

EMERGENCY EPINEPHRINE ACT

PA 97-0361

Physician's Toolkit



*Protecting students
From life-threatening
allergic reactions*

Letter to the Physician

Emergency Epinephrine Act

Standing Order

Prescription for Epinephrine Auto-Injectors

IEMSC Anaphylaxis/Allergic Reaction Protocols

Food Allergy Education Resources

American Academy of Pediatrics
DEDICATED TO THE HEALTH OF ALL CHILDREN[®]
Illinois Chapter



LISA MADIGAN
ILLINOIS ATTORNEY GENERAL

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ILLINOIS ACADEMY OF
FAMILY PHYSICIANS



Illinois
State Board
of Education



Illinois Department of
PUBLIC HEALTH

ILLINOIS DEPARTMENT OF
FINANCIAL & PROFESSIONAL
REGULATION



August 13, 2012

Dear Physician,

We are writing to ask for your help. On August 15, 2011, the Emergency Epinephrine Act, P.A. 97-0361 (the Act) became law in Illinois, permitting schools to stock a supply of epinephrine auto-injectors, authorizing physicians to provide school districts and nonpublic schools with a prescription to obtain the emergency epinephrine auto-injectors from local pharmacists, and giving school nurses the power to administer the epinephrine to any student whom the nurse believes is having an anaphylactic reaction.

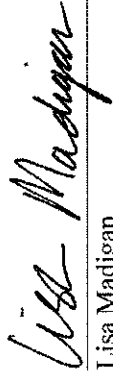
The primary thing stopping school nurses from administering life-saving emergency epinephrine to students is the inability of schools to secure a standing order and prescription for the undesignated epinephrine auto-injectors from a physician. **For the health and safety of Illinois children, we strongly encourage you to fulfill any requests by a school for a standing order and prescription for emergency undesignated epinephrine auto-injectors.** Everything you need is in this packet.

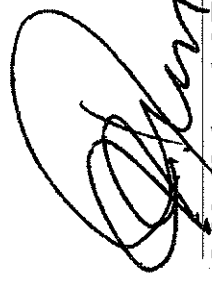
The Illinois Legislature passed this Act in an effort to save the lives of children who, while at school, suffer from anaphylaxis – a severe allergic reaction that can result in death. The leading cause of anaphylaxis in children is food allergies. According to a recent study in *Pediatrics*, one in 13 children suffers from some type of food allergy, and the number is on the rise.¹ For nearly 40% of those children, the allergies are severe and can even be life-threatening.² Food allergies account for over 300,000 hospital visits by children every year,³ and 25% of first time anaphylactic reactions among children occur in school.⁴ These statistics underscore the need to provide access to emergency epinephrine auto-injectors in schools.

We have developed and compiled the enclosed information and forms to assist you in responding to requests from school districts and nonpublic schools. The information included contains an explanation of the Emergency Epinephrine Act, a standardized standing order and prescription form and additional resources that may be provided to school nurses as you deem appropriate.

Thank you in advance for your support. If you have any questions regarding the Emergency Epinephrine Act, P.A. 97-0361, please contact Jessica O'Leary at the Illinois Attorney General's Office at 312-814-1003 or joleary@atg.state.il.us or Craig Conover, MD at the Illinois Department of Public Health at 312-814-4846 or craig.conover@Illinois.gov.

Sincerely,


Lisa Madigan
Attorney General



LaMar Hasbrouck, MD, MPH
Director
Illinois Department of Public Health

¹Gupta et al, "The Prevalence, Severity and Distribution of Food Allergy in the United States," *Pediatrics*, June 20, 2011.

²*Id.*

³*Anaphylaxis*, "The Food Allergy & Anaphylaxis Network," retrieved at <http://www.foodallergy.org/section/a>.

⁴Sicherer et al, "Clinical Report - Management of Food Allergy in the School Setting," *Pediatrics*, December 1, 2010.

Emergency Epinephrine Act

Public Act 97-0361

■ THE LAW

The Emergency Epinephrine Act (the Act), found within the Illinois School Code, 105 ILCS 5/1-1 et seq., specifically authorizes physicians licensed in Illinois to "...prescribe epinephrine auto-injectors in the name of a school district or nonpublic school to be maintained for use when necessary." 105 ILCS 5/22-30(f).

