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SENATE BILL NO. 1114

AMENDMENT IN THE NATURE OF A SUBSTITUTE

(Proposed by the Senate Committee on Education and Health
on January 30, 1997)

(Patron Prior to Substitute—Senator Hawkins)

A BILL to amend the Code of Virginia by adding in Title 54.1 a chapter numbered 34.1, consisting of sections numbered 54.1-3480 through 54.1-3487, relating to the Virginia Anti-Drug Switching Patient Protection Act; penalties.

Be it enacted by the General Assembly of Virginia:

1. That the Code of Virginia is amended by adding in Title 54.1 a chapter numbered 34.1, consisting of sections numbered 54.1-3480 through 54.1-3487, as follows:

CHAPTER 34.1.

VIRGINIA ANTI-DRUG SWITCHING PATIENT PROTECTION ACT.

§ 54.1-3480. Definitions.

As used in this chapter, unless the context requires a different meaning:

"Advertisement" means a representation disseminated in any manner or means, for the purpose of inducing, or which is likely to induce, directly or indirectly, the purchase of a prescription drug. The term does not include any act prohibited by the chapter.

"Caregiver" means (i) a parent or guardian of a minor patient, (ii) a relative, close friend or employee of a patient who provides in-person physical assistance to the patient, or (iii) a person employed by another to care for a patient who provides in-person physical assistance to the patient.

"Chemically dissimilar" means a prescription drug which possesses one or more active ingredients that are different from those of another prescription drug.

"Deliver" means the actual, constructive, or attempted transfer of any item regulated by Chapter 34 of this title, whether or not there exists an agency relationship.

"Dispense" or "dispensing" means to deliver a prescription drug to a patient by or pursuant to the lawful order of a prescribing practitioner.

"Drug" means (i) articles or substances recognized in the official United States Pharmacopoeia National Formulary or official Homeopathic Pharmacopoeia of the United States, or any supplement to any of them; (ii) articles or substances intended for use in the diagnosis, cure, mitigation, treatment or prevention of disease in an individual; (iii) articles or substances, other than food, intended to affect the structure or any function of the body of an individual; or (iv) articles or substances intended for use as a component of any article specified in (i), (ii), or (iii). "Drug" does not include devices or their components, parts or accessories.

"Employer" means a person who provides monetary or other compensation to another person for goods or services, whether the one receiving monetary or other compensation is an employee, agent, partner, independent contractor or other.

"Manufacture" means the production, preparation, propagation, conversion or processing of any item regulated by Chapter 34 of this title, either directly or indirectly by extraction from substances of natural origin, or independently by means of chemical synthesis, or by a combination of extraction and chemical synthesis, and includes any packaging or repackaging of the substance or labeling or relabeling of its container.

"Manufacturer" means any person who manufactures and all agents of that person.

"Monetary incentive" means any rebate, discount, kick-back, fee, special charge or other financial incentive.

"Patient" means an ultimate consumer of a prescription drug who obtains the prescription drug from a licensed pharmacist or practitioner who is authorized by law to prescribe or dispense prescription drugs.

"Person" means any individual, corporation, partnership, association, company, business, trust, joint venture, governmental agency, or other institution or legal entity.

"Pharmacist" means a person duly licensed by the Virginia Board of Pharmacy to practice pharmacy or a person duly licensed by any other state or U.S. territory to practice pharmacy.

"Practitioner" means a person duly licensed by the Commonwealth or by any other state or U.S. territory as a physician, dentist, osteopath, podiatrist, nurse practitioner, TPA-certified optometrist, or physician's assistant.

"Prescribing practitioner" means a practitioner who (i) prescribes a prescription drug for a patient and (ii) is authorized by applicable law to prescribe or administer such drugs.

