
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
18 and used for more than forty years by emergency medical services



1 personnel to reverse opioid overdose. Opioid antagonists have
2 no psychoactive effects and do not have any potential for abuse,
3 and first responders and family members with no medical training
4 can learn to administer them safely. Furthermore, research has
5 shown that the increased availability of opioid antagonists does
6 not encourage people to use more drugs or engage in riskier
7 behavior.

8 The legislature additionally finds that over half of the
9 states in the country have enacted some form of a 911 drug
10 immunity law or have implemented a law or developed a pilot
11 program to allow administration of medication, like opioid
12 antagonists, to reverse the effects of an opiate-related
13 overdose. Numerous state and national organizations also
14 support increased access to naloxone hydrochloride, including
15 but not limited to the American Public Health Association,
16 American Medical Association, American Pharmacists Association,
17 Harm Reduction Coalition, American Society of Addiction
18 Medicine, National Governors Association, law enforcement
19 organizations, and organizations representing first responders.

20 Accordingly, the purpose of this Act is to:



1 § -1 Definitions. The following definitions apply
2 throughout this chapter:

3 "Harm reduction organization" means an organization that
4 provides services, including medical care, counseling, homeless
5 services, or addiction treatment, to individuals at risk of
6 experiencing an opiate-related drug overdose event or to the
7 friends and family members of an at-risk individual.

8 "Health care professional" includes a physician, physician
9 assistant under the authority and supervision of a physician, or
10 advanced practice registered nurse who is authorized to
11 prescribe an opioid antagonist.

12 "Opioid antagonist" means any drug that binds to opioid
13 receptors and blocks or disinhibits the effects of opioids
14 acting on those receptors that is approved by the United States
15 Food and Drug Administration for treating opioid-related drug
16 overdose.

17 "Opioid-related drug overdose" means a condition including
18 but not limited to extreme physical illness, decreased level of
19 consciousness, respiratory depression, coma, or death resulting
20 from the consumption or use of an opioid, or another substance
21 with which an opioid was combined, or a condition that a



1 layperson would reasonably believe to be an opioid-related drug
2 overdose that requires medical assistance.

3 "Pharmacist" means a registered pharmacists as defined in
4 chapter 461.

5 "Standing order" means a prescription order written by a
6 health care professional who is otherwise authorized to
7 prescribe an opioid antagonist that is not specific to and does
8 not identify a particular patient.

9 § -2 Immunity. (a) Notwithstanding any other law or
10 regulation to the contrary, a health care professional otherwise
11 authorized to prescribe an opioid antagonist may, directly or by
12 standing order, prescribe, dispense, and distribute an opioid
13 antagonist to an individual at risk of experiencing an opioid-
14 related overdose, to another person in a position to assist an
15 individual at risk of experiencing an opioid-related overdose,
16 or to a harm reduction organization. Any such prescription
17 shall be regarded as being issued for a legitimate medical
18 purpose in the usual course of professional practice.

19 (b) A health care professional or pharmacist who, acting
20 in good faith and with reasonable care, prescribes, dispenses,
21 or distributes an opioid antagonist shall not be subject to any



1 criminal or civil liability or any professional disciplinary
2 action for:

3 (1) Prescribing, dispensing, or distributing the opioid
4 antagonist; and

5 (2) Any outcomes resulting from the eventual
6 administration of the opioid antagonist.

7 (c) Notwithstanding any other law or regulation to the
8 contrary, any person may lawfully possess an opioid antagonist.

9 (d) A person who, acting in good faith and with reasonable
10 care, administers an opioid antagonist to another person whom
11 the person believes to be suffering an opioid-related drug
12 overdose shall be immune from criminal prosecution, sanction
13 under any professional licensing statute, and civil liability
14 for acts or omissions resulting from the act.

15 § -3 Opioid antagonist administration; emergency
16 personnel and first responders. By January 1, 2017, every
17 emergency medical technician licensed and registered in Hawaii
18 and all law enforcement officers, firefighters, and lifeguards
19 shall be authorized to administer an opioid antagonist as
20 clinically indicated and who, acting in good faith and with
21 reasonable care, administers an opioid antagonist to another



1 person whom the person believes to be suffering an opioid-
2 related drug overdose shall be immune from criminal prosecution,
3 sanction under any professional licensing statute, and civil
4 liability, for acts or omissions resulting from the act.

5 § -4 Medicaid coverage. The department of human
6 services shall ensure that opioid antagonists for outpatient use
7 are covered by the medicaid prescription drug program on the
8 same basis as other covered drugs.

9 § -5 Harm reduction organization; opioid antagonist;
10 exemption. Notwithstanding any other law or regulation to the
11 contrary, a person or harm reduction organization acting under a
12 standing order issued by a health care professional licensed
13 under chapter 453 or chapter 457 who is otherwise authorized to
14 prescribe an opioid antagonist may store an opioid antagonist
15 without being subject to chapter 328, except part VII, and may
16 distribute an opioid antagonist; provided that the distribution
17 is without charge or compensation.

18 § -6 Unintentional drug overdose; reporting. The
19 department of health shall ascertain, document, and publish an
20 annual report on the number of, trends in, patterns in, and risk
21 factors related to unintentional drug overdose fatalities



1 occurring each year within the State. The report shall provide
2 information on interventions that would be effective in reducing
3 the rate of fatal or nonfatal drug overdose.