Once the school district or nonpublic school has a prescription, it may take that prescription to be filled at any pharmacy. School districts and nonpublic schools must maintain this supply of epinephrine auto-injectors in a secured, locked location. 105 ILCS 5/22-30(f).

The Act permits this **emergency supply** of epinephrine auto-injectors to be used in a school under three circumstances:

- 1. Administration of an epinephrine auto-injector to a student, with an unknown allergy, having a first-time anaphylactic reaction**
 - "When a student does not have an epinephrine auto-injector or a prescription for an epinephrine auto-injector on file, [Section 22-30(f) of the Illinois School Code provides that] the school nurse may utilize the school district or nonpublic school supply of epinephrine auto-injectors to respond to anaphylactic reaction, under a standing protocol from a physician licensed to practice medicine in all its branches and the requirements of this Section." 105 ILCS 5/22-30(f).
 - A school nurse may administer an epinephrine auto-injector, as provided for in the standing protocol, to any student that he or she "...in good faith professionally believes is having an anaphylactic reaction." 105 ILCS 5/22-30(b-10)(iii).
- 2. Self-administration of an epinephrine auto-injector by a student with a known allergy who has forgotten his or her auto-injector or it is otherwise unavailable**
 - Section 22-30(f) of the Illinois School Code authorizes school districts and nonpublic schools to provide a student with an epinephrine auto-injector for self-administration, provided the supplied auto-injector meets the student's personal prescription on file with the school. 105 ILCS 5/22-30(f).
- 3. Administration of an epinephrine auto-injector to a student with a known allergy**
 - Section 22-30(f) of the Illinois School Code permits "...any personnel authorized under a student's Individual Health Care Action Plan, Illinois Food Allergy Emergency Action Plan and Treatment Authorization Form, or plan pursuant to Section 504 of the federal Rehabilitation Act of 1973 to administer an epinephrine auto-injector to the student [having an anaphylactic reaction], that meets the [student's] prescription on file." 105 ILCS 5/22-30(f).

■ LIABILITY PROTECTION

The Act provides specific liability protections regardless of whether a student has a prescription for epinephrine on file with the school.

If a parent or guardian provides his or her child's school with a prescription for epinephrine:

The school district or nonpublic school must inform the parents or guardians of the pupil, in writing, that the school district or nonpublic school and its employees and agents, **including a physician providing standing protocol or prescription for school epinephrine auto-injectors**, are to incur no liability, except for willful and wanton conduct, as a result of any injury arising from the self-administration of medication or use of an epinephrine auto-injector regardless of whether authorization was given by the pupil's parents or guardians or by the pupil's physician, physician's assistant, or advanced practice registered nurse. 105 ILCS 22-30(c) [Emphasis added.]

The parent or guardian must sign a statement acknowledging this release of liability.

If a student does not have a prescription for epinephrine on file with the school and the:

...school nurse administers an epinephrine auto injector to a student whom the school nurse in good faith professionally believes is having an anaphylactic reaction, notwithstanding the lack of notice to the parents or guardians of the pupil or the absence of the parents or guardians signed statement acknowledging no liability, except for willful and wanton conduct, the school district or nonpublic school and its employees and agents, **including a physician providing standing protocol or prescription for school epinephrine auto injectors**, are to incur no liability, except for willful and wanton conduct, as a result of any injury arising from the use of an epinephrine auto injector regardless of whether authorization was given by the pupil's parents or guardians or by the pupil's physician, physician's assistant, or advanced practice registered nurse. 105 ILCS 22-30(c) [Emphasis added.]

In addition, physicians should check with their professional liability insurer for coverage information specific to their personal policy.

■ NOTE TO PUBLIC HEALTH PHYSICIANS

The Public Health Standing Orders Act, 410 ILCS 125/1 *et seq.*, does not prevent or limit public health physicians from writing a prescription and standing order for a school district or nonpublic school. Authority to issue the prescription and order arises strictly under the Emergency Epinephrine Act.

