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## Pharmacist Prescriptive Authority for Epinephrine Auto-Injectors in Idaho

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### Abstract

**Objective:** To describe recent legislation in Idaho that granted pharmacists autonomous prescriptive authority for epinephrine auto-injectors.

**Practice Innovation:** States have taken action to increase access to epinephrine auto-injectors by allowing them to be stocked and prepositioned at locations where individuals may encounter allergens. All 50 states have allowed schools to maintain stock supplies of epinephrine auto-injectors and 26 states have allowed other entities, such as summer camps, daycare centers, gymnasiums, and restaurants to begin stocking product as well. In 2016, legislation in Idaho pursued entity stocking while simultaneously granting pharmacists autonomous prescriptive authority for epinephrine auto-injectors.

**Results:** Idaho legislation granted prescriptive authority for pharmacists for epinephrine auto-injectors not just for individual patients, but also for authorized entities. No collaborative practice agreement is necessary. To receive an epinephrine auto-injector, an agent or employee of an authorized entity must present proof that they have completed an appropriate training program. Pharmacists are provided liability protections when prescribing in good faith to an authorized entity.

**Conclusion:** Idaho's legislation provides a potential model for pharmacist prescriptive authority for epinephrine auto-injectors that other states may consider pursuing in the years ahead.

**Key Words:** Pharmacist Prescriptive Authority; Pharmacy Law; Provider Status

In recent years, states have taken action to increase access to epinephrine auto-injectors by allowing them to be stocked and prepositioned at locations where individuals may encounter allergens.<sup>1</sup> Several reasons underpin this. First, life-threatening allergic reactions to foods, insect stings, or other substances are unpredictable and delays in treatment can increase the risk of fatality.<sup>2</sup> Second, epinephrine provides a powerful antidote to anaphylactic reactions, with a strong safety profile and limited risk of adverse effects and no contraindications.<sup>3</sup> Third, certain epinephrine products are supplied as auto-injectors, which can be used safely and appropriately by laypersons.<sup>4</sup> Some auto-injectors are even equipped with audio instructions to guide a layperson through appropriate use in an emergency. Fourth, studies show that 15 to 25% of epinephrine administrations were to individuals who had no previous known allergies.<sup>5-6</sup> Thus, epinephrine auto-injectors are generally safe and easy to use by laypersons, and timely administration can mitigate unpredictable life-threatening allergic reactions.

As of May 2016, all 50 states and the District of Columbia have laws that allow schools to stock epinephrine in primary and secondary schools with some positive results already

documented.<sup>1</sup> A study in the New York public school district revealed epinephrine was administered 338 times over a five-year period, and only 20.7% of administrations were to students with a medication administration form for epinephrine on file.<sup>7</sup> In the Akron (OH) school district, two children were rescued with epinephrine in the first year of the legislation taking effect.<sup>8</sup> Given the positive outcomes achieved in schools, patient advocacy groups have started advancing legislation to broaden epinephrine-stocking laws beyond schools, such as allowing auto-injectors to be prepositioned at summer camps, daycare centers, gymnasiums, and restaurants, among other facilities. Currently, 26 states allow such non-school entities to stock epinephrine.<sup>1,9</sup>

In 2016, legislation was signed into law in Idaho that expanded the authority of entities beyond schools to stock epinephrine auto-injectors.<sup>10</sup> Idaho's legislation -- Senate Bill 1322a -- was unique, however, in that it simultaneously granted pharmacists autonomous prescriptive authority for epinephrine auto-injectors.<sup>11</sup> Idaho is among the first state to grant such broad prescriptive authority for pharmacists not just for individual patients, but also for entities. This manuscript will highlight the Idaho legislation and experience as a model for other states considering such legislation.

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### Core Elements of Idaho Senate Bill 1322a

There are two core components of the Idaho legislation:

### 1. Authorization for Entities to Maintain Epinephrine Auto-Injector Supply

While 26 states have now passed legislation to allow non-schools to stock epinephrine, there are slight variations across states, generally in the definition of authorized entities.<sup>1</sup> Idaho's bill intends to define "authorized entity" broadly, recognizing any organization "at which allergens capable of causing anaphylaxis may be present." The bill offered a non-exclusive list of such entities: "recreation camps, colleges and universities, day care facilities, youth sports leagues, amusement parks, restaurants, places of employment and sports arenas."<sup>11</sup>

Several amendments to existing law were made to remove any barrier to authorized entities stocking epinephrine. For example, the statute outlining criminal penalties for the sale or the possession of a legend drug outside of a valid prescription drug order exempted epinephrine auto-injectors if in compliance with other provisions in Senate Bill 1322a. Similarly, the statute limiting prescriptions to a valid "prescriber-patient relationship" with a documented patient evaluation also exempted epinephrine auto-injectors.

