HOUSE OF REPRESENTATIVES
TWENTY-NINTH LEGISLATURE, 2017
STATE OF HAWAII

H.B. NO. 797

A BILL FOR AN ACT

RELATING TO PHARMACISTS.

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

SECTION 1. Section 329-38, Hawaii Revised Statutes, is amended to read as follows:

"§329-38 **Prescriptions.** (a) No controlled substance in schedule II may be dispensed without a written prescription of a practitioner, except:

(1) In the case of an emergency situation, a pharmacist may dispense a controlled substance listed in schedule II upon receiving oral authorization from a prescribing practitioner; provided that:

(A) The quantity prescribed and dispensed is limited to the amount adequate to treat the patient during the emergency period (dispensing beyond the emergency period must be pursuant to a written prescription signed by the prescribing practitioner);

(B) If the prescribing practitioner is not known to the pharmacist, the pharmacist shall make a

reasonable effort to determine that the oral authorization came from a registered practitioner, which may include a callback to the prescribing practitioner using the phone number in the telephone directory or other good faith efforts to identify the prescriber; and

(C) Within seven days after authorizing an emergency oral prescription, the prescribing practitioner shall cause a written prescription for the emergency quantity prescribed to be delivered to the dispensing pharmacist. In addition to conforming to the requirements of this subsection, the prescription shall have written on its face "Authorization for Emergency Dispensing". The written prescription may be delivered to the pharmacist in person or by mail, and if by mail, the prescription shall be postmarked within the seven-day period. Upon receipt, the dispensing pharmacist shall attach this prescription to the oral emergency prescription, which had earlier been reduced to

writing. The pharmacist shall notify the administrator if the prescribing practitioner fails to deliver a written prescription to the pharmacy within the allotted time. Failure of the pharmacist to do so shall void the authority conferred by this paragraph to dispense without a written prescription of a prescribing individual practitioner. Any practitioner who fails to deliver a written prescription within the seven-day period shall be in violation of section 329-41(a)(1);

(2) When dispensed directly by a practitioner, other than a pharmacist, to the ultimate user. The practitioner in dispensing a controlled substance in schedule II shall affix to the package a label showing:

(A) The date of dispensing;

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

(C) The dispensing practitioner's name and address;

(D) The name of the patient;

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

(i) The expiration date on the manufacturer's or principal labeler's container; or

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

(F) Directions for use, and cautionary statements, if any, contained in the prescription or as required by law.

A complete and accurate record of all schedule II controlled substances ordered, administered, prescribed, and dispensed shall be maintained for five years. Prescriptions and records of dispensing shall otherwise be retained in conformance with the requirements of section 329-36. No prescription for a controlled substance in schedule II may be refilled; or

(3) In the case of an electronic prescription, a pharmacist may dispense a controlled substance listed in schedule II upon receiving an electronic prescription.

(b) A schedule II controlled substance prescription shall:

(1) Be filled within seven days following the date the prescription was issued to the patient; and

(2) Be supplied to a patient only if the prescription has been filled and held by the pharmacy for not more than seven days.

(c) The transfer of original prescription information for a controlled substance listed in schedule III, IV, or V for the purpose of dispensing is permissible between pharmacies on a one time basis only. However, pharmacies electronically sharing a real-time, online database may transfer up to the maximum refills permitted by law and the prescriber's authorization. Transfers are subject to the following requirements:

(1) The transfer shall be communicated directly between two licensed pharmacists, and the transferring pharmacist shall:

(A) Write or otherwise place the word "VOID" on the face of the invalidated prescription;

(B) Record on the reverse of the invalidated prescription the name, address, and Drug Enforcement Administration registration number of the pharmacy to which it was transferred and the

name of the pharmacist receiving the prescription information; and

(C) Record the date of the transfer and the name of the pharmacist transferring the information;

(2) The pharmacist receiving the transferred prescription information shall reduce to writing the following:

(A) Write or otherwise place the word "transfer" on the face of the transferred prescription;

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

(i) The date of issuance of original prescription;

(ii) The original number of refills authorized on original prescription;

(iii) The date of original dispensing;

(iv) The number of valid refills remaining and dates and locations of previous refills;

(v) The pharmacy's name, address, Drug Enforcement Administration registration number, and original prescription number

from which the prescription information was transferred;

(vi) The name of the transferor pharmacist; and

(vii) The pharmacy's name, address, and Drug Enforcement Administration registration number, along with the prescription number from which the prescription was originally filled;

(3) Both the original and transferred prescription shall be maintained for a period of five years from the date of last refill; and

(4) Any pharmacy electronically accessing a prescription record shall satisfy all information requirements of a manual mode prescription transferal.

