



ERIK SEVERSON

STATE REPRESENTATIVE • 28TH ASSEMBLY DISTRICT

Testimony on Assembly Bill 502 Assembly Committee on Health

January 22, 2014

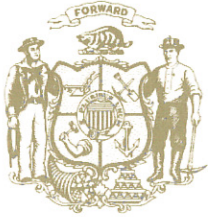
I would like to thank the members of the committee for attending this hearing on Assembly Bill 502, and Senator Vukmir for her leadership on this important issue.

This legislation allows school districts to keep epinephrine auto-injectors on site with a prescription from a health care professional. By passing Assembly Bill 502, we can ensure that children who may be unaware of an allergy or who have forgotten their epinephrine auto-injector have access to this medication as quickly as possible.

Assembly Bill 502 does require School Boards to establish a plan for administering epinephrine and establish training for school employees to administer the drug. These plans must be established in conjunction with a physician to ensure that teachers and other school employees are able to quickly and safely administer epinephrine during a life threatening allergic reaction.

As originally drafted, Assembly Bill 502 unintentionally repealed current law provisions related to school bus operators, school employees, and school volunteers administering epinephrine auto-injectors. This oversight has been corrected in Assembly Amendment 1. This amendment also clarifies that the provisions of Assembly Bill 502 are independent of the authority under current law with regards to students self-administering he or she is experiencing a severe allergic reaction.

As an update for committee members, the companion, Senate Bill 375 was approved by the Senate Committee on Education and is scheduled to be taken up by the Senate later today. Thank you again members for attending this public hearing and I look forward to working with you on the passage of this legislation.



LEAH VUKMIR
STATE SENATOR

Assembly Committee on Health

PUBLIC HEARING / ASSEMBLY BILL 502

January 22, 2013⁴

Mr. Chairman and committee members, thank you for giving Assembly Bill 502 a Public Hearing today. As many of you know, anaphylaxis, which can be caused by food allergies, drug allergies, or even a bee sting, are a real concern for many Wisconsinites. Thankfully, there is a safe and simple solution, epinephrine auto-injectors, or epi-pens.

As you can imagine, the school environment provides endless opportunities for anaphylaxis to threaten students and their health. Given these threats and the availability of epinephrine auto-injectors, AB 502 seeks to ensure that epi-pens can be used in every school to combat this public health challenge.

AB 502 would create a process that enables schools to maintain epinephrine auto-injectors and authorize their use by a trained school official under a physician-approved protocol. This includes the use of an epinephrine auto-injector for persons that do not have a prescription for an auto-injector in the case of an emergency. By allowing both public and private schools to establish a protocol and train school staff and volunteers, school districts will be empowered to save lives and make a difference in their student's health.

Assembly Amendment 1 restores the "Good Samaritan" protections put in place last session and deletes references to "nurse" because a number of schools simply don't have a school nurse.

In the Senate, I have introduced a second amendment that would clarify that you are required to call 911 in all instances. It also provides an exemption from the training requirement for licensed health care providers and deletes the reporting requirement included in the bill.

Assembly Bill 502 is common sense legislation that can make an important difference in our schools. It provides a simple process that would allow schools to put in place a physician approved protocol and empower trained staff and volunteers to address a pressing public health concern and make our schools safer. Thank you for your time this morning and your consideration of AB 502. I hope you can support its passage here in committee.



DATE: Wednesday, January 22, 2014
TO: Representative Severson, Chair
Members, Assembly Committee on Health
FROM: Pharmacy Society of Wisconsin
Anna Legreid Dopp, PharmD, Vice President of Public Affairs

SUBJECT: The use of an epinephrine auto-injector on school premises or at a school-sponsored activity (Assembly Bill 502)

Pharmacy Society of Wisconsin Position: Support

Thank you for the opportunity to provide feedback on Assembly Bill 502 (AB 502), which address the possession and use criteria of an epinephrine auto-injector while on school premises or at a school-sponsored activity. Evidence suggests that the prevalence of allergies and food allergies in school-age children is increasing. In the setting of allergic anaphylaxis, epinephrine is the primary medical therapy; delays in epinephrine administration in these patients is associated with increases in mortality.