"Prescription drug" means any drug required by federal law of regulation to be dispensed only pursuant to a prescription, including finished dosage forms and active ingredients subject to § 503 (b) of

60 *the Federal Food, Drug, and Cosmetic Act.*

61 *"Sells" or "selling" includes barter, exchange, transfer, or gift, or offer therefor.*

62 *§ 54.1-3481. Exceptions to applicability of chapter; no exemption from other provisions of title;*
63 *advertisements.*

64 *A. The provisions of this chapter shall not apply to any prescription drug prescribed by a scientific*
65 *investigator for purposes of research or prescribed by a veterinarian. Where the solicitation or*
66 *encouragement prohibited herein is directed to a practitioner or pharmacist, this chapter shall only*
67 *apply to a solicitation or encouragement where the practitioner or pharmacist has a bona fide*
68 *practitioner-patient or pharmacist-patient relationship with a specific patient for whom a specific drug*
69 *has been prescribed from which a substitution is sought.*

70 *B. This chapter shall not be construed as exempting any person from the requirements of Chapter 33*
71 *(§ 54.1-3300 et seq.) or Chapter 34 (§ 54.1-3400 et seq.) of this title.*

72 *C. The provisions of this chapter shall have no application to advertisements for prescription drugs.*

73 *D. The provisions of this chapter shall also not apply to: (i) the Department of Medical Assistance*
74 *Services, (ii) any health care provider while rendering services pursuant to a provider agreement with*
75 *the Department of Medical Assistance Services, and (iii) any program implemented by the Department of*
76 *Medical Assistance Services through a contract with an insurer proposing to issue individual or group*
77 *accident and sickness insurance policies providing hospital, medical, and surgical or major medical*
78 *coverage on an expense-incurred basis, any corporation providing individual or group accident and*
79 *sickness subscription contracts, and any health maintenance organization providing a health care plan*
80 *for health care services.*

81 *§ 54.1-3482. Unlawful actions.*

82 *A. No person shall solicit or encourage the prescribing practitioner of a patient residing in the*
83 *Commonwealth, while that patient is physically located in the Commonwealth, to substitute a*
84 *prescription drug which the prescribing practitioner originally prescribed for the patient with any*
85 *chemically dissimilar prescription drug, unless the person is the patient, another practitioner or*
86 *pharmacist, or a caregiver of the patient. The foregoing shall in no way limit the ability of any person*
87 *to contact a patient's prescribing practitioner to warn of a contraindication, precaution or adverse*
88 *reaction.*

89 *B. No practitioner or pharmacist shall solicit or encourage the prescribing practitioner of a patient*
90 *residing in the Commonwealth, while that patient is physically located in the Commonwealth, to*
91 *substitute a prescription drug the prescribing practitioner originally prescribed for the patient with any*
92 *chemically dissimilar prescription drug where a purpose of the substitution is to assist the practitioner*
93 *or pharmacist, or an employer of the practitioner or pharmacist, in receiving a monetary incentive*
94 *directly or indirectly from the manufacturer of the chemically dissimilar prescription drug which is*
95 *based upon the substitution of that prescription drug in the place of another prescription drug which is*
96 *chemically dissimilar.*

97 *C. No pharmacist shall sell or dispense a prescription drug to a patient residing in the*
98 *Commonwealth, while that patient is physically located in the Commonwealth, if the pharmacist*
99 *possesses actual knowledge that (i) a person solicited or encouraged the patient's prescribing*
100 *practitioner to substitute the originally prescribed drug with any chemically dissimilar prescription drug,*
101 *and (ii) that a purpose of the substitution is to assist such person or any employer of that person in*
102 *receiving a monetary incentive directly or indirectly from the manufacturer of the chemically dissimilar*
103 *prescription drug which is based upon the substitution of that prescription drug in the place of another*
104 *prescription drug which is chemically dissimilar.*

105 *D. No person shall solicit or encourage (i) a patient residing in the Commonwealth, while that*
106 *patient is physically located in the Commonwealth, (ii) a caregiver of the patient, (iii) a pharmacist of*
107 *the patient or (iv) a practitioner of the patient to request the patient's prescribing practitioner to*
108 *substitute a prescription drug the prescribing practitioner originally prescribed with a chemically*
109 *dissimilar prescription drug where a purpose of the substitution is to assist such person or an employer*
110 *of that person in receiving a monetary incentive directly or indirectly from the manufacturer of the*
111 *chemically dissimilar prescription drug which is based upon the substitution of that prescription drug in*
112 *the place of another prescription drug which is chemically dissimilar.*

113 *§ 54.1-3483. Presumption of violation.*

114 *For purposes of this chapter, where a person or a person's employer receives a monetary incentive*
115 *from a manufacturer of a prescription drug based upon the substitution of that prescription drug in the*
116 *place of another prescription drug which is chemically dissimilar, it shall be presumed to be a violation*
117 *of this chapter.*

