BHM ANAPHYLAXIS PROTOCOL FOR HEALTH SERVICES:

Does the student have signs / symptoms of possible anaphylaxis and was there an exposure to a possible trigger? (Food, insect sting, latex, medication, exercise, or other trigger)

If Yes, proceed with this protocol. If the student has an Emergency Care Plan, follow the plan immediately.

Mild Symptoms:

Mouth: Itchy mouth

Skin: A few hives around mouth/face, mild itch

Gut: Mild nausea/discomfort



Contact the school nurse and parent / guardian. **Observe** for severe signs or symptoms-if any develop, take immediate action. **Call** for additional

health office assistance.

Severe Symptoms:

Lungs: Short of breath, wheeze repetitive cough, difficulty breathing. Heart: Pale, blue, weak pulse, dizzy, confused, low blood pressure.

Throat: Tightening of throat, hoarse, trouble breathing/swallow, cough.

Mouth: Obstructive swelling (tongue and /or lips).

Skin/Gut: Hives over body, vomiting, diarrhea.



- Check list of students contraindicated for Epinephrine located with stock EpiPens. If student is on the list, do not give EpiPen, call 8-911 immediately OR
- 2. If student is not on the list, ADMINISTER EpiPen PER STANDING ORDER: Call 8-911, school nurse, and parent / guardian.
 - Jr Strength 0.15 mg body weight less than 66 pounds or less than 53 inches (measuring tape)
 - 0.3 mg body weight 66 pounds or greater or 53 inches or greater (measuring tape)
 - Pull off safety cap
 - Inject into outer thigh, note time and site of injection (through clothes if necessary)
 - Hold in place for 3- 10 seconds, remove. Massage site.



- 3. Stay with and observe student until ambulance arrives.
 - Maintain airway, monitor circulation, start CPR if necessary.
 - Check and record respirations, pulse, and BP.
 - If a student has lung symptoms and has a prescribed inhaler, administer it now.
 - Keep student calm and position lying down. If vomiting position side lying, difficulty breathing position sitting.
- 4. IF NO IMPROVEMENT OR IF SYMPTOMS WORSEN IN ABOUT 5 OR MORE MINUTES, ADMINISTER A SECOND EPINEPHRINE DOSE in the other leg.
- 5. Provide EMS with identifying information; observe signs and symptoms, time epinephrine administered, send used epinephrine autoinjector to take with to the hospital.
- 6. Transport to the Emergency Department via EMS even if symptoms seem to get better.

Signs, Symptoms & Triggers:

When unsure or unclear, do not let concerns over whether severe difficulty breathing is caused by anaphylaxis or asthma keep you from using epinephrine. Severe asthma can be treated with epinephrine.

MILD SYMPTOMS: Whether or not there was exposure to a known trigger, refer to the school nurse to monitor closely and assess. Do not delay administration of epinephrine if symptoms progress.

