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Fast-Track Regulation Agency Background Document

Agency name	Virginia Department of Education
Virginia Administrative Code (VAC) citation(s)	8 VAC 20-671
Regulation title(s)	<i>Regulations Governing the Operation of Private Schools for Students with Disabilities</i>
Action title	Amendment as required by HB 2216 approved by the 2015 session of the General Assembly
Date this document prepared	September 6, 2016

This information is required for executive branch review and the Virginia Registrar of Regulations, pursuant to the Virginia Administrative Process Act (APA), Executive Orders 17 (2014) and 58 (1999), and the *Virginia Register Form, Style, and Procedure Manual*.

Brief summary

Please provide a brief summary (preferably no more than 2 or 3 paragraphs) of the proposed new regulation, proposed amendments to the existing regulation, or the regulation proposed to be repealed. Alert the reader to all substantive matters or changes. If applicable, generally describe the existing regulation.

The Virginia General Assembly enacted HB 2216 requiring that the Board of Education promulgate regulations for the possession and administration of epinephrine in every school for students with disabilities, to be administered by any employee of the school who is authorized by a prescriber and trained in the administration of epinephrine to any student believed to be having an anaphylactic reaction. The current *Regulations Governing the Operation of Private Schools for Students with Disabilities* contain a section titled Medication and Health, at 8VAC20-671-710, which requires private schools to develop and implement policies and procedures related to several factors related to the possession, use, storage, and accountability of medication; along with some general requirements related to a student's health.

However, these regulations are void of any reference to the possession and/or use of epinephrine. Thus, we propose amending 8 VAC 20-671-710, to reflect new requirements related to the procurement, possession, provision, storage and disposal and administration of epinephrine. Additionally, we propose including clarification on the immunity of the private schools for students with disabilities and their staff against any liability for any civil damages for ordinary negligence in acts or omission resulting from rendering the administration of the epinephrine. Furthermore, we propose including training requirements for private schools with disabilities staff and the documentation and reporting of the use of epinephrine.

Acronyms and Definitions

Please define all acronyms used in the Agency Background Document. Also, please define any technical terms that are used in the document that are not also defined in the "Definition" section of the regulations.

There are no new acronyms in the proposed amendment to the current *Regulations Governing the Operation of Private Schools for Students with Disabilities*. However, there is a reference to the terms EpiPen and EpiPen Jr. These terms are the common name given to the epinephrine auto-injector unit.

Statement of final agency action

Please 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.

On September 22, 2016, the Virginia Board of Education approved the proposed amendments to 8 VAC 671-710 to conform with the intent and requirements of the 2015 session of the General Assembly enacted House Bill 2216, approved on July 1, 2015, and requested that the Virginia Department of Education move forward with the fast track proposed regulatory process.

Legal basis

Please identify the state and/or federal legal authority to promulgate this proposed regulation, including: 1) the most relevant citations to the Code of Virginia or General Assembly chapter number(s), if applicable; and 2) promulgating entity, i.e., agency, board, or person. Your citation should include a specific provision authorizing the promulgating entity to regulate this specific subject or program, as well as a reference to the agency/board/person's overall regulatory authority.

The Virginia General Assembly enacted HB 2216, which amended the *Code of Virginia*, at §8.01-225. Persons rendering emergency care, obstetrical services exempt from liability, by adding the following language to §8.01-225.A.13: Any person who *Is an employee of a school for students with disabilities, as defined in §22.1-319 and licensed by the Board of education, or an employee of a private school that complies with accreditation requirements set forth in §22.1-19 and is accredited by the Virginia Council for Private education who is authorized by a prescriber and trained in the administration of epinephrine and who provides, administers , or assists in the administration of epinephrine to a student believed in good faith to be having an anaphylactic reaction, or is the prescriber of the epinephrine, shall not be liable for any civil damages for ordinary negligence in acts or omission resulting from rendering of such treatment. Whenever any employee is covered by the immunity granted in this subsection, the school shall not be liable for any civil damages for ordinary negligence in acts or omission resulting from such provision, administration, or assistance.*

