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August 31, 2010

Via Facsimile (804-371-6351) & U.S. Mail

The Honorable Robert F. McDonnell
Office of the Governor
Patrick Henry Building, 3rd Floor
1111 East Broad Street
Richmond, Virginia 23219

Re: Proposed Regulations for Licensure of Abortion Clinics

Dear Governor McDonnell:

The Rutherford Institute concurs with Attorney General Ken Cuccinelli's recent opinion that the Commonwealth of Virginia may regulate facilities in which first trimester abortions are performed. This assessment is solidly grounded in the decision of the United States Court of Appeals for the Fourth Circuit in *Greenville Women's Clinic v. Commissioner*, as well as the United States Supreme Court's abortion jurisprudence.¹

The Supreme Court has noted that "abortions are inherently different from other medical procedures..."² This is why federal courts have repeatedly affirmed that states have a legitimate interest in regulating abortion clinics more stringently than other medical facilities. As the attorney general correctly pointed out in his recent opinion, state regulations that serve a valid purpose, such as furthering health and safety, and "do not strike at the [abortion] right itself," are valid and within the states' constitutional

¹ 317 F.3d 357, 361 (4th Cir. 2002), *cert. denied* 538 U.S. 1008 (2003).

² *Harris v. McRae*, 448 U.S. 297, 325 (1980).

authority to enact.³ Federal courts have repeatedly recognized such regulations as legitimate exercises of state power to protect the public's health and welfare.⁴

In the Commonwealth of Virginia, however, many centers in which abortions are performed are treated as regular doctors' offices and not subject to even basic licensing requirements. The Rutherford Institute submits that, in light of the well-recognized state interest in promoting public health and welfare and the serious, invasive nature of abortion, the Commonwealth has both the authority and an obligation to its citizens to adopt reasonable, common-sense regulations such as those upheld by the Fourth Circuit in 2002.⁵

Abortion is certainly different than other medical procedures that are routinely performed in doctors' offices. Potential complications include permanent damage to reproductive and other vital organs, dysfunction of the cardiovascular or respiratory system, internal bleeding or hemorrhaging, embolism, and allergic reactions.⁶ In addition to the more immediate complications of surgery related to abortion, voluminous studies prove that abortion carries many long-term health risks.⁷

Because of the lack of standard reporting requirements within the Commonwealth and across the nation, it is impossible to accurately assess the frequency with which these serious complications actually occur. For instance, the Centers for Disease Control and Prevention (CDC) reports that seven women died from complications of legalized abortions in 2005.⁸ Yet the CDC report explicitly recognized that its data is compromised due to a known, significant under-reporting of the number of clinic abortions performed nationwide.⁹ The CDC report contained no information regarding abortion complications other than death, as this information is apparently not reported or collected in many states, including Virginia. While we know that the risks abortion poses to women's health are many and serious, it is likely that additional regulations, including certain reporting requirements, would help us to understand them better.

³ See *Planned Parenthood v. Casey*, 505 U.S. 833, 878 (1992).

⁴ See, e.g., *Roe v. Wade*, 410 U.S. 113, 150 (1973)(recognizing legitimate state interest in seeing that abortion is performed under circumstances that maximize patient safety); *Akron v. Akron Ctr. for Reproductive Health, Inc.*, 462 U.S. 416, 428-29 (1983)(citing state's legitimate concern for health of women undergoing abortions); *Greenville Women's Clinic, supra*.

⁵ *Greenville Women's Clinic v. Comm'r, S.C. Dep't of Health*, 317 F.3d 357, 361 (4th Cir. 2002), cert. denied 538 U.S. 1008 (2003).

⁶ See *A Woman's Choice – East Side Women's Clinic v. Newman*, 305 F.3d 684, 702 (7th Cir. 2002)(Coffey, C.J., concurring).

⁷ See, e.g., J. S. Brown, Jr., T. Adera, S. W. Masho, "Previous abortion and the risk of low birth weight and preterm births," *Journal of Epidemiology and Community Health* (Vol. 62, Issue 1).

⁸ Center for Disease Control, "Abortion Surveillance – United States, 2006," *Morbidity and Mortality Weekly Report*, available at <http://www.cdc.gov/mmwr/PDF/ss/ss5808.pdf>.

⁹ *Id.*

The known risk factors, combined with the simple fact that abortion is a complicated, invasive surgical procedure, are incongruent with the treatment of abortion facilities as mere doctors' offices. However, as the attorney general explained in his recent opinion, that is precisely how many such abortion facilities are currently classified. While outpatient abortion clinics are specifically included within the definition of outpatient hospitals under one regulation, a separate law makes the hospital licensure regulations specifically inapplicable to physicians' offices unless they are used "principally" for performing surgery.¹⁰ Many clinics that provide other services in addition to performing abortions simply classify themselves as "physicians' offices," thus evading the most basic regulations that apply to other outpatient surgical centers.

The nature of the abortion procedure and its inherent risks are reason enough to advocate for increased regulation of abortion clinics in the Commonwealth. But courts have identified a more fundamental reason for regulating these facilities even more stringently than other outpatient surgical centers. Abortion is different, the Supreme Court has found, "because no other procedure involves the purposeful termination of a potential life."¹¹

Whatever one's position on the emotionally-charged abortion issue, intellectual honesty demands the recognition that abortions—even in the first trimester—are fundamentally different from any other type of medical procedure. It cannot be ignored that the surgery extinguishes the life of a developing human being. One need not be an embryologist to understand this. Indeed, a popular series of articles on WebMD called, "Your Pregnancy Week by Week," states:

By the end of the third month, your baby is fully formed. Your baby has arms, hands, fingers, feet and toes and can open and close its fists and mouth. Fingernails and toenails are beginning to develop and the external ears are formed. The beginnings of teeth are forming.¹²

Surely the Commonwealth of Virginia has significant interests in seeing that the termination of pregnancies at this stage are not treated with as little oversight as the routine removal of warts. In fact, the United States Supreme Court has recently reaffirmed the importance of the state's interest in "promoting respect for human life at all stages in the pregnancy."¹³

¹⁰ See 12 VA. ADMIN. CODE § 5-410-10 (defining "outpatient hospitals"); VA. CODE ANN. § 32.1-124 (making hospital licensure requirements inapplicable to physicians' offices unless used principally for performing surgery).

¹¹ *Harris v. McRae*, 448 U.S. 297, 325 (1980).

¹² <http://www.webmd.com/baby/guide/your-pregnancy-week-by-week-weeks-9-12?page=2>.

¹³ *Gonzales v. Carhart*, 550 U.S. 124, 163 (2007).

The Honorable Robert F. McDonnell

August 31, 2010

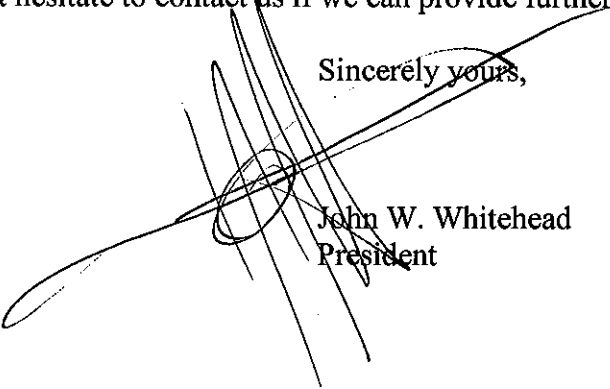
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For the past several years, the General Assembly has considered various bills designed to regulate abortion clinics.¹⁴ These proposals have been treated as political footballs by legislators and other politicians whose views place them either in opposition to or support of abortion. Yet in the process, the health and welfare of women and the public interest in promoting respect for human life have been the losers. When political considerations are cast aside, the facts speak for themselves. And they testify to the urgent need for reasonable regulation.

