ACT 196 S.B. NO. 2678

A Bill for an Act Relating to Wholesale Prescription Drug Distributors.

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

SECTION 1. The purpose of this bill is to provide statutory authority for the board of pharmacy to adopt rules that would establish requirements for licensing wholesale prescription drug distributors in order to comply with the federal Prescription Drug Marketing Act of 1987, Pub. L. 100-293 (PDMA), and for the department of health to establish requirements mandated by the PDMA relating to the storage and handling of wholesale prescription drugs and recordkeeping by wholesale prescription drug distributors.

The PDMA requires each state to have in effect by September 14, 1992, a licensing scheme for wholesale prescription drug distributors that meets the minimum requirements of the guidelines established in 21 C.F.R. part 205. Failure to do so would mean that no prescription drug wholesaler in the State could receive or distribute prescription drugs through interstate commerce.

If this were to happen, prescription drugs may be in short supply, more costly, or both.

SECTION 2. Chapter 328, Hawaii Revised Statutes, is amended by adding a new part to be appropriately designated and to read as follows:

"PART . WHOLESALE PRESCRIPTION DRUGS: STORAGE, HANDLING, AND RECORDKEEPING

§328- Objective. The purpose of this part is to establish the minimum requirements for the storage and handling of wholesale prescription drugs and for the establishment and maintenance of prescription drug distribution records by wholesale distributors, as required by the federal Prescription Drug Marketing Act of 1987, Pub. L. 100-293, and 21 C.F.R. part 205.

§328- Definitions. As used in this part:

"Blood" means whole blood collected from a single donor and processed either for transfusion or for further manufacturing.

"Blood component" means that part of blood separated by physical or mechanical means.

"Common Control" means the power to direct or cause the direction of the management and policies of a person or an organization, whether by ownership of stock, by voting rights, by contract, or otherwise.

"Department" means the department of health except when otherwise provided.

"Drug sample" means a unit of a prescription drug that is not intended to be sold and is intended to promote the sale of the drug.

"Manufacturer" means anyone who is engaged in manufacturing, preparing,

propagating, compounding, processing, packaging, repackaging, or labeling a prescription drug.

"Prescription drug" means any human drug required by federal or state statutes, regulations, or rules to be dispensed only by a prescription, including finished dosage forms and active ingredients subject to section 328-16 or to section 503(b) of the federal Food, Drug, and Cosmetic Act.

"Wholesale distribution" means the distribution of prescription drugs to persons other than a consumer or patient, but does not include:

(1) Intracompany sales, defined as any transaction or transfer between an entity and any division, subsidiary, parent, or affiliated or related company under common ownership and control;

(2) The purchase or other acquisition, by a hospital or other health care entity that is a member of a group purchasing organization, of a drug for the entity's own use, from the group purchasing organization or from other hospitals or health care entities that are members of the group purchasing organization;

(3) The sale, purchase, or trade of a drug or an offer to sell, purchase, or trade a drug by a charitable organization described in section 501(c)(3) of the Internal Revenue Code of 1986, as amended, to a nonprofit affiliate of the organization to the extent otherwise permitted by law;

(4) The sale, purchase, or trade of a drug or an offer to sell, purchase, or trade a drug among hospitals or other health care entities that are under common control;

(5) The sale, purchase, or trade of a drug or an offer to sell, purchase, or trade a drug for emergency medical reasons; for purposes of this definition the term "emergency medical reasons" includes, but is not limited to, transfers of prescription drugs by a retail pharmacy to another retail pharmacy to alleviate a temporary shortage, except that the gross dollar value of such transfers shall not exceed five per cent of the total prescription drug sales revenue of either the transferor or transferee pharmacy during any period of twelve consecutive months;

(6) The sale, purchase, or trade of a drug, or an offer to sell, purchase, or trade a drug, or the dispensing of a drug, pursuant to a prescription;

(7) The distribution of drug samples by manufacturers' representatives or distributors' representatives; or

(8) The sale, purchase, or trade of blood and blood components intended for transfusion.

