Virginia Regulatory Town Hall

townhall.virginia.gov

Proposed Regulation
Agency Background Document

Agency name	Department of Health Professions
Virginia Administrative Code (VAC) citation	18 VAC 76-20
Regulation title	Regulations Governing the Prescription Monitoring Program
Action title	Expansion of program in accordance with statutory mandate
Document preparation date	9/22/05

This information is required for executive branch review and the Virginia Registrar of Regulations, pursuant to the Virginia Administrative Process Act (APA), Executive Orders 21 (2002) and 58 (1999), and the *Virginia Register Form, Style, and Procedure Manual.*

Brief summary

In a short paragraph, please summarize all substantive changes that are being proposed in this regulatory action.

The amended regulations will conform the rules for reporting and disclosure to the changes made during the 2005 Session on the General Assembly in Chapter 25.2 of the Code of Virginia. The law now provides for an expansion of the Prescription Monitoring Program to include reporting of dispensed Schedules III and IV drugs and disclosure of information to dispensers (pharmacies) as well as other additional entities such as the Health Practitioner Intervention Program, the Medical Examiner and the Department of Medical Assistance Services. Regulations will: 1) eliminate provisions that may stand as a barrier to the adoption of electronic requests and disclosures; 2) Provide criteria for requests from prescribers who are not licensed in Virginia; and 3) Establish requirements for notification by a dispenser to his patients about requests for disclosure of prescription information in the Program.

Legal basis

Please identify the state and/or federal legal authority to promulgate this proposed regulation, including (1) the most relevant law and/or regulation, including Code of Virginia citation and General Assembly

chapter number(s), if applicable, and (2) promulgating entity, i.e., the agency, board, or person. Describe the legal authority and the extent to which the authority is mandatory or discretionary.

18VAC76-20-10 et seq. Regulations Governing the Prescription Monitoring Program are promulgated under the legal authority of § 54.1-2505, stating the powers and duties of the Director of the Department and § 54.1-2520, which requires the director to promulgate such regulations as are necessary to implement the prescription monitoring program.

§ 54.1-2505. Powers and duties of Director of Department.

The Director of the Department shall have the following powers and duties:

…14. To promulgate and revise regulations necessary for the administration of the Department and such regulations as are necessary for the implementation of the Health Practitioners' Intervention Program pursuant to Chapter 25.1 (§ 54.1-2515 et seq.) of this title and subdivision 19 of this section; …

20. To establish, and revise as necessary, with such federal funds, grants, or general funds as may be appropriated or made available for this program, the Prescription Monitoring Program pursuant to Chapter 25.2 (§ 54.1-2519 et seq.) of this title; and

§ 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.).

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.

Purpose

Please explain the need for the new or amended regulation by (1) detailing the specific reasons why this regulatory action is essential to protect the health, safety, or welfare of citizens, and (2) discussing the goals of the proposal and the problems the proposal is intended to solve.

The purpose of the regulatory action is to comply with the changes in the Code related to the Prescription Monitoring Program (PMP). Legislation passed by the 2005 General Assembly expanded the schedules of drugs required to be reported to the PMP, included non-resident pharmacies among the required reporters and provided access to disclosure of information to pharmacists and other authorized persons and entities.

The Code requires the Director to promulgate regulations establishing the criteria for reporting and disclosure to include information to ensure the identity of the requester and his authorization for the disclosure. For prescribers and dispensers, there are requirements for consent or notification to ensure that patients are aware that information maintained in the PMP on their prescriptions may be subject to disclosure for the purpose of establishing a treatment history or a bona fide patient/practitioner/pharmacist relationship.

Regulations implement the intent and provisions of Chapter 637 and 678 of the 2005 Acts of the Assembly and were required within 280 days of enactment. This proposed action will replace the emergency regulations currently in effect.

The intent for the promulgation of this regulation is implementation of the statute, specifically Chapter 25.2 of Title 54.1 of the Code of Virginia. The purpose of the regulatory action is to promulgate such regulations as necessary for expansion of the Prescription Monitoring Program in accordance with restrictions set forth in law. Given the recent history of abuse and illegal distribution of certain drugs, the Director has an obligation to protect public health, safety and welfare by promulgating regulations in a timely manner.

Substance

Please briefly identify and explain the new substantive provisions, the substantive changes to existing sections, or both where appropriate. (More detail about these changes is requested in the "Detail of changes" section.)

