ACT 215 H.B. NO. 1819

A Bill for an Act Relating to Prescription Drugs.

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

SECTION 1. Section 328-16, Hawaii Revised Statutes, is amended by amending subsections (a) and (b) to read as follows:

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

(1) The name [and], business address, and telephone number of the seller[, the]. 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 [and] of the prescription;
(4) The date of the prescription or of its filling[, the];
(5) The name of the practitioner if the seller is not the practitioner[, the];
(6) The name, strength, and quantity of the drug[, the];
(7) The date the potency of the drug expires if the date is available from the manufacturer or principal labeler[, and the specific];
(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 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 [sampling] sample contrary to this subsection shall be deemed to be an act [which] 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 [shall not be filled after fifteen months from the date the original prescription was written.] 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.

(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; [and

(vi) The department of health assigning the oral code designation to that subscriber; and]

(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;

(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

(4) By refilling any written or oral prescription if that refilling is authorized by the practitioner either:

(A) In the original prescription; or

(B) By oral order, which shall be reduced promptly to writing and filed by the pharmacist or pharmacy intern."

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 Statutory material to be repealed is bracketed.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

SECTION 3. This Act shall take effect upon its approval.

(Approved June 16, 1997.)