



# 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: 6254 / 10020**  
August 29, 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**

The Board of Pharmacy (Board) proposes to clarify that the requirements for dispensing of naloxone by trained individuals in 18 VAC 110-20-735 only apply to the injectable formulation with a hypodermic needle or syringe.

## **Background**

Naloxone is a medication approved by the Food and Drug Administration designed to rapidly reverse opioid overdose.<sup>2</sup> There are two types of injectables for naloxone. One requires a hypodermic needle or syringe to draw up naloxone from a vial; the other form of injectable is an auto-injector with a built-in needle (like an Epi-Pen).<sup>3</sup> There is also non-injectable naloxone (nasal spray).

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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> Source: <https://www.samhsa.gov/medications-substance-use-disorders/medications-counseling-related-conditions/naloxone>

<sup>3</sup> Source: Department of Health Professions

This action serves to clarify that the regulatory requirements in 18 VAC 110-20-735 only apply to the injectable formulation of naloxone using a hypodermic needle or syringe. Specifically, the Board proposes to add “in an injectable formulation with a hypodermic needle or syringe” to make this clarification. The requirements for the dispensing of naloxone by auto-injector or nasal spray can be found in a Board guidance document called *Naloxone Protocols*.<sup>4</sup> The requirements in *Naloxone Protocols* also apply to the injectable formulation of naloxone using a hypodermic needle or syringe.

### **Estimated Benefits and Costs**

The proposed amendment does not change any requirements. By clarifying that dispensers of naloxone via auto-injector or nasal spray are not subject to the requirements of 18 VAC 110-20-735, it is possible that more people would be willing to dispense naloxone. To the extent that this is the case, the proposed clarification could be beneficial in that it may increase the likelihood that naloxone would be available for someone experiencing an opioid overdose.

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

Code of Virginia § 54.1-3408(Y)<sup>5</sup> states that:

Notwithstanding any other law or regulation to the contrary, a person who is acting on behalf of an organization that provides services to individuals at risk of experiencing an opioid overdose or training in the administration of naloxone for overdose reversal may dispense naloxone, provided that such dispensing is (i) pursuant to a standing order issued by a prescriber and (ii) in accordance with protocols developed by the Board of Pharmacy in consultation with the Board of Medicine and the Department of Health. ...

Thus, organizations that provide services to individuals at risk of experiencing an opioid overdose are particularly affected. The *Naloxone Protocols* are the protocols developed by the Board.

Code of Virginia § 54.1-3408(Y) goes on to state that:

If the person acting on behalf of an organization dispenses naloxone in an injectable formulation with a hypodermic needle or syringe, he shall first obtain authorization from the Department of Behavioral Health and Developmental

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<sup>4</sup> See [https://townhall.virginia.gov/L/GetFile.cfm?File=C:\TownHall\docroot\GuidanceDocs\223\GDoc\\_DHP\\_6099\\_v12.pdf](https://townhall.virginia.gov/L/GetFile.cfm?File=C:\TownHall\docroot\GuidanceDocs\223\GDoc_DHP_6099_v12.pdf)

<sup>5</sup> See <https://law.lis.virginia.gov/vacode/title54.1/chapter34/section54.1-3408/>

Services to train individuals on the proper administration of naloxone by and proper disposal of a hypodermic needle or syringe, and he shall obtain a controlled substance registration from the Board of Pharmacy.

The requirements of VAC 110-20-735 concern the controlled substance registration.

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 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.

### **Small Businesses<sup>7</sup> Affected:<sup>8</sup>**

The proposed amendment does not adversely affect small businesses.

### **Localities<sup>9</sup> Affected<sup>10</sup>**

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

### **Projected Impact on Employment**

The proposed amendment does not appear to affect total employment.

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<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. 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.

<sup>7</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>8</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>9</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>10</sup> § 2.2-4007.04 defines “particularly affected” as bearing disproportionate material impact.

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

The proposed amendment does not appear to affect the use and value of private property or real estate development costs.