Thus, at this time, and for the reasons set forth herein, The Rutherford Institute urges you and your administration to advocate the adoption of common-sense clinic safety regulations for the protection of women undergoing abortions and the promotion of public health. To aid you in this endeavor, we have enclosed a copy of South Carolina's Code of Regulations § 61-12, upheld by the Fourth Circuit Court of Appeals in 2002, which would serve as a good model for the Commonwealth to follow in drafting its own regulations.

Please do not hesitate to contact us if we can provide further assistance.

Sincerely yours,



John W. Whitehead
President

Enclosure

¹⁴ During the 2010 General Assembly session, for instance, Del. Matt Lohr (R-26), sponsored HB 393, a measure for the licensure and regulation of abortion clinics. The bill failed in the Senate Education and Health Committee.

**SOUTH CAROLINA CODE OF REGULATIONS
(Unannotated)**

Current through State Register Volume 33, Issue 9, effective September 25, 2009.

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CHAPTER 61.

DEPARTMENT OF HEALTH AND ENVIRONMENTAL CONTROL

(Statutory Authority: 1976 Code Sections 1-23-10, 1-23-110, 1-23-120(I), 6-19-40, 13-7-10, 13-7-40, 13-7-45 et seq., 13-7-110 et seq., 20-1-350, 20-3-230, 38-25-20, 39-23-40, 40-25-30(9), 44-1-20, 44-1-140, 44-5-120, 44-7-130, 44-7-250, 44-7-260(A), 44-7-430, 44-7-500 through 44-7-590, 44-29-40, 44-41-70(b), 44-53-280(a), 44-53-950, 44-55-10 to 44-55-60, 44-56-30, 44-61-30, 44-63-20, 44-69-10 et seq., 44-87-10, 44-96-80, 44-96-290, 44-96-300, 44-96-320, 44-96-340, 44-96-360, 44-96-380, 44-96-400, 44-96-450, 44-96-460, 48-1-10 et seq., 48-1-30 through 48-1-60 et seq., 48-2-10, 59-111-580)

61-12. Standards for Licensing Abortion Clinics.

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PART I DEFINITIONS AND REQUIREMENTS FOR LICENSURE.

Section 101. Definitions.

For the purposes of these regulations, the following definitions apply:

A. Abortion. The use of an instrument, medicine, drug, or other substance or device with intent to terminate the pregnancy of a woman, known to be pregnant, for reasons other than to increase the probability of a live birth, to preserve the life or health of the child after live birth, or to remove a dead fetus.

B. Abortion Clinic. Any facility, other than a hospital as defined in Section 101.J, in which any second trimester or five or more first trimester abortions per month are performed.

C. Allied Health Professional. A person other than a physician who possesses specialized training and skill acquired by completing certain courses of study or intensive job-related training and, where applicable, has been duly licensed or registered by appropriate licensing or certification agencies. All allied health professionals must be supervised by a physician.

D. Conception. The fecundation of the ovum by the spermatozoa.

E. Consent. A signed and witnessed voluntary agreement to the performance of an abortion.

F. Department. The South Carolina Department of Health and Environmental Control.

G. Emancipated Minor. A minor who is or has been married or has by court order been freed from the care, custody, and control of her parents.

H. Fetal Death. Death prior to the complete expulsion or extraction from its mother of a product of human conception, irrespective of the duration of pregnancy; the death is indicated by the fact that after such expulsion or extraction, the fetus does not breathe or show any other evidence of life, such as beating of the heart, pulsation of the umbilical cord, or definite movement of voluntary muscles.

I. Fire Safety Authority. The State Fire Marshal, or his designee, who performs facility fire and safety inspections.

J. Hospital. An institution licensed for hospital operation by the Department in accordance with the provisions of Article 3, Chapter 7, Title 44, of the S.C. Code of Laws, 1976, as amended, and that has also been certified by the Department to be a suitable facility for the performance of abortion.

K. In Loco Parentis. Any person over the age of 18 who has placed him/herself in the position of a lawful parent by assuming obligations that are incidental to the parental relationship and has so served for a period of 60 days.

L. Licensee. The person, partnership, corporation, association, organization, or professional entity on whom rests the ultimate responsibility and authority for the conduct of the abortion clinic.

M. Medical Emergency. That condition which, on the basis of the physician's good faith judgment, so complicates a pregnancy as to necessitate an immediate abortion to avert the risk of her death or for which a delay will create serious risk of substantial and irreversible impairment of major bodily functions.

N. Minor. A female under the age of 17.

O. Physician. A person licensed to practice medicine in this State.

P. Pregnancy. The condition of a woman carrying a fetus or embryo within her body.

Q. Probable Gestational Age of the Embryo or Fetus.

What, in the judgment of the attending physician, based upon the attending physician's examination and the woman's medical history, is with reasonable probability, the gestational age of the embryo or fetus at the time the abortion is planned to be performed. This estimate must be guided by recommendations found in The American College of Obstetricians and Gynecologists Standards for Obstetric-Gynecologic Services, i.e., calculated from the first day of the last menstrual period.

R. Products of Conception. Fetal and embryonic tissues resulting from implantation in the uterus.

S. Trimester. A 12-week period of pregnancy.

1. First. The first 12 weeks of pregnancy commencing with conception rather than computed on the basis of the menstrual cycle.

2. Second. That portion of a pregnancy following the 12th week and extending through the 24th week of gestation.

3. Third. That portion of pregnancy beginning with the 25th week of gestation.

4. All other references in this regulation to gestational age will refer to that calculated from the first day of the last menstrual period as used in The American College of Obstetricians and Gynecologists Standards for Obstetric-Gynecologic Services. The following is furnished to provide clarification of gestational age:

Calculation Weeks of Gestational Age

Conception 8 10 12 14 16 18 20 22 24

LMP 10 12 14 16 18 20 22 24 26

T. Viability. That stage of human development when the fetus is potentially able to live outside of the mother's womb with or without the aid of artificial life support systems. (Section 44-41-10(I) of the S.C. Code of Laws further states that "for the purposes of this chapter, a legal presumption is hereby created that viability occurs no sooner than the twenty-fourth week of pregnancy." The "twenty-fourth week," as stated in the S.C Code, is based on computation from date of conception, i.e., the twenty-sixth week from the first day of the last menstrual period.)

Section 102. License Requirements.

A. License. It shall be unlawful to operate an abortion clinic within South Carolina without possessing a valid license issued annually by the Department. (I)

B. Issuance of License. A license is issued pursuant to the provisions of Section 44-41-10 et seq., of the S.C. Code of Laws of 1976, as amended, and these standards, and shall be posted in a conspicuous place in a public area within the facility. The issuance of a license does not guarantee adequacy of individual care, treatment, personal safety, fire safety or the well-being of any occupant of a facility. A license is not assignable or transferable and is subject to revocation by the Department for failure to comply with the laws and regulations of the State of South Carolina.

C. **Effective Date and Term of License.** A license shall be effective for a 12-month period following the date of issue and shall expire one year following such date; however, a facility that has not been inspected during that year may continue to operate under its existing license until an inspection has occurred.

D. **Separate Licenses.** Separate licenses are required for facilities not maintained on the same premises.

E. **Licensing Fees.** The initial and annual license fee shall be \$500.00 for each licensed facility. Such fee shall be made payable to the Department. Fees are non-refundable.

F. **Inspections.** Each facility shall be inspected prior to initial licensure and at least annually thereafter by authorized representatives of the Department.

