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HOUSE BILL NO. 1127

House Amendments in [ ] — February 17, 1998

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~~ 54.1-3488] , relating to the Virginia Ethics in Prescription Drug Choice Act.

Patrons—Davies, Cranwell, Hargrove, Jones, S.C., McEachin, Morgan, Moss, Orrock and Shuler; Senators: Hawkins and Stosch

Referred to Committee on Rules

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~~ *54.1-3488*] , as follows:

CHAPTER 34.1.

VIRGINIA ETHICS IN PRESCRIPTION DRUG CHOICE 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. This term is expressly limited to representations currently regulated by the United States Food and Drug Administration, 21 USC § 352, and does not include any act prohibited by this 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 and who provides in-person physical assistance to the patient.

"Chemically dissimilar" means that a prescription drug 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 (§ 54.1-3400 et seq.) 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 clause (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 labels or relabeling of its container.

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

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

"Person" means an individual, partnership, corporation, association, governmental agency, trust, or other institution or entity.

"Practitioner" means a person duly licensed by the Commonwealth or by any other state or U.S. territory as a physician, pharmacist, 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" or "prescribed drug" means any drug required by federal law or regulation to be dispensed only pursuant to prescription, including finished dosage forms and active ingredients subject to § 503 (b) of the federal Food, Drug and Cosmetic Act (21 USCS § 301 et seq.).

"Sell" or "selling" includes barter, exchange, transfer, or gift, or offer thereto.

§ 54.1-3481. Unlawful solicitation; direct or indirect.

A. No person shall solicit or encourage the prescribing practitioner of a patient residing in the Commonwealth, while that patient is physically located in the Commonwealth, to substitute for a prescription drug the prescribing practitioner originally prescribed for the patient any chemically dissimilar prescription drug, where [~~a~~ *the principal*] *purpose of the substitution is to assist such person, or an employer of such person, in receiving, directly or indirectly, from the manufacturer of the chemically dissimilar prescription drug, a rebate, discount, kickback, fee, special charge or other monetary incentive which is based upon said substitution.*

B. No person shall solicit or encourage any other person to solicit or encourage the prescribing practitioner of a patient residing in the Commonwealth, while that patient is physically located in the Commonwealth, to substitute for a prescription drug the prescribing practitioner originally prescribed for the patient any chemically dissimilar prescription drug, where [~~a~~ *the principal*] *purpose of the substitution is to assist either person, or an employer of either person, in receiving, directly or indirectly, from the manufacturer of the chemically dissimilar prescription drug, a rebate, discount, kickback, fee, special charge or other monetary incentive which is based upon said substitution.*

§ 54.1-3482. Unlawful actions.

No person shall sell or dispense a prescription drug to a patient residing in the Commonwealth, while that patient is physically located in the Commonwealth, if such person possesses actual knowledge that any person solicited or encouraged the patient's prescribing practitioner to substitute the originally prescribed drug with any chemically dissimilar prescription drug and possesses actual knowledge that [~~a~~ *the principal*] *purpose of the substitution is to assist any person in receiving, directly or indirectly, from the manufacturer of the chemically dissimilar prescription drug, a rebate, discount, kickback, fee, special charge or other monetary incentive which is based upon said substitution.*

§ 54.1-3483. Exceptions to applicability of chapter; no exemptions from other provisions of title.

A. The provisions of this chapter shall not apply to any of the following: (i) any prescription drug prescribed by a scientific investigator for purposes of research or by a veterinarian; (ii) any prescription drug dispensed by a hospital pharmacy to a patient while that patient is an inpatient at that hospital; (iii) any patient or caregiver of any patient; (iv) any discount received directly or indirectly from a manufacturer of a prescription drug based upon the recipient's volume of purchases of that drug; (v) any advertisement; (vi) any communication regarding a potentially dangerous side effect or drug interaction associated with a particular drug; (vii) any communication regarding the therapeutic effectiveness of a particular drug; and (viii) any communication which informs the recipient of the price of prescription drugs or encourages the consideration of price in any original prescribing decision.

