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Fast-Track Regulation
Agency Background Document

Agency name	Department of Health Professions, PMP
Virginia Administrative Code (VAC) Chapter citation(s)	18VAC76-20
VAC Chapter title(s)	Regulations Governing the Prescription Monitoring
Action title	Removing specific reporting standards for the PMP
Date this document prepared	06/03/2021

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 (1VAC7-10), and the *Form and Style Requirements for the Virginia Register of Regulations and Virginia Administrative Code.*

Brief Summary

Provide a brief summary (preferably no more than 2 or 3 paragraphs) of this regulatory change (i.e., new regulation, amendments to an existing regulation, or repeal of an existing regulation). Alert the reader to all substantive matters. If applicable, generally describe the existing regulation.

The regulation is amended to delete language that requires that dispensers report according to a specific version of the American Society of Automation in Pharmacy (ASAP) standard.

The existing regulation requires all data submitters to transmit data to the Prescription Monitoring Program at Virginia Department of Health Professions (DHP) in compliance with ASAP Version 4.2, which was published in 2011. Since 2011, newer standards have been published. Some dispensers report data to the DHP under Version 4.2 and to other states in newer versions. The Prescription Monitoring Program (PMP) vendor can accommodate reporting of data in ASAP Standard versions 4.2 and 4.2a today. Version 4.2b is used in one state and can be enabled later if necessary.

Acronyms and Definitions

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

ASAP = American Society of Automation in Pharmacy
PMP = Prescription Monitoring Program

Statement of Final Agency Action

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 June 3, 2021, the Director of the Department of Health Professions amended 18VAC76-20, Regulations Governing the Prescription Monitoring Program.

Mandate and Impetus

Identify the mandate for this regulatory change and any other impetus that specifically prompted its initiation (e.g., new or modified mandate, petition for rulemaking, periodic review, or board decision). For purposes of executive branch review, "mandate" has the same meaning as defined in Executive Order 14 (as amended, July 16, 2018), "a directive from the General Assembly, the federal government, or a court that requires that a regulation be promulgated, amended, or repealed in whole or part."

As required by Virginia Code § 2.2-4012.1, also explain why this rulemaking is expected to be noncontroversial and therefore appropriate for the fast-track process.

The impetus for the Department to amend its regulations is the need to recognize all current standards for reporting data for the Prescription Monitoring Program (PMP) without placing additional burden on dispensers by specifying one version and incorporating that version by reference in regulation.

This regulatory action is expected to be noncontroversial because the Director is deleting an outdated standard and allowing more than one standard to be acceptable to dispensers. Provided the data elements specified in § 54.1-2521 of the Code of Virginia and the vendor utilized by the Department of Health Professions (DHP) recognizes the standard, then DHP will recognize it as an acceptable version.

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 and 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 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.

C. The Director may enter into contracts as may be necessary for the implementation and maintenance of the Prescription Monitoring Program.

D. The Director shall provide dispensers with a basic file layout to enable electronic transmission of the information required in this chapter. For those dispensers unable to transmit the required information electronically, the Director shall provide an alternative means of data transmission.

E. The Director shall also establish an advisory committee within the Department to assist in the implementation and evaluation of the Prescription Monitoring Program. Such advisory committee shall provide guidance to the Director regarding information disclosed pursuant to subdivision C 9 of § 54.1-2523.

§ 54.1-2521. Reporting requirements.

A. The failure by any person subject to the reporting requirements set forth in this section and the Department's regulations to report the dispensing of covered substances shall constitute grounds for disciplinary action by the relevant health regulatory board.

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 and, in cases in which the covered substance is cannabidiol oil or THC-A oil, the expiration date of the written certification.
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. Except as provided in subdivision 7 of § 54.1-2522, in cases where the ultimate user of a covered substance is an animal, the dispenser shall report the relevant information required by subsection B for the owner of the animal.
D. The reports required herein shall be made to the Department or its agent within 24 hours or the dispenser's next business day, whichever comes later, and shall be made and transmitted in such manner and format and according to the standards and schedule established in the Department's regulations.

Authority for the Director to establish the PMP is found in:

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

20. To establish, and revise as necessary, with such federal funds, grants, or general funds as may be appropriated or made available for this program, the Prescription Monitoring Program pursuant to Chapter 25.2 (§ 54.1-2519 et seq.) of this title; and

Purpose

Explain the need for the regulatory change, including a description of: (1) the rationale or justification, (2) the specific reasons the regulatory change is essential to protect the health, safety or welfare of citizens, and (3) the goals of the regulatory change and the problems it's intended to solve.

The purpose of the regulatory change is to update the regulations to allow for newer standards for reporting for the Prescription Monitoring Program (PMP) without placing additional burdens on dispensers by specifying the most current version which is the 2019 Version 4b of the ASAP Standard.

