



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: 5966 / 9953
December 29, 2023

The Department of Planning and Budget (DPB) 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 19. The analysis presented below represents DPB’s best estimate of the potential economic impacts as of the date of this analysis.¹

Summary of the Proposed Amendments to Regulation

In response to a petition for rulemaking,² the Board of Pharmacy (Board) proposes to allow nursing homes to use “stat drugs” from an automated dispensing device (ADD), prior to receiving electronic authorization from the pharmacist, provided that delay in use of the drug could harm the patient.

Background

Generally, nursing homes contract with a pharmacy for the drugs their residents need. The traditional delivery of drugs from the pharmacy to the nursing home is usually accomplished by a courier service the pharmacy contracts with. The courier service delivery could either be on a regular schedule, or also “on demand,” depending on the urgency of the need.

In addition, the pharmacy always makes a “stat box” and an “emergency box” of drugs available at the nursing home. Stat drugs are those in which a delay in initiating therapy may

¹ Code § 2.2-4007.04 requires that such economic impact analyses determine the public benefits and costs of the proposed amendments. Further the analysis 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.

² <https://townhall.virginia.gov/l/viewpetition.cfm?petitionid=361>

result in harm to the patient such as antibiotics; and emergency drugs are those used for life threatening emergencies such as an inhaler. The stat and emergency drug boxes are traditionally similar to tackle-boxes secured with a plastic seal. The pharmacy restocks these boxes by replacing opened kits with sealed kits on a regular basis. Both containers are sealed and contain drugs that have already been prescribed for the patient,³ but their presence in a nursing home allows therapy to be initiated “prior to the receipt of ordered drugs from the pharmacy.”

As an alternative to these boxes, stat or emergency drugs may be made available at nursing homes through an ADD. The use of ADDs in nursing homes for dispensing drugs has become increasingly more common. An ADD is a secured dispensing machine about the size of a small refrigerator with electronic connectivity to the pharmacy. The regulation already allows ADDs to be used in nursing homes, and the drugs in an ADD are replenished by a pharmacy technician who travels to the nursing home to restock it.

Currently, the regulation allows a nurse to access a traditional tackle-box “stat box” containing stat drugs without prior electronic authorization from a pharmacist. However, under the current language a nurse may not access such drugs from an ADD without prior electronic authorization from the pharmacy. The petitioner brought to the attention of the Board the discrepancy wherein the prior authorization requirement is based on how the drugs are stored, which the Board acknowledged and affirmed. The Board now proposes to exempt the stat drugs from prior pharmacist authorization requirement when they are accessed through an ADD.

Estimated Benefits and Costs

The proposed changes remove the prior authorization requirement if a stat drug is dispensed from an ADD, provided that “a delay in administration of the drug could result in harm to the patient.” As mentioned, ADD is an alternative or supplemental way of storing and delivering stat and emergency drugs at nursing homes. The removal of the prior authorization requirement would make use of ADDs more attractive for stat drug distribution at nursing homes as it would eliminate an administrative inconvenience.

According to Department of Health Professions (DHP), the cost of a simple ADD varies between \$4,000 and \$7,000, but a more technologically sophisticated ADD could cost as much

³ See page 9 at https://townhall.virginia.gov/l/GetFile.cfm?File=30\4694\7885\AgencyStatement_DHP_7885_v1.pdf

as \$30,000 to \$100,000. Since the use of an ADD is optional, and pharmacies rather than nursing homes would most likely purchase them and keep at the nursing homes, a pharmacy would start using an ADD only if the benefits of an ADD exceed its costs. Thus, we can reliably infer that the proposed changes do not create any additional compliance costs for the pharmacies contracted with nursing homes.

To the extent pharmacies shift their stat drug delivery at nursing homes toward use of ADDs, several indirect effects could be expected. For example, the Board concluded that patient and drug security may both be increased through utilization of ADDs because stat or emergency use drugs stored in an ADD would contain an electronic record of access to those drugs, while the current tackle-box style storage systems do not.⁴ The board also notes that the removal of prior authorization requirement would speed up the ability to access stat drugs from an ADD and thus benefit the patients. As a result, diversion of stat-use medications would be less likely while preserving quick access to these medications.

Also, a shift away from courier drug delivery would reduce the need for courier services and increase demand for pharmacy technicians. Finally, makers of ADDs would likely see an increase in demand for their machines to the extent pharmacies start using them in response to the proposed changes.

Businesses and Other Entities Affected

The proposed changes would primarily effect nursing homes, the pharmacies they contract with, and their residents who use stat drugs. According to Virginia Department of Health, there are nearly 300 licensed nursing homes containing over 33,000 beds.⁵ None of the affected entities appear to be disproportionately affected.

The Code of Virginia requires DPB to assess whether an adverse impact may result from the proposed regulation.⁶ An 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

⁴ See page 2 at https://townhall.virginia.gov/GetFile.cfm?File=30\5966\9953\AgencyStatement_DHP_9953_v3.pdf
⁵ <https://www.vdh.virginia.gov/licensure-and-certification/division-of-long-term-care-services/>

⁶ Pursuant to Code § 2.2-4007.04(D): 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. Statute does not define “adverse impact,” state whether only Virginia entities should be considered, nor indicate whether an adverse impact results from regulatory requirements mandated by legislation.

combined. As noted above, the proposed changes would make use of ADDs more attractive by removing prior authorization from the pharmacy when dispensing a stat drug for urgent use and the use of ADDs is optional. Thus, no direct adverse impact is indicated.

Small Businesses⁷ Affected:⁸

The proposed amendments do not adversely affect small businesses.

Localities⁹ Affected¹⁰

The proposed amendments apply to affected entities in all localities in Virginia.

Projected Impact on Employment

The proposed amendments do not appear to directly affect employment.

Effects on the Use and Value of Private Property

Although the proposed changes may incentivize the use of ADDs for stat drug distribution at nursing homes, no direct impact on the use and value of private property or real estate development costs is expected.

⁷ 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.”

⁸ 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.

⁹ “Locality” can refer to either local governments or the locations in the Commonwealth where the activities relevant to the regulatory change are most likely to occur.

¹⁰ § 2.2-4007.04 defines “particularly affected” as bearing disproportionate material impact.