"Wholesale distributor" means any person or entity engaged in wholesale distribution of prescription drugs, including, but not limited to, manufacturers; repackers; own-label distributors; jobbers; private label distributors; brokers; warehouses, including manufacturers' and distributors' warehouses, chain drug warehouses, and wholesale drug warehouses; independent wholesale drug traders; prescription drug repackagers; physicians; dentists; veterinarians; birth control and other clinics; individuals; hospitals; nursing homes and their providers; health maintenance organizations and other health care providers; and retail and hospital pharmacies that conduct wholesale distributions. The term "wholesale distributor" shall not include any carrier for hire or person or entity hired solely to transport prescription drugs.

§328- Rules. (a) The department may adopt such rules as may be necessary to carry out the purposes and enforce the provisions of this part and to

implement the requirements of 21 C.F.R. part 205, including minimum requirements for the storage and handling of wholesale prescription drugs; the keeping of records regarding their receipt and distribution; written policies and procedures for wholesale prescription drug distributors; and the salvaging and reprocessing of prescription drugs. All rules adopted under this part shall meet or exceed the requirements of the wholesale prescription drug distributor guidelines contained in 21 C.F.R. part 205, and in case of conflict between any rule adopted under this part and the provisions of 21 C.F.R. part 205, the more stringent provision shall prevail.

(b) The director may, without regard to chapter 91, adopt standards regarding conditions and temperatures for the storage of prescription drugs by reference to the provisions of an official compendium such as the United States Pharmacopeia/National Formulary (USP/NF), as updated from time to time.

§328- **Notice.** Before any violation of this part is reported for the institution of a criminal proceeding, the person against whom the proceeding is contemplated shall be given appropriate notice and an opportunity to present the person's views before the department either orally or in writing, in person or by an attorney, with regard to the contemplated proceeding.

§328- **Inspection.** Wholesale distributors shall permit agents of the department, agents of the department of commerce and consumer affairs, and authorized federal, state, or local law enforcement officials to enter and inspect their premises and delivery vehicles, and to audit their records, written operating procedures, and lists of responsible persons, at reasonable times and in a reasonable manner, to the extent authorized by law.

§328- **Penalty; exceptions.** (a) Any person who violates this part or rules adopted under this part shall be fined not more than $500, or imprisoned not more than one year, or both.

(b) No person shall be subject to the penalties of subsection (a) of this section for having violated this part or rules adopted under this part if the person establishes a guaranty or undertaking signed by, and containing the name and address of, the individual from whom the person received the article in good faith, to the effect that the article is not adulterated or misbranded within the meaning of part I of this chapter.

§328- **Administrative penalties.** (a) Any person who violates this part or any rule adopted by the department pursuant to this part shall be fined not more than $10,000 for each separate offense. Any action taken to collect the penalty provided for in this subsection shall be considered a civil action.

(b) In addition to any other administrative or judicial remedy provided by this part, or by rules adopted pursuant to this part, the director may impose by order the administrative penalty specified in this section. Factors to be considered in imposing the administrative penalty include the nature and history of the violation and of any prior violation, and the opportunity, difficulty, and history of corrective action. For any judicial proceeding to recover the administrative penalty imposed, the director need only show that notice was given, a hearing was held, or the time granted for requesting a hearing has expired without such a request, the administrative penalty was imposed, and the penalty remains unpaid.

§328- **Injunctive relief.** The director may institute a civil action in any court of competent jurisdiction for injunctive relief to prevent any violation of

this part or any rule adopted under this part. The court shall have powers to grant relief in accordance with the Hawaii rules of civil procedure.

§328- Minimum requirements for the storage and handling of prescription drugs. Wholesale distributors of prescription drugs and their officers, agents, representatives, and employees shall ensure that the following requirements are met:

(1) Facilities. All facilities at which prescription drugs are stored, warehoused, handled, held, offered for sale or distribution, marketed, or displayed shall:
   (A) Be of suitable size and construction to facilitate cleaning, maintenance, and proper operations;
   (B) Have storage areas designed to provide adequate lighting, ventilation, temperature, sanitation, humidity, space, equipment, and security conditions;
   (C) Have a quarantine area for storage of prescription drugs that are outdated, damaged, deteriorated, misbranded, or adulterated, or that are in immediate containers or sealed secondary containers that have been opened;
   (D) Be maintained in a clean and orderly condition; and
   (E) Be free from infestation by insects, rodents, birds, and vermin of any kind.

