THE SENATE
TWENTY-NINTH LEGISLATURE, 2018
STATE OF HAWAII

S.B. NO. 2247

JAN 19 2018

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 the nationwide opioid epidemic continues to result in an alarming number of opioid overdose deaths. According to the Centers for Disease Control and Prevention, opioid overdose fatalities have increased from 33,000 in 2015 to 53,000 in 2016. Unintentional drug poisonings, commonly referred to as drug overdoses, are one of the leading causes of injury-related mortality in Hawaii. Furthermore, an average of four hundred non-fatal overdoses occur in Hawaii per year, and opioid related overdoses resulted in about $9,800,000 in hospital costs in 2016.

The legislature further finds that deaths caused by opioids are often preventable via timely administration of an opioid antagonist, such as naloxone. 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. Thus, there is a need for increased public access to health care professionals who can

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

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

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

Accordingly, the purpose of this Act is to expand the scope of registered pharmacists' practices by allowing registered pharmacists to prescribe, dispense, and provide related

education of opioid antagonists without the need for a written, approved collaborative agreement.

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

"**§461- Opioid antagonist; authority to prescribe and dispense; requirements.** (a) A pharmacist may prescribe and dispense an opioid antagonist to a patient or family member or caregiver of a patient who is at risk for an opioid overdose regardless of whether the patient has evidence of a previous prescription for an opioid antagonist from a practitioner authorized to prescribe opioids. The opioid antagonist prescribed and dispensed for a family member or caregiver of an individual who is at risk for an opioid overdose shall be prescribed and dispensed in the name of "Opioid Antagonist Recipient" or "OAR".

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

(1) Complete a training program related to prescribing opioid antagonists that is approved by the Accreditation Council for Pharmacy Education (ACPE), a

curriculum-based program from an ACPE-accredited college of pharmacy, a state or local health department program, or a program recognized by the board;

(2) Provide the person who is receiving the opioid antagonist with information and written educational material on risk factors of opioid overdose, signs of an overdose, overdose response steps, and the use of the opioid antagonist;

(3) Obtain an acknowledgment form signed by the person receiving the opioid antagonist. The pharmacist shall notify the practitioner who authorized the original opioid prescription that an opioid antagonist was prescribed and dispensed by the pharmacy. For opioid antagonists that are prescribed to "Opioid Antagonist Recipient" patients, the practitioner shall be notified if applicable. The pharmacy shall maintain the signed acknowledgment form with the prescription record; and

(4) Dispense the opioid antagonist to the individual who is at risk for an opioid overdose, family member, or

caregiver as soon as practicable after the pharmacist issues the prescription.

(c) A pharmacist who prescribes an opioid antagonist pursuant to subsection (a) shall not require the individual who is at risk for an opioid overdose, family member, or caregiver to schedule an appointment with the pharmacist for the prescribing or dispensing of the opioid antagonist."

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

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

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

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

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

""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 licensed advanced practice registered nurse with prescriptive authority, 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 or advanced practice registered nurse with prescriptive authority 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 order of the patient's licensed physician or

advanced practice registered nurse with prescriptive authority, 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;

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

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

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

system shared by the licensed physician or advanced practice registered nurse with prescriptive authority, within twenty-four hours;

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

(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; 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 ACPE, curriculum based programs from an ACPE accredited college of pharmacy, state or local health department programs, or programs recognized by the board,~~] Prescribing and dispensing an opioid antagonist pursuant to section 461- ;

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

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

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

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

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

(1) The name, business address, and telephone number of the seller. The business address shall be the physical location of the pharmacy or the dispensing practitioner's office;

(2) Except as otherwise authorized for expedited partner therapy in section 453-52[~~,~~] or an opioid antagonist in section 461- , the name of the person for whom the drug was prescribed or the name of the owner of the animal for which the drug was prescribed;

(3) The serial number of the prescription;

(4) The date the prescription was prepared;

(5) The name of the practitioner if the seller is not the practitioner;

(6) The name, strength, and quantity of the drug;

(7) The "use by" date for the drug, which shall be:

(A) The expiration date on the manufacturer's container; or

(B) One year from the date the drug is dispensed, whichever is earlier;

(8) The number of refills available, if any;

(9) In the case of the dispensing of an equivalent generic drug product, the statement "same as (brand name of the drug product prescribed or the referenced listed drug name)", or words of similar meaning;

(10) In the case of the dispensing of an interchangeable biological product, the statement "interchangeable with (brand name of the biological product prescribed or the referenced biological drug name)", or words of similar meaning; and

(11) Specific directions for the drug's use; provided that if the specific directions for use are too lengthy for inclusion on the label, the notation "take according

to written instructions" may be used if separate written instructions for use are actually issued with the drug by the practitioner or the pharmacist, but in no event shall the notation "take as directed", referring to oral instructions, be considered acceptable.

If any prescription for a drug does not indicate the number of times it may be refilled, if any, the pharmacist shall not refill that prescription unless subsequently authorized to do so by the practitioner. The act of dispensing a prescription drug other than a professional sample or medical oxygen contrary to this subsection shall be deemed to be an act that results in a drug being misbranded while held for sale.

