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# 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 the nationwide  
2 opioid epidemic continues to result in an alarming number of  
3 opioid overdose deaths. According to the Centers for Disease  
4 Control and Prevention, opioid overdose fatalities have  
5 increased from 53,000 in 2015 to 64,000 in 2016. Unintentional  
6 drug poisonings, commonly referred to as drug overdoses, are one  
7 of the leading causes of injury-related mortality in Hawaii.  
8 Furthermore, an average of four hundred non-fatal overdoses  
9 occur in Hawaii per year, and opioid related overdoses resulted  
10 in about \$9,800,000 in hospital costs in 2016.

11           The legislature further finds that deaths caused by opioids  
12 are often preventable via timely administration of an opioid  
13 antagonist, such as naloxone. Studies have found that providing  
14 opioid overdose training and naloxone kits can help people  
15 identify signs of an opioid-related drug overdose and can help  
16 reduce opioid overdose mortality. Thus, there is a need for  
17 increased public access to health care professionals who can



1 safely provide naloxone and related education about the risks of  
2 opioid misuse.

3       The legislature also finds that pharmacists are well  
4 situated to provide education and access to naloxone and assist  
5 with the prevention and health care burden of addressing opioid  
6 overdose in Hawaii. A good example of how pharmacists can  
7 positively impact the overall public health continuum and reduce  
8 health care costs is seen with pharmacists providing  
9 immunizations. Pharmacists now immunize more patients than any  
10 other group of health care professionals, and immunization rates  
11 have grown, reducing disease and morbidity in the overall  
12 population.

13       The legislature notes that there is significant precedent  
14 in Hawaii law that supports expanded access to opioid  
15 antagonists and the role of registered pharmacists in the  
16 administration, dispensing, and prescription of opioid  
17 antagonists, such as in Act 66, Session Laws of Hawaii 2017, Act  
18 68, Session Laws of Hawaii 2016, and Act 217, Session Laws of  
19 Hawaii 2015.

20       Accordingly, the purpose of this Act is to expand the scope  
21 of registered pharmacists' practices by allowing registered



1 pharmacists to prescribe, dispense, and provide related  
2 education of opioid antagonists without the need for a written,  
3 approved collaborative agreement.

4 SECTION 2. Chapter 461, Hawaii Revised Statutes, is  
5 amended by adding a new section to be appropriately designated  
6 and to read as follows:

7 "§461- Opioid antagonist; authority to prescribe and  
8 dispense; requirements. (a) A pharmacist may prescribe and  
9 dispense an opioid antagonist to an individual who is at risk  
10 for an opioid overdose or a family member or caregiver of an  
11 individual who is at risk of an opioid overdose regardless of  
12 whether the individual has evidence of a previous prescription  
13 for an opioid antagonist from a practitioner authorized to  
14 prescribe opioids. The opioid antagonist prescribed and  
15 dispensed for a family member or caregiver of an individual who  
16 is at risk for an opioid overdose may be prescribed and  
17 dispensed in the name of the individual who is requesting the  
18 opioid antagonist or who is an "Opioid Antagonist Recipient" or  
19 "OAR".

20 (b) A pharmacist who prescribes and dispenses opioid  
21 antagonists pursuant to subsection (a) shall:



- 1        (1) Complete a training program related to prescribing  
2        opioid antagonists that is approved by the  
3        Accreditation Council for Pharmacy Education (ACPE), a  
4        curriculum-based program from an ACPE-accredited  
5        college of pharmacy, a state or local health  
6        department program, or a program recognized by the  
7        board;
- 8        (2) Provide the individual who is receiving the opioid  
9        antagonist with information and written educational  
10       material on risk factors of opioid overdose, signs of  
11       an overdose, overdose response steps, and the use of  
12       the opioid antagonist; and
- 13       (3) Dispense the opioid antagonist to the individual who  
14       is at risk for an opioid overdose, family member, or  
15       caregiver as soon as practicable after the pharmacist  
16       issues the prescription."

17       SECTION 3. Section 461-1, Hawaii Revised Statutes, is  
18 amended as follows:

19       1. By adding two new definitions to be appropriately  
20 inserted and to read:



1        "Caregiver" means an individual who has an established  
2 personal or professional relationship with the individual at  
3 risk for an opioid overdose.

4        "Family member" means an individual who can provide  
5 assistance and is related to the individual at risk for an  
6 opioid overdose."

