Code of Virginia

Title 54.1. Professions and Occupations

Chapter 25.2. Prescription Monitoring Program

§ 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.

2002, c. 481;2005, cc. 637, 678;2014, c. 664;2016, cc. 410, 568.

§ 54.1-2521. Reporting requirements.

A. The failure by any person subject to the reporting requirements set forth in this section and the Department's regulations to report the dispensing of covered substances shall constitute grounds for disciplinary action by the relevant health regulatory board.

- B. Upon dispensing a covered substance, a dispenser of such covered substance shall report the following information:
- 1. The recipient's name and address.
- 2. The recipient's date of birth.
- 3. The covered substance that was dispensed to the recipient.
- 4. The quantity of the covered substance that was dispensed.
- 5. The date of the dispensing.
- 6. The prescriber's identifier number.
- 7. The dispenser's identifier number.
- 8. The method of payment for the prescription.
- 9. Any other non-clinical information that is designated by the Director as necessary for the implementation of this chapter in accordance with the Department's regulations.
- 10. Any other information specified in regulations promulgated by the Director as required in order for the Prescription Monitoring Program to be eligible to receive federal funds.
- C. (Effective until January 1, 2017) The reports required herein shall be made and transmitted in such manner and format and according to the standards and schedule established in the Department's regulations.
- C. (Effective January 1, 2017) The reports required herein shall be made to the Department or its agent within 24 hours or the dispenser's next business day, whichever comes later, and shall be made and transmitted in such manner and format and according to the standards and schedule established in the Department's regulations.

2002, c. <u>481</u>; 2006, c. <u>167</u>; 2012, cc. <u>21</u>, <u>71</u>; 2016, c. <u>309</u>.

## § 54.1-2522. Reporting exemptions

The dispensing of covered substances under the following circumstances shall be exempt from the reporting requirements set forth in § 54.1-2521 :

- 1. Dispensing of manufacturers' samples of such covered substances or of covered substances dispensed pursuant to an indigent patient program offered by a pharmaceutical manufacturer.
- 2. Dispensing of covered substances by a practitioner of the healing arts to his patient in a bona

fide medical emergency or when pharmaceutical services are not available.

- 3. Administering of covered substances.
- 4. Dispensing of covered substances within an appropriately licensed narcotic maintenance treatment program.
- 5. Dispensing of covered substances to inpatients in hospitals or nursing facilities licensed by the Board of Health or facilities that are otherwise authorized by law to operate as hospitals or nursing homes in the Commonwealth.
- 6. Dispensing of covered substances to inpatients in hospices licensed by the Board of Health.
- 7. Dispensing of covered substances by veterinarians to animals within the usual course of their professional practice.
- 8. Dispensing of covered substances as otherwise provided in the Department's regulations. 2002, c. 481.
- § 54.1-2522.1. (Effective until July 1, 2019) Requirements of prescribers.
- A. Any prescriber who is licensed in the Commonwealth to treat human patients and is authorized pursuant to  $\S\S 54.1-3303$  and 54.1-3408 to issue a prescription for a covered substance shall be registered with the Prescription Monitoring Program by the Department of Health Professions.
- B. A prescriber registered with the Prescription Monitoring Program or a person to whom he has delegated authority to access information in the possession of the Prescription Monitoring Program pursuant to § 54.1-2523.2 shall, at the time of initiating a new course of treatment to a human patient that includes the prescribing of opioids anticipated at the onset of treatment to last more than 14 consecutive days, request information from the Director for the purpose of determining what, if any, other covered substances are currently prescribed to the patient. In addition, any prescriber who holds a special identification number from the Drug Enforcement Administration authorizing the prescribing of controlled substances approved for use in opioid addiction therapy shall, prior to or as a part of execution of a treatment agreement with the patient, request information from the Director for the purpose of determining what, if any, other covered substances the patient is currently being prescribed. Nothing in this section shall prohibit prescribers from making additional periodic requests for information from the Director as may be required by routine prescribing practices.
- C. A prescriber shall not be required to meet the provisions of subsection B if:
- 1. The opioid is prescribed to a patient currently receiving hospice or palliative care;
- 2. The opioid is prescribed to a patient as part of treatment for a surgical or invasive procedure and such prescription is not refillable;
- 3. The opioid is prescribed to a patient during an inpatient hospital admission or at discharge;

- 4. The opioid is prescribed to a patient in a nursing home or a patient in an assisted living facility that uses a sole source pharmacy;
- 5. The Prescription Monitoring Program is not operational or available due to temporary technological or electrical failure or natural disaster; or
- 6. The prescriber is unable to access the Prescription Monitoring Program due to emergency or disaster and documents such circumstances in the patient's medical record.