Failure to comply with this subsection shall void the authority of the pharmacy to transfer prescriptions or receive a transferred prescription to or from another pharmacy.

(d) A pharmacy and an authorized central fill pharmacy may share information for initial and refill prescriptions of schedule III, IV, or V controlled substances. The following requirements shall apply:

(1) A pharmacy may electronically transmit, including by facsimile, prescriptions for controlled substances listed in schedule III, IV, or V to a central fill pharmacy. The pharmacy transmitting the prescription information shall:

(A) Ensure that all information required to be on a prescription pursuant to subsection (g) is transmitted to the central fill pharmacy either on the face of the prescription or electronically; and

(B) Keep a record of receipt of the filled prescription, including the date of receipt, the method of delivery (private, common, or contract carrier) and the identity of the pharmacy employee accepting delivery; and

(2) The central fill pharmacy receiving the transmitted prescription shall:

(A) Keep for five years a copy of a prescription received by facsimile or an electronic record of all the information transmitted by the pharmacy, including the name, address, and Drug Enforcement

Administration registration number of the pharmacy transmitting the prescription;

(B) Keep a record of the date of receipt of the transmitted prescription, the name of the licensed pharmacists filling the prescription, and the dates the prescription was filled or is refilled; and

(C) Keep a record of the date the filled prescription was shipped to the pharmacy.

(e) [~~No~~] Except as provided in subsection (o), no controlled substance in schedule III, IV, or V may be dispensed without a written, facsimile of a written, or oral prescription of a practitioner, or receipt of an electronic prescription, except when a controlled substance is dispensed directly by a practitioner, other than a pharmacist, to an ultimate user. The practitioner, in dispensing a controlled substance in schedule III, IV, or V, shall affix to the package a label showing:

(1) The date of dispensing;

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

(3) The dispensing practitioner's name and business address;

(4) The name of the patient;

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

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

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

(6) Directions for use; and

(7) Cautionary statements, if any, contained in the prescription or as required by law.

A complete and accurate record of all schedule III, IV, and V controlled substances administered, prescribed, and dispensed shall be maintained for five years. Prescriptions and records of dispensing shall be retained in conformance with the requirements of section 329-36 unless otherwise provided by law. Prescriptions may not be filled or refilled more than three months after the date of the prescription or be refilled more than two times after the date of the prescription, unless the prescription is renewed by the practitioner.

(f) The effectiveness of a prescription for the purposes of this section shall be determined as follows:

(1) A prescription for a controlled substance shall be issued for a legitimate medical purpose by an individual practitioner acting in the usual course of the practitioner's professional practice. The responsibility for the proper prescribing and dispensing of controlled substances shall be upon the prescribing practitioner, but a corresponding responsibility shall rest with the pharmacist who fills the prescription. An order purporting to be a prescription issued not in the usual course of professional treatment or for legitimate and authorized research shall not be deemed a prescription within the meaning and intent of this section, and the person who knowingly fills such a purported prescription, as well as the person who issues the prescription, shall be subject to the penalties provided for violations of this chapter;

(2) A prescription may not be issued to allow an individual practitioner to obtain controlled substances for supplying the individual practitioner for the purpose of general dispensing to patients;

(3) A prescription may not be issued for the dispensing of narcotic drugs listed in any schedule for the purpose of "detoxification treatment" or "maintenance treatment" except as follows:

(A) The administering or dispensing directly (but not prescribing) of narcotic drugs listed in any schedule to a narcotic drug-dependent person for "detoxification treatment" or "maintenance treatment" shall be deemed to be "in the course of a practitioner's professional practice or research" so long as the practitioner is registered separately with the department and the federal Drug Enforcement Agency as required by section 329-32(e) and complies with Title 21 Code of Federal Regulations section 823(g) and any other federal or state regulatory standards relating to treatment qualification, security, records, and unsupervised use of drugs; and

(B) Nothing in this section shall prohibit a physician or authorized hospital staff from administering or dispensing, but not prescribing,

narcotic drugs in a hospital to maintain or detoxify a person as an incidental adjunct to medical or surgical treatment of conditions other than addiction;

(4) An individual practitioner shall not prescribe or dispense a substance included in schedule II, III, IV, or V for that individual practitioner's personal use, except in a medical emergency; and

(5) A pharmacist shall not dispense a substance included in schedule II, III, IV, or V for the pharmacist's personal use.

