

HAWAII ADMINISTRATIVE RULES

TITLE 16

DEPARTMENT OF COMMERCE AND CONSUMER AFFAIRS

CHAPTER 95

PHARMACISTS AND PHARMACIES

Subchapter 1 General Provisions

§16-95-1	Objective; scope
§16-95-2	Definitions
§16-95-3	Repealed
§16-95-4	Repealed
§16-95-5	Repealed
§16-95-6	Repealed
§16-95-7	Repealed
§16-95-8	Repealed
§16-95-9	Repealed
§16-95-10	Repealed
§16-95-11	Repealed
§16-95-12	Repealed
§16-95-13	Repealed
§16-95-14	Display of license or permit
§16-95-15	Repealed
§16-95-16	Repealed
§16-95-17	Repealed
§16-95-18	License or permit required
§16-95-19	License or permit nontransferable

Subchapter 2 Applications

§16-95-21	Forms, documentation, and notification
§16-95-22	Application and requirements for pharmacist license by examination
§16-95-22.5	Application and requirements for pharmacist license by reciprocity

- §16-95-23 Temporary license
- §16-95-24 Pharmacist assistant permit
- §16-95-25 Repealed
- §16-95-26 Pharmacy permit
- §16-95-27 Repealed
- §16-95-28 Repealed
- §16-95-29 Repealed
- §16-95-30 Wholesale prescription drug distributor license requirements
- §16-95-31 Miscellaneous permit
- §16-95-32 Criminal conviction
- §16-95-32.2 Denial or rejection of application

Subchapter 3 Education and Experience Documentation

- §16-95-33 Education documentation for a pharmacist license
- §16-95-33.2 Education documentation for a pharmacist assistant permit
- §16-95-34 Experience verification for a pharmacist by examination
- §16-95-35 Repealed
- §16-95-36 Experience verification for a pharmacist by reciprocity

Subchapter 4 Repealed

- §16-95-39 Repealed
- §16-95-40 Repealed
- §16-95-41 Repealed
- §16-95-42 Repealed
- §16-95-43 Repealed

Subchapter 5 Repealed

- §16-95-44 Repealed
- §16-95-45 Repealed
- §16-95-46 Repealed
- §16-95-47 Repealed
- §16-95-48 Repealed
- §16-95-49 Repealed
- §16-95-50 Repealed

Subchapter 6 Repealed

§16-95-51	Repealed
§16-95-52	Repealed
§16-95-53	Repealed
§16-95-54	Repealed

Subchapter 7 Repealed

§16-95-55	Repealed
§16-95-56	Repealed
§16-95-57	Repealed
§16-95-58	Repealed
§16-95-59	Repealed
§16-95-60	Repealed
§16-95-61	Repealed
§16-95-62	Repealed
§16-95-63	Repealed
§16-95-64	Repealed

Subchapter 8 Repealed

§16-95-65	Repealed
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Subchapter 9 Renewal

§16-95-70	Notice of renewal
§16-95-71	Date for filing
§16-95-72	Automatic forfeiture for failing to renew
§16-95-73	Restoration of forfeited license or permit
§16-95-74	Board may refuse to renew or restore

Subchapter 10 Scope of Practice

§16-95-79	Supervision by a registered pharmacist
§16-95-80	Physical presence of a registered pharmacist
§16-95-81	Emergency kits
§16-95-82	Valid prescriptions
§16-95-83	Substitution; drug product selection
§16-95-84	Transfer of prescriptions

- §16-95-85 Reserved
- §16-95-86 Scope of a pharmacy technician
- §16-95-87 Return or exchange of drugs prohibited

Subchapter 11 Record Keeping Requirements

- §16-95-93 Records of dispensing
- §16-95-94 Automated data processing systems
- §16-95-95 Security of records
- §16-95-96 Record keeping for wholesale prescription drug distributors

Subchapter 12 Advertising Practices

- §16-95-101 Procedures to advertise prescription drugs
- §16-95-102 Procedures to advertise related pharmacy services
- §16-95-103 Advertising of controlled substances prohibited

Subchapter 13 Disciplinary Sanctions, Application Denial, Hearings, Administrative Practice and Procedure

- §16-95-110 Grounds for revocation, suspension, refusal to renew or restore,
denial, or conditioning of license or permit
- §16-95-111 Denial
- §16-95-112 Demand for hearing; proceedings upon demand for hearing
- §16-95-113 Administrative practice and procedure

Subchapter 14 Oral Testimony

- §16-95-118 Oral testimony

Subchapter 15 Fees

- §16-95-123 Fees established
- §16-95-124 Form of fee
- §16-95-125 Dishonored checks considered failure to meet requirements

Subchapter 16 Emergency Contraception Collaborative Agreement

- §16-95-130 Emergency contraception written collaborative agreement

SUBCHAPTER 1

GENERAL PROVISIONS

§16-95-1 Objective; scope. This chapter is intended to clarify and implement chapter 461, Hawaii Revised Statutes, to the end that the provisions thereunder may be best effectuated and the public interest and welfare most effectively served and protected. Other requirements of state or federal law, including the laws enforced by the state department of health and department of public safety, which also may be applicable to the practice of pharmacy or to licensees or permittees under chapter 461, are not encompassed within the scope of this chapter. [Eff 5/16/64; am and ren §16-95-1, 6/22/81; am and comp 12/24/92; comp 12/25/04] (Auth: HRS §461-4.5) (Imp: HRS §461-4.5, Act 196, SLH 1992)

§16-95-2 Definitions. As used in this chapter unless the context clearly indicates otherwise:

"Automated data processing system" or "ADP system" means a system utilizing computer software and hardware for the purpose of record keeping.

"Department" means the department of commerce and consumer affairs.

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

"Dispense" or "dispensing" means the furnishing of drugs pursuant to a prescription in a suitable container, appropriately labeled for subsequent administration to, or use by, a patient or other individual entitled to receive the drug.

