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SENATE BILL NO. 14

Offered January 12, 2022

Prefiled December 19, 2021

A BILL to amend and reenact § 54.1-3411.1 of the Code of Virginia and to amend the Code of Virginia by adding in Article 3 of Chapter 1 of Title 32.1 a section numbered 32.1-23.5, relating to Department of Health; prescription drug donation; awareness and coordination program.

Patrons—Favola; Delegate: Kory

Referred to Committee on Education and Health

Be it enacted by the General Assembly of Virginia:

1. That § 54.1-3411.1 of the Code of Virginia is amended and reenacted and that the Code of Virginia is amended by adding in Article 3 of Chapter 1 of Title 32.1 a section numbered 32.1-23.5 as follows:

§ 32.1-23.5. Prescription drug donation awareness and coordination program.

The Department shall develop, manage, and maintain a program consistent with § 54.1-3411.1 that supports donations of prescription drugs, re-dispensing of prescription drugs, awareness of collection and distribution sites, and related activities. The Department may develop a clearinghouse system of donated prescription drug availability and a process for transferring prescription drugs to dispensing sites that improve patient access to available drugs. The Department shall coordinate its program activities with the Board and its program set forth in subsection B of § 54.1-3411.1 to ensure compliance of the program with Board regulations.

§ 54.1-3411.1. Prohibition on returns, exchanges, or re-dispensing of drugs; exceptions.

A. Drugs dispensed to persons pursuant to a prescription shall not be accepted for return or exchange for the purpose of re-dispensing by any pharmacist or pharmacy after such drugs have been removed from the pharmacy premises from which they were dispensed except:

1. In a hospital with an on-site hospital pharmacy wherein drugs may be returned to the pharmacy in accordance with practice standards;

2. In such cases where official compendium storage requirements are assured and the drugs are in manufacturers' original sealed containers or in sealed individual dose or unit dose packaging that meets official compendium class A or B container requirements, or better, and such return or exchange is consistent with federal law; or

3. When a dispensed drug has not been out of the possession of a delivery agent of the pharmacy.

B. The Board shall promulgate regulations to establish a prescription drug donation program for accepting unused previously dispensed prescription drugs that meet the criteria set forth in subdivision A 2, for the purpose of re-dispensing such drugs to indigent patients, either through hospitals or through clinics organized in whole or in part for the delivery of health care services to the indigent. Such program shall not authorize the donation of Schedule II-V controlled substances if so prohibited by federal law. No drugs shall be re-dispensed unless the integrity of the drug can be assured. Such program shall accept eligible prescription drugs from individuals, including those residing in nursing homes, assisted living facilities, or intermediate care facilities established for individuals with intellectual disability (ICF/IID), licensed hospitals, or any facility operated by the Department of Behavioral Health and Developmental Services. Additionally, such program shall accept eligible prescription drugs from an agent pursuant to a power of attorney, a decedent's personal representative, a legal guardian of an incapacitated person, or a guardian ad litem donated on behalf of the represented individual.

C. *The Department of Health shall develop, manage, and maintain a program consistent with this section that supports donations of prescription drugs, re-dispensing of prescription drugs, awareness of collection and distribution sites, and related activities. The Department may develop a clearinghouse system of donated prescription drug availability and a process for transferring prescription drugs to dispensing sites that improve patient access to available drugs. The Department shall coordinate its program activities with the Board and its program set forth in subsection B to ensure compliance of the program with Board regulations.*

D. Unused prescription drugs dispensed for use by persons eligible for coverage under Title XIX or Title XXI of the Social Security Act, as amended, may be donated pursuant to this section unless such donation is prohibited.

~~D.~~ E. A pharmaceutical manufacturer shall not be liable for any claim or injury arising from the storage, donation, acceptance, transfer, or dispensing of any drug provided to a patient or any other activity undertaken in accordance with a drug distribution program established pursuant to this section.

59 ~~E.~~ F. Nothing in this section shall be construed to create any new or additional liability, or to
60 abrogate any liability that may exist, applicable to a pharmaceutical manufacturer for its products
61 separately from the storage, donation, acceptance, transfer, or dispensing of any drug provided to a
62 patient in accordance with a drug distribution program established pursuant to this section.

63 ~~F.~~ G. In the absence of bad faith or gross negligence, no person that donates, accepts, or dispenses
64 unused prescription drugs in accordance with this section and Board regulations shall be subject to
65 criminal or civil liability for matters arising from the donation, acceptance, or dispensing of such unused
66 prescription drugs.