The goal of this regulatory action is to simplify and facilitate reliable reporting by allowing dispensers more than one standard to use for reporting to the PMP. The goal of this regulatory change is to simplify the reporting process for dispensers located in Virginia or dispensing to Virginia residents by allowing each dispenser to choose either the older Version 4.2 or a different version.

Reporting of certain data by dispensers to PMP is not only required by the Code of Virginia but essential to ensure the protection of the health, safety, and welfare of the citizens because the PMP is used to track excessive prescribing and dispensing of covered drugs and to alert for possible diversion of such drugs into communities.

Substance

Briefly identify and explain the new substantive provisions, the substantive changes to existing sections, or both. A more detailed discussion is provided in the "Detail of Changes" section below.

Amendments to section 40 delete language that requires that dispensers report according to a specific version of the American Society of Automation in Pharmacy (ASAP) standard.

Issues

Identify the issues associated with the regulatory change, 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, include a specific statement to that effect.

1) The primary advantage to the public of the PMP is that prescribers and dispensers have access to information on patients' prescription history, which ensures that prescribers and dispensers can provide safe courses of treatment that are individualized to patients' particular needs. The regulatory action facilitates the ability of dispensers to share this information through their choice of reporting standard, thus facilitating receipt of this information prior to patients receiving prescriptions in the future. The regulatory change will primarily benefit dispensers that currently report under multiple standards. There are no disadvantages to the public.

2) There are no advantages or disadvantages to this agency or the Commonwealth.

3) The Director of the Department of Health Professions has reviewed the proposal and performed a competitive impact analysis. Such regulations do not conflict with the purposes and intent of this chapter or of Chapter 1 (§ 54.1-100 et seq.) and Chapter 25.2 of Title 54.1. This proposal is consistent with the agency's statutory responsibility to protect public health and safety and to protect the integrity and safety of prescription drugs in the Commonwealth.

Requirements More Restrictive than Federal

Identify and describe any requirement of the regulatory change which is more restrictive than applicable federal requirements. Include a specific citation for each applicable federal requirement, and 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 specific statement to that effect.

There are no applicable federal requirements.

Agencies, Localities, and Other Entities Particularly Affected

Identify any other state agencies, localities, or other entities particularly affected by the regulatory change. "Particularly affected" are those that are likely to bear any identified disproportionate material impact which would not be experienced by other agencies, localities, or entities. "Locality" can refer to either local governments or the locations in the Commonwealth where the activities relevant to the regulation or regulatory change are most likely to occur. If no agency, locality, or entity is particularly affected, include a specific statement to that effect.

Other State Agencies Particularly Affected – None

Localities Particularly Affected - None

Other Entities Particularly Affected - None

Economic Impact

Pursuant to § 2.2-4007.04 of the Code of Virginia, identify all specific economic impacts (costs and/or benefits), anticipated to result from the regulatory change. When describing a particular economic impact, specify which new requirement or change in requirement creates the anticipated economic impact. Keep in mind that this is change versus the status quo.

Impact on State Agencies

For your agency: projected costs, savings, fees or revenues resulting from the regulatory change, including: a) fund source / fund detail; b) delineation of one-time versus on-going expenditures; and c) whether any costs or revenue loss can be absorbed within existing resources	a) As a special fund agency, the Board must generate sufficient revenue to cover its expenditures from non-general funds, specifically the renewal and application fees it charges to practitioners for necessary functions of regulation; b) The agency will incur no additional costs for mailings to the Public Participation Guidelines mailing lists, conducting a public hearing, and sending notice of final regulations to regulated entities.
For other state agencies: projected costs, savings, fees or revenues resulting from the regulatory change, including a delineation of one-time versus on-going expenditures.	None
For all agencies: Benefits the regulatory change is designed to produce.	None

Impact on Localities

Projected costs, savings, fees or revenues resulting from the regulatory change.	None
Benefits the regulatory change is designed to produce.	None

Impact on Other Entities

Description of the individuals, businesses, or other entities likely to be affected by the regulatory change. If no other entities will be affected, include a specific statement to that effect.	Any individuals or entities that dispense a "*covered substance*," as defined in *§ 54.1-2519 of the Code of Virginia* is likely to be affected by the regulatory change.
Agency's best estimate of the number of such entities that will be affected. Include an estimate of the number of small businesses affected. Small	The Department of Health Professions currently receives reports from 2,117 entities. That number includes reports by large national chains that

business means a business entity, including its affiliates, that: a) is independently owned and operated and; b) employs fewer than 500 full-time employees or has gross annual sales of less than $6 million.	report on behalf of individual retail pharmacies, so the number of dispensers reporting to PMP would be considerably higher.
All projected costs for affected individuals, businesses, or other entities resulting from the regulatory change. Be specific and include all costs including, but not limited to: a) projected reporting, recordkeeping, and other administrative costs required for compliance by small businesses; b) specify any costs related to the development of real estate for commercial or residential purposes that are a consequence of the regulatory change; c) fees; d) purchases of equipment or services; and e) time required to comply with the requirements.	There are no costs projected for affected individuals, businesses, or other entities resulting from the regulatory change because the Department is not mandating any particular standard.
Benefits the regulatory change is designed to produce.	All affected individuals and entities will be allowed to choose the version that is most appropriate for them (4.2, 4.2a, or 4.2b); no individual or entity is required to change their current method of reporting provided it is acceptable to the vendor as specified in subsection B of section 40.

