Virginia Regulatory Town Hall

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Proposed Regulation
Agency Background Document

Agency name	Department of Health Professions
Virginia Administrative Code (VAC) citation	18 VAC 76-20-10 et seq.
Regulation title	Regulations Governing the Prescription Monitoring Program
Action title	Requirements for informed consent from patients
Document preparation date	6/18/04

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.

Section 60 sets out the criteria for discretionary disclosure of information from the Prescription Monitoring Program. Under certain conditions, prescribers licensed in Virginia are permitted to query the system to establish a treatment history for a patient. The requirement to submit a copy of the written consent for disclosure has been viewed as burdensome and unnecessary. An amendment would eliminate that requirement and specify that a copy be maintained in the patient record. The prescriber would have to attest on the request form that he has obtained written consent to receive information on a patient's prescription history for Schedule II drugs.

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.

18 VAC 76-20-10 et seq. Regulations Governing the Prescription Monitoring Program is promulgated under the legal authority of § 54.1-2505, stating the powers and duties of the Director of the Department of Health Professions and § 54.1-2520, which requires the director to promulgate such regulations as are necessary to implement the prescription monitoring program. The Code section that sets out the statutory requirements for disclosure is:

§ 54.1-2523. Confidentiality of data; disclosure of information; discretionary authority of Director.

A. All data, records, and reports relating to the prescribing and dispensing of covered substances to recipients and any abstracts from such data, records, and reports that are in the possession of the Prescription Monitoring program pursuant to this chapter and any material relating to the operation or security of the program shall be confidential and shall be exempt from the Virginia Freedom of Information Act (§ 2.2-3700 et seq.) pursuant to subdivision A 78 of § 2.2-3705. Further, the Director shall only have discretion to disclose any such information as provided in subsections B and C.

B. Upon receiving a request for information in accordance with the Department's regulations and in compliance with applicable federal law and regulations, the Director shall disclose the following:

1. Information relevant to a specific investigation of a specific recipient or of a specific dispenser or prescriber to an agent designated by the superintendent of the Department of State Police to conduct drug diversion investigations pursuant to § 54.1-3405.

2. Information relevant to an investigation or inspection of or allegation of misconduct by a specific dispenser or prescriber or information relevant to a disciplinary proceeding before a board or in any subsequent trial or appeal of an action or board order to designated employees of the Department of Health Professions.

3. Information relevant to the proceedings of any investigatory grand jury or special grand jury that has been properly impaneled in accordance with the provisions of Chapter 13 (§ 19.2-191 et seq.) of Title 19.2.

C. In accordance with the Department's regulations and applicable federal law and regulations, the Director may, in his discretion, disclose:

1. Information in the possession of the program concerning a recipient who is over the age of eighteen to that recipient.

2. Information on a specific recipient to a prescriber licensed by the appropriate regulatory board in the Commonwealth for the purpose of establishing the treatment history of the specific recipient when such recipient is either under care and treatment by the prescriber or the prescriber is initiating treatment of such recipient, and the prescriber has obtained written consent to such disclosure from the recipient.

3. Information relevant to an investigation or regulatory proceeding of a specific dispenser or prescriber to other regulatory authorities concerned with granting, limiting or denying licenses, certificates or registrations to practice a health profession when such regulatory authority licenses such dispenser or prescriber or such dispenser or prescriber is seeking licensure by such other regulatory authority.

4. Information relevant to an investigation relating to a specific dispenser or prescriber who is a participating provider in the Virginia Medicaid program or information relevant to an investigation relating to a specific recipient who is currently eligible for and receiving or who has been eligible for and has received medical assistance services to the Medicaid Fraud Control Unit of the Office of the Attorney General.

D. This section shall not be construed to supersede the provisions of § 54.1-3406 concerning the divulging of confidential records relating to investigative information.

E. Confidential information that has been received, maintained or developed by any board or disclosed by the board pursuant to subsection A shall not, under any circumstances, be available for discovery or court subpoena or introduced into evidence in any medical malpractice suit or other action for damages arising out of the provision of or failure to provide services. However, this subsection shall not be construed to inhibit any investigation or prosecution conducted pursuant to Article 1 (§ 18.2-247 et seq.) of Chapter 7 of Title 18.2.

The full citation for Chapter 25.2 of Title 54.1 of the Code of Virginia may be found at:

http://leg1.state.va.us/cgi-bin/legp504.exe?021+ful+CHAP0481

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 Prescription Monitoring Program contains information about Schedule II drugs dispensed in Health Planning Region III (the Western District of Virginia). Prescribers are permitted to request information about a specific patient, provided the prescriber holds a license issued by the appropriate regulatory board in the Commonwealth and provided the request is for the purpose of establishing the treatment history of the specific patient when that patient is either under care and treatment by the prescriber or the prescriber is initiating treatment. The law further requires that the prescriber obtain written consent to such disclosure from the patient.

Prescribers report that the requirement for sending a copy of the written consent is an impediment to requesting information from the Program. While there has been some increase in the number of inquiries from prescribers to the PMP since its inception, the Advisory Committee believes the numbers could increase with the amended regulation.