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

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

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

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

(A) Except as otherwise authorized for expedited partner therapy in section 453-52, the practitioner shall inform the patient, prior to dispensing any drug other than a professional sample, that the patient may have a written, orally ordered, or electronically transmitted or conveyed prescription directed to a pharmacy or a medical oxygen distributor of the patient's own choice;

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

(i) The prescription in full;

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

(iii) The date the drug was dispensed;

(iv) Except as otherwise authorized for expedited partner therapy in section 453-52[~~,~~] or for an opioid antagonist in section 461- , the name and address of the person for whom the

drug was prescribed or the name of the owner of the animal for which the drug was prescribed; and

(v) Prescription drugs dispensed or prescribed for expedited partner therapy as authorized under section 453-52[~~,~~] or for an opioid antagonist in section 461- ;

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

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

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

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

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

(B) Oral prescriptions shall be promptly recorded by the pharmacist or medical oxygen distributor and shall include the practitioner's oral code designation; and

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

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

(ii) An electronic signature;

(iii) A digital signature; or

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

(2) The date of issuance;

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

(4) The name, strength, and quantity of the drug to be dispensed, and specific directions for the drug's use;

(5) Except as otherwise authorized for expedited partner therapy in section 453-52[~~,~~] or for an opioid antagonist in section 461- , the name and address of the person for whom the prescription was written or the name of the owner of the animal for which the drug was prescribed, unless the pharmacy or medical oxygen distributor dispensing the prescription has the address on file accessible within the dispensing area;

(6) The room number and route of administration, if the patient is in an institutional facility; and

(7) The number of allowable refills, if the prescription is refillable. If the number of refills authorized by the practitioner is indicated using the terms "as

needed" or "prn", the prescription may be refilled up to twelve months from the date the original prescription was written. After the twelve-month period, the "as needed" or "prn" prescription may be refilled for a subsequent three-month period; provided:

(A) The prescription is refilled only once during the three-month period;

(B) The refill does not exceed a thirty-day supply of the drug;

(C) The refill does not provide any amount of the drug fifteen months beyond the date the original prescription was written;

(D) In the case of medical oxygen, the duration of therapy indicated on a certificate of medical necessity shall supersede any limitations or restrictions on refilling; and

(E) Subparagraphs (A) to (D) shall apply only to pharmacies and medical oxygen distributors practicing in the State."

2. By amending subsection (g) to read:

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

(1) The name and address of the pharmacy;

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

(3) The name of the practitioner;

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

(5) The directions for use; and

(6) Any cautionary statements contained in the prescription.

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

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

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

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

(1) Note the following on the prescription record: the out-of-state practitioner's full name, address, and telephone number;

(2) Be responsible for validating and verifying the practitioner's prescriptive authority by virtue of a valid out-of-state license, a Drug Enforcement Administration registration number, or other measures as appropriate; and

(3) Except as otherwise authorized for expedited partner therapy in section 453-52[~~,~~] or for an opioid antagonist in section 461- , demand proper identification from the person whose name appears on the prescription prior to filling the prescription, in addition to complying with any identification procedures established by the department for filling and refilling an out-of-state prescription.

(d) Before refilling a transferred out-of-state prescription, a pharmacist or medical oxygen distributor shall:

(1) Except as otherwise authorized for expedited partner therapy in section 453-52[~~,~~] or for an opioid antagonist in section 461- , advise the person whose name appears on the prescription that the prescription on file at the originating out-of-state pharmacy or medical oxygen distributor may be canceled; and

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

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

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

(C) The date the original prescription was dispensed;

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

(E) The out-of-state pharmacy's or out-of-state medical oxygen distributor's name, telephone number, and address, and the original

prescription number or control number from which the prescription information was transferred; and

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

2. By amending subsection (f) to read:

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

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

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

(1) The specific drug product dispensed, including:

(A) The product's national drug code (NDC) number; or

(B) The brand name or the established name and the name or commonly accepted abbreviation of the

principal labeler of the drug product dispensed, the product strength, and the dosage form;

(2) The quantity of the drug;

(3) Directions for use;

(4) The number of allowable refills;

(5) The date of initial dispensing and the dates of all refilling;

(6) The date of any transfer of the prescription;

(7) The name, business address, and telephone number of the recipient pharmacist or medical oxygen distributor for any transfer of prescription;

(8) The prescribing practitioner, including name, business address, and telephone number;

(9) The format (oral, written, or electronic) in which the prescription was received;

(10) Except as otherwise authorized for expedited partner therapy in section 453-52[~~,~~] or for an opioid antagonist in section 461- , the patient, including name, address, and telephone number;

(11) The date of prescribing; and

(12) The name of the practitioner, pharmacist, or medical oxygen distributor dispensing the drug.

Every prescription dispensed shall have the name of the pharmacist, dispensing practitioner, or medical oxygen distributor responsible for the dispensing appended to the prescription record, and every prescription record shall be preserved and legible for a period of not less than five years. The prescription records shall be subject at all times to the inspection of the director of health or the director's agent."

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

SECTION 8. This Act shall take effect upon its approval.

INTRODUCED BY:

S.B. NO. 2247

Report Title:
Opioid Antagonists; Prescriptions; Dispensing; Pharmacists

Description:
Authorizes pharmacists to prescribe and dispense an opioid antagonist to patients and to family members and caregivers of opioid patients without the need for a written, approved collaborative agreement.

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