

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: 4788/7889
May 19, 2017

Summary of the Proposed Amendments to Regulation

As mandated by federal regulation¹, the Board of Pharmacy (Board) proposes to amend its Regulations Governing the Practice of Pharmacy to require correctional facilities to destroy all Schedule II through V drugs onsite rather than allowing them to be returned to the dispensing pharmacy.

Result of Analysis

Benefits likely outweigh costs for all proposed changes.

Estimated Economic Impact

Current Board regulation allows correctional facilities to return unused or discontinued prescription drugs to the dispensing pharmacy which then would destroy them. However, federal Drug Enforcement Administration (DEA) regulation does not allow such returns for Schedule II through V drugs. In order to conform this regulation to DEA rules, the Board now proposes to amend it so that it is clear that correctional facilities are required to destroy unused or discontinued Schedule II through V drugs onsite. Additionally, the Board proposes to specify the manner and timing of such drug destruction.² Further, the Board proposes to specify that drug

¹ 21 CFR 1317.15(b) which can be found at https://www.deadiversion.usdoj.gov/21cfr/cfr/1317/subpart_a.htm#15

² Drugs must be destroyed in a manner that makes them unrecoverable and within 30 days of their discontinued use.

destruction must be performed by a nurse, pharmacist, or physician and must be witnessed by a separate person who is a nurse supervisor, pharmacist or physician.

Correctional facilities will likely only be affected by these changes in Board regulation if they are currently non-compliant with DEA regulations. Affected facilities would likely incur some small time costs involved with destroying drugs onsite but those time costs are likely outweighed by the benefits, for both correctional facilities and their provider pharmacies, of being in compliance with DEA rules. For example, and in particular, such compliance will ensure that pharmacies do not run afoul of federal rules that could result in revocation of the DEA registration that allows them to dispense drugs.

Businesses and Entities Affected

These proposed regulatory changes apply to all correctional facilities in the Commonwealth as well as the provider pharmacies that serve them.

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:

Jails that are run by localities, and are not already in compliance with DEA rules, may incur some small time costs for destroying prescription drugs onsite. These costs would likely be very minimal.

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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