

CHAPTER 461
PHARMACISTS AND PHARMACY

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

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

"Continuing education courses" means courses approved by the American College of Pharmaceutical Education or continuing medical education courses that serve to improve patient safety and to maintain quality national standards in the prevention of medical errors.

"Cosmetics", which includes "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.

"Credit hours", except as otherwise provided, means the value assigned to sixty minutes of instruction.

"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;
- (2) Articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in human beings or animals;
- (3) Articles (other than food or clothing) intended to affect the structure or any function of the body of human beings or animals; and
- (4) Articles intended for use as a component of any articles specified in paragraph (1), (2), or (3) above; provided that the term "drug" shall not include devices or their components, parts, or accessories, cosmetics, or liquor as defined in section 281-1.

"Emergency contraception" means a drug that:

- (1) Is used postcoitally;
- (2) Prevents pregnancy by delaying ovulation, preventing fertilization of an egg, or preventing implantation of an egg in a uterus; and
- (3) Is approved by the United States Food and Drug Administration.

"Encumbered license" means a license issued by any state or territory of the United States for the practice of pharmacy which is revoked, suspended, or made probationary or conditional by the licensing or registering authority in the respective jurisdiction as a result of disciplinary action.

"Institutional facility" means an organization or facility whose primary purpose is to provide a physical environment for patients to obtain health care services or at-home care services, and that uses the services of an on-site pharmacy, an off-site pharmacy, or a pharmacist contractor at which medication storage is managed by personnel of the facility. "Institutional facility" includes but is not limited to a:

- (1) Hospital;
- (2) Convalescent home;
- (3) Skilled nursing facility;
- (4) Intermediate care facility;
- (5) Extended care facility;
- (6) Rehabilitation center;
- (7) Health maintenance organization clinic;
- (8) Psychiatric center;
- (9) Mental retardation center;
- (10) Penal institution;
- (11) Hospice facility;
- (12) Supervised living group; or
- (13) Prescribed practitioner's office.

"Licensed physician" means a physician or osteopathic physician licensed by the Hawaii medical board pursuant to chapter 453.

"Medical oxygen" means the prescription drug oxygen.

"Medical oxygen distributor" means any person, including a prescription drug wholesale distributor, who distributes or dispenses medical oxygen pursuant to a prescription.

"Multiple dose container" means a multiple unit container for articles intended for parenteral administration only.

"Multiple unit container" means a container that permits withdrawal of successive portions of the contents without changing the strength, quality, or purity of the remaining portion.

"Pharmacy" means every store, shop, or place:

- (1) Where prescription drugs are dispensed or sold at retail, or displayed for sale at retail;
- (2) Where practitioners' prescriptions or drug preparations are compounded;
- (3) That has upon it, displayed within it, or affixed to or used in connection with it, a sign bearing the words "pharmacist", "pharmacy", "apothecary", "drug store", "druggist", "drugs", "medicines", "medicine store", "drug sundries", "remedies", or any words of similar or like import; or
- (4) Where any of the above words or combination of words are used in any advertisement.

The term "pharmacy" shall not include any medical oxygen distributor.

"Practice of pharmacy" means:

- (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 therefore; the responsibility for advising when necessary or where regulated, of therapeutic values, content, hazards, and use of drugs and devices;
- (2) Performing the following procedures or functions 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 physician, 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, 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;
 - (B) Ordering drug therapy related laboratory tests;
 - (C) Initiating emergency contraception oral drug therapy in accordance with a written collaborative agreement approved by the board, between a licensed physician and a pharmacist who has received 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 drugs orally, topically, by intranasal delivery, or by injection, pursuant to the patient's licensed physician's order, 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) Administering immunization orally, by injection, or by intranasal delivery, 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;
- (F) As authorized by a licensed physician's written instructions, initiating or adjusting the drug regimen of a patient pursuant to an order or authorization made by the patient's licensed physician and related to the condition for which the patient has been seen by the licensed physician; provided that the pharmacist shall issue written notification to the patient's licensed physician or enter the appropriate information in an electronic patient record system shared by the licensed physician, within twenty-four hours;
- (G) Transmitting a valid prescription to another pharmacist for the purpose of filling or dispensing; or
- (H) 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.

