THE VIRGINIA DEPARTMENT OF HEALTH
THE VIRGINIA DEPARTMENT OF HEALTH PROFESSIONS

Study of the Expansion of Access to Epinephrine Auto-Injectors in the Commonwealth of Virginia

November 2015

Workgroup Participants

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Virginia Academy of Family Physicians (Hunter Jamerson)
Virginia Chapter – American Academy of Pediatricians (Aimee Seibert)
Virginia College of Emergency Physicians (Aimee Seibert)
Medical Society of Virginia (Tyler Cox and Ann Hughes)
Virginia EMS Council (Ed Rhodes)
Virginia School Nurses Association (Becky Bowers-Lanier)
Virginia Academy of Nutrition and Dietetics (Andrew Lamar)
Food Allergy Support Groups of Virginia (Tiffany Glass Ferreira)
No Nuts Moms (Stephanie Gatewood)
Mylan (Michele Satterlund)
Kaleo (Myles Louria)
Sanofi (Kathryn Lavriha & Eric Jones)
Virginia Hospitality and Travel Association (Kristian Havard)
YMCA (Tyler Bishop)
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Study of the Expansion of Access to Epinephrine Auto-Injectors in the Commonwealth of Virginia

Introduction

During the 2015 Session of the General Assembly, Senate Bill 1167 (Hanger) was passed by indefinitely in the Senate Education and Health Committee with the understanding that a letter would be sent requesting the Virginia Department of Health and the Virginia Department of Health Professions to convene a workgroup "aimed at identifying opportunities to expand the number of sites that may choose to voluntarily stock epinephrine auto-injectors for administration by trained individuals in the event of an anaphylactic reaction." Subsequently, the committee chairman sent a letter (Appendix A) with a request for a study in which the following questions were posed:

1. Where, and under what conditions, would it be appropriate for the administration of epinephrine auto-injectors by lay-persons?
2. What liability protections are needed for administration by lay-persons?
3. What is the availability of nationally recognized programs that train lay-persons in the administration of epinephrine auto-injectors?
4. What states currently allow administration of epinephrine auto-injectors by trained lay-people?
5. What states allow stocking of epinephrine auto-injectors at sites other than medical facilities and public schools?
6. What changes must be made to Virginia's laws and regulations in order to expand the use of epinephrine auto-injectors in sites other than medical facilities and public schools?

Accordingly, the Workgroup consisting of representatives from health care provider associations, pharmaceutical companies, business and trade associations, and other organizations was convened to review issues pertaining to the potential expansion of use of epinephrine auto-injectors at sites other than medical facilities and public and private schools in Virginia. The Workgroup met on May 27, 2015 and July 30, 2015.

Workgroup Activities

At the meeting on May 27th, the workgroup reviewed SB1167 and the study mandate as well as the Virginia Drug Control Act and the "Good Samaritan" liability protection provisions in Virginia law. The workgroup received a presentation from the Virginia Department of Health (VDH) concerning anaphylaxis and epinephrine. Information about other states in which epinephrine auto-injectors have been authorized for use in non-health care settings by trained lay-persons was reviewed, including information obtained through interviews with health department staff in states that have enacted such legislation. Particular attention was given to Rhode Island and Florida which were among the first states to enact legislation similar to SB1167 The Workgroup then engaged in a discussion of the study questions posed in the letter

from Senate Education and Health Committee and was requested by staff to submit written responses to the questions prior to the July meeting.

At the meeting on July 30th, the workgroup discussed the responses to the study questions that were received and observed that there was a wide discrepancy among workgroup members concerning the level of support for expansion of access to auto-injectors for authorized entities, i.e., sites other than medical facilities and public and private schools, to be administered by lay-persons. The workgroup examined additional, updated information about other state laws and regulations. The workgroup also received a presentation from VDH about emergency medical services (EMS) calls in response to anaphylaxis, training requirements for EMS personnel, and the type of EMS personnel allowed to administer epinephrine. Several workgroup members raised questions concerning how epinephrine auto-injectors are dispensed and stored in other states where the expansion legislation has been passed, such as whether the auto-injectors are dispensed to the entity or the person who has received the training and which party is responsible for storage.

Medical Overview of Epinephrine for Rapid Treatment of Anaphylaxis

Anaphylaxis is a sudden and severe allergic reaction that typically occurs within minutes of exposure to the allergen and almost always within two hours. The anaphylactic reaction results in a release of chemicals in the blood and body tissue encouraging the dilation of blood vessels, leading to a decrease in blood pressure and fluid leaks (often resulting in hives and swelling). Anaphylaxis can occur as an allergic response to peanuts, tree nuts, shellfish, dairy products, eggs, insect stings, latex, and medications.

