

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: 4453/7355
December 23, 2015

Summary of the Proposed Amendments to Regulation

Pursuant to Chapter 505 of the 2015 Acts of the Assembly, the Board of Pharmacy (Board) proposes to amend its pharmacy regulation to allow programs of all-inclusive care for the elderly (PACE sites) that are licensed by the Department of Social Services and overseen by the Department of Medical Assistance Services to be able to possess, repackage, deliver and administer prescription medications to their patients as community service boards (CSBs) and behavioral health authorities (BHAs) do now.

Result of Analysis

Benefits likely outweigh costs for implementing these proposed changes.

Estimated Economic Impact

Currently, the Board allows CSBs and BHAs who have obtained controlled substances registration to have staff trained in repackaging of prescription drug orders to repackage prescription drugs for these entities' clients. Pursuant to Chapter 505 of the 2015 Acts of the Assembly, the Board now proposes to add PACE sites to the list of entities that may repackage prescriptions for their clients. Pace sites will have to meet the same criteria as do CSBs and BHAs and will have to pay the fees set for approval (and renewal and late renewal) of repackaging training programs (\$50, \$30 and \$10, respectively) and meet criteria for training

programs as well as rules that trained individuals must follow in repackaging drugs. The rules for repackaging include information that must be on packaging labels, information that must be dispensed to clients with the drugs, rules for storage and destruction of drugs and recordkeeping requirements.

PACE sites will incur the same explicit costs as CSBs and BHAs incur now; these costs comprise the \$50 fee for approval of a repackaging training program to train their staff (as well as biennial fees of \$30 for renewal of these programs). PACE sites will also incur implicit costs for staff time spent in training. PACE sites will likely only seek repackaging authority if they believe that the costs they would incur are outweighed by the benefits that will accrue to themselves and their clients. The benefits of these proposed regulations have the potential to be quite large, especially for elderly clients who lack the capacity to independently follow a prescribed drug regimen.

Businesses and Entities Affected

The Department of Health Professions reports that there are 8 PACE provider organizations that serve 12 licensed PACE sites in the Commonwealth. All of these entities and their clients will be affected by these regulations.

Localities Particularly Affected

No locality will be particularly affected by this regulatory change.

Projected Impact on Employment

This regulatory change is unlikely to impact employment in the Commonwealth.

Effects on the Use and Value of Private Property

This regulatory change is unlikely to affect the use or value of private property in Virginia.

Real Estate Development Costs

This proposed change will likely 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

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

Costs and Other Effects

No small business in the Commonwealth is likely to incur net costs on account of this proposed regulatory change.

Alternative Method that Minimizes Adverse Impact

No small business in the Commonwealth is likely to incur net costs on account of this proposed regulatory change.

Adverse Impacts:

Businesses:

No business in the Commonwealth is likely to incur net costs on account of this proposed regulatory change.

Localities:

Localities in the Commonwealth are unlikely to see any adverse impacts on account of this proposed regulatory change.

Other Entities:

No entities in the Commonwealth are likely to suffer any adverse impacts on account of this proposed regulatory change.

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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