#### 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 allergy is the leading 4 cause of severe, life-threatening allergic reactions, known as 5 anaphylaxis, outside the hospital setting. Anaphylaxis is 6 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



risk of fatal or debilitating outcomes associated with
 anaphylaxis, particularly when medical assistance may be
 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.

Accordingly, the purpose of this Act is to authorize health
care practitioners to make undesignated prescriptions of
epinephrine for the purpose of stocking a supply at various
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	" <u>§27-</u> Supply of auto-injectable epinephrine. (a) A	
5	practitioner, including practitioners employed by the department	
6	of health, may prescribe auto-injectable epinephrine in the name	
7	of the State for use in accordance with this section.	
8	Departments and agencies may acquire and stock a supply of auto-	
9	injectable epinephrine pursuant to prescriptions issued under	
10	this subsection.	
11	(b) Each department and agency shall permit employees and	
12	agents to volunteer to provide or administer auto-injectable	
13	epinephrine to any individual who the employee or agent believes	
14	in good faith is experiencing anaphylaxis, regardless of whether	
15	the individual has a prescription for auto-injectable	
16	epinephrine or has previously been diagnosed with an allergy.	
17	(c) Any employee or agent who volunteers to administer	
18	auto-injectable epinephrine shall receive instruction in the	
10		
19	proper administration of auto-injectable epinephrine by a	



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



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1	" <b>§46- Supply of auto-injectable epinephrine</b> . (a) A
2	practitioner, including practitioners employed by the department
3	of health, may prescribe auto-injectable epinephrine in the name
4	of a county for use in accordance with this section. County
5	departments and agencies may acquire and stock a supply of auto-
6	injectable 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 auto-
10	injectable 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	auto-injectable epinephrine or has previously been diagnosed
14	with an allergy.
15	(c) Any employee or agent who volunteers to administer
16	auto-injectable epinephrine shall receive instruction in the
17	proper administration of auto-injectable epinephrine by a
18	practitioner.
19	(d) A county department or agency that possesses and makes
20	available auto-injectable epinephrine and its employees, agents,
21	and other individuals; a practitioner who prescribes or



1	dispenses auto-injectable epinephrine to a department or an
2	agency; and a pharmacist or practitioner who dispenses auto-
3	injectable epinephrine to a department or an agency shall not be
4	liable for any injuries or related damages that result from any
5	act or omission taken pursuant to this section; provided that
6	this immunity shall not apply to acts or omissions constituting
7	wilful or wanton misconduct
8	(e) As used in this section:
9	"Auto-injectable epinephrine" means a single-use device
10	used for the automatic injection of a premeasured dose of
11	epinephrine into the human body.
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 person's practice."
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	" <b>§302A- Auto-injectable epinephrine.</b> (a) A
19	practitioner, including practitioners employed by the department
20	of health or the department, may prescribe auto-injectable
21	epinephrine in the name of the public school for use in



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1	accordance with section 302A-1164 and in accordance with
2	protocol specified by the practitioner. Public schools may
3	acquire and stock a supply of auto-injectable epinephrine
4	pursuant to prescriptions issued under this subsection.
5	(b) As used in this section:
6	"Auto-injectable epinephrine" means a single-use device
7	used for the automatic injection of a premeasured dose of
8	epinephrine into the human body.
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 person's practice."
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- Auto-injectable epinephrine; authority to
16	prescribe and dispense a supply. (a) A practitioner may
17	prescribe auto-injectable epinephrine in the name of an
18	authorized entity for purposes of this section.
19	(b) A pharmacist may dispense auto-injectable 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	auto-injectable epinephrine pursuant to a prescription issued
3	under subsection (a). The auto-injectable epinephrine shall be
4	stored in a location readily accessible in an emergency and in
5	accordance with the auto-injectable epinephrine's instructions
6	for use and any additional requirements that may be established
7	by the department. An authorized entity shall designate
8	employees or agents who have completed the training required by
9	subsection (e) to be responsible for the storage, maintenance,
10	control, and general oversight of auto-injectable epinephrine
11	acquired by the 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 auto-injectable epinephrine prescribed
15	pursuant to subsection (a) to:
16	(1) Provide auto-injectable epinephrine to any individual
17	who the employee, agent, or other individual believes
18	in 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 auto-injectable



