A BILL FOR AN ACT

RELATING TO HEALTH.

BE IT ENACTED BY THE LEGISLATURE OF THE STATE OF HAWAII:

- 1 SECTION 1. The legislature finds that a food allergy
- 2 reaction can cause symptoms that range from mild to life-
- 3 threatening. In the United States, food allergies are the
- 4 leading cause of severe, life-threatening allergic reactions,
- 5 known as anaphylaxis, outside the hospital setting. Anaphylaxis
- 6 is characterized by rapid onset and the involvement of multiple
- 7 organ systems, including the skin, respiratory system,
- 8 gastrointestinal tract, and cardiovascular system. Common
- 9 triggers of anaphylaxis include foods, insect stings,
- 10 medications, and latex particles. People who have previously
- 11 experienced only mild symptoms may suddenly experience a life-
- 12 threatening reaction.
- 13 The legislature further finds that the first-line treatment
- 14 for anaphylaxis is epinephrine, also known as adrenaline.
- 15 Epinephrine is available by prescription in an auto-injector and
- 16 works to reverse the life-threatening symptoms. For this
- 17 reason, the timely administration of epinephrine reduces the



- 1 risk of fatal or debilitating outcomes associated with
- 2 anaphylaxis, particularly when medical assistance may be
- 3 delayed, unavailable, or distant.
- 4 The legislature recognizes that one public health strategy
- 5 to reduce adverse outcomes related to allergic reactions is to
- 6 substantially increase access to epinephrine by allowing various
- 7 entities to stock a supply of undesignated epinephrine. Through
- 8 this strategy, public safety improves as epinephrine
- 9 availability increases, improving survival rates and health
- 10 outcomes for persons affected by severe allergies. This
- 11 strategy was recognized on the federal level through the signing
- 12 of the School Access to Emergency Epinephrine Act in 2013, which
- 13 encouraged schools to plan for severe allergic reactions.
- 14 The legislature notes that more than thirty states have
- 15 enacted this strategy into law; however, Hawaii has yet to
- 16 implement this strategy.
- 17 Accordingly, the purpose of this Act is to authorize health
- 18 care practitioners to make undesignated prescriptions of single-
- 19 use epinephrine for the purpose of stocking a supply at various
- 20 types of businesses and government offices.

1 SECTION 2. Chapter 27, Hawaii Revised Statutes, is amended 2 by adding a new section to part III to be appropriately 3 designated and to read as follows: 4 "§27-Supply of single-use epinephrine. (a) A 5 practitioner, including practitioners employed by the department 6 of health, may prescribe single-use epinephrine in the name of the State for use in accordance with this section. Departments 7 8 and agencies may acquire and stock a supply of single-use 9 epinephrine pursuant to prescriptions issued under this 10 subsection. 11 Each department and agency shall permit employees and 12 agents to volunteer to provide or administer single-use epinephrine to any individual who the employee or agent believes 13 14 in good faith is experiencing anaphylaxis, regardless of whether 15 the individual has a prescription for single-use epinephrine or has previously been diagnosed with an allergy. 16 17 (c) Any employee or agent who volunteers to administer 18 single-use epinephrine shall receive instruction in the proper administration of single-use epinephrine by a practitioner or 19 20 registered nurse.

1	(d) A department or an agency that possesses and makes
2	available single-use epinephrine and its employees, agents, and
3	other individuals; a practitioner who prescribes or dispenses
4	single-use epinephrine to a department or an agency; and a
5	pharmacist or practitioner who dispenses single-use epinephrine
6	to a department or an agency shall not be liable for any
7	injuries or related damages that result from any act or omission
8	taken pursuant to this section; provided that this immunity
9	shall not apply to acts or omissions constituting wilful or
10	wanton misconduct
11	(e) As used in this section:
12	"Practitioner" means an individual licensed by the State or
13	authorized by the laws of the State to prescribe prescription
14	drugs within the scope of the individual's practice.
15	"Single-use epinephrine" means a single-use device used for
16	the automatic injection of a premeasured dose of epinephrine
17	into the human body."
18	SECTION 3. Chapter 46, Hawaii Revised Statutes, is amended
19	by adding a new section to part V to be appropriately designated

and to read as follows:

