Form: TH- 01

Virginia Regulatory Town Hall

Notice of Intended Regulatory Action
Agency Background Document

Agency Name:	Department of Health Professions
VAC Chapter Number:	18 VAC 76-20-10 et seq.
Regulation Title:	Regulations Governing the Prescription Monitoring Program
Action Title:	Requirements for informed consent from patients
Date:	

This information is required prior to the submission to the Registrar of Regulations of a Notice of Intended Regulatory Action (NOIRA) pursuant to the Administrative Process Act § 9-6.14:7.1 (B). Please refer to Executive Order Twenty-Five (98) and Executive Order Fifty-Eight (99) for more information.

Purpose

Please describe the subject matter and intent of the planned regulation. This description should include a brief explanation of the need for and the goals of the new or amended regulation.

Chapter 481 of the 2002 Acts of the Assembly amended the Code of Virginia to establish a Prescription Monitoring Program and granted authority to the Director of the Department of Health Professions to implement the program. The program requires pharmacies to report to the Department certain prescriptions for drugs having a very high potential for abuse. Under limited circumstances, physicians may request information from the program on a particular patient, whom he suspects of "doctor-shopping" or abusing prescription drugs.

The Director is issuing a Notice of Intended Regulatory Action to consider amendments to 18 VAC 76-20-60, the section that sets out procedures by which there can be a discretionary disclosure of information in the prescription monitoring program (PMP). Specifically, the requirements for the patient to sign a separate and distinct consent form for disclosure of drug information in the PMP and for the physician to provide a copy of the signed release from the patient may need to be amended to remove an unnecessary barrier to full utilization of the monitoring system.

Basis

Please identify the state and/or federal source of legal authority to promulgate the contemplated regulation. The discussion of this authority should include a description of its scope and the extent to which the authority is mandatory or discretionary. The correlation between the proposed regulatory action and the legal authority identified above should be explained. Full citations of legal authority and, if available, web site addresses for locating the text of the cited authority must be provided.

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 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

Substance

Please detail any changes that would be implemented: this discussion should include a summary of the proposed regulatory action where a new regulation is being promulgated; where existing provisions of a regulation are being amended, the statement should explain how the existing regulation will be changed. The statement should set forth the specific reasons the agency has determined that the proposed regulatory action would be essential to protect the health, safety or welfare of citizens. In addition, a statement delineating any potential issues that may need to be addressed as the regulation is developed shall be supplied.

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 there are too many impediments to obtaining written consent, especially the regulations requiring the consent form to be a separate and distinct document from all other consent forms. While there has been a noticeable increase in the number of inquiries from prescribers to the PMP, the numbers have been lower than expected – see chart below.

	December-03	January-04	February-04	March 26, '04
Prescribers	53	33	86	117

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 consent form has been an impediment to its full utilization.

Alternatives

Please describe, to the extent known, the specific alternatives to the proposal that have been considered or will be considered to meet 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 and requires that the written consent be separate and distinct from any other consent documents signed by the patient. The Director will consider 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. He will also consider an amendment to eliminate the requirement that the consent for release of prescription information be separate and distinct from any other consent forms. That would allow the prescriber to incorporate consent for release of prescription information in a general consent form signed by patients for disclosure of information to third party payors. 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.

Family Impact Statement

Please provide a preliminary analysis of the potential impact of the proposed regulatory action on the institution of the family and family stability including to what extent the regulatory action will: 1) strengthen or erode the authority and rights of parents in the education, nurturing, and supervision of their children; 2) encourage or discourage economic self-sufficiency, self-pride, and the assumption of responsibility for oneself, one's spouse, and one's children and/or elderly parents; 3) strengthen or erode the marital commitment; and 4) increase or decrease disposable family income.

To the extent rules implementing a prescription monitoring program serve as a preventive to the proliferation and abuse of schedule II drugs which can destroy lives, families and economic self-sufficiency, they will have a positive effect on families. Compliance with these regulations will not increase or decrease disposable family income.