"Practitioner" means an individual licensed by the State or authorized by the laws of the State to prescribe prescription drugs within the scope of the person's practice.

"Prescription" means an order or formula issued by a practitioner licensed by the State or authorized by the laws of the State to prescribe prescription drugs within the scope of the practitioner's practice, for the compounding or dispensing of drugs or an order or formula issued by an out-of-state practitioner in compliance with chapter 328.

"Prescription drug" means any drug dispensed, distributed, or sold pursuant to a practitioner's order.

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

"Remote dispensing" means the practice of dispensing drugs through the use of trained personnel, telecommunications, and information technologies to patients at a remote dispensing pharmacy.

"Remote dispensing machine" means a device used for dispensing unit-of-use drugs that are acquired pursuant to section 340B of the Public Health Service Act, title 42 United States Code section 256b, that is operated using information technologies and is located in a remote dispensing pharmacy.

"Remote dispensing pharmacy" means the area in an institutional facility, including a federally qualified health center, providing outpatient medical care in any county, by dispensing prescription drugs that are acquired pursuant to section 340B of the Public Health Service Act, title 42 United States Code section 256b, through the use of a remote dispensing machine.

"Remote dispensing technician" means an individual who assists the pharmacist in various activities specific to the remote dispensing pharmacy.

"Responsible pharmacy" means a pharmacy that operates a remote dispensing machine located in this State and holds a valid permit issued by the board pursuant to section 461-14.

"Single dose container" means a single unit container for articles intended for parenteral administration only. A single dose container is labeled as such. Examples of single dose containers include pre-filled syringes, cartridges, fusion sealed containers, and closure-sealed containers when so labeled.

"Single unit container" is one that is designed to hold a quantity of drug product intended for administration as a single dose or a single finished device intended for use promptly after the container is opened. Preferably, the immediate container and the outer container or protective packaging shall be so designed as to show evidence of any tampering with the contents. Each single unit container shall be labeled to indicate the identity, quantity and strength, name of the manufacturer, lot number, and expiration date of the article.

"Single user unit" means any single unit container, single dose container, unit dose container, unit of use container, or multiple unit container provided for the exclusive use by a single patient.

"Unit dose container" means a single unit container for articles intended for administration by other than the parenteral route as a single dose, direct from the container.

"Unit of use container" means one that contains a specific quantity of a drug product and that is intended to be dispensed as such without further modification except for the addition of appropriate labeling. A unit of use container is labeled as such.

§461-2 Board of pharmacy; appointment; qualifications. There shall be a board of pharmacy of seven members.

Five members of the board shall be graduates of a school or college of pharmacy and shall have been licensed as pharmacists and actively engaged in the practice of pharmacy for at least five years prior to their appointment and two shall be public members. Four members of the board shall be residents of the city and county of Honolulu and three shall be residents of counties other than the city and county of Honolulu.

§461-3 Records. The executive secretary, subject to the direction of the board, shall make and keep all records and record books required to be kept by the board and shall furnish the department of health with copies of those records as it requires.

§461-4 REPEALED.

§461-4.5 Powers and duties. (a) In addition to any other powers and duties authorized by law, the board:

- (1) Shall adopt, amend, and repeal rules pursuant to chapter 91, as it deems proper for the purposes of this chapter, Public Law 100-293, and 21 Code of Federal Regulations part 205;

- (2) Shall 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) May require the inspection of any wholesale prescription drug distributor premises in the State to ensure compliance with this chapter and rules adopted under this chapter, or may require an applicant for a pharmacy license to submit a statement that the premises, including but not limited to security and sanitation, are in conformance with the board's requirements and that the applicant possesses the reference materials and technical clinical equipment and supplies as may be specified in rules adopted under this chapter; and
 - (4) May 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 board or the department of health of this State.