20

1	"§46- Supply of single-use epinephrine. (a) A
2	practitioner, including practitioners employed by the department
3	of health, may prescribe single-use epinephrine in the name of a
4	county for use in accordance with this section. County
5	departments and agencies may acquire and stock a supply of
6	single-use epinephrine pursuant to prescriptions issued under
7	this subsection.
8	(b) Each county department and agency shall permit
9	employees and agents to volunteer to provide or administer
10	single-use epinephrine to any individual who the employee or
11	agent believes in good faith is experiencing anaphylaxis,
12	regardless of whether the individual has a prescription for
13	single-use epinephrine or has previously been diagnosed with an
14	allergy.
15	(c) Any employee or agent who volunteers to administer
16	single-use epinephrine shall receive instruction in the proper ·
17	administration of single-use epinephrine by a practitioner or a
18	registered nurse.
19	(d) A county department or agency that possesses and makes
20	available single-use epinephrine and its employees, agents, and
21	other individuals; a practitioner who prescribes or dispenses

- 1 single-use epinephrine to a department or an agency; and a
- 2 pharmacist or practitioner who dispenses single-use epinephrine
- 3 to a department or an agency shall not be liable for any
- 4 injuries or related damages that result from any act or omission
- 5 taken pursuant to this section; provided that this immunity
- 6 shall not apply to acts or omissions constituting wilful or
- 7 wanton misconduct
- **8** (e) As used in this section:
- 9 "Practitioner" means an individual licensed by the State or
- 10 authorized by the laws of the State to prescribe prescription
- 11 drugs within the scope of the individual's practice.
- "Single-use epinephrine" means a single-use device used for
- 13 the automatic injection of a premeasured dose of epinephrine
- 14 into the human body."
- 15 SECTION 4. Chapter 302A, Hawaii Revised Statutes, is
- 16 amended by adding a new section to part III, subpart F, to be
- 17 appropriately designated and to read as follows:
- 18 "§302A- Single-use epinephrine. (a) A practitioner,
- 19 including practitioners employed by the department of health or
- 20 the department, may prescribe single-use epinephrine in the name
- of the public school for use in accordance with section 302A-

- 1 1164 and in accordance with protocol specified by the
- 2 practitioner. Public schools may acquire and stock a supply of
- 3 single-use epinephrine pursuant to prescriptions issued under
- 4 this subsection.
- 5 (b) As used in this section:
- 6 "Practitioner" means an individual licensed by the State or
- 7 authorized by the laws of the State to prescribe prescription
- 8 drugs within the scope of the individual's practice.
- 9 "Single-use epinephrine" means a single-use device used for
- 10 the automatic injection of a premeasured dose of epinephrine
- into the human body."
- 12 SECTION 5. Chapter 328, Hawaii Revised Statutes, is
- 13 amended by adding a new section to be appropriately designated
- 14 and to read as follows:
- 15 "\$328- Single-use epinephrine; authority to prescribe
- 16 and dispense a supply. (a) A practitioner may prescribe
- 17 single-use epinephrine in the name of an authorized entity for
- 18 purposes of this section.
- 19 (b) A pharmacist may dispense single-use epinephrine
- 20 pursuant to a prescription issued in accordance with subsection
- **21** (a).



1	(c) An authorized entity may acquire and stock a supply of
2	single-use epinephrine pursuant to a prescription issued under
3	subsection (a). The single-use epinephrine shall be stored in a
4	location readily accessible in an emergency and in accordance
5	with the single-use epinephrine's instructions for use and any
6	additional requirements that may be established by the
7	department. An authorized entity shall designate employees or
8	agents who have completed the training required by subsection
9	(e) to be responsible for the storage, maintenance, control, and
10	general oversight of single-use epinephrine acquired by the
11	authorized entity.
12	(d) An employee or agent of an authorized entity, or any
13	other individual, who has completed the training required by
14	subsection (e) may use single-use epinephrine prescribed
15	pursuant to subsection (a) to:
16	(1) Provide single-use epinephrine to any individual who
17	the employee, agent, or other individual believes in
18	good faith is experiencing anaphylaxis, or to the
19	parent, guardian, or caregiver of such individual, for
20	immediate administration, regardless of whether the
21	individual has a prescription for a single-use