"Immediate supervision" means that a registered pharmacist is physically present in the area or location, and performs a final assessment of each ingredient and quantity used and the prescription label to insure the correctness and accuracy thereof.

"Institutional facility" includes a:

- (1) Hospital;
- (2) Convalescent home;
- (3) Nursing home;
- (4) Extended care facility;
- (5) Mental institution;
- (6) Rehabilitation center;
- (7) Health maintenance organization;
- (8) Psychiatric center;
- (9) Mental retardation center;

- (10) Penal institution; or
- (11) Any other organization whose primary purpose is to provide a physical environment for patients to obtain health care services or at-home care services, except those places where physicians, dentists, veterinarians, osteopaths, podiatrists, or other prescribers who are duly licensed, engage in private practice.

"Institutional pharmacy" means a pharmacy providing services to an institutional facility.

"Pharmacist assistant" means a student or graduate of a school or college of pharmacy issued a permit by the board to work under the immediate supervision of a registered pharmacist.

"Pharmacy technician" means a nonlicensed individual, other than a pharmacy assistant, who assists the pharmacist in various activities under the immediate supervision of a registered pharmacist.

"Prescriber" means a licensed practitioner of medicine, osteopathy, podiatry, dentistry, or veterinary medicine, holding a current and valid license by the proper authority to prescribe drugs.

"Prescription" means a written, facsimile, or telephone order from a prescriber for dispensation of a drug. A telephone order from a prescriber or the prescriber's authorized agent, shall only be valid if the order is immediately reduced to writing by the pharmacist. Prescription also includes an order written in the chart of a patient in an institutional facility by a prescriber.

"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; for purposes of this section, "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, working rights by contract, or otherwise;

- (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 section, "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 percent 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. For purposes of this section, "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; or
- (8) The sale, purchase, or trade of blood and blood components intended for transfusion. For purposes of this section, "blood" means whole blood collected from a single donor and processed either for transfusion or further manufacturing; and "blood component" means that part of blood separated by physical or mechanical means.

"Wholesale distributor" means any person or entity in this State engaged in wholesale distribution of prescription drugs, including, but not limited to, manufacturers; repackers; own label distributors; private label distributors; jobbers; 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. For purposes of this section, "manufacturer" means anyone who is engaged in

§16-95-2

manufacturing, preparing, propagating, compounding, processing, packaging, repackaging, or labeling of a prescription drug; and "prescription drug" means any human drug required by federal law or regulation to be dispensed only by a prescription, including finished dosage forms and active ingredients subject to section 503(b) of the Federal Food, Drug, and Cosmetic Act. [Eff 5/16/64; am 8/7/70; am and ren §16-95-2, 6/22/81; am and comp 12/24/92; comp 12/25/04] (Auth: HRS §461-4.5) (Imp: HRS §461-4.5, Act 196, SLH 1992)

§16-95-3 Repealed. [R 12/24/92]

§16-95-4 Repealed. [R 12/24/92]

§16-95-5 Repealed. [R 12/24/92]

§16-95-6 Repealed. [R 12/24/92]

§16-95-7 Repealed. [R 12/24/92]

§16-95-8 Repealed. [R 12/24/92]

§16-95-9 Repealed. [R 12/24/92]

§16-95-10 Repealed. [R 12/24/92]

§16-95-11 Repealed. [R 12/24/92]

§16-95-12 Repealed. [R 12/24/92]

§16-95-13 Repealed. [R 12/24/92]

§16-95-14 Display of license or permit. The license or permit, together with evidence of current validation, shall be conspicuously displayed in the place of business and the holder of a license shall have the holder's license or evidence of current validation in the holder's possession at all times, provided that a relief pharmacist shall not be required to display a license or permit. [Eff 5/16/64; am and ren §16-95-14, 6/22/81; am and comp 12/24/92; comp 12/25/04] (Auth: HRS §§461-4, 461-9, 461-16) (Imp: HRS §§461-4, 461-9, 461-16)

§16-95-15 Repealed. [R 12/24/92]

§16-95-16 Repealed. [R 12/24/92]

§16-95-17 Repealed. [R 12/24/92]

§16-95-18 License or permit required. It shall be unlawful for a person who is not licensed or who has not been issued a permit under chapter 461, HRS, and this chapter to engage in the practice of a pharmacist, to perform the duties of a pharmacist assistant, to operate a pharmacy, to engage in the wholesale distribution of drugs, or to engage in any activities requiring a miscellaneous permit. [Eff and comp 12/24/92; comp 12/25/04] (Auth: HRS §461-4.5) (Imp: HRS §§461-4.5, 461-10, Act 196, SLH 1992)

§16-95-19 License or permit nontransferable. Any license or permit issued by the board shall be valid only in the name issued and shall not be transferable. [Eff and comp 12/24/92; comp 12/25/04] (Auth: HRS §461-4.5) (Imp: HRS §461-4.5)

SUBCHAPTER 2

APPLICATIONS

§16-95-21 Forms, documentation, and notification. (a) An application for license or permit shall be made under oath on forms provided by the board and shall not be considered complete unless accompanied with the required documentation and fees. It shall be each applicant's responsibility to furnish all information and any documentation requested by the board.

