Virginia Regulatory Town Hall

Proposed Regulation
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:	New regulations
Date:	11/27/2002

This information is required pursuant to the Administrative Process Act (§ 9-6.14:9.1 *et seq.* of the *Code of Virginia*), Executive Order Twenty-Five (98), Executive Order Fifty-Eight (99), and the *Virginia Register Form,Style and Procedure Manual*. Please refer to these sources for more information and other materials required to be submitted in the regulatory review package.

Summary

Please provide a brief summary of the proposed new regulation, proposed amendments to an existing regulation, or the regulation proposed to be repealed. There is no need to state each provision or amendment or restate the purpose and intent of the regulation; instead give a summary of the regulatory action and alert the reader to all substantive matters or changes. If applicable, generally describe the existing regulation.

The Director of the Department of Health Professions has proposed a new set of regulations to implement provisions of Chapter 25.2 of the Code of Virginia, which sets out requirements for a Prescription Monitoring Program and requires the promulgation of regulations. Regulations set criteria for granting waivers of the reporting requirements, standards and a schedule for reporting, and criteria for mandatory and discretionary disclosure of information by the Director.

Basis

Please identify the state and/or federal source of legal authority to promulgate the regulation. The discussion of this statutory authority should: 1) describe its scope and the extent to which it is mandatory or discretionary; and 2) include a brief statement relating the content of the statutory authority to the specific regulation. In addition, where applicable, please describe the extent to which proposed changes exceed federal minimum requirements. Full citations of legal authority and, if available, web site addresses for locating the text of the cited authority must be provided. Please state that the Office of the

Attorney General has certified that the agency has the statutory authority to promulgate the proposed regulation and that it comports with applicable state and/or federal law.

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

The Office of the Attorney General has certified by letter that the Board has the statutory authority to promulgate the proposed regulation and that it comports with applicable state and/or federal law.

Purpose

Please provide a statement explaining the need for the new or amended regulation. This statement must include the rationale or justification of the proposed regulatory action and detail the specific reasons it is essential to protect the health, safety or welfare of citizens. A statement of a general nature is not acceptable, particular rationales must be explicitly discussed. Please include a discussion of the goals of the proposal and the problems the proposal is intended to solve.

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. 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.

Substance

Please identify and explain the new substantive provisions, the substantive changes to existing sections, or both where appropriate. Please note that a more detailed discussion is required under the statement providing detail of the regulatory action's changes.

The proposed regulations 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 set out a process by which requests for waivers could be reviewed and decisions to grant or deny rendered. Waivers would 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 for dispensing in a research project.

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

Regulations set forth the file layout required for reports, which follows examples used in other states using the industry standard coding of reported drugs. Likewise, the frequency or schedule for reporting is specified as bi-monthly.

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

The regulation sets out the specific information that will be required from a person or entity requesting disclosure. To ensure compliance with law and regulation, the Director will require that the request specify the entity making the request for disclosure and stating the reason for the request. Regulations 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 stipulate additional information necessary to ensure that the requestor is so authorized and does meet the statutory requirements.

Issues

Please provide a statement identifying the issues associated with the proposed regulatory action. The term "issues" means: 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 there are no disadvantages to the public or the Commonwealth, please include a sentence to that effect.

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. For the residents in Health Planning District III, this program should be a deterrent to those who would engage in such practices. As proposed, the public (those who are legitimately prescribing, dispensing and consuming Schedule II drugs) should be protected by the requirements for mandatory or discretionary disclosure. Prescribers will be required to obtain written consent from patients before the system can be queried about the patient's prescription history. 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 provided funding can be obtained from federal grants or other sources. Those funds must be sufficient to provide the personnel and resources necessary to implement the Program. Licensee fees will not be used to fund this activity. 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.

Fiscal Impact

Please identify the anticipated fiscal impacts and at a minimum include: (a) the projected cost to the state to implement and enforce the proposed regulation, including (i) fund source / fund detail, (ii) budget activity with a cross-reference to program and subprogram, and (iii) a delineation of one-time versus on-going expenditures; (b) the projected cost of the regulation on localities; (c) a description of the individuals, businesses or other entities that are likely to be affected by the regulation; (d) the agency's best estimate of the number of such entities that will be affected; and e) the projected cost of the regulation for affected individuals, businesses, or other entities.

Projected cost to the state to implement and enforce:

(i) Fund source: As a special fund agency, the Board must generate sufficient revenue to cover its expenditures from non-general funds, specifically the renewal and application fees it charges to practitioners for necessary functions of regulation. However, the fourth enactment of Chapter 481 of the 2002 Acts of the Assembly provides: "That the provisions of this act shall become effective on the date that sufficient federal funds or other grant monies are available to support the development and operation of the prescription monitoring program for its initial year of operation. After such initial year, the continuation of the prescription monitoring program shall be conditioned upon (i) the provision of appropriations from the general fund of the Commonwealth as set forth in the appropriation act or (ii) the receipt by the program of federal funds or other grant moneys or (iii) support provided through a combination of general fund appropriations and federal funds or other grant moneys." Therefore, licensing and renewal fees of health professionals are not to be used as the fund source for this activity.