**Standing Order for the Administration of
School Supplied (Undesignated) Epinephrine
Auto-Injectors for Potentially Life-Threatening
Allergic Reactions (Anaphylaxis) in Individuals
Pursuant to Public Act 97-0361**

ISSUED TO:

NAME OF SCHOOL DISTRICT (PUBLIC) OR NAME OF SCHOOL (NONPUBLIC)

STREET ADDRESS

CITY, ZIP CODE

STANDING ORDER:

Any Registered Nurse working within the Illinois school system (school nurse) may administer epinephrine via an undesignated epinephrine auto-injector to a student who in the school nurse's professional judgment is experiencing a potentially life-threatening allergic reaction. The school nurse must be licensed to practice under the Nurse Practice Act, 225 ILCS 65/50-1 *et seq.*

ASSESSMENT:

The possibility of an allergic anaphylactic reaction will be considered when individuals present with any of the following symptoms, or any combination thereof: The sudden onset of shortness of breath, wheezing, repetitive cough, difficulty swallowing, obstructive swelling of the tongue or throat, hoarse voice, confusion, pallor, cyanosis, syncope, skin symptoms such as diffuse or patchy itching and/or wheals, or intestinal symptoms such as cramping abdominal pain and/or vomiting, or any combinations of possible allergic symptoms arising from other parts of the body, in the absence of what a health professional would consider to be a probable alternative cause.

IMPLEMENTATION AND PHYSICIAN ORDER:

The school nurse will assess the student's symptoms and history. If, in the reasonable opinion of the school nurse, a potentially life-threatening allergic reaction is likely, the school nurse will obtain the undesignated epinephrine auto-injector.

The school nurse will ask or estimate the student's body weight and administer 0.15mg epinephrine via auto-injector for body weight less than 55 lbs (25kg) or 0.3mg epinephrine via auto-injector for body weight greater than 55 lbs (25kg). The epinephrine auto-injector will be injected intramuscularly in the lateral thigh; the time of injection will be noted and the anatomical site of the injection shall be marked with a permanent marker to alert emergency services personnel of its location.

In every case, emergency services will be contacted as soon as possible using available 911 or other municipal service. The student's emergency contacts will be called.

The school nurse will monitor the student for changes in his or her symptoms and will attempt to make the person as comfortable as possible.

If the student's symptoms are not substantially relieved in 3-5 minutes, or if they recur, the school nurse may administer a second dose of epinephrine.

The school nurse will advise the emergency services personnel of the symptoms that required the use of epinephrine, the dose of epinephrine, the anatomical site of the injection, the time administered, and any change in the symptoms or condition of the student. The used epinephrine auto-injector will be given to the emergency services personnel.

The school nurse or other school personnel will accompany the student in the ambulance if required by school policy and as permitted by the local Emergency Medical Services System protocol.

QUALITY ASSURANCE:

The school nurse will complete a written report detailing the name of the student, all of his/her observations, physical assessments, interventions (together with the results of such interventions), the number and dosage of epinephrine administrations, the anatomical injection sites, and times for each. The completed written report shall be signed by the school nurse and submitted to the physician signing this order and the student's primary care physician, if known, within 48 hours.

EXPIRATION AND DISPOSAL OF UNUSED AUTO-INJECTORS:

The school nurse shall check the expiration date located on the undesignated epinephrine auto-injectors monthly and obtain a new prescription for a replacement auto-injector prior to that expiration date.

The school nurse shall dispose of an expired unused epinephrine auto-injector in a manner consistent with current school medication policies or return to the issuing pharmacy for disposal. An inventory log shall be kept by the school nurse indicating the date of receipt of an undesignated epinephrine auto-injector and the date of administration or disposal of the auto-injector.

