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## HOUSE BILL NO. 2183

## AMENDMENT IN THE NATURE OF A SUBSTITUTE

(Proposed by the House Committee on Health, Welfare and Institutions  
on January 23, 2003)

(Patron Prior to Substitute—Delegate O'Bannon)

A BILL to amend and reenact §§ 54.1-3301 and 54.1-3408 of the Code of Virginia and to amend the Code of Virginia by adding sections numbered 32.1-42.1 and 54.1-3307.3, relating to administration or dispensing of drugs and devices during a declared disaster or emergency.

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

**1. That §§ 54.1-3301 and 54.1-3408 of the Code of Virginia are amended and reenacted, and that the Code of Virginia is amended by adding sections numbered 32.1-42.1 and 54.1-3307.3 as follows:**

§ 32.1-42.1. Administration and dispensing of necessary drugs and devices during a declared disaster or state of emergency.

The Commissioner, pursuant to § 54.1-3408, may authorize persons who are not authorized by law to administer or dispense drugs or devices to administer or dispense all necessary drugs or devices in accordance with protocols established by the Commissioner when (i) the Governor has declared a disaster or a state of emergency caused by an act of terrorism or the United States Secretary of Health and Human Services has issued a declaration of an actual or potential bioterrorism incident or other actual or potential public health emergency; (ii) it is necessary to permit the provision of needed drugs or devices; and (iii) such persons have received the training necessary to safely administer or dispense the needed drugs or devices. Such persons shall administer or dispense all drugs or devices under the direction, control and supervision of the Commissioner. For purposes of this section, "administer," "device," "dispense," and "drug" shall have the same meaning as provided in § 54.1-3401. The Commissioner shall develop protocols, in consultation with the Department of Health Professions, that address the required training of such persons and procedures for such persons to use in administering or dispensing drugs or devices.

§ 54.1-3301. Exceptions.

This chapter shall not be construed to:

1. Interfere with any legally qualified practitioner of dentistry, or veterinary medicine or any physician acting on behalf of the Virginia Department of Health or local health departments, in the compounding of his prescriptions or the purchase and possession of drugs as he may require;

2. Prevent any legally qualified practitioner of dentistry, or veterinary medicine or any physician prescriber, as defined in § 54.1-3401, acting on behalf of the Virginia Department of Health or local health departments, from administering or supplying to his patients the medicines that he deems proper under the conditions of § 54.1-3303 or from causing drugs to be administered or dispensed pursuant to §§ 32.1-42.1 and 54.1-3408;

3. Prohibit the sale by merchants and retail dealers of proprietary medicines as defined in Chapter 34 (§ 54.1-3400 et seq.) of this title;

4. Prevent the operation of automated drug dispensing systems in hospitals pursuant to Chapter 34 (§ 54.1-3400 et seq.) of this title;

5. Prohibit the employment of ancillary personnel to assist a pharmacist as provided in the regulations of the Board;

6. Interfere with any legally qualified practitioner of medicine, osteopathy, or podiatry from purchasing, possessing or administering controlled substances to his own patients or providing controlled substances to his own patients in a bona fide medical emergency or providing manufacturers' professional samples to his own patients;

7. Interfere with any legally qualified practitioner of optometry, certified or licensed to use diagnostic pharmaceutical agents, from purchasing, possessing or administering those controlled substances as specified in § 54.1-3221 or interfere with any legally qualified practitioner of optometry certified to prescribe therapeutic pharmaceutical agents from purchasing, possessing, or administering to his own patients those controlled substances as specified in § 54.1-3222 and the TPA formulary or providing manufacturers' samples of these drugs to his own patients;

8. Interfere with any physician assistant with prescriptive authority receiving and dispensing to his own patients manufacturers' professional samples of controlled substances and devices that he is authorized, in compliance with the provisions of § 54.1-2952.1, to prescribe according to his practice setting and a written agreement with a physician or podiatrist;