7        2. By amending the definition of "practice of pharmacy" to  
8 read:

9        "Practice of pharmacy" means:

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



- 1           (2) Performing the following procedures or functions as  
2           part of the care provided by and in concurrence with a  
3           "health care facility" and "health care service" as  
4           defined in section 323D-2, or a "pharmacy" or a  
5           licensed physician or a licensed advanced practice  
6           registered nurse with prescriptive authority, or a  
7           "managed care plan" as defined in section 432E-1, in  
8           accordance with policies, procedures, or protocols  
9           developed collaboratively by health professionals,  
10          including physicians and surgeons, pharmacists, and  
11          registered nurses, and for which a pharmacist has  
12          received appropriate training required by these  
13          policies, procedures, or protocols:
- 14           (A) Ordering or performing routine drug therapy  
15           related patient assessment procedures;
- 16           (B) Ordering drug therapy related laboratory tests;
- 17           (C) Initiating emergency contraception oral drug  
18           therapy in accordance with a written  
19           collaborative agreement approved by the board,  
20           between a licensed physician or advanced practice  
21           registered nurse with prescriptive authority and



1 a pharmacist who has received appropriate  
2 training that includes programs approved by the  
3 [~~American~~] Accreditation Council [~~of~~  
4 ~~Pharmaceutical~~] for Pharmacy Education (ACPE),  
5 curriculum-based programs from an ACPE-accredited  
6 college of pharmacy, state or local health  
7 department programs, or programs recognized by  
8 the board of pharmacy;

9 (D) Administering drugs orally, topically, by  
10 intranasal delivery, or by injection, pursuant to  
11 the order of the patient's licensed physician or  
12 advanced practice registered nurse with  
13 prescriptive authority, by a pharmacist having  
14 appropriate training that includes programs  
15 approved by the ACPE, curriculum-based programs  
16 from an ACPE-accredited college of pharmacy,  
17 state or local health department programs, or  
18 programs recognized by the board of pharmacy;

19 (E) Administering:

20 (i) Immunizations orally, by injection, or by  
21 intranasal delivery, to persons eighteen



1 years of age or older by a pharmacist having  
2 appropriate training that includes programs  
3 approved by the ACPE, curriculum-based  
4 programs from an ACPE-accredited college of  
5 pharmacy, state or local health department  
6 programs, or programs recognized by the  
7 board of pharmacy;

8 (ii) Vaccines to persons between fourteen and  
9 seventeen years of age pursuant to section  
10 461-11.4; and

11 (iii) Human papillomavirus, Tdap (tetanus,  
12 diphtheria, pertussis), meningococcal, and  
13 influenza vaccines to persons between eleven  
14 and seventeen years of age pursuant to  
15 section 461-11.4;

16 (F) As authorized by the written instructions of a  
17 licensed physician or advanced practice  
18 registered nurse with prescriptive authority,  
19 initiating or adjusting the drug regimen of a  
20 patient pursuant to an order or authorization  
21 made by the patient's licensed physician or



1 advanced practice registered nurse with  
2 prescriptive authority and related to the  
3 condition for which the patient has been seen by  
4 the licensed physician or advanced practice  
5 registered nurse with prescriptive authority;  
6 provided that the pharmacist shall issue written  
7 notification to the patient's licensed physician  
8 or advanced practice registered nurse with  
9 prescriptive authority or enter the appropriate  
10 information in an electronic patient record  
11 system shared by the licensed physician or  
12 advanced practice registered nurse with  
13 prescriptive authority, within twenty-four hours;

14 (G) Transmitting a valid prescription to another  
15 pharmacist for the purpose of filling or  
16 dispensing;

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



1 (I) ~~[Dispensing an opioid antagonist in accordance~~  
 2 ~~with a written collaborative agreement approved~~  
 3 ~~by the board, between a licensed physician and a~~  
 4 ~~pharmacist who has received appropriate training~~  
 5 ~~that 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,]~~ Prescribing and dispensing an opioid  
 10 antagonist pursuant to section 461- ;

11 (3) The offering or performing of those acts, services,  
 12 operations, or transactions necessary in the conduct,  
 13 operation, management, and control of pharmacy; and

14 (4) Prescribing and dispensing contraceptive supplies  
 15 pursuant to section 461-11.6."