(g) Prescriptions for controlled substances shall be issued only as follows:

(1) All prescriptions for controlled substances shall originate from within the State and be dated as of, and signed on, the day when the prescriptions were issued and shall contain:

(A) The first and last name and address of the patient; and

(B) The drug name, strength, dosage form, quantity prescribed, and directions for use. Where a

prescription is for gamma hydroxybutyric acid, methadone, or buprenorphine, the practitioner shall record as part of the directions for use, the medical need of the patient for the prescription.

Except for electronic prescriptions, controlled substance prescriptions shall be no larger than eight and one-half inches by eleven inches and no smaller than three inches by four inches. A practitioner may sign a prescription in the same manner as the practitioner would sign a check or legal document (e.g., J.H. Smith or John H. Smith) and shall use both words and figures (e.g., alphabetically and numerically as indications of quantity, such as five (5)), to indicate the amount of controlled substance to be dispensed. Where an oral order or electronic prescription is not permitted, prescriptions shall be written with ink or indelible pencil or typed, shall be manually signed by the practitioner, and shall include the name, address, telephone number, and registration number of the practitioner. The

prescriptions may be prepared by a secretary or agent for the signature of the practitioner, but the prescribing practitioner shall be responsible in case the prescription does not conform in all essential respects to this chapter and any rules adopted pursuant to this chapter. In receiving an oral prescription from a practitioner, a pharmacist shall promptly reduce the oral prescription to writing, which shall include the following information: the drug name, strength, dosage form, quantity prescribed in figures only, and directions for use; the date the oral prescription was received; the full name, Drug Enforcement Administration registration number, and oral code number of the practitioner; and the name and address of the person for whom the controlled substance was prescribed or the name of the owner of the animal for which the controlled substance was prescribed.

A corresponding liability shall rest upon a pharmacist who fills a prescription not prepared in the form prescribed by this section. A pharmacist may

add a patient's missing address or change a patient's address on all controlled substance prescriptions after verifying the patient's identification and noting the identification number on the back of the prescription document on file. The pharmacist shall not make changes to the patient's name, the controlled substance being prescribed, the quantity of the prescription, the practitioner's Drug Enforcement Administration number, the practitioner's name, the practitioner's electronic signature, or the practitioner's signature;

(2) An intern, resident, or foreign-trained physician, or a physician on the staff of a Department of Veterans Affairs facility or other facility serving veterans, exempted from registration under this chapter, shall include on all prescriptions issued by the physician:

(A) The registration number of the hospital or other institution; and

(B) The special internal code number assigned to the physician by the hospital or other institution in

lieu of the registration number of the practitioner required by this section.

The hospital or other institution shall forward a copy of this special internal code number list to the department as often as necessary to update the department with any additions or deletions. Failure to comply with this paragraph shall result in the suspension of that facility's privilege to fill controlled substance prescriptions at pharmacies outside of the hospital or other institution. Each written prescription shall have the name of the physician stamped, typed, or hand-printed on it, as well as the signature of the physician;

(3) An official exempted from registration shall include on all prescriptions issued by the official:

(A) The official's branch of service or agency (e.g., "U.S. Army" or "Public Health Service"); and

(B) The official's service identification number, in lieu of the registration number of the practitioner required by this section. The service identification number for a Public Health

Service employee shall be the employee's social security or other government issued identification number.

Each prescription shall have the name of the officer stamped, typed, or handprinted on it, as well as the signature of the officer; and

(4) A physician assistant registered to prescribe controlled substances under the authorization of a supervising physician shall include on all controlled substance prescriptions issued:

(A) The Drug Enforcement Administration registration number of the supervising physician; and

(B) The Drug Enforcement Administration registration number of the physician assistant.

Each written controlled substance prescription issued shall include the printed, stamped, typed, or hand-printed name, address, and phone number of both the supervising physician and physician assistant, and shall be signed by the physician assistant. The medical record of each written controlled substance prescription issued by a physician assistant shall be

reviewed and initialed by the physician assistant's supervising physician within seven working days.

(h) A prescription for controlled substances may only be filled by a pharmacist acting in the usual course of the pharmacist's professional practice and either registered individually or employed in a registered pharmacy, central fill pharmacy, or registered institutional practitioner. A central fill pharmacy authorized to fill prescriptions on behalf of a pharmacy shall have a contractual relationship with the pharmacy that provides for this activity or shall share a common owner with the pharmacy. A central fill pharmacy shall not prepare prescriptions for any controlled substance listed in schedule II.