9. Interfere with any licensed nurse practitioner with prescriptive authority receiving and dispensing to his own patients manufacturers' professional samples of controlled substances and devices that he is

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60 authorized, in compliance with the provisions of § 54.1-2957.01, to prescribe according to his practice  
61 setting and a written agreement with a physician;

62 10. Interfere with any legally qualified practitioner of medicine or osteopathy participating in an  
63 indigent patient program offered by a pharmaceutical manufacturer in which the practitioner sends a  
64 prescription for one of his own patients to the manufacturer, and the manufacturer donates a stock bottle  
65 of the prescription drug ordered at no cost to the practitioner or patient. The practitioner may dispense  
66 such medication at no cost to the patient without holding a license to dispense from the Board of  
67 Pharmacy. However, the container in which the drug is dispensed shall be labeled in accordance with  
68 the requirements of § 54.1-3410, and, unless directed otherwise by the practitioner or the patient, shall  
69 meet standards for special packaging as set forth in § 54.1-3426 and Board of Pharmacy regulations. In  
70 lieu of dispensing directly to the patient, a practitioner may transfer the donated drug with a valid  
71 prescription to a pharmacy for dispensing to the patient. The practitioner or pharmacy participating in  
72 the program shall not use the donated drug for any purpose other than dispensing to the patient for  
73 whom it was originally donated, except as authorized by the donating manufacturer for another patient  
74 meeting that manufacturer's requirements for the indigent patient program. Neither the practitioner nor  
75 the pharmacy shall charge the patient for any medication provided through a manufacturer's indigent  
76 patient program pursuant to this subdivision. A participating pharmacy may charge a reasonable  
77 dispensing or administrative fee to offset the cost of dispensing, not to exceed the comparable allowable  
78 fee reimbursed by the Virginia Medicaid program. However, if the patient is unable to pay such fee, the  
79 dispensing or administrative fee shall be waived;

80 11. Interfere with any legally qualified practitioner of medicine or osteopathy from providing  
81 controlled substances to his own patients in a free clinic without charge when such controlled substances  
82 are donated by an entity other than a pharmaceutical manufacturer as authorized by subdivision 10. The  
83 practitioner shall first obtain a controlled substances registration from the Board and shall comply with  
84 the labeling and packaging requirements of this chapter and the Board's regulations; or

85 12. Prevent any pharmacist from providing free health care to an underserved population in Virginia  
86 who (i) does not regularly practice pharmacy in Virginia, (ii) holds a current valid license or certificate  
87 to practice pharmacy in another state, territory, district or possession of the United States, (iii) volunteers  
88 to provide free health care to an underserved area of this Commonwealth under the auspices of a  
89 publicly supported all volunteer, nonprofit organization with no paid employees that sponsors the  
90 provision of health care to populations of underserved people throughout the world, (iv) files a copy of  
91 the license or certificate issued in such other jurisdiction with the Board, (v) notifies the Board at least  
92 fifteen days prior to the voluntary provision of services of the dates and location of such service, and  
93 (vi) acknowledges, in writing, that such licensure exemption shall only be valid, in compliance with the  
94 Board's regulations, during the limited period that such free health care is made available through the  
95 volunteer, nonprofit organization on the dates and at the location filed with the Board. The Board may  
96 deny the right to practice in Virginia to any pharmacist whose license has been previously suspended or  
97 revoked, who has been convicted of a felony or who is otherwise found to be in violation of applicable  
98 laws or regulations.

99 This section shall not be construed as exempting any person from the licensure, registration,  
100 permitting and record keeping requirements of this chapter or Chapter 34 of this title.