EFFECTIVE DATE: _____

RENEWAL DATE
(One year from effective date): _____

PHYSICIAN SIGNATURE: _____

PHYSICIAN NAME *(Printed)*: _____

PHYSICIAN CONTACT NUMBER: _____

PHYSICIAN LICENSE NUMBER: _____

Prescription for Undesignated Epinephrine Auto-Injectors for School Use Pursuant to Public Act 97-0361

■ **PHYSICIAN:**

NAME _____
STREET ADDRESS _____
CITY, ZIP CODE _____
PHONE NUMBER _____
DEA NUMBER _____

■ **ISSUED TO:**

NAME OF SCHOOL DISTRICT (PUBLIC) OR NAME OF SCHOOL (NONPUBLIC) _____
STREET ADDRESS _____
CITY, ZIP CODE _____

_____	0.15mg Epinephrine Auto-Injector(s)
_____	0.3mg Epinephrine Auto-Injector(s)

■ **INSTRUCTIONS:**

To be administered, as needed, to a student exhibiting symptoms of anaphylaxis in accordance with the "Standing Order for the Administration of School Supplied (Undesignated) Epinephrine Auto-Injectors for Potentially Life-Threatening Allergic Reactions (Anaphylaxis) in Individuals Pursuant to Public Act 97-0361."

Must be administered by a school nurse unless an Individual Health Care Action Plan, Illinois Food Allergy Emergency Action Plan and Treatment Authorization Form, or plan pursuant to Section 504 of the federal Rehabilitation Act of 1973 for the student is on file with the school.

DATE ISSUED _____ PHYSICIAN SIGNATURE _____



Protecting Students From Life-Threatening Allergic Reactions

Fatal Allergies Among Children Increasing

One in 13 children suffers from some type of food allergy, and the number is on the rise.ⁱ Of those affected, nearly 40% suffer from allergies that are severe and life threatening.ⁱⁱ High school aged children, ages 14-17 years old, are most likely to have a severe food allergy.ⁱⁱⁱ Food allergies are the leading cause of anaphylaxis and account for over 300,000 hospital visits by children every year.^{iv}

25% OF FIRST-TIME ANAPHYLACTIC REACTIONS AMONG CHILDREN OCCUR IN SCHOOL.^v

Access to Epinephrine in Schools

Under Public Act 97-0361 schools *may* maintain a supply of *emergency* epinephrine auto-injectors (EpiPens) for students who have forgotten their EpiPen at home or who do not have a known food allergy. A *school nurse* may administer an EpiPen to *any* student who he or she, in good faith, professionally believes is having an anaphylactic reaction and who does not have an Emergency Action Plan in place.

This Act permits physicians to issue a standing protocol and to prescribe EpiPens to a school district or non-public school to be used, as necessary, by a school nurse. Without this emergency supply, dialing 911 is the only option school personnel have if a student forgets their EpiPen and has an anaphylactic reaction or has a first-time reaction. Any delay in administering epinephrine can be fatal.

Common side effects of using an EpiPen include increased heart rate, sweating, nausea, dizziness, headaches, nervousness, and anxiety.^{vi} However, these side effects pale in comparison to the potentially life-saving benefits of epinephrine in counteracting anaphylaxis until emergency medical help arrives.

SCHOOL ACCESS TO EMERGENCY EPINEPHRINE

PROTECTING THE HEALTH OF CHILDREN WITH LIFE-THREATENING ALLERGIES

The supply of emergency epinephrine allowed under this Act is not intended to replace epinephrine prescribed to students with known allergies. Physicians should still prescribe

epinephrine as appropriate and encourage parents whose children are suffering from a severe allergy to put in place an Emergency Action Plan, an Individual Health Care Plan, or a Section 504 Plan with their child's school.

Exemption From Liability

Under Public Act 97-0361, a physician who provides a standing protocol or prescribes a supply of emergency epinephrine to a school is to incur *no liability*, except for willful and wanton conduct, for any injury arising out of the use of an epinephrine auto-injector.

Therefore, if a student is injured or harmed due to the administration of epinephrine that a physician has prescribed to a school under this Act, the physician will not be held responsible for the injury unless he or she issued the prescription with a conscious disregard for safety.

Questions regarding food allergies and anaphylaxis?

Contact the Food Allergy Initiative at info@faiusa.org or 855-324-9604.

Questions regarding P.A. 97-0361?

Contact Jessica O'Leary at the Illinois Attorney General's Office
at 312-814-1003 or joleary@atg.state.il.us.