§461-5 Qualifications for license. (a) Any applicant for a license as a pharmacist shall submit an application on a form prescribed by the board and shall provide evidence to the board that the applicant:

- (1) Is at least eighteen years of age;
 - (2) Holds a degree from a school or college of pharmacy or department in a university which is recognized and accredited by the American Council of Pharmaceutical Education;
 - (3) Has a minimum of fifteen hundred hours practical experience in any state of the United States in a pharmacy under the supervision of a registered pharmacist. Service and experience in a pharmacy under the supervision of a registered pharmacist as required in this section shall be predominantly related to the selling of drugs, compounding prescriptions, preparing pharmaceutical preparations, and keeping records and making reports required under state and federal statutes. In the event an applicant has no practical experience as required, the applicant may take the examination and upon passing the examination, shall not receive a license until after the fulfillment of the practical experience requirement;
 - (4) Has passed an examination as may be prescribed by the board; and
 - (5) Does not have an encumbered license or a pending disciplinary action or unresolved complaint in the practice of pharmacy in any state or territory of the United States, or if any license has been or is encumbered, the applicant shall provide all information requested by the board.
- (b) Any applicant who is otherwise qualified to apply for a license to practice pharmacy in this State, but who is a graduate of a school or college of pharmacy located outside the United States which has not been recognized by the board as an accredited school, may be deemed to have satisfied the requirement of subsection (a)(2) by providing verification to the board of the applicant's academic record and graduation and by meeting other requirements as the board may establish from time to time. The board shall require the applicant to successfully pass an examination or examinations given or approved by the board to establish proficiency in

English if the school is located outside the United States in a country where the official language is not English, and equivalency of education of the applicant with qualified graduates of a school or college recognized by the board as a prerequisite to taking the licensure examination required by section 461-6.

§461-6 Examination; license. (a) Every applicant for a license as a pharmacist shall meet all qualifications set by the board including, but not limited to, passing all examinations as prescribed by rules of the board. The board shall determine the passing score for each examination.

(b) Every applicant for a license as a pharmacist, except an applicant applying under section 461-8.5, shall apply on a form to be supplied by the board and shall either file the form with the board at least sixty days before the examination, or if taking the examination in another state pursuant to the National Association of Boards of Pharmacy Score Transfer Program, shall file the form no later than ninety days after the examination. Each application shall be accompanied by application and examination fees. The board shall establish the schedule for examinations.

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

(d) An applicant who fails an 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.

§461-7 Temporary license. (a) A registered pharmacist of any state or territory of the United States who does not have an encumbered license or any pending disciplinary action or unresolved complaints in any state or territory of the United States and who is not eligible for licensure by reciprocity under section 461-8.5 may be granted a temporary license by the board; provided that the person shall first pass a jurisprudence examination as required by the board.

(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 remaining 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 licensure examinations are announced; provided that the board may extend any temporary license, upon written request, for good and just cause. Any applicant who fails to take or to pass the next licensure examination shall surrender the temporary license. The board shall receive a fee for the issuance of a temporary license.

§461-8 Renewal of licenses; continuing education requirement. (a) All licenses issued by the board, except temporary licenses issued under section 461-7, shall be renewed biennially on or before December 31 of each odd-numbered year. Failure to pay the biennial fee and, beginning with the renewal for the licensing biennium commencing on January 1, 2008, to satisfy the continuing education requirement on or before December 31 of each odd-numbered year, shall constitute a forfeiture of the license as of the date of expiration.

(b) Any license forfeited pursuant to subsection (a) may be restored within three years upon payment of any penalty fee, the current biennial fees, and the renewal fee for the next biennium, if applicable, upon submission of proof of compliance with the continuing education requirement for the prior biennium, and upon meeting any other requirements specified in rules adopted pursuant to chapter 91.

(c) In the event that the pharmacist has not engaged in the practice of pharmacy in this State or in another state or territory of the United States within the past five years, the board may require the pharmacist to satisfy additional requirements, as specified in rules adopted pursuant to chapter 91, to demonstrate that the pharmacist is competent to practice in this State.