Nearly 20% of epinephrine auto-injector administrations occur on school premises.ⁱ In a survey of epinephrine administration on school premises, approximately 25% of recipients had no previous diagnosis of allergy.ⁱⁱ It is with this knowledge that the Pharmacy Society of Wisconsin (PSW) supports efforts to increase access to epinephrine on school premises whether it is patient-specific or designated for school supply.

We would like to take this opportunity to encourage bill authors and cosponsors to consider the complexities in the administration of epinephrine as AB 502 moves through the legislative process. For example, epinephrine dosing is weight-based and thus school-age children will fall into one of two different dosing regimens. We request that the decision making processes as outlined in AB 502 will require policies to clearly delineate dosing decisions and epinephrine storage and administration considerations (i.e. checking product expiration on an annual basis).

PSW offers to be engaged in discussions surrounding these policy discussions during AB 502 legislative action and law implementation.

The Pharmacy Society of Wisconsin (PSW) is a nonprofit professional association representing nearly 3400 pharmacists, pharmacy technicians, and student pharmacists in the state of Wisconsin. We seek to improve the health outcomes and well-being of patients in Wisconsin, to serve as a unified voice for our members and the practice of pharmacy, and to advance the pharmacy profession.

ⁱ Nowak-Wegrzyn A, Conover-Walker MK, Wood RA. Food-allergic reactions in school and preschools. Arch Pediatr Adolesc Med 2001;155:790-5.

ⁱⁱ McIntyre CL, Sheetz AH, Carroll CR, Young MC. Administration of epinephrine for life-threatening allergic reactions in school settings. Pediatrics 2005;116:1134-40.



WASN

Wisconsin Association of School Nurses

Testimony to the Assembly Committee on Health Regarding AB 502, Relating to the Use of Epipens in School Settings and Activities

January 22, 2014

The Wisconsin Association of School Nurses (WASN) appreciates the heightened awareness surrounding the management of life-threatening allergies in the school setting as reflected in Assembly Bill 502. WASN thanks Chairman Severson for his leadership on this important topic. We believe many of the provisions in AB 502 should be incorporated into the Wisconsin Statutes.

When AB 502, and its companion, SB 375, was first introduced, WASN reviewed the proposal closely. We determined that we could not support the bill as drafted. We offered a statement, which was sent to the bill's authors, requesting three changes. Assembly Amendment 1 would incorporate one of our three requested changes into the bill. It would reinstate the requirement that 911 be called when epinephrine is administered by staff. Assembly Amendment 1 is identical to Senate Amendment 1 to Senate Bill 375, which was adopted by the Assembly Committee on Education.

Unfortunately, amendments have not been drafted to address our other two concerns. For that reason, WASN continues to oppose AB 502. The other requested changes are:

1) It should be a requirement that the medication administration training be approved by the Department of Public Instruction (DPI), as it is under current law. The DPI approval ensures that everyone who will be administering medications receives consistent high-quality training that leads to safe delivery of medications. AB 502 would remove this important safeguard for administration of epipens under the statute created by the bill. This will lead to confusion and dangerous situations.

During consideration of SB 375 in the Senate, WASN was told that an acceptable alternative to DPI approval might be to amend the statutes to specify the elements of quality training. We drafted a statement saying that the following elements should be included:

- That the school district's policy or plan and/or individual student's anaphylaxis plan must be followed (each district may be different as to who can give the injector, where the injectors are kept, how to call for help).
- When to administer an auto-injector -- signs and symptoms of anaphylaxis.
- Who may receive an epinephrine auto-injector -- age, weight, junior vs. adult dosage.
- How to give an epinephrine auto-injector (skill check -- demonstration and return demonstration -- done with demos) -- injection site, mechanics of injector, how to dispose of injector.

- Proper care of the victim.
- That 911 must be dialed.
- What to do if EMS has not arrived within 10-15 minutes of administering an epipen, or symptoms continue/return.

WASN has shared this information with the Senate.

2) **It should be a requirement that a school nurse or school nurses have a role in developing a school district's policy, as is the case under current law.** Section 118.29 currently requires a school board to "seek the assistance of one or more school nurses" in developing its policy for the administration of drugs to pupils and emergency care.

The new statute created in AB 502, 118.2925, does not include a role for school nurses in developing and/or implementing the policy. This will cause further confusion and again lead to dangerous situations.