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2014, cc. 93, 178; 2015, c. 517; 2016, cc. 113, 406.
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§ 54.1-2522.1. (Effective July 1, 2019) Requirements of prescribers.

A. Any prescriber who is licensed in the Commonwealth to treat human patients and is authorized pursuant to  $\S\S 54.1-3303$  and 54.1-3408 to issue a prescription for a covered substance shall be registered with the Prescription Monitoring Program by the Department of Health Professions.

B. Prescribers registered with the Prescription Monitoring Program shall, at the time of initiating a new course of treatment to a human patient that includes the prescribing of benzodiazepine or an opiate anticipated at the onset of treatment to last more than 90 consecutive days, request information from the Director for the purpose of determining what, if any, other covered substances are currently prescribed to the patient. In addition, any prescriber who holds a special identification number from the Drug Enforcement Administration authorizing the prescribing of controlled substances approved for use in opioid addiction therapy shall, prior to or as a part of execution of a treatment agreement with the patient, request information from the Director for the purpose of determining what, if any, other covered substances the patient is currently being prescribed. Nothing in this section shall prohibit prescribers from making additional periodic requests for information from the Director as may be required by routine prescribing practices.

C. The Secretary of Health and Human Resources may identify and publish a list of benzodiazepines or opiates that have a low potential for abuse by human patients. Prescribers who prescribe such identified benzodiazepines or opiates shall not be required to meet the provisions of subsection B. In addition, a prescriber shall not be required to meet the provisions of subsection B if the course of treatment arises from pain management relating to dialysis or cancer treatments.

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2014, cc. <u>93</u>, <u>178</u>; 2015, c. <u>517</u>.
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§ 54.1-2522.2. Requirements for dispensers.

The Department shall register every dispenser licensed by the Board of Pharmacy pursuant to Article 3 (§ <u>54.1-3310</u> et seq.) of Chapter 33 with the Prescription Monitoring Program.

2015, c. <u>517</u>.

§ 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 (§  $\underline{19.2-191}$  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 for purposes of the administration of criminal justice pursuant to Chapter 1 (§ 9.1-100 et seq.) of Title 9.1 to a probation or parole officer as described in Article 2 (§ 53.1-141 et seq.) of Chapter 4 of Title 53.1 or a local community-based probation officer as described in § 9.1-176.1 who has completed the Virginia State Police Drug Diversion School designated by the Director of the Department of Corrections or his designee.
- 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. The information shall be mailed to the street or mailing address indicated on the recipient request form.

- 2. Information on a specific recipient to a prescriber, 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 consulting on or initiating treatment of such recipient. In a manner specified by the Director in regulation, notice shall be given to patients that information may be requested by the prescriber from the Prescription Monitoring Program.
- 3. Information on a specific recipient to a dispenser for the purpose of establishing a prescription history to assist the dispenser in (i) determining the validity of a prescription in accordance with § 54.1-3303 or (ii) providing clinical consultation on the care and treatment of the recipient. In a manner specified by the Director in regulation, notice shall be given to patients that information may be requested by the dispenser 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.
- 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.
- 8. Information relating to prescriptions for covered substances issued by a specific prescriber, which have been dispensed and reported to the Program, to that prescriber.
- 9. Information about a specific recipient who is a member of a Virginia Medicaid managed care program to a physician or pharmacist licensed in the Commonwealth and employed by the Virginia Medicaid managed care program. Such information shall only be used to determine eligibility for and to manage the care of the specific recipient in a Patient Utilization Management Safety or similar program. Notice shall be given to recipients that information may be requested by a licensed physician or pharmacist employed by the Virginia Medicaid managed care program from the Prescription Monitoring Program.
- 10. (Expires July 1, 2022) Information to the Board of Medicine about prescribers who meet a certain threshold for prescribing covered substances for the purpose of requiring relevant continuing education. The threshold shall be determined by the Board of Medicine in consultation with the Program.

- D. The Director may enter into agreements for mutual exchange of information among prescription monitoring programs in other jurisdictions, which shall only use the information for purposes allowed by this chapter.
- E. This section shall not be construed to supersede the provisions of § <u>54.1-3406</u> concerning the divulging of confidential records relating to investigative information.
- F. 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.

