



Economic Impact Analysis Virginia Department of Planning and Budget

**18 VAC 110-20 – Regulations Governing the Practice of Pharmacy
Department of Health Professions
April 30, 2011**

Summary of the Proposed Amendments to Regulation

Pursuant to Chapter 28 of the 2010 Acts of the Assembly, the Board of Pharmacy (Board) proposes to amend its regulations to set rules for community service boards (CSBs) and behavioral health authorities (BHAs) that will be able to possess, repackage, deliver and administer prescription medications. These proposed regulations, and the mandating legislation, will also allow crisis stabilization units to store and administer drugs need for emergency treatment.

Result of Analysis

Benefits likely outweigh costs for implementing these proposed changes.

Estimated Economic Impact

In 2009, budget cuts forced the closing of the Community Resource Pharmacy which dispensed drugs that were distributed through community service boards (CSBs). With the closing of this pharmacy CSBs lost the ability to distribute drugs to their clients, some of whom are homeless or otherwise lacking for a safe place to store drugs, and monitor how they were used. To address the issues caused by the closing of the Community Resource Pharmacy, the General Assembly passed legislation in 2010 and directed the Board to promulgate regulations to implement the legislative changes.

In response to this legislative mandate, the Board now proposes regulatory changes that will allow CSBs, behavioral health authorities (BHAs) and crisis stabilization units to obtain controlled substances registration and will also allow properly trained staff for these entities to have access to prescription drugs so that they can repackage them for clients. The Board also

proposes fees for approval (and renewal and late renewal) of repackaging training programs (\$50, \$30 and \$10, respectively) and criteria for these training programs as well as rules that trained individuals must follow in repackaging drugs. The proposed 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.

Board staff reports that the only explicit costs CSBs and BHAs are likely to incur would be 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). These entities will also incur implicit costs for staff time spent in training. CSBs and BHAs will likely only incur these costs if they believe that they 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 mental health clients who lack the capacity to independently follow a prescribed drug regimen or who are at risk for suicide if they are in possession of a whole month's prescription of their drugs.

Businesses and Entities Affected

The Department of Health Professions (DHP) reports that there are 40 locally run CSBs and that the number of BHAs is unknown. All of these entities and their clients will be affected by these regulations.

Localities Particularly Affected

Localities with CSBs will be particularly affected by this proposed regulatory action.

Projected Impact on Employment

This proposed regulatory action is unlikely to have any effect on employment in the Commonwealth.

Effects on the Use and Value of Private Property

These proposed regulatory changes are unlikely to affect the use or value of private property in the Commonwealth.

Small Businesses: Costs and Other Effects

No small business is likely to incur any costs on account of this regulatory action.

Small Businesses: Alternative Method that Minimizes Adverse Impact

No small business is likely to incur any costs on account of this regulatory action.

Real Estate Development Costs

This regulatory action will likely have no effect on real estate development costs in the Commonwealth.

Legal Mandate

The Department of Planning and Budget (DPB) has analyzed the Board the economic impact of this proposed regulation in accordance with Section 2.2-4007.H of the Administrative Process Act and Executive Order Number 36 (06). Section 2.2-4007.H requires that such economic impact analyses include, but need not be limited to, the projected number of businesses or other entities to whom the regulation would apply, the identity of any localities and types of businesses or other entities particularly affected, the projected number of persons and employment positions to be affected, the projected costs to affected businesses or entities to implement or comply with the regulation, and the impact on the use and value of private property. Further, if the proposed regulation has adverse effect on small businesses, Section 2.2-4007.H requires that such economic impact analyses include (i) an identification and estimate of the number of small businesses subject to the regulation; (ii) the projected reporting, recordkeeping, and other administrative costs required for small businesses to comply with the regulation, including the type of professional skills necessary for preparing required reports and other documents; (iii) a statement of the probable effect of the regulation on affected small businesses; and (iv) a description of any less intrusive or less costly alternative methods of achieving the purpose of the regulation. The analysis presented above represents DPB's best estimate of these economic impacts.