ACT 83 H.B. NO. 2525

A Bill for an Act Relating to Prescription Drugs.

Be It Enacted by the Legislature of the State of Hawaii:

SECTION 1. Section 328-1, Hawaii Revised Statutes, is amended as follows:

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

"'"Certificate of medical necessity" means the United States Department of Health and Human Services, Health Care Financing Administration's FORM HCFA 484, which identifies the patient-recipient, the supplier, and the prescriber of medical services and establishes an estimated length of time of need for equipment or therapy, or both, to treat the ailment indicated by the diagnosis codes listed thereon.

"Medical oxygen" means the prescription drug oxygen.

"Medical oxygen distributor" means any person, including a prescription drug wholesale distributor, who distributes or dispenses medical oxygen pursuant to a prescription.

"Nonprescription drug", "over-the-counter drug", or "nonlegend drug", means any packaged, bottled, or nonbulk chemical, drug, or medicine that may be lawfully sold without a practitioner's order."

2. By amending the definition of "drug" to read:

"'"Drug" means:

(1) Articles recognized in the official United States Pharmacopoeia, official United States Pharmacopoeia Dispensing Information, official Homeopathic Pharmacopoeia of the United States, or official National Formulary, or any supplement to any of them;

(2) Articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in humans or animals;

(3) Articles (other than food[)] or clothing) intended to affect the structure or any function of the body of humans or animals; or

(4) Articles intended for use as a component of any article specified in [this definition above but not including devices or their components, parts, or accessories.] paragraph (1), (2), or (3); provided that the term "drug" shall not include devices or their components, parts or accessories, cosmetics, or liquor as defined in section 281-1."

3. By amending the definition of "prescription drug" to read:

"'"Prescription drug" means [any]:

(1) Any drug required by federal or state statutes, regulations, or rules to be dispensed only [by] upon a prescription, including finished dosage forms and active ingredients subject to section 328-16 or section 503(b) of the Federal Act[.]; or

(2) Any drug product compounded or prepared pursuant to a practitioner's order."

SECTION 2. Section 328-16, Hawaii Revised Statutes, is amended to read as follows:

"**§328-16 Drugs limited to dispensing on prescription.** (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) 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 of the prescription or of its filling;
(5) The name of the practitioner if the seller is not the practitioner;
(6) The name, strength, and quantity of the drug;
(7) The date the potency of the drug expires if the date is available from the manufacturer or principal labeler;
(8) The number of refills available, if any; and
(9) 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 [the] a drug does not indicate the number of times it may be refilled, if any, the pharmacist shall not refill that prescription unless [the pharmacist is] subsequently authorized to do so by the practitioner. The act of dispensing a 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 or a pharmacy intern [upon a written prescription from a practitioner or an out-of-state practitioner as provided in section 328-17.6; provided that all valid written prescriptions shall include the following information:
   (A) The date of issuance;
   (B) The original signature of the practitioner;
   (C) The practitioner's printed name and business address;
   (D) The name, strength, and quantity of the drug, and specific directions for the drug's use;
   (E) 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 filling the prescription has the address on file;
   (F) The room number and route of administration, if the patient is in an institutional facility; and
   (G) 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:
      (i) The prescription is refilled only once during the three-month period;
      (ii) The refill does not exceed a thirty-day supply of the drug;

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

(iv) The provisions listed in this subparagraph shall apply only to pharmacies practicing in the State.] pursuant to a valid prescription;

(2) [Upon an oral prescription from the practitioner; provided that:

(A) The pharmacist or pharmacy intern shall promptly reduce to writing:

(i) The oral prescription in full;

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

(iii) The date the oral prescription was received;

(iv) The name and oral code designation of the practitioner; and

(v) 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, unless the pharmacy filling the prescription has the address on file;

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

(C) The department of health assigns the oral code designation to the practitioner;] By a medical oxygen distributor pursuant to a valid prescription or valid certificate of medical necessity; provided that the drug to be dispensed is medical oxygen; or

(3) By a practitioner[, other than a pharmacist,] to an ultimate user; provided that:

(A) 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; and

(iv) 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

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

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

(1) The date of issuance;

(2) 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 reduced to writing by the pharmacist, pharmacist intern, or medical oxygen distributor, and shall include the practitioner's oral code designation; and

(C) Facsimile or electronic prescriptions shall be traceable to the prescribing practitioner;

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

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

(5) 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 filling the prescription has the address on file;

(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 valid certificate of medical necessity shall supersede any limitations or restrictions on refilling; and

(E) The provisions of subparagraphs (A) to (D) shall apply only to pharmacies and medical oxygen distributors practicing in the State.

