A BILL FOR AN ACT

RELATING TO OPIOID ANTAGONISTS.

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

SECTION 1. The legislature finds that drug overdose deaths in the United States have more than doubled since 1999. According to the most recent data from the federal Centers for Disease Control and Prevention, in 2013, more than 16,000 deaths associated with opioid pain relievers were reported. Deaths involving heroin have also doubled in recent years, with more than 8,000 deaths reported in 2013. According to the Centers for Disease Control and Prevention, overdoses involving prescription painkillers are at epidemic levels. However, deaths caused by opioids are often preventable via timely administration of an opioid antagonist, such as naloxone hydrochloride. Studies have found that providing opioid overdose training and naloxone kits can help people identify signs of an opioid-related drug overdose and can help reduce opioid overdose mortality.

The legislature further finds that opioid antagonist use has been approved by the federal Food and Drug Administration
and used for more than forty years by emergency medical services personnel to reverse opioid overdose. Opioid antagonists have no psychoactive effects and do not have any potential for abuse, and first responders and family members with no medical training can learn to administer them safely. Furthermore, research has shown that the increased availability of opioid antagonists does not encourage people to use more drugs or engage in riskier behavior.

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

Accordingly, the purpose of this Act is to:
(1) Create immunity for health care professionals and pharmacists who prescribe, dispense, distribute, or administer an opioid antagonist such as naloxone hydrochloride to persons who are at risk of experiencing or who are experiencing an opioid-related drug overdose;

(2) Create immunity for emergency personnel and first responders, who administer an opioid antagonist to a person suffering from an opioid-related drug overdose;

(3) Authorize emergency personnel and first responders to administer opioid antagonists;

(4) Require medicaid coverage for opioid antagonists; and

(5) Allow harm reduction organizations to store and distribute opioid antagonists.

SECTION 2. The Hawaii Revised Statutes is amended by adding a new chapter to be appropriately designated and to read as follows:

"CHAPTER

OVERDOSE PREVENTION AND EMERGENCY RESPONSE ACT

§ -1 Definitions. The following definitions apply throughout this chapter:
"Harm reduction organization" means an organization that provides services, including medical care, counseling, homeless services, or addiction treatment, to individuals at risk of experiencing an opiate-related drug overdose event or to the friends and family members of an at-risk individual.

"Health care professional" includes a physician, physician assistant under the authority and supervision of a physician, or advanced practice registered nurse with prescriptive authority.

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

"Opioid-related drug overdose" means a condition including but not limited to extreme physical illness, decreased level of consciousness, respiratory depression, coma, or death resulting from the consumption or use of an opioid, or another substance with which an opioid was combined, or a condition that a layperson would reasonably believe to be an opioid-related drug overdose that requires medical assistance.
"Pharmacist" means a registered pharmacist as defined in chapter 461.

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

§ -2 Immunity. (a) Notwithstanding any other law or regulation to the contrary, a health care professional otherwise authorized to prescribe an opioid antagonist may, directly or by standing order, prescribe, dispense, and distribute an opioid antagonist to:

(1) An individual at risk of experiencing an opioid-related overdose;

(2) Another person in a position to assist an individual at risk of experiencing an opioid-related overdose; or

(3) A harm reduction organization.

Any such prescription shall be regarded as being issued for a legitimate medical purpose in the usual course of professional practice.

(b) A health care professional or pharmacist who, acting in good faith and with reasonable care, prescribes, dispenses,
or distributes an opioid antagonist shall not be subject to any criminal or civil liability or any professional disciplinary action for:

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

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

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

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

§ -3 Opioid antagonist administration; emergency personnel and first responders. By January 1, 2017, every emergency medical technician licensed and registered in Hawaii and all law enforcement officers, firefighters, and lifeguards shall be authorized to administer an opioid antagonist as clinically indicated. Any emergency medical technician licensed
and registered in Hawaii and all law enforcement officers, firefighters, and lifeguards who, acting in good faith and with reasonable care, administers an opioid antagonist to another person whom the emergency medical technician, law enforcement officer, firefighter, or lifeguard believes to be suffering an opioid-related drug overdose shall be immune from criminal prosecution, sanction under any professional licensing statute, and civil liability, for acts or omissions resulting from the act.

