

2015 SPOTLIGHT ARTICLE II

"Entity Laws" Aim to Protect Children Beyond the School Campus

Food allergies – the most common cause of severe allergic reactions – can be triggered anywhere food is prepared and consumed, not just at schools. Therefore, parents, caregivers and families of food allergic individuals are wise to seek ways to protect children at risk of severe allergic reactions beyond the K-12 school setting. Focus is widening to consider epinephrine stocking laws beyond schools and into other “entities” where food is present, such as off-campus activities, sports and recreation venues, summer camps, colleges and universities, and public restaurants.

Food allergy advocates would like for those who handle, prepare, cook or sell food to be better educated about reducing risks of allergic reactions. Patient advocates would also appreciate knowing that the first-line treatment, epinephrine, is readily available to the public in easy to use auto-injector form, much like AEDs⁶⁶ are available in public places like airports and sports arenas for heart attack symptoms. Many would like widespread training for employees to prepare them to administer epinephrine immediately.



Thus, the next milestone for states to consider expanding access to epinephrine for emergencies is extending stocking laws to other entities in addition to K-12 schools. Strategies are under way to help promote this aim.

Some efforts are being undertaken without government involvement. Private sector organizations and corporations are voluntarily acting to promote awareness and to make epinephrine auto-injectors available for emergencies. For instance, Disney Theme Parks and Mylan LLP have joined to promote awareness and prevention at Disney parks and cruise ships.⁶⁷ Park nurses have access to EpiPen® (epinephrine) Auto-Injectors. Facility maps now include locations where guests can find the devices at Disney theme parks and on Disney cruise ships. Disney plans to offer educational materials and programs to promote allergy awareness. Expanding this model to other businesses would represent significant progress.

Voluntary actions are promising but the impact is limited. In addition, current laws can create roadblocks. For instance, an individual using an epinephrine auto-injector on another person might be concerned that such actions could be considered illegally practicing medicine. Potential legal liability may discourage innovative programs. Thus, advocates are considering laws that will enable and encourage interested businesses and individuals to increase awareness and prevention, and to make epinephrine available to treat anaphylaxis.

⁶⁶ AEDs, or automated external defibrillators, are portable units for sensing and treating irregular heart rhythms associated with cardiac arrest.

⁶⁷ *Mylan Signs Strategic Alliance Agreement with Walt Disney Parks and Resorts to Enhance Access to EpiPen® (epinephrine) Auto-Injectors*, PR Newswire, November 7, 2014 (accessed at <http://www.prnewswire.com/news-releases/mylan-signs-strategic-alliance-agreement-with-walt-disney-parks-and-resorts-to-enhance-access-to-epipen-epinephrine-auto-injectors-281903761.html>, 8/1/15)

State Entity Laws Beyond K-12 Schools

States are beginning to consider "entity laws" to extend the protective zone of epinephrine auto-injector availability beyond K-12 schools to other settings where food is eaten. Several states (Colorado, Florida, New York, North Dakota, Ohio, Oregon, and Utah) have enacted entity laws. Many others are considering them. How the laws affect people with food allergies and which types of entities are affected varies from state to state, but a trend is developing. This section summarizes the laws generally. Be sure to check your state law before making any assumptions.

Eligibility. The laws do not require individuals, businesses or any other entity to participate. However, they typically allow individuals, businesses or organizations to participate under the law assuring that those who experience severe allergic reactions have access to an epinephrine auto-injector.

For businesses and organizations, participation means that they are allowed or "authorized" to acquire an epinephrine auto-injector and store it on their site. The list of those that may be authorized usually includes venues that offer activities aimed at children, like summer camps, day camps, sports camps, colleges, pre-schools, day care centers, and theme parks. For instance, the Florida law's eligibility list includes, but is not limited to, restaurants, recreation camps, youth sports leagues, theme parks and resorts, and sports arenas.⁶⁸ Some state laws include other entities that are not necessarily named in the law as long as they take steps to set out in the law to participate. Note that both eligibility and any process to become an authorized business or organization entity vary from state to state.

These laws allow physicians and other named medical providers to prescribe epinephrine auto-injectors to a named authorized entity. Note that New York State requires that the authorized individual or entity have a collaborative agreement with an emergency care provider.

For individuals, participation means being able to administer the medication to another person if the individual believes in good faith that the person is experiencing a severe allergic reaction. Individuals may participate after they become certified to participate. Certification requirements are described by state law and generally require successful completion of a training program and paying a fee. Again, the specific requirements for certification will vary based on each state's law.

Training. Typically, these laws allow an individual over the age of 18 to become certified to administer epinephrine auto-injectors if he or she is properly trained. The required training covers recognizing the signs and symptoms of anaphylaxis and properly using epinephrine auto-injectors. Some laws specify that the training be provided by a specific organization such as a health department, a national organization or a training program approved by the state health department.

Liability Protection. An important feature of these laws is protecting businesses, entities, individuals and physicians or other licensed prescribers, like physicians assistants or advanced practice nurses, from being sued for actions taken (or not taken) as epinephrine auto-injectors are obtained, dispensed, stored, or used, or in training individuals to administer them. Entity laws generally protect participating organizations, their eligible staff and volunteers, as well as other authorized individuals from being held liable for unintentional injury associated with

⁶⁸ Florida HB 1131 (enrolled as Section 381.88, Florida Statutes), (accessed <https://legiscan.com/FL/bill/H1131/2014>, 8/1/15)

administering (or failing to administer) epinephrine auto-injectors. The laws also protect prescribing physicians and pharmacists from liability for writing prescriptions and dispensing to authorized entities.

Impact

Entity laws represent a potential breakthrough for people living with food allergies. These laws help promote awareness of the severity and challenges of food allergies and training programs for food industry personnel. Wherever they go to work, workers will take their food allergy knowledge, awareness and skills with them. Organizations that serve people with food allergies like childcare centers, camps and sports leagues will be able to obtain and keep epinephrine auto-injectors on hand for emergencies. As states with such entity laws gain additional experience with them, the food allergy community can look to the early “adopters” of such legislation to obtain insights and lessons learned for potential applicability in other states.

In the future, epinephrine auto-injectors may be readily available in clearly identified units as standard equipment in office buildings, malls, religious institutions and buildings, restaurants, airports, parks, movie theaters and ballparks, and every public venue imaginable.