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SENATE BILL NO. 1098

Offered January 12, 2005

Prefiled January 12, 2005

A BILL to amend and reenact §§ 54.1-2519, 54.1-2520, 54.1-2523, and 54.1-3434.1 of the Code of Virginia and to amend the Code of Virginia by adding a section numbered 54.1-2523.1, relating to the Prescription Monitoring Program.

Patrons—Wampler and Locke

Referred to Committee on Education and Health

Be it enacted by the General Assembly of Virginia:

1. That §§ 54.1-2519, 54.1-2520, 54.1-2523, and 54.1-3434.1 of the Code of Virginia are amended and reenacted and that the Code of Virginia is amended by adding a section numbered 54.1-2523.1 as follows:

§ 54.1-2519. Definitions.

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

"Administer" means the direct application of a controlled substance, whether by injection, inhalation, ingestion or any other means, to the body of a patient or research subject by (i) a practitioner or, under the practitioner's direction, his authorized agent or (ii) the patient or research subject at the direction and in the presence of the practitioner.

"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.

"Covered substance" means ~~a~~ *all* controlled ~~substance~~ *substances included in Schedules II, III, and IV* that ~~is~~ *are* required to be reported to the Prescription Monitoring Program, pursuant to this chapter.

"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 that (i) is authorized by law to dispense a covered substance or to maintain a stock of covered substances for the purpose of dispensing, and (ii) 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.

"Prescriber" means a practitioner licensed in the Commonwealth who is authorized pursuant to §§ 54.1-3303 and 54.1-3408 to issue a prescription for a covered substance *or a practitioner licensed in another state to so issue a prescription for a covered substance.*

"Recipient" means a person who receives a covered substance from a dispenser.

"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.

§ 54.1-2520. Program establishment; Director's regulatory authority.

A. The Director shall establish, maintain, and administer an electronic system to monitor the dispensing of covered substances to be known as the Prescription Monitoring Program. Covered substances shall include all Schedule II, *III, and IV* controlled substances, as defined in the Drug Control Act (§ 54.1-3400 et seq.).

B. The Director, after consultation with relevant health regulatory boards, 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 prescription monitoring program as provided in this chapter, including, but not limited to, the establishment of criteria for granting waivers of the reporting requirements set forth in § 54.1-2521.

C. The Director may enter into contracts as may be necessary for the implementation and maintenance of the Prescription Monitoring Program.

D. The Director shall provide dispensers with a basic file layout to enable electronic transmission of the information required in this chapter. For those dispensers unable to transmit the required information electronically, the Director shall provide an alternative means of data transmission.

E. The Director shall also establish an advisory committee within the Department to assist in the

implementation and evaluation of the Prescription Monitoring Program.

§ 54.1-2523. Confidentiality of data; disclosure of information; discretionary authority of Director.

A. All data, records, and reports relating to the prescribing and dispensing of covered substances to recipients and any abstracts from such data, records, and reports that are in the possession of the Prescription Monitoring program 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.) pursuant to subdivision 15 of § 2.2-3705.5. Further, the Director shall only have discretion to disclose any such information as provided in subsections B and C.

B. 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 recipient or of a specific dispenser or prescriber to an agent designated by the superintendent of the Department of State Police to conduct drug diversion investigations pursuant to § 54.1-3405.

2. Information relevant to an investigation or inspection of or allegation of misconduct by a specific ~~dispenser or prescriber~~ *person licensed, certified, or registered by or an applicant for licensure, certification, or registration by a health regulatory board;* ~~or~~ 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' Intervention Program pursuant to Chapter 25.1 (§ 54.1-2515 et seq.) of this title*.

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 dispenser or specific prescriber to an agent of the United States Drug Enforcement Administration with authority to conduct drug diversion investigations.

C. In accordance with the Department's regulations and applicable federal law and regulations, the Director may, in his discretion, disclose:

1. Information in the possession of the program concerning a recipient who is over the age of 18 to that recipient.

2. Information on a specific recipient to a prescriber ~~licensed by the appropriate regulatory board in the Commonwealth~~, *as defined in this chapter,* for the purpose of establishing the treatment history of the specific recipient when such recipient is either under care and treatment by the prescriber or the prescriber is initiating treatment of such recipient, and the prescriber has obtained written consent to such disclosure from the recipient.

3. *Information on a specific recipient to a dispenser for the purpose of establishing a prescription history to assist the dispenser in determining the validity of a prescription in accordance with § 54.1-3303 when the recipient is seeking a covered substance from the dispenser or the facility in which the dispenser practices. Dispensers shall provide notice to patients, in a manner specified by the Director in regulation, that such information may be requested by them from the Prescription Monitoring Program.*

4. Information relevant to an investigation or regulatory proceeding of a specific dispenser or prescriber to other regulatory authorities concerned with granting, limiting or denying licenses, certificates or registrations to practice a health profession when such regulatory authority licenses such dispenser or prescriber or such dispenser or prescriber is seeking licensure by such other regulatory authority.