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1		epinephrine or has previously been diagnosed with an
2		allergy; and
3	(2)	Administer auto-injectable epinephrine to any
4		individual who the employee, agent, or other
5		individual believes in good faith is experiencing
6		anaphylaxis, regardless of whether the individual has
7		a prescription for auto-injectable epinephrine or has
8		previously been 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 such 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 auto-injectable epinephrine; and



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



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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	<u>(g)</u>	An authorized entity that possesses and makes
8	available	auto-injectable epinephrine shall submit to the
9	departmen	t, on a form developed by the department, a report
10	including	each incident on the authorized entity's premises that
11	involves	the administration of auto-injectable epinephrine
12	pursuant	to subsection (e) and any other information deemed
13	relevant 1	by the department. The department shall annually
14	publish a	report that summarizes and analyzes all reports
15	submitted	to it under this subsection.
16	<u>(h)</u>	The department shall establish requirements regarding
17	the stora	ge, maintenance, control, and oversight of the auto-
18	injectable	e epinephrine, including but not limited to any
19	temperatu	re limitations and expiration of such auto-injectable
20	epinephri	ne.



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1	(i) The department shall, through rule or other guidance,		
2	identify the types of entities and organizations that are		
3	considered authorized entities no later than January 1, 2026,		
4	and shall review and update such rule or guidance at least		
5	annually thereafter.		
6	(j) As used in this section:		
7	"Authorized entity" means agricultural entities, churches,		
8	conservation entities, corporate offices, daycare centers,		
9	hotels, private schools, restaurants, and other entities as		
10	approved by the department under subsection (i).		
11	"Auto-injectable epinephrine" means a single-use device		
12	used for the automatic injection of a premeasured dose of		
13	epinephrine into the human body."		
14	SECTION 6. Section 328-16, Hawaii Revised Statutes, is		
15	amended as follows:		
16	1. By amending subsections (a) through (c) to read:		
17	"(a) A prescription drug shall be dispensed only if its		
18	label bears the following:		
19	(1) The name, business address, and telephone number of		
20	the seller. The business address shall be the		



1		physical location of the pharmacy or the dispensing
2		practitioner's office;
3	(2)	[Except as otherwise authorized for expedited partner
4		therapy in section 453-52 or an opioid antagonist in
5		section 461-11.8, the] The name of the person for whom
6		the drug was prescribed or the name of the owner of
7		the animal for which the drug was prescribed[+],
8		except as otherwise authorized for:
9		(A) A supply of epinephrine under sections 27- ,
10		46- , 302A- , and 328- ;
11		(B) Expedited partner therapy in section 453-52; or
12		(C) An opioid antagonist in section 461-11.8;
13	(3)	The serial number of the prescription;
14	(4)	The date the prescription was prepared;
15	(5)	The name of the practitioner if the seller is not the
16		practitioner;
17	(6)	The name, strength, and quantity of the drug;
18	(7)	The "use by" date for the drug, which shall be:
19		(A) The expiration date on the manufacturer's
20		container; or
21		(B) One year from the date the drug is dispensed,



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1		whichever is earlier;
2	(8)	The number of refills available, if any;
3	(9)	In the case of the dispensing of an equivalent generic
4		drug product, the statement "same as (brand name of
5		the drug product prescribed or the referenced listed
6		drug name)", or words of similar meaning;
7	(10)	In the case of the dispensing of an interchangeable
8		biological product, the statement "interchangeable
9		with (brand name of the biological product prescribed
10		or the referenced biological drug name)", or words of
11		similar meaning; and
12	(11)	Specific directions for the drug's use; provided that
13		if the specific directions for use are too lengthy for
14		inclusion on the label, the notation "take according
15		to written instructions" may be used if separate
16		written instructions for use are actually issued with
17		the drug by the practitioner or the pharmacist, but in
18		no event shall the notation "take as directed",
19		referring to oral instructions, be considered
20		acceptable.



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1 If any prescription for a drug does not indicate the number of 2 times it may be refilled, if any, the pharmacist shall not 3 refill that prescription unless subsequently authorized to do so 4 by the practitioner or pursuant to section 461-11.9. The act of dispensing a prescription drug other than a professional sample 5 6 or medical oxygen contrary to this subsection shall be deemed to 7 be an act that results in a drug being misbranded while held for 8 sale. 9 In addition to the requirements enumerated in (b) 10 subsection (a), a prescription drug shall be dispensed only: 11 (1)By a pharmacist pursuant to a valid prescription or 12 section 453-52, 461-1, 461-11.8, or 461-11.9; 13 (2) By a medical oxygen distributor pursuant to a 14 prescription or certificate of medical necessity; provided that the drug to be dispensed is medical 15 16 oxygen; or 17 By a practitioner to an ultimate user  $[\div]$ , except as (3) 18 provided for a supply of epinephrine under sections 19 27- , 46- , 302A- , and 328- ; provided that: 20 Except as otherwise authorized for a supply of (A) 21 epinephrine under sections 27- , 46- ,