Amendments are adopted to conform the regulations to the law which now provides for an expansion of the Prescription Monitoring Program to include reporting of dispensed Schedules III and IV drugs and disclosure of information to dispensers (pharmacies) as well as other additional entities such as the Health Practitioner Intervention Program, the Medical Examiner and the Department of Medical Assistance Services. Regulations will: 1) eliminate provisions that may stand as a barrier to the adoption of electronic requests and disclosures; 2) Provide criteria for requests from prescribers who are not licensed in Virginia; and 3) Establish requirements for notification by a dispenser to his patients about requests for disclosure of prescription information in the Program.

Proposed regulations are identical to the emergency regulations that went into effect on July 25, 2005.

Issues

Please identify the issues associated with the proposed regulatory action, including:
1) the primary advantages and disadvantages to the public, such as individual private citizens or businesses, of implementing the new or amended provisions;
2) the primary advantages and disadvantages to the agency or the Commonwealth; and
3) other pertinent matters of interest to the regulated community, government officials, and the public.

If the regulatory action poses no disadvantages to the public or the Commonwealth, please so indicate.

1) The primary advantages and disadvantages to the public:

The primary advantages to the public of the Prescription Monitoring Program, as established by legislation in the Code of Virginia, is the potential for curtailment of abuse and diversion of Schedule II drugs. The impetus for such a program was precipitated by the problem in Southwest Virginia with the over-prescribing and abuse of Oxycontin, with devastating results on families and communities. With the expansion to include Schedule III and IV drugs and all areas of the state, this program should be a deterrent to those who would engage in such practices. As adopted, the regulations should protect the public (those who are legitimately prescribing, dispensing and consuming scheduled drugs) by the requirements for mandatory or discretionary disclosure. Those who engage in law enforcement or Medicaid fraud investigation will have another tool available to detect illegal activity.

2) The primary advantages and disadvantages to the agency or the Commonwealth

There are no advantages or disadvantages to the agency, as it is mandated to establish such a program. As stated above, there will be some advantage to the State Police, the Medicaid Fraud unit and other agencies charged with enforcement of laws related to prescription drugs.

Economic impact

Please identify the anticipated economic impact of the proposed regulation.

Projected cost to the state to implement and enforce the proposed regulation, including (a) fund source / fund detail, and (b) a delineation of one-time versus on-going expenditures	a) The fund source for the Prescription Monitoring Program is a grant award from the Harold Rogers Prescription Drug Monitoring Program from the Federal Bureau of Justice Assistance. b) The agency will incur some one-time costs (less than $1,000) for mailings to the Public Participation Guidelines mailing lists and conducting a public hearing. The on-going expenditures are related to operation of the program rather than to these

	regulations. There are no additional expenditures over and above the current budget, related to a possible increase in the number of queries from prescribers.
Projected cost of the regulation on localities	None
Description of the individuals, businesses or other entities likely to be affected by the regulation	The entities that are likely to be affected by these regulations would be practitioners with prescriptive authority in Virginia and dispensers of prescription medicines.
Agency's best estimate of the number of such entities that will be affected. Please include an estimate of the number of small businesses affected. Small business means a business entity, including its affiliates, that (i) is independently owned and operated and (ii) employs fewer than 500 full-time employees or has gross annual sales of less than $6 million.	The entities that are likely to be affected by this proposed regulation would be dispensers who intend to query the system and must comply with the regulation for notice to patients. With the exception of pharmacies located in major medical centers, it is estimated that most would be small businesses. The current number of licensed pharmacies or physicians licensed to sell drugs is: Pharmacies 1576 Non-resident pharmacies 492 Physicians selling drugs 198
All projected costs of the regulation for affected individuals, businesses, or other entities. Please be specific. Be sure to include the projected reporting, recordkeeping, and other administrative costs required for compliance by small businesses.	The Code (§54.1-2523) requires dispensers to provide notice to patients, "in a manner specified by the Director in regulation." That notice can either be in the form of a sign posted at the location where prescription are accepted for dispensing, written material provided to the patient or written consent obtained from the patient. The least costly alternative provided would be a sign posted at the location where prescriptions are accepted for dispensing. Compliance with this provision could cost a small business less than $5 for printing a sign off the pharmacy computer.

Alternatives

Please describe any viable alternatives to the proposal considered and the rationale used by the agency to select the least burdensome or intrusive alternative that meets the essential purpose of the action.

There are no alternatives to the adoption of regulations; it is required by the third enactment clause of HB2429 and SB1098 passed by the 2005 General Assembly. Provisions in the Code (§ 54.1-2523) for mandatory or discretionary disclosure of information in the Program are conditioned on the adoption of regulations by the Director of the Department. Therefore, the only alternative to accomplish the essential purpose of this action is the promulgation of regulations in accordance with Chapter 25.2 of Title 54.1 of the Code of Virginia.