(d) Beginning with the renewal for the licensing biennium commencing on January 1, 2008, and every biennial renewal thereafter, each licensee shall have completed thirty credit hours in continuing education courses within the two-year period preceding the renewal date, regardless of the licensee's initial date of licensure; provided that a licensee who has graduated from an accredited pharmacy school within one year of the licensee's first license renewal period shall not be subject to the continuing education requirement for the first license renewal. The board may extend the deadline for compliance with the continuing education requirement based on any of the following:

- (1) Illness, as certified by a physician or osteopathic physician licensed under chapter 453 or licensed in the jurisdiction in which the licensee was treated;
- (2) Military service under extended active duty with the armed forces of the United States;
- (3) Lack of access to continuing education courses due to the practice of pharmacy in geographically isolated areas; and
- (4) Inability to undertake continuing education due to incapacity, undue hardship, or other extenuating circumstances.

(e) Each licensee shall maintain the licensee's continuing education records. At the time of renewal, each licensee shall certify under oath that the licensee has complied with the continuing education requirement of this section. The board may require a licensee to submit, in addition to the certification, evidence satisfactory to the Board that demonstrates compliance with the continuing education requirement of this section.

(f) The board may conduct random audits to determine compliance with the continuing education requirement. The board shall provide written notice of an audit to a licensee randomly selected for audit. Within sixty days of notification, the licensee shall provide the board with documentation verifying compliance with the continuing education requirement.

§461-8.5 Reciprocity. (a) Any pharmacist who is registered or licensed under the laws of any state or territory of the United States with qualifications for licensure which equal or exceed those of this State, shall be eligible for licensure; provided that:

- (1) The pharmacist possesses a current valid license;
- (2) The pharmacist has practiced as a registered pharmacist for fifteen hundred hours or more within the five years preceding the date of application;
- (3) There is no disciplinary action pending or other unresolved complaints against the pharmacist in any state or territory of the United States;
- (4) The pharmacist does not have an encumbered license or a pending disciplinary action or unresolved complaint in the practice of pharmacy in any state or territory

of the United States, or if any license has been or is encumbered, the pharmacist shall provide any information requested by the board; and

- (5) The laws of the other state or territory grant reciprocal treatment to licensees of this State.

The board may examine these licensees only as to knowledge of this State's statutes and rules.

(b) An applicant applying for licensure pursuant to this section shall provide proof that the standards upon which licensure was granted by another state or territory of the United States are at least equivalent to the licensing standards that were in effect in this State under sections 461-5 and 461-6 at the time licensure in the other state or territory was granted.

(c) An applicant for reciprocity who is unable to demonstrate that licensure was based on standards at least equal to those in sections 461-5 and 461-6, may be issued a temporary license while fulfilling requirements necessary for licensure in this State. The requirements and limitations of a temporary license shall be the same as those under section 461-7.

§461-8.6 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.

§461-9 Pharmacist in charge; pharmacy personnel. (a) A registered pharmacist shall be in personal and immediate charge of the pharmacy and personnel employed in the pharmacy. Temporary absences of the registered pharmacist shall be unlawful except for periods of time and under circumstances as authorized under the rules of the board. 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 those times of things that might be sold were the pharmacy a store not subject to this chapter. No person other than a registered pharmacist or a pharmacy intern under the registered pharmacist's immediate supervision shall fill or compound prescriptions except as provided by subsection (c).

(b) No person shall practice as a pharmacy intern without having first obtained a permit from the board. The board shall adopt rules pursuant to chapter 91 defining the functions of a pharmacy intern, establishing the requirements to be met by an applicant for a pharmacy intern permit, and specifying the duration of the permit and the procedures for the immediate supervision of the pharmacy intern by a registered pharmacist.

(c) 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 the pharmacy technician and provide the procedures for control and supervision by a registered pharmacist.

