

Office of Regulatory Management  
Economic Review Form

<b>Agency name</b>	Virginia Department of Health
<b>Virginia Administrative Code (VAC) Chapter citation(s)</b>	12 VAC 5-421
<b>VAC Chapter title(s)</b>	Food Regulations
<b>Action title</b>	Amend Food Regulations to conform to Chapter 853 of the 2020 Acts of Assembly; General Medication Storage
<b>Date this document prepared</b>	05/20/2025
<b>Regulatory Stage (including Issuance of Guidance Documents)</b>	Fast Track

### **Cost Benefit Analysis**

Complete Tables 1a and 1b for all regulatory actions. You do not need to complete Table 1c if the regulatory action is required by state statute or federal statute or regulation and leaves no discretion in its implementation.

Table 1a should provide analysis for the regulatory approach you are taking. Table 1b should provide analysis for the approach of leaving the current regulations intact (i.e., no further change is implemented). Table 1c should provide analysis for at least one alternative approach. You should not limit yourself to one alternative, however, and can add additional charts as needed.

Report both direct and indirect costs and benefits that can be monetized in Boxes 1 and 2. Report direct and indirect costs and benefits that cannot be monetized in Box 4. See the ORM Regulatory Economic Analysis Manual for additional guidance.

**Table 1a: Costs and Benefits of the Proposed Changes (Primary Option)**

(1) Direct & Indirect Costs & Benefits (Monetized)	<p>The regulatory action will amend 12VAC5-421-3460 pursuant to Ch. 853 of the 2020 General Assembly to authorize 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. In addition, the proposed regulatory change will allow the storage of medications for use by children at a day care center on the premises of a food establishment. These revisions <i>do not mandate</i> the purchase or procurement of epinephrine.</p> <p>Direct Costs: There are no direct monetized costs associated with this proposed change.</p> <p>Indirect Costs: There are no indirect monetized costs associated with this proposed change.</p> <p>Direct Benefits: There are no direct monetized benefits associated with this proposed change.</p> <p>Indirect Benefits: There are no indirect monetized benefits associated with this proposed change.</p>	
(2) Present Monetized Values	Direct & Indirect Costs	Direct & Indirect Benefits
	(a) N/A	(b) N/A
(3) Net Monetized Benefit	N/A	
(4) Other Costs & Benefits (Non-Monetized)	<p>There are no non-monetized costs associated with this proposed change.</p> <p>As it relates to non-monetized benefits, 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.”<sup>1</sup> Anaphylaxis is a life-</p>	

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

	threatening type of allergic reaction. <sup>2</sup> Thus, allowing food establishments to store epinephrine has the potential to save lives.
(5) Information Sources	<a href="https://medlineplus.gov/ency/article/000844.htm">https://medlineplus.gov/ency/article/000844.htm</a> <a href="https://www.mayoclinic.org/drugs-supplements/epinephrine-injection-route/proper-use/drg-20072429?p=1">https://www.mayoclinic.org/drugs-supplements/epinephrine-injection-route/proper-use/drg-20072429?p=1</a>

**Table 1b: Costs and Benefits under the Status Quo (No change to the regulation)**

(1) Direct & Indirect Costs & Benefits (Monetized)	This change is mandated by Ch. 853 of the 2020 General Assembly Session.	
(2) Present Monetized Values	Direct & Indirect Costs	Direct & Indirect Benefits
	(a) N/A	(b) N/A
(3) Net Monetized Benefit	N/A	
(4) Other Costs & Benefits (Non-Monetized)	N/A	
(5) Information Sources	N/A	

**Impact on Local Partners**

Use this chart to describe impacts on local partners. See Part 8 of the ORM Cost Impact Analysis Guidance for additional guidance.

**Table 2: Impact on Local Partners**

(1) Direct & Indirect Costs & Benefits (Monetized)	<p>Direct Costs: There are no direct monetized costs to local partners associated with this proposed change.</p> <p>Indirect Costs: There are no indirect monetized costs to local partners associated with this proposed change.</p> <p>Direct Benefits: There are no direct monetized benefits to local partners associated with this proposed change.</p>
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<sup>2</sup> See <https://medlineplus.gov/ency/article/000844.htm>

	Indirect Benefits: There are no indirect monetized benefits to local partners associated with this proposed change.	
(2) Present Monetized Values	Direct & Indirect Costs	Direct & Indirect Benefits
	(a) N/A	(b) N/A
(3) Other Costs & Benefits (Non-Monetized)	There are no non-monetized costs or benefits to local partners associated with this proposed change.	
(4) Assistance	N/A	
(5) Information Sources	N/A	

**Impacts on Families**

Use this chart to describe impacts on families. See Part 8 of the ORM Cost Impact Analysis Guidance for additional guidance.

**Table 3: Impact on Families**

(1) Direct & Indirect Costs & Benefits (Monetized)	<p>Direct Costs: There are no direct monetized costs to families associated with this proposed change.</p> <p>Indirect Costs: There are no indirect monetized costs to families associated with this proposed change.</p> <p>Direct Benefits: There are no direct monetized benefits to families associated with this proposed change.</p> <p>Indirect Benefits: There are no indirect monetized benefits to families associated with this proposed change.</p>	
(2) Present Monetized Values	Direct & Indirect Costs	Direct & Indirect Benefits
	(a) N/A	(b) N/A

(3) Other Costs & Benefits (Non-Monetized)	<p>There are no non-monetized costs to families associated with this proposed change.</p> <p>As it relates to non-monetized benefits, families would benefit generally from the allowance of epinephrine in food establishments and especially day cares.</p>
(4) Information Sources	N/A

**Impacts on Small Businesses**

Use this chart to describe impacts on small businesses. See Part 8 of the ORM Cost Impact Analysis Guidance for additional guidance.

**Table 4: Impact on Small Businesses**

(1) Direct & Indirect Costs & Benefits (Monetized)	<p>Direct Costs: There are no direct monetized costs to small businesses associated with this proposed change.</p> <p>Indirect Costs: There are no indirect monetized costs to small businesses associated with this proposed change.</p> <p>Direct Benefits: There are no direct monetized benefits to small businesses associated with this proposed change.</p> <p>Indirect Benefits: There are no indirect monetized benefits to small businesses associated with this proposed change.</p>	
(2) Present Monetized Values	Direct & Indirect Costs	Direct & Indirect Benefits
	(a) N/A	(b) N/A
(3) Other Costs & Benefits (Non-Monetized)	<p>There are no non-monetized costs or benefits to small businesses associated with this proposed change.</p>	
(4) Alternatives	None	
(5) Information Sources	N/A	

**Changes to Number of Regulatory Requirements**

**Table 5: Regulatory Reduction**

For each individual action, please fill out the appropriate chart to reflect any change in regulatory requirements, costs, regulatory stringency, or the overall length of any guidance documents.

*Change in Regulatory Requirements*

<b>VAC Section(s) Involved*</b>	<b>Authority of Change</b>	<b>Initial Count</b>	<b>Additions</b>	<b>Subtractions</b>	<b>Total Net Change in Requirements</b>
12VAC5-421-3460	<b>(M/A):</b>				
	<b>(D/A):</b>				
	<b>(M/R):</b>				
	<b>(D/R):1</b>	1		1	-1
				<b>Grand Total of Changes in Requirements:</b>	<b>(M/A):</b> <b>(D/A):</b> <b>(M/R):</b> <b>(D/R):-1</b>

\*If the agency is modifying a guidance document that has regulatory requirements, it should report any change in requirements in the appropriate chart(s).