ⁱ Gupta et al., "The Prevalence, Severity and Distribution of Food Allergy in the United States," *Pediatrics*, June 20, 2011.

ⁱⁱ *Id.*

ⁱⁱⁱ *Id.*

^{iv} *Anaphylaxis*, The Food Allergy & Anaphylaxis Network, <http://www.foodallergy.org/section/a>.

^v Sicherer et al., "Clinical Report - Management of Food Allergy in the School Setting," *Pediatrics*, Vol. 126, No. 6, December 1, 2010, p. 1232 -1239.

^{vi} Dey Pharma, *Most Common Side Effects*, <http://www.epipen.com/about-epipen/most-common-side-effects>.

STANDING ORDER CERTIFICATION FORM:

Practitioner Name:	
Practitioner Address:	
Practitioner Phone:	
Date:	
<i>Shipment Information</i>	
Recipient Name:	
Recipient Title:	
Recipient Address:	

By signing this Certification form, I certify that, under applicable state law, I may (1) purchase and possess quantities of EpiPen® (epinephrine) or EpiPen Jr® Auto-Injectors (the "Product"), (2) prescribe, furnish and administer the Product to patients, (3) issue standing orders or otherwise delegate to appropriate persons the authority to prescribe, furnish or administer the Product to a student at a School or involved in a School-related activity, and (4) ship, or direct shipment of, quantities of the Product to a School for prescribing, furnishing or administering to a student at the School or involved in a School-related activity.

Practitioner Signature: _____ Date: _____

**CERTIFICATION FORM:
Free EpiPen® (epinephrine) Auto-Injector EpiPen4Schools® Program**

The school and/or school district identified below (the "School") hereby acknowledges and agrees that the Free EpiPen® (epinephrine) Auto-Injector EpiPen4Schools® Program made available by Mylan Specialty L.P. ("Mylan Specialty") to the School is because it is a school and is conditioned upon the undersigned making this certification to Mylan Specialty.

The School represents and warrants to Mylan Specialty that:

- (i) all of the information provided in this certification is true, complete and accurate;
- (ii) the School will only receive EpiPen® (epinephrine) 0.3mg and EpiPen Jr® (epinephrine) 0.15mg Auto-Injectors in accordance with all applicable laws for use by the School, and the School has presented a valid prescription for the product;
- (iii) the School is an entity whose primary purpose is education for students in grades K through 12 that is licensed as an educational facility under all applicable laws;
- (iv) the School shall make best efforts to provide appropriate product training to any School personnel who may administer an EpiPen® or EpiPen Jr® Auto-Injector;
- (v) the person signing this certification on behalf of the School has the requisite authority to make this certification on behalf of the School identified below;
- (vi) such EpiPen® Auto-Injectors received by the School shall be for its own use and the School shall not sell or transfer any such EpiPen® Auto-Injectors received pursuant to the Free EpiPen® Auto-Injector EpiPen4Schools® Program to a non-school third party, unless the prior written approval of Mylan Specialty, in its sole discretion, is obtained; and
- (vii) any transfer of any quantity of EpiPen® Auto-Injectors received pursuant to the Free EpiPen® Auto-Injector EpiPen4Schools® Program available to schools in violation of this certification will be considered a breach of this certification allowing Mylan Specialty to prohibit the School from receiving EpiPen® Auto-Injectors pursuant to the Free EpiPen® Auto-Injector EpiPen4Schools® Program available to schools.

Please input the number of EpiPen 2-Pak® and/or EpiPen Jr 2-Pak® units below.

Authorized Schools are eligible to receive four EpiPen Auto-Injectors in the form of two EpiPen 2-Pak units; or two EpiPen Jr 2-Pak units; or one of each 2-Pak units.
Total quantity ordered must be no more than two 2-Paks.

Two FREE 2-Pak Units (4 Total EpiPen Auto-Injectors)	Quantity Ordered*	Price
EpiPen 2-Pak® Units		FREE
EpiPen Jr 2-Pak® Units		FREE
Total Quantity Ordered (*must be no more than two 2-Pak Units per school†)		FREE
EpiPen 2-Pak Storage Unit (limit one per school)		FREE



Please check if you would like to receive periodic updates about this program or EpiPen Auto-Injector.