Anaphylaxis can present in different ways. Anaphylactic symptoms may be pronounced or they may be subtle and difficult to recognize. A person in anaphylaxis may note swelling of tissues; hives; itching; nausea, vomiting, or diarrhea; dizziness or fainting; coughing or difficulty breathing. A person in anaphylaxis may be found to have rapid, weak pulse; flushed or pale skin; abnormal lung sounds; or loss of consciousness. Untreated anaphylaxis can result in death from asphyxiation due to upper or lower airway obstruction or from cardiovascular collapse. Untreated anaphylaxis itself can lead to chest pain, myocardial infarction, and cardiac arrhythmias. The goal is early recognition of anaphylaxis and treatment with epinephrine to prevent progression to life-threatening respiratory and cardiovascular effects.

Epinephrine is the drug of choice for the emergency treatment of anaphylaxis and other severe allergic reactions. It helps maintain blood pressure by lessening the dilation of blood vessels and fluid leakage from blood vessels that occurs during anaphylaxis. Epinephrine relaxes the smooth muscles in the airways and helps reduce bronchospasm, wheezing and shortness of breath. It reduces itching, hives and generalized swelling. Epinephrine may also relieve gastrointestinal and genitourinary symptoms by relaxing the smooth muscles of the stomach, intestine, uterus, and urinary bladder. Epinephrine can quickly improve a person's symptoms, but the effects are not long lasting. If symptoms recur, referred to as a biphasic reaction, additional doses of epinephrine are needed.

There are no absolute contraindications to the use of epinephrine in a life-threatening situation. The risk of death or serious complications from the loss of oxygen to the brain from inadequately treated anaphylaxis usually outweighs other concerns. Epinephrine is not contraindicated for persons who have heart disease, including cardiac arrhythmias, coronary artery or organic heart disease, or hypertension, if they are having an acute, life-threatening anaphylactic reaction. However, some patients may be at greater risk for developing adverse reactions after epinephrine administration. Persons who might be in a position to administer epinephrine to an elderly individual, pregnant woman, or persons with certain health conditions should be carefully instructed in regard to the circumstances under which epinephrine should be used. Epinephrine should be administered with caution to patients who have heart disease, including patients with cardiac arrhythmias, coronary artery or organic heart disease, or hypertension. In such patients, or in patients who are on drugs that may sensitize the heart to arrhythmias, epinephrine may precipitate or aggravate angina pectoris as well as produce ventricular arrhythmias. Epinephrine should be administered with caution to patients with hyperthyroidism, diabetes, elderly individuals, and pregnant women. Patients with Parkinson's disease may notice a temporary worsening of symptoms. (Source: Full Prescribing Information for Auvi-Q)

Epinephrine administered by any route can cause anxiety, restlessness, headache, dizziness, palpitations, pallor, nausea and vomiting, headache, respiratory difficulties, and/or tremor. The natural epinephrine released in a sudden frightening or life-threatening situation causes similar symptoms. These symptoms occur in some persons receiving therapeutic doses of epinephrine, but are more likely to occur in patients with hypertension or hyperthyroidism. Arrhythmias, including fatal ventricular fibrillation, have been reported, particularly in patients with underlying cardiac disease or those receiving certain drugs. Rapid rises in blood pressure have produced cerebral hemorrhage, particularly in elderly patients with cardiovascular disease. Angina may occur in patients with coronary artery disease. (Source: Full Prescribing Information for Auvi-Q)

The most common adverse event reported to the U. S. Food and Drug Administration associated with epinephrine auto-injectors is unintentional injections. From October 2011 to September 2012, the U.S. Food and Drug Administration received 256 reports of adverse events and the use of epinephrine auto-injectors. The most common reports were: accidental exposure (131); drug ineffective (51); injury associated with device (44); and expired drug administered (40). However, these reports are not verified clinical evidence of an adverse effect. The rate of unintentional injections of epinephrine from auto-injectors is increasing: more than 15,000 events were reported voluntarily to the American Association of Poison Control Centers from 1994 to 2007.

Emergency Medical Services Response to Anaphylaxis

Emergency Medical Technicians (EMT) are to provide basic emergency medical care and transportation for critical and emergent patients who access the emergency medical system. This individual possesses the basic knowledge and skills necessary to provide patient care and transportation. EMTs function as part of a comprehensive EMS response, under medical oversight, and perform interventions with the basic equipment typically found on an ambulance. The EMT is a link from the scene to the emergency health care system.

During 2014, a total of 1,174,253 emergency calls were made to 911 that subsequently involved treatment by EMS. Among those calls, 10,285 (0.88%) were for a person having an allergic/anaphylactic reaction. Among those calls involving anaphylaxis, epinephrine was administered by EMS in 1,070 (10.4%) of the cases. Appendix B contains additional data from the Virginia Department of Health's Office of Emergency Medical Services.

Certification as an EMT in Virginia requires between 150 and 190 hours of training including the four integrated phases of education (didactic, laboratory, clinical and field.) Specific education for the EMT includes but is not limited to:

1. Anatomy and physiology of the immune system
2. Causes of an immune response causing an allergic and anaphylactic reaction
3. Obtaining a history for a current event
4. Signs and symptoms of an allergic and anaphylactic reaction
5. Treatment interventions for such a reaction to include but not limited to:
    a. Airway management
    b. Assuring adequate breathing
    c. Assuring adequate circulation
    d. Assisting / administering appropriate medications:
        i. Oxygen
        ii. Epinephrine

The Virginia EMS Scope of Practice - Procedures allow for the administration of medication by the various types of EMS responders. The Virginia EMS Scope of Practice – Formulary allows for the EMT to administer various drugs, including epinephrine.

