Virginia Regulatory Town Hall

Final 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:	Initial regulation
Date:	6/23/03

Please refer 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* for more information and other materials required to be submitted in the final regulatory action package.

Summary

Please provide a brief summary of the new regulation, amendments to an existing regulation, or the regulation being repealed. There is no need to state each provision or amendment; instead give a summary of the regulatory action. If applicable, generally describe the existing regulation. Do not restate the regulation or the purpose and intent of the regulation in the summary. Rather, alert the reader to all substantive matters or changes contained in the proposed new regulation, amendments to an existing regulation, or the regulation being repealed. Please briefly and generally summarize any substantive changes made since the proposed action was published.

The Director of the Department of Health Professions has adopted 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.

Changes Made Since the Proposed Stage

Please detail any changes, other than strictly editorial changes, made to the text of the proposed regulation since its publication. Please provide citations of the sections of the proposed regulation that have been altered since the proposed stage and a statement of the purpose of each change.

The following changes to proposed regulations have been made in the adoption of final amendments:

18 VAC 76-20-30. Criteria for granting waivers of the reporting requirements.

In response to comment, the word "substantial" was added in the provision that allows the Director to grant a waiver from reporting for a hardship created by a natural disaster or other emergency beyond the control of the pharmacy.

18 VAC 76-20-40. Standards for the manner and format of reports and a schedule for reporting.

- The version of the Telecommunication Format for Controlled Substances that is universally used by pharmacies is the May, 1995 version rather than the August, 1999 version as stated in the proposed regulation, so the change was made to conform the incorporation by reference.

- A requirement to establish a schedule for beginning transmission of data was not included in the proposed regulation, so it has been set on a date to be specified by the Director, no less than 30 days from notification by the Director to dispensers that are required to report.

- Two new subsections were added to this section:

  Subsection C provides that an alternative means of reporting may be approved by the Director under extraordinary circumstances.

  Subsection D provides that data with a substantial number of errors or omissions must be corrected and resubmitted within five business days after receiving notification.

18 VAC 76-20-60. Criteria for discretional disclosure of information by the Director.

- In subsection A, the requirement for a notarized signature by the requesting party was eliminated as not being necessary for all parties to whom the Director may disclose information.

- In subsection B, the following changes were made:

  In #1, a requirement for a notarized signature is inserted for a request from a recipient, since there is no other signature or authorization required on such a request. The requirement for a valid driver's license was also modified to require instead a photo identification issued by a government agency of any jurisdiction in the U. S.

  In #2, the requirement for a prescriber to obtain written consent from a patient to request data from the monitoring system is modified to require the prescriber to submit a copy of the consent rather than just an attestation that it has been obtained.

In #3, it is further specified that the request for data from another regulatory authority must be related to an allegation of a possible controlled substance violation.

- A new subsection D was added to specify that, with the exception of a request from the recipient of the drugs, a request form must include 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.

Statement of Final Agency Action

Please provide a statement of the final action taken by the agency: including the date the action was taken, the name of the agency taking the action, and the title of the regulation.

On June 23, 2003, the Director of the Department adopted final amendments to 18 VAC 76-20-10 et seq., Regulations Governing the Prescription Monitoring Program, in order to implement a statutory mandate.

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, shall be provided. If the final text differs from that of the proposed, please state that the Office of the Attorney General has certified that the agency has the statutory authority to promulgate the final 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 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 final 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 of the regulatory action's detail.

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, and transmission of data must begin on a date specified by the Director, no less than 30 days after notification to dispensers. Regulations allow the Director to approve an alternative method of reporting and specify that data that has substantial error or omissions must be resubmitted with 5 business days of notification.

- 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. Regulations also specify that the requestor must attest that the disclosed information will not be used for any purpose other than that stated in the request.

Issues

Please provide a statement identifying the issues associated with the final regulatory action. The term "issues" means: 1) the advantages and disadvantages to the public of implementing the new provisions; 2) the 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 adopted, the regulations should protect the public (those who are legitimately prescribing, dispensing and consuming Schedule II drugs) 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.

Public Comment

Please summarize all public comment received during the public comment period and provide the agency response. If no public comment was received, please include a statement indicating that fact.

