ACT 143 H.B. NO. 2035-86

A Bill for an Act Relating to Pharmacists and Pharmacy.

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

SECTION 1. Chapter 461, Hawaii Revised Statutes, is amended by adding a new section to be appropriately designated and to read as follows:

"**§461- 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;
(2) Examine, license, and renew the licenses of qualified applicants;
(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, or kept for sale to ensure compliance with this chapter and rules established by the board; and
(4) Fine, suspend, or revoke any license or permit for any cause prescribed by this chapter, or for any violation of the rules, 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 2. Chapter 461, Hawaii Revised Statutes, is amended by adding a new section to be appropriately designated and to read as follows:

"**§461- Disciplinary action.** (a) The board shall have the power to deny, revoke, or suspend any license or permit applied for or issued by the board in accordance with this chapter, and to fine or otherwise discipline a licensee or permit holder for any of the following causes:
(1) Procuring a license through fraud, misrepresentation, or deceit;
(2) Professional misconduct, gross carelessness, or manifest incapacity;
(3) Permitting an unlicensed person to perform activities which require a license under this chapter;
(4) Violation of any of the provisions of this chapter or the rules adopted pursuant thereto;
(5) Violation of any state or federal drug, controlled substance, or poison law;
(6) False, fraudulent, or deceptive advertising;
(7) Any other conduct constituting fraudulent or dishonest dealings;
(8) Failure to comply with a board order;
(9) Making a false statement on any document submitted or required to be filed by this chapter;
(10) Habitual intemperance or addiction to the use of habit-forming drugs.

(b) Any person who violates any of the provisions of this chapter or the rules adopted pursuant thereto shall be fined not less than $100 nor more than $1,000 for each violation.

(c) All proceedings for denial, suspension, fine, or revocation of a license or permit on any grounds specified in subsection (a) shall be conducted pursuant to chapter 91, including the right of judicial review."

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

"**§461- Cumulative remedies.** The remedies or penalties provided by this chapter are cumulative to each other and to the remedies or penalties available under all other laws of this State."

SECTION 4. Section 461-1, Hawaii Revised Statutes, is amended to read as follows:

"**§461-1 Definitions.** For the purposes of this chapter:

[(1) "Pharmacy" means every store, shop, or place where (A) drugs are dispensed or sold at retail, or displayed for sale at retail; or (B) where physicians prescriptions or drug preparations are compounded; or (C) which 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 (D) any store or shop or other place with respect to which any of the above words or combination of words are used in any advertisement.

(2) "Drug" means (A) 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, intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in human beings or animals; and (B) articles (other than food or clothing) intended to affect the structure or any function of the body of human beings or animals; and (C) articles intended for use as a component of any articles specified in clause (A) or (B), above; provided, that the term "drug" shall not include patent medicines, electrical or mechanical devices, cosmetics, and liquor as defined in section 281-1.

(3) "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 is labeled with directions for use, and bears the name and address of the manufacturer or distributor; provided 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.

(4) "Cosmetics", which includes "soap", "dentifrice", and "toilet article", means (A) article 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 (B) articles intended for use as a component of any such articles.

(5) "Prescription" means and includes an order or formula issued by a licensed practitioner of medicine, osteopathy, podiatry, dentistry, or veterinary medicine, for the compounding or dispensing of drugs.
(6) "Registered pharmacist" means a person licensed under this chapter to practice pharmacy except where another meaning is clearly manifested by the context.
(7) "Board" means the board of pharmacy of the State except where another meaning is clearly manifested by the context.]

"Board" means the board of pharmacy of the State except where another meaning is clearly manifested by the context.

"Cosmetics", which include "soap", "dentifrice", and "toilet article", means (1) 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 intended for use as a component of any such articles.

"Director" means the director of commerce and consumer affairs.

"Drug" means (1) 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, intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in human beings or animals; and (2) 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 intended for use as a component of any articles specified in clause (1) or (2), above; provided that the term "drug" shall not include patent medicines, electrical or mechanical devices, cosmetics, and liquor as defined in section 281-1.

