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:	Initial program implementation
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, law enforcement, regulators and health care providers will have access to these records. Presently, the Program is limited to reporting of schedule II drugs and applicable only in State Health Planning Region III. Entities such as hospitals, licensed hospice, veterinary facilities, and narcotic maintenance programs are exempt, as is dispensing of manufacturers' samples in an indigent patient program and in a bona fide emergency or the administration of covered substances. The law provides for penalties for violation of confidentiality of such data maintained by the Department.

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 are necessary for granting waivers of the reporting requirements and additional exemptions for dispensing of covered substances, for reporting of additional non-clinical information, and for establishing the format and schedule for reporting. Rules are also

necessary for the Director's disclosure of reported information to ensure that confidentiality is maintained and that any disclosure is in accordance with the restrictions set forth in law.

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 being 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 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 proposed regulatory action is intended to implement certain provisions of Chapter 25.2, which establishes a prescription monitoring program. The required elements of regulations with the statutory mandate for regulation are as follows:

- Establishment of criteria for granting waivers of the reporting requirements [§ 54.1-2520 (B)].

Regulations may set out a process by which requests for waivers could be reviewed and decisions to grant or deny rendered. Waivers would likely be granted on a case-by-case basis and may be limited to a specified time period based on factors such as hardship created by a natural disaster or state of emergency or a very low volume of dispensing of schedule II drugs.

- Addition of non-clinical information to reporting requirements [§ 54.1-2521 (B) (8)].

Regulations may set out any additional information that is required to be reported. They may also specify a periodic review of reporting data to determine whether additional information is required to accomplish the intent of the act and a process by which data elements could be added to the reporting requirements for dispensers. Clinical information regarding the patient's

illness or condition is not required to be reported and could not be required through promulgation of a regulation.

- Establishment of the standards for the manner and format of reports and a schedule for reporting [§ 54.1-2521 (C)].

Regulations may set forth the file layout required for reports, which would likely be drafted in consultation with information technology staff and would follow examples used in other states. Such rules may specify industry standard coding of reported drugs. Likewise, the frequency or schedule for reporting would be specified in regulations with a range of options from real-time reporting to bi-monthly. In making a determination about frequency, costs, the burden on reporters and other factors will be balanced by consideration for public safety. If a recipient is "doctor-shopping" or obtaining prescription drugs for an illicit purpose, it would be unwise to allow that activity to go unmonitored for a length of time.

- Establishment of an exemption from reporting [§ 54.1-2522 (8)].

Unlike the granting of a waiver, the establishment of an exemption would likely have general applicability and be based on criteria set in regulation. Criteria for granting such an exemption may include provisions such as the entity only dispenses to a specified, limited, controlled population rather than to the general public or a very low volume of schedule II drugs.

- Establishment of criteria for mandatory disclosure of information by the Director [§ 54.1-2523 (B)].

In the regulation, the Director may set out the specific information that will be required from a person or entity requesting disclosure. For example, if the State Police are requesting presriber information relevant to a specific investigation, it would be necessary to have sufficient information to correctly identify the person and specify a time period for which data is being sought. To ensure compliance with law and regulation, the Director may require that the request specify the entity making the request for disclosure and stating the reason for the request. Regulations may require that it be in writing, signed by an authorized individual with 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.

- Establishment of criteria for discretionary disclosure of information by the Director [§ 54.1-2523 (C)].

The Code sets out four categories of individuals or entities to which the Director, in his discretion, may disclose prescription data. He may disclose to: 1) the recipient, provided he is over the age of 18; 2) a prescriber for the purpose of establishing a treatment history, provided the prescriber has obtained written consent from the recipient; 3) another regulatory authority conducting an investigation or disciplinary proceeding or making a decision on the granting of a license or certificate; and 4) the governmental entities charged with the investigation and prosecution of a dispenser, prescriber or recipient participating in the Virginia Medicaid program.

In each of these categories, regulations may need to stipulate any additional information necessary to ensure that the requestor is so authorized and does meet the statutory requirements. For example, a person requesting his own prescription history from the monitoring program may need to provide a driver's license or some other evidence that he meets the age criteria. A prescriber requesting prescription data on a patient may need to provide a copy of the informed consent or attest in writing to having obtained such consent. A request from another regulatory body may need to be signed by the person who is authorized to certify orders or to grant or deny licenses. A request from Medicaid authorities may need to identify the person or persons designated to receive and utilize such information in conformity to law. In each case, the request must be complete and provide sufficient information to ensure the correct identity of the presciber, patient and/or dispenser.

In addition to the aspects of the program for which the Director is required to promulgate regulations, he is authorized to adopt regulations as necessary for implementation of the program. To that end, the Director will consider comments on the NOIRA received from relevant boards and other interested parties and any other information as may become available during the process of developing regulations. Given the recent history of abuse and illegal distribution of certain schedule II drugs, especially in the Southwestern communities of Virginia, the Director has an obligation to protect public health, safety and welfare by promulgating regulations in a timely manner.

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 promulgation of regulations, as the Director of the Department of Health Professions is specifically mandated to do so in Chapter 25.2 of Title 54.1 of the Code of Virginia. Section 54.1-2520 sets forth the regulatory authority of the Director to establish regulations as are necessary to implement the prescription monitoring program. Subsection B specifies that regulations are to be promulgated in accordance with provisions of the Administrative Process Act after consultation with the relevant health regulatory boards, including the Boards of Pharmacy, Medicine and Dentistry. To provide for consultation, the Director proposes to request comment on the Notice of Intended Regulatory Action and on proposed regulations prior to final adoption.

Since the essential elements of the prescription monitoring program are specified in the Code, regulations establishing the reporting requirements, reporting exemptions, confidentiality of data, criteria for disclosure of information, and penalties for unauthorized disclosure, are not required. However, regulations are necessary, as prescribed by law, to supplement the provisions of statute. For example, § 54.1-2521 sets out the specific identifying information a dispenser is required to report, but the statute also provides a requirement for any other non-clinical information designated by the Director in accordance with the Department's regulations. If any additional information is needed, the process for designating an additional reporting requirement must be specified in regulation.

Other aspects of implementation, such as entering into contracts for implementation and maintenance and provision of a basic file layout for electronic data transmission, are also authorized by statute, so regulations will not be necessary.

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 serves 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 no increase or decrease disposable family income.