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**SENATE BILL NO. 839**

Offered January 12, 2005

Prefiled January 10, 2005

*A BILL to amend and reenact § 32.1-123 of the Code of Virginia and to amend the Code of Virginia by adding in Chapter 5 of Title 32.1 an article numbered 1.01, consisting of sections numbered 32.1-137.01 through 32.1-137.06, relating to regulation of abortion clinics; delayed effective date.*

Patrons—Cuccinelli and Bolling

Referred to Committee on Education and Health

**Be it enacted by the General Assembly of Virginia:**

**1. That § 32.1-123 of the Code of Virginia is amended and reenacted, and that the Code of Virginia is amended by adding in chapter 5 of Title 32.1 an article numbered 1.01, consisting of sections numbered 32.1-137.01 through 32.1-137.06 as follows:**

§ 32.1-123. Definitions.

As used in this article unless a different meaning or construction is clearly required by the context or otherwise:

"Certified nursing facility" means any skilled nursing facility, skilled care facility, intermediate care facility, nursing or nursing care facility, or nursing home, whether freestanding or a portion of a freestanding medical care facility, that is certified as a Medicare or Medicaid provider, or both, pursuant to § 32.1-137.

"Class I violation" means failure of a nursing home or certified nursing facility to comply with one or more requirements of state or federal law or regulations which creates a situation that presents an immediate and serious threat to patient health or safety.

"Class II violation" means a pattern of noncompliance by a nursing home or certified nursing facility with one or more federal conditions of participation which indicates delivery of substandard quality of care but does not necessarily create an immediate and serious threat to patient health and safety. Regardless of whether the facility participates in Medicare or Medicaid, the federal conditions of participation shall be the standards for Class II violations.

"Hospital" means any facility licensed pursuant to this article in which the primary function is the provision of diagnosis, of treatment, and of medical and nursing services, surgical or nonsurgical, for two or more nonrelated individuals, including hospitals known by varying nomenclature or designation such as sanatoriums, sanitariums and general, acute, rehabilitation, chronic disease, short-term, long-term, outpatient surgical, and inpatient or outpatient maternity hospitals.

*In addition to the facilities defined as hospitals above, any clinic or other facility performing 25 or more abortions per year shall be designated as a category of outpatient surgical hospital and shall be subject to the requirements of Article 1.01 (§ 32.1-137.01 et seq.) of this chapter.*

"Immediate and serious threat" means a situation or condition having a high probability that serious harm or injury to patients could occur at any time, or already has occurred, and may occur again, if patients are not protected effectively from the harm, or the threat is not removed.

"Inspection" means all surveys, inspections, investigations and other procedures necessary for the Department of Health to perform in order to carry out various obligations imposed on the Board or Commissioner by applicable state and federal laws and regulations.

"Nursing home" means any facility or any identifiable component of any facility licensed pursuant to this article in which the primary function is the provision, on a continuing basis, of nursing services and health-related services for the treatment and inpatient care of two or more nonrelated individuals, including facilities known by varying nomenclature or designation such as convalescent homes, skilled nursing facilities or skilled care facilities, intermediate care facilities, extended care facilities and nursing or nursing care facilities.

"Nonrelated" means not related by blood or marriage, ascending or descending or first degree full or half collateral.

"Substandard quality of care" means deficiencies in practices of patient care, preservation of patient rights, environmental sanitation, physical plant maintenance, or life safety which, if not corrected, will have a significant harmful effect on patient health and safety.

**Article 1.01.****Regulation of Abortion Clinics.**

§ 32.1-137.01. Policy and procedures manual; staffing.

A. Each abortion clinic shall develop a policy and procedures manual that shall include provisions

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59 covering the following items:

- 60 1. The types of emergency and elective procedures that may be performed in the facility;
- 61 2. Types of anesthesia that may be used;
- 62 3. Admissions and discharges, including criteria for evaluating the patient before admission and
- 63 before discharge;
- 64 4. Written informed consent of patient prior to the initiation of any procedures; and
- 65 5. Procedures for housekeeping and infection control.

