

Virginia Department of Planning and Budget **Economic Impact Analysis**

8 VAC 20-790 Child Care Program Department of Education Town Hall Action/Stage: 6381 / 10195

October 15, 2024

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

Pursuant to Chapter 122 and Chapter 123 of the 2023 *Acts of Assembly* (legislation), which amended Code § 22.1-289.059, the Board of Education (Board) proposes several amendments to the regulation concerning the possession and administration of epinephrine at child day programs.

Background

The regulation defines "Child Care Subsidy Program" as the Department of Education (DOE) program that:

assists eligible low-income families with the cost of child care and those activities that assist eligible families in the arrangement for or purchase of child care for children for care that is less than a 24-hour day. It also includes activities that promote parental choice, consumer education to help parents make informed choices about child care, activities to enhance health and safety standards

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.

established by the state, and activities that increase and enhance child care and early childhood development resources in the community.

The proposed amendments pertain to child day centers and family day homes that participate in the Child Care Subsidy Program.

Child Day Centers

Consistent with Code § 22.1-289.02, the regulation defines "child day center" as "a child day program offered to (i) two or more children less than 13 years of age in a facility that is not the residence of the provider or of any of the children in care or (ii) 13 or more children at any location." Pursuant to the legislation, the Board proposes to require in the regulation that 1) child day centers possess and store weight-based dosages of undesignated or stock epinephrine in a locked or inaccessible container or area in the center; 2) the undesignated or stock epinephrine is only administered by a nurse at the center, an employee of a local health department who is authorized by a prescriber and trained in the administration of epinephrine, or staff at the center authorized by a prescriber and trained in the administration of epinephrine, and 3) at least one of the above individuals has the means to access the epinephrine at all times during regular facility hours.

If the person administering the epinephrine is neither a nurse nor an employee of a local health department, the Board proposes to require that their training must be from 1) a program for this purpose developed by the Board of Nursing and taught by a registered nurse, licensed practical nurse, nurse practitioner, physician assistant, doctor of medicine or osteopathic medicine, or pharmacist, 2) a course on this topic developed or approved by DOE in consultation with the Department of Health (VDH), or 3) a course taught by a registered nurse, licensed practical nurse, nurse practitioner, physician assistant, doctor of medicine or osteopathic medicine, or pharmacist that includes the following: a) recognizing signs and symptoms of anaphylaxis, b) emergency procedures for responding to anaphylaxis, and c) instructions and procedures for administering epinephrine. The proposed regulation expands upon the legislation, which only requires that the employee be "trained in the administration of epinephrine."

Family Day Homes

Consistent with Code § 22.1-289.02, the regulation defines "family day home" as "a child day program offered in the residence of the provider or the home of any of the children in care

for one through 12 children less than 13 years of age, exclusive of the provider's own children and any children who reside in the home, when at least one child receives care for compensation." The legislation, as codified in Code § 22.1-289.059, states that

The Board shall amend its regulations to require each family day home provider or at least one other caregiver employed by such provider in the family day home to be trained in the administration of epinephrine and to notify the parents of each child who receives care in such family day home whether the provider stores an appropriate weight-based dosage of epinephrine in the residence or home in which the family day home operates.

The Board proposes to amend the regulation in this manner. The epinephrine training requirements are essentially the same as for child day centers. Unlike child day centers, possession of epinephrine would be optional for family day homes. The family day homes would be required to notify parents in writing whether it stores an appropriate weight-based dosage of undesignated or stock epinephrine in the residence or home in which the family day home operates.

Estimated Benefits and Costs

Anaphylaxis is a severe, life-threatening allergic reaction. It can happen seconds or minutes after a person has been exposed to an allergen.² Immediate use of an epinephrine autoinjector can keep anaphylaxis from worsening and can be lifesaving.³ Thus, the proposed requirements that child day centers possess and store appropriate weight-based dosages of undesignated or stock epinephrine, and that at least one person qualified to administer epinephrine has access to the epinephrine at all times during regular facility hours, has the potential to save the lives of children with undiagnosed allergies in cases when exposure to the allergen may result in anaphylaxis.