The legislation required authorized entities to comply with the following:

- Epinephrine auto-injectors must be stored in a "location readily accessible in an emergency and in accordance with proper instructions for use."
- An employee or agent of the authorized entity must complete a training program by a "nationally recognized organization experienced in training laypersons in emergency health treatment" in order to administer epinephrine. The bill delineated certain required topics, including how to recognize allergic reactions and anaphylaxis, standard procedures of storage, administration, disposal, and emergency follow-up procedures.
- The authorized entity must contact emergency medical services as soon as possible following an administration.<sup>11</sup>

An authorized entity may have its employee or agent who has completed the specified training program directly administer the epinephrine auto-injector to any individual who he or she "believes in good faith to be experiencing anaphylaxis, regardless of whether the individual has previously been diagnosed with an allergy." Alternatively, the employee or agent could provide the epinephrine auto-injector to the patient, parent, guardian or caregiver for immediate administration. Liability protections against injuries or related damages are provided to authorized entities who act in good faith and follow the procedures outlined in the bill, though such protections do not apply to "acts or omissions constituting gross negligence."<sup>11</sup>

### 2. Pharmacist Prescriptive Authority for Epinephrine Auto-Injectors

The Idaho bill contained a provision granting pharmacists the ability to prescribe epinephrine auto-injectors under certain circumstances. The reason for this was two-fold. First, epinephrine auto-injections are still prescription products, and it poses a barrier to access to require an entity to first schedule an appointment with a traditional prescriber in order to gain access to this product. Idaho already ranks low on lists of physicians per capita, and it is likely a misallocation of limited physician time to require a restaurant owner, for example, to set up an appointment with a primary care physician as a pre-requisite to receiving a prescription for an epinephrine auto-injector.

Second, there are infrequent but not uncommon reports of patients experiencing allergic or anaphylactic reactions seeking emergency care at a pharmacy.<sup>12-15</sup> In one such report, a pharmacist refused to provide an epinephrine auto-injector to a patient as the pharmacist cited that a prescription was necessary; the patient died shortly thereafter.<sup>15</sup> While it seems unlikely that a regulatory board would pursue discipline against a pharmacist for engaging in a life-saving action, and some states may already cover such action under Good Samaritan laws, it none-the-less seemed beneficial to explicitly remove any doubt that pharmacists may have.

The legislation grants an unrestricted model of pharmacist prescriptive authority.<sup>16-17</sup> Thus, no collaborative practice agreement is necessary, and there is no statewide protocol to follow. Pharmacists are expected to act "in good faith and exercise reasonable judgment" in prescribing epinephrine auto-injectors. The legislative language was based heavily off of a bill that had successfully passed in the previous Idaho legislative session, granting pharmacist prescriptive authority for opioid antagonists such as naloxone.<sup>18</sup>

Specifically, the bill authorized pharmacists to prescribe to:

- (1) "A person at risk of experiencing anaphylaxis;
- (2) A person in a position to assist a person at risk of experiencing anaphylaxis;
- (3) A person who, in the course of the person's official duties or business, may encounter a person experiencing anaphylaxis; and
- (4) A person who, in the opinion of the prescriber or pharmacist, has a valid reason to be in possession of an epinephrine auto-injector."<sup>11</sup>

Thus, the prescriptive authority is broad and extends beyond a patient currently experiencing anaphylaxis. The bill also explicitly states that a pharmacist or other health care practitioner may prescribe in the name of an authorized entity. Unlike an individual patient, an authorized entity must

first present proof to the pharmacist (or other prescriber) that at least one employee or agent has completed a training program meeting the requirements outlined in statute. Pharmacists were granted liability protections against injuries or other damages that result from the actions of an authorized entity to whom they prescribed.

### The Legislative Process

The bill encountered no formal opposition as it made its way through the legislature; it passed unanimously in both the House and Senate, and was signed into law on March 30, 2016 with an effective date of July 1, 2016.

Legislators appropriately raised several questions during the hearings on the bill. First, some questioned how the training requirements for agents or employees of entities stocking epinephrine would be enforced. The enforcement of the bill would fall under the state's Board of Pharmacy, and since authorized entities are not licensees or registrants of the Board, enforcement would pose challenges. To enhance enforcement, an amendment was drafted that stated an authorized entity must first present proof to a prescriber that at least one employee or agent has completed a national training program prior to receiving a prescription, such as certificate of completion of a qualifying program. This thus places the enforcement of training at the level of the prescriber.

Another question was raised over if laypersons at authorized entities will engage in appropriate follow-up procedures such as removing the patient from the precipitating allergen. Some expressed fear that a layperson would administer epinephrine and believe that this action alone is sufficient for emergency treatment. These concerns were addressed with an amendment that required a layperson to contact emergency medical services as soon after administration as possible. Further, the training program required of agents or employees of authorized entities also necessitates training on appropriate follow-up procedures following administration.

Lastly, a question was raised over the rising cost of epinephrine auto-injectors. One legislator presented data that the price has risen by more than 400% since 2007.<sup>19</sup> It is unlikely that pharmacist prescriptive authority will drive further price increases. Conversely, because pharmacists can prescribe any FDA-approved epinephrine auto-injector, pharmacists could work with patients or entities to find the most appropriate device, taking cost into consideration. In addition, it was noted that authorized entities seeking epinephrine would likely pay cash for the medication, as insurance was unlikely to cover the cost in whole or in part for an entity.

### Discussion

Idaho's bill thus grants prescription authority for epinephrine auto-injectors to pharmacists for both individuals and entities, and as such it stands in contrast to the approach other states have taken. Some states, for example, have limited pharmacists' ability to administer epinephrine without a prescription to treatment of an adverse event stemming from an immunization.<sup>1</sup> In a recent Texas bill, prescriptive authority was limited to patients currently experiencing a life-threatening anaphylactic reaction, and thus did not include other patients.<sup>20</sup> Texas's bill and rules also required specific notification requirements to a patient's primary care physician, recordkeeping requirements of such notifications, and prohibitions on remuneration for epinephrine administration.<sup>20</sup> Idaho's bill, by contrast, was silent on these requirements. Idaho's law combines broad pharmacist prescriptive authority for epinephrine auto-injectors with the allowance for authorized entities to stockpile the product. As such, it provides a potential model for other states to pursue in the years ahead.

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