

ALEDO INDEPENDENT SCHOOL DISTRICT

# FOOD ALLERGY MANAGEMENT PLAN

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AISD SUPPORTS STUDENTS AT RISK FOR  
ANAPHYLAXIS

A food allergy is a potentially serious immune-mediated response that develops after ingesting or direct contact with specific foods or food additives. Anaphylaxis is a rapidly progressing, life-threatening allergic reaction. Caring for children with diagnosed food allergies at-risk for anaphylaxis in the school setting requires a collaborative partnership with the students, parents, healthcare providers and school staff. To access guidelines for the care of students with food allergies at risk for anaphylaxis click : [here](#).

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## Care of the Student with Food Allergies At-Risk for Anaphylaxis

### **Purpose:**

To provide guidance in the management of students with food allergies at-risk for anaphylaxis at school

### **Responsibility:**

School Nurse, Campus Administrators, Teachers, Students, and Parents

**Other applicable policies:** FFAF (legal)

### **Background:**

When you have a *food allergy*, your immune system mistakenly identifies a specific food or a substance in food as something harmful. In response, your immune system triggers cells to release an antibody known as immunoglobulin E (IgE) to neutralize the allergy-causing food or food substance (the allergen). (Mayo Clinic, 2017)

Symptoms of a food induced allergic reaction may range from mild to severe and may become life-threatening. Reactions vary with each person and each exposure to a *food allergen* and the severity of an allergic reaction is not predictable. With the increasing prevalence of food allergies in the past two decades, care of students with life-threatening allergies has become a major issue for school personnel (Sheetz, 2004). School personnel should be ready to effectively manage students with known food allergies and should also be prepared to recognize symptoms of an allergic reaction in both diagnosed and undiagnosed students in order to respond to the student's emergency needs.

Strict avoidance of food allergens and early recognition and management of allergic reactions are important measures to prevent serious health consequences (U. S. Food and Drug Administration, 2008). Children spend up to 50 percent of their waking hours in school, and foods containing allergens are commonly found in schools. Thus, the likelihood of allergic reactions occurring in schools is high (Sheetz, 2004). Studies show that 16-18 percent of children with food allergies have had allergic reactions to accidental ingestion of food allergens while in school. Moreover, food-induced anaphylaxis data reveals that 25 percent of anaphylactic reactions in schools occur among students without a previous food allergy diagnosis (Sicherer, 2010 & Nowak-Wegrzyn, 2001).

Currently, management of food allergies consists of educating children, parents and care providers, including school personnel, about strict avoidance of the food allergen, recognizing the signs and symptoms of an allergic reaction, and initiating emergency treatment in case of an unintended ingestion or exposure. In order to address the complexities of food allergy management in schools, it is important that students, parents/caregivers, and school personnel work cooperatively to create a safe and supportive learning environment (National School Boards Association, 2012).

## Definitions:

<b>Anaphylaxis:</b>	a serious allergic reaction that is rapid in onset and may cause death. Anaphylaxis occurs within a few minutes to several hours after exposure to the allergen.
<b>Auto-injector:</b>	a pre-measured, spring-loaded pen-like device used to administer epinephrine and designed for ease of use by non-medical persons.
<b>Child Nutrition Allergy Form:</b>	<i>Special Diet Physician's Statement - Food Allergy/Disability Substitution Request</i> form signed by a licensed physician that indicates the disability, explains why the disability restricts the child's diet, the major life activity affected by the disability; and the food or foods to be omitted from the child's diet and the food or choice of foods that must be substituted.
<b>Cross Contamination:</b>	when an allergen is transferred from one item (utensils, pots, pans, countertops, surfaces, etc.) to another.
<b>Emergency Action Plan: (EAP)</b>	a personalized emergency plan that specifies the delivery of accommodations and services needed by a student in the event of a food allergy reaction.
<b>Emergency Medical Service (EMS):</b>	an emergency medical technician or paramedic that is training to provide out-of-hospital medical care in urgent situations and providing transportation to the nearest hospital.
<b>Epinephrine: (Adrenaline)</b>	medication used to counteract anaphylaxis; usually administered via an auto-injector.
<b>Food Allergy:</b>	a potentially serious immune-mediated response that develops after ingestion or direct contact with specific foods or food additives.
<b>Food Intolerance:</b>	an unpleasant reaction to a food that, unlike a food allergy, does not involve an immune system response or the release of histamine.

