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Fast-Track Regulation
Agency Background Document

Agency name	Virginia Department of Health
Virginia Administrative Code (VAC) Chapter citation(s)	12 VAC 5-421
VAC Chapter title(s)	Food Regulations
Action title	Amend Food Regulations to conform to Chapter 853 of the 2020 Acts of Assembly; General Medication Storage
Date this document prepared	May 2, 2022

This information is required for executive branch review and the Virginia Registrar of Regulations, pursuant to the Virginia Administrative Process Act (APA), Executive Order 14 (as amended, July 16, 2018), the Regulations for Filing and Publishing Agency Regulations (1VAC7-10), and the *Form and Style Requirements for the Virginia Register of Regulations and Virginia Administrative Code.*

Brief Summary

Provide a brief summary (preferably no more than 2 or 3 paragraphs) of this regulatory change (i.e., new regulation, amendments to an existing regulation, or repeal of an existing regulation). Alert the reader to all substantive matters. If applicable, generally describe the existing regulation.

A regulatory change to the Food Regulations (12VAC5-421 et seq.) is required in order to conform to changes made to § 8.01-225.17 of the Code of Virginia in Chapter 853 of the 2020 Acts of Assembly. The statutory amendment made by Ch. 853 (2020) authorizes any employee of a licensed restaurant to possess and administer epinephrine on the premises of a restaurant at which the employee is employed, provided that such employee is authorized by a prescriber, and is trained in the administration of epinephrine. In addition, trained employees who provide, administer, or assist in the administration of epinephrine to someone who, in good faith they believe is having an anaphylactic reaction, shall not be liable for certain civil damages.

Lastly, the proposed regulatory change will allow the storage of medications for use by children at a day care center on the premise of a food establishment.

Currently, the Food Regulations allow only those medications necessary for the health of employees on the premises of a food establishment. The proposed amendments to the Food Regulations would allow those food establishments that elect to possess epinephrine on the premises in order to respond to an anaphylaxis remain in compliance with the regulations which govern the operation of their establishment.

Acronyms and Definitions

Define all acronyms used in this form, and any technical terms that are not also defined in the "Definitions" section of the regulation.

No technical terms are used that are not defined in the regulations.

Statement of Final Agency Action

Provide a statement of the final action taken by the agency including: 1) the date the action was taken; 2) the name of the agency taking the action; and 3) the title of the regulation.

The Board of Health approved this Fast Track action to amend the Food Regulations at its meeting on June 23, 2022.

Mandate and Impetus

Identify the mandate for this regulatory change and any other impetus that specifically prompted its initiation (e.g., new or modified mandate, petition for rulemaking, periodic review, or board decision). For purposes of executive branch review, "mandate" has the same meaning as defined in Executive Order 14 (as amended, July 16, 2018), "a directive from the General Assembly, the federal government, or a court that requires that a regulation be promulgated, amended, or repealed in whole or part."

As required by Virginia Code § 2.2-4012.1, also explain why this rulemaking is expected to be noncontroversial and therefore appropriate for the fast-track process.

Chapter 853 of the 2020 Acts of Assembly authorizes any employee of a licensed restaurant to possess and administer epinephrine on the premises of a restaurant at which the employee is employed, provided that such employee is authorized by a prescriber, and is trained in the administration of epinephrine. In addition, trained employees who provide, administer, or assist in the administration of epinephrine to someone who in good faith they believe is having an anaphylactic reaction, shall not be liable for certain civil damages. Lastly, Chapter 853 of the 2020 Acts of Assembly required the Virginia Department of Health, in collaboration with the Department of Health Professions, to develop policies and guidelines for the recognition and treatment of anaphylaxis in restaurants with input from select stakeholders.

While the legislative mandate was directed at the development of policies and guidelines, without a regulatory amendment, the possession or storage of epinephrine on the premises of a food establishment is currently not allowed under 12VAC5-421.

In addition, the regulatory change would correct an issue in the current regulations, and allow medication belonging to the children in a day care center to be stored in a food refrigerator on the premises of the day care food establishment. The current language prohibits the storage of any medication on the premises of a food establishment unless it is specifically for the use of employees; whereas 12VAC5-421-3470 allows the storage of medication for children of a day care center on the premises under certain

conditions. The proposed language would remove this conflict, allowing the storage of not only epinephrine, but other life-saving medications such as insulin, inhalers, and over the counter medication, in day care centers.