4 § -7 Drug overdose recognition, prevention, and
5 response. The department of health shall work with community
6 partners to provide or establish any of the following:

- 7 (1) Education on drug overdose prevention, recognition,
8 and response, including opioid antagonist
9 administration;
- 10 (2) Training on drug overdose prevention, recognition, and
11 response, including opioid antagonist administration,
12 for patients receiving opioids and their families and
13 caregivers;
- 14 (3) Opioid antagonist prescription and distribution
15 projects; and
- 16 (4) Education and training projects on drug overdose
17 response and treatment, including opioid antagonist
18 administration, for emergency services and law
19 enforcement personnel, including volunteer
20 firefighter, lifeguards, and emergency services
21 personnel."



1 SECTION 3. Section 461-1, Hawaii Revised Statutes, is
2 amended by amending the definition of "practice of pharmacy" to
3 read as follows:

4 "Practice of pharmacy" means:

- 5 (1) The interpretation and evaluation of prescription
6 orders; the compounding, dispensing, and labeling of
7 drugs and devices (except labeling by a manufacturer,
8 packer, or distributor of nonprescription drugs and
9 commercially legend drugs and devices); the
10 participation in drug selection and drug utilization
11 reviews; the proper and safe storage of drugs and
12 devices and the maintenance of proper records
13 therefor; the responsibility for advising when
14 necessary or where regulated, of therapeutic values,
15 content, hazards, and use of drugs and devices;
- 16 (2) Performing the following procedures or functions as
17 part of the care provided by and in concurrence with a
18 "health care facility" and "health care service" as
19 defined in section 323D-2, or a "pharmacy" or a
20 licensed physician, or a "managed care plan" as
21 defined in section 432E-1, in accordance with



1 policies, procedures, or protocols developed
2 collaboratively by health professionals, including
3 physicians and surgeons, pharmacists, and registered
4 nurses, and for which a pharmacist has received
5 appropriate training required by these policies,
6 procedures, or protocols:

7 (A) Ordering or performing routine drug therapy
8 related patient assessment procedures;

9 (B) Ordering drug therapy related laboratory tests;

10 (C) Initiating emergency contraception oral drug
11 therapy in accordance with a written
12 collaborative agreement approved by the board,
13 between a licensed physician and a pharmacist who
14 has received appropriate training that includes
15 programs approved by the American Council of
16 Pharmaceutical Education (ACPE), curriculum-based
17 programs from an ACPE-accredited college of
18 pharmacy, state or local health department
19 programs, or programs recognized by the board of
20 pharmacy;



- 1 (D) Administering drugs orally, topically, by
2 intranasal delivery, or by injection, pursuant to
3 the patient's licensed physician's order, by a
4 pharmacist having appropriate training that
5 includes programs approved by the ACPE,
6 curriculum-based programs from an ACPE-accredited
7 college of pharmacy, state or local health
8 department programs, or programs recognized by
9 the board of pharmacy;
- 10 (E) Administering:
- 11 (i) Immunizations orally, by injection, or by
12 intranasal delivery, to persons eighteen
13 years of age or older by a pharmacist having
14 appropriate training that includes programs
15 approved by the ACPE, curriculum-based
16 programs from an ACPE-accredited college of
17 pharmacy, state or local health department
18 programs, or programs recognized by the
19 board of pharmacy; and



1 (ii) Vaccines to persons between fourteen and
2 seventeen years of age pursuant to section
3 461-11.4;

4 (F) As authorized by a licensed physician's written
5 instructions, initiating or adjusting the drug
6 regimen of a patient pursuant to an order or
7 authorization made by the patient's licensed
8 physician and related to the condition for which
9 the patient has been seen by the licensed
10 physician; provided that the pharmacist shall
11 issue written notification to the patient's
12 licensed physician or enter the appropriate
13 information in an electronic patient record
14 system shared by the licensed physician, within
15 twenty-four hours;

16 (G) Transmitting a valid prescription to another
17 pharmacist for the purpose of filling or
18 dispensing; [øx]

19 (H) Providing consultation, information, or education
20 to patients and health care professionals based



1 on the pharmacist's training and for which no
2 other licensure is required; [~~and~~] or

3 (1) Dispensing an opioid antagonist in accordance
4 with a written collaborative agreement approved
5 by the board, between a licensed physician and a
6 pharmacist who has received appropriate training
7 that includes programs approved by the American
8 Council on Pharmaceutical Education (ACPE),
9 curriculum-based programs from an ACPE-accredited
10 college of pharmacy, state or local health
11 department programs, or programs recognized by
12 the board; and

13 (3) The offering or performing of those acts, services,
14 operations, or transactions necessary in the conduct,
15 operation, management, and control of pharmacy."

16 SECTION 4. This Act does not affect rights and duties that
17 matured, penalties that were incurred, and proceedings that were
18 begun before its effective date.

19 SECTION 5. Statutory material to be repealed is bracketed
20 and stricken. New statutory material is underscored.

21 SECTION 6. This Act shall take effect on July 1, 2016.



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. (SD1)

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