HOUSE OF REPRESENTATIVES
THIRTY-SECOND LEGISLATURE, 2024
STATE OF HAWAII

H.B. NO. 1836

A BILL FOR AN ACT

RELATING TO HEALTH.

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

SECTION 1. The legislature finds that prescription refills play an important role in allowing patients to get their medication without frequent office visits. Refills also support patient adherence to chronic medications. Typical pharmacotherapy requires a patient's adherence to the regimen to achieve the therapeutic outcome, especially in patients with chronic conditions. Abrupt cessation or unplanned interruption of therapy may lead to undesirable outcomes. It is paramount for the pharmacist to ensure the patient's regimen is not disrupted and medications are dispensed in a timely manner.

The legislature further finds that during times of natural disasters or public health emergencies, there may be significant challenges that impede a patient's ability to timely receive a necessary prescription. For example, the COVID-19 pandemic forced some providers to limit office hours. Additionally, quarantine mandates forced patients to cancel existing

appointments. These challenges resulted in gap periods without medications.

The purpose of this Act is to provide clear guidance for pharmacists to act in the best interest of the patients by minimizing gap periods without medications during a state of emergency by allowing pharmacists to refill prescriptions of up to thirty-day supplies of dangerous drugs and dangerous devices if the prescriber is unavailable to authorize the refill and if, in the pharmacist's professional judgment, failure to refill the prescription may interrupt the patient's ongoing care and have a significant adverse effect on the patient's well-being.

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

"**§461- Refills without prescriber's authorization during state of emergency.** (a) During a state of emergency declared pursuant to section 127A-14, a prescription of up to a thirty-day supply of a dangerous drug or dangerous device may be refilled without the practitioner's authorization if the practitioner is unavailable to authorize the refill and if, in the pharmacist's professional judgment, failure to refill the

prescription may interrupt the patient's ongoing care and have a significant adverse effect on the patient's well-being.

(b) Prior to refilling a prescription pursuant to this section, the pharmacist shall make every reasonable effort to contact the practitioner. The pharmacist shall make an appropriate record, including the basis for proceeding under this section.

(c) The pharmacist shall inform the patient that the prescription was refilled pursuant to this section.

(d) The pharmacist shall make every reasonable effort to contact the practitioner within a reasonable period of time of any refills dispensed pursuant to this section.

(e) The practitioner shall not incur any liability as the result of a refilling of a prescription pursuant to this section.

(f) Notwithstanding any law to the contrary, a person may possess a dangerous drug or dangerous device dispensed pursuant to this section.

(g) For purposes of this section, "dangerous drug or dangerous device" means any drug or device unsafe for self-use in human beings or animals. "Dangerous drug or dangerous

device" includes any drug or device that by federal or state law may be lawfully dispensed only on a practitioner's order. "Dangerous drug or dangerous device" does not include a controlled substance, as defined in section 329-1."

SECTION 3. Section 328-16, Hawaii Revised Statutes, is amended as follows:

1. By amending subsections (a) and (b) 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 461-11.8, 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[~~.~~] or pursuant to section 461- . 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 453-52, 461-1, [~~or~~] 461-11.8[~~.~~], or 461- ;

(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 461-11.8, 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 461-11.8;

(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."

2. By amending subsection (d) to read:

"(d) Any prescription may be refilled by the pharmacy and a prescription for medical oxygen may be refilled by the medical oxygen distributor if that refilling is authorized by the practitioner either:

(1) In the original prescription; or

(2) By oral or electronic order, which shall be promptly recorded and filed by the receiving pharmacist or medical oxygen distributor[~~.~~], or the refilling is conducted pursuant to section 461- ."

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

SECTION 5. This Act shall take effect upon its approval.

INTRODUCED BY: _____

JAN 18 2024

H.B. NO. 1836

Report Title:
Pharmacists; Refills; Dangerous Drugs; Dangerous Devices; State of Emergency

Description:
Allows pharmacists, during declared states of emergency, to refill prescriptions of up to thirty-day supplies of dangerous drugs and dangerous devices if the prescriber is unavailable or cannot be contacted to authorize the refill and if, in the pharmacist's professional judgment, failure to refill the prescription might interrupt the patient's ongoing care and have a significant adverse effect on the patient's well-being.

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