118 *§54.1-3484. Violators entitled to bring suit; civil penalties.*

119 *A. Any person entitled to bring an action pursuant to this chapter as set forth herein may do so*
120 *regardless of whether that person has violated a provision of this chapter himself.*

121 *B. Any practitioner or pharmacist who violates any provision of this chapter shall pay for each*

violation a civil penalty of not more than ten dollars, plus attorney fees and costs. However, if a practitioner or his employer or pharmacist or his employer receives in violation of this chapter any monetary incentive from another person for his assistance in substituting a chemically dissimilar prescription drug for the prescription drug originally prescribed in violation of this chapter, the practitioner or pharmacist shall pay a civil penalty of not more than \$100, plus attorney fees and costs. Any person other than a practitioner or pharmacist who violates any provision of this chapter shall, for each violation, pay a civil penalty of not more than \$5,000, plus attorney fees and costs. The civil penalty shall be in addition to any other causes of action or remedies that may exist against such person and shall be paid into the Literary Fund.

C. Notwithstanding any other provisions of law to the contrary, the Attorney General or the attorney for any city, county or town may cause an action to be brought in the appropriate circuit court in the name of the Commonwealth, the city, county, or town, the Virginia Board of Pharmacy, or the Virginia Board of Medicine, respectively, to enjoin any violation of this chapter, to impose civil penalties as prescribed herein and to recover reasonable attorney fees and costs. Any circuit court having jurisdiction is authorized to issue temporary and permanent injunctions to restrain and prevent violations of this chapter notwithstanding the existence of an adequate remedy at law. In any action under this chapter, it shall not be necessary that damages be proven.

§ 54.1-3485. Investigative orders.

A. Whenever the Attorney General or the attorney for any city, county or town has reasonable cause to believe that any person has engaged in, or is engaging in, or is about to engage in any violation of this chapter, the attorney, if after making a good faith effort to obtain such information, is unable to obtain the data and information necessary to determine whether such violation has occurred, or believes that it is impractical for him to do so, he may apply to the circuit court within whose jurisdiction the person having the information resides, the person has a principal place of business in the Commonwealth, or where any part of the alleged violation occurred in the Commonwealth, which includes without limitation, the jurisdiction of the practitioner's or pharmacist's place of business, the jurisdiction in which the patient resides, and the jurisdiction in which the patient's caregiver resides, for an investigative order requiring such person to furnish to the attorney such data and information as is relevant to the subject matter of the investigation.

B. The circuit courts are empowered to issue investigative orders, authorizing discovery by the same methods and procedures as set forth for civil actions in the Rules of the Supreme Court of Virginia, in connection with investigations of violations of this chapter by the Attorney General or the attorney for any city, county or town. An application for an investigative order shall identify:

1. The specific act or practice alleged to be in violation of this chapter;
2. The grounds which shall demonstrate reasonable cause to believe that a violation of this chapter may have occurred, may be occurring, or may be about to occur;
3. The category or class of data or information requested in the investigative order; and
4. The reasons why the Attorney General or the attorney for any city, county or town is unable to obtain such data and information, or the reason why it is impractical to do so, without a court order.

C. Within twenty-one days after the service upon a person of an investigative order, or at any time before the return date specified in such order, whichever is later, such person may file a motion to modify or set aside such investigative order or to seek a protective order as provided by the Rules of the Supreme Court of Virginia. Such motion shall specify the grounds for modifying or setting aside the order, and may be based upon the failure of the application or the order to comply with the requirements of this chapter, or upon any constitutional or other legal basis or privilege of such person.

D. Where the information requested by an investigative order may be derived or ascertained from the business records of the person upon whom the order is served, or from an examination, audit or inspection of such business records, or from a compilation, abstract or summary thereof, and the burden of deriving or ascertaining the information is substantially the same for the Attorney General or the attorney for any city, county, or town as for the person from whom such information is requested, it shall be sufficient for that person to specify the records from which the requested information may be derived or ascertained, and to afford the Attorney General or the attorney for any city, county, or town reasonable opportunity to examine, audit or inspect such records and to make copies, compilations, abstracts or summaries thereof.