[(4) By refilling any] (d) Any written or oral prescription may be refilled by the pharmacy and a written or oral prescription for medical oxygen may be refilled by the medical oxygen distributor if that refilling is authorized by the practitioner either:

[(A)] (1) In the original prescription; or

[(B)] (2) By oral order, which shall be reduced promptly to writing and filed by the receiving pharmacist [or], pharmacy intern[.], or medical oxygen distributor.

[(c)] (e) For the purposes of this section, a "prescription drug" is a drug intended for use by a person [which] that:

(1) Is a habit forming drug to which section 328-15(4) applies;

(2) Because of its toxicity or other potentiality for harmful effect, or the method of its use, or the collateral measures necessary to its use, is not safe for use except under the supervision of a practitioner; or

(3) Is limited by an approved application under section 505 of the Federal Act, or section 328-17, to use under the professional supervision of a practitioner.

[(d)] (f) Any drug other than medical oxygen dispensed by filling or refilling a [written or oral] prescription of a practitioner 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; and

(4) If stated in the prescription, the name of the patient, and the directions for use and cautionary statements, if any, 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 [subsections] subsection (a) [and], (b) [of this section.], (c), or (d).

[(e)] (g) The director of health, [may,] by [regulation,] rule, may remove drugs subject to sections 328-15(4) and 328-17 from the requirements of [subsections] subsection (a)[and], (b) [of this section], (c), or (d) when such requirements are not necessary for the protection of the public health. Drugs removed from the

prescription requirements of the Federal Act by regulations issued thereunder may also, by [regulations] rules issued by the director, be removed from the requirements of [subsections] subsection (a)[and], (b) [of this section.], (c), or (d).

[(f)] (h) A drug [which] that is subject to [subsections] subsection (a)[and], (b) [of this section], (c), or (d) shall be deemed to be misbranded if at any time prior to dispensing its label fails to bear the statement "Caution: Federal law prohibits dispensing without prescription[,]", or "Caution: State law prohibits dispensing without prescription[.]". A drug to which [subsections] subsection (a) [and], (b) [of this section do], (c), or (d) does not apply, shall be deemed to be misbranded if at any time prior to dispensing its label bears the caution statement quoted in the preceding sentence.

[(g)] (i) Nothing in this section shall be construed to relieve any person from any requirement, prescribed by or under authority of law with respect to drugs now included or [which] that may hereafter be included within the classifications of [narcotic drugs or marijuana] controlled substances as defined in the applicable federal and state laws relating to [narcotic drugs and marijuana.] controlled substances.

(j) Oral code numbers or designations shall be issued by the department of public safety, pursuant to applicable laws and rules."

SECTION 3. Section 328-17.5, Hawaii Revised Statutes, is amended to read as follows:

"**[[]§328-17.5[]] Principal labeler responsibility under recall of drug.** Whenever the manufacturer of a drug voluntarily recalls the drug or the Federal Food and Drug Administration or a court orders the recall of a drug, the principal labeler of the drug shall remove the drug from all pharmacies, prescriber offices, medical oxygen distributors, distributors of non-prescription drugs, and health care facilities."

SECTION 4. Section 328-17.6, Hawaii Revised Statutes, is amended to read as follows:

"**§328-17.6 Out-of-state prescriptions.** (a) An out-of-state practitioner may [make] issue a written or [orally-ordered] oral prescription within the confines of the practitioner's license and in accordance with Hawaii laws and rules. [The prescription may either be filled one time or refilled one time, but not both; provided that:

(1) The prescription filled or refilled pursuant to this section shall be limited to not more than a thirty-day supply of any drug; and
(2) If orally-ordered, the] An oral prescription shall be personally [ordered] communicated by [an] the out-of-state practitioner and received only by a pharmacist[.]; provided that a medical oxygen order may be received by a medical oxygen distributor.

(b) An out-of-state pharmacy may transfer prescription information for refilling purposes and an out-of-state medical oxygen distributor may transfer prescription information for the purpose of refilling a medical oxygen order.

