



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

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### **18 VAC 110-21 Regulations Governing the Licensure of Pharmacists and Registration of Pharmacy Technicians**

**Department of Health Professions**

**Town Hall Action/Stage: 6070 / 10014**

December 19, 2023

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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.<sup>1</sup>

### **Summary of the Proposed Amendments to Regulation**

Among other changes, Chapters 790<sup>2</sup> and 791 (identical) of the 2022 *Acts of Assembly* expanded the conditions for which pharmacists can initiate treatment. The Board of Pharmacy (Board) therefore proposes to amend the *Regulations Governing the Licensure of Pharmacists and Registration of Pharmacy Technicians* to conform it with the amendments made by the legislation to the Code of Virginia.

### **Background**

All of the proposed amendments to the regulation are essentially identical to the changes made to the Code of Virginia by the legislation.<sup>3</sup> Those amendments include the following:

- For persons 18 years of age or older, the list of drugs and devices that a pharmacist may initiate treatment with, dispense, or administer is expanded to include:

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<sup>1</sup> 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.

<sup>2</sup> See <https://lis.virginia.gov/cgi-bin/legp604.exe?221+sum+SB672>

<sup>3</sup> There are additional changes in the legislation that are not pertinent to the regulation.

- Vaccines for COVID-19; and
- Nicotine replacement and other tobacco-cessation therapies, including controlled substances as defined in the Drug Control Act (§ 54.1-3400 et seq. of the Code of Virginia), together with appropriate patient counseling; and
- Both the legislation and the proposed regulation also added that the pharmacist must have a “bona fide pharmacist-patient relationship” with the person 18 years of age or older.
  - Code of Virginia § 54.1-3303 states that a bona fide practitioner-patient relationship exists:
    - “if the practitioner has (i) obtained or caused to be obtained a medical or drug history of the patient; (ii) provided information to the patient about the benefits and risks of the drug being prescribed; (iii) performed or caused to be performed an appropriate examination of the patient, either physically or by the use of instrumentation and diagnostic equipment through which images and medical records may be transmitted electronically; and (iv) initiated additional interventions and follow-up care, if necessary, especially if a prescribed drug may have serious side effects.”
- In addition, for persons three years of age or older a pharmacist may initiate treatment with, dispense, or administer:
  - Vaccines included on the Immunization Schedule published by the Centers for Disease Control and Prevention and vaccines for COVID-19; and
  - Tests for COVID-19 and other coronaviruses.
- Further, a pharmacist who administers a vaccination to a minor shall provide written notice to the parent or guardian that the minor should visit a pediatrician annually.
- For a patient of any age, a pharmacist who initiates treatment with or dispenses or administers a drug or device shall notify the patient's primary health care provider, even if no method exists to send the notification electronically in a manner compliant with the federal Health Insurance Portability and Accountability Act, provided that the patient consents to such notification.
- Pharmacists who initiate treatment with, dispense, or administer a drug, device, controlled paraphernalia, or other supplies or equipment shall obtain a history from the

patient, including questioning the patient for any known allergies, adverse reactions, contraindications, or health diagnoses or conditions that would be adverse to the initiation of treatment, dispensing, or administration.

- Finally, it is established that a pharmacist may initiate treatment with, dispense, or administer drugs, devices, controlled paraphernalia, and other supplies and equipment through telemedicine services, as defined in § 38.2-3418.16 of the Code of Virginia, in compliance with all requirements of § 54.1-3303 of the Code of Virginia and consistent with the applicable standard of care.

### **Estimated Benefits and Costs**

In terms of requirements and opportunities, the proposed amendments to the regulation are essentially identical to the amendments in the legislation. Because the statutory language already requires these changes, amending the regulation would have no impact beyond better informing readers of the regulation of those requirements and opportunities.

### **Businesses and Other Entities Affected**

The 1,756 pharmacies in the Commonwealth and the 16,064 licensed pharmacists in the Commonwealth, as well as patients with whom they initiate treatment, are potentially affected by the legislation.

The Code of Virginia requires DPB to assess whether an adverse impact may result from the proposed regulation.<sup>4</sup> 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 amendments neither increase costs nor reduce net revenue for any entity, no adverse impact is indicated.

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<sup>4</sup> 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 Businesses<sup>5</sup> Affected:<sup>6</sup>**

The proposed amendments do not adversely affect small businesses.

**Localities<sup>7</sup> Affected<sup>8</sup>**

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

**Projected Impact on Employment**

The proposed amendments do not affect total employment.

**Effects on the Use and Value of Private Property**

The proposed amendments do not affect the use and value of private property or real estate development costs.

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<sup>5</sup> 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.”

<sup>6</sup> 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.

<sup>7</sup> “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.

<sup>8</sup> § 2.2-4007.04 defines “particularly affected” as bearing disproportionate material impact.