

Date: March 6, 2015	POLICY BRIEF/ANALYSIS PREPARED FOR THE BOARD OF DIRECTORS	 OF NORTHERN LARIMER COUNTY
Staff: Dan Sapienza		

HB15-1232 - EMERGENCY USE OF EPINEPHRINE AUTO-INJECTORS

Concerning the emergency use of epinephrine auto-injectors by authorized entities

Details

Bill Sponsors:	House – Ginal (D) and Landgraf (R) Senate – Todd (D)
Committee:	House Public Health Care & Human Services
Bill History:	02/19/2015 Introduced In House - Assigned to Public Health Care & Human Services
Next Action:	House PHCHS Committee – March 13, 2015

Bill Summary

This bill permits “entities” to acquire and stock epinephrine auto-injectors; these are for organizations or business where allergens capable of causing anaphylaxis might be present. These entities must have staff that have completed training on the use of the auto-injectors who are responsible for the storage and oversight of their use. The bill then exempts from civil and criminal liability individuals and the entity for the use of the auto-injectors in good faith.

Background

In 2013, House Bill 15-1171 authorized schools to stock epinephrine for use during anaphylaxis. Prior to that bill, students with prescriptions could store their epinephrine with the school nurse, but the 2013 legislation allows the nurse to stock the drug and use it, regardless of whether students had a prescription. That legislation was widely supported and is similar to laws across the nation. A January 2014 article, immediately following the law’s implementation, indicated that schools’ desire to stock the devices varied widely across the state.

Anaphylaxis is a severe, whole-body allergic reaction to an allergen, such as food, a chemical (drug), or a toxin (insect venom). Anaphylaxis is sudden and life-threatening.¹ Epinephrine (adrenaline) is an emergency treatment for anaphylaxis; the drug is highly effective and can immediately reverse severe symptoms.

It is estimated that there are tens of thousands of incidents of anaphylaxis annually in the United States, with a fatality rate of 1%. Based on a 2001 review in the Archives of Internal Medicine, it was estimated that approximately 1500 people die annually in the U.S. from anaphylaxis (though this could be somewhat underreported). Of these, about 500-1000 per year were caused by penicillin, 900 per year by radio contrast media, 3 by latex, 40-100 by insect stings, and about 100 die from food-related anaphylaxis.²

That same review estimated that the U.S. population with a lifetime risk of anaphylaxis is between 3.3 and 43 million. This is a wide range, but narrower than some other estimates. For food allergies, the review estimated that as many as 2 million U.S. residents are at risk. It is very difficult to accurately estimate the

¹ <http://www.nlm.nih.gov/medlineplus/ency/article/000844.htm>

² Neugut, Alfred et al. Anaphylaxis in the United States: An Investigation into its Epidemiology. Arch Intern Med. 2001;161(1):15-21. doi:10.1001/archinte.161.1.15. Available at: <http://archinte.jamanetwork.com/article.aspx?articleid=646961>

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risk, as individuals' risks can change over their lifetime and there is a recent upward trend of unknown origin.³

Epinephrine

Epinephrine auto-injectors are widely prescribed for the emergency treatment of anaphylaxis and is highly effective. It must be used quickly to have maximum effect and some experts recommend those at high risk of anaphylaxis carry two auto-injectors as the therapeutic window is very short. In studies of fatal cases of anaphylaxis, few had auto-injectors available. In a review of 6 fatal and 7 non-fatal similar cases of food-related anaphylaxis in minors, all survivors received epinephrine within a 5 minute window.⁴

The World Allergy Organization indicates that treatment for acute anaphylaxis should include epinephrine administration every 5 to 15 minutes as appropriate. Though an individual might respond favorably to the initial treatment, there is a high risk of recurrent symptoms within minutes to hours later and aftercare is extremely important. A single dose is frequently insufficient.

Epinephrine is generally safe for use, though there are some potential risks, including fatal cardiac arrhythmia, acute myocardial infarction, acute exacerbation of hypertension and other cardiovascular complications. These tend to occur in elderly patients, those with certain chronic conditions, or on certain drugs (beta-blockers).

Reasons to Support

Anaphylaxis is an extremely dangerous condition that can be readily treated in an emergency by epinephrine. For this treatment to be effective, the injection must be administered within a short window. While many individuals diagnosed with allergies and a risk of anaphylaxis will carry epinephrine auto-injectors, many do not. Some studies have seen as many as 50% of those who previously experienced anaphylaxis did not carry epinephrine when prescribed, though education can increase adherence.⁵ In addition, many individuals may experience anaphylaxis with no previous diagnosis.

This bill would allow restaurants and other facilities to stock epinephrine in case an individual experiences an anaphylactic episode, potentially saving lives. In these places, at least one staff person would undergo training to ensure that there was some knowledge of symptoms and signs of anaphylaxis and proper use of epinephrine.

Reasons to Oppose

Epinephrine is generally, but not always, safe. Existing studies of its safety profile are for administration by health professionals or by individuals who are known to be at risk of anaphylaxis. Under existing law in Colorado, schools may stock epinephrine, but these are generally used and managed by school nurses. There is little evidence of the effectiveness of bystander lay-persons in using epinephrine for anaphylactic episodes.

³ Sicherer, Scott, et al. Editor's Correspondence. Underrepresentation of the Risk and Incidence of Anaphylaxis to Foods. *Arch Intern Med*. 2001;161(16):2046-2047. doi:. Available at:

<http://archinte.jamanetwork.com/article.aspx?articleid=648861>

⁴ <http://www.waojournal.org/content/pdf/1939-4551-1-S2-S18.pdf>

⁵ <http://www.waojournal.org/content/pdf/1939-4551-1-S2-S18.pdf>

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The symptoms of anaphylaxis can come on suddenly or gradually, can be mild or severe, and include some combination of symptoms from multiple body systems: generalized itching, skin redness or hives; tingling in the mouth, swelling of the lips, face, or throat; severe sneezing, wheezing or shortness of breath; anxiety, stomach cramps, vomiting or diarrhea; chest pain, lightheadedness and in severe cases loss of consciousness.⁶ Symptoms can vary from person to person and even from one episode to the next. The overlap of these symptoms with symptoms of other conditions such as heart attack, choking, other allergic reactions, and even anxiety attacks can make recognition of anaphylaxis challenging in some cases. A layperson trained to look for anaphylaxis and in use of epinephrine could misdiagnose these conditions and over treat.

The cost per life saved would be extremely high. An EpiPen two-dose pack costs \$340 and the product has a relatively short shelf-life (it expires 18 months from the date of manufacturer). The cost of training staff and storing the product in all the establishments where persons at risk would potentially be exposed to their offending allergens in order to prevent the rare deaths from anaphylaxis would be onerous.

The bill exempts entities and individuals using epinephrine under the bill from liability for its use (or omission of its use) in good faith. There may be some concern that stocking epinephrine and training staff would become a standard, leading to liability for restaurants, businesses, or organizations that fail to stock the drugs and train staff.

About this Summary

This summary was prepared by Health District of Northern Larimer County staff to assist the Health District Board of Directors in determining whether to take an official stand on various health-related issues. The Health District is a special district of the northern two-thirds of Larimer County, Colorado, supported by local property tax dollars and governed by a publicly elected five-member board. The Health District provides medical, mental health, dental, preventive and health planning services to the communities it serves. For more information about this summary or the Health District, please contact Dan Sapienza, Policy Coordinator, at (970) 224-5209, or e-mail at dsapienza@healthdistrict.org.

⁶ <http://www.nlm.nih.gov/medlineplus/ency/article/000844.htm>