By contrast, certification as an Emergency Medical Responder (EMR), formerly known as a First Responder, requires between 48 and 60 hours of training. EMRs are not allowed to administer medication, including epinephrine, with the exception of certain drugs to be administered during an incident involving weapons of mass destruction.

Responses to Study Questions

1. Where, and under what conditions, would it be appropriate for the administration of epinephrine auto-injectors by lay-persons?

There was no consensus among the participants in the Workgroup in response to the question about where such administration would be appropriate. Responses included the following:

Medical Society of Virginia, Virginia Chapter - American Academy of Pediatricians, American College of Emergency Physicians and Virginia Association of Family Physicians

- Administration of epinephrine auto-injectors by lay-persons should occur in "controlled" locations, with an emphasis on those sites at which large groups of children are typically

present, such as private schools, camps, and daycares. These are locations where staff can be appropriately trained and where training can be documented and updated as the technology changes. There is also a higher likelihood that a trained healthcare provider will be present in these "controlled" settings.

- If lay-persons are permitted to administer a prescription medication such as an epinephrine auto-injector, proper training will be critical, particularly in distinguishing anaphylaxis from other conditions. While classic anaphylaxis is quite distinctive, the list of symptoms associated with anaphylaxis is broad and a lay-person could misinterpret symptoms of another medical condition as being caused by anaphylaxis – in which case administration of epinephrine may exacerbate that medical condition or other underlying conditions of the individual. The risk of adverse events resulting from unnecessary administration of epinephrine is higher in elderly individuals than in children and adults.

Virginia Pharmacists Association

- The most appropriate environments for the administration of epinephrine auto-injectors by lay-persons would be those frequented by, or catering specifically to, children. These would include schools, daycare, summer camps and similar environments. These environments should have a responsible party that takes possession of the auto-injector and ensures that all handling and storage requirements are met.

Mylan Pharmaceutical Company

- Supports the position of the American Medical Association and the American Academy of Allergy and Immunology that lay-persons in occupations likely to involve contact with people who may experience an anaphylactic reaction should be allowed to receive training in the symptoms of anaphylaxis.
- Supports additional training specific to the administration of epinephrine by employees of entities that voluntarily choose to stock epinephrine pursuant to a prescription, standing order or protocol.
- Many entities already choose to stock and provide training to employees regarding the use of first-aid supplies, including automated external defibrillators, to individuals who may be injured, ill or experiencing cardiac arrest on the premises of the entity. Allowing epinephrine auto-injectors to be stocked will enable entities to come to the aid of individuals who experience anaphylaxis in a public setting.

Virginia Campground Association

- Opposes expanding the law to allow "any entity" to be allowed to have standing orders for epinephrine auto-injectors. Even if it is optional, they do not believe this is an appropriate function for campgrounds and campground employees to perform because it would be: 1) overly burdensome to stock the necessary amounts of epinephrine auto-injectors for adults and children that visit Virginia campgrounds; 2) cost-prohibitive; and 3) time-consuming to train seasonal workers. It would also create a false sense of security for campground guests if private businesses were allowed the option. Consumers would be confused as to whether a business has auto-injectors and trained staff.

No Nuts Moms

- Supports expanded access to epinephrine auto-injectors in all settings. It will save lives of food-allergic individuals. Even if a food-allergic individual carries his own injector, it could misfire or not inject correctly or a second or third dose might be needed. Food allergies are increasing in children and there are more late-onset allergies occurring.

2. What liability protections are needed for administration by lay-persons?

Section 8.01-225 of the Code of Virginia provides an exemption from liability for:
A. Any person who:
3. In good faith and without compensation, including any emergency medical services provider who holds a valid certificate issued by the Commissioner of Health, administers epinephrine in an emergency to an individual shall not be liable for any civil damages for ordinary negligence in acts or omissions resulting from the rendering of such treatment if such person has reason to believe that the individual receiving the injection is suffering or is about to suffer a life-threatening anaphylactic reaction.

The Medical Society of Virginia, Virginia Chapter - American Academy of Pediatricians, American College of Emergency Physicians and Virginia Association of Family Physicians:

- Good Samaritan laws are in place in Virginia that protect individuals from liability when they are providing emergency care in good faith. However, the locations that stock the epinephrine auto-injectors for lay-person use might need additional liability protections.

Virginia Pharmacists Association:

- Virginia has a "Good Samaritan" law already in statute. However, it is unclear whether this would apply to situations beyond administration of the medication. For example, would it also cover a scenario where an auto-injector was improperly stored or had expired so that efficacy was decreased, therefore resulting in harm?

3. What is the availability of nationally recognized programs that train lay-persons in the administration of epinephrine auto-injectors?

