



Virginia Department of Planning and Budget Economic Impact Analysis

12 VAC 5-421 Food Regulations
Virginia Department of Health
Town Hall Action/Stage: 5941 / 9619
October 27, 2022

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 these economic impacts.¹

Summary of the Proposed Amendments to Regulation

The State Board of Health (Board) proposes to amend 12 VAC 5-421 *Food Regulations* to specify that food establishments may store epinephrine and medicines for the use of children in a day care center. (Note: the existing regulation contains an extensive definition of “food establishment” at 12 VAC 5-421-10 that is not being amended by this proposed action.²)

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 “Food establishment” is defined in the regulation as “an operation that (i) stores, prepares, packages, serves, vends food directly to the consumer, or otherwise provides food to the public for human consumption, such as a restaurant, satellite or catered feeding location, catering operation if the operation provides food directly to a consumer or to a conveyance used to transport people, market, vending location, conveyance used to transport people, institution, or food bank, and (ii) relinquishes possession of food to a consumer directly or indirectly through a delivery service, such as home delivery of grocery orders or restaurant takeout orders, or delivery service that is provided by common carriers.” Further, the regulation states that “ ‘Food establishment’ includes (i) an element of the operation such as a transportation vehicle or a central preparation facility that supplies a vending location or satellite feeding location unless the vending or feeding location is permitted under this chapter; and (ii) an operation that is conducted in a mobile, stationary, temporary, or permanent facility or location where consumption is on or off the premises and regardless of whether there is a charge for the food.” Lastly, the regulation states that “ ‘Food establishment’ does not include: 1. An establishment that offers only prepackaged food that is not time/temperature control for safety food; 2. A produce stand that only offers whole, uncut fresh fruits and vegetables; or 3. A food processing plant, including those that are located on the premises of a food establishment.”

Background

The current 12 VAC 5-421-3460 *Medicines - restriction and storage* states that:³

- A. Except for medicines that are stored or displayed for retail sale, only those medicines that are necessary for the health of employees shall be allowed in a food establishment.
- B. Medicines that are in a food establishment for the employees' use shall be labeled as specified under 12 VAC 5-421-3320 and located to prevent the contamination of food, equipment, utensils, linens, and single-service and single-use articles.

Amendments Pertaining to Epinephrine

Chapter 853 of the 2020 *Acts of Assembly* states in part that:

Pursuant to an order or a standing protocol issued by the prescriber within the course of his professional practice, and in accordance with policies and guidelines established by the Department of Health, such prescriber may authorize any employee of a restaurant^[4] licensed pursuant to Chapter 3 (3 35.1-18 et seq.) of Title 35.1 to possess and administer epinephrine on the premises of the restaurant at which the employee is employed, provided that such person is trained in the administration of epinephrine.

Consequently, the Board proposes to amend 12 VAC 5-421-3460 to indicate that food establishments may store epinephrine.

Amendments Pertaining to Medicines for the Use of Children in a Day Care Center

12 VAC 5-421-3470 *Refrigerated medicines, storage* states that:

Medicines belonging to employees or to children in a day care center that require refrigeration and are stored in a food refrigerator shall be:

1. Stored in a package or container and kept inside a covered, leakproof container that is identified as a container for the storage of medicines; and
2. Located so they are inaccessible to children.

³ The text in the regulation includes superscripts that are not pertinent to the analysis in this report, and have thus been removed from the quoted language.

⁴ According to the Virginia Department of Health (VDH), “restaurant” here is synonymous with “food establishment” in the regulation. The agency states that it uses “food establishment” to be consistent with U.S. Food and Drug Administration model Food Code terminology.

This text indicates that medication belonging to children in a day care center can be stored in a food refrigerator on the premises of the day care food establishment.⁵ This could be interpreted to conflict⁶ with 12 VAC 5-421-3460, which as indicated above states that “Except for medicines that are stored or displayed for retail sale, only those medicines that are necessary for the health of employees shall be allowed in a food establishment.” To eliminate the conflict, the Board proposes to amend 12 VAC 5-421-3460 to state that food establishments may store medicines for the use of children in a day care center.

Estimated Benefits and Costs

According to the Mayo Clinic, “Epinephrine injection is used for emergency treatment of severe allergic reactions (including anaphylaxis) to insect bites or stings, medicines, foods, or other substances. It is also used to treat anaphylaxis caused by unknown substances or triggered by exercise.”⁷ Anaphylaxis is a life-threatening type of allergic reaction.⁸ Thus, allowing food establishments to store epinephrine has the potential to save lives.

Virginia Department of Health (VDH) staff are not aware of any incidences of food establishments associated with child day care centers having been found in violation for storing medication for children on the premises. Nevertheless, the proposal to amend 12 VAC 5-421-3460 to state that food establishments may store medicines for the use of children in a day care center may be beneficial in that food establishments associated with child day care centers could know with certainty that they may do so.

Businesses and Other Entities Affected

The proposed amendments would potentially affect the food establishments that choose to obtain and store epinephrine on the premises. VDH has issued permits to more than 30,000 food establishments.⁹ It is not known how many would choose to obtain and store epinephrine. There are approximately 1,500 food establishments that are associated with child day care centers.¹⁰ To the extent that some have refrained from storing medication for children on the

⁵ According to VDH, a day care center that provides food service beyond the provision of prepackaged items that do not require temperature control would be operating as a food establishment.

⁶ See the third paragraph of the Mandate and Impetus section of the Agency Background Document (pages two and three): https://townhall.virginia.gov/l/GetFile.cfm?File=58\5941\9619\AgencyStatement_VDH_9619_v1.pdf

⁷ See <https://www.mayoclinic.org/drugs-supplements/epinephrine-injection-route/proper-use/drg-20072429?p=1>

⁸ See <https://medlineplus.gov/ency/article/000844.htm>

⁹ Data source: VDH

¹⁰ Ibid

premises due to uncertainty on the law, they may also be affected even if they do not have plans to store epinephrine.

The Code of Virginia requires DPB to assess whether an adverse impact may result from the proposed regulation.¹¹ 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 combined. The proposed amendments neither add cost nor reduce revenue. Thus, no adverse impact is indicated.

Small Businesses¹² Affected:¹³

The proposed amendments do not appear to adversely affect small businesses.

Localities¹⁴ Affected¹⁵

The proposed amendments do not appear to disproportionately affect particular localities or increase costs for local governments.

Projected Impact on Employment

The proposed amendments do not appear to affect total employment.

¹¹ 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.

¹² 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.”

¹³ 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.

¹⁴ “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.

¹⁵ § 2.2-4007.04 defines “particularly affected” as bearing disproportionate material impact.

Effects on the Use and Value of Private Property

The proposal to allow food establishments to store epinephrine would likely lead to some such entities doing so. It would not likely substantively affect the value of these businesses. The proposed amendments do not affect real estate development costs