

STATE OF HAWAI'I DEPARTMENT OF EDUCATION KA 'OIHANA HO'ONA'AUAO P.O. BOX 2360

HONOLULU, HAWAI'I 96804

Date: 02/07/2025 **Time:** 08:45 AM

Location: 329 VIA VIDEOCONFERENCE

Committee: House Health

Department: Education

Person Testifying: Keith T. Hayashi, Superintendent of Education

Bill Title: HB 0872 RELATING TO HEALTH.

Purpose of Bill: Authorizes health care practitioners to make undesignated prescriptions of

epinephrine for the purpose of stocking a supply at various types of businesses

and state and county government offices, including public schools.

Department's Position:

The Hawaii State Department of Education (Department) respectfully provides comments on HB 872, which allow healthcare practitioners to prescribe epinephrine for general use at businesses, government offices, and public schools.

Should the measure move forward, the Department respectfully requests the following amendments to better align with the intent to enhance timely access to life-saving medication.

First, to ensure equitable access to appropriately qualified training staff, the following amendment is requested:

Page 3, line 20: Add "practitioner or Registered Nurse."

Second, in order to reflect updated language, the following amendment is requested throughout the bill:

Replace "auto-injectable epinephrine" with "single-use epinephrine" to ensure emerging devices and formulations are not prohibited in state law.

In summary, anaphylaxis is a serious and life-threatening condition that requires immediate treatment with epinephrine. Quick access to epinephrine can significantly improve health outcomes and save lives. Legislation that makes this medication more readily available in public places, including schools,

is a critical step toward protecting individuals who may experience severe allergic reactions.

Thank you for the opportunity to provide testimony on this measure.

JOSH GREEN, M.D.

GOVERNOR OF HAWAII

KE KIA'ĀINA O KA MOKU'ĀINA 'O HAWAI'I



STATE OF HAWAII DEPARTMENT OF HEALTH KA 'OIHANA OLAKINO

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Testimony COMMENTING on HB0872 RELATING TO HEALTH

REPRESENTATIVE GREGG TAKAYAMA, CHAIR HOUSE COMMITTEE ON HEALTH

Hearing Date, Time, and Room Number: 02/07/25, 8:45 a.m.; Room Number 329

- 1 **Fiscal Implications:** This measure will require additional resources for the Department of
- 2 Health; however, none are included. The additional resources would negatively impact the
- 3 priorities identified in the Governor's Executive Budget Request for the Department of Health's
- 4 ("Department") appropriations and personnel priorities.
- 5 **Department Position:** The Department offers comments on this measure.
- 6 **Department Testimony:** With the low rate of anaphylaxis deaths and the risk of harm, that
- 7 such a program in Hawaii offers a net public health benefit is unclear. The opportunity cost of
- 8 purchasing a EAI instead of receiving cardiovascular pulmonary resuscitation would further
- 9 lessen the net public health benefit. Additionally, in the current version, a new program is
- 10 essentially established in the Department of Health (DOH) without additional resources. The
- 11 DOH responsibilities would include needing to approve EAI training programs; establish
- 12 requirements regarding storage, maintenance, control, and oversight; and approving
- 13 authorized entities.

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For the period 2019 through 2023, twelve individuals had anaphylaxis reported as the

cause of death, for an average of 2.4 deaths from anaphylaxis per year. This compares to

nearly three thousand deaths per year from heart disease. The twelve anaphylaxis deaths

occurred in adults age 36-101 years. An epinephrine auto-injector (EAI) costs approximately

\$350 with a shelf life typically of twelve to eighteen months. A prescription written for the
 name of an entity would not be covered by insurance, and the entity would pay out of pocket.

A lay person's diagnosis of anaphylaxis is not without risk. Anxiety/panic attack, thyroid storm, angioedema, and hypoglycemia could be mistaken for anaphylaxis. Epinephrine causes vasoconstriction, which could exacerbate a cardiovascular condition.

Disposal was not addressed. Used EAIs are medical waste and would be required to be disposed of accordingly. Unused expired EAIs would also need special disposal. A recommendation is that pharmacies upon refilling an EAI prescription take back the unused expired one. Improper disposal of EAIs could pose a risk to someone handling the waste.

However, if the program is deemed of value, it could be streamlined to improve efficiency, participation, and lessen the impact on the DOH. Rather than require DOH to approve trainers, allow any practitioner to train, in addition to allowing training from a nationally recognized organization. Individuals would be required to comply with storage requirements as stated in the package insert as required by the Food and Drug Administration (FDA). (DOH would not otherwise offer guidance difference from FDA's.) For example, here are the storage requirements for one EAI.

- Protect from light. Epinephrine is light sensitive and should be stored in the carrier tube provided to protect it from light.
- Store at 20°C to 25°C (68°F to 77°F); excursions permitted to 15°C to 30°C (59°F to 86°F) [See USP Controlled Room Temperature].
- Do not refrigerate.