HB 2216 further amended the *Code of Virginia*, at 54.1-3408. Professional use by practitioners, by adding the following language to 54.1-3408.D: *Pursuant to an order or a standing protocol issued by the prescriber within the course of his professional practice, any employee of a school for students with disabilities, as defined in §22.1-319 and licensed by the Board of education, or an employee of a private school that complies with accreditation requirements set forth in §22.1-19 and is accredited by the Virginia Council for Private education who is authorized by a prescriber and trained in the administration of epinephrine may possess, provide, and administer epinephrine.*

Additionally, HB 2216 further amended the *Code of Virginia* by adding section number §22.1-321.1 relating to the possession and administration of epinephrine in private schools for students with disabilities. This added section of the *Code of Virginia* reads: *§22.1-321.1. Possession and administration of epinephrine. By the beginning of the 2016-2016 school year, the Board of Education shall promulgate regulations for the possession and administration of epinephrine in every school for students with disabilities, to be administered by any employee of the school who is authorized by a prescriber and trained in the administration of epinephrine to any student believed to be having an anaphylactic reaction.*

HB 2216 was signed by the Governor and became effective on July 1, 2015.

Purpose

Please explain the need for the new or amended regulation. Describe the rationale or justification of the proposed regulatory action. Describe the specific reasons the regulation is essential to protect the health, safety or welfare of citizens. Discuss the goals of the proposal and the problems the proposal is intended to solve.

The proposed amendment to the *Regulations Governing the Operation of Private Schools for Students with Disabilities* is required because HB 2216 which was signed by the Governor and became effective on July 1, 2015 amended the *Code of Virginia* by adding section number §22.1-321.1 relating to the possession and administration of epinephrine in private schools for students with disabilities. This code provision required that the Board of Education shall promulgate regulations for the possession and administration of epinephrine in every school for students with disabilities, to be administered by any employee of the school who is authorized by a prescriber and trained in the administration of epinephrine to any student believed to be having an anaphylactic reaction. Without amending the *Regulations Governing the Operation of Private Schools for Students with Disabilities* to include requirements related to the possession and use of epinephrine students who are believed to be having an anaphylactic reaction could be put at significant risk of a serious medical condition or potentially death. The amended regulations will provide the administrators of private schools for students with disabilities with much needed and requested regulations related to the possession and use of epinephrine.

Rationale for using fast-track process

Please explain the rationale for using the fast-track process in promulgating this regulation. Why do you expect this rulemaking to be noncontroversial?

The reason we are requesting Fast-Track action on the proposed amendments to the *Regulations Governing the Operation of Private Schools for Students with Disabilities* is that: (1) we do not foresee a significant human resource or fiscal impact on the private school facilities,; (2) there is no fiscal impact on the Commonwealth; and (3) these regulations are long awaited by the private school community and its accrediting agencies, primarily the Virginia Council for Private Education (VCPE) and the Virginia Association of Independent Specialized Education Facilities (VAISEF).

Substance

Please 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.

The proposed amendment to the *Regulations Governing the Operation of Private Schools for Students with Disabilities* address the requirements for procurement, storage, and use of epinephrine. These proposed regulations also address the training requirements for staff and the required reporting activities when epinephrine is administered to a student enrolled in a private school licensed by the Virginia Department of Education.

Issues

Please identify the issues associated with the proposed regulatory action, 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, please indicate.

There are no foreseen disadvantages to the public or the Commonwealth.

Requirements more restrictive than federal

Please identify and describe any requirement of the proposal which is more restrictive than applicable federal requirements. Include 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 statement to that effect.

There are no applicable federal requirements related to the possession and administration of epinephrine in private schools for students with disabilities and as such, there are no requirements that exceed applicable federal requirements.

Localities particularly affected

Please identify any locality particularly affected by the proposed regulation. Locality particularly affected means any locality which bears any identified disproportionate material impact which would not be experienced by other localities.

There are no localities which will bear any disproportionate material impact.

Regulatory flexibility analysis

Pursuant to § 2.2-4007.1B of the Code of Virginia, please 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) the establishment of less stringent compliance or reporting requirements; 2) the establishment of less stringent schedules or deadlines for compliance or reporting requirements; 3) the consolidation or simplification of compliance or reporting requirements; 4) the establishment of 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 proposed regulation.

