

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*

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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 [substantial] 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 a subordinate designated 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 initial decision may be filed with the Director who shall appoint an informal fact-finding conference, which shall thereafter make a recommendation to the Director. The decision of the Director shall be final.

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 [~~August 1999~~ May 1995] 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. [Such transmission shall begin on a date specified by the Director, no less than 30 days from notification by the Director to dispensers required to report].

[C. Under extraordinary circumstances, an alternative means of reporting may be approved by the Director.

D. Data not accepted by the vendor due to a substantial number of errors or omissions shall be corrected and resubmitted to the vendor within five business days of receiving notification that the submitted data had an unacceptable number of errors or problems.]

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~~ valid photo identification issued by a government agency of any jurisdiction in the United States] verifying that the recipient is over the age of 18 [and includes a notarized signature of the requesting party]. 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 a copy of the] written consent [obtained] 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 related to an allegation of a possible controlled substance violation and that it] 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 prescriber, 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.

[D. Except as provided in subsection B 1 of this section, the request form 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.]

Certification

I certify that this regulation is full, true, and correctly dated.

Robert A. Nebiker
Director
Virginia Department of Health Professions

Date:_____