101 § 54.1-3307.3. *Waiver of requirements; declared disaster or state of emergency.*

102 *When the Governor has declared a disaster or a state of emergency pursuant to Chapter 3.2*  
103 *(§ 44-146.13 et seq.) of Title 44 and it is necessary to permit the provision of needed drugs, devices,*  
104 *and pharmacy services to the citizens of the Commonwealth, the Board may waive the requirements of*  
105 *this chapter, the Drug Control Act (§ 54.1-3400 et seq.), and the Board's regulations governing the*  
106 *practice of pharmacy (18 VAC 110-20-10 et seq.). However, the Board shall not authorize the*  
107 *administering or dispensing of controlled substances by persons whose scope of practice does not*  
108 *include such authority.*

109 § 54.1-3408. Professional use by practitioners.

110 A practitioner of medicine, osteopathy, podiatry, dentistry, or veterinary medicine or a licensed nurse  
111 practitioner pursuant to § 54.1-2957.01, a licensed physician assistant pursuant to § 54.1-2952.1, or a  
112 TPA-certified optometrist pursuant to Article 5 (§ 54.1-3222 et seq.) of Chapter 32 of this title shall  
113 only prescribe, dispense, or administer controlled substances in good faith for medicinal or therapeutic  
114 purposes within the course of his professional practice.

115 The prescribing practitioner's order may be on a written prescription or pursuant to an oral  
116 prescription as authorized by this chapter. The prescriber may administer drugs and devices, or he may  
117 cause them to be administered by a nurse, physician assistant or intern under his direction and  
118 supervision, or he may prescribe and cause drugs and devices to be administered to patients in  
119 state-owned or state-operated hospitals or facilities licensed as hospitals by the Board of Health or  
120 psychiatric hospitals licensed by the State Mental Health, Mental Retardation and Substance Abuse  
121 Services Board by other persons who have been trained properly to administer drugs and who administer

122 drugs only under the control and supervision of the prescriber or a pharmacist or a prescriber may cause  
 123 drugs and devices to be administered to patients by emergency medical services personnel who have  
 124 been certified and authorized to administer such drugs and devices pursuant to Board of Health  
 125 regulations governing emergency medical services and who are acting within the scope of such  
 126 certification. A prescriber may authorize a certified respiratory therapy practitioner as defined in  
 127 § 54.1-2954 to administer by inhalation controlled substances used in inhalation or respiratory therapy.

128 Pursuant to an oral or written order or standing protocol, the prescriber, who is authorized by state or  
 129 federal law to possess and administer radiopharmaceuticals in the scope of his practice, may authorize a  
 130 nuclear medicine technologist to administer, under his supervision, radiopharmaceuticals used in the  
 131 diagnosis or treatment of disease.

132 Pursuant to an oral or written order or standing protocol issued by the prescriber within the course of  
 133 his professional practice, such prescriber may authorize registered nurses and licensed practical nurses to  
 134 possess (i) epinephrine for administration in treatment of emergency medical conditions and (ii) heparin  
 135 and sterile normal saline to use for the maintenance of intravenous access lines.

136 Pursuant to a written order or standing protocol issued by the prescriber within the course of his  
 137 professional practice, such prescriber may authorize, with the consent of the parents as defined in  
 138 § 22.1-1, an employee of a school board who is trained in the administration of insulin and glucagon to  
 139 assist with the administration of insulin or administer glucagon to a student diagnosed as having diabetes  
 140 and who requires insulin injections during the school day or for whom glucagon has been prescribed for  
 141 the emergency treatment of hypoglycemia. Such authorization shall only be effective when a licensed  
 142 nurse, nurse practitioner, physician or physician assistant is not present to perform the administration of  
 143 the medication.

144 A prescriber may authorize, pursuant to a protocol approved by the Board of Nursing, the  
 145 administration of vaccines to adults for immunization, when a practitioner with prescriptive authority is  
 146 not physically present, (i) by licensed pharmacists, (ii) by registered nurses, or (iii) licensed practical  
 147 nurses under the immediate and direct supervision of a registered nurse. A prescriber acting on behalf of  
 148 and in accordance with established protocols of the Department of Health may authorize the  
 149 administration of vaccines to any person by a pharmacist or nurse when the prescriber is not physically  
 150 present.