66 A copy of the approved policies and procedures and revisions thereto shall be made available to the

67 licensing agency upon request.

68 B. The owner or his representative shall provide a brief narrative which describes the functional

69 space requirements, staffing patterns, departmental relationships, and other basic information relating to

70 the fulfillment of the institution's objective.

71 The extent (number and type) of the diagnostic, clinical, and administrative facilities to be provided

72 shall be determined by the services contemplated and the estimated patient load as described in the

73 narrative program.

74 C. Each abortion clinic shall enforce at least the following personnel requirements:

75 1. Each abortion clinic shall obtain a criminal history record check, as required of all hospitals

76 pursuant to §32.1-126.02, on any compensated employee not licensed by the Board of Pharmacy whose

77 job duties provide access to controlled substances within the outpatient surgical hospital pharmacy.

78 2. The size and organizational structure of the medical staff shall vary depending on the scope of

79 service.

80 3. Professional and clinical services shall be supervised by a physician licensed to practice medicine

81 or surgery in Virginia.

82 4. Surgical procedures shall be performed by a physician licensed to perform such procedures in

83 Virginia.

84 5. Clinical privileges of physician and nonphysician practitioners shall be clearly defined.

85 6. Credentials, including education and experience, shall be reviewed and privileges identified,

86 established, and approved for each person allowed to diagnose, treat patients or perform surgical

87 procedures in the abortion clinic in accordance with guidelines, policies or bylaws adopted by the

88 governing body and approved by the medical staff.

89 7. No medication or treatment shall be given except on the signed order of a person lawfully

90 authorized by Virginia law.

91 8. Abortion clinic personnel, as designated in medical staff bylaws, rules and regulations, or policies

92 and procedures, may accept emergency telephone and other verbal orders for medication or treatment

93 for abortion clinic patients from physicians and other persons lawfully authorized by Virginia law to

94 give patient orders.

95 9. As specified in the abortion clinic's medical staff bylaws, rules and regulations, or policies and

96 procedures, emergency telephone and other verbal orders shall be committed to writing and signed

97 within a reasonable period of time not to exceed 72 hours by the person giving the order, or, when such

98 person is not available, by another physician or other person authorized to give the order.

99 10. The total number of nursing personnel shall vary depending upon the number and types of

100 patients to be admitted and the types of operative procedures to be performed or the services

101 programmed.

102 11. A registered nurse qualified on the basis of education, experience, and clinical ability shall be

103 responsible for the direction of nursing care provided the patients.

104 12. The number and type of nursing personnel, including registered nurses, licensed practical nurses,

105 and supplementary staff, shall be based upon the needs of the patients and the types of services

106 performed.

107 13. At least one registered nurse shall be on duty at all times while the facility is in use.

108 14. Job descriptions shall be developed for each level of nursing personnel and include functions,

109 responsibilities, and qualifications.

110 15. Evidence of current Virginia licensure or certification shall be on file in the facility.

111 16. The anesthesia service shall be directed by and under the supervision of a physician licensed to

112 practice medicine or surgery in Virginia, in accordance with the regulations of the Board of Medicine.

113 17. The physician responsible for the anesthesia service shall be present for the administration of

114 anesthetics and recovery of patients when any general or major regional anesthetic is used.

115 § 32.1-137.02. Environmental and patient safety.

116 A. The following environmental safety requirements shall be implemented:

117 1. There shall be written procedures to assure safety in storage and use of inhalation anesthetics and

118 medical gases.

119 2. Adequate provisions shall be maintained for the processing, sterilizing, storing, and dispensing of

120 clean and sterile supplies and equipment.

3. Written procedures shall be established for the appropriate disposal of pathological and other potentially infectious waste and contaminated supplies.

4. Applicable state and local codes pertaining to receiving, storage, refrigeration, preparation, and serving of food shall be followed.

B. The following patient safety requirements shall be implemented:

1. Each abortion clinic shall develop a written evacuation plan to assure reasonable precautions are taken to protect patients, employees, and visitors from hazards of fire and other disaster. The evacuation plan shall include a program to acquaint all personnel with evacuation procedures. A copy of the plan and procedures shall be made available to the Department of Health, upon request.