16 SECTION 4. Section 328-16, Hawaii Revised Statutes, is  
 17 amended as follows:

18 1. By amending subsections (a) to (c) to read:

19 "(a) A prescription drug shall be dispensed only if its  
 20 label bears the following:



- 1 (1) The name, business address, and telephone number of  
2 the seller. The business address shall be the  
3 physical location of the pharmacy or the dispensing  
4 practitioner's office;
- 5 (2) Except as otherwise authorized for expedited partner  
6 therapy in section 453-52 [7] or an opioid antagonist  
7 in section 461- , the name of the person for whom the  
8 drug was prescribed or the name of the owner of the  
9 animal for which the drug was prescribed;
- 10 (3) The serial number of the prescription;
- 11 (4) The date the prescription was prepared;
- 12 (5) The name of the practitioner if the seller is not the  
13 practitioner;
- 14 (6) The name, strength, and quantity of the drug;
- 15 (7) The "use by" date for the drug, which shall be:
- 16 (A) The expiration date on the manufacturer's  
17 container; or
- 18 (B) One year from the date the drug is dispensed,  
19 whichever is earlier;
- 20 (8) The number of refills available, if any;



- 1           (9) In the case of the dispensing of an equivalent generic  
2           drug product, the statement "same as (brand name of  
3           the drug product prescribed or the referenced listed  
4           drug name)", or words of similar meaning;
- 5           (10) In the case of the dispensing of an interchangeable  
6           biological product, the statement "interchangeable  
7           with (brand name of the biological product prescribed  
8           or the referenced biological drug name)", or words of  
9           similar meaning; and
- 10          (11) Specific directions for the drug's use; provided that  
11          if the specific directions for use are too lengthy for  
12          inclusion on the label, the notation "take according  
13          to written instructions" may be used if separate  
14          written instructions for use are actually issued with  
15          the drug by the practitioner or the pharmacist, but in  
16          no event shall the notation "take as directed",  
17          referring to oral instructions, be considered  
18          acceptable.
- 19          If any prescription for a drug does not indicate the number of  
20          times it may be refilled, if any, the pharmacist shall not  
21          refill that prescription unless subsequently authorized to do so



1 by the practitioner. The act of dispensing a prescription drug  
2 other than a professional sample or medical oxygen contrary to  
3 this subsection shall be deemed to be an act that results in a  
4 drug being misbranded while held for sale.

5 (b) In addition to the requirements enumerated in  
6 subsection (a), a prescription drug shall be dispensed only:

7 (1) By a pharmacist pursuant to a valid prescription~~[7]~~ or  
8 section 461-1, 461-\_\_, or ~~[section]~~ 453-52;

9 (2) By a medical oxygen distributor pursuant to a  
10 prescription or certificate of medical necessity;  
11 provided that the drug to be dispensed is medical  
12 oxygen; or

13 (3) By a practitioner to an ultimate user; provided that:

14 (A) Except as otherwise authorized for expedited  
15 partner therapy in section 453-52, the  
16 practitioner shall inform the patient, prior to  
17 dispensing any drug other than a professional  
18 sample, that the patient may have a written,  
19 orally ordered, or electronically transmitted or  
20 conveyed prescription directed to a pharmacy or a



1 medical oxygen distributor of the patient's own  
2 choice;

3 (B) The practitioner shall promptly record in the  
4 practitioner's records:

5 (i) The prescription in full;

6 (ii) The name, strength, and quantity of the  
7 drug, and specific directions for the drug's  
8 use;

9 (iii) The date the drug was dispensed;

10 (iv) Except as otherwise authorized for expedited  
11 partner therapy in section 453-52 [7] or for  
12 an opioid antagonist in section 461- , the  
13 name and address of the person for whom the  
14 drug was prescribed or the name of the owner  
15 of the animal for which the drug was  
16 prescribed; and

17 (v) Prescription drugs dispensed or prescribed  
18 for expedited partner therapy as authorized  
19 under section 453-52 [7] or for an opioid  
20 antagonist in section 461- ;



1 (C) The records described in subparagraph (B) shall  
2 be subject to the inspection of the department or  
3 its agents at all times; and

4 (D) No undisclosed rebate, refund, commission,  
5 preference, discount, or other consideration,  
6 whether in the form of money or otherwise, has  
7 been offered to the practitioner as compensation  
8 or inducement to dispense or prescribe any  
9 specific drug in preference to other drugs that  
10 might be used for the identical therapeutic  
11 indication.