Alternatives to Regulation

Describe any viable alternatives to the regulatory change that were considered, and the rationale used by the agency to select the least burdensome or intrusive alternative that meets the essential purpose of the regulatory change. 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 regulatory change.

There are no alternatives that meet the essential purpose of protection of the public. The Department considered updating to the most recent version of ASAP reporting standards. However, that would be burdensome to some dispensers if they are reporting to other states with different standards. The regulatory change will allow dispensers to continue to use the older standard or to use one of the newer, acceptable standards as standards are developed.

Regulatory Flexibility Analysis

Pursuant to § 2.2-4007.1B of the Code of Virginia, describe the agency's analysis of alternative regulatory methods, consistent with health, safety, environmental, and economic welfare, that will accomplish the objectives of applicable law while minimizing the adverse impact on small business. Alternative regulatory methods include, at a minimum: 1) establishing less stringent compliance or reporting requirements; 2) establishing less stringent schedules or deadlines for compliance or reporting requirements; 3) consolidation or simplification of compliance or reporting requirements; 4) establishing performance standards for small businesses to replace design or operational standards required in the proposed regulation; and 5) the exemption of small businesses from all or any part of the requirements contained in the regulatory change.

There are no alternative regulatory methods consistent with the statutory requirements of §§ 54.1-2520 and 54.1-2521 of the Code of Virginia.

Public Participation

Indicate how the public should contact the agency to submit comments on this regulation, and whether a public hearing will be held, by completing the text below.

As required by § 2.2-4011 of the Code of Virginia, if an objection to the use of the fast-track process is received within the 30-day public comment period from 10 or more persons, any member of the applicable standing committee of either house of the General Assembly or of the Joint Commission on Administrative Rules, the agency shall: 1) file notice of the objections with the Registrar of Regulations for publication in the Virginia Register and 2) proceed with the normal promulgation process with the initial publication of the fast-track regulation serving as the Notice of Intended Regulatory Action.

If you are objecting to the use of the fast-track process as the means of promulgating this regulation, please clearly indicate your objection in your comment. Please also indicate the nature of, and reason for, your objection to using this process.

The Department is providing an opportunity for comments on this regulatory proposal, including but not limited to (i) the costs and benefits of the regulatory proposal and any alternative approaches, (ii) the potential impacts of the regulation, and (iii) the agency's regulatory flexibility analysis stated in this background document.

Anyone wishing to submit written comments for the public comment file may do so through the Public Comment Forums feature of the Virginia Regulatory Town Hall web site at: https://townhall.virginia.gov. Comments may also be submitted by mail, email or fax to Elaine Yeatts, 9960 Mayland Drive, Henrico, VA 23233; phone (804) 367-4688; fax (804) 527-4434; Elaine.yeatts@dhp.virginia.gov. In order to be considered, comments must be received by 11:59 pm on the last day of the public comment period.

Detail of Changes

List all regulatory changes and the consequences of the changes. Explain the new requirements and what they mean rather than merely quoting the text of the regulation. For example, describe the intent of the language and the expected impact. Describe the difference between existing requirement(s) and/or agency practice(s) and what is being proposed in this regulatory change. Use all tables that apply, but delete inapplicable tables.

If an existing VAC Chapter(s) is being amended or repealed, use Table 1 to describe the changes between existing VAC Chapter(s) and the proposed regulation. If existing VAC Chapter(s) or sections are being repealed and replaced, ensure Table 1 clearly shows both the current number and the new number for each repealed section and the replacement section.

Table 1: Changes to Existing VAC Chapter(s)

Current chapter-section number	New chapter-section number, if applicable	Current requirements in VAC	Change, intent, rationale, and likely impact of new requirements
20-40		Sets out the standards for the manner and format of reports and a schedule for reporting	Subsection A is amended to delete language that requires that dispensers report according to a specific version of the American Society of Automation in Pharmacy (ASAP) standard. The data elements required in a dispensing report are set out in § 54.1-2521 of the Code of Virginia and in subsection E of section 40. The law further provides that the data be *"transmitted in such manner and format and according to the standards and schedule established in the Department's regulations."* Subsection B of section 40 specifies the standard and schedule: "*Data shall be transmitted in a file layout provided by the department and shall be transmitted by a media acceptable to the vendor contracted by the director for the program. Such transmission shall begin on a date specified by the director, no less than 90 days from notification by the director to dispensers required to report."* Since more than one version of the ASAP standard is acceptable to the vendor as required by subsection B, it is recommended that the specific version incorporated by reference in subsection A be deleted.