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 Virginia Board of Pharmacy Regulations
Department of Health Professions
Town Hall Action/Stage: 4337/7354
November 30, 2015

Summary of the Proposed Amendments to Regulation

The proposed regulation will require that entities registered by the federal Drug Enforcement Administration (DEA) to collect and destroy unused drugs from consumers provide certain information to the Virginia Board of Pharmacy to help enforce compliance.

Result of Analysis

The benefits likely exceed the costs for all proposed changes.

Estimated Economic Impact

In 2014, the DEA promulgated federal regulations to allow entities authorized to possess controlled substances to collect previously prescribed but unused drugs from a consumer (ultimate user) for appropriate disposal in a safe and effective manner consistent with controls against diversion. Authorized entities include pharmacies, manufacturers, wholesale distributors, reverse distributors, and narcotic treatment programs. Participation in the federal collection and disposal program is voluntary. Entities may choose to establish disposal programs for various reasons, including for profit, to build goodwill in the community, to attract customers, to advertise businesses, and to preserve the environment.[1]

[1] The participation in the DEA collection and disposal program has certain costs and benefits associated with it. These costs and benefits are not discussed here because they cannot be attributed to this proposed state regulation.

The proposed regulation merely requires that if an authorized Virginia entity participates in the DEA program it provide notification to the Virginia Board of Pharmacy (Board) of its name, address, license number, and the intended methods of collection. No additional fee is required from participants who hold a valid state controlled substances registration. However, if a narcotic treatment program without an in-house pharmacy wants to become an authorized collector, it will need a registration at a one-time cost of $90.

Without the required information, the Board would not have essential information to enforce compliance and would completely rely on DEA. The Board states that DEA typically relies on state boards to conduct inspections and to regulate the safety and integrity of prescription drugs. Thus, the proposed regulation will likely enhance compliance with federal and state rules and reduce opportunities for diversion of donated drugs or adulteration of controlled substances if there is risk of co-mingling with existing stocks. In addition, the Board will be able to list names of collectors on its website to inform the public of where to take their unwanted drugs for destruction and promote collection efforts.

Businesses and Entities Affected

Currently, there are 1836 licensed pharmacies, 71 restricted manufacturers and 122 wholesale distributors. It is estimated that a very small number of those will choose to become authorized collectors.[2]

Localities Particularly Affected

The proposed changes apply throughout the Commonwealth.

Projected Impact on Employment

The proposed amendments are unlikely to significantly affect employment.

Effects on the Use and Value of Private Property

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

Real Estate Development Costs

No impact on real estate development costs is expected.

[2] In a somewhat similar but essentially different program that collects donated drugs, there are only 15 voluntary participants in Virginia.

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 participation in collection of unused drugs is voluntary. Consequently, the proposed regulation does not impose significant costs or other effects on small businesses.

Alternative Method that Minimizes Adverse Impact

No significant adverse impact on small businesses is expected.

Adverse Impacts:

Businesses:

The proposed regulation does not have a significant 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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