



# Virginia Department of Planning and Budget Economic Impact Analysis

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**18 VAC 110-20 Regulations Governing the Practice of Pharmacy**  
**Department of Health Professions**  
**Town Hall Action/Stage: 6081 / 10213**  
May 16, 2024

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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**

Pursuant to Chapter 628 of the 2022 Acts of Assembly,<sup>2</sup> the Board of Pharmacy (Board) proposes to make permanent an emergency regulation<sup>3</sup> related to work environment requirements for pharmacy personnel that protect the health, safety, and welfare of patients.

## **Background**

Chapter 628 directed the Board “to *adopt regulations related to work environment requirements for pharmacy personnel that protect the health, safety, and welfare of patients.*” The mandate further specified that “[s]uch regulations shall include provisions (i) addressing sufficient pharmacy staffing to prevent fatigue, distraction, or other conditions that interfere with a pharmacist’s ability to practice with competence and safety; (ii) stating standards for uninterrupted rest periods and meal breaks for pharmacy personnel; (iii) stating standards that ensure adequate time for pharmacists to complete professional duties and responsibilities,

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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> <https://lis.virginia.gov/cgi-bin/legp604.exe?221+ful+CHAP0628>

<sup>3</sup> <https://townhall.virginia.gov/l/ViewStage.cfm?stageid=9792>

*including drug utilization reviews, immunization administration, patient counseling, and verification of prescription accuracy; and (iv) limiting external factors such as productivity or production quotas to the extent that such factors interfere with the ability to provide appropriate professional services to the public.”*

The Board promulgated emergency regulation effective September 29, 2023. This action would make the emergency regulation permanent.

Relatedly, the Board notes that although the General Assembly, rather than the Board, determined that this legislation required emergency regulations, the emergency is likely related to concern for the safety of pharmacists, pharmacy staff, and patients given the current healthcare climate and increased workloads for pharmacists and other pharmacy personnel.

### **Estimated Benefits and Costs**

The potential for conflict between two parties with different incentives is a common issue in various business settings. This issue is known as the “principal-agent problem” in economics. Applied to this case, the problem may arise when the principle (pharmacy owner), who seeks to maximize profit and ensure the smooth operation of the pharmacy, and the agent (pharmacist in charge or PIC), who is responsible for managing day-to-day operations may have different priorities or incentives.

This understanding is consistent with the Board’s statement that the purpose of the proposed action in part is “ensuring a pharmacist’s authority and control over the practice of pharmacy is not usurped by the pharmacy permit holder.” Furthermore, the mandate’s preferred mechanism appears to be to address such potential conflicts by clearly outlining the expectations and responsibilities of the owner and the PIC, regarding specific issues listed in items (i) through (iv) above, in the regulation.

Generally speaking, the proposed regulatory language appears to be closely aligned with the mandate. Notably, the Board proposes a form titled “Staffing Requests or Concerns”<sup>4</sup> to be used by the PIC to communicate such issues to the pharmacy permit holder. The owner must maintain these forms on record for possible inspections. Thus, the proposed form is expected to

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[https://ris.dls.virginia.gov/uploads/18VAC110/forms/Staffing%20Requests%20or%20Concerns%20Form%20\(eff.%202023\)-20230929153548.pdf](https://ris.dls.virginia.gov/uploads/18VAC110/forms/Staffing%20Requests%20or%20Concerns%20Form%20(eff.%202023)-20230929153548.pdf)

help facilitate and ensure compliance and help improve working conditions for pharmacists and pharmacy technicians. The Board believes that pharmacies may need to hire additional staff if their pharmacies are inadequately staffed, which would add to their compliance costs, although such costs would be related to complying with basic standards of care. Additionally, the Board expects a small administrative cost for pharmacies to keep staffing records on Board provided forms, but expects these costs to be negligible especially if an electronic version of the form is used.

Although the mandate may introduce some costs for pharmacy owners and support the provision of pharmacy services in a safe and efficient manner, given the requirements in the mandate and the presence of the emergency regulation, this action's impact mainly consists of updating the Virginia Administrative Code (VAC) permanently to reflect what has already been implemented in practice since September 29, 2023.

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

The proposed amendments would affect owners of pharmacies, including chain pharmacies, as well as pharmacists and pharmacy technicians. The Board has no estimate of the number of corporations or other entities which may be affected, since many hold more than one pharmacy permit. However, as of September 30, 2023, there were 1,751 permitted pharmacies in the Commonwealth. As of the same date, there were 16,606 licensed pharmacists and 13,310 registered pharmacy technicians.<sup>5</sup> No affected entity appears to be disproportionately affected.

The Code of Virginia requires DPB to assess whether an adverse impact may result from the proposed regulation.<sup>6</sup> An adverse impact is indicated if there is any increase in net cost or reduction in net benefit for any entity, even if the benefits exceed the costs for all entities combined.<sup>7</sup> As noted above, while the legislation may have created some costs for the pharmacy owners and benefits for the pharmacists, pharmacy technicians, and patients, the proposed

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<sup>5</sup> Data source: Department of Health Professions

<sup>6</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.

<sup>7</sup> 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. As a result, DPB has adopted a definition of adverse impact that assesses changes in net costs and benefits for each affected Virginia entity that directly results from discretionary changes to the regulation.

action's main impact is to permanently incorporate the rules that are already in effect into the VAC. Thus, an adverse impact is not indicated.

### **Small Businesses<sup>8</sup> Affected:<sup>9</sup>**

According to the Board, there are fewer than 300 independent pharmacies in the Commonwealth that are most likely to be small businesses. However, the proposed incorporation of the existing rules permanently into the VAC does not adversely affect small businesses.

### **Localities<sup>10</sup> Affected<sup>11</sup>**

The proposed action does not create costs or other effects for localities.

### **Projected Impact on Employment**

The proposed action by itself does not appear to affect employment.

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

No effects on the use and value of private property not on real estate costs is expected on account of this regulatory action by itself.

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<sup>8</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>9</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>10</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>11</sup> § 2.2-4007.04 defines “particularly affected” as bearing disproportionate material impact.