

Adverse impact notification sent to Joint Commission on Administrative Rules, House Committee on Appropriations, and Senate Committee on Finance (COV § 2.2-4007.04.C): Yes Not Needed

If/when this economic impact analysis (EIA) is published in the *Virginia Register of Regulations*, notification will be sent to each member of the General Assembly (COV § 2.2-4007.04.B).



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

18 VAC 85-20 Regulations Governing the Practice of Medicine, Osteopathy, Podiatry, and Chiropractic

Department of Health Professions

Town Hall Action/Stage: 4496/7415

February 4, 2016

Summary of the Proposed Amendments to Regulation

The Board of Medicine proposes to clarify that pharmacists working in physician offices are not allowed to mix, dilute, and reconstitute drugs or perform a second check on such actions performed by another authorized practitioner.

Result of Analysis

The benefits likely exceed the costs for all proposed changes.

Estimated Economic Impact

Pharmacists are allowed to compound drugs, but mixing, diluting, or reconstitution of drugs for the purpose of administration to a patient is not considered compounding pursuant to section 54.1-3401 of the Code of Virginia. In contrast to the statutory definition, this regulation appears to indicate that pharmacists are allowed to mix, dilute, or reconstitute drugs at physician offices for the purpose of administration to a patient and perform a second check if mixing, diluting, or reconstituting is performed by another authorized practitioner. The proposed change will clarify that pharmacists in physician offices are allowed to compound but are not allowed mix, dilute, or reconstitute drugs for the purpose of administration to a patient or perform a second check on such actions performed by another authorized practitioner.

The proposed change will eliminate a potential source of confusion as to the scope of pharmacists' functions in a physician office. The Department of Health Professions notes that pharmacists are always advised to follow United States Pharmacopeia-National Formulary for compounding of drugs pursuant to section 54.1-3410.2 of the Code of Virginia and does not believe mixing, diluting, or reconstitution are currently performed by pharmacists in physician offices for the purpose of administration to a patient. Thus, no significant economic effect is expected from this proposed change other than improving the clarity of the regulation and eliminating a potential source of confusion.

Businesses and Entities Affected

The proposed regulation applies to pharmacists employed in physician offices. Currently, there are 13,429 pharmacists licensed to practice in Virginia. Exactly how many of these pharmacists are employed in physician offices is not known, but estimated to be less than 100.

Localities Particularly Affected

The proposed regulation applies statewide.

Projected Impact on Employment

No impact on employment is expected.

Effects on the Use and Value of Private Property

No impact on the use and value of private property is expected.

Real Estate Development Costs

No impact on real estate development costs is expected.

Small Businesses:

Definition

Pursuant to § 2.2-4007.04 of the Code of Virginia, small business is defined as “a business entity, including its affiliates, that (i) is independently owned and operated and (ii) employs fewer than 500 full-time employees or has gross annual sales of less than \$6 million.”

Costs and Other Effects

The proposed regulation does not impose costs or other effects on small businesses.

Alternative Method that Minimizes Adverse Impact

No adverse impact on small businesses is expected.

Adverse Impacts:

Businesses:

The proposed regulation does not have an impact on non-small businesses.

Localities:

The proposed regulation will not adversely affect localities.

Other Entities:

The proposed regulation will not adversely affect other entities.

Legal Mandates

General: The Department of Planning and Budget has analyzed the economic impact of this proposed regulation in accordance with § 2.2-4007.04 of the Code of Virginia (Code) and Executive Order Number 17 (2014). Code § 2.2-4007.04 requires that such economic impact analyses determine the public benefits and costs of the proposed amendments. Further the report should include but not be limited to: (1) the projected number of businesses or other entities to whom the proposed regulatory action would apply, (2) the identity of any localities and types of businesses or other entities particularly affected, (3) the projected number of persons and employment positions to be affected, (4) the projected costs to affected businesses or entities to implement or comply with the regulation, and (5) the impact on the use and value of private property.

Adverse impacts: Pursuant to Code § 2.2-4007.04(C): In the event this economic impact analysis reveals that the proposed regulation would have an adverse economic impact on businesses or would impose a significant adverse economic impact on a locality, business, or entity particularly affected, the Department of Planning and Budget shall advise the Joint Commission on Administrative Rules, the House Committee on Appropriations, and the Senate Committee on Finance within the 45-day period.

If the proposed regulatory action may have an adverse effect on small businesses, Code § 2.2-4007.04 requires that such economic impact analyses include: (1) an identification and estimate of the number of small businesses subject to the proposed regulation, (2) the projected reporting, recordkeeping, and other administrative costs required for small businesses to comply with the proposed regulation, including the type of professional skills necessary for preparing required reports and other documents, (3) a statement of the probable effect of the proposed regulation on affected small businesses, and (4) a description of any less intrusive or less costly alternative methods of achieving the purpose of the proposed regulation. Additionally, pursuant to Code § 2.2-4007.1, if there is a finding that a proposed regulation may have an adverse impact on small business, the Joint Commission on Administrative Rules shall be notified.

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