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SENATE BILL NO. 973

Offered January 19, 2018

A BILL to amend the Code of Virginia by adding in Chapter 25.3 of Title 54.1 sections numbered 54.1-2527 through 54.1-2534, relating to Track and Trace Program.

Patron—Vogel

Referred to Committee on Education and Health

Be it enacted by the General Assembly of Virginia:

1. That the Code of Virginia is amended by adding in Chapter 25.3 of Title 54.1 sections numbered 54.1-2527 through 54.1-2534 as follows:

§ 54.1-2527. Definitions.

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

"Board" means the Board of Pharmacy.

"Bureau" means the Virginia Department of State Police, Bureau of Criminal Investigation, Drug Diversion Unit.

"Controlled substance" means a drug, substance or immediate precursor in Schedules I through VI of the Drug Control Act, Chapter 34 (§ 54.1-3400 et seq.) of this title.

"Department" means the Virginia Department of Health Professions.

"Director" means the Director of the Virginia Department of Health Professions.

"Dispense" means to deliver a controlled substance to an ultimate user or research subject by or pursuant to the lawful order of a practitioner, including the prescribing and administering, packaging, labeling or compounding necessary to prepare the substance for that delivery.

"Dispenser" means a person or entity (i) that (A) is authorized by law to dispense a covered substance or to maintain a stock of covered substances for the purpose of dispensing, and (B) dispenses the covered substance to a citizen of the Commonwealth regardless of the location of the dispenser, or who dispenses such covered substance from a location in Virginia regardless of the location of the recipient or (ii) as defined in the Drug Supply Chain Security Act (21 U.S.C § 360eee).

"Relevant health regulatory board" means any such board that licenses persons or entities with the authority to prescribe or dispense covered substances, including, but not limited to, the Board of Dentistry, the Board of Medicine, and the Board of Pharmacy.

§ 54.1-2528. Program establishment; Director's reporting requirements and regulatory authority.

A. The Director, after consultation with the Board, shall establish a Track and Trace Program for reporting the movement of controlled substances throughout the distribution chain that utilizes a product identifier pursuant to the Drug Supply Chain Security Act and is capable of providing information that captures, at a minimum, the information required of dispensers under the Drug Supply Chain Security Act, including tracing and transaction information and such other information as the Director deems necessary for the purposes of this chapter.

B. The Track and Trace Program shall be developed and maintained so that dispensers may be in compliance with requirements of the Drug Supply Chain Security Act and to support efforts to curb abuse of controlled substances.

C. The Director shall establish, maintain, and administer an electronic database. The Director shall also develop, maintain and administer interface systems between dispensers and the Track and Trace Program database, input systems integrated with current dispenser systems, and any supporting infrastructure including software updates and storage, all as requested by dispensers to input information into the database, and as necessary to monitor controlled substances in the drug supply chain in Virginia. The Director is further authorized to accept data transfers from existing track and trace systems operating in Virginia to populate the Track and Trace Program database.

B.All dispensers in Virginia shall participate in the Track and Trace Program but may maintain their own track and trace systems.

C. The database shall be designed to flag irregularities to investigate and shall maintain separate records in the database of transactions for each dispenserand in such form as required for reporting to the Food and Drug Administration by each dispenser.

D. The Director shall immediately inform the bureau upon the finding of an irregularity or suspicious finding related to data in the Track and Trace Programfor investigatory purposes.

E. The Director, after consultation with the Board, shall promulgate, in accordance with the provisions of the Administrative Process Act (§ 2.2-4000 et seq.), such regulations as are necessary to implement the Track and Trace Program as provided in this chapter.

F. The Director may enter into contracts as may be necessary for the development, implementation and maintenance of the Track and Trace Program.

G. The Director shall also establish an advisory committee within the Department to assist in the implementation and evaluation of the Track and Trace Program.

§ 54.1-2529. Confidentiality of data; disclosure of information; discretionary authority of Director.

A. All data, records, and reports relating to the Track and Trace Program and any abstracts from such data, records, and reports that are in the possession of the Director pursuant to this chapter and any material relating to the operation or security of the program shall be confidential and shall be exempt from the Virginia Freedom of Information Act (§ 2.2-3700 et seq.). Track and Trace Program records in possession of the Director shall not be available for civil subpoena, nor shall such records be disclosed, discoverable, or compelled to be produced in any civil proceeding, nor shall such records be deemed admissible as evidence in any civil proceeding for any reason. Further, the Director shall only have discretion to disclose any such information as provided in subsections C and D.

B. The Director shall report information requested by the Food and Drug Administration, or as directed by a dispenser, for compliance with the Drug Supply Chain Security Act by each dispenser and shall provide 24-hour access to the electronic database to the Food and Drug Administration.