1	•	epinephrine or has previously been diagnosed with an
2		allergy; and
3	(2)	Administer single-use epinephrine to any individual
4		who the employee, agent, or other individual believes
5		in good faith is experiencing anaphylaxis, regardless
6		of whether the individual has a prescription for
7		single-use epinephrine or has previously been
8		diagnosed with an allergy.
9	<u>(e)</u>	An employee, agent, or other individual described in
10	subsectio	n (c) or (d) shall complete an anaphylaxis training
11	program a	nd repeat the training at least every two years
12	following	completion of the initial anaphylaxis training
13	program.	The training shall be conducted by a nationally
14	recognize	d organization experienced in training laypersons in
15	emergency	health treatment or an entity or individual approved
16	by the de	partment. Training may be conducted online or in
17	person an	d, at a minimum, shall cover:
18	(1)	How to recognize signs and symptoms of severe allergic
19		reactions, including anaphylaxis;
20	(2)	Standards and procedures for the storage and
21		administration of single-use epinephrine: and

1 (3) Emergency follow-up procedures. 2 (f) An authorized entity that possesses and makes 3 available single-use epinephrine and its employees, agents, and 4 other individuals; a practitioner who prescribes or dispenses 5 single-use epinephrine to an authorized entity; a pharmacist or 6 practitioner who dispenses single-use epinephrine to an 7 authorized entity; and an individual or entity that conducts the 8 training described in subsection (e) shall not be liable for any 9 injuries or related damages that result from any act or omission 10 taken pursuant to this section; provided that this immunity 11 shall not apply to acts or omissions constituting wilful or wanton misconduct. The administration of single-use epinephrine 12 13 in accordance with this section shall not be deemed the practice 14 of medicine or any other profession that otherwise requires licensure. This section shall not eliminate, limit, or reduce 15 16 any other immunity or defense that may be available under state 17 law. An entity located in the State shall not be liable for any 18 injuries or related damages that result from the provision or 19 administration of single-use epinephrine outside of the State if 20 the entity:

1	(1)	Would not have been liable for such injuries or
2		related damages had the provision or administration
3		occurred within this State; or
4	(2)	Is not liable for such injuries or related damages
5		under the law of the state in which such provision or
6		administration occurred.
7	(g)	An authorized entity that possesses and makes
8	available	single-use epinephrine shall submit to the department,
9	on a form	developed by the department, a report including each
10	<u>incident</u>	on the authorized entity's premises that involves the
11	administr	ation of single-use epinephrine pursuant to subsection
12	(d) and a	ny other information deemed relevant by the department.
13	The depar	tment shall annually publish a report that summarizes
14	and analy	zes all reports submitted to it under this subsection.
15	(h)	The department shall establish requirements regarding
16	the stora	ge, maintenance, control, and oversight of the single-
17	use epine	phrine, including but not limited to any temperature
18	limitation	ns and expiration of the single-use epinephrine.
19	<u>(i)</u>	The department shall, through rule or other guidance,
20	identify	the types of entities and organizations that are
21	considered	d authorized entities no later than January 1, 2026,

and shall review and update such rule or guidance at least 1 2 annually thereafter. 3 (j) As used in this section: 4 "Authorized entity" means agricultural entities, churches, 5 conservation entities, corporate offices, daycare centers, 6 hotels, private schools, restaurants, and other entities as 7 approved by the department under subsection (i). 8 "Single-use epinephrine" means a single-use device used for 9 the automatic injection of a premeasured dose of epinephrine 10 into the human body." 11 SECTION 6. Section 328-16, Hawaii Revised Statutes, is 12 amended as follows: 1. By amending subsections (a) through (c) to read: 13 14 "(a) A prescription drug shall be dispensed only if its 15 label bears the following: 16 (1)The name, business address, and telephone number of 17 the seller. The business address shall be the 18 physical location of the pharmacy or the dispensing 19 practitioner's office; 20 (2) [Except as otherwise authorized for expedited partner