1. All licensed facilities are subject to inspection at any time.

2. Department inspectors shall have access to all properties and areas, objects, records and reports, and shall have the authority to make photocopies of those documents required in the course of inspections or investigations. (II)

G. **Initial License.** A new facility, or one that has not been continuously licensed under these or prior standards, shall not provide care to patients until it has been issued an initial license. When it is determined that the facility is in compliance with the requirements of these standards, and a properly completed application and licensing fee have been received by the Department, a license shall be issued. Chapter 9 of this regulation sets forth the prerequisites for initial licensure. (I)

H. **License Renewal.** Applicants for an annual license renewal shall file an application with the Department, pay a license fee, and undergo a licensing inspection.

I. **Noncompliance.** When noncompliance(s) with the licensing standards exists, the applicant or licensee shall be notified by the Department of the violation(s) and required to provide information as to how and when each violation will be corrected and how future occurrences may be prevented.

J. **Facility Name.** No proposed abortion clinic shall be named, nor may any existing abortion clinic have its name changed to, the same or similar name as any other abortion clinic licensed in the State. If it is part of a "chain operation" it shall then have the geographic area in which it is located as part of its name.

K. **Change of License.** A facility shall request issuance of an amended license by application to the Department prior to any of the following circumstances:

1. Change of ownership by purchase or lease;

2. Change of facility's name or address.

L. Exceptions to Licensing Standards. The Department may make exception(s) to these standards where it is determined that the health and welfare of the community require the services of the facility and that the exception(s), as granted, will have no significant adverse impact on the health, safety, or welfare of the facility's patients.

Section 103. Penalties.

When it determines that a facility is in violation of any statutory provision, rule or regulation relating to the operation or maintenance of such facility, the Department, upon proper notice, may deny, suspend, or revoke licenses, or assess a monetary penalty. Under such conditions, the following shall apply:

A. Class I violations are those that the Department determines to present an imminent danger to the health, safety, or welfare of the patients of the facility or a substantial probability that death or serious physical harm could result therefrom. A physical condition or one or more practices, means, methods or operations in use in a facility may constitute such a violation. The condition or practice constituting a Class I violation shall be abated or eliminated immediately unless a fixed period of time, as stipulated by the Department, is required for correction. Each day such violation shall exist after expiration of said time shall be considered a subsequent violation.

B. Class II violations are those, other than Class I violations, that the Department determines to have a direct or immediate relationship to the health, safety or well-being of the facility's patients. The citation of a Class II violation shall specify the time within which the violation is required to be corrected. Each day such violation shall exist after expiration of said time shall be considered a subsequent violation.

C. Class III violations are those that are not classified as Class I or II in these regulations or those that are against the best practices as interpreted by the Department. The citation of a Class III violation shall specify the time within which the violation is required to be corrected. Each day such violation shall exist after expiration of said time shall be considered a subsequent violation.

D. Class I and II violations are indicated by notation after each applicable section, i.e., (I) or (II). Violations of sections that are not annotated in that manner denote Class III violations.

E. In arriving at a decision to penalize a facility, the Department will consider the following factors: specific conditions and their impact or potential impact on health, safety or well-being; efforts by the facility to correct; overall conditions; history of compliance; any other pertinent conditions that may be applicable to current statutes and regulations.

F. When a decision is made to assess monetary penalties, the following schedule will be used as a guide to determine the dollar amount:

Frequency of violation of standard within a 24-month period:

MONETARY PENALTY RANGES

FREQUENCY	CLASS I	CLASS II	CLASS III
1st	\$ 200 - 1000	\$ 100 - 500	\$ 0
2nd	500 - 2000	200 - 1000	100 - 500
3rd	1000 - 5000	500 - 2000	200 - 1000
4th	5000	1000 - 5000	500 - 2000
5th	5000	5000	1000 - 5000
6th	5000	5000	5000

G. Any facility that is dissatisfied with Department decisions may request a hearing pursuant to the Administrative Procedures Act.

PART II ADMINISTRATION AND MANAGEMENT.

Section 201. Licensee. (II)

A. The licensee of each facility has the ultimate responsibility for the overall operation of the facility. Every facility shall be organized, equipped, staffed and administered to provide adequate care for each person admitted.

B. Policies and procedures for operation of the facility shall be formulated and reviewed annually by the licensee of the facility. They shall include but not be limited to:

1. Purpose of the facility, to include scope and quality of services;
2. Ensuring compliance with all relevant federal, state, and local laws that govern operations of the facility;
3. Personnel policies and procedures, to include inservice training requirements;
4. The person to whom responsibility for operation and maintenance of the facility is delegated and methods established by the licensee for holding such individual responsible;
5. Provision for annual review and evaluation of the facility's policies, procedures, management and operation;
6. Provision for a facility-wide quality improvement program to evaluate patient care. The program shall be ongoing, have statistical summaries, and have a written plan of implementation.

7. Patient rights and grievance procedures;
8. Functional safety and maintenance policies and procedures;
9. Incident reporting;
10. Consent must be informed, shall be obtained prior to the procedure, and shall include evidence of an explanation by a physician or allied health professional of the services offered and potential risks. Documentation of the informed consent must be filed in the patient's record.

Section 202. Administrator. (II)

An administrator shall be selected by the licensee and shall have the ability and authority to manage and administer the facility. Any change in the position of the administrator shall be reported immediately by the licensee to the Department in writing. An individual shall be appointed in writing to act in the absence of the administrator.

Section 203. Administrative Records.

The following administrative documents and references shall be on file in the facility:

- A. Current policies and procedures concerning the operation of the facility; (II)
- B. Current memorandums of agreement and credentialing documentation.
- C. A current copy of these regulations;
- D. Annual elevator safety inspections, if applicable;
- E. Annual heating, ventilation, and air conditioning inspection report.

Section 204. Personnel. (II)

Each facility shall have a staff that is adequately trained and capable of providing appropriate service and supervision to the patients.

- A. The licensee shall obtain written applications for employment from all employees. The licensee shall obtain and verify information on the application as to education, training, experience, appropriate licensure, if applicable, and health and personal background of each employee.
- B. Prior to performing job duties, all employees, to include volunteers who have direct patient contact within the clinic, shall have tuberculin skin testing conducted unless a previously positive reaction is documented in millimeters. The intradermal (Mantoux) method, using five tuberculin units of stabilized purified protein derivative

(PPD) is to be used. For employees/volunteers who have no documentation of a negative PPD result during the preceding 12 months, then the two-step procedure (one PPD test with negative result followed one to three weeks later by another PPD test) is required to establish a reliable baseline. If employees/volunteers have complete documentation of a negative PPD during the preceding 12 months (may be a single PPD or a two-step PPD), then a single PPD is acceptable to establish the baseline for current employment.

1. Persons with negative tuberculin skin tests who have direct contact with patients shall have an annual tuberculin skin test.
2. There is no need to perform an initial or routine chest X-ray on employees or volunteers with negative tuberculin tests who are asymptomatic.
3. Personnel with a positive reaction to the skin test shall have no patient contact until certified non-contagious by a physician.
4. Employees and volunteers with reactions of 10mm and over to the pre-employment tuberculin test, those new employees/volunteers who have previously-documented positive reactions, those with newly-converted skin tests and those with symptoms suggestive of TB (e.g., cough, weight loss, night sweats, fever, etc.), shall be given a chest X-ray to determine whether TB disease is present. If TB disease is diagnosed, appropriate treatment shall be given and contacts examined.
5. Personnel who are known or suspected to have TB shall be required to be evaluated by a physician and will not be allowed to return to work until they have been certified non-contagious by the physician.
6. Preventive treatment of personnel with new positive reactions is essential, and shall be considered for all infected employees/volunteers who have patient contact, unless specifically contraindicated. Routine annual chest X-rays of persons with positive reactions do not prevent TB and therefore are not a substitute for preventive treatment nor are required.
 - a. Employees and volunteers who complete treatment, either for disease or infection, may be exempt from further routine chest radiographic screening unless they have symptoms of TB.
 - b. Positive reactors who are unable or unwilling to take preventive treatment need not receive an annual chest X-ray. These individuals must be informed of their lifelong risk of developing and transmitting TB to individuals in the institution and in the community. They shall be informed of symptoms which suggest the onset of TB, and the procedure to follow should such symptoms develop.

