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The Stock Epinephrine Law - 5 Years Later and Counting

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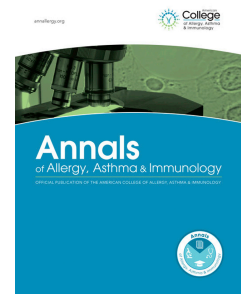
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1 The School Access to Emergency Epinephrine Act was signed into law by President Obama on
2 November 13, 2013 with bipartisan support (Public Law 113-48). The law amended the Public
3 Health Service Act to increase the preference given to certain asthma-related grants in states
4 that allow trained school personnel to administer epinephrine and maintain a stock
5 epinephrine supply to treat suspected anaphylaxis. To qualify, states are also required to
6 provide civil liability protection to trained staff acting in good faith at the elementary and
7 secondary levels. Currently, 49 states and the District of Columbia have laws that allow schools
8 to stock epinephrine; however, only the minority require this practice.

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10 The purpose of the law was to increase epinephrine access within schools, but did it accomplish
11 this goal? The passage of the law was generally seen as a big “win” for the food allergy
12 advocacy community, and it certainly raised awareness of the importance of epinephrine access
13 in anaphylaxis treatment. However, the financial incentive provided to states only pertains to
14 those that *require* schools to maintain stock epinephrine and certify civil liability protection.
15 This unfunded approach to improve access to epinephrine autoinjectors relied on a relatively
16 weak incentive without any mandate or penalty.

17
18 The hope in 2013 was that this law would ignite a cascade of changes within schools on the
19 state level; however, it is difficult to know whether or not this has been achieved because
20 mandatory reporting is not required. Prior to the passage of the law, only four states *required*
21 stock epinephrine in schools, and two years later this number had increased to just twelve.
22 Notably, a research gap exists because current data on states requiring stock epinephrine is not

readily available. In particular, the Food Allergy Research & Education school access to epinephrine map (<https://www.foodallergy.org/education-awareness/advocacy-resources/advocacy-priorities/school-access-to-epinephrine-map>) has not been updated since 2016, as of this writing. While mandated stock epinephrine provides a valuable shared resource, voluntary programs may not address unmet needs of populations at risk for anaphylaxis, such as individuals previously undiagnosed with food allergy. For example, a 3-fold increase in physician documentation of food allergy, epinephrine autoinjector orders, and epinephrine administration was described in New York state, which has required stocking of non-student specific epinephrine since the 2005-2006 school year.¹ More than half of epinephrine autoinjectors used were stock devices, and three-quarters were for students without student-specific orders before the incident.¹ Similarly, in a report by DeSantiago-Cardenas 38 stock devices were administered over the course of a single school year (2012-2013) in the Chicago Public Schools system (>350,000 students). While most devices were used to treat children, it is important to note that 8% of devices were administered to school staff. More than half of devices (55%) were used for individuals without a history of prior anaphylaxis who did not have access to a personal epinephrine autoinjector.² In contrast, a recent survey of school nurses in Ohio, where undesignated epinephrine is optional, reported stock epinephrine was unavailable in 42.5% of schools.³ In this study, cost, administrative discretion, and prescriber willingness were major barriers to implementation (identified by 55%, 50%, and 42% of respondents, respectively).³

Liability concerns are one potential explanation for stock epinephrine prescriber hesitancy³ and more generalized apprehension about sharing epinephrine.⁴ In one recent survey, 71% of caregivers who would not share epinephrine right away expressed liability concerns compared to 56% of those who would immediately share.⁴ Importantly, even in states with mandated stock epinephrine laws, there is variation in liability protection in addition to a lack of clarity regarding delegated prescriber authority. Additional confusion exists regarding the responsibility for statutory enforcement, staff training, and administrative support. Fortunately, the American College of Allergy, Asthma, and Immunology (https://college.acaai.org/sites/default/files/ACAAI_EpinephrineToolkit-2015.pdf) and the Allergy & Asthma Network (<https://www.allergyasthmanetwork.org/education/food-allergies/prevention-school/stock-epinephrine-implementation-tool-kit>) have stock epinephrine toolkits available online which can assist allergists in navigating specific laws within their state and providing a standard order for stock epinephrine.

Rising cost of epinephrine autoinjectors is another important concern, and 47% of caregivers who would not immediately share epinephrine expressed concerns regarding autoinjector expense compared to 31% of those sharing right away.⁴ To some extent, the *Epipen4Schools* program has helped address cost barriers (<https://www.epipen4schools.com>). However, from a societal perspective, a universal approach to shared epinephrine in schools (where the only units at school are stock units, and students need not supply their own individual units) presents a cost-saving strategy with improved health outcomes.⁵ In fact, a recent cost-effectiveness analysis of universal stock school epinephrine demonstrated a cost-savings of

\$7,419 per student at risk.⁵ However, few schools truly have a stock policy where select undesignated units are the sole source at school for everyone - an approach that would not only maximize cost-effective health policy but also decrease device shortages.

The stock school epinephrine laws have been a mixed bag. School policies are generally viewed as helpful, but more needs to be done. Many schools do not have a full-time registered nurse, with some schools having no nursing access at all - raising concerns for how effectively stock epinephrine programs can be implemented. Differences in implementation guidance between states and reporting requirements for when stock epinephrine is used are also problematic. . In addition, the stock epinephrine laws generally do not address post-secondary education – although some states do have laws that address higher education stock epinephrine policies. Maryland, for example, has a law that was passed in 2018 (<http://mgaleg.maryland.gov/webmga/frmMain.aspx?pid=billpage&stab=01&id=hb1473&tab=subject3&ys=2018RS>).

While improved access to epinephrine has certainly occurred over the past five years, the ever-present question is whether or not the compromises reached to create opt-in stock epinephrine laws were worth sacrificing a mandate for stock school epinephrine. As with much national healthcare policy over the past decade, we have made incremental progress in some areas but there is still much work to do. Across our nation, reaching a more consistent and transparent stock school epinephrine policy will likely pay dividends not only in healthcare

87 savings, but also in providing safer environments for our patients with food allergies and peace

88 of mind for their families.

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