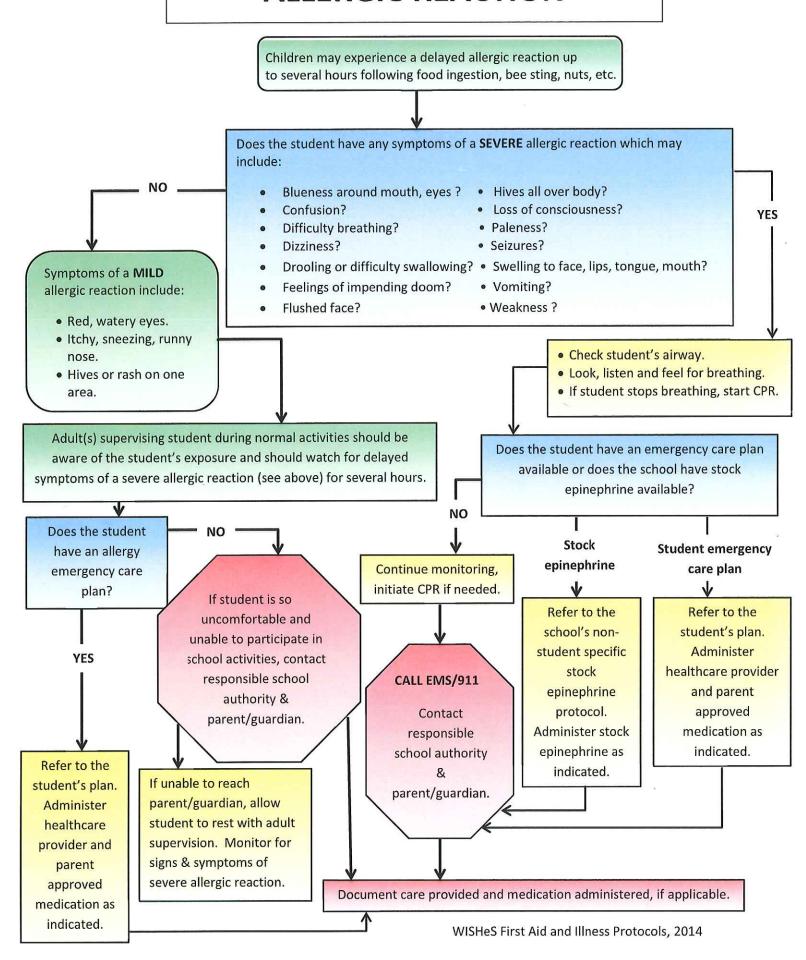
- Do not leave the student. Mild symptoms can quickly become severe. Antihistamines and inhalers/bronchodilators are not to be depended upon to treat severe reaction (anaphylaxis).
 Use Epinephrine
- They are at risk for a secondary or biphasic reaction which may require immediate treatment (as many of 1/3 of children will experience secondary reaction).

After an emergency event:

- Make sure parent/guardians are notified to follow up with private physician. Follow up with family-evaluate plan.
- In the case of the student with known history, discuss how exposure occurred and if new allergen avoidance measures are needed. For students with no previous history of anaphylaxis, consider developing an ECP in collaboration for possible future occurrences.
- Complete documentation per district policy.
- Make sure replacement EpiPen is obtained.
- Review response and emergency communication, update as needed to improve outcomes.

Info from Schoessler, S. & White, M (2013) Recognition and treatment of anaphylaxis in the school setting: The essential role of the school nurse. Journal of School Nursing, 29, 407-415

ALLERGIC REACTION



Buffalo-Hanover-Montrose Schools

Anaphylaxis Treatment Notification to Parents-general population

Dear Parent/Guardian:

Parent Signature

Minnesota statute 121A.2207 permits school districts to possess epinephrine autoinjectors (EA) for a student or other individual experiencing anaphylaxis regardless of whether
the student or individual has a prescription for an EA. Therefore, Buffalo-Hanover-Montrose
school district has adopted a policy allowing the Licensed School Nurse (LSN) or Health ESP to
administer epinephrine for a severe, life-threatening allergic reaction. The emergency
epinephrine will be stored in the school health office and accessible during school hours. It will
not be sent on school based field trips or available before or after the instructional day. This
anaphylaxis protocol is not intended to replace student specific orders or parent/guardian
provided individual medications for students with known allergies.

If your child has a known allergy and has an epinephrine auto-injector (EA) prescribed for him/her, you still need to provide the health office one or preferably 2 with a pharmacy label. An Anaphylaxis/Allergy Action Plan signed by you and your child's healthcare provider is required annually for your child's specific orders. Child specific auto-injectors will be sent on school based field trips.

Anaphylaxis is a rapid, life threatening allergic response requiring immediate treatment. It may be triggered by insect stings, foods, medication, latex, exercise or rare cases by unknown causes. Research documents that it is safer to administer epinephrine than to delay treatment. The EA rapidly delivers a pre-measured, single dose of epinephrine by direct injection through the skin. If your child requires epinephrine administration 911 will be contacted as well as parents and the school nurse (if administered by the Health ESP).

If your child has a heart condition or other chronic condition(s), please talk with his/her health care provider about the safety of administration of epinephrine in the event of a life-threatening anaphylaxis and contact the school health office.

The following is a one-time permission that will follow your child while enrolled in
BHM Schools. Should you change your mind, please notify your child's school in writing
Failure to complete this form will imply consent to administer epinephrine. I have
received and read the Anaphylaxis Treatment Notification and:
I give permission for my child to receive epinephrine if he/she is experiencing a
life-threatening allergic reaction.
I DO NOT give my permission for my child to receive epinephrine if he/she is
experiencing a life-threatening allergic reaction.