The Medical Society of Virginia, American Academy of Pediatricians, American College of Emergency Physicians and Virginia Association of Family Physicians:

- There seem to be a handful of nationally recognized programs available to train lay-persons. These organizations support training programs that are "hands-on." They do not believe that training via a webinar or telephone conference will give the lay-person the appropriate level of knowledge to administer an epinephrine auto-injector. These auto-injectors require a certain handling in order to be administered correctly. That is why "training" epi-pens are manufactured, in order provide a hands-on approach to training. These organizations also believe training in accurate identification of anaphylaxis is critical.

Virginia Pharmacists Association:

- They believe that hands-on training is most appropriate.

Mylan Pharmaceutical Company:

- There are several training programs that train lay persons to recognize the symptoms of allergic reaction/anaphylaxis and to assist in the administration, or to directly administer an epinephrine auto-injector. Nationally-recognized training programs include the Red Cross course entitled "Anaphylaxis and Epinephrine Auto-Injector Online Course;" Wilderness Medical Associates course entitled "Wilderness First Aid;" and American Heart Association course entitled "Heartsaver Pediatric First Aid CPR AED." The Red Cross course costs $20. Training programs can be conducted online or in person. Various free programs in administration of auto-injectors are also available online. Training programs are updated as needed, based on current information.
- Several staff from other state health departments, responsible for implementation of the training component of their state statute, noted that training for this authorization can be completed through programs offered by American Red Cross, American Heart Association, National Safety Council, or any other first aid program that covers epinephrine auto-injectors.

4. What states currently allow administration of epinephrine auto-injectors by trained lay-people?

5. What states allow stocking of epinephrine auto-injectors at sites other than medical facilities and public schools?

Responses to these two questions have been combined for the purposes of this report, as all of the legislation enacted by other states contain provisions that authorize both the administration by lay-people and the stocking at certain sites.

Laws to allow administration of epinephrine auto-injectors by trained lay-people *in connection with an authorized entity* have recently been enacted in a number of states (Appendix C). Rhode Island and Florida passed legislation similar to SB1167 in 2014, which allowed the stocking of the injectors at certain facilities at which allergens capable of causing anaphylaxis may be present, and allowed trained employees of that entity to administer the epinephrine auto-injector to another person they believe to be in an emergency anaphylaxis situation. The two states' laws outline various authorizations, training requirements, liability protections and, in Rhode Island's case, incident reporting requirements.

Similar provisions have been adopted in 14 other states in 2015, including: Arkansas, Colorado, Georgia, Iowa, Indiana, Kentucky, Maine, Minnesota, Nevada, North Carolina, Oklahoma, Utah, West Virginia and Wisconsin. Additionally, similar provisions are currently pending in 5 more states, including: Massachusetts, Michigan, New Jersey, Ohio and Pennsylvania.

These statutes are all fairly similar, and all authorize certain entities to stock epinephrine auto-injectors and allow trained lay people in connection with the authorized entity to administer it to an individual believed to be experiencing anaphylaxis. Most of the statutes apply this authorization to any entity at which allergens capable of causing anaphylaxis may be present, however, a few limit this definition to several explicitly listed types of entities, such as campgrounds. Most of these statutes authorize the state's health commissioner, board of health, or other similar entity or individual to create and maintain a list of entities that will be authorized for these provisions.

The statutes differ slightly in their training requirements (for example, some do not include storage and follow-up emergency procedures as a minimum training requirement) or their reporting requirements (several do not require reporting at all). Additionally, the statutes differ in their requirements for or inclusion of an expanded availability provision: four states allow an untrained layperson at the authorized entity to access the epinephrine auto-injectors from a secure storage container and administer it under direction and authorization of a health practitioner via remote electronic communication,

Aside from these various discrepancies from state to state, as well as other minor differences in the language, these statutes all authorize the administration of epinephrine auto-injectors by trained lay-people in connection with an authorized entity that is authorized to stock and maintain epinephrine auto-injectors.

Among those states that have already enacted this type of legislation, implementation remains in the early stages. During interviews conducted by VDH, staff from health departments in those states were asked how the dispensing and prescribing processes would work, what practitioners would typically be writing these prescriptions, and what individual would be responsible for getting the entity's prescription filled and receiving the auto-injector supply. Given that implementation is still in the early stage, these processes and details had not yet been determined, though some states mentioned an assumption that these responsibilities would belong to the entity's employee who is already responsible for receiving training and for oversight and maintenance of the auto-injector supply. Wisconsin is the only state with epinephrine auto-injector legislation that includes dispensing details, lays out basic requirements as with typical prescription orders, and adds that prescriptions in the case of this type of legislation must include the name and address of the authorized entity receiving the prescription. It does not, however, address who would be the individual to fill and pick up an entity's prescribed epinephrine auto-injectors.

The Board of Pharmacy surveyed the following states to determine the process for authorized entities to obtain epinephrine: West Virginia; Kentucky; Maryland; Georgia; Rhode Island; Oklahoma; and, Florida. Responses were received from Oklahoma and Utah.

