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SENATE BILL NO. 536

Offered January 8, 2014

Prefiled January 8, 2014

A BILL to amend and reenact § 32.1-127 of the Code of Virginia and to amend the Code of Virginia by adding a section numbered 54.1-2962.01, relating to health care provider-owned distributorships.

 Patron—Martin

 Referred to Committee on Education and Health

Be it enacted by the General Assembly of Virginia:

1. That § 32.1-127 of the Code of Virginia is amended and reenacted and that the Code of Virginia is amended by adding a section numbered 54.1-2962.01 as follows:

§ 32.1-127. Regulations.

A. The regulations promulgated by the Board to carry out the provisions of this article shall be in substantial conformity to the standards of health, hygiene, sanitation, construction and safety as established and recognized by medical and health care professionals and by specialists in matters of public health and safety, including health and safety standards established under provisions of Title XVIII and Title XIX of the Social Security Act, and to the provisions of Article 2 (§ 32.1-138 et seq.).

B. Such regulations:

1. Shall include minimum standards for (i) the construction and maintenance of hospitals, nursing homes and certified nursing facilities to assure the environmental protection and the life safety of its patients, employees, and the public; (ii) the operation, staffing and equipping of hospitals, nursing homes and certified nursing facilities; (iii) qualifications and training of staff of hospitals, nursing homes and certified nursing facilities, except those professionals licensed or certified by the Department of Health Professions; (iv) conditions under which a hospital or nursing home may provide medical and nursing services to patients in their places of residence; and (v) policies related to infection prevention, disaster preparedness, and facility security of hospitals, nursing homes, and certified nursing facilities. For purposes of this paragraph, facilities in which five or more first trimester abortions per month are performed shall be classified as a category of "hospital";

2. Shall provide that at least one physician who is licensed to practice medicine in this Commonwealth shall be on call at all times, though not necessarily physically present on the premises, at each hospital which operates or holds itself out as operating an emergency service;

3. May classify hospitals and nursing homes by type of specialty or service and may provide for licensing hospitals and nursing homes by bed capacity and by type of specialty or service;

4. Shall also require that each hospital establish a protocol for organ donation, in compliance with federal law and the regulations of the Centers for Medicare & Medicaid Services (CMS), particularly 42 C.F.R. § 482.45. Each hospital shall have an agreement with an organ procurement organization designated in CMS regulations for routine contact, whereby the provider's designated organ procurement organization certified by CMS (i) is notified in a timely manner of all deaths or imminent deaths of patients in the hospital and (ii) is authorized to determine the suitability of the decedent or patient for organ donation and, in the absence of a similar arrangement with any eye bank or tissue bank in Virginia certified by the Eye Bank Association of America or the American Association of Tissue Banks, the suitability for tissue and eye donation. The hospital shall also have an agreement with at least one tissue bank and at least one eye bank to cooperate in the retrieval, processing, preservation, storage, and distribution of tissues and eyes to ensure that all usable tissues and eyes are obtained from potential donors and to avoid interference with organ procurement. The protocol shall ensure that the hospital collaborates with the designated organ procurement organization to inform the family of each potential donor of the option to donate organs, tissues, or eyes or to decline to donate. The individual making contact with the family shall have completed a course in the methodology for approaching potential donor families and requesting organ or tissue donation that (a) is offered or approved by the organ procurement organization and designed in conjunction with the tissue and eye bank community and (b) encourages discretion and sensitivity according to the specific circumstances, views, and beliefs of the relevant family. In addition, the hospital shall work cooperatively with the designated organ procurement organization in educating the staff responsible for contacting the organ procurement organization's personnel on donation issues, the proper review of death records to improve identification of potential donors, and the proper procedures for maintaining potential donors while necessary testing and placement of potential donated organs, tissues, and eyes takes place. This process shall be followed, without exception, unless the family of the relevant decedent or patient has expressed opposition to

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59 organ donation, the chief administrative officer of the hospital or his designee knows of such opposition,
60 and no donor card or other relevant document, such as an advance directive, can be found;

61 5. Shall require that each hospital that provides obstetrical services establish a protocol for admission
62 or transfer of any pregnant woman who presents herself while in labor;