7. Post-exposure skin tests should be provided for tuberculin negative employees/volunteers within 12 weeks after termination of contact for any suspected exposure to a documented case of pulmonary TB.

8. A person shall be designated in writing at each facility to coordinate TB screening of personnel and any other TB control activities.

C. All professional and allied health professional staff members shall be currently certified with American Red Cross or American Heart Association CPR and capable of recognizing symptoms of distress. A professional or allied health professional staff member who is legally qualified to perform advanced cardiac life support must be present while patients are undergoing abortion procedures/ recovery in the facility. (I)

D. No employee or volunteer of the facility, while afflicted with any infected wounds, boils, sores, or an acute respiratory infection, or any other contagious disease or illness, shall work in any capacity in which there is a likelihood of such person transmitting disease to other individuals.

E. Each facility shall have and execute a written orientation program to familiarize each new staff member with the facility and its policies and procedures, to include, as a minimum, fire safety and other safety measures, medical emergencies, and infection control.

F. Inservice training programs shall be planned and provided for all employees and volunteers to insure and maintain their understanding of their duties and responsibilities. Records shall be maintained to reflect program content and individual attendance. The following training shall be provided at least annually:

1. Infection control, to include as a minimum, universal precautions against blood-borne diseases, general sanitation, personal hygiene such as handwashing, use of masks and gloves, and instruction to staff if there is a likelihood of transmitting a disease to patients or other staff members;

2. Fire protection, to include evacuating patients, proper use of fire extinguishers, and procedures for reporting fires:

3. Confidentiality of patient information and records, and protecting patient rights;

4. Licensing regulations.

G. 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.

H. A personnel file shall be maintained for each employee and for each volunteer. The records shall be completely and accurately documented, readily available, 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 orientation, in-service education, appropriate licensure, if applicable, and TB skin testing.

Section 205. Clinical Staff (II)

A. Physicians, nurses, and allied health professionals shall constitute the clinical staff.

B. The clinical staff shall meet at least quarterly to review and analyze their clinical experiences; minutes shall be maintained of such meetings.

C. Physicians. (I)

1. Abortions shall be performed only by physicians who are licensed to practice medicine in this State and who are properly qualified by training and experience to perform pregnancy termination procedures.

2. The facility shall enter into a signed written agreement with at least one physician board-certified in obstetrics and gynecology (if not one on staff) who has admitting privileges at one or more local hospitals with OB/GYN services to ensure his/her availability to the staff and patients during all operating hours.

3. A physician must remain on the premises until all patients are stable, and are ready for discharge. A physician must sign the discharge order and be readily accessible and available until the last patient has been discharged.

D. Nursing.

1. Nursing care shall be under the supervision of a registered nurse currently licensed in this State.

2. A registered nurse shall be on duty to provide or supervise all nursing care of patients in preparation, during the termination procedure, the recovery period and until discharge by the attending physician.

3. Licensed practical nurses, working under appropriate supervision and direction of a registered nurse, may be employed as components of the nursing staff.

E. Allied health professionals, working under appropriate direction and supervision, may be employed to work only within areas where their competency has been established.

F. If ultrasonography is conducted in the clinic, the procedure shall be conducted by a physician or by an ultrasound technician who shall have documented evidence of completion of a training course in ultrasonography.

Section 206. Consent of the Patient. (I)

A physician shall not perform an abortion without first obtaining a signed and dated consent of the pregnant woman pursuant to the provisions of Section 44-41-30 of the S.C. Code of Laws, 1976, as amended.

Section 207. Abortion Performed Upon Minors. (I)

No person may perform an abortion upon a minor unless consent is obtained pursuant to the provisions of Section 44-41-31 of the S.C. Code of Laws, 1976, as amended.

Section 208. Dissemination of Information. (I)

Clinics must comply with the Woman's Right to Know Act, Section 44-41-310 et seq., of the S.C. Code of Laws, 1976, as amended, and maintain an adequate supply of current printed material from the Department which has not been altered in content.

Section 209. Patients' Rights (II)

A. The facility shall have written policies and procedures to assure the individual patient the right to dignity, privacy, safety, and to register complaints with the Department. These patients' rights shall be approved by the licensee.

B. Each facility shall display in a conspicuous place a copy of the patients' rights. In addition, a copy signed by the patient shall be included in the medical record.

PART III PATIENT CARE.

Section 301. Policies and Procedures. (II)

Abortion clinics shall not serve patients whose needs exceed the resources and/or capabilities of the clinic. The facility shall formulate and adhere to written patient care policies and procedures designed to ensure professional and safe care for patients, to include but not limited to:

- A. Admission criteria;
- B. Physician and nurse responsibilities for the services offered;
- C. Specific details regarding the pre-operative procedures performed, to include:
 - 1. History and physical examination, to include verification of pregnancy, estimation of gestational age, identification of any preexisting conditions or complications;
 - 2. Special examinations, lab procedures, and/or consultations required, to include ultrasonography required when gestational age is clinically estimated to be equal to or more than 14 weeks from the first day of the last menstrual period as established by the physician's performance of a bimanual physical examination. Policies and procedures should also indicate that ultrasound is recommended when gestational age is equal to or more than 12 weeks from the first day of the last menstrual period as established by the performance of a bimanual physical examination or if the physical examination and clinical evidence is inconclusive as to the gestational age.
- D. The actual abortion procedure, to include the use of:
 - 1. IV's;
 - 2. Fluids;
 - 3. Analgesia/anesthesia. General anesthesia shall be administered only by a certified registered nurse anesthetist, anesthesiologist, or dentist anesthetist or physician anesthetist.
 - 4. Tissue examination/disposal.
- E. Post-procedure care/recovery room procedures to include emergency care;
- F. Provisions for the education of patient, family and others, as appropriate in pre and post-procedure care;
- G. Plans for follow-up of patient after discharge from the facility, to include arrangements for post-operative visit, and specific instructions in case of emergency;
- H. Management and appropriate referral of high-risk conditions;
- I. Transfer of patients who, during the course of pregnancy termination are determined to need care beyond that of the facility;

J. Infection control and sanitation procedures to include duties and responsibilities of the infection control committee that shall include the development and implementation of specific patient care and administrative policies aimed at investigating, controlling and preventing infections in the facility;

K. Registration of fetal death or death certificates, when applicable.

Section 302. Limitation of Services Offered by Abortion Clinics (I)

A. Abortions performed in abortion clinics shall be performed only on patients who are within 18 weeks from the first day of their last menstrual period. Those beyond 18 weeks shall be performed in a hospital. A licensed ambulatory surgical facility that is also licensed as an abortion clinic may perform abortions on patients who are up to 26 weeks after the first day of their last menstrual period.

B. Clinics performing abortions beyond 14 weeks from the first day of the last menstrual period must meet the requirements of Section 309.

Section 303. Pharmaceutical Services. (II)

Pharmaceutical services shall be provided in accordance with accepted professional practice and federal, state and local statutes and regulations.