2. Each abortion clinic shall provide emergency service and maintain on the premises adequate monitoring equipment, suction apparatus, oxygen, and related items necessary for resuscitation and control of hemorrhage and other complications.

3. Each abortion clinic shall execute a written agreement that ensures emergency transportation to a licensed general hospital shall be executed with an ambulance service.

4. Each abortion clinic shall execute a written agreement with a general hospital to ensure that any patient of the abortion clinic shall receive needed emergency treatment. The agreement shall be with a general hospital capable of providing full surgical, anesthesia, clinical laboratory, and diagnostic radiology service on 30 minutes notice, which has a physician in the hospital and available for emergency service at all times.

§ 32.1-137.03. Treatment procedures and testing; patient's health records; patients' rights and responsibilities.

A. The following treatment procedures shall be required:

1. Prior to the initiation of any procedure, a medical history and physical examination shall be completed for each patient.

2. Each patient admitted to the abortion clinic shall receive appropriate laboratory testing.

3. Sufficient time shall be allowed between initial examination and initiation of any procedure to permit the reporting and review of laboratory tests by the responsible physician.

4. The diagnosis of pregnancy shall be the responsibility of the physician performing the abortion procedure.

5. Each patient shall be offered appropriate counseling and instruction in the abortion procedure, adoption alternatives, and birth control methods.

6. Each patient shall be observed for post-operative complications under the direct supervision of a registered professional nurse. Recovery room nurses shall have specialized training in resuscitation techniques and other emergency procedures consistent with policies and procedures of the clinic.

7. A physician licensed in Virginia shall be present on the premises at all times during the operative and post-operative period until discharge of the patient.

8. Patients shall be discharged from the recovery only on written order of the attending physician.

9. All tissue removed shall be submitted for histological examination by a pathologist and a written report of his examination provided to the attending physician. The report of findings shall be filed in the patient's health record.

B. An accurate and complete health record shall be maintained on each patient. The record shall contain sufficient information to satisfy the diagnosis or need for any medical or surgical service. It shall include, when applicable, 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. Physician orders;

6. Laboratory tests, pathologist's report of tissue, and radiologist's report of x-rays;

7. Anesthesia record;

8. Operative record;

9. Surgical medication and medical treatments;

10. Recovery room notes;

11. Physicians' and nurses' progress notes;

12. Condition at time of discharge;

13. Patient instructions, preoperative and postoperative; and

14. Names of referral physicians or agencies.

C. In addition to such other federal and state requirements relating to maintaining and disclosing health records, the following requirements shall be implemented:

1. Provisions shall be made for the safe storage of medical records or accurate and legible reproductions thereof.

182 2. All medical records, either original or accurate reproductions, shall be preserved for a minimum  
183 of five years following discharge of the patient.

184 3. Records of minors shall be kept for at least five years after such minor has reached the age of 18  
185 years.

186 4. Birth and death information shall be retained for 10 years.

187 5. Records of abortions and proper information for the issuance of a fetal death certificate shall be  
188 furnished the Division of Vital Records, Virginia Department of Health, within 10 days after the  
189 abortion.

190 6. Where medical evaluation, examination, and referrals are made from a private physician's office,  
191 another hospital, clinic, or medical service, pertinent available records thereof shall be made and  
192 included as a part of the patient's medical record at the time the patient is admitted to the abortion  
193 clinic.

194 D. Each abortion clinic shall establish a protocol relating to the rights and responsibilities of  
195 patients based on Joint Commission on Accreditation of Healthcare Organizations' Standards for  
196 Ambulatory Care (2000 Hospital Accreditation Standards, January 2000). The protocol shall include a  
197 process reasonably designed to inform patients of their rights and responsibilities. Patients shall be  
198 given a copy of their rights and responsibilities upon admission.

199 §32.1-137.04. Infection control and sanitation; fire, electrical, plumbing, water, and sewage safety.