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

§ -5 Harm reduction organization; opioid antagonist; exemption. Notwithstanding any other law or regulation to the contrary, a person or harm reduction organization acting under a standing order issued by a health care professional licensed under chapter 453 or chapter 457 who is otherwise authorized to prescribe an opioid antagonist may store an opioid antagonist 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.

§ -6 Unintentional drug overdose; reporting. (a) The
department of health shall ascertain, document, and publish an
annual report on the number of, trends in, patterns in, and risk
factors related to unintentional drug overdose fatalities
occurring each year within the State. The report shall provide
information on interventions that would be effective in reducing
the rate of fatal or nonfatal drug overdose.

(b) The department of health shall monitor adverse drug
reaction from opiate antagonist use. In order to do so,
hospital emergency departments shall report to the department of
health adverse drug reactions occurring after administration of
an opiate antagonist.

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

(1) Education on drug overdose prevention, recognition,
and response, including opioid antagonist
administration;
(2) Training on drug overdose prevention, recognition, and response, including opioid antagonist administration, for patients receiving opioids and their families and caregivers;

(3) Opioid antagonist prescription and distribution projects; and

(4) Education and training projects on drug overdose response and treatment, including opioid antagonist administration, for emergency services and law enforcement personnel, including volunteer firefighters, lifeguards, and emergency services personnel.

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

"Practice of pharmacy" means:

(1) The interpretation and evaluation of prescription orders; the compounding, dispensing, and labeling of drugs and devices (except labeling by a manufacturer, packer, or distributor of nonprescription drugs and commercially legend drugs and devices); the
participation in drug selection and drug utilization reviews; the proper and safe storage of drugs and devices and the maintenance of proper records therefor; the responsibility for advising when necessary or where regulated, of therapeutic values, content, hazards, and use of drugs and devices;

(2) Performing the following procedures or functions as part of the care provided by and in concurrence with a "health care facility" and "health care service" as defined in section 323D-2, or a "pharmacy" or a licensed physician, or a "managed care plan" as defined in section 432E-1, in accordance with policies, procedures, or protocols developed collaboratively by health professionals, including physicians and surgeons, pharmacists, and registered nurses, and for which a pharmacist has received appropriate training required by these policies, procedures, or protocols:

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

(B) Ordering drug therapy related laboratory tests;
(C) Initiating emergency contraception oral drug therapy in accordance with a written collaborative agreement approved by the board, between a licensed physician and a pharmacist who has received appropriate training that includes programs approved by the American Council of Pharmaceutical Education (ACPE), curriculum-based programs from an ACPE-accredited college of pharmacy, state or local health department programs, or programs recognized by the board of pharmacy;

(D) Administering drugs orally, topically, by intranasal delivery, or by injection, pursuant to the patient's licensed physician's order, by a pharmacist having appropriate training that includes programs approved by the ACPE, curriculum-based programs from an ACPE-accredited college of pharmacy, state or local health department programs, or programs recognized by the board of pharmacy;

(E) Administering:
(i) Immunizations orally, by injection, or by intranasal delivery, to persons eighteen years of age or older by a pharmacist having appropriate training that includes programs approved by the ACPE, curriculum-based programs from an ACPE-accredited college of pharmacy, state or local health department programs, or programs recognized by the board of pharmacy; and

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

(F) As authorized by a licensed physician’s written instructions, initiating or adjusting the drug regimen of a patient pursuant to an order or authorization made by the patient’s licensed physician and related to the condition for which the patient has been seen by the licensed physician; provided that the pharmacist shall issue written notification to the patient’s licensed physician or enter the appropriate
information in an electronic patient record

system shared by the licensed physician, within
twenty-four hours;

(G) Transmitting a valid prescription to another

pharmacist for the purpose of filling or
dispensing; [e×]

(H) Providing consultation, information, or education
to patients and health care professionals based
on the pharmacist's training and for which no
other licensure is required; [and] or

(I) Dispensing an opioid antagonist in accordance

with a written collaborative agreement approved

by the board, between a licensed physician and a

pharmacist who has received appropriate training

that includes programs approved by the American

Council on Pharmaceutical Education (ACPE),
curriculum-based programs from an ACPE-accredited
college of pharmacy, state or local health
department programs, or programs recognized by
the board; and
(3) The offering or performing of those acts, services, 
operations, or transactions necessary in the conduct, 
operation, management, and control of pharmacy."

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

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

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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