ACT 25 H.B. NO. 1895-84

A Bill for an Act Relating to the Dispensing of Drugs.

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

SECTION 1. Section 328-16, Hawaii Revised Statutes, is amended to read as follows:

"**§328-16 Drugs limited to dispensing on prescription.** (a) A prescription drug [intended for use by man which (1) is a habit-forming drug to which section 328-15(4) applies; or (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 licensed by law to administer the drug; 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 licensed by law to administer the drug,] shall be dispensed only if its label bears the name and address of the seller, the serial number and date of the prescription or of its filling, the name of the practitioner if the seller is not the practitioner, the name, strength, and quantity of the drug, the date the potency of the drug expires if the date is available from the manufacturer or principal labeler, and the specific directions for 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, but in no event shall the notation "take as directed," referring to oral instructions, be considered acceptable. If any prescription for the drug does not indicate the times it may be refilled, if any, a 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 sampling contrary to this subsection shall be deemed to be an act which 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:

[(A) upon] (1) Upon a written prescription of a practitioner licensed by law to administer the drug[,]; or

[(B) upon] (2) Upon an oral prescription of the practitioner, provided the seller promptly [records in his books] reduces to writing the oral prescription in full, the [kind,] name, strength, and quantity of the drug, [and] directions for use, the date the oral prescription is received, the name of the seller, the name and code designation of the prescriber, [and] the name and address of the person for whom the drug is prescribed or the name of the owner of the animal for which the drug is prescribed, the department of health assigning [such] the code designation to [such] that subscriber, and [such books] those prescriptions or records being subject at all times to the inspection of the department or its agents[,]; or

(3) By a practitioner, other than a pharmacist, to an ultimate user; provided that the practitioner promptly records in the practitioner's

records the prescription in full, the name, strength, and quantity of the drug and directions for its use, the date the drug is dispensed, the name and address of the person for whom the drug is prescribed or the name of the owner of the animal for which the drug is prescribed, and those records being subject at all times to the inspection of the department or its agents; or

[(C) by] (4) By refilling any [such] written or oral prescription if [such] that refilling is authorized by the prescriber either in the original prescription or by oral order which is reduced promptly to writing and filed by the pharmacist[, and (D) its label bears the name and place of business of the seller, the serial number and date of the prescription, the name of the practitioner, the name, strength, and quantity issued of the drug, the date the potency of the drug expires, if the date is available from the manufacturer or principal labeler, and the specific directions for 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, but in no event shall the notation "take as directed," referring to oral instructions, be considered acceptable. If any prescription for such drug does not indicate the times it may be refilled, if any, such prescription may not be refilled unless the pharmacist is subsequently authorized to do so by the practitioner. The act of dispensing a drug contrary to this subsection shall be deemed to be an act which results in a drug being misbranded while held for sale].

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

(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 licensed by law to administer the drug; 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 licensed by law to administer the drug."

[(b)] (d) Any drug dispensed by filling or refilling a written or oral prescription of a practitioner licensed by law to administer the drug 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 the name and address of the dispenser, the serial number and date of the prescription or of its filling, the name of the prescriber

and, 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 [subsection (a)] subsections (a) and (b) of this section.

[(c)] (e) The director of health, may, by regulation, remove drugs subject to [section] sections 328-15(4) and [section] 328-17 from the requirements of [subsection] subsections (a) and (b) of this section 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 issued by the director, be removed from the requirements of [subsection] subsections (a) and (b) of this section.

[(d)] (f) A drug which is subject to [subsection] subsections (a) and (b) of this section 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 [subsection] subsections (a) and (b) of this section [does] do 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.

[(e)] (g) 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 may hereafter be included within the classifications of narcotic drugs or [marihuana] marijuana as defined in the applicable [Federal and State] federal and state laws relating to narcotic drugs and [marihuana.] marijuana.

SECTION 2. Section 329-38, Hawaii Revised Statutes, is amended by amending subsections (a) and (b) to read as follows:

"(a) No controlled substance in Schedule II may be dispensed without a written prescription of a practitioner, except:

(1) In an emergency situation, [such] those drugs may be dispensed upon oral prescription of a practitioner, provided that promptly thereafter the prescription is reduced to writing by the practitioner and filed by the pharmacy; or

(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 the date of dispensing, the name, strength, and quantity issued of the drug, the dispensing practitioner's name and address, the name of the patient, the date the potency of the drug expires if that date is available from the manufacturer or principal labeler, directions for

use, and cautionary statements, if any, contained in [such] the prescription or as required by law. Prescriptions and records of dispensing shall be retained in conformance with the requirements of section 329-36. No prescription for a controlled substance in Schedule II may be refilled.

(b) No controlled substance in Schedule III or IV may be dispensed without a written or oral prescription of a practitioner, except when dispensed directly by a practitioner, other than a pharmacist, to an ultimate user. The practitioner in dispensing a controlled substance in Schedule III and IV shall affix to the package a label showing the date of dispensing, the name, strength, and quantity issued of the drug, the dispensing practitioner's name and address, the name of the patient, the date the potency of the drug expires if that date is available from the manufacturer or the principal labeler, directions for use, and cautionary statements, if any, contained in [such] the prescription or as required by law. Prescriptions and records of dispensing shall be retained in conformance with the requirements of section 329-36. [Such] Those prescriptions may not be filled or refilled more than three months after the date thereof or be refilled more than two times after the date of the prescription unless renewed by the practitioner."

SECTION 3. Statutory material to be repealed is bracketed. New material is underscored.

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

(Approved April 14, 1984.)