Virginia Department of Planning and Budget

Economic Impact Analysis

18 VAC 76-20 Regulations Governing the Prescription Monitoring Program
Department of Health Professions
Town Hall Action/Stage: 5733/9276
August 12, 2021

Summary of the Proposed Amendments to Regulation

The Department of Health Professions (DHP) seeks to repeal discretionary language that requires dispensers of certain covered substances to use a specific version of a reporting standard when submitting data to the Prescription Monitoring Program (PMP).[1] DHP seeks to repeal this language because that specific version has since been superseded by newer versions of the standard. Further, DHP does not seek to add a reference to the newer version since the existing regulatory text already directs dispensers to use a specific file layout, which implicitly reflects the reporting standard. Dispensers using the older file layout will be able to continue to do so; thus, the regulatory change is intended to provide dispensers with greater flexibility.

Background

The PMP is a database containing information on dispensed controlled substances in Schedule II, III and IV; those in Schedule V for which a prescription is required; naloxone, all drugs of concern, and cannabidiol oil or THC-A oil dispensed by a pharmaceutical processor in Virginia.[2] As per 18 VAC 76-20-40 *Standards for the manner and format of reports and a schedule for reporting*, "Data shall be transmitted to the department or its agent within 24 hours of dispensing or the dispenser's next business day, whichever comes later, as provided in the Electronic Reporting Standard for Prescription Monitoring Programs, Version 4.2 (September 2011) of the American Society of Automation in Pharmacy (ASAP), which are hereby

[1] See § 54.1-2519 of the Code of Virginia for the definition of covered substances with respect to the PMP: https://law.lis.virginia.gov/vacode/title54.1/chapter25.2/section54.1-2519/.
[2] See https://www.dhp.virginia.gov/PractitionerResources/PrescriptionMonitoringProgram/.

incorporated by reference into this chapter" (emphasis added). DHP seeks to repeal the underlined text, as well as the document incorporated by reference.

ASAP has released newer versions of the electronic reporting standard since 2011. Some dispensers report data to DHP under Version 4.2 and to other states' monitoring programs using these newer versions. The Virginia PMP vendor can currently accommodate reporting of data in ASAP reporting standard versions 4.2 and 4.2a.[3] Paragraph B of the same section of the regulation requires dispensers to transmit the data using a file layout provided by the director of the PMP, beginning no less than 90 days from notification by the director to dispensers required to report. The latest version of the Dispenser Guide, effective June 2020, contains the file layout for ASAP version 4.2a.[4] However, dispensers would not be required to switch to the newer file layout. Thus, repealing the reference to version 4.2 and the document incorporated by reference would provide dispensers with the option of using either version of the reporting standard.

Estimated Benefits and Costs

DHP anticipates that dispensers who already use the file layout for ASAP 4.2a to report prescription data to other states' monitoring programs will start using it for reports to the Virginia PMP as well. These dispensers would likely benefit from having consistent reporting requirements across different states to the extent that it reduces their overall cost of meeting reporting requirements. Pharmaceutical processors and dispensaries are the current most probable users of ASAP 4.2a because of their unique regulatory status. However, dispensers currently using the file layout corresponding to the ASAP 4.2 standards may continue to do so without facing any additional costs.

Businesses and Other Entities Affected

The proposed amendments primarily affect any individuals or entities that dispense a "covered substance" as defined in § 54.1-2519 of the Code of Virginia. DHP reports that there are 2,117 entities currently reporting prescription data to DHP.

[3] See Agency Background Document https://townhall.virginia.gov/l/GetFile.cfm?File=59\5733\9276\AgencyStatement_DHP_9276_v2.pdf.
[4] See Appendix A of the Virginia PMP Dispenser's Guide: https://www.dhp.virginia.gov/media/dhpweb/docs/pmp/VA%20Data%20Submission%20Dispenser%20Guide_v%202.4.pdf

Small Businesses[5] Affected

The proposed amendments do not create any new costs, and therefore would not adversely affect any small businesses. Pharmacies or dispensaries that are small businesses could benefit to the extent that the proposed amendment would allow them to standardize their prescription reporting across multiple states including Virginia.

Localities[6] Affected[7]

The proposed amendments do not introduce new costs for local governments and are unlikely to affect any locality in particular.

Projected Impact on Employment

The proposed amendments are unlikely to impact employment by dispensers of covered substances.

Effects on the Use and Value of Private Property

To the extent that the option to use ASAP 4.2a reporting standards allows some dispensers to reduce their overall reporting costs by streamlining their reporting process, the value of those entities may see a modest increase. Real estate development costs are not affected.

Legal Mandates

General: The Department of Planning and Budget has analyzed the economic impact of this proposed regulation in accordance with § 2.2-4007.04 of the Code of Virginia (Code) and Executive Order 14 (as amended, July 16, 2018). Code § 2.2-4007.04 requires that such economic impact analyses determine the public benefits and costs of the proposed amendments. Further the report should include but not be limited to: (1) the projected number of businesses or other entities to whom the proposed regulatory action would apply, (2) the identity of any localities and types of businesses or other entities particularly affected, (3) the projected number of persons and employment positions to be affected, (4) the projected costs to affected businesses or entities to implement or comply with the regulation, and (5)the impact on the use and value of private property.

Adverse impacts: Pursuant to Code § 2.2-4007.04(D): In the event this economic impact analysis reveals that the proposed regulation would have an adverse economic impact on businesses or would impose a significant adverse economic impact on a locality, business, or entity particularly affected, the Department of Planning and Budget shall advise the Joint Commission on Administrative Rules, the House Committee on Appropriations, and the Senate Committee on Finance within the 45-day period.

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[5] Pursuant to § 2.2-4007.04 of the Code of Virginia, small business is defined as "a business entity, including its affiliates, that (i) is independently owned and operated and (ii) employs fewer than 500 full-time employees or has gross annual sales of less than $6 million."

[6] "Locality" can refer to either local governments or the locations in the Commonwealth where the activities relevant to the regulatory change are most likely to occur.

[7] § 2.2-4007.04 defines "particularly affected" as bearing disproportionate material impact.

If the proposed regulatory action may have an adverse effect on small businesses, Code § 2.2-4007.04 requires that such economic impact analyses include: (1) an identification and estimate of the number of small businesses subject to the proposed regulation, (2) the projected reporting, recordkeeping, and other administrative costs required for small businesses to comply with the proposed regulation, including the type of professional skills necessary for preparing required reports and other documents, (3) a statement of the probable effect of the proposed regulation on affected small businesses, and (4) a description of any less intrusive or less costly alternative methods of achieving the purpose of the proposed regulation. Additionally, pursuant to Code § 2.2-4007.1, if there is a finding that a proposed regulation may have an adverse impact on small business, the Joint Commission on Administrative Rules shall be notified.