§461-10 Pharmacies. Any proprietor or manager of a pharmacy who fails or neglects to place a registered pharmacist in charge thereof or who permits the compounding of prescriptions, or the vending of drugs, except by or under the immediate supervision of a registered pharmacist, shall be deemed to have violated this chapter. Any person who, not being a registered pharmacist, compounds prescriptions or vends drugs, while not subject to the immediate supervision of a registered pharmacist, shall be deemed to have violated this chapter.

§461-10.5 Remote dispensing pharmacy; operations. (a) A remote dispensing pharmacy shall be under the direct supervision of the registered pharmacist in charge of the responsible pharmacy who shall:

- (1) Ensure that the remote dispensing pharmacy is in compliance with all laws and rules governing the practice of pharmacy and remote dispensing;
- (2) Ensure that the remote dispensing pharmacy is appropriately staffed by a qualified remote dispensing technician; and
- (3) Be responsible for the integrity of the drugs in the remote dispensing machine and ensure that drugs for the remote dispensing machine are provided to the remote dispensing pharmacy only from the responsible pharmacy.

(b) A remote dispensing pharmacy shall:

- (1) Be effectively secured to prevent unauthorized access at all times and limit entry to authorized personnel only;
- (2) Be connected via live computer link, video link, and audio link to the responsible pharmacy through the information technology system of the responsible pharmacy;
- (3) Conspicuously display at the remote dispensing machine:
 - (A) A copy of the license of the responsible pharmacy; and
 - (B) A copy of the license of the pharmacist in charge of the responsible pharmacy; and
- (4) Have a confidential area available for communication between the patient and the pharmacist at the responsible pharmacy.

(c) No remote dispensing pharmacy shall operate within a five mile radius of any pharmacy as defined under section 461-1; provided that:

- (1) This subsection shall not apply to any remote dispensing pharmacy established prior to July 3, 2008 that has previously dispensed and will continue to dispense only prescription medications acquired pursuant to section 340B of the Public Health Service Act, Title 42 United States Code section 256b;
- (2) If an appropriately designated pharmacy, as defined in section 461-1, is established within a five mile radius of an existing remote dispensing pharmacy exempted by this subsection, all appropriate measures shall be taken to encourage the relocation of the existing remote dispensing machine within the newly established pharmacy; and
- (3) This subsection shall not apply to any remote dispensing pharmacy established in a facility operated by a health maintenance organization regulated pursuant to chapter 432D for the exclusive use of patients served at the facility.

(d) Remote dispensing pharmacies shall not provide medications to patients with health insurance coverage, except for:

- (1) Patients covered by QUEST;
- (2) Patients served at a facility operated by a health maintenance organization regulated pursuant to chapter 432D; or
- (3) Patients residing on an island without a pharmacy or in remote areas without an existing pharmacy within a five mile radius. A remote dispensing pharmacy established pursuant to this subsection may continue to operate in the same location if a pharmacy is subsequently established on the same island as the remote dispensing pharmacy or in the remote area without an existing pharmacy within a

five mile radius; provided that the remote dispensing pharmacy shall no longer be authorized to dispense controlled substances.

(e) The remote dispensing technician shall offer each patient the option of receiving counseling by a pharmacist at the responsible pharmacy for all prescriptions.

(f) A pharmacist at the responsible pharmacy shall approve each prescription before it is dispensed to the patient.

(g) Each remote dispensing machine shall be operated by only one responsible pharmacy. A responsible pharmacy may operate more than one remote dispensing machine.