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

(1) Note the following on the [pharmacist's] prescription record: the out-of-state practitioner's full name, address, and telephone number[, and Drug Enforcement Administration registration number; provided that the Drug Enforcement Administration registration number shall be required only for original fills communicated via telephone or facsimile];

(2) Be responsible for validating [the authenticity of the out-of-state practitioner's Drug Enforcement Administration registration number;] 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) 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.

[(c)] (d) Before refilling [an] a transferred out-of-state prescription, a pharmacist or medical oxygen distributor [receiving transferred prescription information] shall:

(1) 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 [before the pharmacist can refill the prescription]; and

(2) Record all information required to be on a prescription, including[, but not limited to]:

(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[,] and address,[and Drug Enforcement Administration registration number,] 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.

[(d)] (e) A pharmacist or medical oxygen distributor who fills or refills an out-of-state prescription shall be responsible if the prescription is not written in the form prescribed by Hawaii laws and rules.

[(e)] (f) [The pharmacist shall follow all labeling procedures established by the department for filling and refilling an out-of-state prescription. The] An out-of-state prescription shall be appropriately identified as "Out-of-State Filled" or "Out-of-State Refilled[,]", and shall state the date of filling or refilling and the local address of the person whose name appears on the prescription.

[(f)] (g) All transferred prescriptions shall be maintained for a period of five years from the date of filling or refilling. Filled out-of-state prescriptions shall be kept in a special file for five years. The department may establish additional recordkeeping and reporting procedures for filled and refilled out-of-state prescriptions.

[(g)] (h) This section shall not apply to prescriptions for controlled substances and habit forming drugs."

SECTION 5. Section 328-17.7, Hawaii Revised Statutes, is amended to read as follows:

"**§328-17.7 Record of prescriptions.** Every practitioner [or], pharmacist, or medical oxygen distributor, who compounds, sells, or delivers any [prescription containing any poisonous drug, or substance deleterious to human life, to be used as medicine, shall enter upon the practitioner's or pharmacist's books the prescription written out in full, with the date thereof, with the practitioner's or pharmacist's own

name appended thereto, or the name of the practitioner who prescribed the same, and the person to whom the same was delivered.] prescribed drug to a patient or a patient's agent shall maintain records that identify:

(1) The specific drug product;
(2) The prescribing practitioner;
(3) The patient;
(4) The date of prescribing or filling; and
(5) The name of the practitioner, pharmacist, or medical oxygen distributor dispensing the drug.

No prescription shall be compounded, sold, or delivered unless the name of the person compounding, selling, or delivering the same, or the name of the practitioner prescribing the same, is appended to the prescription in full, and every prescription shall be preserved for a period of not less than five years. The [books and prescriptions] prescription records shall be subject at all times to the inspection of the director of health or the director's agent."

SECTION 6. Section 461-1, Hawaii Revised Statutes, is amended as follows:

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

""Medical oxygen" means the prescription drug oxygen.

"Medical oxygen distributor" means any person, including a prescription drug wholesale distributor, who distributes or dispenses medical oxygen pursuant to a prescription.

"Prescription drug" means any drug dispensed, distributed, or sold pursuant to a practitioner's order."

2. By amending the definition of "cosmetics" to read:

""Cosmetics", which includes "soap", "dentifrice", and "toilet article", means:

(1) [articles] Articles intended to be rubbed, poured, or sprinkled on, introduced into, or otherwise applied to the human body, or any part thereof, for cleansing, beautifying, or promoting attractiveness; and
(2) [articles] Articles intended for use as a component of any such articles."

3. By amending the definition of "drug" to read:

""Drug" means:

(1) [articles] Articles recognized in the official United States pharmacopoeia, official homeopathic pharmacopoeia of the United States, or official national formulary, or any supplement to any of them[,];
(2) Articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in human beings or animals; [and (2) articles]
(3) Articles (other than food or clothing) intended to affect the structure or any function of the body of human beings or animals; and [(3) articles]
(4) Articles intended for use as a component of any articles specified in [clause] paragraph (1), [or] (2), or (3), above; provided that the term "drug" shall not include [patent medicines, electrical or mechanical devices,] devices or their components, parts, or accessories, cosmetics, [and] or liquor as defined in section 281-1."