Oklahoma reported that the epinephrine law will be handled under a protocol or order from the physician. The physician will determine who he or she will authorize to have the epinephrine under the authority. The pharmacy will fill a prescription written by the physician using the entity name as the patient name on the prescription. The physician, e.g., a medical director

associated with the entity, will be responsible for assuring the entity he authorizes to have the medication is trained properly and has an appropriate policy and procedure.

Utah's legislation states that a qualified entity may obtain from a physician, pharmacist, or any other person or entity authorized to prescribe or dispense prescription drugs, a prescription for a supply of epinephrine auto-injectors. The epinephrine must be stored on the qualified entity's premises and used by a qualified adult. The entity must also designate an individual to complete an initial and annual refresher training program regarding the proper storage and emergency use of an epinephrine auto-injector and store the epinephrine auto-injectors in accordance with regulations to be promulgated by the department.

6. What changes must be made to Virginia's laws and regulations in order to expand the use of epinephrine auto-injectors in sites other than medical facilities and public schools?

The Medical Society of Virginia, Virginia Chapter - American Academy of Pediatricians, American College of Emergency Physicians and Virginia Association of Family Physicians posed a series of questions that they believe need to be addressed as a prerequisite to considering the types of changes that are needed to Virginia's laws and regulations:

- Would this be voluntary? How would immunity be handled? Where does the funding come from? Or would this be an unfunded mandate, if not voluntary? Are private physicians writing the standing orders or are VDH physicians? Who would create the regulations? How would the current standing order language need to be changed?

Virginia Pharmacists Association (VPhA)

- There must be clarity as to who possesses the auto-injector and who is responsible for safe handling and storage. Specific concerns of VPhA were:
  1) Possession and storage. The responsible party must be clearly defined. The responsibilities of that person as related to possession and storage must also be clearly delineated;
  2) Diagnosis of anaphylactic shock. When a child is diagnosed with food allergies and a prescription is written for an auto-injector the parents or guardians know to expect anaphylaxis and to use the auto-injector appropriately. A lay person has no such fore-knowledge when an unknown individual presents symptoms. VPhA would have serious concerns with the scenario of, for example, an 18 year old, part-time food service employee attempting to diagnose anaphylaxis. They also have concerns that underlying medical conditions may be exacerbated by the improper use of the auto-injector especially in older adults.
  3) VPhA is not sure that making auto-injectors administered by lay-persons more widely available would promote improved public health or reduce medical expenses. VPhA's understanding is that the main argument made by proponents for making auto-injectors more widely available in public settings is to be able to treat anaphylaxis in individuals who are unaware that they have food sensitivity. It is also their understanding that when a food sensitivity first presents the reaction is generally mild and not life threatening. The situation is often handled by EMS which then decides the course of initial treatment. When EMS does

treat with an auto-injector it is their understanding that the patient will most likely also be taken to an emergency department.

Mylan Pharmaceutical Company

- In 2012, Virginia laid the foundation for entity prescribing by allowing prescribers, pursuant to an order or standing protocol, to provide any individual who is an employee of a public school system, local governing body, or local health department who has received training, to possess and administer epinephrine to an individual experiencing anaphylaxis in a public school setting. The school guidelines provide a framework that can be used by entities other than public schools, for prescribing epinephrine to non-specific individuals.
- In 2015, Virginia passed legislation to expand the availability of epinephrine to employees of a school for students with disabilities, or of a private school that complies with the accreditation requirements set forth in § 22.1-19 and is accredited by the Virginia Council for Private Education.
- Legislation passed in 2015 also allows a prescriber, pursuant to an order or standing protocol, to dispense naloxone to a person who may administer the drug to another person who is experiencing a life-threatening opiate overdose. However, the model used for prescribing naloxone is not being recommended by Mylan for prescribing epinephrine auto-injectors.
- Virginia laws provide a framework from which drug products may be dispensed to individuals or entities, other than the intended recipient of the medication, and most notably, demonstrate that medications may be prescribed and dispensed outside the requirements of §54.1-3303 of the Code.

In order to authorize the dispensing of epinephrine by oral or written order or standing protocol to an employee of an authorized entity, § 54.1-3408 of the Drug Control Act would need to be amended similar to authorization in subsection D for an employee of a local school board to possess and administer epinephrine. Currently, § 8.01-225 of the Code of Virginia provides an exemption from liability for any person who in good faith and without compensation administers epinephrine in an emergency to an individual if such person has reason to believe that the individual receiving the injection is suffering or is about to suffer a life-threatening anaphylactic reaction. However, there may need to be additional protection from civil liability for the entity that stocks the auto-injectable epinephrine.

CONCLUSION

The Workgroup conducted a review of existing laws and regulations and responded to the six questions identified by the Chairman of the Senate Committee on Education and Health. Though the Workgroup actively engaged in the discussion of the study questions and received extensive information about epinephrine and legislative initiatives in other states, it was unable to reach consensus on a policy recommendation concerning the expansion of authorization for unlicensed persons in entities other than schools to possess and administer auto-injectable epinephrine. Members of the Workgroup representing health care provider organizations remain concerned about potential adverse events relating to recognition of anaphylaxis and unnecessary administration. Representatives of entities, such as restaurants and campgrounds, that would potentially be authorized to stock epinephrine and train employees in administration remain

concerned about costs, liability, and public expectations. Representatives of pharmaceutical companies with auto-injectable epinephrine products and allergy advocacy groups continue to support increased access in entities where allergens may be present. While legislation similar to SB1167 has been enacted in 16 other states, it appears that additional stakeholder engagement may be necessary in order to move forward with developing new state policy in this area.