A. Emergency Drugs:

1. Emergency Kit or Emergency Drugs. Each facility shall maintain an emergency kit or stock supply of drugs and medicines for the use of the physician in treating the emergency needs of patients. This kit or medicine shall be stored in such a manner as to prohibit its access by unauthorized personnel. A listing of contents by drawer or shelf shall be placed on the cabinet or emergency cart to allow quick retrieval. Contents shall correspond with the inventory list. Drugs and equipment must be available within the facility to treat, as a minimum, the following conditions: (I)

- a. Cardiac arrest;
- b. Seizure;
- c. Asthmatic attack;
- d. Allergic reaction;
- e. Narcotic toxicity;
- f. Hypovolemic shock;

g. Vasovagal shock.

2. Drug Reference Sources. Each facility shall maintain reference sources for identifying and describing drugs and medicines.

B. Administering Drugs and Medicines. Drugs and medicines shall not be administered to individual patients or to anyone within or outside the facility except by those authorized by law under orders of a physician duly licensed to prescribe drugs. Such orders shall be in writing and signed personally by the physician who prescribes the drug or medicine.

C. Medicine Storage. Medicines and drugs maintained in the facility for daily administration shall not be expired and shall be properly stored and safeguarded in enclosures of sufficient size that are not accessible to unauthorized persons. Refrigerators used for storage of medications shall maintain an appropriate temperature as determined by the requirements established on the label of medications. A thermometer accurate to +3 degrees Fahrenheit shall be maintained in these refrigerators. Only authorized personnel shall have access to storage enclosures. Controlled substances and ethyl alcohol, if stocked, shall be stored under double locks and in accordance with applicable state and federal laws.

D. Medicine Preparation Area. Medicines and drugs shall be prepared for administration in an area that contains a counter and a sink. This area shall be located in such a manner as to prevent contamination of medicines being prepared for administration.

E. Controlled Substances Registration.

1. If a stock of controlled drugs is to be maintained at the facility, a physician on the clinic staff shall obtain an individual practitioner South Carolina Controlled Substances Registration and a Drug Enforcement Administration (DEA) Registration as registrant for the facility. This physician shall be responsible for the proper safeguarding and handling of controlled substances within the facility, and shall be certain that all possible control measures are observed and that any suspected diversion or mishandling of controlled substances is reported immediately to the Bureau of Drug Control of the Department.

2. With a written power of attorney, this physician may grant permission to any other physician who possesses an individual practitioner South Carolina Controlled Substances Registration and a DEA Registration to administer, order for administration, or dispense any controlled substances maintained by the facility.

F. Records. Records shall be kept of all stock supplies of controlled substances giving an accounting of all items received and/or administered.

G. Poisonous Substances. All poisonous substances must be plainly labeled and kept in a cabinet or closet separate from medicines and drugs to be prepared for administration. (I)

Section 304. Laboratory Services. (II)

A. 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).

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.

B. Prior to the procedure, laboratory tests shall include a recognized urine pregnancy test unless the physician identifies fetal heart beats or fetal movements on physical examination. If positive, the following additional tests are required:

1. Urinalysis including albumin and glucose examination;
2. Hematocrit or hemoglobin;
3. Determination of Rh factor (including the Du variant when the patient is Rh negative); Rh (D) immune globulin (human) shall be administered, prior to discharge, to patients who are determined to be Rh negative.

C. Other laboratory tests to be administered:

1. Testing for Chlamydia and gonorrhea;
2. Syphilis serology shall be offered;
3. A Papanicolaou procedure shall be offered;
4. Referral for chest X-ray, if indicated;
5. Other tests as deemed appropriate by the physician.

D. Aspirated tissues shall be examined to verify that villi or fetal parts are present; if villi or fetal parts cannot be identified with certainty, the tissue specimen shall be sent for further pathologic examination and the patient alerted to the possibility of an ectopic pregnancy.

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

F. If a patient is bleeding profusely and a transfusion of red blood cells is necessary, she should be administered fluids and transported immediately to a hospital that routinely performs crossmatches and transfuses patients.

G. All laboratory supplies shall be monitored for expiration dates, if applicable.

H. Products of conception resulting from the abortion procedure must be managed in accordance with requirements for pathological waste pursuant to Department R.61-105, Infectious Waste Management Regulations. All contaminated dressings and/or similar waste shall be properly disposed of in accordance with R.61-105.

Section 305. Emergency Care. (I)

A. All staff and/or consulting physicians shall have admitting privileges at one or more local hospitals that have appropriate obstetrical/gynecological services or shall have in place documented arrangements approved by the Department for the transfer of emergency cases when hospitalization becomes necessary.

B. Equipment and services shall be provided to render emergency resuscitative and life-support procedures pending transfer of the patient to a hospital.

C. The facility shall inform, in writing, the local ambulance service which provides emergency care and transport of patients, of the location of the facility, and the nature of medical problems which may result from abortions.

Section 306. Equipment and Supplies. (II)

There shall be appropriate equipment and supplies maintained for the patients to include but not limited to:

A. A bed or recliner suitable for recovery;

B. Oxygen with flow meters and masks or equivalent; (I)

C. Mechanical suction; (I)

D. Resuscitation equipment to include, as a minimum, resuscitation bags and oral airways; (I)

E. Emergency medications, intravenous fluids, and related supplies and equipment; (I)

F. A clock with a sweep second hand;

- G. Sterile suturing equipment and supplies;
- H. Adjustable examination light;
- I. Containers for soiled linen and waste materials with covers;
- J. Refrigerator;
- K. Appropriate equipment for the administering of general anesthesia, if applicable.

Section 307. Consultation. (II)

Arrangements shall be made for consultation or referral services in the specialties of obstetrics/gynecology, anesthesiology, surgery, psychiatry, psychology, clinical pathology and pathology, clergy, and social services, as well as any other indicated field, to be available as needed.

Section 308. Quality Improvement. (II)

A. The facility shall establish and implement a written plan for a quality improvement program for patient care. The plan shall specify the individual responsible for coordinating the quality improvement program and shall provide for ongoing monitoring of staff and patient care services.

B. There shall be an ongoing process for monitoring and evaluating patient care services, staffing, infection prevention and control, housekeeping, sanitation, safety, maintenance of physical plant and equipment, patient care statistics, and discharge planning services.

C. Evaluation of patient care throughout the facility shall be criteria-based, so that certain actions are taken or triggered when specific quantified, predetermined levels of outcomes or potential problems are identified.

D. The quality improvement process shall incorporate quarterly review of a minimum of five per cent of medical records of patients undergoing procedures during a given quarter, but not less than five records shall be reviewed.

E. The quality improvement process shall include evaluation by patients of care and services provided by the facility. If the families of patients are involved in the care and services provided by the facility, the quality improvement process shall include a means for obtaining input from families of patients.

F. The administrator shall review the findings of the quality improvement program to ensure that effective corrective actions have been taken, including as a minimum, policy revisions, procedural changes, educational activities, and follow-up on recommendations, or that additional actions are no longer indicated or needed.

G. The quality improvement program shall identify and establish indicators of quality care, specific to the facility, that shall be monitored and evaluated.

H. The results of the quality improvement program shall be submitted to the licensee for review at least annually and shall include at least the deficiencies found and recommendations for corrections or improvements. Deficiencies that jeopardize patient safety shall be reported immediately in writing to the licensee.

Section 309. Requirements for Clinics Performing Abortions Beyond 14 Weeks. (I)

Clinics which perform abortions beyond 14 weeks from the first day of the last menstrual cycle shall, in addition to those requirements in all other sections of this regulation, have the following in place:

- A. Physicians shall be board-certified or a candidate for board-certification in obstetrics and gynecology, general surgery, or family practice;
- B. Physicians shall have admitting privileges at one or more local hospitals that have appropriate obstetrical/gynecological services;
- C. Laryngoscopes, endotracheal tubes, and defibrillator;
- D. Laboratory tests/procedures shall include:
 - 1. White blood count and determination of blood type;
 - 2. Sickle cell, when indicated;
 - 3. Ultrasonogram.