151 A dentist may cause Schedule VI topical drugs to be administered under his direction and  
 152 supervision by either a dental hygienist or by an authorized agent of the dentist.

153 This section shall not prevent the administration of drugs by a person who has satisfactorily  
 154 completed a training program for this purpose approved by the Board of Nursing and who administers  
 155 such drugs in accordance with a physician's instructions pertaining to dosage, frequency, and manner of  
 156 administration, and in accordance with regulations promulgated by the Board of Pharmacy relating to  
 157 security and record keeping, when the drugs administered would be normally self-administered by (i) a  
 158 resident of a facility licensed or certified by the State Mental Health, Mental Retardation and Substance  
 159 Abuse Services Board; (ii) a resident of any assisted living facility which is licensed by the Department  
 160 of Social Services; (iii) a resident of the Virginia Rehabilitation Center for the Blind and Vision  
 161 Impaired; (iv) a resident of a facility approved by the Board or Department of Juvenile Justice for the  
 162 placement of children in need of services or delinquent or alleged delinquent youth; (v) a program  
 163 participant of an adult day-care center licensed by the Department of Social Services; or (vi) a resident  
 164 of any facility authorized or operated by a state or local government whose primary purpose is not to  
 165 provide health care services.

166 In addition, this section shall not prevent the administration of drugs by a person who administers  
 167 such drugs in accordance with a physician's instructions pertaining to dosage, frequency, and manner of  
 168 administration and with written authorization of a parent, and in accordance with school board  
 169 regulations relating to training, security and record keeping, when the drugs administered would be  
 170 normally self-administered by a student of a Virginia public school. Training for such persons shall be  
 171 accomplished through a program approved by the local school boards, in consultation with the local  
 172 departments of health.

173 *In addition, this section shall not prevent the administration or dispensing of drugs and devices by*  
 174 *persons if they are authorized by the State Health Commissioner in accordance with protocols*  
 175 *established by the State Health Commissioner pursuant to § 32.1-42.1 when (i) the Governor has*  
 176 *declared a disaster or a state of emergency caused by an act of terrorism or the United States Secretary*  
 177 *of Health and Human Services has issued a declaration of an actual or potential bioterrorism incident*  
 178 *or other actual or potential public health emergency; (ii) it is necessary to permit the provision of*  
 179 *needed drugs or devices; and (iii) such persons have received the training necessary to safely administer*  
 180 *or dispense the needed drugs or devices. Such persons shall administer or dispense all drugs or devices*  
 181 *under the direction, control and supervision of the State Health Commissioner.*

182 Nothing in this title shall prohibit the administration of normally self-administered oral or topical

183 drugs by unlicensed individuals to a person in his private residence.

184 This section shall not interfere with any prescriber issuing prescriptions in compliance with his  
185 authority and scope of practice and the provisions of this section to a Board agent for use pursuant to  
186 subsection G of § 18.2-258.1. Such prescriptions issued by such prescriber shall be deemed to be valid  
187 prescriptions.

188 Nothing in this title shall prevent dialysis care technicians, in the ordinary course of their duties in a  
189 Medicare-certified renal dialysis facility, from administering heparin, topical needle site anesthetics,  
190 dialysis solutions and sterile normal saline solution for the purpose of facilitating renal dialysis  
191 treatment, provided such administration of medications occurs under the orders of a licensed physician  
192 and under the immediate and direct supervision of a licensed registered nurse. The dialysis care  
193 technician administering the medications must have been trained in renal dialysis practices and  
194 procedures by a licensed nurse, and must have demonstrated competency as evidenced by satisfactory  
195 completion of a training program in accordance with the Core Curriculum for the Dialysis Technician,  
196 also known as the Amgen Core Curriculum, or a comparable education and training curriculum.

197 **2. That an emergency exists and this act is in force from its passage.**