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- Before using, check to make sure the solution in the auto-injector is clear and colorless.
- Replace the auto-injector if the solution is discolored (pinkish or brown color), cloudy, or contains particle.
 - Properly dispose all used, unwanted or expired EpiPen and EpiPen Jr auto-injectors.
- And allow any entity to participate subject to receiving a prescription from a licensed provider and required training, i.e. not require authorization of entities by DOH.

Following are proposed amendments: 1 2 SECTION 2. Chapter 27, Hawaii Revised Statutes, is amended by adding a new section to part 3 III to be appropriately designated and to read as follows: 4 5 "**§27**- Supply of auto-injectable epinephrine. (a) A practitioner, including practitioners employed by the department of health, may prescribe auto-injectable epinephrine in the name 6 7 of the State for use in accordance with this section. Departments and agencies may acquire 8 and stock a supply of auto-injectable epinephrine pursuant to prescriptions issued under this 9 subsection. (b) Each department and agency shall permit employees and agents to volunteer to provide 10 or administer auto-injectable epinephrine to any individual who the employee or agent believes 11 12 in good faith is experiencing anaphylaxis, regardless of whether the individual has a prescription for auto-injectable epinephrine or has previously been diagnosed with an allergy. 13 14 (c) Any employee or agent who volunteers to administer auto-injectable epinephrine shall 15 receive instruction in the proper administration of auto-injectable epinephrine by a practitioner]. 16 (d) A department or an agency that possesses and makes available auto-injectable 17 epinephrine and its employees, agents, and other individuals; a practitioner who prescribes or 18 19 dispenses auto-injectable epinephrine to a department or an agency; [and] a pharmacist or 20 practitioner who dispenses auto-injectable epinephrine to a department or an agency, and an 21 individual who provides training on the proper administration shall not be liable for any injuries 22 or related damages that result from any act or omission taken pursuant to this section; 23 provided that this immunity shall not apply to acts or omissions constituting wilful or wanton 24 misconduct (e) As used in this section: 25 "Auto-injectable epinephrine" means a single-use device used for the automatic injection of 26

a premeasured dose of epinephrine into the human body.

1	"Practitioner" means an individual licensed by the State or authorized by the laws of the
2	State to prescribe prescription drugs within the scope of the person's practice."
3	SECTION 3. Chapter 46, Hawaii Revised Statutes, is amended by adding a new section to part
4	V to be appropriately designated and to read as follows:
5	"§46- Supply of auto-injectable epinephrine. (a) A practitioner, including practitioners
6	employed by the department of health, may prescribe auto-injectable epinephrine in the name
7	of a county for use in accordance with this section. County departments and agencies may
8	acquire and stock a supply of auto-injectable epinephrine pursuant to prescriptions issued
9	under this subsection.
10	(b) Each county department and agency shall permit employees and agents to volunteer to
11	provide or administer auto-injectable epinephrine to any individual who the employee or agent
12	believes in good faith is experiencing anaphylaxis, regardless of whether the individual has a
13	prescription for auto-injectable epinephrine or has previously been diagnosed with an allergy.
14	(c) Any employee or agent who volunteers to administer auto-injectable epinephrine shall
15	receive instruction in the proper administration of auto-injectable epinephrine [by a
16	practitioner].
17	(d) A county department or agency that possesses and makes available auto-injectable
18	epinephrine and its employees, agents, and other individuals; a practitioner who prescribes or
19	dispenses auto-injectable epinephrine to a department or an agency; [and] a pharmacist or
20	practitioner who dispenses auto-injectable epinephrine to a department or an agency, and an
21	<u>individual who provides training on the proper administration</u> shall not be liable for any injuries
22	or related damages that result from any act or omission taken pursuant to this section;
23	provided that this immunity shall not apply to acts or omissions constituting wilful or wanton
24	<u>misconduct</u>
25	(e) As used in this section:
26	"Auto-injectable epinephrine" means a single-use device used for the automatic injection of

a premeasured dose of epinephrine into the human body.

"Practitioner" means an individual licensed by the State or authorized by the laws of the 1 2 State to prescribe prescription drugs within the scope of the person's practice." 3 SECTION 4. Chapter 302A, Hawaii Revised Statutes, is amended by adding a new section to part III, subpart F, to be appropriately designated and to read as follows: 4 5 **"§302A- Auto-injectable epinephrine.** (a) A practitioner, including practitioners employed by the department of health or the department, may prescribe auto-injectable 6 7 epinephrine in the name of the public school for use in accordance with section 302A-1164 and 8 in accordance with protocol specified by the practitioner. Public schools may acquire and stock 9 a supply of auto-injectable epinephrine pursuant to prescriptions issued under this subsection. 10 (b) As used in this section: "Auto-injectable epinephrine" means a single-use device used for the automatic injection of 11 12 a premeasured dose of epinephrine into the human body. "Practitioner" means an individual licensed by the State or authorized by the laws of the 13 State to prescribe prescription drugs within the scope of the person's practice." 14 15 SECTION 5. Chapter 328, Hawaii Revised Statutes, is amended by adding a new section to be 16 appropriately designated and to read as follows: "§328- Auto-injectable epinephrine; authority to prescribe and dispense a supply. (a) A 17 practitioner may prescribe auto-injectable epinephrine in the name of an [authorized] entity for 18 19 purposes of this section. 20 (b) A pharmacist may dispense auto-injectable epinephrine pursuant to a prescription issued 21 in accordance with subsection (a). 22 (c) An [authorized] entity may acquire and stock a supply of auto-injectable epinephrine 23 pursuant to a prescription issued under subsection (a). The auto-injectable epinephrine shall 24 be stored in a location readily accessible in an emergency and in accordance with the auto-