200 A. At least the following procedures for infection control and sanitation shall be implemented:

201 1. All parts of the abortion clinic and its premises shall be kept clean, neat, and free of litter and  
202 rubbish.

203 2. Hazardous cleaning solutions, compounds, and substances shall be labeled, stored in a safe place,  
204 and kept in an enclosed section separate from other materials.

205 3. Each abortion clinic shall make provisions for the cleaning of all linens.

206 4. There shall be distinct areas for the separate storage and handling of clean and soiled linens.

207 5. All soiled linen shall be placed in closed containers prior to transportation.

208 B. Each abortion clinic shall establish a monitoring program for the internal enforcement of all  
209 applicable fire and safety laws and regulations. Adequate fire protection facilities or fire department  
210 services shall be available.

211 C. Policies and procedures shall also be established to minimize the hazards in the use and  
212 operation of all electrical equipment. All electrical appliances used by the abortion clinic shall have the  
213 Underwriters Laboratories label or be approved by the local electrical inspection authority.

214 D. All plumbing material and plumbing systems or parts thereof shall meet the minimum  
215 requirements of the Uniform Statewide Building Code. All plumbing shall be installed in such a manner  
216 as to prevent back-siphonage or cross-connections between potable and nonpotable water supplies.

217 E. Water shall be obtained from an approved water supply system. The water shall be distributed to  
218 conveniently located taps and fixtures throughout the facility and shall be adequate in volume and  
219 pressure for all hospital purposes, including fire fighting.

220 F. Existing and new facilities shall be connected to an approved sewage system. The sanitation,  
221 water supply, sewage, and disposal facilities shall comply with the applicable state and local codes and  
222 ordinances.

223 Pathological and bacteriological wastes, dressings, and other contaminated wastes shall be  
224 incinerated in an approved incinerator or by other methods of disposal as approved by the licensing  
225 agency.

226 G. If the abortion clinic is a physical part of an inpatient hospital and is intended to serve inpatients  
227 as well as outpatients, the relevant requirements of this chapter and the Board's regulations shall be  
228 met.

229 § 32.1-137.05. Other site or structural requirements.

230 A. All construction of new buildings and additions, alterations or repairs to existing buildings for  
231 occupancy as an abortion clinic shall conform to state and local codes, local zoning and building  
232 ordinances, and the Statewide Uniform Building Code requirements applicable to the type of occupancy.  
233 All codes applicable to the abortion clinic shall be noted on the preliminary and working drawings.

234 Conversions of existing buildings to abortion clinic occupancy shall be acceptable only in those  
235 buildings which meet or can be remodeled to meet the applicable requirements of the Statewide Uniform  
236 Building Code.

237 B. Facilities not located on the ground floor of a building shall be served by at least one elevator  
238 capable of accommodating a standard stretcher or a stairway 5 feet wide or more that connects the  
239 floor(s) on which the facility is located to the ground floor.

240 Facilities shall be located in buildings providing emergency electrical service. The emergency  
241 electrical service may be provided by an auxiliary generator, or, if available from the power company,  
242 two separate lines, each supplied from a separate generating source. The emergency electrical service  
243 shall have the capability to cover at least the operating, procedure, and recovery rooms' lighting and

electrical equipment for a sufficient period to safely conclude all procedures under way and complete care for all patients.

C. Preliminary drawings and outline specifications shall be submitted to the licensing agency with a program narrative description for review and approval prior to starting construction of a new facility.

D. The following structural elements shall be required:

1. Entrance to the building shall be located at grade level and be able to accommodate wheelchairs;

2. The same room may serve more than one function. The design shall assure that adequate space is available for all administrative services;

3. Work space shall provide privacy for obtaining confidential information and discussing financial arrangements;

4. Adequate waiting space shall be provided for at least one family member or friend per patient. The waiting area shall include public toilets, public telephone(s), drinking fountains(s), and wheelchair storage;

5. Adequate space to assure privacy shall be provided in dressing rooms and patient lockers, toilet and bathing facilities, preoperative preparation, medication administration, and patient holding areas;

6. Private space shall be provided for patient counseling;

7. Facilities and space may be provided for preparation of light nourishment, with appropriate equipment for refrigeration and cooking. Hand washing facilities shall be provided in such room;

