# A BILL FOR AN ACT

RELATING TO OPIOID ANTAGONISTS.

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

- 1 SECTION 1. The legislature finds that drug overdose deaths
- 2 in the United States have more than doubled since 1999.
- 3 According to the most recent data from the federal Centers for
- 4 Disease Control and Prevention, in 2013, more than 16,000 deaths
- 5 associated with opioid pain relievers were reported. Deaths
- 6 involving heroin have also doubled in recent years, with more
- 7 than 8,000 deaths reported in 2013. According to the Centers
- 8 for Disease Control and Prevention, overdoses involving
- 9 prescription painkillers are at epidemic levels. However,
- 10 deaths caused by opioids are often preventable via timely
- 11 administration of an opioid antagonist, such as naloxone
- 12 hydrochloride. Studies have found that providing opioid
- 13 overdose training and naloxone kits can help people identify
- 14 signs of an opioid-related drug overdose and can help reduce
- 15 opioid overdose mortality.
- 16 The legislature further finds that opioid antagonist use
- 17 has been approved by the federal Food and Drug Administration

1 and used for more than forty years by emergency medical services 2 personnel to reverse opioid overdose. Opioid antagonists have 3 no psychoactive effects and do not have any potential for abuse, 4 and first responders and family members with no medical training 5 can learn to administer them safely. Furthermore, research has 6 shown that the increased availability of opioid antagonists does 7 not encourage people to use more drugs or engage in riskier 8 behavior. 9 The legislature additionally finds that over half of the 10 states in the country have enacted some form of a 911 drug 11 immunity law or have implemented a law or developed a pilot 12 program to allow administration of medication, like opioid 13 antagonists, to reverse the effects of an opiate-related 14 overdose. Numerous state and national organizations also 15 support increased access to naloxone hydrochloride, including 16 but not limited to the American Public Health Association, 17 American Medical Association, American Pharmacists Association, 18 Harm Reduction Coalition, American Society of Addiction 19 Medicine, National Governors Association, law enforcement 20 organizations, and organizations representing first responders.

Accordingly, the purpose of this Act is to:

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1	(1)	Create immunity for health care professionals and
2		pharmacists who prescribe, dispense, distribute, or
3		administer an opioid antagonist such as naloxone
4		hydrochloride to persons who are at risk of
5		experiencing or who are experiencing an opioid-related
6		drug overdose;
7	(2)	Create immunity for emergency personnel and first
8		responders, who administer an opioid antagonist to a
9		person suffering from an opioid-related drug overdose;
10	(3)	Authorize emergency personnel and first responders to
11		administer opioid antagonists;
12	(4)	Require medicaid coverage for opioid antagonists; and
13	(5)	Allow harm reduction organizations to store and
14		distribute opioid antagonists.
15	SECT	ION 2. The Hawaii Revised Statutes is amended by
16	adding a	new chapter to be appropriately designated and to read
17	as follow	s:
18		"CHAPTER
19		OVERDOSE PREVENTION AND EMERGENCY RESPONSE ACT
20	S	-1 Definitions. The following definitions apply
21	throughou	t this chapter:

•	harm reduction organization means an organization that
2	provides services, including medical care, counseling, homeless
3	services, or addiction treatment, to individuals at risk of
4	experiencing an opiate-related drug overdose event or to the
5	friends and family members of an at-risk individual.
6	"Health care professional" includes a physician, physician
7	assistant under the authority and supervision of a physician, or
8	advanced practice registered nurse with prescriptive authority.
9	"Opioid antagonist" means any drug that binds to opioid
· 10	receptors and blocks or disinhibits the effects of opioids
11	acting on those receptors, and that is approved by the United
12	States Food and Drug Administration for treating opioid-related
13	drug overdose.
14	"Opioid-related drug overdose" means a condition including
15	but not limited to extreme physical illness, decreased level of
16	consciousness, respiratory depression, coma, or death resulting
17	from the consumption or use of an opioid, or another substance
18	with which an opioid was combined, or a condition that a
19	layperson would reasonably believe to be an opioid-related drug
20	overdose that requires medical assistance.