Date

BUFFALO HANOVER MONTROSE SCHOOLS Epinephrine Auto-injector Parent/Guardian Informed Consent Form

According to school records your child has a history of a heart condition and/or heart murmur. A severe allergic reaction (anaphylaxis) can occur in a previously unidentified individual. An individual can exhibit an allergic response to insect sting venom, foods, pollens, latex, exercise, extreme heat/cold, chemicals, drugs or idiopathic (unknown). Allergic responses can range from mild to a severe anaphylactic reaction. A severe reaction can occur quickly and can become life threatening within minutes. It is well documented that it is safer to administer epinephrine than to delay treatment for anaphylaxis. Epinephrine, like any medication, has potential side effects. They include fast, irregular or pounding heartbeat, sweating, headache, weakness, shakiness, paleness, anxiety, dizziness, nausea, vomiting and breathing problems. Since your child has a known heart condition, please talk with his/her health care provider about the safety and side effects of administration of epinephrine in the event of a life threatening allergic reaction (anaphylaxis). Once you have done so, please complete this form.

By consenting, you are authorizing the Licensed School Nurse or Health ESP to administer emergency epinephrine (0.3 mg if 66 pounds or greater, 0.15 mg if less than 66 pounds) if in his/her professional judgment, your child's health is in danger if not used. Epinephrine auto-injectors rapidly deliver a premeasured, sterile, single dose of epinephrine by direct injection through the skin. If your child requires epinephrine administration, 911, parents and the Licensed School Nurse (if administered by Health ESP) will be called immediately. If symptoms persist or recur, a second dose of epinephrine will be administered 5 to 15 minutes after the first. The emergency epinephrine will be kept in the school health office and will not be sent on school based field trips or available before or after the instructional day.

Informed Consent-Please put an X on the appropriate line ____ I consent to have BHM Schools administer an epinephrine auto-injector to my child if my child is experiencing a life threatening allergic reaction/anaphylaxis; even though my child has a heart condition and knowing that the side effects of epinephrine affect the heart. This is a one-time consent and will follow your child through their BHM School career. _____ I do not consent to have BHM Schools to administer epinephrine auto-injector to my child, even if my child is experiencing a life threatening allergic reaction/anaphylaxis. Child's Name:______ Date of Birth______ Parent Signature_____ Date______

Please return this form as soon as possible to your child's school.

If you have questions, please contact your child's school health office.

MINNESOTA BOARD OF PHARMACY

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Metro and Non-Metro; 800-627-3529 E-Mail Address: Pharmacy.Board@state.mn.us

Web Site: www.pharmacy.state.mn.us

Bioridge Pharma LLC 100 Campus Drive, Suite 300 Florham Park, NJ 07932

Re: Life-threatening allergies in schools; stock supply of epinephrine auto-injectors

To Whom It May Concern:

Under Minnesota law, a prescription is not necessary for schools to obtain and possess epinephrine auto-injectors. Specifically, Minn. Stat. § 121A.2207 provides:

"Notwithstanding [prescription requirements under Minnesota's Pharmacy Practice Act of 1988], districts and schools may obtain and possess epinephrine auto-injectors to be maintained and administered by school personnel to a student or other individual if, in good faith, it is determined that person is experiencing anaphylaxis regardless of whether the student or other individual has a prescription for an epinephrine auto-injector. The administration of an epinephrine auto-injector in accordance with this section is not the practice of medicine."

This means that schools may obtain epinephrine auto-injectors, at wholesale, from licensed drug manufacturers and wholesalers. Schools may not obtain epinephrine auto-injectors from a pharmacy unless the pharmacy is also licensed as a drug wholesaler.

Sincerely,

Cody Wiberg, Pharm.D., M.S., R.Ph.

lody Wiberg

Executive Director

cc: Mylan Specialty L.P.



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

The school and/or school district identified below (the "School") hereby acknowledges and agrees that the Free EpiPen® (epinephrine injection) 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;
- the School will only receive EpiPen® (epinephrine injection) 0.3mg and EpiPen Jr® (epinephrine injection) 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;
- 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;
- 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 <u>Free EpiPen[®] Auto-Injector EpiPen4Schools</u> Program to a non-school third party, unless the prior written approval of Mylan Specialty, in its sole discretion, is obtained;
- written approval of Mylan Specialty, in its sole discretion, is obtained;
 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;
- (viii) neither the School, nor any healthcare professional associated with or providing medical services on behalf of the School, will bill any patient or any third-party payer/government program for any free EpiPen® or EpiPen Jr® Auto-Injector administered to any patient; and
- (ix) the School agrees to Mylan Specialty's use of the School's name for promotional purposes.