**Individualized Healthcare Plan (IHP):** a plan written by the School Nurse (RN) that details accommodations and/or nursing services to be provided to a student because of the student's medical condition based on medical orders written by a health care provider in the student's medical home.

**School Nurse:** a person who holds a current license as a registered professional nurse (RN) from the Texas Board of Nursing as outlined in the Texas Administrative Code, § 153.1021.

**School-Sponsored Activity:** any activity, event, or program occurring on or off school grounds, whether during or outside of regular school hours, which is organized and/or supported by the school.

**Severe Food Allergy:** a dangerous or life-threatening reaction of the human body to a food-borne allergen induced by inhalation, ingestion or skin contact that requires immediate medical attention.

## PROCEDURE:

Notification of a food allergy

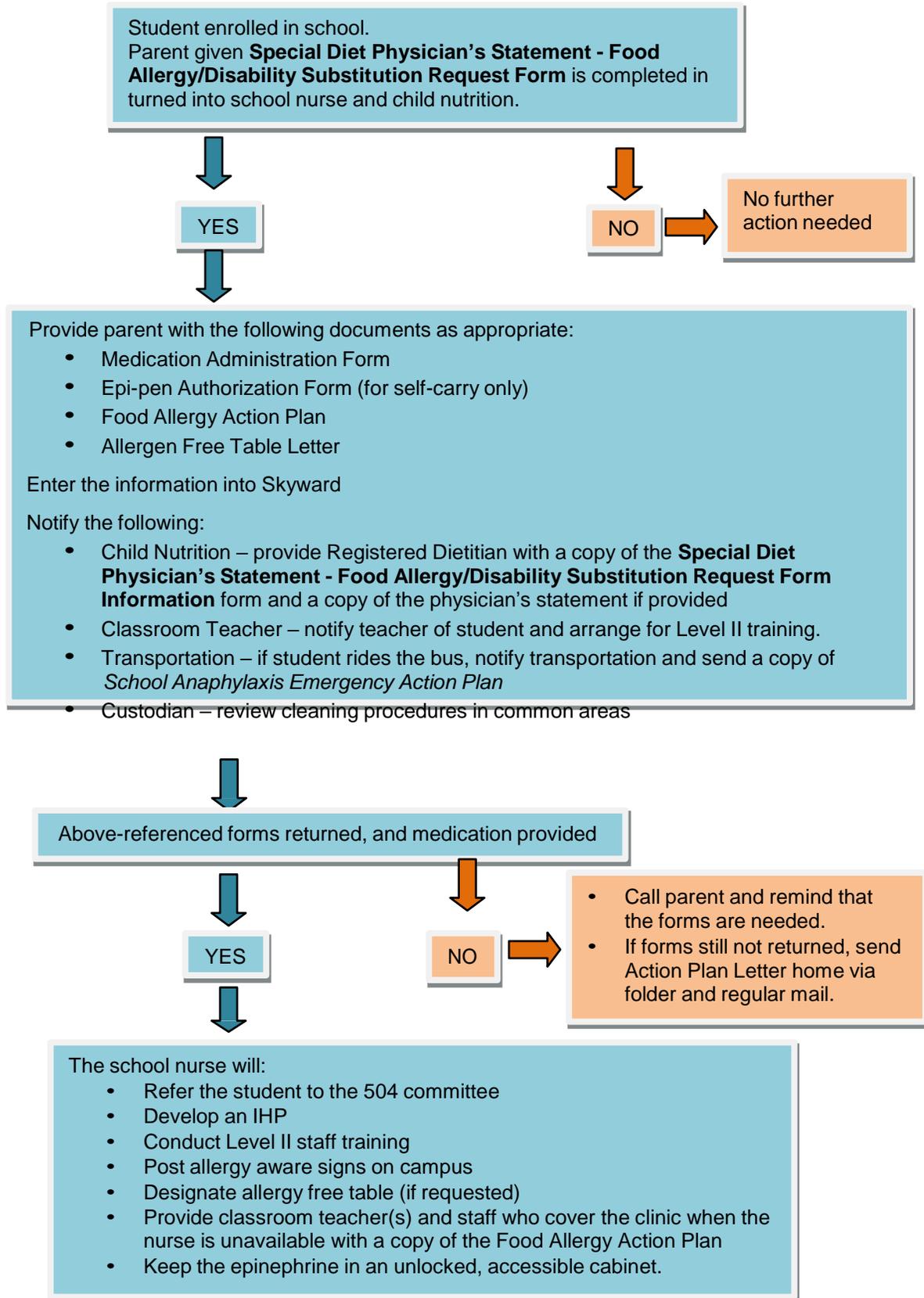
Upon enrollment of a new student, the parent or guardian will be provided access with the following form:

1. Child Nutrition **Special Diet Physician's Statement - Food Allergy/Disability Substitution Request** Form
2. Diet Physician's Statement - Food Allergy/Disability Substitution Request forms will be available at fall school registrations and schedule pick-ups.
3. Based on information provided by the parents and/ or upon receipt of the AISD Health Services *School Anaphylaxis Emergency Action Plan* or *Special Diet Physician's Statement - Food Allergy/Disability Substitution Request form*, the school nurse will:
  - Develop an **Emergency Action Plans (EAC)**.
  - Develops the **Individualized Health Care Plans (IHP)** for Students with Food Allergies At-risk for Anaphylaxis
  - Initiate or assists in the 504 process, if appropriate
  - For students without an EAC, campus nurses will follow NASN's **Suggested Emergency Nursing Protocol for Students with Possible Food Allergy Symptoms Who Don't Have a Personal Emergency Care Plan**.
  - The campus nurse collaborates with parents, administration, child nutrition, teachers and custodial staff to implement strategies to reduce the student's risk of exposure to diagnosed allergen.
  - After an anaphylaxis reaction, an **Anaphylaxis Event and/or Epinephrine Administration Review form** will be completed by campus nurse. Within ten working days, a copy must be sent to the physician or person who has been delegated prescriptive authority under Occupations Code Chapter 157 and has prescribe epinephrine auto-injectors in the name of a school district in accordance with law. *Education Code 38.211*
4. Environmental Controls will be established on the campus through:
  - Designation of the campus as "Allergy Aware"
  - Establishing an allergen free zone in the student's classroom(s)
  - Offering a "allergen free table" in the cafeteria, if needed
  - Implementing appropriate cleaning protocols in the school with special attention given to high risk areas
  - Hand washing before and after meals
5. School nurse provides/coordinates education and training for school personnel.
  - Training will be conducted annually at the beginning of the school year.
  - *FFAC (Legal) 1/09/2019* AISD has adopted and implemented a policy regarding the maintenance, administration, and disposal of unassigned epinephrine auto-injectors at each campus in the district.  
*The district has an unassigned epinephrine auto-injector written policy that outlines training school personnel in recognizing anaphylaxis signs and symptoms and administration of an unassigned epinephrine auto-injector. Readily accessible epinephrine auto-injectors are integral to the emergency treatment of students with severe allergies. To ensure optimal epinephrine access for students*

*at risk for anaphylaxis with an epinephrine prescription, policy for providing personally prescribed epinephrine auto-injectors remains unchanged.*