(h) The remote dispensing machine shall have the following features to ensure that it is appropriately secure at all times and that all transactions are properly documented:

- (1) Secure double-locked cabinets;
 - (2) Bar-coding or similar technology that effectively recognizes the product;
 - (3) A cabinet that delivers only one bar-coded unit-of-use container per dispensation, per prescription;
 - (4) A scanner and printer that, upon releasing the unit-of-use container from the remote dispensing machine, scans the container to confirm it is the correct container, and if confirmed, prints a patient-specific label that has a bar code which is scanned to confirm it is the correct label for the prescription; and
 - (5) A video component that allows the patient to have a "face-to-face" consultation with the pharmacist at the responsible pharmacy.
- (i) A pharmacist shall be in charge of the remote dispensing machine and shall ensure

that:

- (1) Written policies and procedures are developed before the machine is used that:
 - (A) Ensure the safe and effective dispensing of pharmaceutical products;
 - (B) Ensure that the remote dispensing pharmacy and the remote dispensing machine are operating safely, accurately, and securely; and
 - (C) Define the conditions for access to the remote dispensing machine and to medications contained within or associated with the machine, including policies that assign, discontinue, or change access to the remote dispensing machine and medications;
- (2) A pharmacist licensed in this State and employed by the responsible pharmacy has secured access to the drugs in the remote dispensing machine;
- (3) Access to the drugs in the remote dispensing machine complies with state and federal laws, rules, and regulations;
- (4) No prescription drug is dispensed at the remote dispensing pharmacy until a pharmacist at the responsible pharmacy has verified the finished prescription;
- (5) Only one prescription is dispensed and labeled from the remote dispensing machine at a time;
- (6) All prescriptions dispensed have a label affixed to the final drug container that meets the requirements set forth in section 328-16 and includes the address of the remote dispensing pharmacy;
- (7) If a patient refuses the prescription drug at the time it is dispensed, the prescription drug is locked in a secured cabinet;
- (8) There is proper inventory control at the remote dispensing pharmacy and only a registered pharmacist or a remote dispensing technician assigned by the

pharmacist in charge of the responsible pharmacy shall stock the remote dispensing machine;

- (9) A reconciliation of the physical inventory of the remote dispensing pharmacy is conducted at least annually;
- (10) All personnel who operate the remote dispensing machine at the remote dispensing pharmacy are properly trained. Training shall ensure the competence and ability of all personnel who operate any component of the remote dispensing machine and the remote dispensing pharmacy. Documentation of training shall be kept by the responsible pharmacy; and
- (11) The remote dispensing machine is stocked accurately and in accordance with established written policies and procedures. The pharmacist shall check the accuracy of the product supplied for stocking the remote dispensing machine.
 - (j) Controlled substances shall not be dispensed from any remote dispensing machine or remote dispensing pharmacy, except:
 - (1) On islands without a pharmacy, or in remote areas without an existing pharmacy within a five mile radius; and
 - (2) In a facility operated by a health maintenance organization regulated pursuant to chapter 432D for the exclusive use of patients served at the facility.
 - (k) Drugs dispensed from the remote dispensing machine shall be dispensed as packaged, with no changes to the drug, its strength, or its unit quantity, except for the addition of water for reconstitution of dry powder drugs.
 - (l) Prescription labels for the product dispensed from the remote dispensing machine shall only be generated at the remote dispensing pharmacy.
 - (m) Records of prescriptions filled at the remote dispensing pharmacy shall be maintained at the responsible pharmacy and shall be distinguishable from those records filled at the responsible pharmacy. All responsible pharmacies shall maintain, on-site at the remote dispensing pharmacy and have available for inspection at all times, records and documentation of the following:
 - (1) All prescriptions dispensed at the remote dispensing pharmacy;
 - (2) All inventory movement at the remote dispensing pharmacy; and
 - (3) A policies and procedures manual of the remote dispensing pharmacy.
 - (n) No health insurance provider group, hospital, or medical service plan regulated under article 431-10A or 432-1 shall operate a remote dispensing pharmacy.
 - (o) This section shall not apply to:
 - (1) Mobile medical clinics, provided that no such clinic shall operate in counties with a population less than one hundred thousand persons; or
 - (2) Federally qualified health centers, provided that no remote dispensing pharmacy shall operate within a five mile radius of any pharmacy as defined under section 461-1, except for those federally qualified health centers that are exempt under subsection (c) (1).

As used in this subsection, "mobile medical clinic" means a motor vehicle retrofitted for exclusive use as a medical office or clinic for medical services licensed under chapter 321.