E. It shall be the duty of the Attorney General or the attorney for any city, county or town, his assistants, employees and agents, to maintain the secrecy of all evidence, documents, data and information obtained through the use of investigative orders or obtained as a result of the voluntary act of the person under investigations and it shall be unlawful for any person participating in such investigations to disclose to any other person not participating in such investigation any information so obtained. Any person violating this subsection shall be subject to a civil penalty not to exceed \$25,000 and contempt of court. Notwithstanding the foregoing, this section shall not preclude the presentation

183 and disclosure of any information obtained pursuant to this section in any suit or action in any court of
184 this Commonwealth wherein it is alleged that a violation of this chapter has occurred, is occurring or
185 may occur, nor shall this section prevent the disclosure of any such information by the Attorney General
186 or the attorney for any city, county or town to any federal or state law-enforcement authority that has
187 restrictions governing confidentiality and the use of such information similar to those contained in this
188 subsection.

189 F. Upon the failure of a person without lawful excuse to obey an investigative order under this
190 section, the Attorney General or the attorney for any city, county or town may initiate contempt
191 proceedings in the circuit court that issued the order to hold such person in contempt.

192 G. No information, facts or data obtained through an investigative order shall be admissible in any
193 civil or criminal proceedings other than for the enforcement of this chapter and the remedies provided
194 herein.

195 § 54.1-3486. Tolling of limitation.

196 When any of the authorized government agencies file suit under this chapter, the time during which
197 such governmental suit and all appeals therefrom are pending shall not be counted as any part of the
198 period within which a private cause of action under this chapter shall be brought.

199 § 54.1-3487. Individual action for damages or penalty; statute of limitations.

200 A. If a person who is not a practitioner or pharmacist solicits or encourages a patient, a caregiver
201 of the patient, a practitioner of the patient, or pharmacist of the patient, in violation of any provision of
202 this chapter or if a person who is not a practitioner or pharmacist violates any other provision of this
203 chapter, the patient shall be entitled to initiate an action against such person to recover actual
204 damages, if any, or liquidated damages of \$5,000 per violation, whichever is greater, to enjoin the
205 person from continuing such activities in the Commonwealth, and to recover reasonable attorney fees
206 and costs expended in pursuit of the matter.

207 B. If any practitioner or pharmacist solicits or encourages a patient in violation of any provision of
208 this chapter or if any practitioner or pharmacist violates any other provision of this chapter, the patient
209 shall be entitled to initiate an action against such practitioner or pharmacist to recover actual damages,
210 if any, or liquidated damages of ten dollars per violation whichever is greater, to enjoin the person
211 from continuing such activities in the Commonwealth, and to recover reasonable attorney fees and costs
212 expended in pursuit of the matter; however, if the practitioner or his employer or the pharmacist or his
213 employer receives any monetary incentive from another person for his assistance in committing an act
214 that is in violation of this chapter, the patient may recover actual damages or liquidated damages of
215 \$100 per violation, in lieu of the ten dollars liquidated damages provision, whichever is greater, in
216 addition to injunctive relief, reasonable attorney fees and costs.

217 C. Any caregiver, practitioner or pharmacist who is solicited or encouraged in violation of any
218 provision of this chapter by a person who is not a practitioner or pharmacist shall be entitled to initiate
219 an action against such person to recover actual damages, if any, or liquidated damages of \$5,000 per
220 violation, whichever is greater, to enjoin the person from continuing such activities in the
221 Commonwealth, and to recover reasonable attorney fees and costs.

222 D. Any caregiver, practitioner or pharmacist who is solicited or encouraged in violation of any
223 provision of this chapter by a practitioner or pharmacist shall be entitled to initiate an action against
224 such practitioner or pharmacist to recover actual damages, if any, or liquidated damages of ten dollars
225 per violation, whichever is greater, to enjoin the person from continuing such activities in the
226 Commonwealth, and to recover reasonable attorney fees and costs; however, if the practitioner or his
227 employer or the pharmacist or his employer receives any monetary incentive from another person for his
228 assistance in committing an act that is in violation of this chapter, the caregiver, practitioner or
229 pharmacist may recover actual damages or liquidated damages of \$100 per violation, in lieu of the ten
230 dollars liquidated damages provision, whichever is greater, in addition to injunctive relief, reasonable
231 attorney fees and costs.

232 E. Except as provided in § 54.1-3486, any claim arising under this chapter shall be brought within
233 two years of the wrongful act or discovery of the act, whichever is later.