An Alternative: Amend Current Law to Encourage Stocking of Epinephrine

While WASN will continue to advocate for our three requested amendments to AB 502, we feel we must point out that the legislation will inevitably lead to duplication and confusion in the statutes. If this legislation is adopted, we will be left with three separate and sometimes conflicting statutes relating to the administration of epipens in schools.

An alternative to the language in AB 502 would be to simply amend "Written Policies" (118.29(4)) to encourage schools to include in their medication policies a policy that allows the stocking of epinephrine auto injectors to be used in the event of a student experiencing a severe allergic reaction, including anaphylaxis, that requires the administration of epinephrine to avoid severe injury or death. It could require that this provision be approved by a physician.

Language could also be added to existing law making it clear that prescriptions can be made in the name of the school for the purpose of stocking.

This would connect the language directly with current law and rules, which already authorize school personnel to administer epinephrine (with DPI-approved training), allows pupils to self-administer epipens, and requires a physician to serve as medical advisor for nursing services.

Assembly Committee on Health
January 22, 2014

Wisconsin Department of Public Instruction
Testimony on 2013 Assembly Bill 502

I want to thank Chairman Severson and members of the committee for the opportunity to testify before you today on Assembly Bill 502 (AB 502). My name is Jennifer Kammerud and I am the legislative liaison for the Department of Public Instruction and am here today to testify in opposition to AB 502 due to concerns over student safety.

AB 502 would create a new section of statutes related solely to the use of epinephrine auto-injectors. It would allow schools who adopt a management plan for life-threatening allergies to provide epinephrine auto-injectors to students and administer an auto-injector to a student regardless of whether there is a prescription on file for that student.

The department's two main concerns with the bill revolve around the requirement to call 911 and consistency with current law surrounding training. I want to thank Representative Severson for offering Assembly Amendment 1 to AB 502, which would reinstate the requirement to call 911.

The department remains opposed to the bill, however, due to a lack of minimal training requirements for school staff. This could lead to confusion by school staff regarding procedures to follow and lead to harmful situations as a result. \

Current law requires DPI approved training of school staff who will be administering injected, inhaled, and rectally administered medications, along with medications administered through nasogastric, gastrostomy, and jejunostomy tubes, as these are more invasive types of medication administrations.

The department does not seek to approve training plans under this bill. Rather, the department would like to see the following minimal training elements that are currently required by the state for the aforementioned types of medication administration included as part of any board approved plan under the bill to ensure a consistency of care:

1. Knowing when to give auto-injector- Signs and symptoms of anaphylaxis.
2. Knowing who may receive an epinephrine auto-injector—age, weight, junior vs. adult dosage.
3. How to give an epinephrine auto-injector (with an in-person skill check, demonstration and return demonstration)—including injection site, mechanics of injector, how to dispose of injector.
4. Care of the victim.

The medicine contained in an auto-injector is emergency medication meant to keep a student from an anaphylactic reaction or treat the reaction until further medical attention can be received. When this medicine wears off the life-threatening reaction can return. It is critical that the medication is administered correctly and the right dosage is given as the auto-injector dosage used is based on weight. If the wrong dosage is used emergency attention needs to be received immediately.

The department is asking that AB 502 be amended to include these minimal requirements and make it clear that the state is not lowering the medication administration standard for care in current law.

Thank you for the opportunity to testify and I would be happy to answer any questions at this time.

TESTIMONY OF

Colin Chiles
Director, State Government Relations
Mylan Inc.

Good morning. Thank you for the opportunity to speak with you today.

My name is Colin Chiles and I am the Director of State Government Relations for Mylan Inc. Mylan is a leading U.S. based manufacturer of generic and specialty medications. We have operations in eight states, as well as Puerto Rico, and provide generic medicines in more than 140 countries and territories worldwide.

Food allergies, which can sometimes lead to a life-threatening allergic reaction, or anaphylaxis, are a large and growing public health problem.^{1,3} Today, an estimated one out of 13 children in the U.S. has a food allergy, a considerably higher number than previously known.²

We support AB 502 which will ensure that Wisconsin schools can be well prepared in the event a student experiences an anaphylactic reaction at school. Schools are a critical component in the effort to increase access to epinephrine auto-injectors for those at risk from food and other allergies. Thirty-one states currently allow (or require) schools to stock and administer epinephrine auto-injectors in schools and three additional states have legislation that has already passed in one chamber of their Legislature. Thank you for considering AB 502 and your interest in adding Wisconsin to this growing list of states.

