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Final 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	10/11/16

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 of the proposed new regulation, proposed amendments to the existing regulation, or the regulation proposed to be repealed.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

Statement of final agency action

Please provide a statement of the final action taken by the agency including:1) the date the action was taken;2) the name of the agency taking the action; and 3) the title of the regulation.

On October 11, 2016, the Director of the Department of Health Professions amended 18VAC76-20, Regulations Governing the 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.

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) The Director of the Department of Health Professions has reviewed the proposal and performed a competitive impact analysis. The Board is authorized under 54.1-2400 "*To promulgate regulations in accordance with the Administrative Process Act (§ 2.2-4000 et seq.) which are reasonable and necessary to administer effectively the regulatory system...*" Additionally, the Code of Virginia requires: *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.*

Therefore, the proposed amendments are a foreseeable result of the statute requiring the Board to protect the safety and efficacy of prescription drugs in the Commonwealth. Any restraint on competition that results from this regulation is in accord with the General Assembly's policy as articulated in § 54.1-100 and is necessary for the preservation of the health, safety, and welfare of the public and will further the public's need for assurances of prescription drug safety.

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.

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.

There is no impact on the family.

Changes made since the proposed stage

*Please list all changes that made to the text of the proposed regulation and the rationale for the changes; explain the new requirements and what they mean rather than merely quoting the proposed text of the regulation. *Please put an asterisk next to any substantive changes.*

There were no changes made to the text of the proposed regulation.

Public comment

Please summarize all comments received during the public comment period following the publication of the proposed stage, and provide the agency response. If no comment was received, please so indicate. Please distinguish between comments received on Town Hall versus those made in a public hearing or submitted directly to the agency or board.

There was a 60-day comment period between 7/25/16 and 9/23/16; no comment was received or posted on Virginia Regulatory Townhall. There was a public hearing on September 14, 2016; no comment was made.

All changes made in this regulatory action

Please list all changes that are being proposed and the consequences of the proposed changes. Describe new provisions and/or all changes to existing sections. Explain the new requirements and what they mean rather than merely quoting the proposed text of the regulation

Current section number	Proposed new section number, if applicable	Current requirement	Proposed change and rationale
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.