

Adverse impact notification sent to Joint Commission on Administrative Rules, House Committee on Appropriations, and Senate Committee on Finance (COV § 2.2-4007.04.C): Yes Not Needed

If/when this economic impact analysis (EIA) is published in the *Virginia Register of Regulations*, notification will be sent to each member of the General Assembly (COV § 2.2-4007.04.B).



Virginia Department of Planning and Budget Economic Impact Analysis

18 VAC 110-20 Regulations Governing the Practice of Pharmacy
Department of Health Professions
Town Hall Action/Stage: 4536 / 7510
May 11, 2016

Summary of the Proposed Amendments to Regulation

The Board of Pharmacy (Board) proposes to amend this regulation to allow a provider pharmacist, in consultation with medical and nursing staff, to include diazepam rectal gel in an emergency kit maintained in a long-term care facility.

Result of Analysis

The benefits likely exceed the costs for all proposed changes.

Estimated Economic Impact

The Regulations Governing the Practice of Pharmacy specify that pharmacists may prepare an emergency kit for a long-term care facility in which access to the kit is restricted to a licensed nurse, pharmacist, or prescriber under certain conditions.¹ The current regulation limits the contents of the kit to “drugs for administration by injection or inhalation only, except that Nitroglycerin SL may be included.” The Board proposes to additionally allow diazepam rectal gel in the kit. Diazepam rectal gel is used in emergency situations to stop cluster seizures (episodes of increased seizure activity) in people who are taking other medications to treat epilepsy (seizures).²

¹ <http://law.lis.virginia.gov/admincode/title18/agency110/chapter20/section540/>

² Source: U.S. National Library of Medicine (<https://www.nlm.nih.gov/medlineplus/druginfo/meds/a605033.html>)

Children and adults in long-term care facilities who suffer from complex physical and neurological diseases and experience frequent seizures would benefit from having immediate access to diazepam rectal gel in the facilities' emergency boxes. Under the current regulation the gel can only be obtained by prescription as needed. The proposed amendment will be beneficial in that it will likely help improve patient outcomes for patients having seizures by allowing for immediate access to the gel. Since the regulation authorizes correctional facilities that employ one or more full-time physicians, nurses, or physician assistants to obtain an emergency kit in accordance with the regulation, patients in correctional facilities may also benefit from the inclusion of this drug in an emergency kit. Since there is no apparent cost to the proposed amendment, the proposed addition of diazepam rectal gel to the allowable contents of emergency kits for long-term facilities creates a net benefit.

Businesses and Entities Affected

The proposed amendment potentially affects 162 skilled nursing facilities in the Commonwealth,³ as well as correctional facilities.

Localities Particularly Affected

The proposed amendment does not disproportionately affect particular localities.

Projected Impact on Employment

The proposed amendment does not significantly affect employment.

Effects on the Use and Value of Private Property

The proposed amendment does not have significant effect on the use and value of private property.

Real Estate Development Costs

The proposed amendment does not affect real estate development costs.

Small Businesses:

Definition

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

³ The number of affected facilities was estimated by Omnicare, a CVS Health Company, which supplies the facilities.

(ii) employs fewer than 500 full-time employees or has gross annual sales of less than \$6 million.”

Costs and Other Effects

The proposed amendment does not significantly affect costs for small businesses.

Alternative Method that Minimizes Adverse Impact

The proposed amendment does not adversely affect small businesses.

Adverse Impacts:

Businesses:

The proposed amendment does not adversely affect businesses.

Localities:

The proposed amendment does not adversely affect localities.

Other Entities:

The proposed amendment does not adversely affect other entities.

Legal Mandates

General: The Department of Planning and Budget 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 Number 17 (2014). Code § 2.2-4007.04 requires that such economic impact analyses determine the public benefits and costs of the proposed amendments. Further the report 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.

Adverse impacts: Pursuant to Code § 2.2-4007.04(C): 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 within the 45-day period.

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.

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