To meet the funding mandate for the Program, the Department submitted an application for funding this summer as required by legislation passed by the 2002 Virginia General Assembly requiring the Director to establish a Prescription Monitoring Program (PMP). The Department of Health Professions has been notified that it will be the recipient of expecting the announcement of grant awards for the Harold Rogers Prescription Drug Monitoring Program from the Federal Bureau of Justice Assistance. Once the amount of the grant has been determined and other sources of funding identified, the Department will enter the implementation phase of the Program with a target date of July 1, 2003.

(ii) Budget activity by program or subprogram: There is no change required in the budget of the Commonwealth as a result of this program.

(iii) One-time versus ongoing expenditures: There are no additional expenditures associated with these regulations. Expenditures related to the Prescription Monitoring Program, estimated at $360,069 for the first full year of operation, plus approximately six months of start-up costs, are those required to implement the program as mandated by the statute. Those expenditures include personnel and fringe benefits, equipment and supplies, travel to the region, and consultants and contracts.

Projected cost on localities:

There are no projected costs to localities.

Description of entities that are likely to be affected by regulation:

The entities that are likely to be affected by these regulations would be pharmacies that dispense drugs in Southwest Virginia or Health Planning Region III. The entities that could request disclosure of information contained in the system include: those specified in the law, recipients of the dispensed drugs, prescribers, and other governmental agencies.

Estimate of number of entities to be affected:

There are approximately 300 pharmacies in Health Planning Region III that will be required to report dispensing records for Schedule II drugs. The number of entities that may request information from the system is unknown.

Projected costs to the affected entities:

Since the data system used for prescription monitoring will be the same system pharmacies now use for third party payments, there should be no additional cost for compliance. The program and instructions for reporting to the Department will be provided to all affected dispensers. There is no cost to entities who request a query of the system on a particular patient or prescriber.

Detail of Changes

Please detail any changes, other than strictly editorial changes, that are being proposed. Please detail new substantive provisions, all substantive changes to existing sections, or both where appropriate. This statement should provide a section-by-section description - or cross-walk - of changes implemented by the proposed regulatory action. Where applicable, include citations to the specific sections of an existing regulation being amended and explain the consequences of the proposed changes.

18 VAC 76-20-10. Definitions.
The regulation references words and terms defined in § 54.1-2519 of the Code of Virginia and adds a definition for "program."

18 VAC 76-20-20. General provisions.
This section specifies the statutory authority for the Director of the Department of Health Professions to establish and administer a program for monitoring the dispensing of Schedule II controlled substances.

18 VAC 76-20-30. Criteria for granting waivers of the reporting requirements.
Subsection A specifies that the Director may grant a waiver of all or some of the reporting requirements to an entity who files a request in writing on a form provided by the Department if it meets the criteria for such a waiver.

Subsection B establishes the criteria for such a waiver to include a history of compliance with laws and regulations by the pharmacy, the pharmacist-in-charge, and other pharmacists regularly practicing at that location. The criteria may also include a hardship created by a natural disaster or other emergency beyond the control of the pharmacist or pharmacy or dispensing in a controlled research project approved by a regionally accredited institution of higher education or under the supervision of a governmental agency.

Subsection C provided that a waiver may be granted on a case-by-case basis and in accordance with the Administrative Process Act, subject to terms and conditions stated in an order with a specified time period and subject to being vacated. The initial waiver decision is to be made by a subordinate appointed by the Director. An appeal of the initial decision may be filed with the Director who shall appoint an informal fact-finding conference, which shall make a recommendation to the Director. The final decision rests with the Director

18 VAC 76-20-40. Standards for the manner and format of reports and a schedule for reporting.
Subsection A provides that data must be transmitted to the Department or its agent on a semi-monthly basis in the Telecommunication Format for Controlled Substances of the American Society of Automation in Pharmacy (ASAP) and that format is incorporated by reference into this chapter.

Subsection B provides that data must be transmitted in a file layout provided by the Department and by a media acceptable to the vendor contracted by the Director for the program.

18 VAC 76-20-50. Criteria for mandatory disclosure of information by the Director.
Subsection A requires an individual to be registered with the Director as an authorized agent entitled to receive reports under § 54.1-2523 (B) of the Code of Virginia in order to request disclosure of information contained in the program. Requirements for registration include: 1) the request for registration must contain an attestation from the applicant's employer of the eligibility and identity of such person; and 2) 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.

Subsection B requires an authorized agent to request in writing, on a form provided by the Department, disclosure of information related to a specific investigation. The request must contain a case identifier number, a specified time period to be covered in the report, and the specific recipient, prescriber or dispenser for which the report is to be made, and an identifier number for the subject of the disclosure.

Subsection C requires that the request be signed 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.

18 VAC 76-20-60. Criteria for discretionary disclosure of information by the Director.
Subsection A provides for the discretionary disclosure of information if the request is in writing and contains a notarized signature of the requesting party.

