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 110-50 – Regulations Governing Wholesale Distributors, Manufacturers and Warehousers
Department of Health Professions
Town Hall Action/Stage: 4678/7717
January 5, 2017

Summary of the Proposed Amendments to Regulation

Pursuant to Chapter 221 of the 2016 Acts of the Assembly[1] and to conform to requirements in the federal Drug Quality and Security Act (DQSA – 2013)[2], the Board of Pharmacy (Board) proposes to amend its regulation that governs wholesale distributers, manufacturers and warehousers of drugs. Specifically, the Board proposes to 1) remove definitions from the regulation that have been made obsolete by, or are duplicative of, definitions in Chapter 221, 2) provide for some individuals currently licensed as nonresident wholesale distributers and resident wholesale distributers to be permitted as third-party logistics providers or registered as nonresident manufacturers, 3) amend language to clarify that the newly categorized nonresident manufacturers follow the same rules as resident manufacturers, and 4) eliminate the susceptible drugs and pedigree requirements and authentications sections in this regulation and replace them with a reference to federal requirements for an electronic, interoperable system to identify trace and verify prescription drugs as they are distributed.

Result of Analysis

Benefits outweigh costs for all proposed changes.

[1] http://leg1.state.va.us/cgi-bin/legp504.exe?161+ful+CHAP0221

[2] https://www.gpo.gov/fdsys/pkg/PLAW-113publ54/pdf/PLAW-113publ54.pdf

Estimated Economic Impact

Current regulation licenses all third-party logistics providers[3] as wholesale distributers or nonresident wholesale distributers. In 2013, the United States Congress passed the DQSA and it was signed into law. The DQSA preempts states from licensing out-of-state manufacturers and in-state and out-of-state third party logistics providers as wholesale distributers and nonresident wholesale distributers. In 2016, the General Assembly passed Chapter 221 to conform state law to the DQSA. In order to implement Chapter 221 and conform this regulation to the DQSA, the Board now proposes to 1) remove definitions that are obsolete or duplicative of those in state legislation, 2) create two new categories of licensure to cover third-party logistics providers and nonresident manufacturers, 3) amend language to clarify that the newly categorized nonresident manufacturers follow the same rules as resident manufacturers, and 4) eliminate the susceptible drugs and pedigree requirements and authentications sections in this regulation and replace them with a reference to federal requirements for an electronic, interoperable system to identify trace and verify prescription drugs as they are distributed.

No entities are likely to incur additional costs on account of these proposed changes as they strictly clarify and conform regulation to state and federal law. Specifically, third-party logistics providers and nonresident manufacturers will not incur additional costs because their fees for permits and registration will be that same as the fees they paid to be licensed as wholesale distributers and nonresident wholesale distributers and their renewal cycle will not change. All affected entities will benefit from this regulatory action as it will eliminate confusion about the rules for drug wholesale distributers, manufacturers and warehousers.

Businesses and Entities Affected

Board staff reports that there are 759 nonresident wholesale distributers and 120 resident wholesale distributers that are governed by this regulation and that some of these distributers will change to a new category of licensure on account of this proposed regulation. Affected entities will pay the same fees and follow the same rules as they do currently. Only the name of their license will change.

[3] Third party logistics providers are entities licensed by the Board as wholesale distributors or registered as nonresident wholesale distributors that contract with a manufacturer to provide or coordinate warehousing, distribution, or other services on behalf of a manufacturer for a prescription drug, but do not take title to the prescription drug and only sell, distribute, or otherwise dispose of the prescription drug at the direction of the manufacturer.

Localities Particularly Affected

No locality is likely to be particularly affected by these proposed regulatory changes.

Projected Impact on Employment

These proposed regulatory changes are unlikely to affect employment in the Commonwealth.

Effects on the Use and Value of Private Property

These proposed regulatory changes are unlikely to affect the use or value of private property in the Commonwealth.

Real Estate Development Costs

These proposed regulatory changes are unlikely to affect real estate development costs in the Commonwealth.

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

No small businesses will be adversely affected by these proposed regulatory changes.

Alternative Method that Minimizes Adverse Impact

No small businesses will be adversely affected by these proposed regulatory changes.

Adverse Impacts:

Businesses:

No businesses will be adversely affected by these proposed regulatory changes.

Localities:

Localities in the Commonwealth are unlikely to see any adverse impacts on account of these proposed regulatory changes.

Other Entities:

No other entities are likely to be adversely affected by these proposed changes.

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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