*Please note there are two auto-injectors per EpiPen 2-Pak or EpiPen Jr 2-Pak. Example: if you wish to order 2 EpiPen Auto-Injectors and 2 EpiPen Jr Auto-Injectors, put the number 1 in the Quantity Ordered box next to EpiPen 2-Pak and 1 in the Quantity Ordered box next to EpiPen Jr 2-Pak. If you wish to order 4 EpiPen Jr Auto-Injectors, put the number 2 in the Quantity Ordered box next to EpiPen Jr 2-Pak and 0 (zero) in the Quantity Ordered box next to EpiPen 2-Pak.

† **ORDERING FOR MULTIPLE SCHOOLS:** If you are ordering for multiple schools within a single school district, you may order up to two 2-Pak Units per school. For example, if you are ordering two EpiPen Jr 2-Paks for each of 10 schools, you should enter 20 in the Quantity Ordered column next to EpiPen Jr 2-Pak Units. Under this scenario, your total quantity ordered cannot exceed the number of schools multiplied by 2.

If the terms and conditions provided in this certification are amended, modified or altered in any way, it will be considered null and void.

School/School District Name:	
School Address:	
City/State/Zip:	
School Phone:	
Authorized School Signatory Name:	
Authorized School Signatory Title:	
Authorized School Signatory E-mail:	
Signature:	Date:

Please fax the completed Certification Form and a copy of a valid EpiPen Auto-Injector prescription to BioRidge Pharma, LLC

Attn: Kristina Paich
Fax: 973-718-4328 or e-mail scan to: info@bioridgepharma.com
Phone: 973-845-7600



Protecting Students From Life-Threatening Allergic Reactions Fatal Allergies Among Children Increasing

One in 13 children suffers from some type of food allergy, and the number is on the rise.¹ Of those affected, nearly 40% suffer from allergies that are severe and life threatening.² High school aged children, ages 14-17 years old, are most likely to have a severe food allergy.³ Food allergies are the leading cause of anaphylaxis, a severe allergic reaction that can result in death, and account for over 300,000 hospital visits by children every year.⁴

It is crucial that children with life-threatening allergies have access to emergency epinephrine when anaphylaxis occurs. Epinephrine can save your child's life by opening his or her airways until emergency personnel arrive. Without this emergency supply, dialing 911 is the only option school personnel have if a student forgets his or her EpiPen and has an anaphylactic reaction or has a first-time reaction. Any delay in administering epinephrine can be fatal.

25% OF FIRST-TIME SEVERE ALLERGIC REACTIONS AMONG CHILDREN OCCUR IN SCHOOL.⁵

Access to Epinephrine in Schools

Public Act 97-0361 allows your child's school to maintain a supply of emergency epinephrine auto-injectors for students who have forgotten their EpiPen at home. In addition, a *school nurse* may administer an EpiPen to *any* student suffering from anaphylaxis.

If your child has no known allergies, ask your child's school to obtain an emergency supply of epinephrine auto-injectors for unforeseeable situations. If your child does have severe allergies, ask the school to implement an Emergency Action Plan, an Individual Health Care Plan, or a Section 504 Plan. The supply of emergency epinephrine allowed under this Act is not intended to replace epinephrine prescribed to students with known allergies. We encourage you to work with your school to develop a plan that accommodates your child's needs throughout the school, including in the classroom, in the cafeteria, at after-care programs, during school-sponsored activities, and on the school bus.

Questions regarding food allergies and anaphylaxis?

Contact the Food Allergy Initiative at info@faiusa.org or 855-324-9604.

¹ Gupta et al., "The Prevalence, Severity and Distribution of Food Allergy in the United States," *Pediatrics*, June 20, 2011.

² *Id.*

³ *Id.*

⁴ *Anaphylaxis*, The Food Allergy & Anaphylaxis Network, <http://www.foodallergy.org/section/a>.

⁵ Sicherer et al., "Clinical Report - Management of Food Allergy in the School Setting," *Pediatrics*, Vol. 126, No. 6, December 1, 2010, p. 1232 -1239.