- 1 "Pharmacist" means a registered pharmacist as defined in2 chapter 461.
- 3 "Standing order" means a prescription order written by a
- 4 health care professional who is otherwise authorized to
- 5 prescribe an opioid antagonist that is not specific to and does
- 6 not identify a particular patient.
- 7 § -2 Immunity. (a) Notwithstanding any other law or
- 8 regulation to the contrary, a health care professional otherwise
- 9 authorized to prescribe an opioid antagonist may, directly or by
- 10 standing order, prescribe, dispense, and distribute an opioid
- 11 antagonist to:
- 12 (1) An individual at risk of experiencing an opioid-
- related overdose;
- 14 (2) Another person in a position to assist an individual
- 15 at risk of experiencing an opioid-related overdose; or
- 16 (3) A harm reduction organization.
- 17 Any such prescription shall be regarded as being issued for
- 18 a legitimate medical purpose in the usual course of professional
- 19 practice.
- 20 (b) A health care professional or pharmacist who, acting
- 21 in good faith and with reasonable care, prescribes, dispenses,

- 1 or distributes an opioid antagonist shall not be subject to any
- 2 criminal or civil liability or any professional disciplinary
- 3 action for:
- 4 (1) Prescribing, dispensing, or distributing the opioid
- 5 antagonist; and
- 6 (2) Any outcomes resulting from the eventual
- 7 administration of the opioid antagonist.
- 8 (c) Notwithstanding any other law or regulation to the
- 9 contrary, any person may lawfully possess an opioid antagonist.
- 10 (d) A person who, acting in good faith and with reasonable
- 11 care, administers an opioid antagonist to another person whom
- 12 the person believes to be suffering an opioid-related drug
- 13 overdose shall be immune from criminal prosecution, sanction
- 14 under any professional licensing statute, and civil liability
- 15 for acts or omissions resulting from the act.
- 16 § -3 Opioid antagonist administration; emergency
- 17 personnel and first responders. By January 1, 2017, every
- 18 emergency medical technician licensed and registered in Hawaii
- 19 and all law enforcement officers, firefighters, and lifequards
- 20 shall be authorized to administer an opioid antagonist as
- 21 clinically indicated. Any emergency medical technician licensed

- 1 and registered in Hawaii and all law enforcement officers,
- 2 firefighters, and lifeguards who, acting in good faith and with
- 3 reasonable care, administers an opioid antagonist to another
- 4 person whom the emergency medical technician, law enforcement
- 5 officer, firefighter, or lifeguard believes to be suffering an
- 6 opioid-related drug overdose shall be immune from criminal
- 7 prosecution, sanction under any professional licensing statute,
- 8 and civil liability, for acts or omissions resulting from the
- 9 act.
- 10 § -4 Medicaid coverage. The department of human
- 11 services shall ensure that opioid antagonists for outpatient use
- 12 are covered by the medicaid prescription drug program on the
- 13 same basis as other covered drugs.
- 14 § -5 Harm reduction organization; opioid antagonist;
- 15 exemption. Notwithstanding any other law or regulation to the
- 16 contrary, a person or harm reduction organization acting under a
- 17 standing order issued by a health care professional licensed
- 18 under chapter 453 or chapter 457 who is otherwise authorized to
- 19 prescribe an opioid antagonist may store an opioid antagonist
- 20 without being subject to chapter 328, except part VII, and may

- 1 distribute an opioid antagonist; provided that the distribution
- 2 is without charge or compensation.
- 3 § -6 Unintentional drug overdose; reporting. (a) The
- 4 department of health shall ascertain, document, and publish an
- 5 annual report on the number of, trends in, patterns in, and risk
- 6 factors related to unintentional drug overdose fatalities
- 7 occurring each year within the State. The report shall provide
- 8 information on interventions that would be effective in reducing
- 9 the rate of fatal or nonfatal drug overdose.
- 10 (b) The department of health shall monitor adverse drug
- 11 reaction from opiate antagonist use. In order to do so,
- 12 hospital emergency departments shall report to the department of
- 13 health adverse drug reactions occurring after administration of
- 14 an opiate antagonist.
- 15 § -7 Drug overdose recognition, prevention, and
- 16 response. The department of health shall work with community
- 17 partners to provide or establish any of the following:
- 18 (1) Education on drug overdose prevention, recognition,
- and response, including opioid antagonist
- **20** administration;

1	(2)	Training on drug overdose prevention, recognition, and
2		response, including opioid antagonist administration,
3		for patients receiving opioids and their families and
4		caregivers;
5	(3)	Opioid antagonist prescription and distribution
6		projects; and
7	(4)	Education and training projects on drug overdose
8		response and treatment, including opioid antagonist
9		administration, for emergency services and law
10		enforcement personnel, including volunteer
11		firefighters, lifeguards, and emergency services
12		personnel."
13	SECT	ION 3. Section 461-1, Hawaii Revised Statutes, is
14	amended by	y amending the definition of "practice of pharmacy" to
15	read as fo	ollows:
16	""Pra	actice of pharmacy" means:
17	(1)	The interpretation and evaluation of prescription
18		orders; the compounding, dispensing, and labeling of
19		drugs and devices (except labeling by a manufacturer,
20		packer, or distributor of nonprescription drugs and