(2) Security.
   (A) All facilities used for wholesale distribution, storage, or warehousing of prescription drugs shall be secure from unauthorized entry.
      (i) Access from outside the premises shall be kept to a minimum and shall be well controlled.
      (ii) The outside perimeter of the premises shall be well lighted.
      (iii) Entry into areas where prescription drugs are held shall be limited to authorized personnel.
   (B) All facilities shall be equipped with an alarm system to detect entry after hours.
   (C) All facilities shall be equipped with a security system that will provide suitable protection against theft and diversion. When appropriate, the security system shall provide protection against theft or diversion that is facilitated or hidden by tampering with computers or electronic records.

(3) Storage. All prescription drugs shall be stored at appropriate temperatures and under appropriate conditions in accordance with the requirements, if any, in the labeling of the drugs, or in accordance with the standards regarding conditions and temperatures for the storage of prescription drugs adopted under the new part in section 2 of this Act.[1]
   (A) If no storage requirements are established for a prescription drug, the drug may be held at controlled room temperature, as defined in an official compendium, to help ensure that its identity, strength, quality, and purity are not adversely affected.
   (B) Appropriate manual, electromechanical, or electronic temperature and humidity recording equipment, devices, or logs shall be used to document the proper storage of prescription drugs.

(4) Examination of materials.
   (A) Upon receipt, each outside shipping container of prescription drugs shall be examined visually to confirm the identity of the drugs and to prevent the acceptance of contaminated prescription drugs or prescription drugs that are otherwise unfit for distribution. This examination shall be adequate to reveal container damage that would suggest possible contamination or other damage to the contents.
   (B) Each outgoing shipment of prescription drugs shall be inspected carefully to confirm the identity of the drugs and to ensure that no prescription drugs are delivered that have been damaged in storage or held under improper conditions.
   (C) The recordkeeping requirements in section 8 of this Act[1] shall be followed for all incoming and outgoing prescription drugs.

(5) Returned, damaged, outdated, deteriorated, misbranded, and adulterated prescription drugs.
   (A) Prescription drugs that are damaged, outdated, deteriorated, misbranded, or adulterated shall be physically separated from other prescription drugs and stored, in such a way that no cross-contamination or confusion are possible, until they are destroyed or returned to the supplier.
   (B) Any prescription drugs whose immediate or sealed outer or sealed secondary containers are found upon arrival to have been opened or used shall be identified as such, and shall be physically separated from other prescription drugs and stored, in such a way that no cross-contamination or confusion are possible, until they are destroyed or returned to the supplier.
   (C) If the conditions under which a prescription drug has been returned cast doubt on the drug's safety, identity, strength, quality, or purity, then the drug shall be either destroyed or returned to the supplier, unless examination, testing, or other investigation proves that the drug meets appropriate standards of safety, identity, strength, quality, and purity. In determining whether the conditions under which a drug has been returned cast doubt on the drug's safety, identity, strength, quality, or purity, the wholesale distributor shall consider, among other things, the conditions under which the drug has been held, stored, or shipped before or during its return and the condition of the drug and its container, carton, or labeling as a result of storage or shipping.
   (D) The recordkeeping requirements in section 8 of this Act[1] shall be followed for all outdated, damaged, deteriorated, misbranded, adulterated or returned prescription drugs.

§328- **Recordkeeping**. (a) Wholesale distributors shall establish and maintain inventories and records of all transactions regarding the receipt and distribution or other disposition of prescription drugs. These records shall include the following information:
(1) The source of the drugs, including the name and principal address of the seller or transferor, and the address of the location from which the drugs were shipped;
(2) The identity and quantity of the drugs received and distributed or disposed of; and

(3) The dates of receipt and distribution or other disposition of the drugs.

(b) Inventories and records shall be made available for inspection and photocopying by the department or any authorized federal, state, or local law enforcement officials for a period of five years following disposition of the drugs.

(c) Records described in this section that are kept at the inspection site or that can be retrieved immediately by computer or other electronic means shall be readily available for authorized inspection during the retention period. Records kept at a central location apart from the inspection site and not electronically retrievable shall be made available for inspection within two working days of a request by the department or any authorized official of a federal, state, or local law enforcement agency.

§328- **Written policies and procedures.** Wholesale distributors shall establish, maintain, and follow written policies and procedures for the receipt, security, storage, inventory, and distribution of prescription drugs, including policies and procedures for identifying, recording, and reporting losses or thefts and for correcting all errors and inaccuracies in inventories. Wholesale distributors shall include in their written policies and procedures the following:

(1) A procedure whereby the oldest approved stock of a prescription drug is distributed first. The procedure may permit deviation from this requirement if the deviation is temporary and appropriate.

