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Proposed Regulation
Agency Background Document

Agency name	Department of Health Professions
Virginia Administrative Code (VAC) citation(s)	18VAC76-20-10
Regulation title(s)	Regulations Governing the Prescription Monitoring Program
Action title	Standards and schedule for reporting
Date this document prepared	2/4/16

This information is required for executive branch review and the Virginia Registrar of Regulations, pursuant to the Virginia Administrative Process Act (APA), Executive Orders 17 (2014) and 58 (1999), and the *Virginia Register Form, Style, and Procedure Manual.*

Brief summary

Please provide a brief summary (preferably no more than 2 or 3 paragraphs) of the proposed new regulation, proposed amendments to the existing regulation, or the regulation proposed to be repealed. Alert the reader to all substantive matters or changes. If applicable, generally describe the existing regulation.

The proposed regulatory action will update the required version for reporting data electronically to the Prescription Monitoring Program (PMP) and include several new data elements in the report that have been identified as useful in tracking information and providing prescriber feedback reports. The intent of the regulatory action is to make the PMP an even more useful tool in the efforts against prescription drug abuse in the Commonwealth.

Acronyms and Definitions

Please define all acronyms used in the Agency Background Document. Also, please define any technical terms that are used in the document that are not also defined in the "Definition" section of the regulations.

PMP = Prescription Monitoring Program

Legal basis

Please identify the state and/or federal legal authority to promulgate this proposed regulation, including: 1) the most relevant citations to the Code of Virginia or General Assembly chapter number(s), if applicable; and 2) promulgating entity, i.e., agency, board, or person. Your citation should include a specific provision authorizing the promulgating entity to regulate this specific subject or program, as well as a reference to the agency/board/person's overall regulatory authority.

The statutory authority for the Director of the Department to promulgate regulations is found in:

§ 54.1-2520. Program establishment; Director's regulatory authority.

B. The Director, after consultation with relevant health regulatory boards, shall promulgate, in accordance with the provisions of the Administrative Process Act (§ 2.2-4000 et seq.), such regulations as are necessary to implement the prescription monitoring program as provided in this chapter, including, but not limited to, the establishment of criteria for granting waivers of the reporting requirements set forth in § 54.1-2521.

Statutory authority for specifying data elements contained in and the format for the PMP report is found in:

§ 54.1-2521. Reporting requirements.

B. Upon dispensing a covered substance, a dispenser of such covered substance shall report the following information:

1. The recipient's name and address.

2. The recipient's date of birth.

3. The covered substance that was dispensed to the recipient.

4. The quantity of the covered substance that was dispensed.

5. The date of the dispensing.

6. The prescriber's identifier number.

7. The dispenser's identifier number.

8. The method of payment for the prescription.

9. Any other non-clinical information that is designated by the Director as necessary for the implementation of this chapter in accordance with the Department's regulations.

10. Any other information specified in regulations promulgated by the Director as required in order for the Prescription Monitoring Program to be eligible to receive federal funds.

C. The reports required herein shall be made and transmitted in such manner and format and according to the standards and schedule established in the Department's regulations.

Purpose

Please explain the need for the new or amended regulation. Describe the rationale or justification of the proposed regulatory action. Describe the specific reasons the regulation is essential to protect the health, safety or welfare of citizens. Discuss the goals of the proposal and the problems the proposal is intended to solve.

Prescription drug abuse is one of the leading causes of death in the Commonwealth. The Governor's Task Force on Prescription Drug and Heroin Abuse has been studying ways to combat the problem from several perspectives, including data collection and monitoring. It is their recommendation that updating the reporting format and including additional data elements will assist prescribers and other providers in a better understanding of the standard of care for prescribing opioids and other drugs with potential for abuse. To the extent that collection of more precise data on prescribing and dispensing can address the issue of prescription drug abuse, this regulatory action is necessary to protect the health and safety of the citizens of the Commonwealth.

Substance

Please briefly identify and explain the new substantive provisions, the substantive changes to existing sections, or both. A more detailed discussion is provided in the "Detail of changes" section below.

The format for reporting data to the PMP is amended to Version 4.2 (2011) of the Electronic Reporting Standard for Prescription Monitoring Programs of the American Society of Automation in Pharmacy (ASAP). The requirement for notifying dispensers and software providers when a new file layout with new data elements is prescribed in regulation is amended from 30 days to 90 days to give them longer to conform.