8. Space for general storage for office supplies, sterile supplies, pharmacy and housekeeping supplies shall be provided;

9. Adequate janitors' closets with floor receptor or service sink shall be provided; and

10. The size and design of units shall be in accordance with individual programs; however, the following basic elements shall be incorporated in all facilities:

a. The plumbing, heating, and electrical systems for the surgical suite or procedure room shall meet all relevant Building Code and other requirements;

b. The architectural design of the facilities shall provide a sufficient number of rooms for the projected case load and types of procedures to be performed. Operating rooms shall have minimum dimensions of 16' X 18';

c. Scrub sinks shall be provided. Scrub facilities shall be arranged to minimize any incidental splatter on nearby personnel or supply carts;

d. The recovery room shall have hand washing facilities, medication storage space, clerical work space, storage for clerical supplies, linens, and patient care supplies and equipment, and an adjoining toilet which shall have a water closet and hand washing lavatory;

e. The preoperative preparation area may be designed and equipped for examination. Each room shall have a hand washing lavatory and be equipped for patient examination;

f. Separate work and storage rooms shall be provided for clean and sterile holding and for instrument or equipment clean up functions;

g. Unless the narrative program and governing body prohibit the use of flammable anesthetics in writing, a separate anesthesia storage room shall be provided for storage of flammable gases;

h. Anesthesia workroom and equipment storage facilities with adequate ventilation, work counter and sink shall be provided;

i. Sufficient clerical control stations shall be appropriately designed and located, for, among other functions, nursing activities related to medication administration and treatments;

j. Space and equipment requirements for laboratory and radiological services shall be determined by the workload described in the narrative program. These services may be provided within the abortion clinic or through an effective contractual arrangement with nearby facilities. If laboratory or radiology services or both are not provided by contractual agreement, all relevant requirements of law and regulation shall apply;

k. Minimum public corridor width shall be 5'0" (1.52m);

l. Exits and fire safety shall be in accordance with the Virginia Statewide Fire Prevention Code (13VAC5-50-10 et seq.);

m. Items such as drinking fountains, telephone booths, vending machines and portable equipment shall be located so as not to restrict corridor traffic or reduce the corridor width below the required width;

n. Toilet rooms that may be used by patients shall be equipped with doors and hardware that will permit access from the outside in any emergency;

o. The minimum width of doors for patient access to examination and treatment rooms shall be 3'0" (.91m);

p. No door shall swing into a corridor in a manner that might obstruct traffic flow or reduce the required corridor width, except doors to space such as small closets which are not subject to occupancy;

305 *q. Rooms containing ceiling mounted equipment and those that have ceiling mounted surgical light*  
306 *fixtures shall have the height required to properly accommodate the equipment or fixture;*  
307 *r. Cubicle curtains and draperies shall be noncombustible or rendered flame retardant;*  
308 *s. Floor materials shall be easily cleanable and have wear resistance appropriate for the location*  
309 *involved; and*  
310 *t. Wall finishes shall be washable and, in the immediate area of plumbing fixtures, shall be smooth*  
311 *and moisture resistant.*  
312 *§ 32.1-137.06. Compliance with certain regulatory programs not required of abortion clinics.*  
313 *Abortion clinics licensed pursuant to this article shall not be subject to the requirements of (i)*  
314 *Article 1.1 (§ 32.1-102.1 et seq.) of Chapter 4 of this title, relating to Medical Care Facilities Certificate*  
315 *of Public Need; or (ii) Chapter 7.2 (§ 32.1-276.2 et seq.) of this Title, relating to Health Care Data*  
316 *Reporting.*  
317 **2. That the provisions of this act shall become effective on January 1, 2006.**  
318 **3. That the Board of Health shall promulgate regulations to implement the provisions of this act to**  
319 **be effective within 280 days of its enactment. In promulgating the regulations, the Board shall**  
320 **establish licensure fees for abortion clinics in an amount calculated to cover only the costs of the**  
321 **regulation required in this act.**