Subsection B sets out to whom the Director may disclose information to include: 1) the recipient of the dispensed drugs, provided the request is accompanied by a copy of a driver's license verifying that the recipient is over the age of 18 and provided the report is mailed to the address on the license or delivered to the recipient at the Department; 2) 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 an attestation that he has obtained written consent from the recipient. The written consent from the patient must be separate and distinct from any other consent documents required by the practitioner; 3) another regulatory authority conducting an investigation or disciplinary proceeding or making a decision on the granting of a license or certificate, provided the request is accompanied by the signature of the chief executive officer who is authorized to certify orders or to grant or deny licenses; and 4) governmental entities charged with the investigation and prosecution of a dispenser, prescriber or recipient participating in the Virginia Medicaid program, provided the request is accompanied by the signature of the official within the Office of the Attorney General responsible for the investigation.

Subsection C requires that the request must be complete and provide sufficient information to ensure the correct identity of the presciber, recipient and/or dispenser. Requests shall be

submitted in writing by mail, private delivery service, in person at the Department offices or by facsimile.

Alternatives

Please describe the specific 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 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 requested 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 are not necessary.

Although the Code authorizes the adoption of regulations for additions to the non-clinical information required to be reported [§ 54.1-2521 (B) (8)] and for the establishment of an exemption from reporting [§ 54.1-2522 (8)], regulations are not proposed for those purposes. The Director determined that there were no additional data elements that should 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. The Director also determined that there should be no general exemptions from reporting (other than those set out in the Code). Unlike the granting of a waiver, the establishment of an exemption would have general applicability, and a need for additional exemptions has not been established. Should an exemption become necessary for good cause, an entity or individual could apply for a waiver.

Public Comment

Please summarize all public comment received during the NOIRA comment period and provide the agency response.

An announcement of the board's intent to amend its regulations was posted on the Virginia Regulatory Townhall, sent to the Registrar of Regulations, and sent to persons on the PPG mailing list for the Boards of Medicine, Pharmacy and Dentistry. Public comment was received from July 15, 2002 to August 14, 2002.

During the 30-day comment period, the Director conducted a public hearing at Wytheville Community College in Health Planning District II, the region designated by the law for monitoring. The 10 persons at the hearing received an explanation of the legislation and development of regulations. Questions were answered, and the suggestion made to utilize a format consistent with the electronic reporting used by pharmacies for third-party payments.

Two written comments on the NOIRA were received:

The National Association of Chain Drug Stores made the following recommendations: 1) The program should be electronic and information should be transmitted as a batch file on a monthly or semi-monthly basis rather than on-line real processing; 2) physicians who dispense should also be required to report; 3) the data elements should be consistent with protocols for electronic reporting by the American Society for Automation in Pharmacy; and 4) the monitoring program should be designed to be consistent with HIPAA.

The Virginia Dental Association commented that it does not foresee any impact on the practice of dentistry. There was concern expressed about the cost of the program, especially if federal funds are not available.

The agency has responded to the comments by establishing requirements for the transmission to be in file format on a semi-monthly basis in a format consistent with the ASAP. Confidentiality of patient information is maintained, except as provided in the law for a specific investigation of a possible violation of law. The definition of dispenser in § 54.1-2519 would cover physicians authorized by the Board of Pharmacy to sell drugs. Dispensing by physicians of manufacturers' samples, in a bona fide medical emergency or covered substances pursuant to an indigent patient program are specifically exempted from reporting by law (§ 54.1-2522).

In addition, two comments were received on the draft proposal that was sent to the affected boards:

A member of the Board of Medicine commented that the written consent form signed by a patient giving permission for a prescriber to query the monitoring should be submitted with the request for disclosure of information from the Program. The Director modified the proposed regulation to require that the written consent from the patient be separate and distinct from other consent forms so the patient is aware of what he is signing. That change addressed the intent of the comment.

A member of the Board of Pharmacy requested that the report be submitted monthly instead of semi-monthly and that it not be due until the 15th of the following month to allow for shipment of data. The Director did not amend the proposal because the data is shipped by a keystroke to the vendor; there should be no need for a delay in receiving the information.

Clarity of the Regulation

Please provide a statement indicating that the agency, through examination of the regulation and relevant public comments, has determined that the regulation is clearly written and easily understandable by the individuals and entities affected.

The regulations have been developed by staff of the Department based on provisions in the law, regulations of similar programs in other states, and comments received from the public on the development of regulations. The Assistant Attorney General who provides counsel to the Board has been involved during the development and adoption of proposed regulations to ensure clarity and compliance with law and regulation.

Periodic Review

Please supply a schedule setting forth when the agency will initiate a review and re-evaluation to determine if the regulation should be continued, amended, or terminated. The specific and measurable regulatory goals should be outlined with this schedule. The review shall take place no later than three years after the proposed regulation is expected to be effective.

Public participation guidelines require the Board to review regulations each biennium or as required by Executive Order. Regulations governing the prescription monitoring program will be reviewed again after the program has been implemented or by the 2004-05 fiscal year.

Family Impact Statement

Please provide an analysis of the proposed regulatory action that assesses the potential impact on the institution of the family and family stability including the extent to which 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 not increase or decrease disposable family income.