Public comment

Please summarize all comments received during public comment period following the publication of the NOIRA, and provide the agency response.

Draft emergency regulations were sent to affected parties with a request for comment over a 30-day comment period which ended on June 10, 2005. The draft was provided to persons on public participation guidelines lists for the Director and for the Board of Pharmacy, to the Prescription Monitoring Program Advisory Committee, and to board members for the affected professions of pharmacy, medicine, dentistry, optometry, nurse practitioners and physician assistants. No comment was received in response to the draft emergency regulations.

The Notice of Intended Regulatory Action was published in the Register on August 22, 2005 and sent to the Public Participation Guidelines list with comment requested until September 21, 2005. There were no comments on the NOIRA.

Family impact

Please assess the impact of the proposed regulatory action on the institution of the family and family stability.

There is no impact on the institution of the family and family stability.

Detail of changes

Please detail all changes that are being proposed and the consequences of the proposed changes. Detail all new provisions and/or all changes to existing sections.

Current section number	Current requirement	Proposed change and rationale
20	States that Program includes monitoring of Schedule II controlled substances	Amendments to Chapter 25.2 require reporting and monitoring of Schedules II, III and IV. Regulations are amended for consistency with the Code.
30	Sets the criteria for granting a waiver from reporting requirements	Current requirements for waivers are only applicable to pharmacies, but not to other dispensers – such as physicians permitted to sell drugs. An amendment would expand the criteria to include dispensers other than pharmacies and pharmacists and authorize the Director to grant a waiver on a case-by-case basis for good cause shown.
50	Specifies the format for requesting information by an authorized agent of an entity entitled to receive	In subsections B and C, the changes would: 1) Add requests from the Health Practitioners' Intervention Program (HPIP) for disclosure of information related to a specific applicant for or participant in HPIP (as mandated by

	reports	the amended Code section, § 54.1-2523). 2) Specify that requests shall be made in a format designated by the department, rather than in writing to permit submission of electronic requests, at such time when the agency has instituted a system that ensures confidentiality and security.
60	Establishes the content of a request from an entity to which the Director is allowed to disclose information in the Program.	In subsection A, the amendment would allow an electronic request (see above). In subsection B, subdivision 2: 1) The prescriber is allowed to request information about a patient or prospective patient for the purpose of establishing a treatment history. The Code also allows the prescriber to query if he is initiating treatment for a prospective patient. 2) The prescriber's request must be accompanied by the prescriber's registration number with the United States Drug Enforcement Administration (DEA) rather than a license number issued by the Department. The Code was amended to allow a prescriber licensed in another state to query the Program, so it was necessary to establish another identifier to verify authorization to prescribe. 3) The amendments would eliminate the requirement that the written consent be separate and distinct from any other consent documents required by the practitioner. In subsection B, subdivision 5: In accordance with statutory authority to disclose information to a dispenser for the purpose of establishing a prescription history for a specific person to assist in determining the validity of a prescription, subdivision 5 is added to establish the criteria for submission of such a request. The request must be accompanied by the dispenser's license number issued by the relevant licensing authority in Virginia or if the dispensing occurs in a pharmacy located outside Virginia, the request must include the registration number issued by the Virginia Board of Pharmacy for a non-resident pharmacy. It must also include an attestation that the dispenser is in compliance with patient notice requirements of 18VAC76-20-70. Subsections C and D are amended to eliminate the need for the request to be submitted in writing or by facsimile (see above) with a "signed" request form. Subsection E is added to include provisions for release of information to the Office of the Chief Medical Examiner or to a designated employee of the Department of Medical Assistance Services to receive reports under § 54.1-2523 (C) of the Code of Virginia. The requirements for filing such a request include registration with the Director to include an attestation from the applicant's employer of the eligibility and identity of such person. Registration as an agent authorized to receive

		reports expires 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. The requirements for registration as an agent or designated employee are the same as those set out in Section 50, which specifies the criteria for mandatory disclosure of information by the Director to authorized agencies.
n/a	70	The Code (§54.1-2523) requires dispensers to provide notice to patients, "in a manner specified by the Director in regulation," so Section 70 establishes requirements for notification to the public by a dispenser who intends to request disclosure of information from the Program relating to a recipient or prospective recipient. That notice can either be in the form of a sign posted at the location where prescription are accepted for dispensing, written material provided to the patient or written consent obtained from the patient.