(i) Partial filling of controlled substance prescriptions shall be determined as follows:

(1) The partial filling of a prescription for a controlled substance listed in schedule II is permissible if the pharmacist is unable to supply the full quantity called for in a written, electronic prescription, or emergency oral prescription and the pharmacist makes a notation of the quantity supplied on the face of the

written prescription (or written record of the electronic prescription or emergency oral prescription). The remaining portion of the prescription may be filled within seventy-two hours of the first partial filling; provided that if the remaining portion is not or cannot be filled within the seventy-two-hour period, the pharmacist shall notify the prescribing individual practitioner. No further quantity shall be supplied beyond seventy-two hours without a new prescription;

(2) The partial filling of a prescription for a controlled substance listed in schedule III, IV, or V is permissible; provided that:

(A) Each partial filling is recorded in the same manner as a refilling;

(B) The total quantity dispensed in all partial fillings does not exceed the total quantity prescribed;

(C) No dispensing occurs more than three months after the date on which the prescription was issued; and

(D) The prescription is refilled no more than two times after the initial date of the prescription, unless the prescription is renewed by the practitioner; and

(3) A prescription for a schedule II controlled substance issued for a patient in a long-term care facility or for a patient with a medical diagnosis documenting a terminal illness may be filled in partial quantities to include individual dosage units. If there is any question whether a patient may be classified as having a terminal illness, the pharmacist shall contact the practitioner prior to partially filling the prescription. Both the pharmacist and the prescribing practitioner have a corresponding responsibility to assure that the controlled substance is for a terminally ill patient. The pharmacist shall record on the prescription document on file whether the patient is "terminally ill" or a "long-term care facility patient". For the purposes of this section, "TI" means terminally ill and "LTCF" means long-term care facility. A prescription that is partially

filled and does not contain the notation "TI" or "LTCF patient" shall be deemed to have been filled in violation of this section. For each partial filling, the dispensing pharmacist shall record on the back of the prescription (or on another appropriate record, uniformly maintained, and readily retrievable) the date of the partial filling, quantity dispensed, remaining quantity authorized to be dispensed, and the identification of the dispensing pharmacist. The total quantity of schedule II controlled substances dispensed in all partial fillings shall not exceed the total quantity prescribed, nor shall a prescription be partially filled more than three times after the initial date of the prescription. Schedule II controlled substance prescriptions for patients in a long-term care facility or patients with a medical diagnosis documenting a terminal illness shall be valid for a period not to exceed thirty days from the issue date unless sooner terminated by the discontinuance of medication.

(j) A prescription for a schedule II controlled substance may be transmitted by the practitioner or the practitioner's agent to a pharmacy by facsimile equipment; provided that the original written, signed prescription is presented to the pharmacist for review prior to the actual dispensing of the controlled substance, except as noted in subsections (k), (l), and (m). The original prescription shall be maintained in accordance with section 329-36. A prescription for a schedule III, IV, or V controlled substance may be transmitted by the practitioner or the practitioner's agent to a pharmacy by facsimile; provided that:

(1) The information shall be communicated only between the prescribing practitioner or the prescriber's authorized agent and the pharmacy of the patient's choice. The original prescription shall be maintained by the practitioner in accordance with section 329-36;

(2) The information shall be communicated in a retrievable, recognizable format acceptable to the intended recipient and shall include the physician's oral code designation and the name of the recipient pharmacy;

(3) No electronic system, software, or other intervening mechanism or party shall alter the practitioner's prescription, order entry, selection, or intended selection without the practitioner's approval on a per prescription per order basis. Facsimile prescription information shall not be altered by any system, software, or other intervening mechanism or party prior to receipt by the intended pharmacy;

(4) The prescription information processing system shall provide for confidentiality safeguards required by federal or state law; and

(5) Prescribing practitioners and pharmacists shall exercise prudent and professional judgment regarding the accuracy, validity, and authenticity of any facsimile prescription information. The facsimile shall serve as the original written prescription for purposes of this section and shall be maintained in accordance with section 329-36.

(k) A prescription prepared in accordance with subsection (g) written for a narcotic listed in schedule II to be compounded for the direct administration to a patient by

parenteral, intravenous, intramuscular, subcutaneous, or intraspinal infusion, but does not extend to the dispensing of oral dosage units of controlled substances, may be transmitted by the practitioner or the practitioner's agent to the pharmacy by facsimile. The original prescription shall be maintained by the practitioner in accordance with section 329-36. The pharmacist shall note on the face of the facsimile prescription in red ink "Home Infusion/IV" and this facsimile shall serve as the original written prescription for purposes of this section and it shall be maintained in accordance with section 329-36.