Schools nationwide have made efforts to reduce exposure to allergens in the school environment—a critical first step in managing the risk of life-threatening allergic reactions. While practicing allergen avoidance is imperative, accidental contact can still happen, which is why it is important that epinephrine auto-injectors are accessible.

Over the past two years, there have been tragedies at schools around the country that resulted in the death of a student from anaphylaxis from exposure to an allergen. Deaths in Illinois (in 2011) and Virginia (in 2012) resulted in significant attention to the issue and much discussion on how to best address it. Sixteen states have already signed legislation into law this year and the Michigan Legislature sent a bill to the Governor just last week that is very similar to the legislation we are here to support today.

In the last several months, the American Red Cross launched a training program on anaphylaxis and administration of epinephrine auto-injectors, and the U.S. Centers for Disease Control and Prevention issued voluntary guidelines for managing food allergies in schools. Oregon now allows entities like restaurants and summer camps to stock and administer epinephrine auto-injectors and New York

State allows summers camps to stock and administer epinephrine auto-injectors. Much progress is being made in the effort to prevent tragedies from food and other allergens.

A Mylan subsidiary, Mylan Specialty, markets and distributes one of several epinephrine auto-injectors in the United States. Mylan Specialty has long-standing relationships with a number of leading patient advocacy organizations, working closely on educational and awareness efforts relating to food and other allergies and anaphylaxis. We look forward to working with this committee, the Legislature and school officials as you work to address this important issue.

In December 2010, the National Institute of Allergy and Infectious Diseases (NIAID), a division of the National Institutes of Health (NIH), introduced the "Guidelines for the Diagnosis and Management of Food Allergy in the United States." These guidelines state that epinephrine is the first-line treatment for anaphylaxis.⁵ Epinephrine works to relieve the life-threatening symptoms of anaphylaxis, giving affected individuals more time to seek additional emergency medical treatment.⁶

The more rapidly anaphylaxis develops, the more likely the reaction is to be severe and potentially life-threatening. Prompt recognition of signs and symptoms of anaphylaxis is crucial. If there is any doubt, it is generally better to administer epinephrine.⁷ Failure to administer epinephrine early in the course of treatment has been repeatedly implicated with anaphylaxis fatalities.

The NIH-NIAID guidelines also state that antihistamines are not effective in treating the symptoms of anaphylaxis. The use of antihistamines is the most common reason reported for not using epinephrine and may place a patient at significantly increased risk for progression toward a life-threatening reaction.⁵

In 2011, the Illinois Legislature passed legislation to allow schools to stock epinephrine auto-injectors for use in response to an anaphylactic emergency and in 2012, the Virginia, Maryland and Louisiana Legislatures passed legislation that requires schools to stock epinephrine auto-injectors for use in response to an anaphylactic emergency. School nurses and other trained personnel are authorized to administer epinephrine auto-injectors to any student who they believe is experiencing an anaphylactic reaction.

Massachusetts addressed this issue more than a decade ago following the deaths of two students while Missouri and Kansas passed legislation more recently. Georgia passed legislation this year to allow school personnel to administer epinephrine auto-injectors and Rhode Island passed legislation to allow school bus drivers and monitors to administer epinephrine auto-injectors.

To our knowledge, every state, including Wisconsin, now allows students who have been prescribed an epinephrine auto-injector to bring their auto-injector to school although the rules may vary among school districts. Unfortunately, some children who are at risk have never been diagnosed and do not

know they could be subject to an anaphylactic reaction. Massachusetts compiles a report each year of administrations of auto-injectors in their schools. According to the Massachusetts Department of Public Health, a survey conducted in 109 Massachusetts school districts from 2001 to 2003 evaluating the use of epinephrine for anaphylaxis management in schools, found that up to 24% of anaphylactic reactions occurred in individuals who were not known by school personnel to have a prior history of life-threatening allergies. This number is particularly disturbing.

Mylan is committed to working with states on this going forward. That is why I am pleased to have the opportunity to speak with you today. We learned through our discussions with Massachusetts and Illinois officials that cost of epinephrine auto-injectors presented a challenge to school budgets. As a result, we created a program to provide up to four free epinephrine auto-injectors per school year, upon qualification, which includes having a valid prescription, to public and private kindergarten, elementary, middle and high schools in the U.S.

