



Economic Impact Analysis Virginia Department of Planning and Budget

**18 VAC 85-20 – Regulations Governing the Practice of Medicine, Osteopathic Medicine,
Podiatry and Chiropractic**
Department of Health Professions
January 12, 2010

Summary of the Proposed Amendments to Regulation

As a result of the periodic review process, the Board Medicine (Board) proposes to amend its Regulations Governing the Practice of Medicine, Osteopathic Medicine, Podiatry and Chiropractic to make several clarifying and substantive changes. Specifically, the Board proposes to:

- Clarify that the cost for reinstatement of licensure includes both the reinstatement application fee and a late fee by combining the fees,
- Remove a restriction that only allows interns and residents to renew licensure five times,
- Remove the requirement that individuals who are renewing their licenses also fill out a form that lists their continuing education activities and
- Create an exception to the 10 hour definition of immediate use so that drugs that include a fat emulsion must be used within one hour of being mixed, diluted or reconstituted.

Result of Analysis

The benefits likely exceed the costs for most proposed changes. There is insufficient information to ascertain whether benefits will outweigh costs for one proposed change. Benefits and costs for all changes are discussed below.

Estimated Economic Impact

Current regulations list reinstatement application fees and late fees separately even though individuals who are reinstating a license would have to pay both fees. The Board

proposes to amend the fee structure in these regulations so that these fees are added together in one place. No entity will incur any new costs on account of this proposed change. To the extent that the old fee structure may have led to confusion for individuals seeking to reinstate their licenses, this proposed change will bring the benefit of clarity.

Current regulations allow individuals who are completing an internship or residency to be licensed and to renew their licenses up to five times with the recommendation of the director of their intern or residency program. The Board proposes to eliminate the restriction on the number of times that an intern or resident may renew his or her license because the recommendation of a director is considered sufficient to ensure that interns and residents are working toward being fully licensed in as timely a manner as possible. No entity is likely to incur costs on account of this proposed change. Interns and residents are likely to benefit from the added flexibility to manage their internships and residencies that removing the restriction on license renewal will give them.

Current regulations require individuals who are renewing their licenses to both attest that they have completed required continuing education (by checking a box on their renewal form) and to fill out a form listing the continuing education completed. In the distant past, the Continued Competency Activity and Assessment form was used to help licensees plan out their future continuing education. This form no longer serves this purpose and is duplicative of the attestation on the renewal form. The Board now proposes to eliminate the requirement that licensees complete this form. Because the Board will retain the ability to audit licensees' continuing education by requiring them to produce certificates of successful completion, no entity is likely to be worse off on account of the elimination of this form. Licensees will save the time and expense it would have taken them to complete the form and deliver it to Board staff.

Current regulations require that sterile drugs that are mixed, diluted or reconstituted for use in doctors' offices be administered within 10 hours of the completion time of preparation. This allows doctors' offices that administer, for example, chemotherapy drugs to mix larger batches that will treat multiple patients. The Board now proposes one exception to the 10 hour rule. Under these proposed regulations, drugs that include a fat emulsion will have to be used within one hour of being mixed, diluted or reconstituted. Board staff report that this change is proposed because drugs that include a fat emulsion are more prone to microbial contamination

that may cause infections in patients to whom they are administered. Doctors who administer drugs that include fat emulsions will incur increased costs on account of this proposed change because they will potentially have to prepare these drugs several times a day rather than preparing one, larger, batch. These addition costs will likely, however, be small because the percentage of drugs covered by the 10 hour rule that include a fat emulsion is small. Because Board staff reports that there have been no specific complaints that would indicate that patients have actually suffered harm from immediate use drugs that include a fat emulsion, there is insufficient information to decide whether benefits will outweigh costs.

Businesses and Entities Affected

The Department of Health Professions (DHP) reports that the Board currently licenses 27,191 doctors of medicine and 1,145 doctors of osteopathic medicine. These individuals plus future licensees will be affected by these proposed regulations.

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 business medical practices in the Commonwealth may incur some additional costs on account of the new requirement for using immediate use drugs that include a fat emulsion within one hour of them being mixed, diluted or reconstituted. These costs are likely to be very small because the vast majority of drugs that are mixed, diluted or reconstituted for immediate use in doctors' offices do not contain a fat emulsion.

Small Businesses: Alternative Method that Minimizes Adverse Impact

There are likely no alternate methods that The Board could have employed in writing the requirement for immediate use drugs that would have both accomplished the Board's goal of

decreasing the chance of patient harm and further minimized any adverse impact on 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 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.