- Training will be consistent with <https://www.cdc.gov/healthyschools/foodallergies/index.htm>
  - Overview Training: This includes district wide education to all school personnel on every campus. Training will cover the following subjects:
    - Most common food allergens
    - Hazards related to the use of food for instructional purposes
    - Importance of environmental controls
    - Signs and symptoms of an anaphylactic reaction
    - How to use an EAP
    - How to administer epinephrine
  - Child Specific Training: This review is for all employees who are associated with the student including but not limited to the classroom teacher(s), cafeteria personnel, club sponsors, coaches and before/after school care givers. Review will cover the following subjects:
    - Specific students at risk for anaphylaxis
    - Planning for students who do not have epinephrine at school
    - Implementation of EAP/504 plan(s)
    - Communication procedures for initiating emergency protocols, including substitute staff.
    - Environmental control factors including hand washing and cleaning procedures
    - Working with EMS
    - Post anaphylaxis debriefing
  - Training school personnel in the administration of an epinephrine auto-injector must be completed annually; provided in a formal training session or through online education; and include information on recognizing the signs and symptoms of anaphylaxis, administering an epinephrine auto-injector, implementing emergency procedures, if necessary, after administering an epinephrine auto-injector, and properly disposing of used or expired epinephrine auto-injectors. A district shall maintain records on the required training. (Education Code 38.210)
6. In the event of an anaphylactic event, a post exposure conference will be held on the campus. The following will be addressed in the debriefing:
- Identification of the source of the allergen exposure
  - Steps to prevent future exposure
  - Review allergy action plan
  - Interview of the student and witnesses regarding events leading up to incident
  - Work with Child Nutrition if allergen was due to food served by the school
  - Review EAP/IHP/504 plan(s)
  - Replacement of epinephrine if used at school
7. In the rare event of a fatal reaction, the district's crisis plan will be activated.

## Anaphylaxis Planning Algorithm



## Severe Food Allergy – Actions for Classroom Teacher

In promoting a safe school environment for children with food allergies at-risk for anaphylaxis, students, parents, and school personnel should work as a team in identifying students at-risk for anaphylaxis, reducing the risk of exposure to food allergens and to react quickly should an exposure or allergic reaction occur.

### Classroom:

- Complete annual and child specific Food Allergy training.
- Review the Emergency Action Plan (EAC) for your student.
- Review communication plan with the front office and/or school nurse.
- Keep accessible the EAC with a photo of the student
- Ensure that volunteers, student teachers, aides, specialist and substitute teachers are informed of the student's food allergy and take necessary safeguards.
- Leave information in an organized, prominent and accessible format for the substitute teacher(s) and other appropriate staff.
- Be aware of how the student with food allergies is being treated; enforce school rules on bullying and threats.
- Work with the school nurse to educate other parents about the presence and needs of students with life-threatening food allergies in the classroom.
- Inform parents and school nurse of any of any school events where food will be served.
- Consider eliminating or limiting food in classrooms and other learning environments.
- Avoid isolating or stigmatizing a student with food allergies and adhere to the AISD policy on bullying.
- Ensure that a student suspected of having an allergic reaction is accompanied by an adult (preferably) or student to the clinic.
- Do not put a student on the bus if there are any signs or symptoms of an allergic reaction.

### Classroom Activities:

- Avoid use of foods for classroom activities (e.g., arts and crafts, counting, science projects, parties, holidays and celebrations, cooking or other projects).
- Welcome parental involvement in organizing planning class parties and special events. Consider non-food treats.
- Use non-food items such as stickers, pencils, etc. as rewards instead of food.

### Snack time/Lunchtime:

- Establish processes to ensure that the student with life-threatening food allergies eats only what she/he brings from home and/or is known to be safe.
- Encourage hand washing before and after snacks and lunch. *Alcohol-based hand sanitizers are NOT effective in removing allergens from hands.*
- Prohibit students from sharing or trading food.
- Encourage parents/guardians to send a box of “safe” snacks for their child.

### Field Trips:

- Give the nurse at least a **two-day** notice prior to field trips.
- Ensure the EAP and the student's epinephrine is taken on the field trip and all outings.
- Collaborate with parents of student with food allergies when planning field trips.
- If field trip timing is during lunch, plan for reduction of exposure to a student's life-threatening food allergy.
- Invite parents of students at risk for anaphylaxis to accompany their child on school trips, and/or to act as a chaperone. However, the student's safety or attendance must not be a condition on the parent's presence on the trip.
- Ensure that 1 or 2 people on the field trip are trained in recognizing signs and symptoms of life-threatening allergic reactions and are trained to use an epi-pen.
- Consider ways to wash hands and encourage hand washing before and after eating (e.g. provision for hand wipes, etc.)

