March 24, 2014

Oregon Department of Education
255 Capitol Street NE
Salem, OR 97310-0203
Re: Revision of OAR 581-021-0037

Oregon Food Allergy Network (OFAN) is a not-for-profit support group recognized by the leading national non-profit for individuals living with food allergy, Food Allergy Research & Education, Inc. (FARE). OFAN represents over 150 families across the state of Oregon. OFAN is a group of parents and caregivers who gather and work to better the lives of families living with food allergies through education, support, and community advocacy.

As parents of food allergic children in Oregon k12 schools, we would like the following:

i. All staff responsible for a food allergic student in school, at a school sponsored activity, while under the supervision of school personnel, in before-school or after-school child care programs on school-owned property, in transit to or from school or school sponsored activities to recognize the onset of an anaphylactic reaction; and
ii. the nearest epinephrine auto-injector be administered to a student exposed to a known allergen or exhibiting symptoms of an allergic reaction without hesitation or concern for liability;
iii. by anyone aware of student's anaphylactic condition (peer, staff, volunteer) or who is trained to recognize the onset of anaphylaxis

On behalf of the Oregon Food Allergy Network (OFAN), a team of eleven parents of food allergic children including two state employees, a board licensed pharmacist, and a nurse have reviewed the revisions to OAR 581-021-0037 and suggest the following changes.

1. Anaphylaxis is a serious, life-threatening, allergic reaction, it is most commonly caused by food, insect stings, latex, or medications.[i] We suggest the definition of serious allergy in item 1(f) be modified to read:

   (1)(f) "Severe allergy" means a life-threatening hypersensitivity to a specific substance such as **but not limited to** food, ~~pollen or dust~~, **insects, or latex**;

2. Senate Bill 611 calls for school boards to adopt policies and procedures for the administration of epinephrine to students by trained personnel and student self-medication. To achieve this we suggest omitting the word "self" in item 3(E).

(3)(E) A school district board shall adopt policies and procedures that provide for ~~self-~~ administration of medication by kindergarten through grade 12 students with asthma or severe allergies:

3. An epinephrine auto-injector is a disposable, pre-filled, automatic injection device. As such we suggest the definition of prescription medicine reflect this fact. This would affect language in (1)(i). We suggest the following alternative language:

> (1)(i) For the purpose of this rule, "prescription medication" means any ~~noninjectable~~ drug, chemical compound, suspension or preparation in suitable form for use as a curative or remedial substance taken either internally or externally by a student under the written direction of a physician. **Prescription m**Medication **is non-injectable with the exception of autoinjectable epinephrine, will** includes ~~any prescription for~~ bronchodilators**,** ~~or autoinjectable epinephrine~~ **and must be** prescribed by a student's ~~Oregon~~ **Board** licensed health care professional. ~~for asthma or severe allergies~~ Prescription medication does not include dietary food supplements;

4. The examples given in the definition of non-prescription medicines do not constitute an exhaustive list of possibilities. This would affect language in (1)(g) We suggest the following wording change:

> (1)(g) "Nonprescription medication" means only commercially prepared, nonalcohol-based medication to be taken at school that is necessary for the child to remain in school. This shall **not** be limited to eyes, nose and cough drops, cough suppressants, analgesics, decongestants, antihistamines, topical antibiotics, anti-inflammatories and antacids that do not require written or oral instructions from a physician. Nonprescription medication does not include dietary food supplements;

5. In Oregon prescriptions written by providers licensed in other states are valid to fill. We suggest that licensure not be limited to Oregon. This would affect language in 1(h), (i), & (j) and 3 (g) & (h). We suggest the following alternative language:

> (1)(h) "Physician" means:
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> (A) A doctor of medicine or osteopathy or a physician assistant licensed ~~to practice by the~~ **by a** Board of Medical Examiners ~~for~~ **recognized by** the State of Oregon;
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> (B) A nurse practitioner with prescriptive authority licensed by ~~the~~ **an approved** ~~Oregon State~~ Board of Nursing **recognized by the State of Oregon**;
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> (C) A dentist licensed by **an approved** ~~the~~ Board of Dentistry **recognized by** ~~for~~ the State of Oregon;
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> (D) An optometrist licensed by **an approved** ~~the~~ Board of Optometry ~~for~~ **recognized by** the State of Oregon; or
>
> (E) A naturopathic physician licensed by **an approved** ~~the~~ Board of Naturopathy ~~for~~ **recognized by** the State of Oregon;

(1)(i) For the purpose of this rule, "prescription medication" means any ~~noninjectable~~ drug, chemical compound, suspension or preparation in suitable form for use as a curative or remedial substance taken either internally or externally by a student under the written direction of a physician. **Prescription m**~~M~~edication **is non-injectable with the exception of autoinjectable epinephrine, will** includes ~~any prescription for~~ bronchodilators~~, or autoinjectable epinephrine~~ **and must be** prescribed by a student's ~~Oregon~~ **Board** licensed health care professional. ~~for asthma or severe allergies~~ Prescription medication does not include dietary food supplements;

(1)(j) "Qualified trainer" means a person who is familiar with the delivery of health services in a school setting and who is:

(A) A Registered Nurse licensed by **an approved** ~~the Oregon State~~ Board of Nursing **recognized by the State of Oregon**;

(B) A physician; or

(C) A pharmacist licensed by ~~the State~~ **an approved** Board of Pharmacy **recognized by** ~~for~~ the State of Oregon;

(3)(g) Require that ~~an Oregon~~ **a Board** licensed health care professional prescribe the medication to be used by the student during school hours and instruct the student in the correct and responsible use of the medication;

(3)(h) Require that ~~an Oregon~~ **a Board** licensed health care professional, acting within the scope of the person's license; formulate a written treatment plan for managing the student's asthma or severe allergy;

6. A method of administration would only be given for non-oral route medications. These directions are usually included in the package insert of the medication and show pictures (inhalers, epi-pens). We suggest amending items (1)(A)(iv) and (1)(e)(D)

(1)(A)(iv) Method of administration **for non-oral route medications**;

(1)(D) Method of administration **for non-oral route medications;**

7. Prescription labels are required to state the route for administration, such as but not limited to oral, rectal, subcutaneous, intramuscular, topical, nasally, ophthalmic, ear canal. We suggest adding back the line for route of medication administration in items (1)(A) and (1)(e).