To facilitate collection of meaningful data that is more useful in developing reports on prescribing of controlled substances, section 40 is amended to include the following data elements: 1) the National Provider Identifier which identifies the specialty area of practice, 2) the Species Code which identified whether the prescription is written for a human or animal, 3) the Gender Code, 4) the Electronic Prescription Reference Number if it is an electronic prescription, and 5) an indicator if the prescription is a partial fill.

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 there are no disadvantages to the public or the Commonwealth, please indicate.

1) The primary advantage to the public would be more complete information in the PMP and more timely reporting so prescribers and dispensers have sufficient data to make appropriate decisions for patients. There are no disadvantages to the public.
2) There are no advantages or disadvantages to the agency or the Commonwealth.
3) There are no other pertinent matters.

Requirements more restrictive than federal

Please identify and describe any requirement of the proposal which is more restrictive than applicable federal requirements. Include a rationale for the need for the more restrictive requirements. If there are no applicable federal requirements or no requirements that exceed applicable federal requirements, include a statement to that effect.

There are no requirements more restrictive than federal.

Localities particularly affected

Please identify any locality particularly affected by the proposed regulation. Locality particularly affected means any locality which bears any identified disproportionate material impact which would not be experienced by other localities.

There are no localities particularly affected.

Public participation

Please include a statement that in addition to any other comments on the proposal, the agency is seeking comments on the costs and benefits of the proposal and the impacts of the regulated community.

In addition to any other comments, the board/agency is seeking comments on the costs and benefits of the proposal and the potential impacts of this regulatory proposal. Also, the agency/board is seeking information on impacts on small businesses as defined in § 2.2-4007.1 of the Code of Virginia. Information may include 1) projected reporting, recordkeeping and other administrative costs, 2) probable effect of the regulation on affected small businesses, and 3) description of less intrusive or costly alternative methods of achieving the purpose of the regulation.

Anyone wishing to submit written comments may do so via the Regulatory Townhall website, www.townhall.virginia.gov, or by mail to Elaine Yeatts at Department of Health Professions, 9960 Mayland Drive, Suite 300, Richmond, VA 23233 or elaine.yeatts@dhp.virginia.gov or by fax to (804) 527-4434. Written comments must include the name and address of the commenter. In order to be considered comments must be received by the last date of the public comment period.

A public hearing will be held and notice of the public hearing may appear on the Virginia Regulatory Town Hall website (www.townhall.virginia.gov) and the Commonwealth Calendar. Both oral and written comments may be submitted at that time.

Economic impact

Please identify the anticipated economic impact of the proposed new regulations or amendments to the existing regulation. When describing a particular economic impact, please specify which new requirement or change in requirement creates the anticipated economic impact.

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 expenditures**	There are no projected costs to implement and enforce the proposed regulation. All dispensers will be notified electronically by the PMP of new reporting requirements. Dispensers will have 90 days to comply, versus the current requirement of 30 days.
Projected cost of the new regulations or changes to existing regulations on localities.	There are no projected costs.
Description of the individuals, businesses, or other entities likely to be affected by the new regulations or changes to existing regulations.	Individuals or entities that dispense drugs in Schedules II, III and IV, including pharmacies, dentists, and physicians are affected.
Agency's best estimate of the number of such entities that will be affected. Please include an estimate of the number of small businesses affected. Small business means a business entity, including its affiliates, that: a) is independently owned and operated and; b) employs fewer than 500 full-time employees or has gross annual sales of less than $6 million.	There are 2183 dispensers reporting the PMP; most are pharmacies, but that number includes physicians and dentists who dispense drugs.
All projected costs of the new regulations or changes to existing regulations for affected individuals, businesses, or other entities. Please be specific and include all costs including: **a) the projected reporting, recordkeeping, and other administrative costs required for compliance by small businesses; and** **b) specify any costs related to the development of real estate for commercial or residential purposes that are a consequence of the proposed regulatory changes or new regulations.**	Most software applications already include the data elements under consideration because they are necessary for third-party reimbursements by Medicaid or other providers or are required elements for other state PMP's.
Beneficial impact the regulation is designed to produce.	The additional data elements will make it easier to detect drug abuse or unusual patterns of

	prescribing and dispensing. To the extent, prescribers and dispensers use the PMP as a tool for making clinical decisions, the proposal will benefit patients and the public at large.

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. Also, include discussion of less intrusive or less costly alternatives for small businesses, as defined in § 2.2-4007.1 of the Code of Virginia, of achieving the purpose of the regulation.

