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 110-20 Regulations Governing the Practice of Pharmacy
Department of Health Professions
Town Hall Action/Stage: 4968 / 8585
June 14, 2019

Summary of the Proposed Amendments to Regulation

Under specified circumstances, the Board of Pharmacy (Board) proposes to ease burdens related to the delivery of prescription drugs from a pharmacy to an alternative delivery site. The alternative delivery site may be another pharmacy, a practitioner of the healing arts licensed to practice pharmacy or to sell controlled substances, or an authorized person or entity holding a controlled substances registration. The Board also proposes to prohibit delivering dispensed drugs to a patient's residence that are intended to be subsequently transported by the patient or patient's agent to a hospital, medical clinic, prescriber's office, or pharmacy for administration if the drugs require special storage, reconstitution or compounding prior to administration.

Result of Analysis

The benefits likely exceed the costs for one or more proposed changes. For other amendments, whether the benefits exceed the costs depend on the policy views of the observer.

[1] Adverse impact is indicated if there is any increase in net cost or reduction in net revenue for any entity, even if the benefits exceed the costs for all entities combined.

Estimated Economic Impact

Background

In addition to direct hand delivery to a patient or patient's agent or delivery to a patient's residence, under specified conditions a pharmacy may deliver a dispensed prescription drug order for Schedule VI controlled substances to another pharmacy, to a practitioner of the healing arts licensed to practice pharmacy or to sell controlled substances, or to an authorized person or entity holding a controlled substances registration issued for this purpose in compliance with this section and any other applicable state or federal law. Prescription drug orders for Schedule II through Schedule V controlled substances may not be delivered to an alternate delivery location, unless such delivery is authorized by federal law and regulations of the Board.

When the delivery is to another pharmacy, the two pharmacies must have the same owner, or have a written contract or agreement specifying the services to be provided by each pharmacy, the responsibilities of each pharmacy (including counseling, return of any prescription medications not delivered to the patient, etc.), and the manner in which each pharmacy will comply with all applicable federal and state law. When the delivery is to a practitioner of the healing arts licensed by the Board to practice pharmacy or to sell controlled substances or another authorized person or entity holding a controlled substances registration authorized for this purpose, there must be a written contract or agreement between the two parties describing the procedures for such a delivery system and the responsibilities of each party. According to the Department of Health Professions, sometimes this is impractical or causes delay in the delivery of a medication that a patient needs. If a specialty drug is needed, the pharmacy benefits manager or insurer may require that the drug be obtained from a specialty pharmacy or the pharmacy to which the prescription is sent may not carry that drug.

Proposals

The Board proposes to permit deliveries from a pharmacy to an alternative delivery site without the detailed written contract or same ownership if the alternate delivery site does not routinely receive deliveries from the pharmacy and producing and agreeing to the contract and paperwork details would create a delay in delivery that may result in potential patient harm. The pharmacy would be required to notify the alternate delivery site of the anticipated arrival date of the shipment, the exact address to where the drug was shipped, the name of the patient for whom

the drug was dispensed, and any special storage requirements. Similar to current requirements, 1) the pharmacy would have to provide counseling or ensure a process is in place for the patient to receive counseling, 2) prescriptions delivered to the alternate delivery site would have to be stored in a lockable room or lockable cabinet, cart, or other device that cannot be easily moved and that shall be locked at all times when not in use, and 3) the pharmacy would have to provide a procedure for the return of any prescription drugs not delivered or subsequently administered to the patient.

This proposed amendment may substantially reduce delays in some patients receiving needed medications. Consequently, it may produce large health benefits. Given the safety procedures accompanying the proposal, it seems unlikely that there would be an increase in health risk. Thus, the benefits very likely exceed the costs.

The Board also proposes to prohibit delivering dispensed drugs to a patient's residence that are intended to be subsequently transported by the patient or patient's agent to a hospital, medical clinic, prescriber's office, or pharmacy for administration if the drugs require special storage, reconstitution or compounding prior to administration. The proposed language includes an exception for patients with hemophilia who may require emergent blood factor treatment.

When drugs require special storage, reconstitution or compounding, there is increased risk that they may become ineffective or dangerous if not handled properly. Prohibiting the delivery of such drugs to a patient's residence that are intended to be subsequently transported as described above would likely reduce the occurrences where drugs that become ineffective or dangerous due to mishandling are administered to patients. This is beneficial. On the other hand, there may be circumstances where such delivery is the most practical way for certain patients to quickly receive needed treatment. The Board has recognized this by providing the exemption for patients with hemophilia. There may be other patients for which this is true who are not exempted by the proposal. In addition, some individuals may believe that they should not be prevented from taking their own informed risks.

Businesses and Entities Affected

The proposed amendments potentially affect the 1,813 pharmacies, practitioners of the healing arts licensed to practice pharmacy or to sell controlled substances, authorized persons or entities holding a controlled substances registration, and patients.

Localities Particularly Affected

The proposed amendments do not disproportionately affect particular localities.

Projected Impact on Employment

The proposed amendments are unlikely to substantially affect employment.

Effects on the Use and Value of Private Property

The proposal to permit deliveries from a pharmacy to an alternative delivery site without a detailed written contract may reduce costs for small firms involved. This may modestly increase their value.

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 proposal to permit deliveries from a pharmacy to an alternative delivery site without a detailed written contract may reduce costs for small firms involved.

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.