ACT 256 H.B. NO. 1842

A Bill for an Act Relating to the Practice of Pharmacy.

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

SECTION 1. The legislature finds that active participation of pharmacists in drug therapy improves patient outcomes, improves medication safety, and reduces the cost of health care. Increasingly, the complexity of drug therapy being provided inside and outside of hospitals and health care facilities requires the pharmacist to participate in the treatment of, and be the advocate for, the patient, in collaboration with other health care professionals. The legislature further finds that pharmaceutical care should help patients make the best use of their medications to achieve desired therapeutic outcomes.

The purpose of this Act is to enable pharmacists to provide their services in a broader range of clinical settings, including pharmacies and health care facilities.

SECTION 2. Section 461-1, Hawaii Revised Statutes, is amended by amending the definition of ''practice of pharmacy'' to read as follows:

''''Practice of pharmacy'' means [~~the~~]:

(1) The interpretation and evaluation of prescription orders; the compounding, dispensing, and labeling of drugs and devices (except labeling by a

manufacturer, packer, or distributor of nonprescription drugs and commercially legend drugs and devices); the participation in drug selection and drug utilization reviews; the proper and safe storage of drugs and devices and the maintenance of proper records therefor; the responsibility for advising when necessary or where regulated, of therapeutic values, content, hazards, and use of drugs and devices; [~~performing~~]

(2) Performing the following procedures or functions [~~in a licensed acute care hospital~~] as part of the care provided by and in concurrence with a ''health care facility'' and ''health care service'' as defined in section 323D-2, or a ''pharmacy'' or a licensed medical doctor, or a ''managed care plan'' as defined in section 432E-1, in accordance with policies, procedures, or protocols developed collaboratively by health professionals, including physicians and surgeons, pharmacists, and registered nurses, [~~with the concurrence of the facility administrator: ordering~~] and for which a pharmacist has received appropriate training required by these policies, procedures, or protocols:

(A) Ordering or performing routine drug therapy related patient assessment procedures [~~including temperature, pulse, and respiration; ordering~~]

(B) Ordering drug therapy related laboratory tests; [~~administering drugs and biologicals by injection pursuant to a licensed medical doctor's order; and adjusting the dosage of a patient's drug regimen pursuant to a licensed medical doctor's or osteopathic physician's order or authorization; and the~~]

(C) Administering drugs orally, topically, or by injection, pursuant to the patient's licensed medical doctor's order, by a pharmacist having appropriate training that includes programs approved by the American Council of Pharmaceutical Education (ACPE), curriculum-based programs from an ACPE-accredited college of pharmacy, state or local health department programs, or programs recognized by the board of pharmacy;

(D) Administering immunization by injection to persons eighteen years of age or older, by a pharmacist having appropriate training that includes programs approved by the ACPE, curriculum-based programs from an ACPE-accredited college of pharmacy, state or local health department programs, or programs recognized by the board of pharmacy;

(E) As authorized by a licensed medical doctor's written instructions, initiating or adjusting the drug regimen of a patient pursuant to an order or authorization made by the patient's licensed medical doctor and related to the condition for which the patient has been seen by the licensed medical doctor; provided that the pharmacist shall issue written notification to the patient's licensed medical doctor or enter the appropriate information in an electronic patient record system shared by the licensed medical doctor, within twenty-four hours;

(F) Transmitting a valid prescription to another pharmacist for the purpose of filling or dispensing; or

(G) Providing consultation, information, or education to patients and health care professionals based on the pharmacist's training and for which no other licensure is required; and

(3) The offering or performing of those acts, services, operations, or transactions necessary in the conduct, operation, management, and control of pharmacy. [~~Licensed acute care hospital means an acute care~~

~~hospital licensed by the department of health pursuant to chapter 321. Licensed medical doctor~~]

"Licensed medical doctor" means a medical doctor licensed by the board of medical examiners pursuant to chapter 453 or the board of osteopathic examiners under chapter 460."

SECTION 3. Section 328-6, Hawaii Revised Statutes, is amended to read as follows:

"**§328-6 Prohibited acts.** The following acts and the causing thereof within the State by any person are prohibited:

(1) The manufacture, sale, delivery, holding, or offering for sale of any food, drug, device, or cosmetic that is adulterated or misbranded;

(2) The adulteration or misbranding of any food, drug, device, or cosmetic;

(3) The receipt in commerce of any food, drug, device, or cosmetic that is adulterated or misbranded, and the delivery or proffered delivery thereof for pay or otherwise;

(4) The sale, delivery for sale, holding for sale, or offering for sale of any article in violation of section 328-11, 328-12, or 328-17;

(5) The dissemination of any false advertisement;

(6) The refusal to permit entry or inspection, or to permit the taking of a sample, as authorized by sections 328-22[~~,~~] and 328-23 to 328-27, or to permit access to or copying of any record as authorized by section 328-23;

(7) The giving of a guaranty or undertaking which guaranty or undertaking is false, except by a person who relied on a guaranty or undertaking to the same effect signed by, and containing the name and address of the person residing in the State from whom [~~he~~] the person received in good faith the food, drug, device, or cosmetic;