For these reasons, the proposed regulatory action is expected to be noncontroversial, allowing use of the fast-track process.

Legal Basis

Identify (1) the promulgating agency, and (2) the state and/or federal legal authority for the regulatory change, including the most relevant citations to the Code of Virginia and Acts of Assembly chapter number(s), if applicable. Your citation must include a specific provision, if any, authorizing the promulgating agency to regulate this specific subject or program, as well as a reference to the agency's overall regulatory authority.

Sections 35.1-11 and 14 of the Code of Virginia authorize the Board to make, adopt, promulgate, and enforce regulations governing restaurants in accordance with the provisions of Title 35.1 of the Code of Virginia.

Purpose

Explain the need for the regulatory change, including a description of: (1) the rationale or justification, (2) the specific reasons the regulatory change is essential to protect the health, safety or welfare of citizens, and (3) the goals of the regulatory change and the problems it's intended to solve.

Chapter 853 of the 2020 Acts of Assembly adds language to § 8.01-225 to authorize any employee of a licensed restaurant to possess and administer epinephrine in response to an individual having an anaphylactic reaction on the premises of a restaurant at which the employee is employed, provided that such employee is authorized by a prescriber and trained in the administration of epinephrine.

The Food Regulations prohibits medications on the premises of a food establishment unless it is specifically for the use of an employee. Approximately 32 million people (1 in every 13 children) in the United States have food allergies, and each year nearly 200,000 people require emergency medical care for allergic reactions to food.[1] Other common allergens include latex allergies (4.3% of population), insect allergies (5%of the population), and drug allergies(10% of the population).[2]

In addition, this regulatory action would allow properly trained food establishment employees to act as a first line of response to serious medical emergencies where time is of the essence, and remain in compliance with the regulatory standards pertaining to storage of medication on the premises. The proposed language would also allow day care centers with a license to operate as a food establishment to store the medications of the children within their care. Current regulatory sections are in conflict and the proposed language will resolve this issue.

[1] Food Allergy Research and Education (2020, June 4) *Food Allergy Facts and Statistics for the U.S.* **https://www.foodallergy.org/media/1012/download**

[2] Asthma and Allergy Foundation of America (2021) *Allergy Facts and Figure.* **https://www.aafa.org/allergy-research/**

Substance

Briefly identify and explain the new substantive provisions, the substantive changes to existing sections, or both. A more detailed discussion is provided in the "Detail of Changes" section below.

In Section 12VAC5-421-3460, the proposed regulations were amended to allow the storage of epinephrine on the premises of a food establishment and to allow the storage of medication for children attending day care in a facility that also has a food establishment license.

Issues

Identify the issues associated with the regulatory change, including: 1) the primary advantages and disadvantages to the public, such as individual private citizens or businesses, of implementing the new or amended provisions; 2) the primary advantages and disadvantages to the agency or the Commonwealth; and 3) other pertinent matters of interest to the regulated community, government officials, and the public. If there are no disadvantages to the public or the Commonwealth, include a specific statement to that effect.

The primary advantage of the proposed regulatory action to the public is the accessibility of epinephrine to properly trained food establishment employees to assist facility patrons who are experiencing anaphylaxis due to an allergic reaction. In the event of an allergic reaction, food establishment staff can serve as the first response to administer aid until medical professionals arrive to further assist. In addition, the proposed regulations would allow the storage of epinephrine in a food refrigerator of a day care center. This is particularly advantageous when space is limited in a facility. There are no known disadvantages to the public.

There are no known disadvantages to the agency or the Commonwealth.

Requirements More Restrictive than Federal

Identify and describe any requirement of the regulatory change which is more restrictive than applicable federal requirements. Include a specific citation for each applicable federal requirement, and a rationale for the need for the more restrictive requirements. If there are no applicable federal requirements, or no requirements that exceed applicable federal requirements, include a specific statement to that effect.

There are no requirements more restrictive than applicable federal requirements.

Agencies, Localities, and Other Entities Particularly Affected

Identify any other state agencies, localities, or other entities particularly affected by the regulatory change. "Particularly affected" are those that are likely to bear any identified disproportionate material impact which would not be experienced by other agencies, localities, or entities. "Locality" can refer to either local governments or the locations in the Commonwealth where the activities relevant to the regulation or regulatory change are most likely to occur. If no agency, locality, or entity is particularly affected, include a specific statement to that effect.

