



## **Economic Impact Analysis Virginia Department of Planning and Budget**

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**18 VAC 110-20 – Regulations Governing the Practice of Pharmacy  
Department of Health Professions  
March 14, 2013**

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### **Summary of the Proposed Amendments to Regulation**

Pursuant to Chapter 124 of the 2011 Acts of the Assembly, and as a replacement for emergency regulations that expire September 30, 2013, the Board of Pharmacy (Board) proposes to amend its regulations to set rules for a continuous quality improvement (CQI) program. The purpose of the CQI program is to have pharmacists systematically record and report drug dispensing errors so that they can be analyzed and avoided in the future.

### **Result of Analysis**

Benefits likely outweigh costs for these proposed regulations.

### **Estimated Economic Impact**

Prior to 2011, the Board of Pharmacy (Board) enforced a code of behavior for pharmacists that required they handle errors in an appropriate manner so that patients were not harmed and also supported the institution of continuous quality improvement programs that would facilitate protecting patient safety and eliminating repeated errors. In 2011, the General Assembly passed legislation that required the Board to promulgate regulations for a CQI program that provides “a systematic ongoing process of analysis of dispensing errors that uses findings to formulate an appropriate response and to develop or improve pharmacy systems and workflow processes designed to prevent or reduce future errors”. The Board promulgated emergency regulations to meet this mandate and these regulations became effective October 1, 2012. These proposed regulations will serve as a more permanent replacement for the emergency regulations that will expire September 30<sup>th</sup> of this year.

This action adds several definitions to these regulations, including definitions for the activity reports that pharmacies will have to compile and submit to a patient safety organization after a dispensing error occurs and also includes a long but intuitive list of things that fall under the heading “dispensing error”. The proposed regulations contain notification requirements (both for pharmacy staff to notify the pharmacist on duty and for the pharmacist to notify the affected patient and, when appropriate, the prescribing physician) and also specify that pharmacies can meet their error reporting and analysis obligations under the CQI program by either reporting errors and analysis to a patient safety organization or by independently keeping track of and analyzing dispensing errors. Records of errors, both those reported to patient safety organizations and those independently tracked by pharmacies, will be required to be kept for 12 months.

Pharmacies that are subject to these regulations will incur some costs, mainly for time spent on new record keeping requirements and on analysis activities related to dispensing errors that occur but also for time spent educating pharmacy staff on CQI procedures as well as the outcome of error analysis. Pharmacies will be able to report errors to patient safety organizations at no cost but may also choose to pay for additional analysis services that these organizations offer. Pharmacies are unlikely to pay for these additional services unless they perceive that the benefits of doing so outweigh the costs. Patients will likely benefit to the extent that these regulations reduce dispensing errors and improve patient safety.

### **Businesses and Entities Affected**

The Department of Health Professions (DHP) reports that there are 1,764 resident pharmacies and 511 non-resident pharmacies permitted to dispense drugs 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**

DHP reports that they do not know how many of the entities affected by these proposed regulations would qualify as small businesses but also report that most pharmacies are part of a national chain or health care system that would not qualify. Affected small businesses will likely incur extra bookkeeping and reporting costs as well as costs associated with completing analysis of any errors that occur. Most of these costs would be for time spent at these activities instead of doing some other job related tasks.

## **Small Businesses: Alternative Method that Minimizes Adverse Impact**

There are likely no alternative methods for doing the tasks mandated by these regulations that would both meet the Board's (and the General Assembly's) aims and also further minimize any adverse impact on affected small businesses.

## **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.