



Economic Impact Analysis Virginia Department of Planning and Budget

**18 VAC 110-50 – Regulations Governing Wholesale Distributors, Manufacturers and
Warehousers
Department of Health Professions
March 8, 2013**

Summary of the Proposed Amendments to Regulation

As a result of a periodic review, the Board of Pharmacy (Board) proposes to amend its regulations for wholesalers, manufacturers and warehousers. Specifically, the Board proposes to add clarifying language to the regulations, amend the requirements for information on a application to be licensed or registered and allow licensees to file an attestation disclosing any criminal history rather than requiring a sworn statement or affirmation.

Result of Analysis

Benefits likely outweigh costs for implementing these proposed changes.

Estimated Economic Impact

Currently, 18 VAC 110-50-40(A) requires the holder of a license to restrict access to all areas in which prescription drugs are stored or kept for sale but does not specify which holders of what licenses are being referenced. Although this requirement is in the Virginia Administrative Code chapter that governs wholesale distributors, manufacturers and warehousers, and so the implication is that the requirement would apply to these licensees, the Board proposes to add these entities explicitly into the regulatory text so that it is clear who is required to restrict access to stored prescription drugs. No affected entity will incur any additional costs on account of this proposed change. To the extent that this change may forestall any misunderstanding of what is required of licensees, this proposed change will benefit all interested parties.

Current regulations require all partners in a covered partnership business to provide name, address, and social security number or control number on the application for licensure or

registration and also require the name, address, social security number or control number and title of each corporate officer for businesses that are incorporated and applying for licensure or registration. Board staff reports that the Board “does not believe it is reasonable to require social security or control numbers for all partners or all officers or directors of a corporation unless the individuals are directly involved in the operation of the distributorship”. Consequently, the Board now proposes to amend the requirements for information so that only individuals who are specifically responsible for the operation of a facility will be required to provide identifying information to the Board. No entity is likely to be harmed by this regulatory change because the Board will still have information for the individual that they will hold responsible should there be an issue that the Board needs to address. Potential licensees or registrants will benefit from this change as it will make the process of filling out an application less time consuming and intrusive.

Current regulations require that the person who is named as the responsible party on the application for licensure provide a statement sworn or affirmed before a notary public that discloses any criminal convictions and any pending criminal charges. The named party also had to undergo a criminal background check. Since a notary public can only swear that the person signing the statement is who he says he is but cannot swear that the statement being signed is truthful, the Board proposes to change this requirement so that the named responsible party will just have to attest that they are being truthful. They will also still have to undergo a criminal background check so the information available to the Board before a license or registration is issued should not be adversely affected. Named responsible parties will likely benefit from this change as they will no longer have to take the time to go to a notary public and will also not have to incur the costs of any fee that the notary public might charge.

Businesses and Entities Affected

The Department of Health Professions (DHP) reports that there are 768 non-resident wholesaler distributors and 116 Virginia wholesale distributors that are licensed to do business in the Commonwealth. All of these entities will be affected by these proposed regulations.

Localities Particularly Affected

No locality will be particularly affected by the proposed regulations.

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 have any impact on 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 economic impact of this proposed regulation in accordance with Section 2.2-4007.H of the Administrative Process Act and Executive Order Number 14 (10). 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.