



Virginia Department of Planning and Budget **Economic Impact Analysis**

18 VAC 110-30 Regulations for Practitioners of the Healing Arts to Sell Controlled Substances

Department of Health Professions

Town Hall Action/Stage: 5927/9931

August 24, 2023

The Department of Planning and Budget (DPB) 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 19. The analysis presented below represents DPB's best estimate of the potential economic impacts as of the date of this analysis.¹

Summary of the Proposed Amendments to Regulation

As a result of a 2021 periodic review,² the Board of Pharmacy (Board) proposes to make discretionary amendments to the regulation for practitioners of the healing arts who are licensed to sell controlled substances. The proposed changes would require permitted facilities to post changes to their hours of operation, and also specify that facility permits shall not be issued to private dwellings or residences.

Background

This regulation establishes qualifications for a practitioner of the healing arts³ to sell controlled substances in their practices and sets standards for the facility. The Department of Health Professions (DHP) reports that this regulation is for a relatively small number of practitioners who seek to dispense drugs from their offices; these facilities are typically smaller

¹ Code § 2.2-4007.04 requires that such economic impact analyses determine the public benefits and costs of the proposed amendments. Further the analysis 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.

² See <https://townhall.virginia.gov/l/ViewPReview.cfm?PRid=2015>.

³ The regulation defines this term to include a doctor of medicine, osteopathic medicine or podiatry who possesses a current active license issued by the Board.

outpatient facilities, including chains like Patient First and also independent clinics. The vast majority of practitioners may give patients medication samples but do not seek licensure to sell controlled substances on-site.

Specifically, the Board seeks to make the following changes:

- Section 21 (*Application for facility permit*) would be amended to require practitioners applying for a facility license to designate the hours of operation the location will be open to service the public.
- Section 55 (*Change of hours in a permitted facility*) would be newly created to require that practitioners provide notice to the public and to the Board for any change in the hours of operation that is expected to last more than one week. Specifically, the proposed text would require that,

“At least 14 days prior to the anticipated change, notice shall be posted in a conspicuous place to provide notice to the public and provided to the board in writing unless the change is necessitated by emergency circumstances beyond the control of the practitioner, or unless the change will result in an expansion of the current hours of operation. If the facility is not able to post the changes 14 days in advance, the practitioner shall ensure that the board is notified as soon as he knows of the change and disclose the emergency circumstances preventing the required notification.”

The proposed requirements match the current requirements for pharmacies to notify the public and the board for a change in the hours of operation.⁴

- Section 80 (*Inspection and notice required*) would be amended to specify that, “No facility permit shall be issued to a private dwelling or residence for the purpose of selling controlled substances.” DHP noted that this addition was not in response to any complaints or inspection findings.

Estimated Benefits and Costs

The proposed changes are intended to increase clarity and transparency for the public so that patients are informed about when they can or cannot get their prescriptions filled at a facility permitted under this regulation, in the same way that they would be informed of operating hours at a pharmacy. Sale of controlled substances is optional, but facilities permitted under this regulation may incur some costs associated with providing the required notice for changes in

⁴ See 18 VAC 110-20-35 <https://law.lis.virginia.gov/admincode/title18/agency110/chapter20/section135/>.

hours of operation. However, if providing the advance notice results in more patients filling their prescriptions at the facility, rather than being forced to go elsewhere upon unexpectedly finding it closed, the facility would capture revenue that would otherwise have been lost. This revenue would likely outweigh the cost of providing notice. Patients do not have to obtain controlled substances from a practitioner's facility, but those who chose to do so would likely benefit from additional clarity regarding hours of operation.

Businesses and Other Entities Affected

The proposed amendments affect the 565 practitioners who are licensed to sell controlled substances, and the 131 permitted facilities where they are authorized to do so.⁵ The changes also affect their patients, especially those who choose to have their prescriptions filled at these locations rather than at a pharmacy.

The Code of Virginia requires DPB to assess whether an adverse impact may result from the proposed regulation.⁶ An adverse impact is indicated if there is any increase in net cost or reduction in net revenue for any entity, even if the benefits exceed the costs for all entities combined. As described above, the proposed changes are not anticipated to create any new net costs. Thus, an adverse impact is not indicated.

Small Businesses⁷ Affected:⁸

Most of the 131 permitted locations where physicians are licensed to sell controlled substances are likely small businesses, and some may be non-profit organizations, but DHP does

⁵ Source: <https://www.dhp.virginia.gov/about/stats/2023Q4/04CurrentLicenseCountQ4FY2023.pdf>.

⁶ 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. Statute does not define "adverse impact," state whether only Virginia entities should be considered, nor indicate whether an adverse impact results from regulatory requirements mandated by legislation.

⁷ 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."

⁸ 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.

not have data on the number of practitioners that meet the definition of a small business. The proposed amendments are unlikely to result in an increase in net costs and thus are not expected to have an adverse impact on small businesses.

Localities⁹ Affected¹⁰

The proposed amendments do not appear to disproportionately affect any particular localities, nor introduce costs for local governments.

Projected Impact on Employment

The proposed amendments are not likely to have a substantive impact on total employment.

Effects on the Use and Value of Private Property

The proposed amendments are not expected to affect the value of private property. The proposed amendments do not affect real estate development costs.

⁹ “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.

¹⁰ § 2.2-4007.04 defines “particularly affected” as bearing disproportionate material impact.