therapy in section 453-52 or an opioid antagonist in

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1		section 461-11.8, the] The name of the person for whom
2		the drug was prescribed or the name of the owner of
3		the animal for which the drug was prescribed[$\dot{\tau}$]
4		except as otherwise authorized for:
5		(A) A supply of single-use epinephrine under sections
6		27- , 46- , 302A- , and 328- ;
7		(B) Expedited partner therapy in section 453-52; or
8		(C) An opioid antagonist in section 461-11.8;
9	(3)	The serial number of the prescription;
10	(4)	The date the prescription was prepared;
11	(5)	The name of the practitioner if the seller is not the
12		practitioner;
13	(6)	The name, strength, and quantity of the drug;
14	(7)	The "use by" date for the drug, which shall be:
15		(A) The expiration date on the manufacturer's
16		container; or
17		(B) One year from the date the drug is dispensed,
18		whichever is earlier;
19	(8)	The number of refills available, if any;
20	(9)	In the case of the dispensing of an equivalent generic
21		drug product, the statement "same as (brand name of

	the drug product prescribed or the referenced listed
	drug name)", or words of similar meaning;
(10)	In the case of the dispensing of an interchangeable
	biological product, the statement "interchangeable
	with (brand name of the biological product prescribed
	or the referenced biological drug name)", or words of
	similar meaning; and
(11)	Specific directions for the drug's use; provided that
	if the specific directions for use are too lengthy for
	inclusion on the label, the notation "take according
	to written instructions" may be used if separate
	written instructions for use are actually issued with
	the drug by the practitioner or the pharmacist, but in
	no event shall the notation "take as directed",
	referring to oral instructions, be considered
	acceptable.
If any pro	escription for a drug does not indicate the number of
times it n	may be refilled, if any, the pharmacist shall not
refill tha	at prescription unless subsequently authorized to do so
by the pro	actitioner or pursuant to section 461-11.9. The act of
dispensin	g a prescription drug other than a professional sample
	(11) If any protimes it is refill that by the pro

	or mearca	i oxygen contrary to this subsection shall be deemed to
2	be an act	that results in a drug being misbranded while held for
3	sale.	
4	(b)	In addition to the requirements enumerated in
5	subsection	n (a), a prescription drug shall be dispensed only:
6	(1)	By a pharmacist pursuant to a valid prescription or
7		section 453-52, 461-1, 461-11.8, or 461-11.9;
8	(2)	By a medical oxygen distributor pursuant to a
9		prescription or certificate of medical necessity;
10		provided that the drug to be dispensed is medical
11		oxygen; or
12	(3)	By a practitioner to an ultimate user[+], except as
13		provided for a supply of single-use epinephrine under
14		sections 27- , 46- , 302A- , and 328- ;
15		<pre>provided that:</pre>
16		(A) Except as otherwise authorized for a supply of
17		single-use epinephrine under sections 27- ,
18		46- , 302A- , and 328- and expedited
19		partner therapy in section 453-52, the
20		practitioner shall inform the patient, before
21		dispensing any drug other than a professional

samp	le, that the patient may have a written,
oral	ly ordered, or electronically transmitted or
conv	eyed prescription directed to a pharmacy or a
medi	cal oxygen distributor of the patient's own
choi	ce;
(B) The	practitioner shall promptly record in the
prac	titioner's records:
(i)	The prescription in full;
(ii)	The name, strength, and quantity of the
	drug, and specific directions for the drug's
	use;
(iii)	The date the drug was dispensed;
(iv)	[Except as otherwise authorized for
	expedited partner therapy in section 453-52
	or for an opioid antagonist in section 461-
	11.8, the] The name and address of the
	person for whom the drug was prescribed or
	the name of the owner of the animal for
	which the drug was prescribed[;], except as
	otherwise authorized for a supply of single-
	use epinephrine under sections 27- ,
	oral conv medi choi (B) The prac (i) (ii)