We are pleased that more than 30,000 schools have already taken advantage of this program. There have been a number of situations where schools across the country have used these free epinephrine auto-injectors to treat an anaphylactic reaction, underscoring the positive impact of the program. We will continue to work with stakeholders including physicians, allergy advocacy organizations, school officials, school nurses, the American Red Cross and others to learn more about the ways to address potentially life-threatening food allergies and anaphylaxis in the schools.

There are a number of important statistics that have been cited with regard to food allergies and anaphylaxis, but I would like to mention just four key points here:

- Nearly 6 million or 8% of children in the U.S. have food allergies (~ one in 13).²
- The Centers for Disease Control and Prevention report that food allergies result in more than 300,000 ambulatory-care visits a year among children under the age of 18.¹⁰
- Food allergens account for 30% of fatal cases of anaphylaxis.⁷
- Anaphylaxis results in approximately 1,500 deaths annually.¹¹

My colleagues and I at Mylan would like to work with you to ensure that Wisconsin schools are prepared to address anaphylaxis so that emergencies do not turn into tragedies. As I already mentioned, Mylan currently offers a program to help schools address the cost issue associated with stocking of epinephrine auto-injectors and we continue to look for additional ways that we can help.

Thank you for your time and your consideration today. I would be pleased to take any questions and to work with the committee and other interested parties as you consider this legislation.

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People with Life-Threatening Allergies Need to be Better Prepared

The Issue

There is a growing rate of life-threatening allergic reactions, or anaphylaxis, in the U.S., creating a public health concern and a major safety issue. Estimates indicate that anaphylaxis causes approximately 1,500 deaths annually.¹ Children and adolescents are among those most at risk for anaphylaxis.²

Food allergies are the most common cause of anaphylaxis, and the prevalence of food allergies is on the rise.^{3,4} Today, food allergies affect an estimated one out of 13 children in the U.S., a considerable increase from previously reported figures.⁵

Schools nationwide have made efforts to reduce exposure to allergens in the school environment—a critical first step in managing the risk of life-threatening allergic reactions. While practicing allergen avoidance is imperative, accidental contact can still happen, which is why it is important that epinephrine auto-injectors are accessible.^{4,6}

MORE AMERICANS NEED TO

- be **AWARE** of the risk of anaphylaxis,
- understand the signs and symptoms of anaphylaxis,
- be **PREPARED** to respond when anaphylaxis occurs and
- have immediate **ACCESS** to epinephrine auto-injectors.

Epinephrine is the First-line Treatment for Anaphylaxis⁷

According to food allergy guidelines released in December 2010 by the National Institute of Allergy and Infectious Diseases (NIAID), a division of the National Institutes of Health (NIH), epinephrine is the only first-line treatment in all cases of anaphylaxis (including from food allergies) and should be available at all times for people at risk for anaphylaxis. According to the NIAID guidelines, if experiencing anaphylaxis, a person should use an epinephrine auto-injector and seek immediate emergency medical attention.

Common side effects of epinephrine may include upset stomach, vomiting, sweating, dizziness, nervousness, weakness, pale skin, headache and shaking, difficulty breathing and pounding, fast, or irregular heartbeat.⁸

The more rapidly anaphylaxis develops, the more likely the reaction is to be severe and potentially life-threatening. Prompt recognition of signs and symptoms of anaphylaxis is critical.⁹ If there is any doubt, it is better to administer epinephrine. Failure to administer epinephrine early in the course of treatment has been repeatedly implicated with anaphylaxis fatalities.^{9,10,11}

IMMEDIATE ACTION IS NEEDED IN SCHOOLS

Recent tragedies have brought significant attention to the issue of managing anaphylaxis at school and raised much discussion on how to best address the problem.

Following the deaths of two students a decade ago, Massachusetts became the first state to address the issue of anaphylaxis management at school. A survey conducted in 109 Massachusetts school districts from 2001 to 2003 evaluating the use of epinephrine for anaphylaxis management in schools, found that up to **24% of anaphylactic reactions occurred in individuals who were not known by school personnel to have a prior history of life-threatening allergies.**¹³



What is anaphylaxis? (pronounced a-na-fi-LAX-is)

Anaphylaxis is a life-threatening allergic reaction that is rapid in onset and may cause death, either through swelling that shuts off airways or through a significant drop in blood pressure.²

What are the common triggers of anaphylaxis?

