Physicians' and nurses' progress notes;
 - h. Condition at time of discharge;
 - i. Patient instructions (preoperative and postoperative); and
 - j. Names of referral physicians or agencies; and
6. Any other information required by law to be maintained in the health information record.

Statutory Authority

§ 32.1-127 of the Code of Virginia.

Historical Notes

Derived from Virginia Register Volume 29, Issue 19, eff. June 20, 2013; amended, Virginia Register Volume 33, Issue 13, eff. March 22, 2017.

12VAC5-412-310. Records storage.

Provisions shall be made for the safe storage of medical records or accurate and eligible reproductions thereof according to applicable federal and state law, including the Health Insurance Portability and Accountability Act (42 USC § 1320d et seq.).

Statutory Authority

§§ 32.1-12 and 32.1-127 of the Code of Virginia.

Historical Notes

Derived from Virginia Register Volume 29, Issue 19, eff. June 20, 2013.

12VAC5-412-320. Required reporting.

A. Abortion facilities shall comply with the fetal death and induced termination of pregnancy reporting provisions in the Board of Health Regulations Governing Vital Records (12VAC5-550-120). **The VDH Reports of Induced Termination of Pregnancy for any individual abortion whether surgical or medical shall not be disclosed to the public by any means.**

B. The abortion facility shall report the following events to OLC:

1. Any patient, staff, or visitor death;
2. Any serious injury to a patient;
3. Medication errors that necessitate a clinical intervention other than monitoring; and
4. A death or significant injury of a patient or staff member resulting from a physical assault that occurs within or on the abortion facility grounds;

C. Notification of the events listed in subsection B of this section shall be required within 24 hours of occurrence. Each notice shall contain the:

1. Abortion facility name;
2. Type and circumstance of the event being reported;
3. Date of the event; and
4. Actions taken by the abortion facility to protect patient and staff safety and to prevent recurrence.

D. Compliance with this section does not relieve the abortion facility from complying with any other applicable reporting or notification requirements, such as those relating to law-enforcement or professional regulatory agencies.

E. Records that are confidential under federal or state law shall be maintained as confidential by the OLC and shall not be further disclosed by the OLC, except as required or permitted by law.

F. Abortion facilities shall ensure that employees mandated to report suspected child abuse or neglect under § 63.2-1509 of the Code of Virginia comply with the reporting requirements of § 63.2-1509 of the Code of Virginia.

Statutory Authority

§ 32.1-127 of the Code of Virginia.

Historical Notes

Derived from Virginia Register Volume 29, Issue 19, eff. June 20, 2013; amended, Virginia Register Volume 33, Issue 13, eff. March 22, 2017.

PART VI

FUNCTIONAL SAFETY AND MAINTENANCE

12VAC5-412-330. Abortion facility security and safety.

The abortion facility shall develop, implement, and maintain policies and procedures to ensure safety within the abortion facility and on its grounds and to minimize hazards to all occupants. The policies and procedures shall include, but not be limited to safety rules and practices pertaining to personnel, equipment, gases, liquids, drugs, supplies, and services. **These plans, policies, and procedures shall not be available through any open records or freedom of information requests.**

Statutory Authority

§ 32.1-127 of the Code of Virginia.

Historical Notes

Derived from Virginia Register Volume 29, Issue 19, eff. June 20, 2013; amended, Virginia Register Volume 33, Issue 13, eff. March 22, 2017.

~~12VAC5-412-340. Disaster preparedness.~~

~~A. Each abortion facility shall develop, implement, and maintain policies and procedures to ensure reasonable precautions are taken to protect all occupants from hazards of fire and other disasters. The policies and procedures shall include provisions for evacuation of all occupants in the event of a fire or other disaster.~~

~~B. An abortion facility that participates in community disaster planning shall establish plans, based on its capabilities, to meet its responsibilities for providing emergency care.~~

Statutory Authority

§§ 32.1-12 and 32.1-127 of the Code of Virginia.

Historical Notes

Derived from Virginia Register Volume 29, Issue 19, eff. June 20, 2013.

12VAC5-412-350. Maintenance.

When patient monitoring equipment is utilized, a written preventive maintenance program shall be developed and implemented. This equipment shall be checked and/or tested in accordance with manufacturer's specifications at periodic intervals, not less than annually, to ensure proper operation and a state of good repair. After repairs and/or alterations are made to any equipment, the equipment shall be thoroughly tested for proper operation before it is returned to service. Records shall be maintained on each piece of equipment to indicate its history of testing and maintenance.

Statutory Authority

§ 32.1-127 of the Code of Virginia.

Historical Notes

Derived from Virginia Register Volume 29, Issue 19, eff. June 20, 2013; amended, Virginia Register Volume 33, Issue 13, eff. March 22, 2017.

12VAC5-412-360. (Repealed.)

Historical Notes

Derived from Virginia Register Volume 29, Issue 19, eff. June 20, 2013; repealed, Virginia Register Volume 33, Issue 13, eff. March 22, 2017.

PART VII

DESIGN AND CONSTRUCTION

12VAC5-412-370. Local and state codes and standards.

All construction of new buildings and additions or major renovations to existing buildings for occupancy as an abortion facility shall comply with all applicable state and local codes and ordinances.

Statutory Authority

§ 32.1-127 of the Code of Virginia.

Historical Notes

Derived from Virginia Register Volume 29, Issue 19, eff. June 20, 2013; amended, Virginia Register Volume 33, Issue 13, eff. March 22, 2017.

Forms (12VAC5-412)

[Application for Abortion Facility Licensure \(eff. 5/03\).](#)

[OSHA Forms for Recording Work-Related Injuries and Illnesses, 2004.](#)

Documents Incorporated by Reference (12VAC5-412)

Guidelines for Cardiopulmonary Resuscitation and Emergency Cardiovascular Care, 2015, American Heart Association, 7272 Greenville Avenue, Dallas, TX 75231-4596

[\(https://eccguidelines.heart.org/index.php/circulation/cpr-ecc-guidelines-2/\)](https://eccguidelines.heart.org/index.php/circulation/cpr-ecc-guidelines-2/)

Sexually Transmitted Diseases Treatment Guidelines, 2015, Centers for Disease Control and Prevention, U.S. Department of Health and Human Services

[\(http://www.cdc.gov/std/tg2015/default.htm\)](http://www.cdc.gov/std/tg2015/default.htm)

Bloodborne Pathogens - OSHA's Bloodborne Pathogens Standard, OSHA Fact Sheet and Quick Reference Guide, 2011 U.S. Occupational Safety and Health Administration

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