C. Upon receiving a request for information in accordance with the Department's regulations and in compliance with applicable federal law and regulations, the Director shall disclose the following:

1. Information relevant to a specific investigation of a specific dispenser, wholesale distributor, repackager or manufacturer, as each are defined in the Drug Supply Chain Security Act, to the bureau.

2. Information relevant to an investigation or inspection of or allegation of misconduct by a specific person licensed, certified, or registered by or an applicant for licensure, certification, or registration by a health regulatory board; information relevant to a disciplinary proceeding before a health regulatory board or in any subsequent trial or appeal of an action or board order to designated employees of the Department of Health Professions; or to designated persons operating the Health Practitioners' Monitoring Program pursuant to Chapter 25.1 (§ 54.1-2515 et seq.).

3. Information relevant to the proceedings of any investigatory grand jury or special grand jury that has been properly impaneled in accordance with the provisions of Chapter 13 (§ 19.2-191 et seq.) of Title 19.2.

4. Information relevant to a specific investigation of a specific dispenserto an agent of a federal law-enforcement agency with authority to conduct drug diversion investigations.

D. In accordance with the Department's regulations and applicable federal law and regulations, the Director may, in his discretion, disclose information relevant to an investigation or regulatory proceeding of a specific dispenser, wholesale distributor, repackager or manufacturer, as each are defined in the Drug Supply Chain Security Act, to other regulatory authorities concerned with granting, limiting or denying licenses, certificates or registrations to provide, dispense, manufacture, or improve controlled substances in the supply chain when such regulatory authority licenses, certifies or registers such dispenser, wholesale distributor, repackager or manufacturer.

E. The Director may enter into agreements for mutual exchange of information among track and trace programs in other jurisdictions, which shall only use the information for purposes allowed by this chapter.

F. This section shall not be construed to supersede the provisions of § 54.1-3406 concerning the divulging of confidential records relating to investigative information.

§ 54.1-2530. Criteria for indicators of supply chain investigation.

A. The Director shall develop, in consultation with an advisory panel which shall include representatives of the Board, criteria for indicators of unusual patterns of transactions, sales, use, processing, or dispensing of controlled substances by dispensers and misuse of controlled substances by recipients and a method for analysis of data collected from the database.

B. The Director is authorized to utilize consultants, state agency resources and third parties in developing the criteria and methods for analysis of the information in the database

§ 54.1-2531. Authority to access database.

A. The bureau shall have 24-hour access to the electronic database administered by the Director.

B. The Director shall be authorized to enter into memoranda of understandings with agencies of the Commonwealth for data sharing purposes, as deemed necessary by the Director to meet the purposes of this chapter.

C. The Director shall provide 24-hour access to the electronic database to each dispenser to the data provided by such dispenser.

§ 54.1-2532. Immunity from liability.

A. The Director and the employees of the Department of Health Professions shall not be liable for any civil damages resulting from the accuracy or inaccuracy of any information reported to and compiled and maintained by the Department pursuant to this chapter.

Further, the Director and the employees of the Department of Health Professions shall not be liable

for any civil damages resulting from the disclosure of or failure to disclose any information in compliance with subsections B and C of § 54.1-2529 and the Department's regulations.

§ 54.1-2533. Unlawful disclosure of information; disciplinary action authorized; penalties.

A. It shall be unlawful for any person having access to the confidential information in the possession of the program or any data or reports produced by the program to disclose such confidential information except as provided in this chapter. Any person having access to the confidential information in the possession of the program or any data or reports produced by the program who discloses such confidential information in violation of this chapter shall be guilty of a Class 1 misdemeanor upon conviction.

B. It shall be unlawful for any person who lawfully receives confidential information from the Prescription Monitoring Program to redisclose or use such confidential information in any way other than the authorized purpose for which the request was made. Any person who lawfully receives information from the Prescription Monitoring Program and discloses such confidential information in violation of this chapter shall be guilty of a Class 1 misdemeanor upon conviction.

C. Nothing in this section shall prohibit (i) a person who prescribes or dispenses a covered substance required to be reported to the program from redisclosing information obtained from the Program to another prescriber or dispenser who has prescribed or dispensed a covered substance to a recipient or (ii) a person who prescribes a covered substance from placing information obtained from the Program in the recipient's medical record.

D. Unauthorized use or disclosure of confidential information received from the Prescription Monitoring Program shall also be grounds for disciplinary action by the relevant health regulatory board.

§ 54.1-2534. Exemption of information systems from provisions related to the Virginia Information Technologies Agency.

The provisions of Chapter 20.1 (§ 2.2-2005 et seq.) of Title 2.2 shall not apply to the Track and Trace Program pursuant to this chapter operated by the Department of Health Professions.