1			46- , 302A- , and 328- ; expedit	<u>ed</u>
2			partner therapy in section 453-52; or	<u>an</u>
3			opioid antagonist in section 461-11.8;	and
4			(v) Prescription drugs dispensed or prescr	ibed
5			for expedited partner therapy as autho	rized
6			under section 453-52 or for an opioid	
7			antagonist in section 461-11.8;	
8		(C)	The records described in subparagraph (B) s	hall
9			be subject to the inspection of the department	ent or
10			its agents at all times; and	
11		(D)	No undisclosed rebate, refund, commission,	
12			preference, discount, or other consideration	n,
13			whether in the form of money or otherwise,	has
14			been offered to the practitioner as compense	ation
15			or inducement to dispense or prescribe any	
16			specific drug in preference to other drugs	that
17			might be used for the identical therapeutic	
18			indication.	
19	(C)	A pr	scription may be communicated in writing, or	rally,
20	or by ele	ctron	c transmission, and shall include the follow	wing
21	informati	on:		

1	(1)	The authoriz	ation of the practitioner noted as
2		follows:	
3		(A) Written	prescriptions shall include the original
4		signatu	re of the practitioner;
5		(B) Oral pr	escriptions shall be promptly recorded by
6		the pha	rmacist or medical oxygen distributor and
7		shall i	nclude the practitioner's oral code
8		designa	tion; and
9		(C) Electro	nic prescriptions shall be irrefutably
10		traceab	le to the prescribing practitioner by a
11		recogni	zable and unique practitioner identifier
12		such as	:
13		(i) A]	oitmap or graphic image of the
14		pre	escriber's handwritten signature and the
15		pre	escriber's oral code designation (or
16		lio	cense number or other identifier if the
17		pre	escriber is an out-of-state practitioner)
18		(ii) An	electronic signature;
19		(iii) A	digital signature; or
20		(iv) By	other means as approved by the director;
21	(2)	The date of :	issuance;

1	(3)	The practitioner's name, business telephone number,
2		and business address, unless the practitioner is
3		otherwise uniquely identified and the pharmacy or
4		medical oxygen distributor dispensing the prescription
5		has the prescriber's contact information on file
6		accessible within the dispensing area;
7	(4)	The name, strength, and quantity of the drug to be
8		dispensed, and specific directions for the drug's use;
9	(5)	[Except as otherwise authorized for expedited partner
10		therapy in section 453-52 or for an opioid antagonist
11		in section 461-11.8, the] The name and address of the
12		person for whom the prescription was written or the
13		name of the owner of the animal for which the drug was
14		prescribed, unless the pharmacy or medical oxygen
15		distributor dispensing the prescription has the
16		address on file accessible within the dispensing
17		area[+], except as otherwise authorized for:
18		(A) A supply of single-use epinephrine under sections
19		27- , 46- , 302A- , and 328- ;
20		(B) Expedited partner therapy in section 453-52; or
21		(C) An opioid antagonist in section 461-11.8;



1	(6)	The room number and route of administration, if the
2		patient is in an institutional facility; and
3	(7)	The number of allowable refills, if the prescription
4		is refillable. If the number of refills authorized by
5		the practitioner is indicated using the terms "as
6		needed" or "prn", the prescription may be refilled up
7		to twelve months from the date the original
8		prescription was written. After the twelve-month
9		period, the "as needed" or "prn" prescription may be
10		refilled for a subsequent three-month period;
11		provided:
12		(A) The prescription is refilled only once during the
13		three-month period;
14		(B) The refill does not exceed a thirty-day supply of
15		the drug;
16		(C) The refill does not provide any amount of the
17		drug fifteen months beyond the date the original
18		prescription was written;
19		(D) In the case of medical oxygen, the duration of
20		therapy indicated on a certificate of medical

