

Virginia Department of Planning and Budget Economic Impact Analysis

18 VAC 110-21 Regulations Governing the Licensure of Pharmacists and Registration of Pharmacy Technicians Department of Health Professions Town Hall Action/Stage: 6200 / 10279 November 7, 2024

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

The identical Chapters 171 and 172 of the 2023 *Acts of Assembly*² (legislation) expanded the conditions for which pharmacists can initiate treatment. The legislation additionally required that the Board of Pharmacy (Board) promulgate emergency regulations to reflect the change to be effective within 280 days of enactment. The Board did promulgate such emergency regulations,³ and now proposes to make the amendment permanent.

Background

The proposed amendment to the regulation is essentially identical to the change made to the Code by the legislation. Specifically, the following would be added to the list of drugs and devices that a pharmacist may initiate treatment with, dispense, or administer to persons 18 years of age or older:

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 <u>https://legacylis.virginia.gov/cgi-bin/legp604.exe?231+ful+CHAP0171+hil</u>

³ See <u>https://townhall.virginia.gov/L/ViewStage.cfm?stageid=9951</u>.

Controlled substances or devices for the initiation of treatment of the following diseases or conditions for which clinical decision making can be guided by a clinical test that is classified as waived under the federal Clinical Laboratory Improvement Amendments of 1988, 42 USC § 263a:

- a. Group A Streptococcus bacteria infection;
- b. Influenza virus infection;
- c. COVID-19 virus infection; and
- d. Urinary tract infection.

Estimated Benefits and Costs

Since the proposed amendment to the regulation is essentially identical to the amendment to the Code in the legislation, amending the regulation would have no impact beyond better informing readers of the regulation of the additional items that statute already allows a pharmacist to initiate treatment with, dispense, or administer.

Businesses and Other Entities Affected

The 1,737 permitted pharmacies and the 16,357 licensed pharmacists in the Commonwealth, as well as patients with whom they may initiate treatment, are potentially affected by the legislation.⁴

The Code of Virginia requires DPB to assess whether an adverse impact may result from the proposed regulation.⁵ 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 the proposed amendment neither increases costs nor reduces net revenue for any entity, no adverse impact is indicated.

⁴ Data source: <u>https://www.dhp.virginia.gov/about/stats/2024Q4/04CurrentLicenseCountQ4FY2024.pdf</u>.

⁵ 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.

Small Businesses⁶ Affected:⁷

The proposed amendment does not adversely affect small businesses.

Localities⁸ Affected⁹

The proposed amendment does not disproportionally affect any particular localities, nor introduce costs for local governments.

Projected Impact on Employment

The proposed amendment does not affect total employment.

Effects on the Use and Value of Private Property

The proposed amendment does not affect the use and value of private property nor real estate development costs.

⁶ 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."

⁷ 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.

⁸ "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.

⁹ § 2.2-4007.04 defines "particularly affected" as bearing disproportionate material impact.