(b) The application form may require the applicant and any personnel of the applicant to provide the following:

- (1) The applicant's full name;
- (2) A statement that the applicant has attained the age of majority;
- (3) The applicant's current business or mailing address for publication, and the applicant's current residence address;
- (4) The applicant's social security number;
- (5) The applicant's educational history and evidence of the education;
- (6) The date and place of any conviction of a crime directly related to the practice of pharmacy, drugs, drug samples, wholesale or retail drug distribution, or distribution of controlled substances, unless the conviction has been expunged or annulled or is otherwise precluded from consideration by section 831-3.1, HRS;
- (7) The state(s) or United States territory in which the applicant is currently licensed, and any information regarding any disciplinary proceedings pending or disciplinary actions taken by any state or jurisdiction against the license;
- (8) A photograph of the applicant for identification purposes;
- (9) A statement that the applicant is a United States citizen or an alien authorized to work in the United States;
- (10) The names, addresses, phone numbers, and social security numbers of corporate officers or partners or other personnel of the applicant;
- (11) Verification that the corporation, partnership, or entity is properly registered with the business registration division of the department of commerce and consumer affairs;
- (12) Verification that the trade name, if any, is properly registered with the business registration division of the department of commerce and consumer affairs;

- (13) The name and license number of the pharmacist in charge of the prescription area and the name(s) and license number(s) of any other pharmacists employed;
 - (14) The name, position, and title of any person responsible for the distribution of drugs; and
 - (15) Any other information the board may require to investigate the applicant's qualifications for license or permit.
- (c) Any requirement that the board provide notice to licensees or permittees shall be deemed met if notice is sent to the address on file with the board.
- (d) Any change in the application or of any information filed with the board shall be reported to the board, in writing, within ten days of the change. [Eff 5/16/64; am and ren §16-95-21, 6/22/81; am and comp 12/24/92; comp 12/25/04] (Auth: HRS §461-4.5) (Imp: HRS §§461-4.5, 461-5, 461-6, 461-7, 461-14, 461-15, Act 196 SLH 1992)

Historical note: The substance of this section is based in part upon sections 16-95-13 and 16-95-35. [Eff 5/12/64; am and ren §§16-95-13, 16-95-35, 6/22/81; R 12/24/92]

§16-95-22 Application and requirements for pharmacist license by examination. (a) An application for license by examination shall be filed at least sixty days before the examination date and must be accompanied by the required application fee which shall not be refunded and by the examination fee. An examination fee may be refunded provided a written request for refund is made prior to the application deadline.

- (b) An applicant shall:
 - (1) Have attained the age of majority; and
 - (2) Hold a degree from a school or college of pharmacy which has received candidate status with or has been accredited by the American Council on Pharmaceutical Education (ACPE);
- (c) For issuance of the license, the applicant shall provide evidence of:
 - (1) At least two thousand hours of practical experience; and
 - (2) Passage of the National Association of Boards of Pharmacy Licensing Examination (NABPLEX), the Federal Drug Law Examination (FDLE), and a state jurisprudence examination by a passing score of at least seventy-five points.

§16-95-22

(d) An applicant who is a participant in the National Association of Boards of Pharmacy (NABP) score transfer program shall be responsible for having the score report sent to the board.

(e) A foreign graduate, in addition to the above and in lieu of the candidacy or accreditation requirements by the ACPE in (b)(2), shall provide verification of passing the following:

- (1) The Foreign Pharmacy Graduate Equivalency Examination (FPGEE);
- (2) The Test of English as a Foreign Language (TOEFL); and
- (3) The Test of Spoken English (TSE). [Eff 5/16/64; am 3/16/80; am and ren §16-95-22, 6/22/81; am and comp 12/24/92; comp 12/25/04] (Auth: HRS §461-4.5) (Imp: HRS §§461-5, 461-6)

§16-95-22.5 Application and requirements for pharmacist license by reciprocity. (a) An application for license by reciprocity shall be filed on forms provided by the board. The applicant shall submit:

- (1) Evidence of current and valid licensure to practice pharmacy in another state or jurisdiction with qualifications which equal or exceed those of this State;
- (2) Information regarding any disciplinary action taken or any unresolved complaints pending against the applicant;
- (3) Evidence of having practiced for at least two thousand hours as a licensed pharmacist within the five years preceding the date of application; and
- (4) A completed official NABP licensure transfer application within ninety days from the date of issuance by the NABP, unless extended by the NABP.

(b) The board shall not issue a license by reciprocity unless the other state or jurisdiction grants reciprocal licensure to this state's licensees.

(c) The board may deny licensure by reciprocity if the applicant has had any disciplinary action taken or if any unresolved complaints are pending. [Eff and comp 12/24/92; comp 12/25/04] (Auth: HRS §461-4.5) (Imp: HRS §461-8.5)

§16-95-23 Temporary license. (a) An application for temporary license may be filed at the same time as an application for examination and shall be accompanied by the required application fee which shall not be refunded and an

examination fee. Following a determination by the board that the qualifications for admission to the examinations listed in §461-6 exist, a temporary license to practice pharmacy may be issued, provided the applicant:

- (1) Passes the state jurisprudence examination with a score of not less than seventy-five points;
- (2) Submits a photocopy of a current and valid license to practice pharmacy in the other state or jurisdiction; and
- (3) Submits evidence that the applicant has practiced for at least two thousand hours as a licensed pharmacist within the five years preceding the date of application.

(b) The temporary license shall be valid only until the results of the next administration of the NABPLEX and FDLE examinations are received by the board.

(c) In the event the pharmacist fails to take and pass the examinations, the temporary license may be extended, for good and just cause, provided a request for extension is made in writing. In no case shall the temporary license be extended beyond three consecutive administrations of the examinations. [Eff 5/16/64; am 3/16/80; am and ren §16-95-23, 6/22/81; am and comp 12/24/92; comp 12/25/04] (Auth: HRS §§461-4.5, 461-7) (Imp: HRS §§461-4.5, 461-7)

§16-95-24 Pharmacist assistant permit. (a) An application for a permit to work as an assistant to a pharmacist may be filed at any time. The board may delegate to the board's executive secretary the authority to issue a pharmacist assistant permit to qualified applicants.

(b) An applicant shall provide verification that the applicant has satisfactorily completed at least one year of instruction in a college of pharmacy and is currently enrolled in or is a graduate of a college of pharmacy which has received candidate status with or has been accredited by the ACPE.

(c) A copy of the applicant's diploma or official transcript showing the date of graduation or a letter from the dean or registrar that the applicant has completed the first year of school at a college of pharmacy shall be submitted with the application.