"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 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.

"Pharmacy" means every store, shop, or place where (1) drugs are dispensed or sold at retail, or displayed for sale at retail; or (2) where physicians prescriptions or drug preparations are compounded; or (3) which 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 any of the above words or combination of words are used in any advertisement.

"Prescription" means an order or formula issued by a licensed practitioner of medicine, osteopathy, podiatry, dentistry, or veterinary medicine, for the compounding or dispensing of drugs.

"Registered pharmacist" means a person licensed under this chapter to practice in a pharmacy except where another meaning is clearly manifested by the context."

SECTION 5. Section 461-3, Hawaii Revised Statutes, is amended to read as follows:

"§461-3 **Officers.** (a) The board [of pharmacy] shall [select a chairman, a secretary, and a treasurer.] elect one of its members to serve as chairman. The chairman of the board shall preside at all meetings and in [his] the chairman's absence the members present shall select a chairman pro tem.

(b) The executive secretary shall, subject to the direction of the board, make and keep all records and record books required to be kept by the board and [he] shall furnish the department of health with copies [of such] of those records as it requires. [The records and record books of the board as made and kept by the secretary shall be prima facie evidence of the matter therein recorded in any court of law.

All fees collected shall be deposited by the director of commerce and consumer affairs with the director of finance to the credit of the general fund.]"

SECTION 6. Section 461-4, Hawaii Revised Statutes, is amended to read as follows:

"§461-4 **Meetings; [powers and duties of board.] quorum.** [(a) Meetings.] The board [of pharmacy] shall [hold meetings in April and September of each year, and at such other times as it deems necessary.] meet at least once a year and as many other times as the board may deem necessary to discharge its duties. A majority of the board shall constitute a quorum, and the concurrence of a majority of the members present shall be necessary to make any action of the board valid.

[(b) Power to suspend or revoke license. The board may suspend or revoke any license of any pharmacist to practice pharmacy, issued under this chapter, for:

(1) Professional misconduct,
(2) Gross carelessness,
(3) Manifest incapacity of a licensee, or
(4) Any violation by the licensee of this chapter or of any rule prescribed pursuant thereto.

No such license shall be suspended or revoked except upon due notice to the licensee of the charge against him and only after an opportunity for a full and fair hearing.

(c) Power to suspend or revoke permits. The board may suspend or revoke any permit to operate a pharmacy or to sell or distribute drugs, issued under this chapter, in any case, where the permittee has violated any of the provisions of this chapter or of any rule prescribed pursuant thereto. No permit shall be suspended or revoked except upon due notice to the permittee of the charge against him and only after an opportunity for a full and fair hearing.

(d) Power to regulate. The board may make such rules, not inconsistent with law, as may be necessary to carry out the purpose of this chapter, which purpose is hereby declared to be the protection of the public health and safety. The rules shall be prescribed in the manner provided in chapter 91 and with the approval of the governor and the director of commerce and consumer affairs. They shall have the force and effect of law.

(e) Power to inspect. The board or any duly authorized representative thereof may inspect drugs packed, packaged, compounded, sold, offered for sale, exposed for sale, or kept for sale in the State and for this purpose it may, during reasonable hours, enter and inspect any pharmacy or premises in the State where drugs are packed, packaged, compounded, sold, offered for sale, exposed for sale, or kept for sale.

(f) Power to investigate. The board or any member thereof, or any person designated by the board for the purpose, may investigate any violation or suspected violation of this chapter or of any rules duly prescribed by the board.

(g) Oaths. Each member of the board may administer oaths in connection with the duties of the board.

(h) Department of health, powers. Nothing in this chapter shall modify or limit any powers of the department of health of the State.]"