Proposed regulations were published in the Virginia Register of Regulations on April 4, 2003. Public comment was requested for a 60-day period ending June 6, 2003. A Public Hearing before the Director of the Department was held on April 23, 2003 at which comments were received on proposed regulations. A summary of the written and oral comments is as follows:

A representative of the Virginia Hospice Association testified that his organization represents patients who are coping with terminal illnesses often necessitating substantial use of schedule II drugs for pain management. There is concern that the PMP will intimidate prescribers who will be reluctant to prescribe adequate amounts of pain medications, but additional protection of patient privacy may allay those concerns for prescribers and patients. Suggested changes to the regulation were: 1) In section 60, the prescriber who is requesting disclosure of information on a patient from the system should be required to provide written consent of the recipient rather than an attestation that he has obtained consent; and 2) In section 60, the regulatory authorities and governmental agencies that may request data from the system should have to show probable cause in addition to providing a signature to access the PMP data. There should be greater justification for querying the system than a simple request from the agency head. This change would assure prescribers that PMP data is not being used to investigate practitioners without probable cause and not being used merely to collect data on prescribers who are outside the norm in their prescribing. The commenter also requested a thorough evaluation of the project before it is expanded to other areas of the state and offered involvement of his group in evaluating the program.

> **Response to comment:** The Director assured all commenters that there was no intent to intimidate prescribers or place any barriers that would inhibit the legitimate prescribing and dispensing of medications. Efforts have been made throughout the legislative and

regulatory process to ensure adequate protection for prescribers or persons who are the recipients of such prescribing. In response to specific recommendations, the Director amended section 60 to require that the patient's written consent for a prescriber to request information from the system be attached to the request to the Director. The Director did not amend the regulation to specify that probably cause must be demonstrated by a regulatory or law enforcement authority seeking information. The statute requires that the information requested be relevant to a specific investigation or proceeding on a specific dispenser or prescriber; it limits queries to the system to information based on some evidence or specific allegation of violation. To ensure that the request is specifically related to a possible controlled substance violation, the Director added that requirement to subsection B 3 in section 60, so information from the system could not be obtained for an investigation unrelated to controlled substances. Finally, the Director explained that the statute requires an evaluation of the project before it is expanded to other areas of the state; it is his intention to involve the parties concerned about pain management and hospice patient in the group evaluating the program.

A representative of the American Cancer Society spoke about the mandatory and discretionary disclosure by the Director and advocated for patient privacy and confidentiality in requesting that sections 50 and 60 that disclosure must comply with federal rules on privacy of patient records. He also requested that the evaluation of the program try to assess any negative impact on patients in consultation with providers, patients, pharmacists and advocacy groups.

Response to comment: Statutory language on confidentiality clearly states that it is unlawful for any person having access to confidential information or any reports produced by the program to disclose such information unless specifically provided by law and regulation. Such disclosure could result in the person being found guilty of a Class I misdemeanor (§ 54.1-2525). Further, § 54.1-2523 provides that the Director may only disclose information upon receiving a request "in compliance with applicable federal law and regulations." As stated above, an evaluation of the program is mandated and will include consultation with all interested parties and affected groups.

A representative of the Virginia Cancer Pain Initiative spoke about the study of the triplicate prescription program in California but was not aware of any studies that have been concluded regarding the effect of electronic monitoring on availability of pain medication. He suggested an initial survey to get a baseline from which to measure effect and effectiveness. He also expressed concern about the ability of patients to find prescribers and dispensers who would assist them in adequately managing their pain.

Response to comment: The design and execution of an evaluative study of prescription monitoring and its effect on pain management are not regulatory issues and are not addressed in this action. However, the Director took note of the suggestions that were made and of the advocacy groups that are interested in participating in such a study.

The president of the Virginia Cancer Pain Initiative requested that there be collaboration between members of the intake unit at DHP and law enforcement agencies, so that any disciplinary actions would rest with the Department. He also suggested that Virginia address issues related to inappropriate requests for disclosure, so as has been done in Tennessee. He requested that an educational effort be undertaken to help dispensers and prescribers understand the program and offered support for an evaluation process.

Response to comment: It is certainly the intent of the Director that there be collaboration between the intake unit in DHP investigations and law enforcement agencies. Disciplinary actions would rest with the Department, but violations of law may be pursued by the State Police. An educational effort is being planned to address issues such as mandated reports and appropriate requests for information and disclosure.

