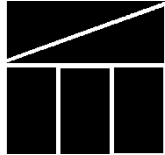


Adverse impact notification sent to Joint Commission on Administrative Rules, House Committee on Appropriations, and Senate Committee on Finance (COV § 2.2-4007.04.C): Yes¹ Not Needed

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: 5210 / 8512
March 18, 2019

Summary of the Proposed Amendments to Regulation

The Board of Pharmacy (Board) proposes to update the definition of cold to mirror that of United States (U.S.) Pharmacopeia.

Result of Analysis

There is insufficient data to accurately compare the magnitude of the benefits versus the costs.

Estimated Economic Impact

Currently, the definition of cold in this regulation contains a temperature range for freezers (i.e. between -20 and -10 degrees Celsius or -4 and 14 degrees Fahrenheit). This language reflects the definition in the U.S. Pharmacopeia prior to its 2017 revision. Under the revised version, the freezer temperature range is -25 and -10 degrees Celsius or -13 and 14 degrees Fahrenheit.² The Board proposes to amend the regulation to reflect that change. Since the proposed range is broader than the current range, existing freezers at pharmacies would be sufficient to maintain the new range. Thus, no significant effect on pharmacies is expected from this change.

¹ Adverse impact is indicated if there is any increase in net cost for any entity, even if the benefits exceed the costs for all entities combined.

² See page 6 <659> at https://www.uspnf.com/sites/default/files/usp_pdf/EN/USPNF/revisions/659_rb_notice.pdf

The 2017 version of the U.S. Pharmacopeia also established a new temperature range for articles that are recommended to be stored at a specific temperature that is below -20 Celsius or -4 degrees Fahrenheit. In those cases, the U.S. Pharmacopeia states the temperature of the storage location should be controlled to plus or minus 10 degrees of the recommended temperature.³ The Board also proposes to incorporate this new range for articles that have a recommended storage condition. This new language can, theoretically, create a need to purchase new equipment for storage of such items or lead to no longer carrying those items if the pharmacy does not maintain the storage temperature within the recommended range. For example, a -40 degrees of Celsius recommended storage range would require the capability to control the temperature at -30 degrees of Celsius which is outside the temperature range of a freezer. The Board staff believes that this new language is unlikely to necessitate purchase of new equipment because most likely the pharmacies would already have the capability to maintain manufacturers recommended storage temperature range, or they would not stock those items. However, whether this change would lead to purchases of new equipment or no longer carrying some items at some pharmacies, or no effect at all on any pharmacies, cannot be ascertained with any degree of certainty. Thus, the net impact of this change is not known.

Businesses and Entities Affected

The proposed amendments apply to 1,813 permitted pharmacies.

Localities Particularly Affected

The proposed amendments do not disproportionately affect particular localities.

Projected Impact on Employment

The proposed amendments are unlikely to significantly affect employment.

Effects on the Use and Value of Private Property

The proposed amendments are unlikely to significantly affect the use and value of private property.

Real Estate Development Costs

The proposed amendments are unlikely to affect real estate development costs.

³ Ibid.

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

Costs and Other Effects

Most pharmacies are owned by large retail chains. Whether the proposed amendments would have any costs or other effects on small businesses is not known.

Alternative Method that Minimizes Adverse Impact

Whether the proposed amendments would adversely affect small businesses is not known.

Adverse Impacts:**Businesses:**

Whether the proposed amendments would adversely affect businesses is not known.

Localities:

The proposed amendments do not adversely affect localities.

Other Entities:

The proposed amendments do 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 14 (as amended, July 16, 2018). 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.