63 6. Shall also require that each licensed hospital develop and implement a protocol requiring written
64 discharge plans for identified, substance-abusing, postpartum women and their infants. The protocol shall
65 require that the discharge plan be discussed with the patient and that appropriate referrals for the mother
66 and the infant be made and documented. Appropriate referrals may include, but need not be limited to,
67 treatment services, comprehensive early intervention services for infants and toddlers with disabilities
68 and their families pursuant to Part H of the Individuals with Disabilities Education Act, 20 U.S.C.
69 § 1471 et seq., and family-oriented prevention services. The discharge planning process shall involve, to
70 the extent possible, the father of the infant and any members of the patient's extended family who may
71 participate in the follow-up care for the mother and the infant. Immediately upon identification, pursuant
72 to § 54.1-2403.1, of any substance-abusing, postpartum woman, the hospital shall notify, subject to
73 federal law restrictions, the community services board of the jurisdiction in which the woman resides to
74 appoint a discharge plan manager. The community services board shall implement and manage the
75 discharge plan;

76 7. Shall require that each nursing home and certified nursing facility fully disclose to the applicant
77 for admission the home's or facility's admissions policies, including any preferences given;

78 8. Shall require that each licensed hospital establish a protocol relating to the rights and
79 responsibilities of patients which shall include a process reasonably designed to inform patients of such
80 rights and responsibilities. Such rights and responsibilities of patients, a copy of which shall be given to
81 patients on admission, shall be based on Joint Commission on Accreditation of Healthcare Organizations'
82 standards;

83 9. Shall establish standards and maintain a process for designation of levels or categories of care in
84 neonatal services according to an applicable national or state-developed evaluation system. Such
85 standards may be differentiated for various levels or categories of care and may include, but need not be
86 limited to, requirements for staffing credentials, staff/patient ratios, equipment, and medical protocols;

87 10. Shall require that each nursing home and certified nursing facility train all employees who are
88 mandated to report adult abuse, neglect, or exploitation pursuant to § 63.2-1606 on such reporting
89 procedures and the consequences for failing to make a required report;

90 11. Shall permit hospital personnel, as designated in medical staff bylaws, rules and regulations, or
91 hospital policies and procedures, to accept emergency telephone and other verbal orders for medication
92 or treatment for hospital patients from physicians, and other persons lawfully authorized by state statute
93 to give patient orders, subject to a requirement that such verbal order be signed, within a reasonable
94 period of time not to exceed 72 hours as specified in the hospital's medical staff bylaws, rules and
95 regulations or hospital policies and procedures, by the person giving the order, or, when such person is
96 not available within the period of time specified, co-signed by another physician or other person
97 authorized to give the order;

98 12. Shall require, unless the vaccination is medically contraindicated or the resident declines the offer
99 of the vaccination, that each certified nursing facility and nursing home provide or arrange for the
100 administration to its residents of (i) an annual vaccination against influenza and (ii) a pneumococcal
101 vaccination, in accordance with the most recent recommendations of the Advisory Committee on
102 Immunization Practices of the Centers for Disease Control and Prevention;

103 13. Shall require that each nursing home and certified nursing facility register with the Department of
104 State Police to receive notice of the registration or reregistration of any sex offender within the same or
105 a contiguous zip code area in which the home or facility is located, pursuant to § 9.1-914;

106 14. Shall require that each nursing home and certified nursing facility ascertain, prior to admission,
107 whether a potential patient is a registered sex offender, if the home or facility anticipates the potential
108 patient will have a length of stay greater than three days or in fact stays longer than three days;

109 15. Shall require that each licensed hospital include in its visitation policy a provision allowing each
110 adult patient to receive visits from any individual from whom the patient desires to receive visits,
111 subject to other restrictions contained in the visitation policy including, but not limited to, those related
112 to the patient's medical condition and the number of visitors permitted in the patient's room
113 simultaneously;

114 16. Shall require that each nursing home and certified nursing facility shall, upon the request of the
115 facility's family council, send notices and information about the family council mutually developed by
116 the family council and the administration of the nursing home or certified nursing facility, and provided
117 to the facility for such purpose, to the listed responsible party or a contact person of the resident's
118 choice up to six times per year. Such notices may be included together with a monthly billing statement
119 or other regular communication. Notices and information shall also be posted in a designated location
120 within the nursing home or certified nursing facility; and

17. Shall require that each nursing home and certified nursing facility maintain liability insurance coverage in a minimum amount of \$1 million, and professional liability coverage in an amount at least equal to the recovery limit set forth in § 8.01-581.15, to compensate patients or individuals for injuries and losses resulting from the negligent or criminal acts of the facility. Failure to maintain such minimum insurance shall result in revocation of the facility's license; and

18. Shall require that each licensed hospital comply with the provisions of § 54.1-2962.01 regarding health care provider-owned distributorships.