(d) The applicant shall provide the name and license number of the supervising pharmacist and the name and address of the pharmacy at which the applicant is employed or will be employed. [Eff 5/16/64; am and ren §16-95-24, 6/22/81; am and comp 12/24/92; comp 12/25/04] (Auth: HRS §461-4.5) (Imp: HRS §§461-4.5, 461-5, 461-9)

§16-95-24

Historical note: The substance of this section is based substantially upon §16-95-44 and §16-95-45. [Eff 5/16/64; am 8/7/70; am 6/11/77; am and ren §§16-95-44, 16-95-45, 6/22/81; R 12/24/92]

§16-95-25 Repealed. [R 12/24/92]

§16-95-26 Pharmacy permit. (a) An application for a pharmacy permit shall be filed in duplicate at least fifteen days before a board meeting and must be accompanied by the application fee which shall not be refunded.

(b) The application shall include:

- (1) A floor plan of the prescription area which shall diagram the space and location of fixtures such as counters, tables, drawers, shelves, storage cabinets including a locked cabinet, library, sink with hot and cold water, proper sewage outlet, and refrigeration storage equipment;
- (2) The date the pharmacy will be ready for inspection;
- (3) The name and license number of the pharmacist in charge and any other pharmacists employed;
- (4) A letter of verification that the pharmacy has been bought with the effective date of sale if the pharmacy was purchased;
- (5) Evidence that the entity is currently registered with the business registration division (BREG), department of commerce and consumer affairs. If a corporation or partnership has been registered for more than one year, a "Certificate of Good Standing" or "Certificate of Qualification" shall be attached. If a corporation or partnership has been registered for less than one year, a "file-stamped" copy of the document filed with BREG shall be attached; and
- (6) Evidence that the trade name, if any, is properly registered with the business registration division, department of commerce and consumer affairs.

(c) A permit shall not be issued prior to an inspection report by the regulated industries complaints office (RICO) of the department of commerce and consumer affairs which indicates that the applicant has the minimum reference materials and technical clinical equipment and supplies.

- (1) The minimum reference materials that a pharmacy shall possess are as follows:

- (A) United States Pharmacopeia National Formulary, and all supplements;
 - (B) Federal Drug Enforcement Agency Regulations;
 - (C) State uniform controlled substances laws, Hawaii Revised Statutes, chapter 329, and Hawaii Administrative Rules, chapter 11-32;
 - (D) State food and drug laws, Hawaii Revised Statutes, chapter 328;
 - (E) State pharmacy law, Hawaii Revised Statutes, chapter 461, and Hawaii Administrative Rules, chapter 16-95; and
 - (F) Prescription files.
- (2) The minimum technical equipment and supplies that a pharmacy shall possess are as follows:
- (A) Class A prescription balance or a balance of greater sensitivity and appropriate weights;
 - (B) Mortar and pestle (glass or porcelain);
 - (C) Refrigerator;
 - (D) Bottles and vials of assorted sizes;
 - (E) Graduates or other similar measuring device; and
 - (F) Prescription labels.
- (d) No permit shall be issued unless all deficiencies have been corrected and approved by the board.
- (e) The board may delegate to its executive secretary the authority to issue a permit upon receipt of the inspection report from RICO verifying that all requirements have been met. [Eff 5/16/64; am and ren §16-95-26, 6/22/81; am and comp 12/24/92; comp 12/25/04] (Auth: HRS §461-4.5) (Imp: HRS §§461-4.5, 461-12, 461-14)

Historical note: The substance of this section is substantially based upon section 16-95-51. [Eff 5/16/64; am 6/11/77; am and ren §16-95-51, 6/22/81; R 12/24/92]

§16-95-27 Repealed. [R 12/24/92]

§16-95-28 Repealed. [R 12/24/92]

§16-95-29 Repealed. [R 12/24/92]

§16-95-30 Wholesale prescription drug distributor license requirements.

(a) Application for a wholesale prescription drug distributor license shall be made under oath on a form to be provided by the board. In addition to providing information required by §16-95-21(b), the applicant shall provide the following information as it pertains to the applicant including any officer, director, manager, or other persons in charge of wholesale drug distribution, storage, or handling:

- (1) Any convictions under any federal, state, or local laws relating to drug samples, wholesale or retail drug distribution, or distribution of controlled substances;
- (2) Any felony conviction under federal, state, or local laws;
- (3) Each person's past experience in the manufacture or distribution of prescription and controlled drugs;
- (4) Any suspension or revocation by any federal, state, or local government of any license currently or previously held for the manufacture or distribution of any drugs, including controlled substances;
- (5) Verification of at least one year of experience in the distribution or handling of prescription drugs for any person responsible for the distribution of drugs; and
- (6) A current list 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.

(b) A map of the facilities shall also be submitted. The map shall identify:

- (1) The storage area for drugs;
- (2) The storage area for quarantined drugs; and
- (3) The placement of the lighting, ventilation, and temperature control equipment.

(c) No license shall be issued prior to receipt of a satisfactory inspection report from the department of health. At a minimum, the department of health shall insure that:

- (1) The facilities are of suitable size and construction to facilitate cleaning, maintenance, and proper operations;
- (2) The storage areas are designed to provide adequate ventilation, temperature, sanitation, humidity, space, equipment, and security conditions;
- (3) A quarantine area is available for prescription drugs that are outdated, damaged, deteriorated, misbranded, or adulterated, or

whose immediate or sealed outer or sealed secondary containers have been opened;

- (4) The facility is maintained in a clean and orderly fashion;
- (5) The facility is free from infestation by insects, rodents, birds, or vermin of any kind;
- (6) The facility is secure from unauthorized entry;
- (7) Access from outside the premises is kept to a minimum and well controlled;
- (8) The outside perimeter of the premises is well-lighted;
- (9) Entry into areas where prescription drugs are held is limited to authorized personnel;
- (10) The facilities are equipped with an alarm system to detect entry after hours;
- (11) The facilities are equipped with a security system that will provide suitable protection against theft and diversion;
- (12) All prescription drugs are stored at appropriate temperatures and under appropriate conditions in accordance with 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 by the state department of health.
 - (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;
- (13) Upon receipt, each outside shipping container of prescription drugs is examined visually to confirm the identity of the drugs and to prevent the acceptance of contaminated prescription drugs that are unfit for distribution. This examination shall be adequate to reveal container damage that would suggest possible contamination or other damage to the contents;
- (14) Each outgoing shipment of prescription drugs is 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;