## Severe Food Allergy – Actions for Family & Student

In promoting a safe school environment for children with food allergies at-risk for anaphylaxis, students, parents, and school personnel should work as a team in identifying students at-risk for anaphylaxis, reducing the risk of exposure to food allergens and to react quickly should an exposure or allergic reaction occur.

### **The family is encouraged to:**

- Notify the school of the student's allergies in accordance with TEC, Section 25.022. Use of the Child Nutrition Special Diet Physician's Statement - Food Allergy/Disability Substitution Request Form is needed for any food substitution in cafeteria.
- Work with the School Nurse to develop and review the EAP and IHP as well as discuss accommodations the student will need throughout the school day, during school-sponsored activities, and on the school bus.
- Provide completed and signed AISD medication authorization, School Anaphylaxis Action Plan (signed by the physician- necessary to carry EpiPen) to the school nurse.
- Provide properly labeled medications and replace medications after use or upon expiration.
- Work with your child in the self-management of their food allergy including:
  - Safe and unsafe foods,
  - Strategies for avoiding exposure to unsafe foods,
  - Symptoms of allergic reactions,
  - How and when to tell and adult they may be having an allergy-related problem,
  - How to read food labels (age appropriate),
  - If age appropriate, the importance of carrying and administering their personal asthma and anaphylaxis medications as prescribed.
- Meet with the school nurse and other school personnel as needed for post-exposure conference.
- Provide emergency contact information and *update when needed*.

### **The responsibilities of the family for before/after school childcare at the school include:**

- Working with the Kids Klub staff to develop and review the EAP as well as discuss accommodations the student will need during the before/after school program.
- Completing Kids Klub medication authorization forms.
- Providing properly labeled medications and replace medications after use or upon expiration.

**The responsibilities of the student include:**

- No trading of food with others.
- Not eating anything with unknown ingredients or known to contain any allergen.
- Being proactive in the care and management of their food allergies and reactions (as developmentally appropriate).
- Immediately notifying an adult if they eat something they believe may contain a food to which they are allergic.

## Severe Food Allergy – Actions for the School Nurse (RN)

In promoting a safe school environment for children with food allergies at-risk for anaphylaxis, students, parents, and school personnel should work as a team in identifying students at-risk for anaphylaxis, reducing the risk of exposure to food allergens and to react quickly should an exposure or allergic reaction occur.

Responsibilities of school nurse (RN) and Licenced Vocational Nurse under direction of the RN:

- Review the AISD Registration Information and eSchool for Food Allergy Information.
- Work with parent/guardian and student in development of EAP and IHP.
- Ensure that required paperwork has been submitted.
- Notify Child Nutrition, Transportation, Teachers, Kids Klub of the enrollment of the student with a severe food allergy as appropriate.
- Provide classroom teacher(s), Transportation, Kids Klub and any other staff with a need to know with a copy of the EAP .
- Send home the food allergy letter notifying parents that a student in their student's classroom has a severe food allergy and what their role is in keeping the class room environment safe.
- Ensure that medications are properly labeled and note expiration date.
- Encourage parent to keep extra epinephrine in the clinic if the student will be carrying the medication with them.
- Store medication in an accessible but unlocked cabinet in the case of an emergency.
- Provide Overview and Child Specific Food Allergy training/ education as outlined in the Care of the Student with Food Allergies At-Risk for Anaphylaxis guideline.
- Maintain documentation of annual Anaphylaxis training.
- Periodically assess staff readiness to administer epinephrine when needed.
- Review child specific information with staff member attending field trips, school outings if parents are not in attendance.

## Severe Food Allergy – Actions for Child Nutrition

In promoting a safe school environment for children with food allergies at-risk for anaphylaxis, students, parents, and school personnel should work as a team in identifying students at-risk for anaphylaxis, reducing the risk of exposure to food allergens and to react quickly should an exposure or allergic reaction occur.