4. By amending the definition of "pharmacy" to read:

""Pharmacy" means every store, shop, or place [where]:

(1) Where prescription drugs are dispensed or sold at retail, or displayed for sale at retail; [or]
(2) [where physicians] Where practitioners' prescriptions or drug preparations are compounded; [or]
(3) [which] That has upon it [or], displayed within it, or affixed to or used in connection with it, a sign bearing the [word or] words "pharmacist",

"pharmacy", "apothecary", "drug store", "druggist", "drugs", "medicines", "medicine store", "drug sundries", "remedies", or any [word or] words of similar or like import; or

(4) [any store or shop or other place with respect to which] Where any of the above words or combination of words are used in any advertisement.

The term "pharmacy" shall not include any medical oxygen distributor."

5. By repealing the definition of "patent medicine".

["'"Patent medicine" means any packaged, bottled, or nonbulk chemical, drug, or medicine, when identified by and sold under a trademark, trade name, or other trade symbol privately owned or registered in the United States Patent Office, or registered as provided by the laws of the State, and [which] that[1] is labeled with directions for use, and bears the name and address of the manufacturer or distributor; provided that the chemical, drug, or medicine meets the requirements of the pure food and drug laws of the United States and the State. "Patent medicine" shall not include therapeutic vitamins when used either alone, or in combination with other drugs."]

SECTION 7. Section 461-15, Hawaii Revised Statutes, is amended by amending subsection (a) to read as follows:

"(a) It shall be unlawful:

(1) For any person to sell or offer for sale at public auction, or to sell or offer for sale at private sale in a place where public auctions are conducted, any prescription drugs without first obtaining a permit from the board of pharmacy to do so;

(2) For any person to [in any manner] distribute or dispense samples of any prescription drugs [or medical supplies] without first obtaining a permit from the board to do so; provided that nothing in this paragraph shall interfere with the furnishing of samples or drugs directly to physicians, druggists, dentists, veterinarians, and optometrists for use in their professional practice;

(3) For wholesalers to sell, distribute, or dispense any prescription drug, except to a pharmacist, physician, dentist, veterinarian, or optometrist who is allowed to use pharmaceutical agents under chapter 459 or to a generally recognized industrial, agricultural, manufacturing, or scientific user of drugs for professional or business purposes; provided that it shall be unlawful for wholesalers to sell, distribute, or dispense any prescription pharmaceutical agent [which] that is not listed under section [459-15] 459-7.4(c) to any optometrist;

(4) For any wholesale prescription drug distributor to sell or distribute medical oxygen except to a:

(i) Licensed practitioner with prescriptive authority;

(ii) Pharmacist;

(ii)[1] Medical oxygen distributor;

(iii) Patient or a patient's agent pursuant to a prescription; or

(iv) Emergency medical services for administration by trained personnel for oxygen deficiency and resuscitation;

(5) For any medical oxygen distributor to supply medical oxygen pursuant to a prescription order, to a patient or a patient's agent, without first obtaining a permit from the board to do so; and

[(4)] (6) For any person, as principal or agent, to conduct or engage in the business of preparing, manufacturing, compounding, packing, or repacking any drug without first obtaining a permit from the board to do so; and

[(5)] (7) For any out-of-state pharmacy or entity engaging in the practice of pharmacy, in any manner to distribute, ship, mail, or deliver prescription drugs or devices into the State without first obtaining a permit from the board; provided that the applicant shall:

(A) Provide the location, names, and titles of all principal corporate officers;

(B) Attest that the applicant or any personnel of the applicant has not been found in violation of any state or federal drug laws, including the illegal use of drugs or improper distribution of drugs;

(C) Submit verification of a valid unexpired license, permit, or registration in good standing to conduct the pharmacy in compliance with the laws of the home state and agree to maintain in good standing [such] the license, permit, or registration; and

(D) Have in its employ a registered pharmacist whose registration is current and in good standing."

SECTION 8. Section 461-16, Hawaii Revised Statutes, is amended by amending subsection (a) to read as follows:

"(a) The board shall collect application, license, and permit fees for each permit to operate a pharmacy or for each license to operate as a wholesale prescription drug distributor and a fee for the issuance of a permit in accordance with section 461-15(a)(1), [(4), and] (5)[.], (6) and (7)."

SECTION 9. Statutory material to be repealed is bracketed. New statutory material is underscored.

SECTION 10. This Act shall take effect upon its approval.

(Approved April 27, 2000.)

Note

1. So in original.