- (15) Returned, damaged, outdated, deteriorated, mishandled, or adulterated prescription drugs are physically separated from other prescription drugs and stored, in such a way that no cross-contamination or confusion is possible, until they are destroyed or returned to the supplier;
 - (16) Any prescription drugs whose immediate or sealed outer or sealed secondary containers are found upon arrival to have been opened or used are identified as such, and are physically separated from other prescription drugs and stored, in such a way that no cross-contamination or confusion is possible, until they are destroyed or returned to the supplier; and
 - (17) 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 is 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) 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 shall be submitted. Written policies and procedures shall include:
- (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 procedures shall be adequate to deal with recalls and withdrawals caused by:
 - (A) Any action initiated at the request of the department of health, 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; and
 - (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. The documentation shall be maintained for five years after disposition of the outdated drugs. [Eff and comp 12/24/92; comp 12/25/04] (Auth: HRS §461-4.5) (Imp: §461-4.5, Act 196, SLH 1992)

§16-95-31 Miscellaneous permit. An application for a miscellaneous permit shall be filed at least fifteen days before a board meeting and must be accompanied by the application fee, which shall not be refunded, and required fees. [Eff and comp 12/24/92; comp 12/25/04] (Auth: HRS §461-4.5) (Imp: HRS §§461-4.5, 461-16)

§16-95-32 Criminal conviction. When an applicant or the applicant's personnel has been convicted of a crime related to the pharmacy profession and it is determined that the conviction may be considered under section 831-3.1, HRS, the board may request the following documents from the applicant:

- (1) Copies of any court records, orders, or other documents that state the facts and statutes upon which the applicant was convicted, the verdict of the court with regard to that conviction, the sentence imposed, and the actual terms of the sentence; and
- (2) Affidavits from any parole officer, employer, or other persons who can attest to a firm belief that the applicant has been sufficiently rehabilitated to warrant the public trust. [Eff and comp 12/24/92; comp 12/25/04] (Auth: HRS §461-4.5) (Imp: HRS §§461-4.5, 461-21)

§16-95-32.2

§16-95-32.2 Denial or rejection of application. (a) An application for issuance of a license or permit shall be denied when an application is insufficient or incomplete; is not accompanied with the required fees; or when an applicant has failed to provide satisfactory proof that the applicant meets the requirements for the license or permit. In addition, the board may deny issuance of a license or permit:

- (1) When the applicant or the applicant's personnel is known to have committed any of the acts for which a license or permit may be suspended or revoked under subchapter 13; or
 - (2) If the applicant has had any disciplinary action taken by any jurisdiction, including any federal or state regulatory body.
- (b) An application shall be automatically rejected and the applicant shall be denied a license or permit when the applicant, after having been notified to do so:
- (1) Fails to pay the appropriate fees within sixty days from notification; or
 - (2) Fails to submit, after notification, any of the information or documentation requested to comply with any of the requirements for licensure or certification within sixty days of notification.
- (c) Any application which has been denied or rejected shall remain in the possession of the board and shall not be returned.
- (d) An applicant, whose application has been denied or rejected, may file for an administrative hearing pursuant to chapter 91, HRS. [Eff and comp 12/24/92; comp 12/25/04] (Auth: HRS §461-4.5) (Imp: HRS §§461-4.5, 461-5, 461-14, 461-15, 461-21)

SUBCHAPTER 3

EDUCATION AND EXPERIENCE DOCUMENTATION

§16-95-33 Education documentation for a pharmacist license. (a) The board will accept the following as verification of education requirements for a pharmacist:

- (1) A photostat or certified copy of a diploma or a certified copy of an official transcript showing the date of graduation from a college of pharmacy which has received candidate status with or has been accredited by the American Council on Pharmaceutical Education (ACPE).

- (2) In lieu of the above, at the time of application, the board will accept a certified letter from the college registrar or dean verifying that the applicant is on track to graduate. However, prior to being allowed to sit for any examination, the applicant shall provide a copy of the diploma or a certified letter from the college registrar that all credits have been completed and that the applicant has graduated and has been conferred a degree.
- (b) The board will accept the following as verification of education requirements from a foreign graduate:
 - (1) A photostat or certified copy of the foreign diploma or a certified copy or official transcript showing the date of graduation from the foreign college of pharmacy; and
 - (2) Photostat or certified copies of the certificates evidencing the passage of the TOEFL, TSE, and the FPGEE examinations. [Eff 5/16/64; am 6/11/77; am and ren §16-95-33, 6/22/81; am and comp 12/24/92; comp 12/25/04] (Auth: HRS §461-4.5) (Imp: HRS §461-5)

§16-95-33.2 Education documentation for a pharmacist assistant permit.

The board will accept the following as verification of education requirements for a pharmacist assistant permit:

- (1) A photostat or certified copy of a diploma or a certified copy of an official transcript showing the date of graduation from a college of pharmacy which has received candidate status with or has been accredited by the ACPE; or
- (2) A verification letter from the college dean or registrar that the applicant has completed the first year of pharmacy school at a school or college which has received candidate status with or has been accredited by the ACPE. [Eff and comp 12/24/92; comp 12/25/04] (Auth: HRS §461-4.5) (Imp: HRS §§461-4.5, 461-5, 461-9)

Historical note: The substance of this section is based substantially upon sections 16-95-44 and 16-95-45. [Eff 5/16/64; am 8/7/70; am 6/11/77; am and ren §§16-95-44, 16-95-45, 6/22/81; R 12/24/92]

§16-95-34 Experience verification for a pharmacist by examination. (a)

The board will accept a notarized statement to verify at least two thousand hours of practical experience under the supervision of a registered pharmacist. Practical experience shall have been acquired subsequent to graduation or completion of the first year's attendance at a school or college of pharmacy which has received candidate status with or has been accredited by the ACPE and may include:

- (1) Post graduate experience;
- (2) Supervised practice during vacations;
- (3) Experience gained concurrent with attendance at a pharmacy school; and
- (4) Experience gained during pharmacy school coordinated externships and clinical clerkship programs.