C. Upon obtaining the appropriate license, if applicable, licensed hospitals, nursing homes, and certified nursing facilities may operate adult day care centers.

D. All facilities licensed by the Board pursuant to this article which provide treatment or care for hemophiliacs and, in the course of such treatment, stock clotting factors, shall maintain records of all lot numbers or other unique identifiers for such clotting factors in order that, in the event the lot is found to be contaminated with an infectious agent, those hemophiliacs who have received units of this contaminated clotting factor may be apprised of this contamination. Facilities which have identified a lot which is known to be contaminated shall notify the recipient's attending physician and request that he notify the recipient of the contamination. If the physician is unavailable, the facility shall notify by mail, return receipt requested, each recipient who received treatment from a known contaminated lot at the individual's last known address.

§ 54.1-2962.01. Health care provider-owned distributorships.

A. For the purposes of this section:

"Health care provider" means (i) a person, corporation, facility, or institution licensed by the Commonwealth to provide health care or professional services as a physician or hospital; (ii) a professional corporation, all of whose shareholders or members are so licensed; (iii) a partnership, all of whose partners are so licensed; (iv) a professional limited liability company composed of members who are so licensed; or (v) a director, officer, employee, independent contractor, or agent of the person or entity referenced in clauses (i) through (iv) of this definition, acting within the course and scope of his employment or engagement as related to health care or professional services.

"Immediate family member" means an individual's spouse, child, child's spouse, stepchild, stepchild's spouse, grandchild, grandchild's spouse, parent, stepparent, parent-in-law, or sibling.

"Medical device" means any medical device classified by the U.S. Food and Drug Administration as a Class I or Class II implantable medical device.

"Medical device distributor" means any entity that manufactures, distributes, or supplies medical devices.

"Ownership interest" means (i) the ownership or holding of an equity or debt security, including shares of stock in a corporation, interests or units of a partnership, bonds, debentures, notes, or other equity or debt instruments, or (ii) any employment interest, including wages, salaries, commissions, or any other compensation.

B. No health care provider shall (i) use, recommend, order, or arrange for the acquisition of a medical device in the treatment of a patient if the medical device was supplied directly or indirectly by a medical device distributor in which he has an ownership interest or (ii) refer a patient to another health care provider that uses, recommends, orders, or arranges for the acquisition of a medical device in the treatment of the referred patient if the medical device was supplied directly or indirectly by a medical device distributor in which either he or the health care provider to whom the patient was referred has an ownership interest.

C. A health care provider shall not be in violation of subsection B if the medical device distributor in which he has an ownership interest is a publicly traded entity and all of the following conditions are met:

1. The entity's stock is listed for trading on the New York Stock Exchange or the American Stock Exchange or is a national market system security traded under an automated interdealer quotation system operated by the National Association of Securities Dealers;

2. The entity had, at the end of the corporation's most recent fiscal year, total net assets of at least \$50 million related to the furnishing of health services;

3. The entity markets and furnishes its services to health care providers with ownership interests and health care providers without ownership interests on the same and equal terms;

4. All stock of the entity, including the stock of any predecessor privately held company, is one class without preferential treatment as to status or remuneration;

5. The entity does not issue loans or guarantee any loans for health care providers who are in a position to use, refer, recommend, order, or arrange for the acquisition of medical devices;

6. The income on the health care provider's investment is not tied to the usage, referral, recommendation, ordering, or acquisition of medical devices and is based on the health care provider's equity interest in the entity; and

182 7. *The health care provider's investment interest does not exceed one-half of one percent of the*
183 *entity's total equity.*
184 D. *For the purposes of this section, the ownership interest of any immediate family member of a*
185 *health care provider shall be considered the ownership interest of the health care provider.*