Appendix A: Letter from Chairman of Senate Committee on Education & Health

COMMONWEALTH OF VIRGINIA

STEPHEN H. MARTIN
11th SENATORIAL DISTRICT
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SENATE

COMMITTEE ASSIGNMENTS:
EDUCATION AND HEALTH, CHAIR
GENERAL LAWS AND TECHNOLOGY
LOCAL GOVERNMENT
PRIVILEGES AND ELECTIONS
RULES

February 16, 2015

The Honorable Marissa Levine
Commissioner
Virginia Department of Health
109 Governor Street
Richmond, Virginia 23219

The Honorable David Brown
Director
Virginia Department of Health Professions
9960 Mayland Drive
Ste. 300
Richmond, VA 23233-1463

RE: Senate Bill 1167 (Hanger): Expansion of Access to Epinephrine Auto-Injectors Request that the Virginia Department of Health Professions and the Virginia Department of Health Convene an Epinephrine Auto-Injector Access Workgroup

Dear Dr. Brown and Dr. Levine,

On Thursday, February 4, 2015, the Virginia General Assembly voted unanimously to pass by Senate Bill 1167 with a letter requesting the Virginia Department of Health and the Virginia Department of Health Professions to convene a workgroup aimed at identifying opportunities to expand the number of sites that may choose to voluntarily stock epinephrine auto-injectors for administration by trained individuals in the event of an anaphylactic reaction.

In 2012, the Virginia General Assembly laid the foundation to save lives by mandating that public schools stock and train public school and local government employees to administer epinephrine auto-injectors to students experiencing anaphylaxis. The legislation authorized practitioners to prescribe, via a standing order or protocol, epinephrine auto-injectors to a public school rather than a particular individual.

Allergic reactions, however, don't just happen at a public schools setting, and as the number of individuals (of all ages) suffering from life-threatening anaphylaxis continues to grow, it is important that the Commonwealth find solutions for expanding access to epinephrine—which is the only first-line treatment for anaphylaxis.

The goal of the workgroup shall be to review existing laws and regulations and to provide a report by November 15, 2015 that considers, at a minimum, the following:

1. Where, and under what conditions, would it be appropriate for the administration of epinephrine auto-injectors by lay-persons?
2. What liability protections are needed for administration by law-persons?
3. What is the availability of nationally recognized programs that train lay-persons in the administration of epinephrine auto-injectors?
4. What states currently allow administration of epinephrine auto-injectors by trained lay-people?
5. What states allow stocking of epinephrine auto-injectors at sites other than medical facilities and public schools?
6. What changes must be made to Virginia's laws and regulations in order to expand the use of epinephrine auto-injectors in sites other than medical facilities and public schools?

A list of potential workgroup participants is attached.

If you have any questions, please do not hesitate to contact me.

Sincerely,

Stephen H. Martin
Senate of Virginia

cc: The Honorable Emmett Hanger

Enclosure

Epinephrine Auto-Injector Expansion Work Group: Suggested Participants

- Virginia Department of Health Professions (The Hon. Dr. David Brown/Elaine Yeatts)
- Virginia Department of Health (The Hon. Marissa Levine/Joe Hilbert)
- Virginia Department of Health Board of Pharmacy (Caroline Juran)
- Virginia Association of Pharmacists (James Pickral)
- Virginia Association of Plastic Surgeons (James Pickral)
- Food Allery Support Groups of Virginia (Tiffany Glass Ferreira)
- No Nuts Moms (Stephanie Gatewood)
- Mylan (Michele Satterlund)
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- Association of Family Physicians (Hunter Jamerson)
- Association of Pediatric Physicians (Aimee Seibert)
- Virginia College of Emergency Physicians (Aimee Seibert)
- Virginia Association of Allergists (TBD)
- Virginia Hospitality Association (Kristian Havard)
- YMCA (Tyler Bishop)
- Campground Association (Lauren Schmitt)
- Afterschool Care Association (Tia Campbell)
- Daycare Association (Matt Benedetti)
- Virginia School Nurses (Becky Bowers Lanier)
- Virginia EMS Council (Ed Rhodes)
- Medical Society of Virginia (Tyler Cox)
- Virginia Academy of Nutrition and Dietetics (Andrew Lamar)

Appendix B: Anaphylaxis Data from the Virginia Department of Health's Office of Emergency Medical Services