(A) For purposes of this section, externship means a pharmacy school coordinated practical experience program which was:

- (i) Conducted outside the classroom in licensed pharmacies;
- (ii) Developed to provide a broad experience in all distributive and patient oriented practice tasks;
- (iii) Supervised by a licensed preceptor or licensed pharmacist with a one to one teaching and supervisory relationship between the preceptor or pharmacist and the extern; and
- (iv) A component of the pharmacy school's curriculum for which academic credit is given.

(B) For purposes of this section, clinical clerkship means a pharmacy school coordinated practical experience program which:

- (i) Was conducted in patient care settings where the student is provided with actual experience in patient care;
- (ii) Placed emphasis on all phases of drug therapy relative to the disease states of individual patients;
- (iii) Provided clinical service on either an outpatient or an inpatient basis as a primary student activity;
- (iv) May minimize general drug distributive functions; and
- (v) Is a component of the pharmacy school's curriculum for which academic credit is given.

(b) The board will accept a notarized statement of practical experience signed by a licensed pharmacist who is licensed in any state of the United States attesting that the applicant worked under the direct supervision of the pharmacist in a pharmacy in the United States selling drugs, billing prescriptions, preparing pharmaceutical preparations, and keeping records and making reports required under state and federal statutes. The statement shall also show the beginning and ending dates of the applicant's practical experience and the total number of hours worked.

(c) The board will not accept any pro gratis practical experience hours granted upon graduation for which an applicant has not actually worked. [Eff 5/16/64; am 6/11/77; am and ren §16-95-34, 6/22/81; am and comp 12/24/92; comp 12/25/04] (Auth: HRS §461-4.5) (Imp: HRS §§461-4.5, 461-5)

Historical note: The substance of this section is based substantially upon sections 16-95-44, 16-95-45 and 16-95-47. [Eff 5/16/64; am 8/7/70; am 6/11/77; am and ren §§16-95-44, 16-95-45, 16-95-47, 6/22/81; R 12/24/92]

§16-95-35 Repealed. [R 12/24/92]

§16-95-36 Experience verification for a pharmacist by reciprocity. The board will accept the following to verify two thousand hours of practical experience as a registered pharmacist within five years preceding the date of application:

- (1) A statement signed by an official of the licensing authority attesting that the license is valid and in good standing and a statement signed by the applicant's employer or employers attesting that the applicant has practiced pharmacy as a licensed pharmacist for two thousand hours or more within the five years preceding the date of application; or
- (2) If the applicant is not an employee, a notarized statement by the applicant attesting that the applicant owned and operated an independent pharmacy and that the applicant has practiced pharmacy as a licensed pharmacist for two thousand hours or more within the five years preceding the date of application. [Eff and comp 12/24/92; comp 12/25/04] (Auth: HRS §461-4.5) (Imp: HRS §§461-4.5, 461-5, 461-8.5)

§16-95-39

SUBCHAPTER 4

§16-95-39 Repealed. [R 12/24/92]

§16-95-40 Repealed. [R 12/24/92]

SUBCHAPTER 5

§16-95-44 Repealed. [R 12/24/92]

§16-95-45 Repealed. [R 12/24/92]

§16-95-46 Repealed. [R 12/24/92]

§16-95-47 Repealed. [R 12/24/92]

SUBCHAPTER 6

§16-95-51 Repealed. [R 12/24/92]

SUBCHAPTER 7

§16-95-55 Repealed. [R 12/24/92]

§16-95-56 Repealed. [R 12/24/92]

§16-96-57 Repealed. [R 12/24/92]

§16-95-58 Repealed. [R 12/24/92]

§16-95-59 Repealed. [R 12/24/92]

§16-95-60 Repealed. [R 12/24/92]

§16-95-61 Repealed. [R 12/24/92]

SUBCHAPTER 8

§16-95-65 Repealed. [R 12/24/92]

SUBCHAPTER 9

RENEWAL

§16-95-70 Notice of renewal. All licenses and permits (except the pharmacist assistant permit) shall expire on December 31 of each odd-numbered year. Before November 30 of each odd-numbered year the board's authorized delegate shall mail to every license and permit holder, except those whose license or permit has been forfeited, suspended, or revoked, a renewal application to the address of the license or permit holder on record. [Eff and comp 12/24/92; comp 12/25/04] (Auth: HRS §461-4.5) (Imp: HRS §§461-4.5, 461-8; 461-16, Act 196, SLH 1992)

§16-95-71 Date for filing. All licensees and permit holders shall complete and submit a renewal application together with the required fees on or before December 31 of the odd-numbered year. A completed renewal application with the required fees sent by the United States mail shall be considered timely filed if the envelope bears a postmark no later than December 31 of the odd-numbered year. [Eff and comp 12/24/92; comp 12/25/04] (Auth: HRS §461-4.5) (Imp: HRS §§461-8, 461-16)

Historical note: The substance of this section is based in part upon section 16-95-15. [Eff 5/16/64; am and ren §16-95-15, 6/22/81; R 12/24/92]

§16-95-72 Automatic forfeiture for failing to renew. The failure to timely renew the license or permit or to pay the applicable fees or paying fees with a check which is dishonored upon first deposit shall cause the license or permit to be automatically forfeited. [Eff and comp 12/24/92; comp 12/25/04] (Auth: HRS §461-4.5) (Imp: HRS §§461-4.5, 461-8, 461-16, Act 196, SLH 1992)

§16-95-73 Restoration of forfeited license or permit. (a) A pharmacist license which has been forfeited may be restored within three years of the forfeiture provided the applicant:

- (1) Submits a notarized statement from a licensed pharmacist attesting that the applicant has been employed for a minimum of two thousand hours as a pharmacist within the previous five years; or
- (2) If the applicant is licensed out-of-state, a copy of the out-of-state license and a statement signed by the out-of-state licensing official that the out-of-state license is current and in good standing and that the applicant has been employed for a minimum of two thousand hours within the preceding five years;
- (3) Takes and passes the Hawaii state jurisprudence examination; and
- (4) Pays the penalty, current biennial, and renewal fees.

