Economic Impact Analysis
Virginia Department of Planning and Budget

18 VAC 110-20 – Regulations Governing the Practice of Pharmacy
Department of Health Professions
June 10, 2013

Summary of the Proposed Amendments to Regulation

As part of the regulatory reform initiative, the Board of Pharmacy (Board) proposes to amend its Regulations Governing the Practice of Pharmacy to: 1) delete fees that no longer are applicable, 2) allow licensees to attest that they have completed their required continuing education hours for license renewal, 3) allow more than one pharmacist to verify the accuracy of a prescription, 4) change the requirements for labeling an individual patient's drug drawer, 5) allow a pharmacy providing services to a hospital or long term care facility to use a robotic pharmacy system that dispenses drugs in bar-coded unit doses or compliance packaging and 6) allow an exemption to alarm system requirements for teaching institutions that only stock schedule IV drugs.

Result of Analysis

Benefits likely outweigh costs for these proposed regulatory changes.

Estimated Economic Impact

Current regulations contain one-time fees that were imposed for renewals between December 31, 2009 and April 30, 2010. As these fees are no longer applicable, the Board proposes to remove them from the regulations. No entity will incur costs on account of this change. Affected entities will likely benefit from the added clarity that removing obsolete, and potentially confusing, language brings.

Current regulations require pharmacy technician to provide proof that they completed continuing education in order to renew their licenses. Board staff reports, however, that the Board has not actually required pharmacy technicians to submit such proof since 2009. The

Board now proposes to eliminate the requirement for proof in these regulations and instead require pharmacy technicians to attest that they have completed required continuing education when they renew their licenses. This change will benefit licensees by bringing regulations into conformity with current practice and by saving them possible bookkeeping and mailing expenses in the future if the Board left this requirement intact and instead decided that licensees once again needed to comply with regulations and provide proof of continuing education.

Board staff reports that currently section 270 of these regulations, which speaks of one pharmacist verifying the accuracy of a prescription, could be read to contradict section 276 of these regulations, which requires the identification of individual pharmacists who, jointly would be responsible for prescription dispensing functions. To fix this contradiction, the Board now proposes to add rules for multiple pharmacists to verify a dispensed prescription. These rules will require that a record be maintained identifying the date of dispensing, the name of each pharmacist involved in dispensing and the individual task for which he or she is responsible in the verification process. Affected entities will likely benefit from the added clarity that this change brings to these regulations.

Current regulations require that patients' individual drug drawers in hospitals or long term care facilities be labeled with their names. As this may violate HIPPA privacy requirements, the Board proposes to change this and instead require that drawers be labeled "in such a manner as to identify the patient and his location without violating health privacy laws". This change will likely benefit patients, as their privacy will be protected, and will also benefit licensees, as they will no longer be required in regulation to violate federal law.

Currently, pharmacies that provide services for hospitals and long term care facilities may in general use a robotic pharmacy system to dispense unit dose bar-coded drugs. There is a Board approved pilot program that allows dispensing of drugs in compliance packaging, also. The Board now proposes to allow these pharmacies to use robotic pharmacy systems to dispense both drugs in bar-coded unit doses and in compliance packaging. This change will benefit pharmacies that provide services for hospitals and long term care facilities by allowing them greater flexibility in choosing how to dispense drugs without paying the $250 fee and accruing time costs associated with applying to be part of the pilot program. No entity is likely to incur additional net costs on account of this change.

Current regulations require that any facility that is not staffed 24 hours a day store drugs in a fixed secured location with an alarm. These regulations currently exempt researchers, animal control officers, humane societies, alternate delivery sites and emergency medical services agencies that only stock intravenous fluids with no added drugs from this alarm requirement. The Board proposes to add teaching institutions possessing only schedule IV drugs (with low risk of theft or abuse) to the list of groups that are exempt from having to have an alarm system. This change will save eligible teaching institutions from bearing the expense of installing alarm systems on their drug closets.

Businesses and Entities Affected

The Department of Health Professions (DHP) reports that there are 1,772 pharmacies, 11,941 pharmacists and 12,227 pharmacy technicians licensed to do business in the Commonwealth. All of these entities will be affected by these proposed regulations.

Localities Particularly Affected

No localities 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 additional expense on account of these regulatory changes.

Small Businesses: Alternative Method that Minimizes Adverse Impact

No small business is likely to incur any additional expense on account of these regulatory changes.

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 2.2-4007.04 of the Administrative Process Act and Executive Order Number 14 (10). Section 2.2-4007.04 requires that such economic impact analyses include, but need not be limited to, a determination of the public benefit, 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 an adverse effect on small businesses, Section 2.2-4007.04 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.