Economic Impact Analysis
Virginia Department of Planning and Budget

18 VAC 110-20 – Regulations Governing the Practice of Pharmacy
Department of Health Professions
September 7, 2012

Summary of the Proposed Amendments to Regulation

As a result of several petitions for rulemaking, the Board of Pharmacy (Board) proposes to amend its regulations to make requirements for verification of storage, location, expiration dates, drug security and access codes for automated dispensing devices (ADD) less burdensome. Specifically, the Board proposes to:

1) Re-organize the regulations so the rules for using ADDs are clear;
2) Make a distinction between audits and reviews (these words are used interchangeably in the current regulations) so that it is clear to pharmacies when they must take each action;
3) Allow pharmacies whose ADDs have the capacity to perpetually monitor schedule II-V drugs to limit their required monthly audit so that they are just auditing discrepancies or exceptions identified through the ADDs' perpetual monitoring systems and
4) Provide an exception to the rules that require monthly inspection of ADDs to check proper storage, location of drugs, expiration dates and security of drugs within the ADD as well as the validity of access codes to dispense those drugs. Under these proposed regulations, pharmacies may forego most parts of this monthly inspection so long as the ADD is capable of performing self-inspections that meet criteria set by the Board.

Result of Analysis

Benefits likely outweigh costs for implementing these proposed changes.

Estimated Economic Impact

Among the changes that the Board proposes for these regulations is a reorganization of the requirements for use of automated dispensing devises (ADD). These changes have no costs attached for any affected entities because no requirements are changing. Affected entities may, however, benefit from these changes as they make the requirements for ADD use easier to find or understand.

Currently, Board staff reports, these regulations use the terms audit and review interchangeably. As this can lead to confusion, the Board proposes to separate usage of these terms in the regulatory text so that affected entities clearly know when they need to perform an audit and when they need to perform a review. Again, these changes will not impose any extra burden on any regulated entity so these entities will likely not incur any extra costs. To the extent that the current text is opaque as to what is required of affected entities, they will get the benefit of additional clarity from the changes that the Board now proposes.

Current regulations require a monthly audit to review distribution and administration of Schedule II through V drugs from any ADD. The Board proposes to allow pharmacies whose ADDs have perpetual inventory management software to only audit dispensing discrepancies and exceptions that are identified by the ADDs. Further, the Board proposes an exemption to monthly administration audits so long as the ADD reconciliation software provides a statistical analysis based on peer-to-peer comparisons of use for the ADD unit or department and the software provides monitoring of overrides and discrepancies. If suspicious activity is identified by the monthly reports generated through these statistical analyses, that activity would then be subject to a focused audit. Hospital pharmacies that have ADDs with software that would allow them to just audit discrepancies and suspicious behavior will likely benefit from staff time saved from having to perform monthly audits.

Current regulations require monthly inspections of ADDs to check proper storage, location of drugs, expiration dates and security of drugs within the ADD as well as the validity of access codes to dispense those drugs. The Board proposes an exemption to most parts of these inspections for ADDs so long as the ADD software performs: 1) at least daily monitoring of temperature controlled storage, 2) automatic identification and isolation of the location of each drug within the devise, 3) electronic tracking of drug expiration dates and 4) electronic detection

of when, and by whom, the devise is opened. Pharmacies that meet the criteria for this exemption will still have to perform inspections of look-alike and sound-alike drugs within matrix drawers or open access areas of each ADD. These changes will again likely benefit affected hospital pharmacies by allowing less staff time to be used performing inspections.

Businesses and Entities Affected

The Department of Health Professions (DHP) reports that these proposed regulations will affect all hospital pharmacies that dispense drugs with ADDs. DHP does not know how many pharmacies that would be because the Board does not license pharmacies by type of practice.

Localities Particularly Affected

No locality will be particularly affected by these 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 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 he 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.