(b) A pharmacy or miscellaneous permit, or a wholesale distributor license which has been forfeited may be restored within three years of the forfeiture provided the applicant:

- (1) Pays all penalty fees, current biennial, and renewal fees; and
- (2) In the case of a pharmacy, passes a pharmacy inspection conducted by the regulated industries complaints office of the department; or
- (3) In the case of a wholesale distributor, passes a facility inspection conducted by the department of health.

(c) The board may deny restoration of a forfeited license or permit against which disciplinary action has been taken since the date of forfeiture of the license or permit, or if the applicant or applicant's personnel has been convicted of any crime directly related to the practice of pharmacy, drugs, drug samples, wholesale or retail drug distribution, or distribution of controlled substances unless the conviction has been expunged or annulled or is otherwise precluded from consideration by chapter 831-3.1, HRS.

(d) A person whose license or permit has been forfeited and who fails to restore the license or permit as provided in this section, shall apply as a new

applicant. [Eff and comp 12/24/92; comp 12/25/04] (Auth: HRS §461-4.5) (Imp: HRS §§461-4.5, 461-8, 461-16)

Historical note: The substance of this section is based substantially upon sections 16-95-16 and 16-95-17. [Eff 5/16/64; am 3/16/80; am and ren §§16-95-16, 16-95-17, 6/22/81; R 12/24/92]

§16-95-74 Board may refuse to renew or restore. (a) The board may refuse to renew or restore a license or permit for failure or refusal of the licensee or permit holder to:

- (1) Properly complete or timely submit the renewal application form and submit all fees and required documentation;
- (2) Meet and maintain the conditions and requirements necessary to qualify for the issuance of the license or permit; and
- (3) Comply with chapter 461, HRS, and this chapter.

(b) An applicant, whose application has not been renewed or restored for the above reasons, may file for an administrative hearing as provided for in subchapter 13. [Eff and comp 12/24/92; comp 12/25/04] (Auth: HRS §461-4.5) (Imp: HRS §461-4.5)

SUBCHAPTER 10

SCOPE OF PRACTICE

§16-95-79 Supervision by a registered pharmacist. (a) A pharmacist shall directly supervise all activities and operations of a pharmacy, and the functions and activities of pharmacist assistants and pharmacy technicians to insure that all functions and activities are performed in accordance with procedures and the scope of a pharmacist assistant or a pharmacy technician and further shall initial all prescriptions filled by pharmacist assistants and pharmacy technicians.

(b) A pharmacist either employed within an institutional facility or providing services to an institutional facility shall be responsible for ensuring that the institutional facility establishes, maintains, and operates in accordance with written policies and procedures as outlined in §16-95-80. [Eff and comp 12/24/92; comp 12/25/04] (Auth: HRS §461-4.5) (Imp: HRS §§461-9, 461-10, 461-11, 461-12, 461-13)

Historical note: The substance of this section is based in part on section 16-95-46. [Eff 5/16/64; am and ren §16-95-46, 6/22/81; R 12/24/92]

§16-95-80 Physical presence of a registered pharmacist. (a) A pharmacist must be physically present during the hours of operation of a prescription area.

(b) At any time a registered pharmacist is not in the prescription area, (except in cases of emergencies), the entire stock of prescription drugs shall be secured from access to unauthorized persons and the means of access shall only be in the possession of the pharmacist.

(c) A pharmacist in an institutional pharmacy shall ensure that written policies and procedures have been established by the institutional facility for provision of drugs to the medical staff and other authorized personnel of the institutional facility by use of night cabinets, and access to the institutional pharmacy and emergency kits when the pharmacist is not in the area. A night cabinet is a cabinet, room, or any other enclosure not located within the prescription area. The written policies and procedures shall provide that a pharmacist shall be "on call" during those periods and shall provide policies and procedures regarding the following:

- (1) Security of the night cabinet to ensure that the night cabinet is sufficiently secured to deny access to unauthorized persons by force or otherwise;
- (2) The development of an inventory listing of all drugs included in the cabinet and the requirement that the pharmacist ensures, at a minimum, that:
 - (A) Drugs available therein are properly labeled;
 - (B) Only prepackaged drugs are available therein in amounts sufficient for immediate therapeutic requirements;
 - (C) A prescription is attached to the inventory list for any drug that was withdrawn from the cabinet;
 - (D) All drugs therein are inventoried no less than once per calendar quarter; and
 - (E) A complete audit of all activity concerning such cabinet is conducted no less than once per month.
- (3) Access to the pharmacy. In the event a drug is not available from floor supplies or night cabinets and the drug is required to treat the immediate needs of a patient whose health would otherwise be jeopardized, the drug may be obtained from the institutional

pharmacy in accordance with this subsection. Authorized personnel may remove drugs therefrom provided:

- (A) The authorized personnel are designated, in writing, by the institutional facility;
 - (B) The authorized personnel have been instructed by the pharmacist of the proper methods of access, and the records and procedures regarding removal of the drugs; and
 - (C) The authorized personnel are required to complete a form which shall include the patient's name and room number, the name of drug, drug strength, dosage, date, time, and the signature of the authorized personnel.
- (4) Use of drugs that have a "stop date." For purposes of this section, "stop date" in an institutional setting is the length of time to administer a medication as indicated on a drug order. In the absence of such a notation, if an order is necessary or advisable to stop the particular drug, a committee of the institutional facility will have determined by policy, the length of time for administration of the drug. [Eff and comp 12/24/92; comp 12/25/04] (Auth: HRS §461-4.5) (Imp: HRS §§461-1, 461-9, 461-10, 461-11, 461-12)

Historical note: The substance of this section is based in part on section 16-95-4. [Eff 5/16/64; am and ren §16-95-4, 6/22/81; R 12/24/92]

§16-95-81 Emergency kits. (a) A pharmacist may provide emergency kits to an institutional facility which does not have an institutional pharmacy to meet the immediate therapeutic needs of patients.