Other State Agencies Particularly Affected

No other state agencies will be particularly affected.

Localities Particularly Affected

No localities will be particularly affected.

Other Entities Particularly Affected

The food establishments licensed pursuant to the Food Regulations will be affected.

Economic Impact

Pursuant to § 2.2-4007.04 of the Code of Virginia, identify all specific economic impacts (costs and/or benefits), anticipated to result from the regulatory change. When describing a particular economic impact, specify which new requirement or change in requirement creates the anticipated economic impact. Keep in mind that this is change versus the status quo.

Impact on State Agencies

For your agency: projected costs, savings, fees or revenues resulting from the regulatory change, including: a) fund source / fund detail; b) delineation of one-time versus on-going expenditures; and c) whether any costs or revenue loss can be absorbed within existing resources	None
For other state agencies: projected costs, savings, fees or revenues resulting from the regulatory change, including a delineation of one-time versus on-going expenditures.	None
For all agencies: Benefits the regulatory change is designed to produce.	None

Impact on Localities

Projected costs, savings, fees or revenues resulting from the regulatory change.	None
Benefits the regulatory change is designed to produce.	None

Impact on Other Entities

Description of the individuals, businesses, or other entities likely to be affected by the regulatory change. If no other entities will be affected, include a specific statement to that effect.	Only those food establishments that elect to obtain and store epinephrine on the premises or who operate as a day care with a food establishment license would be impacted by the regulatory change.

Agency's best estimate of the number of such entities that will be affected. Include an estimate of the number of small businesses affected. Small business means a business entity, including its affiliates, that: a) is independently owned and operated and; b) employs fewer than 500 full-time employees or has gross annual sales of less than $6 million.	The Virginia Department of Health permits approximately 30,000+ food establishments of which some or none could elect to obtain and store epinephrine on the premises. The number of food establishments that could classify as "small business" is unknown. Approximately 1,500 food establishments are associated with child day care centers.
All projected costs for affected individuals, businesses, or other entities resulting from the regulatory change. Be specific and include all costs including, but not limited to: a) projected reporting, recordkeeping, and other administrative costs required for compliance by small businesses; b) specify any costs related to the development of real estate for commercial or residential purposes that are a consequence of the regulatory change; c) fees; d) purchases of equipment or services; and e) time required to comply with the requirements.	Only those food establishments that elect to obtain and store epinephrine on the premise will bear any of the following costs: (1) a epi-pen pack (two auto-injectors) can range from $150 to $400 and (2) staff member training on epinephrine administration can range from $35 to $50.
Benefits the regulatory change is designed to produce.	This regulatory change is intended to allow the storage of epinephrine on the premises of food establishments for the use of trained employees to administer epinephrine in response to anaphylaxis in a patron. In addition, the proposed language is intended to remove a conflict in the regulations to allow the storage of medication belonging to children of a day care center that also possesses a restaurant license.

Alternatives to Regulation

Describe any viable alternatives to the regulatory change that were considered, and the rationale used by the agency to select the least burdensome or intrusive alternative that meets the essential purpose of the regulatory change. Also, include discussion of less intrusive or less costly alternatives for small businesses, as defined in § 2.2-4007.1 of the Code of Virginia, of achieving the purpose of the regulatory change.

No alternative to this regulation was considered, as the proposed change is required to allow those food establishments and child day care centers who elect to obtain and store epinephrine on their premises to do so and remain in compliance with 12VAC5-421.

Regulatory Flexibility Analysis

Pursuant to § 2.2-4007.1B of the Code of Virginia, describe the agency's analysis of alternative regulatory methods, consistent with health, safety, environmental, and economic welfare, that will accomplish the objectives of applicable law while minimizing the adverse impact on small business. Alternative regulatory methods include, at a minimum: 1) establishing less stringent compliance or reporting requirements; 2) establishing less stringent schedules or deadlines for compliance or reporting requirements; 3) consolidation or simplification of compliance or reporting requirements; 4) establishing performance standards for small businesses to replace design or operational standards required in the

proposed regulation; and 5) the exemption of small businesses from all or any part of the requirements contained in the regulatory change.

There are no regulatory alternatives that would be less stringent that are consistent with protecting public health. The proposed language would allow those food establishments who elect to obtain and store epinephrine on the premises for the use by trained employees in response to potential anaphylactic events to do so while remaining in compliance with the Food Regulations.