1	302A- , and 328- and expedited partner
2	therapy in section 453-52, the practitioner shall
3	inform the patient, before dispensing any drug
4	other than a professional sample, that the
5	patient may have a written, orally ordered, or
6	electronically transmitted or conveyed
7	prescription directed to a pharmacy or a medical
8	oxygen distributor of the patient's own choice;
9	(B) The practitioner shall promptly record in the
10	practitioner's records:
11	(i) The prescription in full;
12	(ii) The name, strength, and quantity of the
13	drug, and specific directions for the drug's
14	use;
15	(iii) The date the drug was dispensed;
16	(iv) [ <del>Except as otherwise authorized for</del>
17	expedited partner therapy in section 453-52
18	or for an opioid antagonist in section 461-
19	11.8, the] The name and address of the
20	person for whom the drug was prescribed or
21	the name of the owner of the animal for



1		which the drug was prescribed[;], except as
2		otherwise authorized for a supply of
3		epinephrine under sections 27-, 46-,
4		302A- , and 328- ; expedited partner
5		therapy in section 453-52; or an opioid
6		antagonist in section 461-11.8; and
7		(v) Prescription drugs dispensed or prescribed
8		for expedited partner therapy as authorized
9		under section 453-52 or for an opioid
10		antagonist in section 461-11.8;
11	(C)	The records described in subparagraph (B) shall
12		be subject to the inspection of the department or
13		its agents at all times; and
14	(D)	No undisclosed rebate, refund, commission,
15		preference, discount, or other consideration,
16		whether in the form of money or otherwise, has
17		been offered to the practitioner as compensation
18		or inducement to dispense or prescribe any
19		specific drug in preference to other drugs that
20		might be used for the identical therapeutic
21		indication.



1	(c)	A pi	rescri	ption may be communicated in writing, orally,
2	or by ele	electronic transmission, and shall include the following		
3	informati	on:		
4	(1)	The	autho	rization of the practitioner noted as
5		foll	ows:	
6		(A)	Writ	ten prescriptions shall include the original
7			sign	ature of the practitioner;
8		(B)	Oral	prescriptions shall be promptly recorded by
9			the	pharmacist or medical oxygen distributor and
10			shal	l include the practitioner's oral code
11			desi	gnation; and
12		(C)	Elec	tronic prescriptions shall be irrefutably
13			trac	eable to the prescribing practitioner by a
14			reco	gnizable and unique practitioner identifier
15			such	as:
16			(i)	A bitmap or graphic image of the
17				prescriber's handwritten signature and the
18				prescriber's oral code designation (or
19				license number or other identifier if the
20				prescriber is an out-of-state practitioner);
21			(ii)	An electronic signature;



1		(iii) A digital signature; or
2		(iv) By other means as approved by the director;
3	(2)	The date of issuance;
4	(3)	The practitioner's name, business telephone number,
5		and business address, unless the practitioner is
6		otherwise uniquely identified and the pharmacy or
7		medical oxygen distributor dispensing the prescription
8		has the prescriber's contact information on file
9		accessible within the dispensing area;
10	(4)	The name, strength, and quantity of the drug to be
11		dispensed, and specific directions for the drug's use;
12	(5)	[Except as otherwise authorized for expedited partner
13		therapy in section 453-52 or for an opioid antagonist
14		in section 461-11.8, the] The name and address of the
15		person for whom the prescription was written or the
16		name of the owner of the animal for which the drug was
17		prescribed, unless the pharmacy or medical oxygen
18		distributor dispensing the prescription has the
19		address on file accessible within the dispensing
20		area[+], except as otherwise authorized for:



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1		(A) A supply of epinephrine under sections 27- ,
2		<u>46-</u> , 302A-, and 328-;
3		(B) Expedited partner therapy in section 453-52; or
4		(C) An opioid antagonist in section 461-11.8;
5	(6)	The room number and route of administration, if the
6		patient is in an institutional facility; and
7	(7)	The number of allowable refills, if the prescription
8		is refillable. If the number of refills authorized by
9		the practitioner is indicated using the terms "as
10		needed" or "prn", the prescription may be refilled up
11		to twelve months from the date the original
12		prescription was written. After the twelve-month
13		period, the "as needed" or "prn" prescription may be
14		refilled for a subsequent three-month period;
15		provided:
16		(A) The prescription is refilled only once during the
17		three-month period;
18		(B) The refill does not exceed a thirty-day supply of
19		the drug;