PART IV MEDICAL RECORDS AND REPORTS.

Section 401. Medical Records. (II)

Medical records shall be maintained for all patients examined or treated in the clinic. The records shall be completely and accurately documented, readily available, and systematically organized to facilitate the compilation and retrieval of information. All information shall be centralized in the patient's medical record. All entries shall be legibly written or typed, dated and signed.

- A. The record shall include as a minimum the following information:
 - 1. A face sheet with patient identification data, to include but not be limited to: name, address, telephone number, social security number, date of birth, father's and mother's names when patient is a minor, husband's name, and name, address and telephone number of person to be notified in the event of an emergency;

2. Signed consent for the procedure;
3. Date of initial examination;
4. Date of abortion;
5. Referring and attending physicians' names and phone numbers, if applicable;
6. Complete medical history to include medications currently being taken;
7. Physical examination, to the extent necessary to determine the health status of the patient, within 15 days of the procedure, including detail of findings of pelvic examination and estimated gestational age, according to the first day of the last menstrual period;
8. Results of diagnostic tests and/or examinations, e.g., X-ray, electrocardiography, clinical laboratory, pathology, consultations, ultrasound;
9. Pre-operative diagnosis;
10. Counselor's notes;
11. Physician's orders;
12. Complete record of abortion procedure to include:
 - a. Vital signs, i.e., temperature, pulse, respiration, and blood pressure, prior to and following the procedure;
 - b. Name of procedure performed;
 - c. Anesthetic agent utilized;
 - d. Name of attending physician performing the procedure;
 - e. Names of clinical assistants in attendance, to include other physicians, physician's assistants, anesthesiologists, nurses, or specially-trained technicians;
 - f. Signature of physician performing the procedure.
13. Nurses' notes;
14. Progress notes to include a post-anesthesia note if general anesthesia is utilized;
15. Attending physician's description of gross appearance of tissue removed;

16. Final diagnosis;
17. Condition on discharge;
18. Post-op orders and follow-up care;
19. Documented verification that the woman has been presented printed materials as required in the Woman's Right-to-Know Act;
20. In the case of an unemancipated minor or mentally incompetent person, a copy of the court order or written consent authorizing the abortion.

B. The attending physician must complete and sign the medical record within 72 hours following discharge.

Section 402. Records Storage.

All records shall be treated as confidential and shall be stored in a safe location for a minimum of 10 years. When records are stored in a location other than the clinic, and upon closure of the clinic, for any reason, the medical records shall be stored in a safe location for that minimum period, with the Department informed of that location. The medium in which the records are stored, e.g., optical disk, microfiche, is a facility decision.

Section 403. Reports. (II)

A. The following shall be reported to Vital Records and Public Health Statistics of this Department:

1. Any abortion performed, to be reported by the performing physician on the standard form for reporting abortions, within seven days after the abortion is performed;
2. A fetal death when the fetus has completed or passed the age or weight requiring a report, pursuant to the standards in Department R. 61-19, Vital Statistics.

B. A record of each accident or incident occurring in the facility which involves patients, staff, or visitors, including medication errors and adverse drug reactions, shall be prepared immediately. Accidents or incidents resulting in serious injury shall be reported, in writing, to the Department within 10 days of the occurrence; if a death occurs, other than a fetal death, it shall be reported to the Department not later than the next Department work day (Monday through Friday). Accidents and incidents that must be reported include, but are not limited to:

1. Those leading to hospitalization;

2. Those leading to death, other than a fetal death;
3. Adverse drug reactions.

PART V FUNCTIONAL SAFETY AND MAINTENANCE. (II)

Section 501. Policies and Procedures.

- A. Written policies and procedures shall be developed to enhance safety within the facility and on its grounds and to minimize hazards to patients, staff and visitors.
- B. The policies and procedures shall include, but not be limited to:
 1. Safety rules and practices pertaining to personnel, equipment, gases, liquids, drugs, supplies and services;
 2. Provisions for reporting and investigating accidental events regarding patients, visitors and personnel and corrective action taken;
 3. Provisions for disseminating safety-related information to employees and users of the facility;
 4. Provision for syringe and needle handling and storage.
 5. Provisions for managing infectious waste from generation to disposal according to Regulation 61-105.

Section 502. Disaster Preparedness.

- A. The facility shall have posted, in conspicuous places throughout the facility, a plan for evacuation of patients, staff, and visitors in case of fire or other emergency. (I)
- B. A facility that participates in a community disaster plan shall establish plans, based on its capabilities, to meet its responsibilities for providing emergency care.

Section 503. Maintenance.

- A. Facility Maintenance. A facility's structure, its component parts, and all equipment such as elevators, furnaces and emergency lights, shall be kept in good repair and operating condition. Areas used by patients shall be maintained in good repair and kept free of hazards. All wooden surfaces shall be sealed with non-lead-based paint, lacquer, varnish, or shellac that will allow sanitization.
- B. Equipment 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 insure 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 returning it to service. Records shall be maintained on each piece of equipment to indicate its history of testing and maintenance.

PART VI INFECTION CONTROL AND SANITATION. (II)

Section 601. General.

Policies and procedures shall be established in writing to assure safe and aseptic treatment and protection of all patients and personnel against cross-infection.

Section 602. Sterilization Procedures.

A. Adequate space shall be provided for storage, maintenance and distribution of sterile supplies and equipment.

B. Sterile supplies and equipment shall not be mixed with unsterile supplies, and shall be stored in dust-proof and moisture-free units. They shall be properly labeled.

C. Sterilizing equipment of appropriate type shall be available and of adequate capacity to properly sterilize instruments and materials. The sterilizing equipment shall have approved control and safety features.

1. There must be documentation of each load run daily. A biological test of the autoclave shall be run daily and the results maintained on a log.

2. Each separate package of instruments to be sterilized must have internal and external chemical indicators.

3. The accuracy of instrumentation and equipment shall be provided by periodic calibration and/or preventive maintenance as necessary, but not less than annually, and a log maintained.

D. The policies and procedures shall indicate how the shelf life of a packaged sterile item is determined. Methods approved for use are:

1. Date of expiration being marked on the item; or

2. Event-related, i.e., day-to-day expiration, utilizing such wording as, "sterile unless the integrity of the package is compromised."

Section 603. Linen and Laundry.

A. An adequate supply of clean linen or disposable materials shall be maintained in order to insure change of linen on procedure tables between patients.

B. Provisions for proper laundering of linen and washable goods shall be made. Soiled and clean linen shall be handled and stored separately. Storage shall be in covered containers.

C. A sufficient supply of cloth or disposable towels shall be available so that a fresh towel can be used after each handwashing. Towels shall not be shared.

Section 604. Housekeeping.

A. General. A facility shall be kept neat, clean and free from odors. Accumulated waste material must be removed daily or more often if necessary. There must be frequent cleaning of floors, walls, ceilings, woodwork, and windows. The premises must be kept free from rodent and insect infestation. Bath and toilet facilities must be maintained in a clean and sanitary condition at all times.

B. Cleaning materials and supplies shall be stored in a safe manner. All harmful agents shall be locked in a closet or cabinet used for this purpose only.

C. Dry sweeping and dusting of walls and floors are prohibited.

Section 605. Refuse and Waste Disposal.

A. All garbage and waste shall be collected, stored and disposed of in a manner designed to prevent the transmission of disease. Containers shall be washed and sanitized before being returned to work areas. Disposable type containers shall not be reused.

