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# Notice of Intended Regulatory Action (NOIRA)
# Agency Background Document

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| **Agency name** | Department of Health Professions |
| **Virginia Administrative Code (VAC) citation(s)** | 18VAC76-20-10 et seq. |
| **Regulation title(s)** | Regulations Governing the Prescription Monitoring Program |
| **Action title** | Change to standards and format for reports to PMP |
| **Date this document prepared** | 4/20/15 |

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.*

## Subject matter and intent

*Please describe briefly the subject matter, intent, and goals of the planned regulatory action.*

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.

## Legal basis

*Please identify the (1) the agency (includes any type of promulgating entity) and(2) the state and/or federal legal authority for the proposed regulatory action, including the most relevant citations to the Code of Virginia or General Assembly chapter number(s), if applicable. Your citation should 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'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 describe the specific reasons why the agency has determined that the proposed regulatory action is essential to protect the health, safety, or welfare of citizens. In addition, please explain any potential issues that may need to be addressed as the regulation is developed.*

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 that are being considered, the substantive changes to existing sections that are being considered, or both.*

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 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.

## 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.

## Public participation

*Please indicate whether the agency is seeking comments on the intended regulatory action, including ideas to assist the agency in the development of the proposal and the costs and benefits of the alternatives stated in this notice or other alternatives. Also, indicate whether a public hearing is to be held to receive comments. Please include one of the following choices: 1) a panel will be appointed and the agency's contact if you're interested in serving on the panel is _____; 2) a panel will not be used; or 3) public comment is invited as to whether to use a panel to assist in the development of this regulatory proposal.*

The agency is seeking comments on this regulatory action, including but not limited to: ideas to be considered in the development of this proposal, the costs and benefits of the alternatives stated in this background document or other alternatives, and the potential impacts of the regulation.

The agency is also seeking information on impacts on small businesses as defined in § 2.2-4007.1 of the Code of Virginia. Information may include: projected reporting, recordkeeping, and other administrative costs; the probable effect of the regulation on affected small businesses; and the description of less intrusive or costly alternatives for achieving the purpose of the regulation.

Anyone wishing to submit comments may do so via the Regulatory Town Hall website (**http://www.townhall.virginia.gov**), or by mail, email, or fax to Elaine Yeatts, Agency Regulatory Coordinator, 9960 Mayland Drive, Henrico, VA 23233 or at elaine.yeatts@dhp.virginia.gov. Written comments must include the name and address of the commenter. In order to be considered, comments must be received by midnight on the last day of the public comment period.

A public hearing will be held following the publication of the proposed stage of this regulatory action and notice of the hearing will be posted on the Virginia Regulatory Town Hall website (**http://www.townhall.virginia.gov**) and on the Commonwealth Calendar website (https://www.virginia.gov/connect/commonwealth-calendar). Both oral and written comments may be submitted at that time. The Prescription Monitoring Advisory Committee will serve as a regulatory panel for this action.