Frequencies for FY14 (7/1/13 to 6/30/14)							
EMS Region	**Population Estimate for 2013**	**All 911 (Treated) Events**	**Anaphylactic Reaction**	**Any Epi Given**	***Epinephrine 1:1000***	***Epi-Pen Adult***	***Epi-Pen Junior***
Blue Ridge	256,455	45,542	485	22	*19*	*3*	*1*
Central Shenandoah	291,649	60,210	621	71	*42*	*30*	*3*
Lord Fairfax	228,087	33,827	218	25	*14*	*13*	*0*
Northern Virginia	2,388,316	206,517	2,438	361	*349*	*9*	*3*
Old Dominion	1,398,792	233,598	2,111	182	*148*	*30*	*5*
Peninsulas	623,676	75,401	709	57	*44*	*11*	*3*
Rappahannock	504,372	66,025	627	78	*72*	*4*	*2*
Southwest Virginia	395,939	81,468	418	34	*31*	*3*	*0*
Thomas Jefferson	254,064	42,381	542	65	*51*	*15*	*1*
Tidewater	1,214,817	206,709	1,129	113	*102*	*9*	*4*
Western Virginia	704,238	122,575	987	62	*42*	*17*	*4*
Total (Statewide)	*8,260,405*	*1,174,253*	*10,285*	*1,070*	*914*	*144*	*26*

Rates for FY14 (7/1/13 to 6/30/14)				
EMS Region	**911 (Treated) Events/100K**	**Anaphylaxis Events/100K**	**Anaphylaxis/100K Events**	**Epi Given/1K Anaphylaxis Events**
Blue Ridge	1,776	19	5	45
Central Shenandoah	2,064	21	12	114
Lord Fairfax	1,483	10	7	115
Northern Virginia	865	10	17	148
Old Dominion	1,670	15	8	86
Peninsulas	1,209	11	8	80
Rappahannock	1,309	12	12	124
Southwest Virginia	2,058	11	4	81
Thomas Jefferson	1,668	21	15	120
Tidewater	1,702	9	5	100
Western Virginia	1,741	14	5	63
Total (Statewide)	1,422	12	9	104

Epinephrine 1:1000 - This is a high concentration form of the drug often administered subcutaneously by EMTs for treating allergic reactions. It is not available as an auto-injector.

Epi-Pen Adult and Epi-Pen Jr. are auto-injectors that contain a pre-determined single dose of epinephrine that is administered intramuscularly or subcutaneously into the thigh.

Anaphylaxis Events/100K - Allergic reactions per 100,000 population.
Anaphylaxis /100K Events - Allergic reactions per 100,000 EMS events
Epi Given/1K Anaphylaxis Events - Epinephrine administration per 1,000 Anaphylaxis Events

This data does not include instances where an individual who was experiencing anaphylaxis may have been administered epinephrine, in any form, prior to EMS arrival.

Frequencies for FY14 (7/1/13 to 6/30/14) -- Anaphylaxis Events by Location Type

EMS Region	Total	Airport	Farm	Health Care Facility (clinic, urgent Care Ctr,hospital)	Home/ Residence	Industrial Place and Premises	Lake, River, Ocean	Other Location
Blue Ridge	485	0	0	35	331	5	0	12
Central Shenandoah	621	0	0	49	361	10	1	9
Lord Fairfax	218	0	1	36	112	5	0	8
Northern	2,438	49	1	312	1,060	15	2	68
Old Dominion	2,111	3	3	186	1,311	12	0	24
Peninsulas	709	0	0	48	446	8	1	15
Rappahannock	627	0	0	73	343	2	0	7
Southwest	418	0	0	30	278	3	0	5
Thomas Jefferson	542	0	1	29	336	2	1	11
Tidewater	1,129	7	2	131	639	17	6	24
Western	987		1	90	674	4		9
Total (Statewide)	*10,285*	*59*	*9*	*1,019*	*5,891*	*83*	*11*	*192*

Continued: Frequencies for FY14 (7/1/13 to 6/30/14) -- Anaphylaxis Events by Location Type

EMS Region	Place of Recreation or Sport	Public Building (schools, gov, offices)	Residential Institution (nursing home, jail/prison)	Street or Highway	Trade or Service (Business, bars, restaurants, etc.)	Unspecified place	Not Available
Blue Ridge	3	47	9	13	34	1	1
Central Shenandoah	1	85	23	20	62	1	0
Lord Fairfax	7	21	7	10	11	0	0

EMS Region	Place of Recreation or Sport	Public Building (schools, gov, offices)	Residential Institution (nursing home, jail/prison)	Street or Highway	Trade or Service (Business, bars, restaurants, etc.)	Unspecified place	Not Available
Northern	27	617	38	81	173	4	4
Old Dominion	25	256	65	85	145	3	0
Peninsulas	19	94	15	13	38	2	10
Rappahannock	9	103	22	23	45	0	2
Southwest	1	26	25	16	32	2	0
Thomas Jefferson	10	71	15	26	40	1	0
Tidewater	9	148	40	31	76	0	
Western	11	80	39	26	52		1
Total (Statewide)	*122*	*1,548*	*298*	*344*	*708*	*14*	*18*

Appendix C: Memorandum of Comparative Analysis of Epinephrine Auto-Injector Use Expansion Legislation in Other States

During the consideration of SB1167 in Virginia, proponents identified two states with similar existing laws – Rhode Island and Florida, both of which were enacted in 2014. These laws outline various authorizations, training requirements, liability protections and, in Rhode Island's case, incident reporting requirements. Oregon, North Dakota and Maryland utilize a different statutory framework for ensuring the availability of epinephrine in emergency situations in non-school settings, one that is focused on a trained individual rather than an authorized entity.