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

§ 54.1-3484. Presumption of violation.

For the purposes of this chapter, where a person or such person's employer receives a rebate, kickback, fee, special charge or other monetary incentive directly or indirectly from a manufacturer of a prescription drug based upon the substitution of that prescription drug in the place of another chemically dissimilar prescription drug which was originally prescribed by a practitioner, it shall be presumed that [~~a~~ *the principal*] *purpose of the substitution was to receive a rebate, discount, kickback, fee, special charge or other monetary incentive directly or indirectly from a manufacturer.*

§ 54.1-3485. Violations; enforcement; remedies.

A. Any individual who violates any provision of this chapter shall be punished for each violation by a civil penalty of not more than ten dollars, plus reasonable attorney's fees and costs; however, if such individual receives, or has actual knowledge that his employer receives any rebate, discount, kickback, fee, special charge or other 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, then such individual shall pay a civil penalty of not more than $100 for each violation, plus reasonable attorney's fees and costs. The civil penalty shall be in addition to any other causes of action or remedies that may exist against such individual.

B. Any person not an individual which violates any provision of this chapter shall pay a civil penalty of not more than $100 for each violation, plus reasonable attorney's fees and costs; however, if such person receives any rebate, discount, kickback, fee, special charge or other monetary incentive from another person for its assistance in substituting a chemically dissimilar prescription drug for the prescription drug originally prescribed in violation of this chapter, then such person shall pay a civil penalty of not more than $1,000 for each violation, plus reasonable attorney's fees and costs. The civil penalty shall be in addition to any other causes of action or remedies that may exist against such person.

C. Notwithstanding any other provisions of law to the contrary, the Attorney General, the attorney for any city, county, or town, the attorney for the Virginia Board of Pharmacy, or the attorney for the

Virginia Board of Medicine 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's fees and costs expended in pursuit of the matter. 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 actions under this chapter, it shall not be necessary that damages be proven.

§ 54.1-3486. Individual action for damages or remedy; statute of limitations; tolling of limitations.

A. If an individual solicits or encourages a patient, a caregiver of the patient, or a practitioner of the patient in violation of any provision of this chapter, or if an individual violates any other provision of this chapter, the patient, caregiver of the patient, or practitioner of the patient shall be entitled to initiate an action against such individual to recover actual damages, if any, or liquidated damages of ten dollars per violation, whichever is greater, to enjoin the individual from continuing such activities in the Commonwealth and to recover reasonable attorney's fees and costs expended in pursuit of the matter; however, if such individual receives, or has actual knowledge that his employer receives any rebate, discount, kickback, fee, special charge or other monetary incentive from another person for his assistance in committing an act that is in violation of this chapter, the patient, caregiver of the patient, or practitioner of the patient may recover against such individual actual damages or liquidated damages of $100 per violation, whichever is greater, in addition to injunctive relief and reasonable attorney's fees and costs.

B. If a person not an individual solicits or encourages a patient, a caregiver of the patient, or a practitioner of the patient in violation of any provision of this chapter or if a person not an individual violates any other provision of this chapter, the patient, caregiver of the patient, or practitioner of the patient shall be entitled to initiate an action against such person to recover actual damages, if any, or liquidated damages of $100 per violation, whichever is greater, to enjoin the person from continuing such activities in the Commonwealth, and to recover reasonable attorney's fees and costs expended in pursuit of the matter; however, if such person receives any rebate, discount, kickback, fee, special charge or other monetary incentive from another person for its assistance in committing an act that is in violation of this chapter, the patient, caregiver of the patient, or practitioner of the patient may recover against such person actual damages or liquidated damages of $1,000 per violation, whichever is greater, in addition to injunctive relief and reasonable attorney's fees and costs.

C. Except as provided in subsection D of this section, any claim arising under this section must be brought within two years of the wrongful act or discovery of the act, whichever is later.

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

§ 54.1-3487. Violators entitled to bring suit.

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

[*§ 54.1-3488. Termination.*

This act shall expire on July 1, 1999.]