injectable epinephrine's instructions for use [and any additional requirements that may be

established by the department]. An [authorized] entity shall designate employees or agents

who have completed the training required by subsection (e) to be responsible for the storage,

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- maintenance, control, and general oversight of auto-injectable epinephrine acquired by the 1 2 [authorized] entity. (d) An employee or agent of an [authorized] entity, or any other individual, who has 3 completed the training required by subsection (e) may use auto-injectable epinephrine 4 5 prescribed pursuant to subsection (a) to: (1) Provide auto-injectable epinephrine to any individual who the employee, agent, or other 6 7 individual believes in good faith is experiencing anaphylaxis, or to the parent, guardian, or 8 caregiver of such individual, for immediate administration, regardless of whether the individual 9 has a prescription for auto-injectable epinephrine or has previously been diagnosed with an 10 allergy; and (2) Administer auto-injectable epinephrine to any individual who the employee, agent, or 11 12 other individual believes in good faith is experiencing anaphylaxis, regardless of whether the individual has a prescription for auto-injectable epinephrine or has previously been diagnosed 13 14 with an allergy. 15 (e) An employee, agent, or other individual described in subsection (c) or (d) shall complete 16 an anaphylaxis training program and repeat such training at least every two years following completion of the initial anaphylaxis training program. The training shall be conducted by a 17 nationally recognized organization experienced in training laypersons in emergency health 18 treatment or a practitioner[an entity or individual approved by the department]. Training may 19 20 be conducted online or in person and, at a minimum, shall cover: 21 (1) How to recognize signs and symptoms of severe allergic reactions, including anaphylaxis; 22 (2) Standards and procedures for the storage and administration of auto-injectable 23 epinephrine; and 24 (3) Emergency follow-up procedures.
- (f) An [authorized] entity that possesses and makes available auto-injectable epinephrine
 and its employees, agents, and other individuals; a practitioner who prescribes or dispenses
 auto-injectable epinephrine to an [authorized] entity; a pharmacist or

- 1 practitioner who dispenses auto-injectable epinephrine to an [authorized] entity; and an
- 2 individual or entity that conducts the training described in subsection (e) shall not be liable for
- 3 any injuries or related damages that result from any act or omission taken pursuant to this
- 4 section; provided that this immunity shall not apply to acts or omissions constituting willful or
- 5 <u>wanton misconduct. The administration of auto-injectable epinephrine in accordance with this</u>
- 6 section shall not be deemed the practice of medicine or any other profession that otherwise
- 7 requires licensure. This section shall not eliminate, limit, or reduce any other immunity or
- 8 defense that may be available under state law. An entity located in the State shall not be liable
- 9 for any injuries or related damages that result from the provision or administration of auto-
- injectable epinephrine outside of the State if the entity:
- 11 (1) Would not have been liable for such injuries or related damages had the provision or
- 12 <u>administration occurred within this state; or</u>
- 13 (2) Is not liable for such injuries or related damages under the law of the state in which such
- 14 provision or administration occurred.
- 15 (g) An [authorized] entity that possesses and makes available auto-injectable epinephrine
- shall submit to the department, on a form developed by the department, a report including
- each incident on the [authorized] entity's premises that involves the administration of auto-
- injectable epinephrine pursuant to subsection (e) and any other information deemed relevant
- 19 by the department. The department shall annually publish a report that summarizes and
- analyzes all reports submitted to it under this subsection.
- 21 [(h) The department shall establish requirements regarding the storage, maintenance,
- 22 control, and oversight of the auto-injectable epinephrine, including but not limited to any
- 23 temperature limitations and expiration of such auto-injectable epinephrine.
- 24 (i) The department shall, through rule or other guidance, identify the types of entities and
- 25 organizations that are considered authorized entities no later than January 1, 2026, and shall
- 26 review and update such rule or guidance at least annually thereafter.
- $\frac{(i)}{(h)}$ As used in this section:

- 1 ["Authorized entity"] "Entity" means agricultural entities, churches, conservation entities,
- 2 corporate offices, daycare centers, hotels, private schools, restaurants, and other entities [as
- 3 approved by the department under subsection (i)].
- 4 "Auto-injectable epinephrine" means a single-use device used for the automatic injection of
- 5 <u>a premeasured dose of epinephrine into the human body."</u>

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Thank you for the opportunity to testify on this measure.