



Economic Impact Analysis Virginia Department of Planning and Budget

18 VAC 110-20 – Regulations Governing the Practice of Pharmacy
18 VAC 110-50 – Regulations Governing Wholesale Distributors, Manufacturers and
Whalers
Department of Health Professions
February 4, 2009

Summary of the Proposed Amendments to Regulation

The Board of Pharmacy (Board) proposes to amend its Regulations Governing the Practice of Pharmacy and its Regulations Governing Wholesale Distributors, Manufacturers and Whalers so the licenses, permits and registrations issued under these regulations do not all expire on the same day each year. These amended regulations will replace emergency provisions that are set to expire September 22, 2009.

Result of Analysis

The benefits likely exceed the costs for all proposed changes.

Estimated Economic Impact

Prior to the promulgation of emergency regulations (effective September 23, 2008), all Board licenses, permits and registrations expired on December 31 each year. The Department of Health Professions (DHP) reports that this not only led to an uneven workload for Board staff but was also burdensome for pharmacies that chose to pay for the renewal of the pharmacy's permit and also for the renewal of licenses and registrations held by pharmacy staff.

These proposed regulations, and the emergency regulations that they replace, institute a staggered schedule for renewal. Under these regulations, pharmacist active license, pharmacist inactive license and pharmacist technician registration renewals are still due December 31 each year. Physician permit to practice pharmacy, medical equipment supplier permit, Humane Society permit and controlled substances registration renewals are due February 28 each year. Pharmacy permit and nonresident pharmacy permit renewals are due April 30 each year. All

licenses, permits and registrations issued under 18 VAC 110-50 will need to be renewed February 28th each year. Current facility permits and registrations that would have expired on the 31st of December will be valid until the new expiration dates set out in these proposed regulations.

It is unlikely that any regulated entity will incur any costs on account of these proposed regulations. Both Board employees and regulated entities will likely benefit under these regulatory changes. Board employees will likely benefit from having their renewal workload more widely distributed. Pharmacies that choose to pay for renewal of employee licenses and registrations as well as paying for the renewal of their pharmacy permit will likely benefit from having these fees due over a span of several months rather than all at once. Permit and registration holders who would have had to renew on December 31, but will now have until the end of February or the end of April to do so, will receive a one time benefit as their permits/registrations will be good for 14 or 16 months rather than 12 months.

Businesses and Entities Affected

These proposed regulations will affect all pharmacies, non-resident pharmacies, drug manufacturers, drug wholesale distributors, drug warehouse, physicians who are permitted to practice pharmacy, medical equipment suppliers and holders of controlled substance registrations in the Commonwealth. DHP reports that the Board currently permits 1,663 pharmacies, 541 nonresident pharmacies, 96 manufacturers, 42 warehouse, 14 physicians who are permitted to practice pharmacy and 421 medical equipment suppliers. DHP also reports that there are 746 wholesale distributors currently licensed by the Board and that there are 673 controlled substance registrations held in the Commonwealth. DHP does not know the exact number of affected license, permit or registration holders that would qualify as small businesses but suspects it is a small number since most pharmacies are now owned by large national chains.

Localities Particularly Affected

No locality will be particularly affected by this proposed regulatory action.

Projected Impact on Employment

This regulatory action will likely have no impact on employment in the Commonwealth.

Effects on the Use and Value of Private Property

This regulatory action will likely have no effect on the use or value of private property in the Commonwealth.

Small Businesses: Costs and Other Effects

Small businesses in the Commonwealth are unlikely to incur any costs on account of this regulatory action.

Small Businesses: Alternative Method that Minimizes Adverse Impact

Small businesses in the Commonwealth are unlikely 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 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.