Foods, insect stings, medications, latex, other allergens or an unknown trigger.²

What are the most common foods to cause anaphylaxis?

Milk, egg, wheat, soy, peanut, tree nut, fish and shellfish.⁷

Did you know?

- A 2010 study indicated that anaphylaxis results in 90,000 emergency department visits per year for food allergies alone.¹²
- In 2008 the CDC reported that an 18% increase in food allergy was seen between 1997 and 2007.³
- Food allergens account for 30% of fatal cases of anaphylaxis.⁴
- Data on anaphylaxis incidence and prevalence are sparse and often imprecise; however, estimates indicate that anaphylaxis may affect 3 to 43 million Americans. As evidenced by the range provided, more research needs to be conducted.¹



On Dec. 20, 2010, 13-year-old Katelyn Carlson of Chicago, Ill. had a life-threatening allergic reaction to peanut oil from Chinese food ordered for a class party. She was rushed to a nearby hospital and pronounced dead due to anaphylaxis. Katelyn had been previously diagnosed with life-threatening food allergies but did not have an epinephrine auto-injector on hand to administer. As a result, on Aug. 15, 2011, Illinois signed into law the School Access to Emergency Epinephrine Act, permitting access to undesignated epinephrine auto-injectors in Illinois schools for students who suffer from a severe allergic reaction.¹⁴

On Jan. 2, 2012, seven-year-old Amarria Johnson of Chesterfield, Va. died at school after she suffered an allergic reaction to a peanut product. She did not have an epinephrine auto-injector on hand and was in cardiac arrest by the time emergency crews arrived and was pronounced dead shortly after. Amarria's death caused Virginia to make a change. On April 26, 2012, legislation requiring Virginia schools to stock epinephrine auto-injectors for use by school nurses and other trained personnel to administer to any student who they believe is experiencing an anaphylactic reaction became law.¹⁴

These are just a few of the tragic examples that demonstrate why each school should have a comprehensive anaphylaxis action plan,^{15,16,17} so that students, teachers and school employees:

- Understand the risk of anaphylaxis
- Avoid allergic triggers
- Recognize the signs and symptoms
- Are prepared with access to epinephrine auto-injectors (two doses)⁷
- Know to seek emergency medical care following administration of treatment

THE NEED FOR EPINEPHRINE ACCESS ALSO EXTENDS BEYOND SCHOOLS

A first reaction, whether it is from food, an insect sting or medications, can happen anywhere and may be severe enough to cause death.⁴

On Aug. 16, 2011, 15-year-old Jharell Dillard, who had a life threatening allergy to peanuts, went to a shopping center in Atlanta, Ga. with his mother and two sisters. While there, he ran outside to grab a cookie from the car. What he thought was simply a chocolate chip cookie actually contained nuts. He immediately went into anaphylactic shock, and was not carrying his epinephrine auto-injector. By the time he was airlifted to the local children's hospital it was too late. Jharell was pronounced dead due to anaphylaxis.¹⁴

Change in schools means

- Standardizing and implementing guidelines for managing life-threatening allergies in schools
- Allowing schools to maintain a supply of undesignated epinephrine auto-injectors
- Allowing medical professionals and trained non-medical professionals to administer epinephrine auto-injectors to students with or without a prescription on file
- Protecting good samaritans who administer an epinephrine auto-injector in an emergency situation
- Allowing physicians to prescribe epinephrine auto-injectors to an entity, like a school
- Tracking epinephrine auto-injector administration in schools

A number of states have taken action to address anaphylaxis in schools:

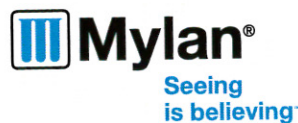
- Examples include: Maryland, Virginia, California, Georgia, Illinois, Kansas, Missouri, Nebraska and Massachusetts¹⁴
- Rhode Island passed legislation to allow school bus drivers and monitors to administer epinephrine auto-injectors¹⁴
- Texas published statewide food allergy guidelines, making it the 15th U.S. state requiring public schools and open-enrollment charter schools to implement strategies for special care of students with food allergies¹⁴

Change beyond schools means

- Allowing for undesignated epinephrine auto-injectors at restaurants, camps and other public venues, including public transportation
- Requiring all emergency first responders to carry epinephrine and to be trained and authorized to administer epinephrine auto-injectors

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(as of Nov. 20, 2012)