1			necessity shall supersede any limitations or
2			restrictions on refilling; and
3		(E)	Subparagraphs (A) to (D) shall apply only to
4			pharmacies and medical oxygen distributors
5			practicing in the State."
6	2.	By am	ending subsection (g) to read:
7	" (g)	Any	drug other than medical oxygen dispensed pursuant
8	to a pres	cript	ion shall be exempt from the requirements of
9	section 3	28-15	(except paragraphs (1), (9), (11), and (12), and
10	the packa	ging	requirements of paragraphs (7) and (8)), if the
11	drug bear	s a l	abel containing:
12	(1)	The	name and address of the pharmacy;
13	(2)	The	serial number and the date of the prescription or
14		of i	ts filling;
15	(3)	The	name of the practitioner;
16	(4)	[Exc	ept as otherwise authorized for expedited partner
17		ther	apy in section 453-52 or for an opioid antagonist
18		in s	ection 461-11.8, the The name of the patient[;],
19		exce	ot as otherwise authorized for:
20		<u>(A)</u>	A supply of single-use epinephrine under sections
21			27- , 46- , 302A- , and 328- ;



1	(B) Expedited partner therapy in section 453-52; or
2	(C) An opioid antagonist in section 461-11.8;
3	(5) The directions for use; and
4	(6) Any cautionary statements contained in the
5	prescription.
6	This exemption shall not apply to any drug dispensed in the
7	course of the conduct of a business of dispensing drugs pursuan
8	to diagnosis by mail, or to a drug dispensed in violation of
9	subsection (a), (b), (c), or (d)."
10	SECTION 7. Section 328-17.7, Hawaii Revised Statutes, is
11	amended by amending subsection (a) to read as follows:
12	"(a) Every practitioner, pharmacist, or medical oxygen
13	distributor who compounds, sells, or delivers any prescribed
14	drug to a patient or a patient's agent shall maintain records
15	that identify:
16	(1) The specific drug product dispensed, including:
17	(A) The product's national drug code (NDC) number; o
18	(B) The brand name or the established name and the
19	name or commonly accepted abbreviation of the
20	principal labeler of the drug product dispensed,
21	the product strength, and the dosage form;

1	(2)	The quantity of the drug;
2	(3)	Directions for use;
3	(4)	The number of allowable refills;
4	(5)	The date of initial dispensing and the dates of all
5		refilling;
6	(6)	The date of any transfer of the prescription;
7	(7)	The name, business address, and telephone number of
8		the recipient pharmacist or medical oxygen distributor
9		for any transfer of prescription;
10	(8)	The prescribing practitioner, including name, business
11		address, and telephone number;
12	(9)	The format (oral, written, or electronic) in which the
13		prescription was received;
14	(10)	[Except as otherwise authorized for expedited partner
15		therapy in section 453-52 or for an opioid antagonist
16		in section 461-11.8, the] The patient, including name,
17		address, and telephone number[;], except as otherwise
18		authorized for:
19		(A) A supply of single-use epinephrine under sections
20		27- , 46- , 302A- , and 328- ;
21		(B) Expedited partner therapy in section 453-52; or



1 (C) An opioid antagonist in section 461-11.8; 2 (11)The date of prescribing; and 3 (12)The name of the practitioner, pharmacist, or medical 4 oxygen distributor dispensing the drug. 5 Every prescription dispensed shall have the name of the pharmacist, dispensing practitioner, or medical oxygen 6 7 distributor responsible for the dispensing appended to the 8 prescription record, and every prescription record shall be 9 preserved and legible for a period of not less than five years. 10 The prescription records shall be subject at all times to the 11 inspection of the director of health or the director's agent." 12 SECTION 8. Statutory material to be repealed is bracketed 13 and stricken. New statutory material is underscored. 14 SECTION 9. This Act shall take effect on July 1, 3000.

Report Title:

Health; Epinephrine; Stock; State; Counties; Public Schools

Description:

Authorizes health care practitioners to make undesignated prescriptions of single-use epinephrine for the purpose of stocking a supply at various types of businesses and state and county government offices, including public schools. Effective 7/1/3000. (HD1)

The summary description of legislation appearing on this page is for informational purposes only and is not legislation or evidence of legislative intent.