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

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

Two FREE 2-Pak Cartons (4 Total EpiPen® Auto-Injectors)	Quantity Ordered*	Price
EpiPen 2-Pak [®] Cartons		FREE
EpiPen Jr 2-Pak® Cartons		FREE
Total Quantity Ordered (*must be no more than two 2-Pak		FREE
EpiLocker™ (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 cartons per school. For example, if you are ordering two EpiPen Jr 2-Pak® cartons for each of 10 schools, you should enter 20 in the Quantity Ordered column next to EpiPen Jr 2-Pak® cartons. 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:	8
School Phone:	u.
Authorized School Signatory Name:	
Authorized School Signatory Title:	1
Authorized School Signatory Email:	
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 email scan to: info@bioridgepharma.com

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

Indications

EpiPen® (epinephrine injection) 0.3 mg and EpiPen Jr® (epinephrine injection) 0.15 mg Auto-Injectors are for the emergency treatment of life-threatening allergic reactions (anaphylaxis) caused by allergens, exercise, or unknown triggers; and for people who are at increased risk for these reactions. EpiPen® and EpiPen Jr® are intended for immediate administration as emergency supportive therapy only. Seek immediate emergency medical help right away.

Important Safety Information

EpiPen® and EpiPen Jr® Auto-Injectors contain a single dose of epinephrine, which you (or your caregiver or others who may be in a position to administer EpiPen® or EpiPen Jr®) inject into the middle of your outer thigh (upper leg) (through clothing, if necessary). Get emergency medical help right away. You may need further medical attention. Only a health care professional should give additional doses of epinephrine if you need more than two injections for a single anaphylactic episode. DO NOT INJECT INTO YOUR VEINS, BUTTOCKS, FINGERS, TOES, HANDS OR FEET. In case of accidental injection, please seek immediate medical treatment. Epinephrine should be used with caution if you have heart disease or are taking certain medicines that can cause heart-related (cardiac) symptoms.

Tell your doctor if you have certain medical conditions such as asthma, depression, thyroid disease, Parkinson's disease, diabetes, high blood pressure or heart disease, have any other medical conditions, are pregnant or plan to become pregnant, or are breastfeeding or plan to breastfeed. Be sure to also tell your doctor all the medicines you take, especially medicines for asthma. If you have certain medical conditions, or take certain medicines, your condition may get worse or you may have longer lasting side effects when you use EpiPen® or EpiPen Jr®.

The most common side effects may include increase in heart rate, stronger or irregular heartbeat, sweating, nausea or vomiting, difficulty breathing, paleness, dizziness, weakness, shakiness, headache, apprehension, nervousness or anxiety. These side effects may go away if you rest. **Tell your health care professional if you have any side effect that bothers you or that does not go away.**

Please see the full Prescribing Information and Patient Information.

You are encouraged to report negative side effects of prescription drugs to the FDA.

Visit www.fda.gov/medwatch or call 1-800-FDA-1088.

For additional information, please contact us at 800-395-3376.

EpiPen[®], EpiPen Jr[®], EpiPen 2-Pak[®] and EpiPen Jr 2-Pak[®] are registered trademarks of Mylan Inc. licensed exclusively to its wholly-owned subsidiary, Mylan Specialty L.P. *EpiPen4Schools*[®] is a registered trademark of Mylan Inc. EpiLockerTM is a trademark of Mylan Inc.

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February 4, 2014

TO WHOM IT MAY CONCERN:

This letter is to support the request of the nurses working in the Buffalo Hanover Montrose school district, ISD 877, to have auto-injectors of epinephrine available for emergency use in our local schools. As medical providers in the community we know how unexpected and dangerous allergic reactions can be. The Minnesota legislature wisely amended statute 121A.22 to allow schools to obtain and use epinephrine auto-injectors without an individual prescription in potentially life-threatening situations. We agree that enacting an emergency action plan and having this medication available is a valuable safety measure for the children of our community.

Sincerely,
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