Form: TH-07 August 2022



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# Periodic Review and Small Business Impact Review Report of Findings

Agency name	Department of Health Professions
Virginia Administrative Code (VAC) Chapter citation(s)	18VAC76-20
VAC Chapter title(s)	Regulations Governing the Prescription Monitoring Program
Date this document prepared	November 28, 2023

This information is required for executive branch review and the Virginia Registrar of Regulations, pursuant to the Virginia Administrative Process Act (APA), Executive Order 19 (2022) (EO 19), any instructions or procedures issued by the Office of Regulatory Management (ORM) or the Department of Planning and Budget (DPB) pursuant to EO 19, the Regulations for Filing and Publishing Agency Regulations (1 VAC 7-10), and the *Form and Style Requirements for the Virginia Register of Regulations and Virginia Administrative Code*.

## **Acronyms and Definitions**

Define all acronyms used in this Report, and any technical terms that are not also defined in the "Definitions" section of the regulation.

N/A

# **Legal Basis**

Identify (1) the promulgating agency, 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 agency to regulate this specific subject or program, as well as a reference to the agency's overall regulatory authority.

Regulations governing the Prescription Monitoring Program are promulgated under Virginia Code §§ 54.1-2520, 54.1-2521, and 54.1-2505.

# **Alternatives to Regulation**

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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 regulation. To alter existing regulations, the Department must file a regulatory action.

### **Public Comment**

<u>Summarize</u> all comments received during the public comment period following the publication of the Notice of Periodic Review, and provide the agency's response. Be sure to include all comments submitted: including those received on Town Hall, in a public hearing, or submitted directly to the agency. Indicate if an informal advisory group was formed for purposes of assisting in the periodic review.

There was no public comment.

### **Effectiveness**

Pursuant to § 2.2-4017 of the Code of Virginia, indicate whether the regulation meets the criteria set out in the ORM procedures, 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 database which contains information on dispensed controlled substances included in Schedules II through 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**

Explain the basis for the promulgating agency's decision (retain the regulation as is without making changes, amend the regulation, or repeal the regulation).

If the result of the periodic review is to retain the regulation as is, complete the ORM Economic Impact form.

The Director of the PMP, the Director of the Department, and the Regulatory Coordinator for the Department reviewed the regulations and recommended that the Chapter be retained with amendments.

# **Small Business Impact**

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As required by § 2.2-4007.1 E and F of the Code of Virginia, discuss the agency's consideration of: (1) the continued need for the regulation; (2) the nature of complaints or comments received concerning the regulation; (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 applicable law, will minimize the economic impact of regulations on small businesses.

The statutory requirement to for regulations to implement the PMP still exists in Code; therefore the regulations are needed. Additionally, PMP is used by thousands of practitioners, dispensers, patients, and law enforcement personnel. The agency has not received any comments related to this periodic review. The regulations are not complex. The regulations do not overlap, duplicate, or conflict with state or federal law or regulation. This chapter has been amended eleven times in the last twenty years.