	December-03	January-04	February-04	March 04	April-04	May 04
Prescribers	53	33	86	107	89	78

Deaths related to prescription drugs continue to be a major problem in that region, as verified by the medical examiner. In 2003, there were 213 drug deaths in the Western District – of those deaths, there were findings of methadone in 85, hydrocodone in 47, and oxycodone in 44. In 1994, there were findings of methadone in 1 case, hydrocodone in 0 cases, and oxycodone in 0 cases. The majority of the deaths a decade ago related to cocaine, whereas today, prescription drugs (sometimes in combination with cocaine) represent a serious problem. There is a need to facilitate access to information by prescribers, so it can be determined whether a patient is "doctor-shopping" or the recipient of multiple prescriptions. Prescription drug abuse and drug deaths in that region have created a significant threat to public health and safety. The Monitoring Program was intended to provide one strategy for addressing that problem, and the requirement to submit the consent form has been an impediment to its full utilization.

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.)

The amended regulation would eliminate the requirement for submitting a copy of the consent and allow the prescriber to attest to having obtained written consent from the recipient. In addition, the written consent for disclosure must be maintained as part of the patient record.

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 advantage 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. For the residents in Health Planning District III, this program should be a deterrent to those who would engage in such practices. Prescribers are required to obtain written consent from patients before the system can be queried about the patient's prescription history, so there are no disadvantages to the public. Consent will still be required, and a copy of such consent maintained in the patient record.

2) There are no disadvantages to the agency or the Commonwealth. To the extent queries from prescribers may deter prescribing for abusers of Schedule II controlled substances, there would be advantages to the Commonwealth in general.

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	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

expenditures	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. 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 doctors of medicine, osteopathy, and podiatry, medical interns and residents, and dentists
Agency's best estimate of the number of such entities that will be affected	Doctors of Medicine 29,106 Doctors of Osteopathic Medicine 1085 Doctors of Podiatry 488 Interns & Residents 2750 Dentists 5338
Projected cost of the regulation for affected individuals, businesses, or other entities	There should be no cost for compliance with the proposed amendments, as they are intended to make queries to the PMP less costly for the prescriber.

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 requiring written consent from a patient to allow a prescriber to have access to his Schedule II prescription records kept by the PMP. § 54.1-2523 C 2 of the Code of Virginia permits the Director to disclose: *"Information on a specific recipient to a prescriber licensed by the appropriate regulatory board in the Commonwealth for the purpose of establishing the treatment history of the specific recipient when such recipient is either under care and treatment by the prescriber or the prescriber is initiating treatment of such recipient, and the prescriber has obtained written consent to such disclosure from the recipient."*.

The alternative is an amendment to 18 VAC 76-20-60 B 2, which currently requires the prescriber to provide a copy of the written consent obtained from the recipient. The Director has adopted amendments to eliminate the requirement for provision of a copy of the written consent and replace it with a requirement for the prescriber to attest that he has obtained written consent and an amendment to require a copy to be maintained in the patient record. Modification of the consent regulation is intended to ease the burden of the prescriber and facilitate utilization of the PMP for the purpose of establishing a treatment history on a patient.

The requirement for the written consent to be separate and distinct from any other consent documents required by the practitioner was not eliminated. The proposed amendments are consistent with the recommendation of the Advisory Committee, which represents patient groups, law enforcement, regulators, providers and prescribers.

Public comment

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

The NOIRA was published on May 17, 2004 and comment closed on June 16, 2004. During that period, there was no public comment.

The Prescription Monitoring Program Advisory Committee discussed the notice of intended regulatory action at its meeting on June 9, 2004. The Advisory Committee consists of 13 representatives appointed by the Director, including representatives from: Department's Enforcement Division, Virginia State Police, Virginia Medical Examiners Office, Medicaid Fraud Control Unit, American Cancer Association, Virginia Association for Hospices, Board of Medicine, Board of Pharmacy, a prescriber familiar with pain management, a pharmacist from an affected pharmacy, and such additional members as the Director may designate. The committee voted unanimously to recommend that the patient consent be maintained in the patient's chart and that the prescriber would attest to having received consent on the request form for receiving information from the Program.

Family impact

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

The proposed regulatory action would not have a direct 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.

If the proposed regulation is intended to replace an emergency regulation, please list separately (1) all changes between the pre-emergency regulation and the proposed regulation, and (2) only changes made since the publication of the emergency regulation.

Current section number	Proposed new section	Current requirement	Proposed change and rationale

	number, if applicable		
60 B 2	n/a	Section 60 provides that 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. Subsection B lists the persons and entities to whom the Director may disclose information and the requirements for such disclosure. Subdivision 2 includes disclosure 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 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.	The amended regulation would eliminate the requirement for submitting a copy of the consent and allow the prescriber to attest to having obtained written consent from the recipient. In addition, the written consent for disclosure must be maintained as part of the patient record. The amendment will relieve the prescriber of the responsibility of sending a copy of the consent form for each request for information on the prescriptions for Schedule II drugs that may have been written by other prescribers.