In 2015, 14 states joined Rhode Island and Florida in enacting legislation that authorizes trained laypersons, in connection with certain authorized entities, to administer epinephrine auto-injectors to persons believed to be experiencing an anaphylactic emergency. Those states were Arkansas, Colorado, Georgia, Iowa, Indiana, Kentucky, Maine, Minnesota, Nevada, North Carolina, Oklahoma, Utah, West Virginia and Wisconsin. An additional 5 states – Massachusetts, Michigan, New Jersey, Ohio and Pennsylvania – have similar legislation currently pending, and 13 states – Alabama, Arizona, California, Hawaii, Illinois, Missouri, New Hampshire, New York, Oregon, South Carolina, Vermont, Virginia and Washington – proposed this type of legislation in their 2015 legislative sessions, but did not enact it.

The basic provisions of each of these bills is the same – authorizing certain entities to obtain a prescription of and stock on their premises epinephrine auto-injectors, authorizing health practitioners to provide the prescription, and pharmacists to dispense the prescription. The entity must have a trained employee responsible for oversight of the auto-injectors, and who is authorized to administer it to an individual believed to be experiencing an anaphylactic emergency. The bills all note liability protections and set up the various provisions necessary to carry out the provisions of the bill. However, where these bills differ is in the specific definition of an authorized entity, the training requirements, reporting requirements, and expanded availability provision. Please see the table below for a comparative analysis of all of the passed bills of this nature.

The second column of the below table evaluates whether the term "authorized entity" is defined in the legislation as one in which allergens capable of causing anaphylaxis may be present. In the various states' bills, this definition will often include a few types of entities that would potentially fall under this definition, such as youth camps or sports arenas, but do not limit the definition to those. This list of authorized entities is also often subject to change and regular updating by the state's department of health or commissioner of health.

The last column evaluates whether the bill contains an expanded availability provision. This means that the legislation allows an authorized entity stocking a prescription of epinephrine auto-injectors to make them available for administration by non-trained laypersons if they are stored in a locked, secure container and made available to such individuals for use in a believed anaphylactic emergency upon remote authorization by a health care provider by electronic communication (audio, televideo, etc.).

	Authorized entity is defined as one in which allergens capable of causing anaphylaxis may be present	Training by nationally recognized organization or other entity approved by department, board or commissioner	Training - minimum requirements include recognition of anaphylaxis and administration of epinephrine auto-injector	Training - minimum requirements include storage requirements and follow-up emergency procedures	Authorized entities required to report to the department or board incidents of epinephrine auto-injector administration on their premises	Contains expanded availability provision
RI	✓	✓	✓	✓	✓	✓
FL	✓	✓	✓	X	X	✓
AR	✓	✓	✓	X	✓	X
CO	✓	✓	✓	✓	✓	✓
GA	✓	✓	✓	✓	✓	X
IA	X –"facility" means "a food establishment as defined in section 137F.1, a carnival as defined in section 88A.1, a recreational camp, a youth sports facility, or a sports area"	X – no training requirements; left to be decided in the regulations that are to be adopted to implement this bill	X – no training requirements; left to be decided in the regulations that are to be adopted to implement this bill	X – no training requirements; left to be decided in the regulations that are to be adopted to implement this bill	X	X
IN	X – "entity" is any business, association, or governmental entity, including any branch location of the entity	X – training by a health care provider who is licensed or certified in Indiana, for whom the administration of auto-injectable epinephrine is within the health care provider's scope of practice, who has received training in the administration of auto-injectable epinephrine, and who is knowledgeable in recognizing the symptoms of anaphylaxis and the administration of auto-injectable epinephrine.	✓	X	X	X
KY	✓	✓	✓	X	X	X

	Authorized entity is defined as one in which allergens capable of causing anaphylaxis may be present	Training by nationally recognized organization or other entity approved by department, board or commissioner	Training - minimum requirements include recognition of anaphylaxis and administration of epinephrine auto-injector	Training - minimum requirements include storage requirements and follow-up emergency procedures	Authorized entities required to report to the department or board incidents of epinephrine auto-injector administration on their premises	Contains expanded availability provision
ME	✓	✓	✓	✓	X	X
MN	X	✓	✓	✓	X	X
NV	✓	✓	✓	✓	✓	X
NC	✓	✓	✓	✓	X	X
OK	✓	✓	✓	✓	X	✓
UT	X – "qualified entity" means a facility or organization that employs, contracts with, or has a similar relationship with a qualified adult who is likely to have contact with another person who may experience anaphylaxis	X – local health department or local EMS director designates what entities approved to provide this training	✓	✓	X	X
WV	✓	✓	✓	X	X	X
WI	✓	✓	✓	✓	X	X