Not Applicable

Economic impact

Please identify the anticipated economic impact of the proposed new regulations or amendments to the existing regulation. When describing a particular economic impact, please specify which new requirement or change in requirement creates the anticipated economic impact.

<p>Projected cost to the state to implement and enforce the proposed regulation, including: a) fund source / fund detail; and b) a delineation of one-time versus on-going expenditures</p>	<p>There is no fiscal impact on the Commonwealth. All costs associated with becoming complaint with the amended regulations will be borne by the private school facilities.</p>
<p>Projected cost of the new regulations or changes to existing regulations on localities.</p>	<p>There are no projected costs on localities.</p>
<p>Description of the individuals, businesses, or other entities likely to be affected by the new regulations or changes to existing regulations.</p>	<p>Private day and residential schools which are licensed by the Virginia Department of Education.</p>
<p>Agency’s best estimate of the number of such entities that will be affected. Please 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.</p>	<p>There are 136 licensed private schools within the Commonwealth.</p>
<p>All projected costs of the new regulations or changes to existing regulations for affected individuals, businesses, or other entities. Please be specific and include all costs including: a) the projected reporting, recordkeeping, and other administrative costs required for compliance by small businesses; and b) specify any costs related to the development of real estate for commercial or residential purposes that are a consequence of the proposed regulatory changes or new</p>	<p>The projected cost for the initial procurement of the required number of epinephrine auto-injector units is between \$1200 and \$1600. Thereafter, the replacement costs for used and expired auto-injectors is projected to be at the same rate.</p> <p>The administrative costs for recordkeeping, and other administrative costs required for compliance is projected at \$240 (1hr per month at \$20 per hour).</p> <p>There are not projected costs associated with the</p>

regulations.	development of real estate for commercial or residential purposes.
Beneficial impact the regulation is designed to produce.	The proposed regulations are intended to ensure the safety of students who are believed to be in an emergency situation do to an anaphylactic reaction.

Alternatives

Please describe any viable alternatives to the proposal considered and the rationale used by the agency to select the least burdensome or intrusive alternative that meets the essential purpose of the action. 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 regulation.

The Board of Education was required by an amendment to the *Code of Virginia* to promulgate the proposed amendment to the *Regulations Governing the Operation of Private Schools for Students with Disabilities*. Therefore, there were no alternatives to consider.

Public participation notice

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.

Periodic review and small business impact review report of findings

If this fast-track is the result of a periodic review/small business impact review, use this form to report the agency's findings. Please (1) summarize all comments received during the public comment period following the publication of the Notice of Periodic Review and (2) indicate whether the regulation meets the criteria set out in Executive Order 17 (2014), e.g., is necessary for the protection of public health, safety, and welfare, and is clearly written and easily understandable. In addition, as required by 2.2-4007.1 E and F, please include a discussion of the agency's consideration of: (1) the continued need for the regulation; (2) the nature of complaints or comments received concerning the regulation from the public; (3) the complexity of the regulation; (4) the extent to the which the regulation overlaps, duplicates, or conflicts with federal or state law or regulation; and (5) the length of time since the regulation has been evaluated or the degree to which technology, economic conditions, or other factors have changed in the area affected by the regulation.

Commenter	Comment	Agency response

Not Applicable

Family impact

Please assess the impact of this regulatory action on the institution of the family and family stability including to what extent the regulatory action will: 1) strengthen or erode the authority and rights of parents in the education, nurturing, and supervision of their children; 2) encourage or discourage economic self-sufficiency, self-pride, and the assumption of responsibility for oneself, one’s spouse, and one’s children and/or elderly parents; 3) strengthen or erode the marital commitment; and 4) increase or decrease disposable family income.

Not Applicable

Detail of changes

Please list all changes that are being proposed and the consequences of the proposed changes; explain the new requirements and what they mean rather than merely quoting the proposed text of the regulation. If the proposed regulation is a new chapter, describe the intent of the language and the expected impact. Please describe the difference between existing regulation(s) and/or agency practice(s) and what is being proposed in this regulatory action. If the proposed regulation is intended to replace an emergency regulation, please follow the instructions in the text following the three chart templates below.