- Review the legal protections for students with life-threatening allergies and ensure that students with severe food allergies that participate in the federally-funded school meal program are given safe food items as outlined by the physician's signed statement.
- After receiving notice from healthcare provider, make appropriate substitutions or modifications for meals served to students with food allergies.
- Read all food labels and recheck routinely for potential allergens.
- Train all child nutrition staff and substitutes to read food labels and recognize food allergies.
- Maintain contact information for manufacturers of food products (Consumer Hotline).
- Review and follow sound food handling practices to avoid cross-contamination with potential food allergens.
- Follow cleaning and sanitation protocol to avoid cross-contamination.
- Provide Overview anaphylaxis training to all child nutrition personnel.
- Avoid use of latex gloves, use non-latex gloves.
- Provide access of the menu to the parent/guardian of students with food allergy, and notification if menu changes. Consider how to provide specific ingredient lists to parents upon request.
- Be prepared to take emergency action for a student in the cafeteria in the event of an allergic reaction.

## Severe Food Allergy - Actions for School Administrators

In promoting a safe school environment for children with food allergies at-risk for anaphylaxis, students, parents, and school personnel should work as a team in identifying students at-risk for anaphylaxis, reducing the risk of exposure to food allergens and to react quickly should an exposure or allergic reaction occur.

Campus administrator should:

- Collaborate with School Nurse to ensure a process is in place for identifying students with food allergies who are at-risk for anaphylaxis.
- Ensure that staff complete Anaphylaxis Food Allergy training annually.
- Collaborate with School Nurse to ensure that at least one trained staff member attends field trips when a student with food allergies who are at-risk for anaphylaxis is participating the event.
- Collaborate with School Nurse to ensure that a plan is in place to notify substitute teachers if they have a student with food allergies who are at-risk for anaphylaxis in their classroom.
- Collaborate with School Nurse to ensure that a plan is in place to respond to exposure or allergic reactions when a school nurse is not available.
- Ensure that a plan is in place to designate a table(s) as allergy free in the cafeteria, if appropriate.
- Collaborate with School Nurse to ensure that the campus is designated as a food allergy aware campus through posting of signs at entrances into the school building.
- Limit use of food as rewards and manipulatives in classrooms.

## Severe Food Allergy – Actions for Transportation Department

In promoting a safe school environment for children with food allergies at-risk for anaphylaxis, students, parents, and school personnel should work as a team in identifying students at-risk for anaphylaxis, reducing the risk of exposure to food allergens and to react quickly should an exposure or allergic reaction occur.

Transportation department should:

- Provide Overview Anaphylaxis Food Allergy training to all bus drivers.
- Provide Level II Food Allergy training to bus drivers who have a student with food allergies who are at-risk for anaphylaxis on their route.
- Obtain a copy of the EAP from the school nurse for students with food allergies who are at-risk for anaphylaxis who ride the bus,
- **Maintain a policy of no consumption of food or drinks on the buses.**
- Ensure that bus drivers know how to contact EMS in the event of an emergency.

## **Severe Food Allergy – Actions for Coaches/Sponsors of Before and After School Sponsored Activities**

In promoting a safe school environment for children with food allergies at-risk for anaphylaxis, students, parents, and school personnel should work as a team in identifying students at-risk for anaphylaxis, reducing the risk of exposure to food allergens and to react quickly should an exposure or allergic reaction occur.

Coaches/sponsors should:

- Conduct the school sponsored activity in accordance with school policies and procedures regarding students with food allergies who are at-risk for anaphylaxis.
- Obtain a copy of the EAP from the school nurse for students with food allergies who are at-risk for anaphylaxis who participating in the activity.
- Collaborate with School Nurse to ensure coaches/sponsors of the activity receive Food Allergy training.
- Collaborate with School Nurse to ensure coaches/sponsors know if the student is self-carrying epinephrine and/or where the student(s) epinephrine is located on the campus.
- Discourage trading or sharing of food and utensils.
- Promote and monitor good hand washing practices.
- Restrict the use of foods that are known allergens.

## **Severe Food Allergy – Actions for Custodial Staff**

In promoting a safe school environment for children with food allergies at-risk for anaphylaxis, students, parents, and school personnel should work as a team in identifying students at-risk for anaphylaxis, reducing the risk of exposure to food allergens and to react quickly should an exposure or allergic reaction occur.

