Virginia Regulatory Town Hall

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Emergency Regulation and Notice of Intended Regulatory Action (NOIRA) 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	6/17/05

This form is used when an agency wishes to promulgate an emergency regulation (to be effective for up to one year), as well as publish a Notice of Intended Regulatory Action (NOIRA) to begin the process of promulgating a permanent replacement regulation.

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.*

Preamble

The APA (Code of Virginia § 2.2-4011) states that an "emergency situation" is: (i) a situation involving an imminent threat to public health or safety; or (ii) a situation in which Virginia statutory law, the Virginia appropriation act, or federal law requires that a regulation shall be effective in 280 days or less from its enactment, or in which federal regulation requires a regulation to take effect no later than 280 days from its effective date.

1) Please explain why this is an "emergency situation" as described above.
2) Summarize the key provisions of the new regulation or substantive changes to an existing regulation.

The adoption of an "emergency" regulation by the Director of the Department of Health Professions is required to comply with amendments to Chapter 25.2 of Title 54.1 and the third enactment clause of HB2429 and SB1098 enacted by the 2005 General Assembly, which requires: "*That the Director of the Department of Health Professions shall promulgate regulations to implement the provisions of this act to be effective within 280 days of its*

enactment." Chapters 637 and 678 were enacted on March 23, 2005, the day HB2429 and SB1098 were signed by the Governor.

The amended regulations will: 1) Include provisions for expansion of the Program such as 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; 2) Eliminate provisions that may stand as a barrier to the adoption of electronic requests and disclosures; 3) Provide criteria for requests from prescribers who are not licensed in Virginia; and 4) Establish requirements for notification by a dispenser to his patients about requests for disclosure of prescription information in the Program.

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.

Legal basis

Other than the emergency authority described above, 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., 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 describe the subject matter and intent of the planned regulatory action. Also include a brief explanation of the need for and the goals of the new or amended regulation.

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 are required within 280 days of enactment.

Substance

Please detail any changes that are proposed. Please outline new substantive provisions, all substantive changes to existing sections, or both where appropriate. Set forth the specific reasons why the regulation

is essential to protect the health, safety, or welfare of Virginians. Delineate any potential issues that may need to be addressed as a permanent final regulation is developed.

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 reports	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 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.

Alternatives

Please describe all viable alternatives to the proposed regulatory action that have been or will be considered to meet 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. 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.

Family impact

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

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