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 110-20 Regulations Governing the Practice of Pharmacy
Department of Health Professions
Town Hall Action/Stage: 4452 / 7508
June 24, 2016

Summary of the Proposed Amendments to Regulation

In accordance with Chapter 300, 2015 Virginia Acts of the Assembly,[1] the Board of Pharmacy (Board) proposes to: 1) require that facilities in the Commonwealth engaged in the sterile compounding of drugs or devices to be dispensed without a prescription for a specific patient obtain a permit as an outsourcing facility from the Board, 2) require that outsourcing facilities located outside of the Commonwealth that deliver in any manner Schedule II through VI drugs or devices into Virginia without a prescription for a specific patient be registered with the Board, 3) establish various requirements for the permits and registrations, and 4) set fees for the approval of applications and renewal of permits and registrations.

Result of Analysis

The benefits likely exceed the costs for all proposed changes.

Estimated Economic Impact

Chapter 300, 2015 Virginia Acts of the Assembly establishes that, "[n]o person shall act as an outsourcing facility without first obtaining a permit from the Board." Further the legislation defines "outsourcing facility" as "a facility that is engaged in the compounding of sterile drugs

[1]To view this Chapter, see http://leg1.state.va.us/cgi-bin/legp504.exe?151+ful+CHAP0300

and is currently registered as an outsourcing facility with the U.S. Secretary of Health and Human Services and that complies with all applicable requirements of federal and state law, including the Federal Food, Drug, and Cosmetic Act." Outsourcing facilities typically compound drugs without a patient-specific prescription to supply large health systems.

This legislation was prompted by a 2012 meningitis outbreak from contaminated drugs compounded by the New England Compounding Center that sickened 751 people and killed 64 people, including five Virginians. In response to this outbreak, Congress passed the Drug Quality and Security Act (2013). This act created a new licensing category under Section 503B of the Federal Food, Drug, and Cosmetic Act for outsourcing facilities. These entities are large-scale sterile compounding facilities that provide compounded drugs predominantly to hospitals, physician offices, or medical clinics for administration to patients. Due to the risk associated with compounding sterile drugs on a large scale, these facilities are required under federal law to compound in compliance with Current Good Manufacturing Practices, similar to a pharmaceutical manufacturer. The legislation is intended to ensure that outsourcing facilities located in the Commonwealth or are shipping drugs into Virginia are subject to oversight to protect public health and safety.

There are approximately 59 outsourcing facilities currently registered with the FDA and likely more will register. Without establishing Board permit and registration requirements to regulate these facilities, these entities are unlikely to be able to ship within or into the Commonwealth. This would have the potential to negatively impact access to critically needed compounded drugs.

There is an emergency regulation currently in effect that allows permitting of in-state facilities and registration of non-resident outsourcing facilities. The emergency regulation is set to expire on June 6, 2017. This proposed regulation will allow the shipping of critically needed compounded drugs on a permanent basis. Additionally, the proposed requirements help reduce the likelihood that contaminated drugs will be distributed in the Commonwealth. Thus the proposed regulation will be beneficial.

Businesses and Entities Affected

The proposed amendments affect large-scale sterile compounding facilities that provide compounded drugs predominantly to hospitals, physician offices, or medical clinics for

administration to patients. The FDA has currently registered 59 such facilities. The Virginia Board currently has 19 applications pending registration under the emergency rule.

Localities Particularly Affected

The proposed amendments do not disproportionately affect particular localities.

Projected Impact on Employment

Enabling the shipping of compounded drugs may have a small positive impact on employment.

Effects on the Use and Value of Private Property

The proposed amendments allow the shipping of critically needed compounded drugs beyond June 6, 2017.

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

The proposed amendments do not increase costs for small businesses.

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 will not adversely affect localities.

Other Entities:

The proposed amendments 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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