12 (c) A prescription may be communicated in writing, orally,  
13 or by electronic transmission, and shall include the following  
14 information:

15 (1) The authorization of the practitioner noted as  
16 follows:

17 (A) Written prescriptions shall include the original  
18 signature of the practitioner;

19 (B) Oral prescriptions shall be promptly recorded by  
20 the pharmacist or medical oxygen distributor and



1           shall include the practitioner's oral code  
2           designation; and

3           (C) Electronic prescriptions shall be irrefutably  
4           traceable to the prescribing practitioner by a  
5           recognizable and unique practitioner identifier  
6           such as:

7           (i) A bitmap or graphic image of the  
8           prescriber's handwritten signature and the  
9           prescriber's oral code designation (or  
10          license number or other identifier if the  
11          prescriber is an out-of-state practitioner);

12          (ii) An electronic signature;

13          (iii) A digital signature; or

14          (iv) By other means as approved by the director;

15          (2) The date of issuance;

16          (3) The practitioner's name, business telephone number,  
17          and business address, unless the practitioner is  
18          otherwise uniquely identified and the pharmacy or  
19          medical oxygen distributor dispensing the prescription  
20          has the prescriber's contact information on file  
21          accessible within the dispensing area;



- 1 (4) The name, strength, and quantity of the drug to be  
2 dispensed, and specific directions for the drug's use;
- 3 (5) Except as otherwise authorized for expedited partner  
4 therapy in section 453-52[7] or for an opioid  
5 antagonist in section 461- , the name and address of  
6 the person for whom the prescription was written or  
7 the name of the owner of the animal for which the drug  
8 was prescribed, unless the pharmacy or medical oxygen  
9 distributor dispensing the prescription has the  
10 address on file accessible within the dispensing area;
- 11 (6) The room number and route of administration, if the  
12 patient is in an institutional facility; and
- 13 (7) The number of allowable refills, if the prescription  
14 is refillable. If the number of refills authorized by  
15 the practitioner is indicated using the terms "as  
16 needed" or "prn", the prescription may be refilled up  
17 to twelve months from the date the original  
18 prescription was written. After the twelve-month  
19 period, the "as needed" or "prn" prescription may be  
20 refilled for a subsequent three-month period;  
21 provided:



- 1 (A) The prescription is refilled only once during the
- 2 three-month period;
- 3 (B) The refill does not exceed a thirty-day supply of
- 4 the drug;
- 5 (C) The refill does not provide any amount of the
- 6 drug fifteen months beyond the date the original
- 7 prescription was written;
- 8 (D) In the case of medical oxygen, the duration of
- 9 therapy indicated on a certificate of medical
- 10 necessity shall supersede any limitations or
- 11 restrictions on refilling; and
- 12 (E) Subparagraphs (A) to (D) shall apply only to
- 13 pharmacies and medical oxygen distributors
- 14 practicing in the State."

15 2. By amending subsection (g) to read:

16 "(g) Any drug other than medical oxygen dispensed pursuant  
17 to a prescription shall be exempt from the requirements of  
18 section 328-15 (except paragraphs (1), (9), (11), and (12), and  
19 the packaging requirements of paragraphs (7) and (8)), if the  
20 drug bears a label containing:

- 21 (1) The name and address of the pharmacy;



1 (2) The serial number and the date of the prescription or  
2 of its filling;

3 (3) The name of the practitioner;

4 (4) Except as otherwise authorized for expedited partner  
5 therapy in section 453-52[7] or for an opioid  
6 antagonist in section 461- , the name of the patient;

7 (5) The directions for use; and

8 (6) Any cautionary statements contained in the  
9 prescription.

10 This exemption shall not apply to any drug dispensed in the  
11 course of the conduct of a business of dispensing drugs pursuant  
12 to diagnosis by mail, or to a drug dispensed in violation of  
13 subsection (a), (b), (c), or (d)."