The Data and Monitoring Workgroup of the Governor's Taskforce on Prescription Drug and Heroin Abuse has recommended that some additional data is needed for better analysis of prescribing and dispensing of controlled substances that are being abused. Specifically, the Workgroup recommended the addition of the National Provider Identifier and the Species Code as required data elements.

The Prescription Monitoring Advisory Committee has considered alternatives and has recommended updating the ASAP version for electronic reporting that most pharmacies already employ. Likewise, the additional data elements are necessary for better analysis of PMP information and for more meaningful feedback to providers about appropriate prescribing. The Committee represents a broad spectrum of interested parties, including the prescribers, Medicaid Fraud Control Unit in the Office of the Attorney General, MD's who are pain management specialists, State Police, DBHDS, the Office of the Medical Examiner, and an independent pharmacist representing small businesses.

Regulatory flexibility analysis

Pursuant to § 2.2-4007.1B of the Code of Virginia, please describe the agency's analysis of alternative regulatory methods, consistent with health, safety, environmental, and economic welfare, that will accomplish the objectives of applicable law while minimizing the adverse impact on small business. Alternative regulatory methods include, at a minimum: 1) the establishment of less stringent compliance or reporting requirements; 2) the establishment of less stringent schedules or deadlines for compliance or reporting requirements; 3) the consolidation or simplification of compliance or reporting requirements; 4) the establishment of performance standards for small businesses to replace design or operational standards required in the proposed regulation; and 5) the exemption of small businesses from all or any part of the requirements contained in the proposed regulation.

There are no alternative regulatory methods consistent with public health and safety.

Public comment

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

Commenter	Comment	Agency response
Jill McCormack Nat'l Association of Chain Drug Stores	Pharmacies are required to comply with the PMP's for multiple states so uniformity in data elements to be reported is necessary to avoid difficulty in filling a prescription. NACDS supports adoption of the ASAP 4.2 standard which is used by the majority of the states. Data required should be limited to information required for process third party claims. Collecting information for extraneous fields, such as a patient identification number and/or purchaser identification, delays provision of health care.	The Department has adopted proposed regulations consistent with the comment; it has not adopted extraneous fields not already required for submitting third party claims.

Family impact

Please assess the impact of this 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.

If these changes to the PMP can prevent a small number of drug-seeking patients from having access to addictive substances, families in Virginia may benefit.

Detail of changes

Please list all changes that are being proposed and the consequences of the proposed changes; explain the new requirements and what they mean rather than merely quoting the proposed text of the regulation. If the proposed regulation is a new chapter, describe the intent of the language and the expected impact. Please describe the difference between existing regulation(s) and/or agency practice(s) and what is being proposed in this regulatory action. If the proposed regulation is intended to replace an emergency regulation, please follow the instructions in the text following the three chart templates below.

For changes to existing regulation(s), please use the following chart:

Current section number	Proposed new section number, if applicable	Current requirement	Proposed change, intent, rationale, and likely impact of proposed requirements
40	n/a	Sets out the format for reports to the PMP and the required data elements in the reports	Currently, the format for reporting data to the PMP is Version 4.1 (2009) of the Electronic Reporting Standard for

			Prescription Monitoring Programs of the American Society of Automation in Pharmacy (ASAP). The updated version (since 2011) is 4.2, so the regulation should be consistent. When a new file layout with new data elements is prescribed in regulation, the director of the program is required to notify dispensers whose transmissions must be in compliance in no less than 30 days from the date specified. To benefit dispensers and software providers who may have to adjust automated programs, the proposed regulation would change 30 days to 90 days or perhaps even longer. Certain data elements are specified in the Code of Virginia in § 54.1-2521, which also provided that: "*The reports required herein shall be made and transmitted in such manner and format and according to the standards and schedule established in the Department's regulations*." To facilitate collection of meaningful data that is more useful in developing reports on prescribing of controlled substances, the Prescription Monitoring Advisory Committee has recommended that the Director of the Department consider amending section 40 to include data elements such as the National Provider Identifier which identifies the specialty area of practice, the Species Code which identified whether the prescription is written for a human or animal, the Gender Code, the Electronic Prescription Reference Number if it is an electronic prescription, and an indicator if the prescription is a partial fill. Many software applications already include the data elements under consideration because they are necessary for third-party reimbursements by Medicaid or other providers or are required elements for other state PMP's.