Virginia Regulatory Town Hall

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Periodic Review / Retain Regulation
Agency Background Document

Agency name	Department of Health Professions
Virginia Administrative Code (VAC) citation	18VAC76-20-10 et seq.
Regulation title	Regulations Governing the Prescription Monitoring Program
Document preparation date	3/8/13

This form is used when the agency has done a periodic review of a regulation and plans to retain the regulation without change. This information is required pursuant to Executive Orders 14 (2010) and 58 (1999).

Legal basis

Please identify the state and/or federal legal authority for the regulation, including (1) the most relevant law and/or regulation, and (2) promulgating entity, i.e., agency, board, or person.

18VAC76-20-10 et seq. Regulations Governing the Prescription Monitoring Program are 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.

§ 54.1-2505. Powers and duties of Director of Department.

The Director of the Department shall have the following powers and duties:

…14. To promulgate and revise regulations necessary for the administration of the Department and such regulations as are necessary for the implementation of the Health Practitioners' Intervention Program pursuant to Chapter 25.1 (§ 54.1-2515 et seq.) of this title and subdivision 19 of this section; …

§ 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. Covered substances shall include all Schedule II, III, and IV controlled substances, as defined in the Drug Control Act (§ 54.1-3400 et seq.).

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 all viable alternatives for achieving the purpose of the existing regulation that have been considered as part of the periodic review process. Include an explanation of why such alternatives were rejected and why this regulation is the least burdensome alternative available for achieving the purpose of the regulation.

The regulation was reviewed by staff of the Prescription Monitoring Program and the Department of Health Professions to identify any regulation that could be revised pursuant to the Governor's regulatory reform project. There were no problems identified with the understanding of or compliance with the existing regulations.

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. Please indicate if an informal advisory group was formed for purposes of assisting in the periodic review.

Notice of Periodic Review was posted on the Virginia Regulatory Townhall and sent to interested parties with comment requested from November 5, 2013 to December 5, 2013. There were no comments received.

Effectiveness

Please indicate whether the regulation meets the criteria set out in Executive Order 14 (2010), e.g., is necessary for the protection of public health, safety, and welfare, and is clearly written and easily understandable.

Through its review of 18VAC76-20-10 et seq., Regulations Governing the Prescription Monitoring Program, the Department determined that the regulation is necessary to protect the public. Neither the staff of the Department nor affected entities identified any language that was not clearly written and easily understandable.

Result

Please state that the agency is recommending that the regulation should stay in effect without change.

As a result of the periodic review conducted in accordance with the Governor's regulatory reform project, the Department has determined that the regulation should stay in effect without change.

Small business impact

In order to minimize the economic impact of regulations on small business, please include, pursuant to § 2.2-4007.1 E and F, 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, include a discussion of the agency's determination whether the regulation should be amended or repealed, consistent with the stated objectives of applicable law, to minimize the economic impact of regulations on small businesses.

1) In accordance with the § 54.1-2520 of the Code of Virginia, the Director of the Department must adopt regulations: "*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….*" Therefore, there is a continued need for the regulation.
2) There have been no complaints or comments received from the public.
3) The regulation is organized and clearly written.
4) The regulation is consistent with federal and state law but does not overlap such laws.
5) The regulation has been amended four times since initial regulations became effective in 2003 in response to changes in state or federal law or to respond to a problem identified by implementation of the law.
Since the data system used for prescription monitoring is the same system that pharmacies use for third party payments, there is no additional cost for compliance. The program and instructions for reporting to the Department is provided to all affected dispensers without charge. There is no cost to entities who request a query of the system on a particular patient or prescriber.

Family impact

Please provide an analysis of the regulation's impact on the institution of the family and family stability.

There is no impact on the institution of the family and family stability.