B. Containers for garbage and refuse shall be covered and stored outside and placed on an approved platform to prevent overturning by animals, the entrance of flies or the creation of a nuisance. All solid waste shall be disposed of at sufficient frequencies in a manner so as not to create a rodent, insect or other vermin problem.

C. Immediately after emptying, containers for garbage shall be cleaned.

D. All waste meeting the definition of "infectious waste" as defined in Regulation 61-105 must be managed according to the requirements of that regulation.

Section 606. Outside Areas.

All outside areas, grounds and/or adjacent buildings shall be kept free of rubbish, grass, and weeds that may serve as a fire hazard or as a haven for insects, rodents and other pests. Outside stairs, walkways, ramps and porches shall be maintained free from accumulations of water, ice, snow and other impediments.

PART VII FIRE PROTECTION AND PREVENTION. (I)

Section 701. Fire-fighting Equipment and Systems.

A. All facilities located outside a fire protected area shall have a contract with the nearest fire department.

B. An evacuation plan shall be posted in prominent places and staff members shall be trained as part of their responsibilities to guide patients to the designated exits.

C. All fire protection and alarm systems and other fire fighting equipment shall be inspected and tested at least once each year, and more often if necessary to maintain them in serviceable condition.

D. Fire extinguishers of the proper type shall be installed in accordance with NFPA 10 (National Fire Protection Association) 10 requirements or as otherwise directed by fire authorities.

1. Fire extinguishers shall be kept in condition for instant use and shall be inspected monthly by facility staff with the date of inspection recorded on a tag affixed to the extinguisher.

2. Fire extinguishers shall be inspected and/or serviced annually by personnel licensed or certified to perform fire extinguisher servicing. Servicing/inspection records shall be kept on the fire extinguishers.

E. No portable electric, open flame, or unvented heaters shall be allowed in the facility.

F. Fire Drills.

1. A fire drill shall be conducted at least once every three months. New facilities shall conduct a fire drill within the first 48 hours of operation. Each employee shall participate in a fire drill at least twice each year.

2. Records of drills shall be maintained to report the date, time, description, and evaluation of the drill, to include the names of participating staff and time for total evacuation.

G. Corridor Obstructions. All corridors and other means of egress or exit from the building shall be maintained clear and free of obstructions.

H. Corridor and Stairway Illumination. Corridors, stairs and other means of egress shall be lighted at all times with a minimum of one foot-candle at finish floor level along the path of travel.

Section 702. Alarms.

A fire alarm system shall be provided in accordance with the provisions of NFPA 72. The fire alarm system shall be tested monthly and each detector tested annually. Records of all tests shall be retained for at least one year.

Section 703. Gas Storage.

Gases (flammable and nonflammable) shall be handled and stored in accordance with the provisions of applicable NFPA codes.

PART VIII DESIGN AND CONSTRUCTION.

Section 801. General.

Every facility must be planned, designed and equipped to provide adequate facilities for the care and comfort of each patient.

Section 802. Local and State Codes and Standards. (II)

A. Facilities shall comply with pertinent local and state laws, codes, ordinances and standards with reference to design and construction. Abortion clinics are categorized as a "business occupancy" as defined in the Standard Building Code. No facility will be licensed unless the Department has assurance that responsible local officials have approved the facility.

B. The Department uses as its basic codes: the Standard Building Code, Standard Plumbing Code, Standard Mechanical Code, and National Electrical Code. Buildings designed in accordance with the above mentioned codes will be acceptable to the Department, provided, however, that the requirements set forth in this regulation are also met.

Section 803. Submission of Plans and Specifications.

A. New Buildings, Additions or Major Alterations to Existing Buildings. (II)

1. When construction is contemplated either for new buildings, additions or major alterations to existing buildings, the facility must contact the Division of Health Facilities Construction of this Department to discuss code and regulation requirements that apply to that project. Plans and specifications shall be submitted to the Department for review. Where the Standard Building Code or other regulations require fire-rated walls or other fire-rated structural elements, these plans and specifications shall be prepared by an architect registered in the State of South Carolina and shall bear his/her seal.

2. All plans shall be drawn to scale with the title and date shown thereon. Construction work shall not be started until approval of the final drawings or written permission has been received from the Department. Any construction changes from the approved documents require approval by the Department.

B. Preliminary submission shall include the following:

1. Plot plan showing size and shape of entire site; orientation and location of proposed building; location and description of any existing structures, adjacent streets, highways, sidewalks, railroads, et cetera, properly designated; size, characteristics and location of all existing public utilities, including information concerning water supply available for fire protection;

2. Floor plans showing overall dimensions of buildings; locations, size and purpose of all rooms; location and size of doors, windows and other openings with swing of doors properly indicated; locations of smoke partitions and firewalls; locations of stairs, elevators, dumbwaiters, vertical shafts and chimneys;

3. Outline specifications listing a general description of construction including interior finishes and mechanical systems.

C. Final submission shall include the following: Complete working drawings and contract specifications, including layouts for plumbing, air conditioning, ventilation and electrical work and complete fire protection layout, if applicable.

D. In construction delayed for a period exceeding 12 months from the time of approval of final submission, a new evaluation and/or approval is required.

E. One complete set of as-built drawings shall be filed with DHEC.

Section 804. Licensure of Existing Structures. (II)

When an existing structure is contemplated for licensure it must meet the same building code requirements as a "new" facility (see Section 803.A). If an expansion or renovation to an existing facility is contemplated, the facility must contact the Division of Health Facilities Construction of this Department to discuss code and regulatory requirements that apply to that project. The following shall be submitted to the Department:

A. If the physical dimensions of the building are affected, a plot plan in accordance with Section 803.B.1;

B. A floor plan in accordance with Section 803.B.2;

C. Description of construction including outside walls, partitions, floor, ceiling and roof. The method of heating and cooling shall also be included.

NOTE: Those existing abortion clinics that have been identified by the Department, through submission of regular reports of abortions performed, may be licensed in their current buildings. However, upon initial licensure, these facilities will be required to submit a plan that will bring them into full compliance with this chapter within two years from date of licensure.

Section 805. Minor Alterations in Licensed Facilities.

When alterations that involve construction that may affect walls, ceilings, floors, or fire and life safety are contemplated, preliminary drawings and specifications, accompanied by a narrative completely describing the proposed work, shall be submitted to the Department for review and approval to insure that the proposed alterations comply with current safety and building standards and determine if an architect need be involved.

Section 806. Location.

A. Transportation. The facility must be served by roads that are passable at all times and are adequate for the volume of expected traffic.

B. Parking. The facility shall have parking space to reasonably satisfy the needs of patients, staff, and visitors.

C. Communications. A telephone must be provided on each floor used by patients and additional telephones or extensions must be provided, as required, to summon help in case of fire or other emergency. Pay station telephones are not acceptable for this purpose.

Section 807. Physical Facilities.

A. An adequate number of examination/procedure rooms shall be provided. A procedure room shall be sized, shaped, and arranged to allow unfettered movement for all persons involved in the procedure.

B. Each procedure room shall be provided:

1. A suitable gynecological procedure table;

2. Equipment necessary to treat patients for hemorrhage, shock, cardiac arrest and other emergencies (an emergency "crash" cart in the immediate vicinity is acceptable); (I)

C. An area shall be provided for use by nurses in preparing medications for patients and keeping patient medical records. A room or cabinets shall be provided for storing medications and shall be kept locked except when medications are being prepared for administering. Narcotics shall be double-locked. An adequate supply of drugs shall be on hand at all times.

D. An adequate number of recovery room(s) or area(s) shall be provided. There shall be clear space on both sides and at the foot of each recovery bed/recliner to allow unencumbered movement by staff and patients.