(1)(A)Route of administration, such as but not limited to oral, rectal, subcutaneous, intramuscular, topical, nasally, ophthalmic, ear canal.

(1)(e)Route of administration, such as but not limited to oral, rectal, subcutaneous, intramuscular, topical, nasally, ophthalmic, ear canal.

8. The responsibility to ensure a student's safety begins when supervision transfers from the parent (or parent designated caregiver) to a personnel running a school permitted or sponsored function. So when a child boards the morning bus, or is dropped off at a before-school care program. It continues through the school day, including off-campus school sponsored field trips. Continuing until that child has gotten off the bus, or has been picked up at the end of the school day, aftercare program at the school, or extracurricular club on school owned property by the parent or parent designated caregiver. To reflect this obligation we suggest the following language change to item 3(g)

   (3)(g) Require that an Oregon licensed health care professional prescribe the medication to be used by the student ~~during school hours~~ **in school, at a school-sponsored activity, while under the supervision of school personnel, in before-school or after-school programs on school-owned property, in transit to or from school or school-sponsored activities** and instruct the student in the correct and responsible use of the medication;

9. We would like to see language added to 581-021-0037 allowing students to self-carry auto injectable epinephrine with provision for trained school personnel to administer or assist a student in injecting self-carried epinephrine.

   The reasons for this are two-fold. First, a major concern is the ready availability of the emergency rescue medicine (epinephrine) in the event of anaphylaxis. In fatal cases of anaphylaxis, the median time to cardiac arrest was 15 minutes for insect stings and 30 minutes following food allergen ingestion, meaning half of all cases progressed more quickly. Delay in administering epinephrine is a major factor in nearly all cases of fatal anaphylaxis[ii,iii,iv]. Recent research supports a timeframe of less than 15 minutes from reaction onset for administration of epinephrine leading to a favorable outcome of an anaphylactic reaction[v]. This time window leaves little room for error or oversight on the part of responsible staff to recognize an anaphylactic reaction in progress. This is an especially intimidating prospect given the increasing class sizes in Oregon and across the nation. In fact, one study identified that many children in the school setting are at increased risk due to restricted access of their epinephrine auto-injectors and encouraged that students who are at risk of anaphylaxis self-carry their epinephrine[vi].

   Second, while children entering school with food allergies are keenly aware of how to use an auto-injector, this does not imply an ability to self-administer in an emergency. Parental reports indicate a few common responses to an allergic reaction in children, including but not limited to:

   i. Student will recognize symptoms of a reaction, report them to an adult, and seek treatment
   ii. Student will recognize symptoms of a reaction, hide them from an adult to avoid epinephrine injection. In some cases an extra adult will be required to restrain child for proper medication administration.
   iii. Student may be incapacitated and unable to elicit assistance.

iv. Student will not recognize symptoms of a reaction and deny need for treatment.
v. Student will not recognize symptoms of a reaction and accept treatment.

In light of these concerns, a student self-carrying, but not required to self-administer epinephrine is a viable and proven solution in many schools, allowing the assigned epinephrine auto-injector to be available immediately upon recognition of a reaction in progress.

10. Staff designation when a student is qualified as disabled is not addressed within this administrative rule. In this instance the student receives services from staff reporting to the district special education office in addition to the building administrator. We would like to see language added perhaps within item (2) and (3) to reflect the need to develop a procedure for coordinating staff designations, utilizing the expert judgment of a board licensed health care professional, such as a school nurse or physician.

Respectfully submitted on behalf of Oregon Food Allergy Network, representing food allergic parents across Oregon.

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[i] American Academy of Allergy, Asthma, and Immunology

[ii] "Lessons for management of anaphylaxis from a study of fatal reactions.", Pumphrey et al. *Clin Exp Allergy*. 2000 Aug;30(8):1144-50.

[iii] "Further fatalities caused by anaphylactic reactions to food, 2001-2006.", Bock et al. J Allergy Clin Immunol. 2007 Apr;119(4):1016-8. Epub 2007 Feb 15.

[iv] " Further fatal allergic reactions to food in the United Kingdom, 1999-2006.", Pumphrey et al. J Allergy Clin Immunol. 2007 Apr;119(4):1018-9. Epub 2007 Mar 8.

[v]"Effect of epinephrine on platelet-activating factor-stimulated human vascular smooth muscle cells.", Vadas et al. J Allergy Clin Immunol. 2012 May;129(5):1329-33. doi: 10.1016/j.jaci.2012.02.027. Epub 2012 Mar 27.

[vi] Availability of the epinephrine autoinjector at school in children with peanut allergy., Ben-Shoshan et al. Ann Allergy Asthma Immunol. 2008 Jun;100(6):570-5. doi: 10.1016/S1081-1206(10)60056-7.