If a new regulation is being promulgated, that is not replacing an existing regulation, please use this chart:

Section number	Proposed requirements	Other regulations and law that apply	Intent and likely impact of proposed requirements
710.E	Each private school for students with disabilities shall develop a written policy related to its procedures to address students with severe allergies who may be at risk of an anaphylactic reaction necessitating the use of an epinephrine auto-injector. The policy shall address, but is not limited to: (1) an overview of anaphylaxis and its symptoms; (2) staff training in the possession and administration of epinephrine auto-injectors; (3) standing orders; (4) responding to anaphylaxis; (5) post administration of epinephrine actions; and (6) storage, access, and maintenance. School administrators shall ensure that the school’s policy is consistent with the <i>Guidelines for Recognition and Treatment of Anaphylaxis in the School Setting</i> which are published on	None	The need to develop policies related to the possession and use of epinephrine will have minimal impact on human resources and the day-to-day operation of private schools.

	the Virginia Department of Education’s (VDOE) website.		
710.F	Each private school for students with disabilities shall ensure that it has at least two (2) auto-injectable epinephrine units in both dosage sizes, 0.3 mg for students weighing more than 66 pounds and 0.15 mg for students who weigh 33 to 66 pounds, on school premises, to be administered by any employee of a school for students with disabilities licensed by the Board of Education who is authorized by a prescriber and trained in the administration of epinephrine to any student believed to be having an anaphylactic reaction. Stock epinephrine is intended for use on school premises and should not be carried offsite. Additional epinephrine should be made available along with arrangements for administration during field trips and other official offsite school activities.	The <i>Code of Virginia</i> , at §8.01-225.A.13.	The need to procure the required number of epinephrine auto-injectors will have minimal impact on human resources and the day-to- day operation of private schools. As to the fiscal impact, it is projected the costs will be between \$1200 and \$1600.
710.G	<ol style="list-style-type: none"> 1. All medications shall be accepted only in the original container with written permission signed and dated by the parent to administer to the child. 2. The use of all prescriptive medication must be authorized in writing by a licensed prescriber. 3. For students enrolled in private schools for students with disabilities with known life threatening allergies or anaphylaxis the school administrator shall obtain, through the student’s parent or legal guardian, “student specific” written instructions from the student’s health care provider for handling anaphylaxis and all necessary medications for implementing the student specific order on an annual basis. 4. The private school for 	None	This section of the proposed regulations will have no human resources or fiscal impact on the day-to- day operation of private schools.

	<p>students with disabilities administrator shall designate an authorized medical provider with prescriptive authority, such as a medical doctor, doctor of osteopathy, physician’s assistant, or nurse practitioner, and obtain a standing order to prescribe “non-student specific” epinephrine for students within the school who do not presently have a health care plan addressing the administration of epinephrine, to be administered to any student believed to be having an anaphylactic reaction.</p> <p>5. School administrators shall coordinate with, among other resources as they deem appropriate, placing school divisions, local health department directors, local practitioners, and the Virginia Chapter of the American Academy of Pediatrics to assist them in obtaining the required standing orders for treatment of anaphylaxis and prescriptions to order auto-injectable epinephrine.</p> <p>6. Standing orders and prescriptions shall be renewed annually and with any change in prescriber.</p>		
<p>710.H</p>	<p>The expiration date of epinephrine solutions shall be checked periodically; but not less than monthly. The auto-injector unit should be replaced if it is approaching its expiration date. The contents should be inspected through the clear window of the auto-injector. The solution should be clear; if it is discolored or contains solid particles, discard and replace the unit. Used, expired, or epinephrine auto-injectors with discolored solution or solid particles shall not be used and shall be discarded in a sharps container. The school shall maintain a sufficient number of extra</p>	<p>None</p>	<p>The need to inspect and record the status of the epinephrine auto-injectors will have minimal impact on the human and fiscal resources of private schools. It is estimated that the time necessary to carry out the requirements of this regulatory provision is less than one hour.</p>