An EpiPen package comes with two auto-injectors of 0.3 mg and is approved for adults and children who weigh 66 lbs. or more. The EpiPen JR package comes with two auto-injectors of 0.15 mg and is approved for children who weigh 33 lbs. to 66 lbs.⁴ There are now also Food and Drug Administration (FDA) approved epinephrine auto-injectors of 0.1 mg for infants and

² Source: Mayo Clinic https://www.mayoclinic.org/diseases-conditions/anaphylaxis/symptoms-causes/syc-20351468

³ Source: Mayo Clinic https://www.mayoclinic.org/diseases-conditions/anaphylaxis/diagnosis-treatment/drc-20351474

⁴ See https://www.goodrx.com/epinephrine-epipen/how-to-save-cost

toddlers.⁵ Retail prices for a package of two brand name epinephrine auto-injectors range from \$650 to \$750 without insurance.⁶ FDA-authorized generic epinephrine is available from CVS at \$109.99 per two-pack.⁷ Epinephrine autoinjectors have a shelf life of 12 to 18 months from the date of manufacture.⁸ For a child day center with children that fall into all three weight groups, and uses the FDA-authorized generic epinephrine from CVS, it would cost approximately \$330 annually to maintain non-expired epinephrine on hand.⁹

DOE has indicated that it has no estimate for the costs of training for epinephrine administration. The American Red Cross has an online course called *Anaphylaxis and Epinephrine Auto-Injector*.¹⁰ The following is the course description: "This online course will teach you the signs and symptoms of anaphylaxis and how to care for a person having a severe allergic reaction including how to administer epinephrine using an auto-injector device. The course which includes video activities that reinforce key information and a learning assessment will take approximately 30 minutes to complete." The fee is \$35, but it does not appear to meet all of the requirements for training as described in the proposed regulation. Accordingly, the potential cost of the required training is not known.

Businesses and Other Entities Affected

The proposed amendments would affect the 531 child day programs (includes child day centers and family day homes) that participate in the Child Care Subsidy Program. DOE believes that most would qualify as small businesses.

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

⁷ See https://www.cvs.com/content/epipen-alternative

⁵ See https://www.fda.gov/media/127806/download

⁶ Supra, note 4.

⁸ See https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5720482/

⁹ Average of \$110 per epinephrine auto-injector package, and three separate packages for the three different weight groups.

¹⁰ See https://www.redcross.org/take-a-class/classes/anaphylaxis-and-epinephrine-auto-injector---online-course/a6R0V0000015EUe.html

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.

reduction in net benefit for any entity, even if the benefits exceed the costs for all entities combined.¹²

The costs from requiring that child day centers possess and store appropriate weight-based dosages of undesignated or stock epinephrine stem from the legislation. Requiring training for the administration of epinephrine is also in the legislation, but the proposed text on training is more restrictive than the legislation. For example, the \$35 half hour online course from the American Red Cross would appear to qualify for training as described in the legislation, but appears to not qualify in the proposed regulatory text. DOE does not have estimates for training costs that meet the proposed regulatory options, and the option of completing a training course developed or approved by DOE in consultation with VDH has not been developed, but it seems likely the costs in dollars and/or time would be higher to meet the regulatory requirements than the statutory requirement. Thus, an adverse impact is indicated.

Small Businesses¹³ Affected:¹⁴

Types and Estimated Number of Small Businesses Affected

Per DOE, most of the 531 child day programs would qualify as small businesses.

Costs and Other Effects

Requiring that child day centers possess and store appropriate weight-based dosages of undesignated or stock epinephrine increases costs for the small centers as described above. Requiring training for child day centers and family day homes also increases costs.

¹² 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. As a result, DPB has adopted a definition of adverse impact that assesses changes in net costs and benefits for each affected Virginia entity that directly results from discretionary changes to the regulation.

¹³ 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."

¹⁴ 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.

Alternative Method that Minimizes Adverse Impact

Permitting anaphylaxis and epinephrine auto-injector training via online courses such as that provided by the American Red Cross could potentially reduce adverse impact.

Localities¹⁵ Affected¹⁶

The proposed amendments neither appear to disproportionally affect particular localities nor affect costs for local governments.

Projected Impact on Employment

The proposed amendments do not appear to substantively affect total employment.

Effects on the Use and Value of Private Property

The increase in costs, which are largely due to the legislation, may moderately reduce the value of some child day programs. The proposed amendments do not affect real estate development costs.

¹⁵ "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.

¹⁶ § 2.2-4007.04 defines "particularly affected" as bearing disproportionate material impact.