In addition the following written comment was received:

A representative of the Virginia Cancer Pain Initiative provided written comment that reiterated concerns expressed at the public hearing about any further barriers to prescribing of adequate and appropriate pain medications.

Response to comment: See response above to comment from the Hospice Association.

A representative of the Department of State Police recommended the following additions: 1) putting the word "substantial" before a hardship request for granting a waiver from reporting; 2) permitting further disclosure to counsel or Commonwealth's Attorney in criminal trial; 3) providing data to a grand jury that has been impaneled; 4) allowing other types of photo identification issued by a governmental agency to serve as verification of a recipient's identify in a request to the Director for data; and 5) language in section 60 that is identical to that currently in section 50 that requires an attestation from the person requesting information that it will only be used for the purpose stated in the request and in accordance with the law.

Response to comment: The Director's response is as follows:

1) The Director accepted the recommendation to add "substantial" hardship in order to request a waiver from reporting.

2) The entities to whom the Director may disclose information from the profile are set out in subsections B and C of § 54.1-2523; any change or additions to those specified entities would necessitate a change in the Code rather than in regulation. The prescription monitoring profile is intended to be an investigative tool to increase efficiency of investigations and decrease time and cost. The information can be provided to a grand jury, but was not intended to be a substitute for subpoenaing pharmacy records as evidence in a trial.

3) The statute provides for mandatory disclosure of information relevant to the proceedings of any investigatory or special grand jury (§ 54.1-2523 B 3). It is not necessary to repeat that provision in regulation.

4) The Director amended section 60 to accept any other governmental photo identification in addition to a driver's license.

5) Subsection D was added to section 60 that requires an attestation from the person requesting information that it will only be used for the purpose stated in the request and in accordance with the law.

The Executive Director of the Virginia Board of Pharmacy recommended the following changes: 1) in section 40 A, use "a nationally recognized standard specified by the Director" rather than the 1999 ASAP standard currently incorporated by reference in the regulation; 2) in section 40 B, add a clarification that reporters must "submit reports on a date specified by the Director or 30 days after receiving instructions on procedures on submission of data;" 3) addition of subsection

C to provide for an alternative means of reporting to be approved by the Director under extraordinary circumstances; 4) addition of subsection D to section 40 to require that data not acceptable to the vendor due to omissions or errors must be corrected within 5 business days of notification from the vendor and 5) in section 60, clarify that the notarization of the signature is only needed from a recipient of the prescriptions making a request for disclosure of his prescription data;.

Response to comment:

1) The regulated public needs to know what standard is acceptable, so the Director modified the proposed regulation (section 40 A) to specify the May, 1995 ASAP standard as incorporated by reference in the regulation.

2) In section 40, subsection B, language is added to specify when reports must be transmitted, which is on a date specified by the Director or 30 days after receiving instructions on procedures on submission of data.

3) Subsection C of section 40 was added to provide for an alternative means of reporting to be approved by the Director under extraordinary circumstances.

4) Subsection D of section 40 was added to require that data not acceptable to the vendor due to omissions or errors must be corrected within 5 business days of notification from the vendor.

5) Subsection 60 was modified to clarify that the notarization of the signature is only needed from a recipient of the prescriptions making a request for disclosure of his prescription data.

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 crosswalk - of changes implemented by the proposed regulatory action. Include citations to the specific sections of an existing regulation being amended and explain the consequences of the 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 substantial 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 (May, 1995) 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. A requirement to establish a schedule for beginning transmission of data was not included in the proposed regulation, so it has been set on a date to be specified by the Director, no less than 30 days from notification by the Director to dispensers that are required to report.

Subsection C provides that an alternative means of reporting may be approved by the Director under extraordinary circumstances.

Subsection D provides that data with a substantial number of errors or omissions must be corrected and resubmitted within five business days after receiving notification from the vendor.

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 on a form provided by the Department.

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 notarized signature and a copy of a photo identification issued by a government agency of any jurisdiction in the U. S. 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 a copy of the written consent obtained 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 provided the request for data is related to an allegation of a possible controlled substance violation; 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.

Subsection D was added to specify that, with the exception of a request from the recipient of the drugs, a request form must include 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.

Family Impact Statement

Please provide an analysis of the regulatory action that assesses the 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 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.