	doses of epinephrine for replacement of used or expired school stock on the day it is used or discarded. Each school shall maintain documentation that its stock of epinephrine has been checked on a monthly basis to ensure proper storage, review of expiration dates, medication stability, and replacement upon use or disposal under the aforementioned criteria.		
710.I	All medication and medical paraphernalia, with the exception of epinephrine auto-injectors shall be properly labeled and securely locked or stored in accordance with the Virginia School Health Guidelines. Epinephrine auto-injectors must be stored in a safe, unlocked and accessible location, in a dark place at room temperature (between 59°F - 86°F). Epinephrine cannot be stored in a refrigerator. Although epinephrine should not be maintained in a locked cabinet or behind locked doors, precautions must be in place to ensure that the epinephrine auto-injectors are not readily available to student access. The location of the epinephrine must be clearly marked at the storage location and staff must be made aware of the storage location in each school.	None	This section of the proposed regulations will have no human resources or fiscal impact on the day-to- day operation of private schools.
710.K	Once epinephrine is administered, local Emergency Medical Services (911) shall be activated and the student transported to the emergency room for follow up care. In some reactions, the symptoms go away, only to return one to three hours later. This is called a “biphasic reaction.” Often these second-phase symptoms occur in the respiratory tract and may be more severe than the first-phase symptoms. Therefore, follow up care with	None	The need to report the administration of epinephrine will have minimal impact on the human and fiscal resources of private schools. It is estimated that the time necessary to carry out the requirements of this regulatory provision is less than one hour.

	<p>a health care provider is necessary. The student will not be allowed to remain at school or return to school on the day epinephrine is administered. The administration of epinephrine shall be treated as a serious incident and shall be reported to the parent or legal guardian immediately using all means of contact provided by the parent, such as their home, cell, or work phone numbers or an e-mail address, but no later than the end of the school day. The school administrator shall ensure that an appropriate serious incident form is completed by the end of the day on which the administration of epinephrine occurred. The incident report shall include, but is not limited to, the following information: (1) the date and time the incident occurred; (2) the name of the staff who administered the epinephrine; (3) a record of the attempt(s) made (including date, time, mode of communication, and name of employee making the attempt) to notify the parent of the use of the epinephrine; (4) summary of contact with parent; and (5) the name of the person who completed the incident report. The school administrator shall provide a copy of the incident report, via e-mail or facsimile, to the Department within 24 hours of completing the report.</p>		
710.N.2	<p>The school administrator shall identify an appropriate number of staff, but not less than two employees, in addition to the school nurse, as appropriate, to be trained in the administration of epinephrine by auto-injector. Only trained personnel shall administer epinephrine to a student believed to be having an anaphylactic reaction. Training shall be conducted in</p>	None	<p>The need to train staff on the use of epinephrine auto-injectors will have minimal impact on human resources and the day-to-day operation of private schools.</p> <p>As to the fiscal impact, it is projected the costs will be between \$200 and \$400 per staff member.</p>

	<p>accordance with the most current edition of the Virginia Department of Education’s <i>Manual for Training Public School Employees in the Administration of Medication</i> or other approved training programs, such as, Medication Administration Training for Youth (MATY) or Medication Administration Training (MAT). Training shall be conducted as often as needed to ensure adequate staff are trained, but not less than annually.</p>		
710.P	<p>The requirements outlined above related to the possession and administration of epinephrine extend to activities which may occur off the school premises. Therefore, school policies shall include specific protocols for responding to anaphylaxis in the school setting, both onsite and at offsite school events, such as field trips.</p>	None	<p>This section of the proposed regulations will have no human resources or fiscal impact on the day-to- day operation of private schools.</p>
710.Q	<p>In accordance with §8.01-225 A 13 of the <i>Code of Virginia</i>, any person who is an employee of a school for students with disabilities, as defined in §22.1-319 and licensed by the Board of Education, who is authorized by a prescriber and trained in the administration of epinephrine and who administers or assists in the administration of epinephrine to a student believed in good faith to be having an anaphylactic reaction shall not be liable for any civil damages for ordinary negligence in acts or omissions resulting from the rendering of such treatment. Whenever any employee is covered by the immunity granted in §8.01-225 A 13 Code of Virginia, the school shall not be liable for any civil damages for ordinary negligence in acts or omissions resulting from such administration or assistance.</p>	<p>The <i>Code of Virginia</i>, at §8.01-225.A.13.</p>	<p>This section of the proposed regulations will have no human resources or fiscal impact on the day-to- day operation of private schools.</p>

