Commonwealth of Virginia

VIRGINIA DEPARTMENT OF HEALTH PROFESSIONS

REGULATIONS GOVERNING THE PRESCRIPTION MONITORING PROGRAM

Title of Regulations: 18 VAC 76-20-10 et seq.

Statutory Authority: §§ 54.1-2505 and § 54.1-2520 of the ***Code of Virginia***

6603 West Broad Street, 5th Floor
Richmond, Virginia 23230-1712
www.dhp.state.va.us

(804) 662-9919 (TEL)
(804) 662-9114 (FAX)
robert.nebiker@dhp.state.va.us (email)

18 VAC 76-20-10. Definitions.

The following words and terms when used in this chapter shall have the following meaning ascribed to them in § 54.1-2519 of the Code of Virginia unless the context clearly indicates otherwise:

"Department"

"Director"

"Dispense"

"Prescriber"

"Recipient"

In addition, the following words and terms when used in this chapter shall have the following meaning unless the context clearly indicates otherwise:

"Program" means the Prescription Monitoring Program.

18 VAC 76-20-20. General provisions.

In accordance with Chapter 25.2 of Title 54.1 of the Code of Virginia and this chapter, the Director of the Department of Health Professions shall establish and administer a program for monitoring the dispensing of Schedule II controlled substances.

18 VAC 76-20-30. Criteria for granting waivers of the reporting requirements.

A. The Director may grant a waiver of all or some of the reporting requirements established in § 54.1-2521 of the Code of Virginia to an individual or entity who files a request in writing on a form provided by the Department and who meets the criteria for such a waiver.

B. Criteria for a waiver of the reporting requirements shall include a history of compliance with laws and regulations by the pharmacy, the pharmacist-in-charge, and other pharmacists regularly practicing at that location and may include, but not be limited to:

1. A hardship created by a natural disaster or other emergency beyond the control of the pharmacist or pharmacy; or

2. Dispensing in a controlled research project approved by a regionally accredited institution of higher education or under the supervision of a governmental agency.

C. Consistent with the Administrative Process Act (§§ 2.2-4000 et seq. of the Code of Virginia), a waiver may be granted by the Director on a case-by-case basis, subject to terms and conditions stated in an order with a specified time period and subject to being vacated. An appeal of the Director's decision may be filed with an informal conference committee or a formal conference, comprised of agency officials designated by the Director.

18 VAC 76-20-40. Standards for the manner and format of reports and a schedule for reporting.

A. Data shall be transmitted to the Department or its agent on a semi-monthly basis in the Telecommunication Format for Controlled Substances of the American Society of Automation in Pharmacy (ASAP), which are hereby incorporated by reference into this chapter.

B. Data shall be transmitted in a file layout provided by the Department and shall be transmitted by a media acceptable to the vendor contracted by the Director for the program.

18 VAC 76-20-50. Criteria for mandatory disclosure of information by the Director.

A. In order to request disclosure of information contained in the program, an individual shall be registered with the Director as an authorized agent entitled to receive reports under § 54.1-2523 (B) of the Code of Virginia.

1. Such request for registration shall contain an attestation from the applicant's employer of the eligibility and identity of such person.

2. Registration as an agent authorized to receive reports shall expire on June 30 of each even-numbered year or at any such time as the agent leaves or alters his current employment or otherwise becomes ineligible to receive information from the program.

B. An authorized agent shall request in writing, on a form provided by the Department, disclosure of information related to a specific investigation. The request shall contain a case identifier number, a specified time period to be covered in the report, and the specific recipient, prescriber or dispenser for which the report is to be made, and an identifier number for the subject of the disclosure.

C. The request from an authorized agent shall be signed with an attestation that the prescription data will not be further disclosed and only used for the purposes stated in the request and in accordance with the law.

18 VAC 76-20-60. Criteria for discretionary disclosure of information by the Director.

A. In accordance with § 54.1-2523 (C) of the Code of Virginia, the Director may disclose information in the program to certain persons provided the request is made in writing on a form provided by the Department and which contains a notarized signature of the requesting party.

B. The Director may disclose information:

1. To the recipient of the dispensed drugs, provided the request is accompanied by a copy of a driver's license verifying that the recipient is over the age of 18. The report shall be mailed to the address on the license or delivered to the recipient at the Department.

2. To the prescriber for the purpose of establishing a treatment history, provided the request is accompanied by the prescriber's license number issued by the Department, the signature of the prescriber, and an attestation that he has obtained written consent from the recipient. Such written consent shall be separate and distinct from any other consent documents required by the practitioner.

3. To another regulatory authority conducting an investigation or disciplinary proceeding or making a decision on the granting of a license or certificate, provided the request is accompanied by the signature of the chief executive officer who is authorized to certify orders or to grant or deny licenses.

4. To governmental entities charged with the investigation and prosecution of a dispenser, prescriber or recipient participating in the Virginia Medicaid program, provided the request is accompanied by the signature of the official within the Office of the Attorney General responsible for the investigation.

C. In each case, the request must be complete and provide sufficient information to ensure the correct identity of the presciber, recipient and/or dispenser. Such request shall be submitted in writing by mail, private delivery service, in person at the Department offices or by facsimile.