4*5*. Information relevant to an investigation relating to a specific dispenser or prescriber who is a participating provider in the Virginia Medicaid program or information relevant to an investigation relating to a specific recipient who is currently eligible for and receiving or who has been eligible for and has received medical assistance services to the Medicaid Fraud Control Unit of the Office of the Attorney General *or to designated employees of the Department of Medical Assistance Services, as appropriate*.

6. Information relevant to determination of the cause of death of a specific recipient to the designated employees of the Office of the Chief Medical Examiner.

7. Information for the purpose of bona fide research or education to qualified personnel; however, data elements that would reasonably identify a specific recipient, prescriber, or dispenser shall be deleted or redacted from such information prior to disclosure. Further, release of the information shall only be made pursuant to a written agreement between such qualified personnel and the Director in order to ensure compliance with this subdivision.

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

E. Confidential information that has been received, maintained or developed by any board or

disclosed by the board pursuant to subsection A shall not, under any circumstances, be available for discovery or court subpoena or introduced into evidence in any medical malpractice suit or other action for damages arising out of the provision of or failure to provide services. However, this subsection shall not be construed to inhibit any investigation or prosecution conducted pursuant to Article 1 (§ 18.2-247 et seq.) of Chapter 7 of Title 18.2.

§ 54.1-2523.1. Criteria for indicators of misuse; Director's authority to disclose information; intervention.

The Director shall develop, in consultation with an advisory panel, criteria for indicators of misuse and a method for analysis of data collected by the Prescription Monitoring Program using the criteria for indicators of misuse. Upon the development of such criteria and data analysis, the Director may, in addition to the discretionary disclosure of information pursuant to § 54.1-2523, disclose information using the criteria that indicates potential misuse by recipients of covered substances to their specific prescribers for the purpose of intervention to prevent such misuse.

§ 54.1-3434.1. Nonresident pharmacies to register with Board.

A. Any pharmacy located outside ~~this~~ *the* Commonwealth which ships, mails, or delivers, in any manner, Schedule II through VI drugs or devices pursuant to a prescription into ~~this~~ *the* Commonwealth shall be considered a nonresident pharmacy, shall be registered with the Board, and shall disclose to the Board all of the following:

1. The location, names, and titles of all principal corporate officers and all pharmacists who are dispensing prescription drugs or devices to residents of ~~this~~ *the* Commonwealth. A report containing this information shall be made on an annual basis and within ~~thirty~~ *30* days after any change of office, corporate officer, or principal pharmacist.

2. That it complies with all lawful directions and requests for information from the regulatory or licensing agency of the Commonwealth in which it is licensed as well as with all requests for information made by the Board pursuant to this section. The nonresident pharmacy shall maintain, at all times, a valid unexpired license, permit, or registration to conduct the pharmacy in compliance with the laws of the state in which it is a resident. As a prerequisite to registering with the Board, the nonresident pharmacy shall submit a copy of the most recent inspection report resulting from an inspection conducted by the regulatory or licensing agency of the state in which it is located.

3. That it maintains its records of prescription drugs or dangerous drugs or devices dispensed to patients in ~~this~~ *the* Commonwealth so that the records are readily retrievable from the records of other drugs dispensed and provides a copy or report of such dispensing records to the Board, its authorized agents, or any agent designated by the Superintendent of the Department of State Police upon request within seven days of receipt of a request.

4. That its pharmacists do not knowingly fill or dispense a prescription for a patient in Virginia in violation of § 54.1-3303.

B. Any pharmacy subject to this section shall, during its regular hours of operation, but not less than six days per week, and for a minimum of ~~forty~~ *40* hours per week, provide a toll-free telephone service to facilitate communication between patients in ~~this~~ *the* Commonwealth and a pharmacist at the pharmacy who has access to the patient's records. This toll-free number shall be disclosed on a label affixed to each container of drugs dispensed to patients in ~~this~~ *the* Commonwealth.

C. *Pharmacies subject to this section shall comply with the reporting requirements of the Prescription Monitoring Program as set forth in § 54.1-2521.*

D. The registration fee shall be the fee specified for pharmacies within Virginia.

2. That the fourth and fifth enactment clauses of Chapter 481 of the 2002 Acts of Assembly are repealed.

3. That the Director of the Department of Health Professions shall promulgate regulations to implement the provisions of this act to be effective within 280 days of its enactment.

4. That, notwithstanding the in due course effective date of this act, the provisions of this act shall not be implemented or enforced until the regulations promulgated pursuant to the third enactment clause shall become effective.

5. That the Director of the Department of Health Professions shall notify all dispensers that will be newly subject to the reporting requirements of § 54.1-2521 pursuant to this act of such reporting requirements prior to the effective date of the regulations promulgated pursuant to the third enactment clause.