



Economic Impact Analysis Virginia Department of Planning and Budget

18 VAC 110-20 – Regulations Governing the Practice of Pharmacy
Department of Health Professions
December 3, 2012

Summary of the Proposed Amendments to Regulation

The Board of Pharmacy (Board) proposes to eliminate the current requirement that bulk bins in an automated counting device be “run dry” every 60 days. In addition, the Board proposes to specify that: 1) only if there is a drug recall within the last three months or if it is known that a recalled drug is in the device will it be required that drugs be removed, and 2) if the device has technology that ensures a particular lot has been cleared or if the bin has been allowed to “run dry” since the addition of the recalled lot, it will not be necessary to remove all drugs in the bin in the event of a recall.

Result of Analysis

The benefits likely exceed the costs for all proposed changes.

Estimated Economic Impact

Under the current regulations, if only one lot is added to a bin at one time, but a subsequent lot is added before the first has cleared, the bin is required to "run dry" where all product is completely removed prior to filling at least once every 60 days with a record made of the run dry dates. The Board proposes to repeal this mandate to have the pharmaceuticals completely removed prior to filling at least once every 60 days; but at the same the Board proposes to specify that:

In the event of a drug recall involving one of multiple lots placed in a bin of an automated counting device in the last three months or if a recalled drug is known to remain in the bin, all drugs shall be removed from the bin and not used for patient care. The removal of drugs from the bin is not required if:

a. The technology of the automated counting device can ensure drugs in a particular lot have been cleared; or

b. The bin has been run dry, with a record made of the run dry date, since the addition of the recalled lot number in which all drugs were completely removed prior to filling with a subsequent lot number.

The proposal to eliminate the “run dry” requirement will result in cost savings – both in staff time consumed with meeting the current 60-day run-dry requirement and in the unnecessary loss of drugs that are removed every 60 days when the bin must be “run dry.” Public safety is maintained by no longer requiring the removal of pharmaceuticals when there is no clear benefit, but requiring removal when there is a risk of recalled drugs being present. Thus, the proposed amendments produce a net benefit.

Businesses and Entities Affected

The proposed amendments affect the 1760 pharmacies in Virginia that have a current license (permit).

Localities Particularly Affected

The proposed amendments do not disproportionately affect particular localities.

Projected Impact on Employment

The proposed amendments are unlikely to significantly affect employment.

Effects on the Use and Value of Private Property

The proposed amendments modestly reduce costs for pharmacies by eliminating the requirement that bulk bins in an automated counting device be “run dry” every 60 days.

Small Businesses: Costs and Other Effects

The proposal to eliminate the “run dry” requirement will result in cost savings for small businesses both in staff time consumed and in the unnecessary loss of drugs that are removed every 60 days when the bin must be run dry.

Small Businesses: Alternative Method that Minimizes Adverse Impact

The proposed amendments do not adversely affect small businesses.

Real Estate Development Costs

The proposed amendments do not affect real estate development costs.

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, 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 2.2-4007.04 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.