(2) A procedure for handling recalls and withdrawals of prescription drugs. The procedure shall be adequate to deal with recalls and withdrawals caused by:
   (A) Any action initiated at the request of the department, the Food and Drug Administration, or any other federal, state, or local law enforcement or other government agency;
   (B) Any voluntary action by the manufacturer to remove defective or potentially defective drugs from the market; or
   (C) Any action undertaken to promote public health and safety by replacing existing merchandise with an improved product or new package design.

(3) A procedure to ensure that the distributor prepares for, protects against, and handles properly any crisis that affects security or operation of any facility in the event of strike, fire, flood, or other natural disaster, or in other emergencies.

(4) A procedure to ensure that all outdated prescription drugs are segregated from other drugs and either returned to the manufacturer or destroyed. This procedure shall require written documentation of the disposition of outdated prescription drugs, which documentation shall be maintained for five years after disposition of the outdated drugs.

§328- **Responsible persons.** Wholesale distributors shall establish and maintain current lists of officers, directors, managers, and other persons in charge of the wholesale distribution, storage, and handling of prescription drugs, including a description of each person's duties and a summary of each person's qualifications.

§328- **Salvaging and reprocessing.** Wholesale distributors shall be subject to the provisions of 21 C.F.R., parts 207, 210, and 211, regarding salvaging and reprocessing of prescription drugs."

SECTION 3. Chapter 461, Hawaii Revised Statutes, is amended by adding a new section to be appropriately designated and to read as follows:

"**§461- Wholesale prescription drug distributor license.** It shall be unlawful for any person to operate, maintain, open, change location, or establish any wholesale prescription drug distribution business within the State without first having obtained a license from the board."

SECTION 4. Section 461-4.5, Hawaii Revised Statutes, is amended to read as follows:

"[]**§461-4.5[]] Powers and duties.** (a) The board shall:

(1) Adopt, amend, and repeal rules pursuant to chapter 91, as it deems proper for the purposes of this chapter[;], Pub. L. 100-293 and 21 C.F.R. part 205;

(2) Examine, license, reinstate, and renew the licenses of qualified applicants[;] for registered pharmacists and wholesale prescription drug distributors, and issue and renew permits to operate pharmacies;

(3) Inspect, or may designate a duly authorized representative to inspect, any pharmacy or premises in the State where drugs are packed, packaged, compounded, sold, offered for sale, exposed for sale, stored, warehoused, or kept for sale or distribution to ensure compliance with this chapter and rules [established by the board;] adopted under this chapter; and

(4) Fine, suspend, or revoke any license or permit for any cause prescribed by this chapter, or for any violation of the rules[,] adopted under this chapter, and refuse to grant or renew any license or permit for any cause which would be ground for revocation or suspension of a license or permit.

(b) Nothing in this chapter shall modify or limit any powers of the department of health of this State."

SECTION 5. Section 461-6, Hawaii Revised Statutes, is amended by amending subsection (a) to read as follows:

"(a) Every applicant for a license as a pharmacist shall pass the National Association of Boards of Pharmacy Licensure Examination (NABPLEX) with a score of not less than seventy-five, the Federal Drug Law Examination (FDLE) with a score of not less than seventy-five, and the state jurisprudence examination with a score of not less than seventy-five."

SECTION 6. Section 461-16, Hawaii Revised Statutes, is amended to read as follows:

"**§461-16 Fees for permits**[;] **and licenses; renewal.** (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(1) or (4).

(b) Permits issued under sections 461-14 and 461-15 and licenses issued under section 461- shall be conspicuously displayed in the place for which the permit or license was granted. The permits and licenses shall not be transferable, shall expire on December 31 of each odd-numbered year following the date of

issuance, and shall be renewed biennially.

(c) The holder of an expired permit or an expired license to operate as a wholesale prescription drug distributor may have the same restored within three years of the date of expiration upon due application therefor and payment of the delinquent fees and a penalty fee."

SECTION 7. Statutory material to be repealed is bracketed. New statutory material is underscored.[2]

SECTION 8. This Act shall take effect upon its approval.

(Approved June 12, 1992.)

Notes

1. So in original.
2. Edited pursuant to HRS §23G-16.5.