(8) The removal or disposal of a detained or embargoed article in violation of sections 328-25 to 328-27;

(9) The alteration, mutilation, destruction, obliteration, or removal of the whole or any part of the labeling of, or the doing of any other act with respect to a food, drug, device, or cosmetic, if the act is done while the article is held for sale and results in the article being adulterated or misbranded;

(10) Forging, counterfeiting, simulating, or falsely representing, or without proper authority using any mark, stamp, tag, label, or other identification device authorized or required by [~~regulations promulgated~~] rules adopted under this part or regulations adopted under the Federal Act;

(11) The [~~using,~~] use, on the labeling of any drug or in any advertisement relating to the drug, of any representation or suggestion that an application with respect to the drug is effective under section 328-17, or that the drug complies with [~~the provisions of such~~] that section;

(12) The [~~using~~] use by any person to [~~his~~] the person's own advantage, or revealing other than to the department of health or to the courts when relevant in any judicial proceeding under this part, any information acquired under authority of section 328-11, 328-12, 328-17, or 328-23, concerning any method or process which as a trade secret is entitled to protection;

(13) In the case of a prescription drug distributed or offered for sale in this State, the failure of the manufacturer, packer, or distributor thereof to maintain for transmittal, or to transmit, to any practitioner who makes written request for information as to the drug, true and correct copies of

all printed matter which is required to be included in any package in which that drug is distributed or sold, or such other printed matter as is approved under the Federal Act. Nothing in this paragraph shall be construed to exempt any person from any labeling requirement imposed by or under other provisions of this part;

(14) (A) Placing or causing to be placed upon any drug or device or container thereof, with intent to defraud, the trade name or other identifying mark, or imprint of another or any likeness of any of the foregoing; or

(B) Selling, dispensing, disposing of, or causing to be sold, dispensed, or disposed of, or concealing or keeping in possession, control, or custody, with intent to sell, dispense, or dispose of, any drug, device, or any container thereof, with knowledge that the trade name or other identifying mark or imprint of another or any likeness of any of the foregoing has been placed thereon in a manner prohibited by subparagraph (A) [~~hereof~~]; or

(C) Making, selling, disposing of, or causing to be made, sold, or disposed of, or keeping in possession, control, or custody, or concealing, with intent to defraud, any punch, die, plate, or other thing designed to print, imprint, or reproduce that trade name or other identifying mark or imprint of another or any likeness of any of the foregoing upon any drug, device, or container thereof;

(15) Except as provided in part VI[~~,~~] and section 461-1, dispensing or causing to be dispensed a different drug or brand of drug in place of the drug or brand of drug ordered or prescribed without express permission in each case of the person ordering or prescribing;

(16) The distribution in commerce of a consumer commodity as defined in this part, if such commodity is contained in a package, or if there is affixed to that commodity a label, which does not conform to [~~the provisions of~~] this part and of rules adopted under authority of this part; provided that this prohibition shall not apply to persons engaged in business as wholesale or retail distributors of consumer commodities except to the extent that such persons:

(A) Are engaged in the packaging or labeling of such commodities; or

(B) Prescribe or specify by any means the manner in which such commodities are packaged or labeled;

(17) The selling or dispensing in restaurants, soda fountains, drive-ins, lunch wagons, or similar public eating establishments of imitation milk and imitation milk products in place of fresh milk and fresh milk products respectively; of liquid or dry products which simulate cream but do not comply with content requirements for cream in place of cream; of non-dairy frozen desserts which do not comply with content requirements for dairy frozen desserts in place of dairy frozen desserts; and of any other imitation food or one made in semblance of a genuine food in place of such genuine food, unless the consumer is notified by either proper labeling or conspicuous posted signs or conspicuous notices on menu cards and advertisements informing of such substitution, to include but not limited to the substitution of imitation milk in milk shake and malted milk drinks;

(18) Wilfully and falsely representing or using any devices, substances, methods, or treatment as effective in the diagnosis, cure, mitigation, treatment, or alleviation of cancer. [~~The provisions of this~~] This paragraph shall not apply to any person who depends exclusively upon

prayer for healing in accordance with teachings of a bona fide religious sect, denomination, or organization, nor to a person who practices such teachings;

(19) The selling or offering for sale at any food facility which serves or sells over the counter directly to the consumer an unlabeled or unpackaged food that is a confectionery which contains alcohol in excess of one-half of one per cent by weight unless the consumer is notified of that fact by either proper labeling or conspicuous posted signs or conspicuous notices on menu cards and advertisements;

(20) The sale to a person below the age of twenty-one years of any food which is a confectionery which contains alcohol in excess of one-half of one per cent by weight."

SECTION 4. Section 328-16, Hawaii Revised Statutes, is amended by amending subsection (b) to read as follows:

"(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 461-1;

(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) 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; 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;

(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."

SECTION 5. Statutory material to be repealed is bracketed and stricken. New statutory material is underscored.

SECTION 6. This Act shall take effect upon its approval.

(Approved July 5, 2002.)