SECTION 7. Section 461-6, Hawaii Revised Statutes, is amended to read as follows:

"**§461-6 Examination; license.** (a) Every applicant shall pass [an examination with a general average of not less than seventy per cent in the subjects of pharmacy, materia medica, chemistry, toxicology and posology, compounding of prescriptions, identification of drugs, state laws, and public health rules relating to drugs, poisons, and devices used in the practice of pharmacy in the State, and such other subjects relating to the practice of pharmacy as the board of pharmacy may deem necessary for the protection of the public health.] 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 per cent, and the state jurisprudence examination with a score of not less than seventy-five per cent.

(b) Every application for examination shall be made on a form to be supplied by the board and shall be filed with the board at least [thirty] sixty days before the examination. Each application shall be accompanied by application and examination fees. Examinations shall be held at least twice a year. [Notice of the examination shall be given each applicant by registered mail.]

(c) Each applicant who successfully passes the examination and meets all other requirements of the board shall pay a license fee.

(d) Applicants who fail the NABPLEX, or FDLE, or state jurisprudence examination shall file an application for reexamination in the examination for which a passing score was not achieved and shall not be licensed until the applicant successfully passes all of the licensure examinations."

SECTION 8. Section 461-7, Hawaii Revised Statutes, is amended to read as follows:

"**§461-7 Temporary license.** (a) An applicant for examination who is a registered pharmacist as specified in section 461-5(b), may be granted a temporary license by the board; provided that the person shall first pass [a preliminary examination] the state jurisprudence examination with a [grade] score of not less than [seventy] seventy-five per cent [covering state laws and public health rules relating to drugs, poisons, and devices used in the practice of pharmacy in the State].

(b) A temporary license shall not entitle the holder to a permanent license, and no permanent license shall be issued until the person has passed the [regular examination] licensure examinations set forth in section 461-6. Only one temporary license shall be issued to the same applicant.

(c) A temporary license shall only remain in effect until the results of the next [regular examination] licensure examinations are announced; provided that the board may extend any temporary license, upon written application, for good and just cause. Any applicant who fails to take or to pass the next [regular] licensure examination shall surrender the temporary license. The board shall receive a fee for the issuance of a temporary license."

SECTION 9. Section 461-8, Hawaii Revised Statutes, is amended to read as follows:

"**§461-8 Renewal of licenses.** (a) [Renewal required.] All licenses issued by the board [of pharmacy], except temporary licenses issued under section 461-7, shall [expire on December 31 of each odd-numbered year next following the date of issuance of the same.] be renewed biennially on or before December 31 of each odd-numbered year.

[(b) Every registered pharmacist shall pay to the treasurer of the board biennially between December 1 and December 31 a renewal fee for the biennium next following. The payment of the renewal fee shall entitle the registrant to renewal of the license.

(c)] (b) Any holder of any expired license may be reinstated as a registered pharmacist upon payment of a penalty fee and all fees which the person would have paid if the person had continuously renewed the [person's] license."

SECTION 10. Section 461-9, Hawaii Revised Statutes, is amended to read as follows:

"**§461-9 Pharmacist in charge.** (a) A registered pharmacist shall be in personal and immediate charge of [every] the pharmacy[.] and personnel employed in the pharmacy. Temporary absences of the registered pharmacist shall be unlawful except for [such] periods of time and under [such] circumstances as authorized under the rules of the board [of pharmacy]. During any absence of the registered pharmacist, prescriptions may not be filled, compounded, or received by telephone and no drugs shall be sold; provided that this shall not preclude the sale at such times of [such] things as might be sold were the pharmacy a store not subject to this chapter. No person other than a registered pharmacist or an assistant under [his] the registered pharmacist's immediate supervision shall fill or compound prescriptions.

(b) A pharmacy technician may be employed to assist the registered pharmacist under rules adopted by the board pursuant to chapter 91 that define the qualifications and functions of [such] the pharmacy technician and provide the procedures for their control and supervision by a registered [pharmacists.] pharmacist."

