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# Periodic Review Report of Findings

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| **Agency name** | Department of Health Professions |
| **Virginia Administrative Code (VAC) citation** | 18VAC76-20 |
| **Regulation title** | Regulations Governing the Prescription Monitoring Program |
| **Date this document prepared** | 3/8/19 |

This information is required for executive branch review and the Virginia Registrar of Regulations, pursuant to the Virginia Administrative Process Act (APA), Executive Order 14 (as amended, July 16, 2018), the Regulations for Filing and Publishing Agency Regulations (1 VAC7-10), and the *Virginia Register Form, Style, and Procedure Manual for Publication of Virginia Regulations.*

## Acronyms and Definitions

*Please define all acronyms used in this Report. 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 (1) the agency or other promulgating entity, and (2) the state and/or federal legal authority for the regulatory change, including the most relevant citations to the Code of Virginia or Acts of Assembly chapter number(s), if applicable. Your citation must include a specific provision, if any, authorizing the promulgating entity to regulate this specific subject or program, as well as a reference to the agency or promulgating entity's overall regulatory authority.*

Regulations Governing the Prescription Monitoring Program are adopted by the Director of the Department of Health Professions and promulgated under the statutory mandate in;

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

*A. The Director shall establish, maintain, and administer an electronic system to monitor the dispensing of covered substances to be known as the Prescription Monitoring Program.*
*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.*

## Alternatives

*Please describe any viable alternatives for achieving the purpose of the regulation that were considered as part of the periodic review. Include an explanation of why such alternatives were rejected and why this regulation is the least burdensome alternative available for achieving its purpose.*

There are no alternatives to the purpose of the regulation which is mandated by the Code of Virginia.

## Public Comment

*Please summarize all comments received during the public comment period following the publication of the Notice of Periodic Review, and provide the agency response. Ensure to include all comments submitted: including those received on Town Hall, in a public hearing, or submitted directly to the agency or board. Please indicate if an informal advisory group was formed for purposes of assisting in the periodic review.*

A Notice of Periodic Review was posted on Townhall and published in the Register of Regulations with comment requested from December 10, 2018 to January 9, 2019. There were no comments posted or received by the Department.

## Effectiveness

*Pursuant to § 2.2-4017, please indicate whether the regulation meets the criteria set out in Executive Order 14 (as amended, July 16, 2018), including why the regulation is (a) necessary for the protection of public health, safety, and welfare, and (b) is clearly written and easily understandable.*

Virginia's Prescription Monitoring Program is a 24/7 database containing information on dispensed controlled substances included in Schedule II, III and IV; those in Schedule V for which a prescription is required; naloxone, and all other drugs of concern. The primary purpose of the PMP is to promote safe prescribing and dispensing practices for covered substances by providing timely and essential information to healthcare providers. Law enforcement and health profession licensing boards use the PMP to support investigations related to doctor shopping, diversion, and inappropriate prescribing and dispensing.

The Department has reviewed the current chapter, noted that it is mandated by the law and necessary for public health, welfare and safety. The regulation has been amended several times

to update the reporting format and data elements collected and to conform to changes in federal and state law. The Department has determined that it is effective and clearly understood by users and reporters.

## Decision

*Please explain the basis for the rulemaking entity's decision (retain the regulation as is without making changes, amend the regulation, or repeal the regulation).*

The Director of the PMP, the Chief Deputy Director of the Department, and the Regulatory Coordinator for the Department have reviewed the regulation and recommended that it be retained without amendments.

## Small Business Impact

*As required by § 2.2-4007.1 E and F of the Code of Virginia, include a discussion of the agency's consideration of: (1) the continued need for the regulation; (2) the nature of complaints or comments received concerning the regulation from the public; (3) the complexity of the regulation; (4) the extent to the which the regulation overlaps, duplicates, or conflicts with federal or state law or regulation; and (5) the length of time since the regulation has been evaluated or the degree to which technology, economic conditions, or other factors have changed in the area affected by the regulation. Also, discuss why the agency's decision, consistent with the stated objectives of applicable law, will minimize the economic impact of regulations on small businesses.*

(1) The regulation is necessary for public protection since there is a statutory mandate for licensure in: *§ 54.1-2520... 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,*
(2) There have been no complaints or comments on the content of the regulation.
(3) The Program is overseen by an Advisory Committee that includes a community pharmacist, a hospital pharmacist, a primary care physician, a pain management physician, an addiction physician, a nurse practitioner, and representatives from State Police, Office of the Medical Examiner, Attorney General's Medicaid Fraud Unit, Behavioral Health, DMAS, and an organization concerned with the adequate relief of pain (Hospice). This Committee informs the Director if there is a need for clarification or amendment to regulations governing the operation of the PMP.
(4) These regulations do not overlap, duplicate, or conflict with state or federal law. The regulations are consistent with federal requirements for interoperability with other states and with military treatment facilities under the Department of Defense.
(5) Amendments to this chapter have been promulgated 10 since inception of the program in 2003 in keeping with changes in the law relating to the scope and nature of the program.