2015 SPOTLIGHT ARTICLE I

From Statehouse to Schoolhouse: Implementing Epinephrine Stocking Laws

No nationwide campaign takes-off without widespread recognition that there is a problem. In 2012, a first-grader died from an allergic reaction while at school. Her sudden death shocked the nation. Food allergy advocates believed that her death might have been prevented if the medication epinephrine had been administered in time. Reportedly, none was available to her at school. Most states had already allowed students to carry and use their own epinephrine at school. However, only a handful of states allowed schools to stock epinephrine auto-injectors for emergencies. By law, schools were not allowed to treat allergic reactions with the epinephrine unless the medication was prescribed by a medical professional for a specific student. The problem was in the law.

Fortunately, over the following 3 years, lawmakers acted. On November 13, 2013, President Obama signed the School Access to Emergency Epinephrine Act into law. This federal law encouraged states to implement policies requiring schools to stock undesignated epinephrine auto-injectors for use in emergencies.

By 2015, food allergy advocates could celebrate an important milestone. Lawmakers in 46 states approved laws making epinephrine auto-injectors available to their schools for allergy emergencies.

Getting epinephrine school stocking laws on the books is a first step on the path to getting epinephrine auto-injectors into the schools. The next step is implementing these laws. Implementing a law is arguably more complex than passing a law because multiple public agencies and private sector organizations may be involved, and each may have its own decision-making processes and time-lines.

In the case of school epinephrine stocking laws, the public agencies involved might include the office of the governor, state departments of education and health, local school districts and systems, state attorney general offices, and potentially other state health and medical regulatory bodies. Parents, families and caregivers can also participate. Professional and trade associations, unions, and clinical specialty societies may also become involved.

In general, these laws include provisions to address four major target areas:

**Enabling schools to acquire and keep epinephrine on-hand.** In order for schools to stock epinephrine auto-injectors, they must be able to acquire them legally. These devices are available by prescription only. Therefore, the school stocking laws have to modify the prescription requirement for schools by authorizing doctors or other prescribers to write a prescription to a school rather than to a specific patient. Doing so could involve having state medical licensing boards enable such arrangements by regulation or rule.

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School systems have a major role to play in order to assure that the requirements of the law are understood and carried out consistently. They have to develop forms that align with the new laws, such as forms for schools to report when and why the medication is used. School systems may have to develop agreements with physicians or other prescribers for schools to use when ordering the epinephrine auto-injectors. In addition, they set minimum levels of the devices to stock at schools and need to identify, develop and establish standard operating processes and procedures. Training for non-clinical, non-licensed school personnel is needed. However, laws vary about permitting a school to designate one or more non-nurse staff members to receive training so they can administer the medication in an emergency. State laws and nurse practice acts differ from state to state, so each school district and each school nurse must ensure before enacting any protocol that it is consistent with applicable state laws and regulations, including those governing delegation.\textsuperscript{60}

State agencies can help enable implementation by communicating clearly with schools and other stakeholders. For example, in order to clarify the myriad of requirements under the recent laws state governing allergy and asthma medications at school, the Illinois State Board of Education published \textit{guidance} for schools in a simple question and answer table.

Physicians need guidance, too. For example, Illinois developed a \textit{toolkit for physicians} to help them navigate the process of setting standing orders of the medication for schools. State licensing boards and even malpractice insurance carriers may become involved.

Importantly, school systems must also budget and allocate resources to purchase epinephrine auto-injectors. As a way of easing the cost burden to school systems, one manufacturer (Mylan, L.P.) is offering free devices to systems that have signed prescriptions.\textsuperscript{61}

\textbf{Authorizing people (other than the students themselves) to appropriately administer epinephrine to children.} Allowing states to keep emergency medications on hand is insufficient if school staff or other third parties hesitate, do not know how, or refuse to use them on a student. In addition to relying on school nurses on site, states are implementing other ways to help overcome this challenge. Training designated school staff in addition to school nurses, and volunteers to recognize the signs and symptoms of anaphylaxis and how to access and use the epinephrine auto-injector is paramount. School systems may specifically develop and offer such training programs. Some may require training for certain staff and authorized volunteers. Caution is encouraged to assure that training that it is consistent with applicable state laws and regulations, including those governing delegation, as well as applicable school district policies and procedures.\textsuperscript{62}

\textbf{Encouraging people to act swiftly and appropriately in an emergency.} In general, laws do not require people to act to save a life. To the contrary, they are discouraged from doing so by laws that may hold them responsible for injuring a person while they sincerely try to save a life.