Public Participation

Indicate how the public should contact the agency to submit comments on this regulation, and whether a public hearing will be held, by completing the text below.

As required by § 2.2-4011 of the Code of Virginia, if an objection to the use of the fast-track process is received within the 30-day public comment period from 10 or more persons, any member of the applicable standing committee of either house of the General Assembly or of the Joint Commission on Administrative Rules, the agency shall: 1) file notice of the objections with the Registrar of Regulations for publication in the Virginia Register and 2) proceed with the normal promulgation process with the initial publication of the fast-track regulation serving as the Notice of Intended Regulatory Action.

If you are objecting to the use of the fast-track process as the means of promulgating this regulation, please clearly indicate your objection in your comment. Please also indicate the nature of, and reason for, your objection to using this process.

The Board is providing an opportunity for comments on this regulatory proposal, including but not limited to (i) the costs and benefits of the regulatory proposal and any alternative approaches, (ii) the potential impacts of the regulation, and (iii) the agency's regulatory flexibility analysis stated in this background document.

Anyone wishing to submit written comments for the public comment file may do so through the Public Comment Forums feature of the Virginia Regulatory Town Hall website at: https://townhall.virginia.gov. Comments may also be submitted by mail, email or fax to Kristin Marie Clay, Senior Policy Analyst, 109 Governor Street, Office of Environmental Health Services, 5th Floor, Richmond, VA 23219, Phone: 804-864-7474, Email: Kristin.Clay@vdh.virginia.gov. In order to be considered, comments must be received by 11:59 pm on the last day of the public comment period.

Detail of Changes

List all regulatory changes and the consequences of the changes. Explain the new requirements and what they mean rather than merely quoting the text of the regulation. For example, describe the intent of the language and the expected impact. Describe the difference between existing requirement(s) and/or agency practice(s) and what is being proposed in this regulatory change. Use all tables that apply, but delete inapplicable tables.

If an existing VAC Chapter(s) is being amended or repealed, use Table 1 to describe the changes between existing VAC Chapter(s) and the proposed regulation. If existing VAC Chapter(s) or sections are being repealed and replaced, ensure Table 1 clearly shows both the current number and the new number for each repealed section and the replacement section.

Table 1: Changes to Existing VAC Chapter(s)

Current chapter -section number	New chapter-section number, if applicable	Current requirements in VAC	Change, intent, rationale, and likely impact of new requirements
3460		**12VAC5-421-3460. Medicines - restriction and storage.** 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. Pf B. Medicines that are in a food establishment for the employees' use shall be labeled as specified under 12VAC5-421-3320 and located to prevent the contamination of food, equipment, utensils, linens, and single-service and single-use articles. P	**CHANGE:** The Board is proposing the following amendments: **12VAC5-421-3460. Medicines - restriction and storage.** ~~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. Pf~~ ~~B. Medicines that are in a food establishment for the employees' use shall be labeled as specified under 12VAC5-421-3320 and located to prevent the contamination of food, equipment, utensils, linens, and single-service and single-use articles. P~~ A. No food establishment may display medicines other than medicines for retail sale. Pf B. No food establishment may store medicines other than the following: 1. Medicines for the use of children in a day care center P; 2. Medicines that are referenced in subdivision A 17 of § 8.01-225 of the Code of Virginia P; and 3. Medicines that are necessary for the health of employees. P C. Medicines that are stored or displayed in a food establishment shall be labeled as specified under 12VAC5-421-3320 and located to prevent the contamination of food, equipment, utensils, linens, and single-service and single-use articles. P **INTENT:** The intent of the change is to conform 12VAC5-421-3460 to the Code of Virginia and clarify the requirements regarding the storing of medications for children in a day care center. **RATIONALE:** The rationale for the change is that Code of Virginia § 8.01-225 was amended to authorize employees of a licensed restaurant to provide, administer, or assist in the

			administration of epinephrine to an individual believed to be having an anaphylactic reaction on the premises. Additionally, 12VAC5-421-3470 currently lists storage requirements for the medicine of employees or of children in a day care center, but section 3460 does not provide for the storage of medicine other than for retail sale or the health of employees. **LIKELY IMPACT:** The likely impact of the change is that restaurant employees may elect to store epinephrine on the premises, and children in day care centers associated with a licensed food establishment store their medications on the premises.