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HOUSE BILL NO. 1044

AMENDMENT IN THE NATURE OF A SUBSTITUTE

(Proposed by the House Committee on Health, Welfare and Institutions
on February 9, 2016)

(Patron Prior to Substitute—Delegate Landes)

A *BILL to amend and reenact §§ 54.1-2520 and 54.1-2523 of the Code of Virginia, relating to Prescription Monitoring Program; disclosures.*

Be it enacted by the General Assembly of Virginia:

1. That §§ 54.1-2520 and 54.1-2523 of the Code of Virginia are amended and reenacted as follows:
§ 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.), and any other drugs of concern identified by the Board of Pharmacy pursuant to § 54.1-3456.1.

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. *Such advisory committee shall provide guidance to the Director regarding information disclosed pursuant to subdivision C 9 of § 54.1-2523.*

§ 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. Records in possession of the Prescription Monitoring Program 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 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 who has completed the Virginia State Police Drug Diversion School designated by the superintendent of the Department of State Police or designated by the chief law-enforcement officer of any county, city, or town or campus police department 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 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 recipient, dispenser, or prescriber to an agent of a federal law-enforcement agency with authority to conduct drug diversion investigations.

5. Information relevant to a specific investigation, supervision, or monitoring of a specific recipient

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60 for purposes of the administration of criminal justice pursuant to Chapter 1 (§ 9.1-100 et seq.) of Title
61 9.1 to a probation or parole officer as described in Article 2 (§ 53.1-141 et seq.) of Chapter 4 of Title
62 53.1 or a local community-based probation officer as described in § 9.1-176.1 who has completed the
63 Virginia State Police Drug Diversion School designated by the Director of the Department of
64 Corrections or his designee.

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

67 1. Information in the possession of the program concerning a recipient who is over the age of 18 to
68 that recipient. The information shall be mailed to the street or mailing address indicated on the recipient
69 request form.

70 2. Information on a specific recipient to a prescriber, as defined in this chapter, for the purpose of
71 establishing the treatment history of the specific recipient when such recipient is either under care and
72 treatment by the prescriber or the prescriber is initiating treatment of such recipient. In a manner
73 specified by the Director in regulation, notice shall be given to patients that information may be
74 requested by the prescriber from the Prescription Monitoring Program.

75 3. Information on a specific recipient to a dispenser for the purpose of establishing a prescription
76 history to assist the dispenser in determining the validity of a prescription in accordance with
77 § 54.1-3303 when the recipient is seeking a covered substance from the dispenser or the facility in
78 which the dispenser practices. In a manner specified by the Director in regulation, notice shall be given
79 to patients that information may be requested by the dispenser from the Prescription Monitoring
80 Program.

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

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

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

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

99 8. Information relating to prescriptions for covered substances issued by a specific prescriber, which
100 have been dispensed and reported to the Program, to that prescriber.

101 9. *Information about a specific recipient who is a member of a Virginia Medicaid managed care*
102 *program to a physician or pharmacist licensed in the Commonwealth and employed by the Virginia*
103 *Medicaid managed care program. Such information shall only be used to determine eligibility for and to*
104 *manage the care of the specific recipient in a Patient Utilization Management Safety or similar*
105 *program. Notice shall be given to recipients that information may be requested by a licensed physician*
106 *or pharmacist employed by the Virginia Medicaid managed care program from the Prescription*
107 *Monitoring Program.*

108 D. The Director may enter into agreements for mutual exchange of information among prescription
109 monitoring programs in other jurisdictions, which shall only use the information for purposes allowed by
110 this chapter.

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

113 F. Confidential information that has been received, maintained or developed by any board or
114 disclosed by the board pursuant to subsection A shall not, under any circumstances, be available for
115 discovery or court subpoena or introduced into evidence in any medical malpractice suit or other action
116 for damages arising out of the provision of or failure to provide services. However, this subsection shall
117 not be construed to inhibit any investigation or prosecution conducted pursuant to Article 1 (§ 18.2-247
118 et seq.) of Chapter 7 of Title 18.2.