Therefore, stock epinephrine in school laws contain provisions allowing people to act without fear of liability for administering epinephrine auto-injectors as long as they have acted in good faith, not intending to injure.

\textsuperscript{61}https://www.epipen4schools.com
These laws also encourage action by providing for training. Training enables people to recognize signs and symptoms of severe allergic reactions and to administer the epinephrine auto-injector properly. Training enhances confidence and minimizes delay.

**Evaluation, tracking emergency incidents and reporting results.** How effective is stocking epinephrine auto-injectors at schools? In order to maintain the practice of stocking these medications, advocates need to show positive results. Reporting incidents to a publically accessible database can help to facilitate improvements in allergy care and treatment at school. Some laws detail reporting requirements like keeping track of the times when epinephrine auto-injectors are used at schools and the circumstances of their use. Whether required by law or not, school systems should put incident tracking in place as part of stocking programs.

**The Implementation Process**

Typically, these laws leave it up to a school district to adopt detailed rules and forms that implement the targets listed above. The specific provisions of these laws vary from state to state and so does the implementation process. Some laws include more detail than others do and others delegate most of the detail to other administrative bodies to develop and enforce. For instance, some laws say schools must keep the medications in a locked location, but others leave it up to the schools or school district to determine who will have access and where it will be maintained.

**Getting Involved**

State agencies, including departments of education, health, and professional licensing bureaus, must follow what is referred to as "due process" before implementing rules and regulations that are effective. Typically, "due process" means that after the agency drafts new rules and regulations to spell out what is required under new laws, they must provide the public with notice and an opportunity to comment. State agencies may be obligated to provide public notice and a chance to comment as they develop rules implementing school stocking. For instance, parents may have a chance to hear about new rules and to comment at public school board meetings.

Because of strong advocacy by parents to get new school epinephrine stocking laws passed, school administrators who are tasked with writing implementation rules may consult them during the drafting process. Whether or not this is the case, the obligation to share draft rules and accept public comment may provide an important chance for advocates to intervene.

The ultimate point of evaluation is at the school. Simply checking in with the school nurse or administration office with specific questions can help parents and other caregivers evaluate the four implementation targets presented in this article.

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63 For example, Louisiana LA 2012 SB 119 chaptered Act 624
64 For example, California SB 1266, 2015 (http://www.leginfo.ca.gov/pub/13-14/bill/sen/sb_1251-1300/sb_1266_bill_20140915_chaptered.html, accessed 8/1/15)
Key Questions for Parents and Caregivers Regarding Implementation

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<thead>
<tr>
<th>School Stocking</th>
<th>Who Administers</th>
<th>Encourage Action</th>
<th>Evaluation</th>
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<tbody>
<tr>
<td>Where is epinephrine kept?</td>
<td>School nurses only?</td>
<td>Training available for volunteers?</td>
<td>Incident tracking?</td>
</tr>
<tr>
<td>How is it accessed?</td>
<td>May others administer to students?</td>
<td>Other requirements for volunteers?</td>
<td>Public reporting of results?</td>
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<tr>
<td>Who has access to it?</td>
<td>Training required for others?</td>
<td>&quot;Good Samaritan&quot; liability limited?</td>
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<tr>
<td>In what form?</td>
<td>School system liability limited?</td>
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<td>How many doses?</td>
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Once parents, families, caregivers and guardians have information about how schools approach these questions, they will be in a better position to evaluate whether the implementation of these laws is succeeding where it counts— at school.

Resources

To effectively manage food allergies and the risks associated with these conditions, many people inside and outside the school or early childhood education (ECE) program should come together to develop a comprehensive plan. The US Centers for Disease Control, in collaboration with other organizations offers guidelines for preparing a Food Allergy Management and Prevention Plan (FAMPP).\(^6\) This plan should include all strategies and actions needed to manage food allergies in the school or ECE program.

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