14 SECTION 5. Section 328-17.6, Hawaii Revised Statutes, is  
15 amended as follows:

16 1. By amending subsections (c) and (d) to read:

17 "(c) Any pharmacist or medical oxygen distributor who  
18 fills or refills a prescription from an out-of-state  
19 practitioner shall:



- 1 (1) Note the following on the prescription record: the
- 2 out-of-state practitioner's full name, address, and
- 3 telephone number;
- 4 (2) Be responsible for validating and verifying the
- 5 practitioner's prescriptive authority by virtue of a
- 6 valid out-of-state license, a Drug Enforcement
- 7 Administration registration number, or other measures
- 8 as appropriate; and
- 9 (3) Except as otherwise authorized for expedited partner
- 10 therapy in section 453-52 [7] or for an opioid
- 11 antagonist in section 461- , demand proper
- 12 identification from the person whose name appears on
- 13 the prescription prior to filling the prescription, in
- 14 addition to complying with any identification
- 15 procedures established by the department for filling
- 16 and refilling an out-of-state prescription.
- 17 (d) Before refilling a transferred out-of-state
- 18 prescription, a pharmacist or medical oxygen distributor shall:
- 19 (1) Except as otherwise authorized for expedited partner
- 20 therapy in section 453-52 [7] or for an opioid
- 21 antagonist in section 461- , advise the person whose



1 name appears on the prescription that the prescription  
2 on file at the originating out-of-state pharmacy or  
3 medical oxygen distributor may be canceled; and

4 (2) Record all information required to be on a  
5 prescription, including:

6 (A) The date of issuance of the original  
7 prescription;

8 (B) The number of refills authorized on the original  
9 prescription;

10 (C) The date the original prescription was dispensed;

11 (D) The number of valid refills remaining and the  
12 date of the last refill;

13 (E) The out-of-state pharmacy's or out-of-state  
14 medical oxygen distributor's name, telephone  
15 number, and address, and the original  
16 prescription number or control number from which  
17 the prescription information was transferred; and

18 (F) The name of the transferor pharmacist or the  
19 medical oxygen distributor's agent."

20 2. By amending subsection (f) to read:



1           "(f) An out-of-state prescription record shall state the  
2 date of filling or refilling and, except as otherwise authorized  
3 for expedited partner therapy in section 453-52[7] or for an  
4 opioid antagonist in section 461- , the local address of the  
5 person whose name appears on the prescription."

6           SECTION 6. Section 328-17.7, Hawaii Revised Statutes, is  
7 amended by amending subsection (a) to read as follows:

8           "(a) Every practitioner, pharmacist, or medical oxygen  
9 distributor who compounds, sells, or delivers any prescribed  
10 drug to a patient or a patient's agent shall maintain records  
11 that identify:

- 12           (1) The specific drug product dispensed, including:
  - 13               (A) The product's national drug code (NDC) number; or
  - 14               (B) The brand name or the established name and the
  - 15                     name or commonly accepted abbreviation of the
  - 16                     principal labeler of the drug product dispensed,
  - 17                     the product strength, and the dosage form;
- 18           (2) The quantity of the drug;
- 19           (3) Directions for use;
- 20           (4) The number of allowable refills;



- 1 (5) The date of initial dispensing and the dates of all
- 2 refilling;
- 3 (6) The date of any transfer of the prescription;
- 4 (7) The name, business address, and telephone number of
- 5 the recipient pharmacist or medical oxygen distributor
- 6 for any transfer of prescription;
- 7 (8) The prescribing practitioner, including name, business
- 8 address, and telephone number;
- 9 (9) The format (oral, written, or electronic) in which the
- 10 prescription was received;
- 11 (10) Except as otherwise authorized for expedited partner
- 12 therapy in section 453-52[7] or for an opioid
- 13 antagonist in section 461- , the patient, including
- 14 name, address, and telephone number;
- 15 (11) The date of prescribing; and
- 16 (12) The name of the practitioner, pharmacist, or medical
- 17 oxygen distributor dispensing the drug.

18 Every prescription dispensed shall have the name of the  
19 pharmacist, dispensing practitioner, or medical oxygen  
20 distributor responsible for the dispensing appended to the  
21 prescription record, and every prescription record shall be



1 preserved and legible for a period of not less than five years.  
2 The prescription records shall be subject at all times to the  
3 inspection of the director of health or the director's agent."

4 SECTION 7. Statutory material to be repealed is bracketed  
5 and stricken. New statutory material is underscored.

6 SECTION 8. This Act shall take effect on July 1, 2050.



**Report Title:**

Opioid Antagonists; Prescriptions; Dispensing; Pharmacists

**Description:**

Authorizes pharmacists to prescribe, dispense, and provide related education on opioid antagonists to individuals at risk of opioid overdose and to family members and caregivers of individuals at risk of opioid overdose without the need for a written, approved collaborative agreement; subject to certain conditions. (SB2247 HD1)

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