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[1] ☐ 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 90-30 Regulations Governing Wholesale Distributors, Manufacturers and Warehousers
Department of Health Professions
Town Hall Action/Stage: 5084 / 8584
June 10, 2019

Summary of the Proposed Amendments to Regulation

Pursuant to Chapter 241 of the 2018 Acts of the Assembly,[2] the Board of Pharmacy (Board) proposes to permanently allow certain regulated entities to deliver Schedule VI medical devices directly to a consumer on behalf of an equipment supplier. These changes have already been implemented under an emergency regulation.[3]

Result of Analysis

The benefits likely exceed the costs for all proposed changes.

Estimated Economic Impact

Pursuant to the 2018 General Assembly mandate, the Board proposes to permanently set out the requirements for delivery of Schedule VI devices directly to an ultimate user or consumer on behalf of a medical equipment supplier upon a valid order from a prescriber or upon request from the medical director of home health agency, nursing home, assisted living facility or hospice.

[1] Adverse impact is indicated if there is any increase in net cost for any entity, even if the benefits exceed the costs for all entities combined.
[2] http://lis.virginia.gov/cgi-bin/legp604.exe?181+ful+CHAP0241
[3] https://townhall.virginia.gov/l/ViewStage.cfm?stageid=8333

Schedule VI devices are complex or invasive devices that have the potential for harm if incorrectly used (e.g. nebulizer, ostomy bags, catheters, etc.). Prior to the emergency regulation, direct delivery of these devices to the ultimate user was not permitted. A medical supplier would had to first obtain the possession of the device then deliver it to the ultimate user. Under the new language, a medical supplier can enter into agreements with its sources and have the device directly delivered to the patient. This change eliminates the need to store the equipment at the medical equipment supplier and an extra step in the purchase process. Thus, the change has the potential to reduce storage/delivery costs and speed up the delivery. However, according to the Department of Health Professions (DHP), some suppliers had already been facilitating direct delivery and are unlikely to be affected other than coming into compliance under the new language.

Businesses and Entities Affected

Currently, there are 28 manufacturers, 81 wholesale distributors, 98 warehousers, 5 third-party logistics providers, 134 nonresident manufacturers, 673 nonresident wholesale distributors, and 237 medical suppliers regulated by the Board. DHP has no estimate on the number of entities that may take advantage of the new delivery model permitted by the proposed changes.

Localities Particularly Affected

No locality is expected to be particularly affected.

Projected Impact on Employment

The proposed amendments eliminate the need to store Schedule VI devices at the medical suppliers' location and may reduce the demand for labor associated with that type of storage.

Effects on the Use and Value of Private Property

The proposed changes may benefit some medical equipment suppliers in terms of reduced storage/delivery costs which would positively affect their asset values.

Real Estate Development Costs

The proposed amendments do not affect real estate development costs.

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

How many of the medical equipment suppliers are small business is not known. However, the proposed amendments may reduce the storage/delivery costs for some medical equipment suppliers as discussed above.

Alternative Method that Minimizes Adverse Impact

The proposed amendments do not adversely affect small businesses.

Adverse Impacts:

Businesses:

The proposed amendments do not adversely affect businesses.

Localities:

The proposed amendments do not adversely affect localities.

Other Entities:

The proposed amendments do 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 14 (as amended, July 16, 2018). 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.