1. There shall be a toilet room immediately accessible from the recovery area. This room shall contain a commode with grab bars or recessed hand-holds and handwashing lavatory, operable without the use of hands, soap dispenser with soap, and paper towel dispensers with paper towels, or hot air dryer;
2. There shall be a signal system for each patient bath and toilet that shall include an audible alarm that can be heard and location identified by staff;
3. There shall be a readily accessible safe and sanitary storage area for patients' clothing and personal effects;
4. There must be provisions to afford privacy upon request of a patient, e.g., curtains, screens, private room.

E. A room for the temporary storage of soiled linen and waste in covered containers shall be provided. This room shall be provided with at least 10 air changes per hour with all air continuously exhausted to the outside.

F. There must be an area to accommodate the sterilization procedures as described in Section 602. There shall be sufficient surgical instruments sterilized and available for each patient who presents herself for abortion. The area shall be arranged to prevent cross traffic of clean and dirty material. Air flow in this area shall be from the "clean" area toward the "dirty" area.

G. Suitable dressing room space shall be provided for physicians and nursing staff. Scrub facilities shall be provided and located conveniently to the procedure room(s).

H. Procedure and recovery room(s) shall be located on an exit access corridor that provides unimpeded, rapid access to an exit of the building. This exit must accommodate emergency transportation vehicles and equipment.

I. In multi-storied buildings where the facility is not located on the floor of entry to/exit from the building, there must be at least one elevator that serves the clinic floor(s). The elevator must accommodate emergency transportation equipment.

J. Adequate fixed or portable work surface areas shall be maintained for use in each procedure room.

K. Doors providing access into the facility and procedure room(s) shall be at least 36 inches wide to accommodate maneuvering of ambulance stretchers and wheelchairs and other emergency equipment. All corridors shall be at least 48 inches wide.

L. Heating and ventilation.

1. Lighting, heating, and ventilation systems shall comply with local and state codes. There shall be approved equipment capable of maintaining a minimum temperature of 72 degrees Fahrenheit and a maximum temperature of 76 degrees Fahrenheit in patient areas.

2. The procedure room(s) and the recovery room(s) shall be provided a minimum of six air changes per hour. Air supplied to all areas shall be filtered through filters of at least 25 percent efficiency rating.

3. Mechanically operated systems shall be used to supply air to and exhaust air from soiled workrooms or soiled storage areas, janitor's closets, toilet rooms, and from spaces that are not provided with operable windows or outside doors.

M. The entrance shall be at grade level or above, be sheltered from the weather, and accommodate wheelchairs.

N. There shall be adequate storage areas for supplies and other storage. Sterile supplies shall be stored separate from other supplies.

O. One or more janitor's closets shall be provided throughout the facility as required to maintain a clean and sanitary environment. Each shall contain a floor receptor or service sink and storage space for housekeeping equipment and supplies.

P. A clean work area shall contain space for handwashing and clean storage and may include clean linen storage.

Q. There shall be at least two exits remote from each other.

R. Items such as drinking fountains, machines, and portable equipment or any other items shall not be located in the required exit corridors to restrict corridor traffic.

S. Thresholds and expansion joint covers shall be made sufficiently flush with the floor surface to accommodate wheeled service carts, wheelchairs, gurneys, etc.

T. All corridor glazing materials that extend within 18 inches of the floor shall be of safety glass, plastic, wireglass, or other material that will resist breaking and will not create dangerous cutting edges when broken. Safety glass or plastic glazing materials shall be used for any shower doors or bath enclosures.

U. Cubicle curtains and draperies shall be noncombustible or rendered flame retardant.

V. Wall finishes shall be washable and, in the immediate area of plumbing fixtures, shall be smooth and moisture resistant.

W. Wall bases in soiled equipment and material workrooms and other areas that are frequently subject to wet cleaning methods shall be tightly sealed and constructed without voids that can harbor insects.

X. Floor and wall penetrations by pipes, ducts, and conduits shall be tightly sealed to minimize entry of rodents and insects. Joints of structural elements shall be similarly sealed.

Y. Interior finish materials shall comply with the Standard Building Code requirements for "business occupancy."

Z. Adequate space shall be provided for reception, waiting, interviewing, administrative, and business office functions. Space provided for interviewing and admitting shall be located and designed to provide privacy.

Section 808. Water Supply and Plumbing. (II)

A. Water Supply. Water shall be obtained from a community water system and shall be distributed to conveniently located taps and fixtures throughout the facility and shall be adequate in volume and pressure for all purposes including fire fighting. Patient and staff handwashing lavatories shall be supplied with hot water that shall be thermostatically controlled to a temperature between 100 and 125 degrees Fahrenheit.

B. Plumbing.

1. All plumbing material and plumbing systems or parts thereof installed shall meet the minimum requirements of the Standard Plumbing Code.

2. All plumbing shall be installed in such a manner as to prevent back siphonage or cross-connections between potable and non-potable water supplies. There shall be, at a minimum, an approved double-check assembly on the water supply to the facility.

Section 809. Emergency Power and Lighting Requirements.

A. The facility shall be equipped with automatic emergency power adequate to maintain the operation of lighting for procedure rooms, egress, fire detection equipment, and alarms. (I)

B. There shall be sufficient safe lighting for all activities, including suitable lighting for corridors. (II)

PART IX PREREQUISITES FOR INITIAL LICENSURE.

Prior to admission of patients to, and issuance of a license for new facilities or additional procedure rooms, the following actions must be accomplished:

A. Plans and construction must be approved by the Division of Health Facilities Construction of this Department.

B. The facility shall submit a completed application for license on forms that shall be furnished by the Division of Health Licensing. The following documents shall be submitted with the application:

1. Final construction approval of both water and wastewater systems by the appropriate District Environmental Quality Control Office of this Department (includes satisfactory laboratory reports of water samples).

2. Approval from the appropriate building official stating that all applicable local codes and ordinances have been complied with.

a. If the facility is located within town or city limits, approval by the local fire chief stating that all applicable requirements have been met, or

b. If the facility is located outside town or city limits, a written letter of agreement with the nearest fire department that will provide protection and respond in case of fire at the facility shall be obtained. This letter shall indicate that they have the equipment, personnel, and/or agreements with other departments to adequately respond to this type of facility.

3. Certification and laboratory test reports, provided by the manufacturer or supplier, that all carpeting purchased by the facility meets the requirements of the Standard Building Code.

4. Certification by the contractor that only the carpeting described in B.3 above was installed in the facility.

5. Certification by the manufacturer or supplier that all drapes and cubicle curtains purchased by the facility are flame or fire resistant or retardant.

6. Certification by the owner or contractor that only materials described in B.5 above were installed.

7. Certification by the manufacturer or supplier that all wall covering materials purchased by the facility are fire or flame resistant or retardant.

8. Certification by the contractor that only the materials described in 7 above were installed.

9. Certification by the engineer that all fire alarm and smoke detection systems have been installed according to plans and specifications, have been tested and operate satisfactorily.

10. Certification by the contractor that the automatic sprinkler system, if required or installed, has been completed and tested in accordance with the approved plans and specifications and NFPA No. 13. Include a copy of the approval letter of the sprinkler shop drawings.

11. Certification that all medical gas systems have been properly installed and tested.

C. The facility must register as an infectious waste generator as outlined in Regulation 61-105.

D. Required personnel must be employed, available, trained, and capable of performing their duties.

E. The Division of Health Licensing shall inspect the facility and require compliance with these regulations.

F. The facility must pay the required licensing fee.

PART X GENERAL.

Conditions arising that have not been addressed in these regulations shall be managed in accordance with the best practices as interpreted by the Department.