(l) A prescription prepared in accordance with subsection (g) written for a schedule II substance for a patient enrolled in a hospice care program certified or paid for by medicare under Title XVIII or a hospice program that is licensed by the State may be transmitted by the practitioner or the practitioner's agent to the dispensing pharmacy by facsimile. The original prescription shall be maintained by the practitioner in accordance with section 329-36. The practitioner or practitioner's agent shall note on the prescription that the patient is a hospice patient. The pharmacist shall note on the face of the facsimile prescription

in red ink "HOSPICE" and this facsimile shall serve as the original written prescription for purposes of this section and it shall be maintained in accordance with section 329-36.

(m) A prescription prepared in accordance with subsection (g) written for a schedule II controlled substance for a resident of a state-licensed long-term care facility may be transmitted by the practitioner or the practitioner's agent to the dispensing pharmacy by facsimile. The original prescription shall be maintained by the practitioner in accordance with section 329-36. The pharmacist shall note on the face of the facsimile prescription in red ink "LTCF" and this facsimile shall serve as the original written prescription for purposes of this section and it shall be maintained in accordance with section 329-36.

(n) An electronic prescription for a schedule II, III, IV, or V controlled substance may be electronically transmitted by the practitioner to a pharmacy; provided that:

(1) The information shall be communicated only between the prescribing practitioner and the pharmacy of the patient's choice. The electronic prescription shall

be maintained by the practitioner in accordance with section 329-36;

(2) The information shall be communicated in a retrievable, recognizable format acceptable to the intended recipient;

(3) No electronic system, software, or other intervening mechanism or party shall alter the practitioner's prescription, order entry, selection, or intended selection without the practitioner's approval on a per-prescription, per-order basis. Transmitted prescription information shall not be altered by any electronic system, software, or other intervening mechanism or party prior to receipt by the intended pharmacy;

(4) The prescription information processing system shall provide for confidentiality safeguards required by any applicable federal or state law; and

(5) Prescribing practitioners and pharmacists shall exercise prudent and professional judgment regarding the accuracy, validity, and authenticity of any electronic prescription information.

(o) A pharmacy may dispense a controlled substance in schedule III, IV, or V without a written, facsimile of a written, or oral prescription of a practitioner if all of the following conditions are met:

(1) The pharmacy has a record of a prescription for the drug in the name of the patient who is requesting it, but the prescription does not provide for a refill or the time permitted under rules adopted by the board of pharmacy for providing refills has elapsed;

(2) The pharmacy is unable to obtain authorization to refill the prescription from the practitioner who issued the prescription or another practitioner responsible for the patient's care;

(3) In the exercise of the pharmacy's professional judgment:

(A) The drug is essential to sustain the life of the patient or continue therapy for a chronic condition of the patient; and

(B) Failure to dispense the drug to the patient could result in harm to the health of the patient;

(4) The amount of the drug that is dispensed under this subsection does not exceed a seventy-two-hour supply as provided in the prescription; provided that a pharmacy shall not dispense a particular drug to the same patient in an amount described in this paragraph more than once in any twelve-month period;

(5) The pharmacy does all of the following:

(A) For one year after the date of dispensing, maintain a record in accordance with this subsection of the drug dispensed, including the name and address of the patient and the individual receiving the drug if the individual receiving the drug is not the patient, the amount dispensed or sold, and the original prescription number;

(B) Notify the practitioner who issued the prescription described in paragraph (1) or another practitioner responsible for the patient's care not later than seventy-two hours after the drug is dispensed; and

(C) If applicable, obtain authorization for additional dispensing from one of the practitioners described in subparagraph (B); and

(6) A pharmacy who dispenses a drug under this subsection may do so only once for each prescription described in paragraph (1)."

SECTION 2. Statutory material to be repealed is bracketed and stricken. New statutory material is underscored.

SECTION 3. This Act does not affect rights and duties that matured, penalties that were incurred, and proceedings that were begun before its effective date.

SECTION 4. This Act shall take effect upon its approval.

INTRODUCED BY: _____

JAN 2 1 2017

H.B. NO. 797

Report Title:
Pharmacies; Controlled Substances; Prescriptions

Description:
Authorizes pharmacies to dispense controlled substances, other than Schedule II substances, without an authorization to refill a prescription under limited conditions.

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