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2002, c. <u>481</u>; 2004, c. <u>690</u>; 2005, cc. <u>637</u>, <u>678</u>; 2009, cc. <u>158</u>, <u>162</u>, <u>472</u>; 2012, cc. <u>21</u>, <u>71</u>; 2013, c. <u>739</u>; 2014, cc. <u>12</u>, <u>97</u>; 2015, cc. <u>118</u>, <u>507</u>; 2016, cc. <u>309</u>, <u>410</u>, <u>447</u>, <u>568</u>.
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§ 54.1-2523.1. Criteria for indicators of misuse; Director's authority to disclose information; intervention.

A. The Director shall develop, in consultation with an advisory panel which shall include representatives of the Boards of Medicine and Pharmacy, criteria for indicators of unusual patterns of prescribing or dispensing of covered substances by prescribers or dispensers and misuse of covered substances by recipients and a method for analysis of data collected by the Prescription Monitoring Program using the criteria for indicators of misuse to identify unusual patterns of prescribing or dispensing of covered substances by individual prescribers or dispensers or potential misuse of a covered substance by a recipient.

- B. In cases in which analysis of data collected by the Prescription Monitoring Program using the criteria for indicators of misuse indicates an unusual pattern of prescribing or dispensing of a covered substance by an individual prescriber or dispenser or potential misuse of a covered substance by a recipient, the Director may, in addition to the discretionary disclosure of information pursuant to § 54.1-2523:
- 1. Disclose information about the unusual prescribing or dispensing of a covered substance by an individual prescriber or dispenser to the Enforcement Division of the Department of Health Professions; or
- 2. Disclose information about the specific recipient to (i) the prescriber or prescribers who have prescribed a covered substance to the recipient for the purpose of intervention to prevent misuse of such covered substance or (ii) an agent who has completed the Virginia State Police Drug Diversion School designated by the Superintendent of State Police or designated by the chief law-enforcement officer of any county, city, or town or campus police department for the purpose of an investigation into possible drug diversion.

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2005, cc. <u>637</u>, <u>678</u>; 2012, cc. <u>21</u>, <u>71</u>; 2013, c. <u>739</u>; 2016, c. <u>98</u>.
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§ 54.1-2523.2. (Effective until July 1, 2019) Authority to access database.

Any prescriber or dispenser authorized to access the information in the possession of the Prescription Monitoring Program pursuant to this chapter may, pursuant to regulations promulgated by the Director to implement the provisions of this section, delegate such authority to individuals who are employed or engaged at the same facility and under the direct supervision of the prescriber or dispenser and (i) are licensed, registered, or certified by a health regulatory board under the Department of Health Professions or in another jurisdiction or (ii) have routine access to confidential patient data and have signed a patient data confidentiality agreement.

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2009, cc. 158, 162; 2012, cc. 21, 71; 2014, c. 72; 2016, cc. 113, 406.
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§ 54.1-2523.2. (Effective July 1, 2019) Authority to access database.

Any prescriber or dispenser authorized to access the information in the possession of the Prescription Monitoring Program pursuant to this chapter may, pursuant to regulations promulgated by the Director to implement the provisions of this section, delegate such authority to health care professionals who are (i) licensed, registered, or certified by a health regulatory board under the Department of Health Professions or in another jurisdiction and (ii) employed at the same facility and under the direct supervision of the prescriber or dispenser.

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2009, cc. <u>158</u>, <u>162</u>; 2012, cc. <u>21</u>, <u>71</u>; 2014, c. <u>72</u>.
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§ 54.1-2524. 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 § 54.1-2523 and the Department's regulations.

B. In the absence of gross negligence or willful misconduct, prescribers or dispensers complying in good faith with the reporting requirements of this chapter shall not be liable for any civil damages for any act or omission resulting from the submission of such required reports.

2002, c. 481.

§ 54.1-2525. 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.

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2002, c. <u>481</u>; 2011, cc. <u>812</u>, <u>844</u>; 2016, c. <u>309</u>.
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§ 54.1-2526. 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 Prescription Monitoring Program pursuant to this chapter operated by the Department of Health Professions until July 1, 2012, unless an alternate date is mutually agreed upon.

2009, cc. <u>158</u>, <u>162</u>.