Custodial staff should:

- Attend/participate in annual Overview Anaphylaxis Food Allergy training.
- Clean desks, tables, chairs, and other surfaces with special attention to designated areas for students with food allergies who are at-risk for anaphylaxis.
- Collaborate with the School Nurse to be aware of areas that may require specialized cleaning.

Resources:

- Branum, A. L. (2008, October). *Unites States Department of Health and Human Services*. Retrieved from NCHS Data Brief Number 10.
- Branum, A. L. (2009). Food allergy among children in the United States. *Pediatrics*, 1549-1555.
- Centers for Disease Control and Prevention. Voluntary Guidelines for Managing Food Allergies in Schools and Early Care and Education Programs. Washington, DC: US Department of Health and Human Services; 2019.
- Food Allergy Research & Education (2019). *Your Back to School Headquarters* Retrieved June 18, 2011, from School Guidelines for Managing Students with Food Allergy:  
<http://www.foodallergy.org/page/food-allergy--anaphylaxis-network-guidelines>
- Food Allergy and Anaphylaxis Network. (2011). *School Guidelines for Managing Students with Food Allergies*. Retrieved June 2011, from Food Allergy and Anaphylaxis Network:  
<http://www.foodallergy.org/page/school-guidelines-for-managing-students-with-food-allergies>
- Food Allergy Initiative. (2011). *School Guidelines for Managing Students With Food Allergies*. Retrieved June 17, 2011, from Food Allergy Initiative: <http://www.faiusa.org/admin/document.doc?id=76>
- Greenhawt, M. (2011, July 25). *Helping families manage food allergies in school*. Retrieved from Medscape: [www.medscape.com/veiwarticle/746589\\_print](http://www.medscape.com/veiwarticle/746589_print)
- Gupta, R. S. (2011). The prevalence, severity, and distribution of childhood food allergy in the United States. *Pediatrics*, e9-e17.
- National Association of School Nurses. (2019). *Tools and Resources*. Retrieved June 2012, from Food Allergy and Anaphylaxis: <http://www.nasn.org/ToolsResources/FoodAllergyandAnaphylaxis>
- National Institute of Allergy and Infectious Disease. (2010, November). Retrieved from National Institute of Allergy and Infectious Disease: [www](http://www.niaid.nih.gov)
- Nowak-Wegrzyn, A. C.-W. (2001 Jul;155(7)). Food-allergic reactions in schools and pre-schools. *Archives of Pediatric and Adolescent Medicine*, 790-795.
- Sheetz, A. G. (2004 (74)5 ). Guidelines for managing life-threatening food allergies in Massachusetts schools. *Journal of School Health*, 155-160.
- Sicherer, S. ((78) 2011). Food allergy. *Mount Sanai Journal of Medicine*, 683-696.
- Sicherer, S. (2002). Food allergy. *Lancet* (360), 701-710.
- Sicherer, S. M. (2010). Clinical Report: Management of food allergy in the school setting. *Pediatrics*, 1232-1239.
- Sicherer, S. S. (2010). Food allergy. *Journal of Allergy and Clinical Immunology*, S116-S125.
- Texas Department of Agriculture. (2011, November). Accomodating children with special dietary needs. *USDA Child Nutrition Guidelines*. Austin, Texas : Texas Department of Agriculture.
- Texas Department of Agriculture. (2011). *Accomodating children with special dietary needs*. Austin: Texas Department of Agriculture.
- Texas Department of State Health Services. (2011, December). *The Texas Guide to School Helath Programs*. Retrieved from Texas Department of State Health Services:  
<http://www.dshs.state.tx.us/schoolhealth/pgtoc.shtm>
- Texas Department of State Health Services. (2013, June) *Guidelines for the Care of Students With Food Allergies At-Risk for Anaphylaxis*  
To Implement Senate Bill 27 (82nd Legislative Session) Retrieved from Texas Department of State Health Services: <https://www.dshs.state.tx.us/schoolhealth/Food-Allergies.aspx>
- U. S. Food and Drug Administration. (2008). *Center for Safe and Applied Nutirion*. Retrieved from Food allergies: What you need to know: [www.cfsan.fda.gov/~dms/ffalrgn.html](http://www.cfsan.fda.gov/~dms/ffalrgn.html)