

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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18VAC76-20-20. 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~~ Schedules II, III and IV controlled substances.

18VAC76-20-30. 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~~ dispensers 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.

18VAC76-20-50. 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 only request in writing, on a form provided by the Department, disclosure of information related to a specific investigation, or in the case of a request from the Health Practitioners' Intervention Program (HPIP) disclosure of information related to a specific applicant for or participant in HPIP. Requests shall be made in a format designated by the department and ~~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~~ include 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.

18VAC76-20-60. 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~~ a format designated by the Department.

B. The Director may disclose information:

1. To the recipient of the dispensed drugs, provided the request is accompanied by a copy of a 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 for a patient or prospective patient, provided the request is accompanied by the prescriber's ~~license number issued by the Department~~ registration number with the United States Drug Enforcement Administration (DEA), the signature of the prescriber, and attestation of having obtained written consent for such disclosure from the recipient. Such written consent ~~shall be separate and distinct from any other consent documents required by the practitioner and~~ shall be maintained as part of the patient record.

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.

5. To a dispenser for the purpose of establishing a prescription history for a specific person to assist in determining the validity of a prescription, provided the request is accompanied by the dispenser's license number issued by the relevant licensing authority in Virginia and an attestation that the dispenser is in compliance with patient notice requirements of 18VAC76-20-70. If the dispensing occurs in a pharmacy located outside Virginia, the request shall include the registration number issued by the Virginia Board of Pharmacy for a non-resident pharmacy.

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~~ include 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.

E. In order to request disclosure of information contained in the program, a designated employee of the Department of Medical Assistance Services or of the Office of the Chief Medical Examiner shall register with the Director as an authorized agent entitled to receive reports under § 54.1-2523 (C) of the Code of Virginia.

1. Such request for registration shall include 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.

18VAC76-20-70.

Any dispenser who intends to request information from the Program for a recipient or prospective recipient of a Schedule II, III, or IV controlled substance shall post a sign which can be easily viewed by the public at the place where the prescription is accepted for dispensing, and which discloses to the public that the pharmacist may access information contained in the Program files on all Schedule II, III or IV prescriptions dispensed to a patient. In lieu of posting a sign, the dispenser may provide such notice in written material provided to the recipient, or may obtain written consent from the recipient.