§461-11 Duties of registered pharmacist. Every registered pharmacist in charge of a pharmacy shall comply with all laws and rules. The pharmacist shall be responsible for the

management of the pharmacy and every activity thereof which is subject to this chapter shall be under the pharmacist's complete control.

All registered pharmacists shall notify the board of changes of business address within ten days.

§461-11.5 Return of prescription drugs. Prescription drugs previously dispensed or distributed by a pharmacy for administration to patients in an institutional facility by personnel of the institutional facility may be returned to and redispensed or redistributed by the pharmacist if the prescription drug:

- (1) Is in:
 - (A) Its original dispensed, unopened, untampered multiple dose container or unopened, untampered single user unit; or
 - (B) An in-use multiple dose container subject to appropriate safeguards as defined in rules for public health or operational considerations;
- (2) Has remained at all times under the control or direction of a person in the institutional facility or the pharmacy trained and knowledgeable in the storage of drugs, including periods in transit by any carrier for hire or person or entity hired solely to transport prescription drugs;
- (3) Is not adulterated or misbranded;
- (4) Has been stored under conditions meeting United States Pharmacopoeia standards;
- (5) Is returned and redispensed or redistributed before the expiration date or use by date on the multiple dose container or single user unit;
- (6) Has not been in the possession of an individual member of the public; and
- (7) Is not included within the classification of controlled substances, as defined in applicable federal and state laws.

Nothing in this subsection shall be construed to relieve any person from any requirement prescribed by law with respect to drugs included or that may be included within the classification of controlled substances, as defined in applicable federal and state laws. Previously billed returned drugs shall be subject to crediting to the payer pursuant to chapter.

§461-12 Adequate equipment. A pharmacy that compounds drugs shall be equipped with adequate pharmaceutical equipment to ensure the proper compounding of prescriptions. The board shall by rules prescribe the minimum of professional and technical equipment and reference materials that a pharmacy shall at all times possess.

§461-13 Prescription record. A pharmacy shall keep prescription records of each prescription compounded or dispensed at the pharmacy for a period of not less than five years. The prescription records shall at all times be open to inspection by the board of pharmacy and other law enforcement officers.

§461-14 Permits for operation of pharmacy; notification of remote dispensing pharmacy. (a) It shall be unlawful for any person to operate, maintain, open, change location,

or establish any pharmacy or remote dispensing pharmacy within the State without having first obtained a permit or prior notification from the board.

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

(c) On evidence satisfactory to the board, a permit or notification shall be issued; provided that:

- (1) The pharmacy for which the permit or notification is sought is or will be in full compliance with this chapter and rules of the board;
- (2) 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) The pharmacy will be under the personal and immediate supervision of a registered pharmacist.

(d) An application for a permit shall be refused for noncompliance with this section but only after notice to the applicant and a full and fair hearing.

(e) To operate a remote dispensing pharmacy, a responsible pharmacy shall submit to the board the following information:

- (1) A completed form prescribed by the board;
- (2) The name, address, and permit number of the responsible pharmacy;
- (3) The name and license number of the pharmacist in charge of the responsible pharmacy;
- (4) The name of the institutional health care facility and the address of the remote dispensing pharmacy;
- (5) A floor plan of the remote dispensing pharmacy, which shall indicate the space or location of the remote dispensing machine;
- (6) The date the remote dispensing pharmacy will be ready for operations;
- (7) A description of the security system;
- (8) A description of the computer link, video link, and audio link; and
- (9) Photographs of the remote dispensing pharmacy area, including but not limited to the remote dispensing machine, the security system, computer link, video link, audio link, confidential-communications area, and locked cabinet.

A remote dispensing pharmacy's failure to notify the board in writing within thirty days of any changes to the information described in paragraphs (1) to (9) or failure to comply with this chapter shall be considered a violation of this chapter and shall result in disciplinary action against the pharmacist in charge and the responsible pharmacy.