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1	(C)	The refill does not provide any amount of the
2		drug fifteen months beyond the date the original
3		prescription was written;
4	(D)	In the case of medical oxygen, the duration of
5		therapy indicated on a certificate of medical
6		necessity shall supersede any limitations or
7		restrictions on refilling; and
8	(E)	Subparagraphs (A) to (D) shall apply only to
9		pharmacies and medical oxygen distributors
10		practicing in the State."
11	2. By am	ending subsection (g) to read:
12	"(g) Any	drug other than medical oxygen dispensed pursuant
13	to a prescript.	ion shall be exempt from the requirements of
14	section 328-15	(except paragraphs (1), (9), (11), and (12), and
15	the packaging	requirements of paragraphs (7) and (8)), if the
16	drug bears a la	abel containing:
17	(1) The 1	name and address of the pharmacy;
18	(2) The :	serial number and the date of the prescription or
19	of i	ts filling;
20	(3) The 1	name of the practitioner;

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1	(4)	[Except as otherwise authorized for expedited partner
2		therapy in section 453-52 or for an opioid antagonist
3		in section 461-11.8, the] The name of the patient[;],
4		except as otherwise authorized for:
5		(A) A supply of epinephrine under sections 27- ,
6		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	(5)	The directions for use; and
10	(6)	Any cautionary statements contained in the
11		prescription.
12	This exemp	ption shall not apply to any drug dispensed in the
13	course of	the conduct of a business of dispensing drugs pursuant
14	to diagnos	sis by mail, or to a drug dispensed in violation of
15	subsection	n (a), (b), (c), or (d)."
16	SECT	ION 7. Section 328-17.7, Hawaii Revised Statutes, is
17	amended by	y amending subsection (a) to read as follows:
18	"(a)	Every practitioner, pharmacist, or medical oxygen
19	distributo	or who compounds, sells, or delivers any prescribed
20	drug to a	patient or a patient's agent shall maintain records
21	that ident	tify:



1	(1)	The specific drug product dispensed, including:
2		(A) The product's national drug code (NDC) number; or
3		(B) The brand name or the established name and the
4		name or commonly accepted abbreviation of the
5		principal labeler of the drug product dispensed,
6		the product strength, and the dosage form;
7	(2)	The quantity of the drug;
8	(3)	Directions for use;
9	(4)	The number of allowable refills;
10	(5)	The date of initial dispensing and the dates of all
11		refilling;
12	(6)	The date of any transfer of the prescription;
13	(7)	The name, business address, and telephone number of
14		the recipient pharmacist or medical oxygen distributor
15		for any transfer of prescription;
16	(8)	The prescribing practitioner, including name, business
17		address, and telephone number;
18	(9)	The format (oral, written, or electronic) in which the
19		prescription was received;
20	(10)	[Except as otherwise authorized for expedited partner
21		therapy in section 453-52 or for an opioid antagonist



1		in section 461-11.8, the] The patient, including name,
2		address, and telephone number[+], except as otherwise
3		authorized for:
4		(A) A supply of epinephrine under sections 27- ,
5		46- , 302A- , and 328- ;
6		(B) Expedited partner therapy in section 453-52; or
7		(C) An opioid antagonist in section 461-11.8;
8	(11)	The date of prescribing; and
9	(12)	The name of the practitioner, pharmacist, or medical
10		oxygen distributor dispensing the drug.
11	Every pre	scription dispensed shall have the name of the
12	pharmacis	t, dispensing practitioner, or medical oxygen
13	distribut	or responsible for the dispensing appended to the
14	prescript	ion record, and every prescription record shall be
15	preserved	and legible for a period of not less than five years.
16	The presc	ription records shall be subject at all times to the
17	inspectio	n of the director of health or the director's agent."
18	SECT	ION 8. Statutory material to be repealed is bracketed
19	and stric	ken. New statutory material is underscored.
20	SECT	ION 9. This Act shall take effect upon its approval.
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INTRODUCED BY:

JAN 2 1 2025



#### Report Title:

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

#### Description:

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.

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

