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: 4694/7885
May 27, 2017

Summary of the Proposed Amendments to Regulation

In response to a petition for rulemaking[1], the Board of Pharmacy proposes to allow a pharmacist to dispense a quantity of certain Schedule VI drugs greater than the face amount prescribed, up to the total amount authorized in refills. In response to a separate petition for rulemaking[2], the Board proposes to allow the use of automated drug dispensing devices in nursing homes in lieu of manual emergency drug kits and stat-drug boxes.

Result of Analysis

Benefits likely outweigh costs for all proposed changes.

Estimated Economic Impact

Current regulation only allows pharmacists to dispense Schedule VI medication at, or less than, the quantity for which a prescription is written. As requested in a petition for rulemaking, the Board now proposes to authorize pharmacists to dispense any Schedule VI drugs not

[1] This petition can be found here: http://townhall.virginia.gov/l/viewpetition.cfm?petitionid=245 .

[2] This petition can be found here: http://townhall.virginia.gov/l/viewpetition.cfm?petitionid=247 .

specifically excluded by this proposed regulation[3] in a quantity in excess of the face amount prescribed and not exceeding the total quantity authorized in refills. Under this proposed rule, a pharmacist will be able to dispense Schedule VI medications in these larger allowable quantities if 1) a patient has requested that his medication be dispensed in a larger quantity than is written on his prescription and 2) it is deemed appropriate by the pharmacist using his professional judgement. Since Schedule VI drugs are deemed at low risk of abuse, and the Schedule VI drugs that are possibly more dangerous are excluded from the proposed rule change, no entity is likely to be harmed by this proposed change. Consumers are likely to benefit from this change as it allows them greater flexibility to manage the timing of medication purchases.

Current regulation requires that nursing homes have a controlled substances registration (if they do not have an in-house pharmacy) in order to use an automated drug dispensing system in all instances. This rule is more stringent than Drug Enforcement Administration (DEA) rules which allow nursing homes to use automated drug dispensing systems to dispense emergency or first dose medications without having to obtain a controlled substances registration. As requested in a petition for rulemaking, the Board now proposes to also allow the use of automated drug dispensing systems, that are stocked exclusively with drugs that would be stocked in a stat-drug box or an emergency drug kit, to dispense emergency or first dose medications without a controlled substances registration so long as access to the automated drug dispensing systems are restricted to licensed nurses, pharmacists, prescribers and registered medication technicians. The Board also proposes to allow automated drug dispensing systems to be stocked, with drugs that would be stocked in a stat-drug box, in quantities determined by provider pharmacies rather than in quantities specified by this regulation for stat-drug boxes. No entity is likely to be harmed by these changes. Both nursing homes and their patients are likely to benefit from having added flexibility as to how drugs that may be necessary to maintain the health of patients, in the case of an emergency or after hours, are stored and dispensed.

Businesses and Entities Affected

These proposed regulatory changes will affect pharmacies that dispense Schedule VI drugs, provider pharmacies and nursing homes that have automated dispensing devices. Board

[3] This new proposed rule will not apply to Schedule VI drugs that are classified by the American Hospital Formulary Service as psychotherapeutic agents, anxiolytics, sedatives or hypnotics. Anxiolytics are medications that inhibit anxiety in a patient.

staff reports that there are 1,852 pharmacies that are permitted by the Board to dispense medication in Virginia.

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 are likely to incur any additional costs on account of these proposed regulatory changes.

Alternative Method that Minimizes Adverse Impact

No small businesses are likely to incur any additional costs on account of these proposed regulatory changes.

Adverse Impacts:

Businesses:

No businesses are likely to incur any additional costs on account of 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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