SECTION 11. Section 461-11, Hawaii Revised Statutes, is amended to read as follows:

"**§461-11 Duties of registered pharmacist.** Every registered pharmacist in charge of a pharmacy shall comply with all laws and rules. [He] The pharmacist shall be responsible for the management of the pharmacy; and every activity thereof which is subject to this chapter shall be under [his] the pharmacist's complete control. All registered pharmacists shall notify the board [of pharmacy] of changes of business address within ten days."

SECTION 12. Section 461-12, Hawaii Revised Statutes, is amended to read as follows:

"**§461-12 Adequate equipment.** Every pharmacy compounding drugs shall be equipped with proper pharmaceutical utensils so that the prescriptions can be properly compounded. The board [of pharmacy] shall by [regulation] rules prescribe the minimum of [such] professional and technical equipment which a pharmacy shall at all times possess, and the list shall include copies of the latest revisions of the United States [pharmacopoeia and the national

formulary,] Pharmacopoeia National Formulary, and all supplements [to them]."

SECTION 13. Section 461-14, Hawaii Revised Statutes, is amended to read as follows:

"**§461-14 Permits for operation of pharmacy.** (a) It shall be unlawful for any person to operate, maintain, open, change location, or establish any pharmacy within the State without first having obtained a permit [so to do] from the board [of pharmacy].

(b) Application for permits shall be made on a form to be prescribed by the board. Separate application shall be made and separate permits issued for each separate place at which is carried on any of the operations for which a permit is required.

(c) On evidence satisfactory to the board[:] a permit shall be issued, provided:

(1) That the pharmacy for which the permit is sought is or will be, in full compliance with [all state drug, narcotic, and poison laws and] this chapter and rules of the board;

(2) That the location and appointments of the pharmacy are such that it can be operated and maintained without endangering the public health or safety; and

(3) That the pharmacy will be under the personal and immediate supervision of a registered pharmacist[, a permit shall be issued].

(d) No application for a permit shall be refused except pursuant to this section and only after notice to the applicant and a full and fair hearing."

SECTION 14. Section 461-16, Hawaii Revised Statutes, is amended to read as follows:

"**§461-16 Fees for permits; renewal.** (a) The board [of pharmacy] shall collect application and permit fees for each permit to operate a pharmacy [or to conduct or engage in the business of preparing, manufacturing, compounding, packing, or repacking any drug,] and a fee for [each permit to conduct a single auction.] the issuance of a permit in accordance with section 461-15(1) or (4).

(b) Permits issued under sections 461-14 and 461-15 shall be conspicuously displayed in the place for which the permit was granted. The permits shall not be transferable, shall expire on December 31 of each odd-numbered year following the date of issuance, and shall be renewed biennially. [A biennial renewal fee for each permit to operate a pharmacy or to conduct or engage in the business of preparing, manufacturing, compounding, packing, or repacking any drug shall be collected by the board.]

(c) The holder of an expired permit 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 15. Section 461-16.5, Hawaii Revised Statutes, is amended to read as follows:

"[ ]§461-16.5[ ] Disposition of fees; establishment of fees by rule. [All fees required by this chapter or rules adopted by the board] Application, examination, license, renewal, temporary license, and pharmacy permit fees required by this chapter, none of which are refundable, shall be as provided in rules adopted by the director of commerce and consumer affairs pursuant to chapter 91. All fees [required by this chapter] shall be paid to the director and shall be deposited with the director of finance to the credit of the general fund."

SECTION 16. Section 461-18, Hawaii Revised Statutes, is amended to read as follows:

"**§461-18 Right of injunction.** The [board of pharmacy] department may, in addition to [the remedy set forth in section 461-17,] any other remedies available, apply to a court having competent jurisdiction [over the parties and subject matter] for an injunction to restrain [violations] any violation of this chapter."

SECTION 17. Statutory material to be repealed is bracketed. New statutory material is underscored.[1]

SECTION 18. This Act shall take effect upon its approval.

(Approved May 12, 1986.)

Note

1. Edited pursuant to HRS §23G-16.5.