(f) Permits and licenses issued under this section and section 461-15 may be closed upon written request from the holder of the permit or license. The board shall approve all requests by the holder for closure of a permit or license. Once the closure is approved, the holder of the closed permit or license shall be required to reapply as a new applicant to conduct business where a permit or license is required.

§461-15 Miscellaneous permits. (a) It shall be unlawful:

- (1) For any person to sell or offer for sale at public auction, or to sell or offer for sale at private sale in a place where public auctions are conducted, any prescription drugs without first obtaining a permit from the board of pharmacy to do so;
 - (2) For any person to distribute or dispense samples of any prescription drugs without first obtaining a permit from the board to do so; provided that nothing in this paragraph shall interfere with the furnishing of samples or drugs directly to physicians, druggists, dentists, veterinarians and optometrists for use in their professional practice;
 - (3) For wholesalers to sell, distribute, or dispense any prescription drug, except to a pharmacist, physician, dentist, veterinarian, or optometrist who is allowed to use pharmaceutical agents under chapter 459 or to a generally recognized industrial, agricultural, manufacturing, or scientific user of drugs for professional or business purposes; provided that it shall be unlawful for wholesalers to sell, distribute, or dispense any prescription pharmaceutical agent that is not approved by the board examiners in optometry;
 - (4) For any wholesale prescription drug distributor to sell or distribute medical oxygen except to a:
 - (A) Licensed practitioner with prescriptive authority;
 - (B) Pharmacist;
 - (C) Medical oxygen distributor;
 - (D) Patient or a patient's agent pursuant to a prescription; or
 - (E) Emergency medical services for administration by trained personnel for oxygen deficiency and resuscitation;
 - (5) For any medical oxygen distributor to supply medical oxygen pursuant to a prescription order, to a patient or a patient's agent, without first obtaining a permit from the board to do so; and
 - (6) For any person, as principal or agent, to conduct or engage in the business of preparing, manufacturing, compounding, packing, or repacking any drug without first obtaining a permit from the board to do so; and
 - (7) For any out-of-state pharmacy or entity engaging in the practice of pharmacy, in any manner to distribute, ship, mail, or deliver prescription drugs or devices into the State without first obtaining a permit from the board; provided that the applicant shall:
 - (A) Provide the location, names, and titles of all principal corporate officers;
 - (B) Attest that the applicant or any personnel of the applicant has not been found in violation of any state or federal drug laws, including the illegal use of drugs or improper distribution of drugs;
 - (C) Submit verification of a valid unexpired license, permit, or registration in good standing to conduct the pharmacy in compliance with the laws of the home state and agree to maintain in good standing the license, permit, or registration; and
 - (D) Have in its employ a registered pharmacist whose registration is current and in good standing.
- (b) A person whose application for a permit has been denied may file an administrative hearing in conformity with chapter 91.

§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(a)(1), (5), (6) and (7).

(b) Permits issued under sections 461-14 and 461-15 and licenses issued under section 461-8.6 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; provided that in the case of an expired permit, the holder of the expired permit meets the requirements for the renewal of permits.

§461-16.5 REPEALED.

§461-17 Penalties. Any person violating this chapter or the rules duly prescribed by the board of pharmacy shall be fined not more than \$500, or imprisoned not more than six months, or both.

§461-18 Right of injunction. The department may, in addition to any other remedies available, apply to a court having competent jurisdiction for an injunction to restrain any violation of this chapter.

§461-19 Application of law. This chapter shall not apply to any practitioner legally licensed by the State or authorized by the laws of the State to prescribe prescription drugs within the scope of the practitioner's practice when the practitioner is handling drugs in the course of the practitioner's professional duties or prohibit the practitioner from personally supplying the practitioner's own patients with such prescription drugs if the prescription drugs fall within the practitioner's scope of authorized practice.

§461-20 Poison law not amended. Nothing in this chapter amends chapter 330.

§461-21 Disciplinary action. (a) In addition to any other actions authorized by law, 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 cause authorized by law, including but not limited to the following:

- (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, including a false certification of compliance with the continuing education requirement; or
 - (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.

[§461-22] 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.