commercially legend drugs and devices); the

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ī		participation in drug selection and drug utilization
2		reviews; the proper and safe storage of drugs and
3		devices and the maintenance of proper records
4		therefor; the responsibility for advising when
5		necessary or where regulated, of therapeutic values,
6	•	content, hazards, and use of drugs and devices;
7	(2)	Performing the following procedures or functions as
8		part of the care provided by and in concurrence with a
9		"health care facility" and "health care service" as
10		defined in section 323D-2, or a "pharmacy" or a
11		licensed physician, or a "managed care plan" as
12		defined in section 432E-1, in accordance with
13		policies, procedures, or protocols developed
14		collaboratively by health professionals, including
15		physicians and surgeons, pharmacists, and registered
16		nurses, and for which a pharmacist has received
17		appropriate training required by these policies,
18		procedures, or protocols:
19		(A) Ordering or performing routine drug therapy
20		related patient assessment procedures;
21		(B) Ordering drug therapy related laboratory tests;

1	(C)	Initiating emergency contraception oral drug
2		therapy in accordance with a written
3		collaborative agreement approved by the board,
4		between a licensed physician and a pharmacist who
5		has received appropriate training that includes
6		programs approved by the American Council of
7 .		Pharmaceutical Education (ACPE), curriculum-based
8		programs from an ACPE-accredited college of
9		pharmacy, state or local health department
10		programs, or programs recognized by the board of
11		pharmacy;
12	(D)	Administering drugs orally, topically, by
13		intranasal delivery, or by injection, pursuant to
14		the patient's licensed physician's order, by a
15		pharmacist having appropriate training that
16		includes programs approved by the ACPE,
17		curriculum-based programs from an ACPE-accredited
18		college of pharmacy, state or local health
19		department programs, or programs recognized by
20		the board of pharmacy;
21	(E)	Administering:

1	(i) Immunizations orally, by injection, or by
2	intranasal delivery, to persons eighteen
3	years of age or older by a pharmacist having
4	appropriate training that includes programs
5	approved by the ACPE, curriculum-based
6	programs from an ACPE-accredited college of
7	pharmacy, state or local health department
8	programs, or programs recognized by the
9	board of pharmacy; and
10	(ii) Vaccines to persons between fourteen and
11	seventeen years of age pursuant to section
12	461-11.4;
13	(F) As authorized by a licensed physician's written
14	instructions, initiating or adjusting the drug
15	regimen of a patient pursuant to an order or
16	authorization made by the patient's licensed
17	physician and related to the condition for which
18	the patient has been seen by the licensed
19	physician; provided that the pharmacist shall
20	issue written notification to the patient's
21	licensed physician or enter the appropriate

1		information in an electronic patient record
2		system shared by the licensed physician, within
3		twenty-four hours;
4	(G)	Transmitting a valid prescription to another
5		pharmacist for the purpose of filling or
6		dispensing; [ex]
7	(H)	Providing consultation, information, or education
8		to patients and health care professionals based
9		on the pharmacist's training and for which no
10		other licensure is required; [and] or
11	<u>(I)</u>	Dispensing an opioid antagonist in accordance
12		with a written collaborative agreement approved
13		by the board, between a licensed physician and a
14		pharmacist who has received appropriate training
15		that includes programs approved by the American
16		Council on Pharmaceutical Education (ACPE),
17		curriculum-based programs from an ACPE-accredited
18		college of pharmacy, state or local health
19		department programs, or programs recognized by
20		the board; and

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1 (3) The offering or performing of those acts, services, 2 operations, or transactions necessary in the conduct, 3 operation, management, and control of pharmacy." 4 SECTION 4. This Act does not affect rights and duties that 5 matured, penalties that were incurred, and proceedings that were 6 begun before its effective date. 7 SECTION 5. Statutory material to be repealed is bracketed 8 and stricken. New statutory material is underscored. 9 SECTION 6. This Act shall take effect on July 1, 2112.

#### Report Title:

Opioid Antagonist; Naloxone Hydrochloride; Drug Overdose Prevention; Emergency Response; Medical Immunity

#### Description:

Creates immunity for health care professionals and pharmacists who prescribe, dispense, or administer an opioid antagonist such as naloxone hydrochloride to assist an individual at risk of experiencing an opioid-related drug overdose or to a harm reduction organization. Creates immunity for first responders, harm reduction organizations, and individuals who administer opioid antagonists to persons believed to be suffering an opioid-related drug overdose. Authorizes emergency personnel to administer an opioid antagonist. Requires medicaid coverage for opioid antagonists for outpatient use. Authorizes certain persons or organizations acting under standing orders issued by a licensed health care professional to store opioid antagonists without being subject to the Hawaii Food, Drug, and Cosmetic Act, except the portion regarding the storage of wholesale prescription drugs, and to distribute opioid antagonists without charge or compensation. (SB2392 HD1)

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