(b) The pharmacist and the medical staff of the institutional facility shall jointly determine the drugs, and quantity, to be included in the emergency kit.

(c) The exterior of emergency kits shall be labeled by the pharmacist to clearly and unmistakably indicate that the kit is an emergency drug kit and that the kit is for use in emergencies only. In addition, the label shall also contain a listing of the drugs contained therein, including name, strength, quantity, and expiration date of the contents, and the name, address, and telephone number of the supplying pharmacist.

§16-95-81

(d) All drugs contained within the emergency kit shall be labeled to identify, at a minimum, the brand or generic name, strength, route, quantity, source, lot number, expiration date, and other information as may be required by the medical staff of the institutional facility to prevent any misunderstanding or risk of harm to the patients of the facility.

(e) On or before the earliest expiration date of any drug contained in the emergency kit, the pharmacist shall replace any expired drugs, relabel, and reseal the kit.

(f) The pharmacist shall ensure that the institutional facility has established written policies and procedures which shall provide, but not be limited to, policies and procedures covering:

- (1) Storage of emergency kits in secured areas which shall be in an environment for preservation of the drugs;
- (2) Procedures to ensure that drugs are removed only pursuant to a valid prescription and recordation of any removal; and
- (3) Procedures to notify the pharmacist within twenty-four hours of any removal of any drug from the emergency kit. [Eff and comp 12/24/92; comp 12/25/04] (Auth: HRS §461-4.5) (Imp: HRS §§461-1, 461-9, 461-10, 461-11, 461-12)

§16-95-82 Valid prescriptions. (a) A pharmacist may fill and dispense prescriptions provided the prescription is valid. A valid prescription shall be legibly written and contain, at the minimum, the following information:

- (1) The date of issuance;
- (2) The original signature of the prescriber;
- (3) The prescriber's name and business address;
- (4) The name, strength, quantity, and directions;
- (5) The name and address of the person for whom the prescription was filled or the name and address of the owner of the animal for which the drug is prescribed (unless the pharmacy filling the prescription has such address on file);
- (6) The room number and route of administration if the patient is in an institutional facility; and
- (7) If refillable, the number of allowable refills.

(b) Except where a written prescription is required by law, a phone order is acceptable from prescribers or their authorized agent provided:

- (1) Only a pharmacist shall receive the oral prescription;
- (2) The oral prescription is promptly reduced to writing and kept on file for five years; and

- (3) The oral prescription contains all of the information required under subsection (a).
- (c) A faxed prescription for a noncontrolled substance is acceptable from prescribers provided the facsimile is sent by the prescriber or the prescriber's authorized agent, and contains all of the information required under subsection (a) and kept on file for five years.
- (d) No prescription which is coded shall be filled or dispensed.
- (e) Any pharmacist shall comply with any applicable state or federal laws or rules governing the validity of prescriptions. [Eff and comp 12/24/92; comp 12/25/04] (Auth: HRS §461-4.5) (Imp: HRS §§461-11, 461-13)

Historical note: §16-95-82 is based in part upon §§16-95-9 and 16-95-10. [Eff 5/16/64; am and ren §§16-95-9, 16-95-10, 6/22/81; R 12/24/92]

§16-95-83 Substitution; drug product selection. (a) It shall be unlawful to dispense a different drug in place of the drug prescribed without the express consent of the person prescribing.

(b) Drug product selection shall comply with Part VI of chapter 328, HRS. [Eff and comp 12/24/92; comp 12/25/04] (Auth: HRS §461-4.5) (Imp: HRS §§461-11, 461-13, 328)

Historical note: §16-95-83 is based substantially upon §16-95-11. [Eff 5/16/64; am and ren §16-95-11, 6/22/81; R 12/24/92]

§16-95-84 Transfer of prescriptions. (a) Transfers of prescription information for the purpose of refill dispensing is permissible between pharmacies provided the pharmacist transferring the prescription provides all information necessary for a valid prescription, and:

- (1) Writes the words "void" and "invalid" on the face of the prescription; and
 - (2) Records on the reverse side of the prescription, the name of the pharmacist receiving the prescription information, the date of transfer, and the name of the pharmacist transferring the prescription.
- (b) The pharmacist receiving the transferred prescription information shall:

§16-95-84

- (1) Write the word "Transfer" on the face of the valid transferred prescription; and
- (2) The name of the pharmacist transferring the prescription as well as the pharmacy's name, location, and original prescription number. [Eff and comp 12/24/92; comp 12/25/04] (Auth: HRS §461-4.5) (Imp: HRS §§461-10, 461-11, 461-13)

§16-95-85 Reserved.

§16-95-86 Scope of a pharmacy technician. A pharmacy technician may perform the following tasks, not requiring professional judgment, under the immediate supervision of a pharmacist:

- (1) Typing of prescription labels, drug packaging, stocking, delivery, record keeping, pricing, documentation of third party reimbursements, and preparing, compounding, storing, and providing medication;
- (2) Mixing drugs with parenteral fluids provided that the pharmacy technician:
 - (A) Has a working knowledge of the pharmaceutical medical terms, abbreviations, and symbols commonly used in the prescribing, dispensing, and charting of medications;
 - (B) Is able to perform the arithmetic calculations required for the usual dosage determination and solution preparation;
 - (C) Has a thorough knowledge and understanding of the pharmacy technician's duties and responsibilities, including standards of ethics governing the practice of pharmacy;
 - (D) Has a working knowledge of drug dosages, route of administration, and dosage forms;
 - (E) Has a working knowledge of the procedures and operations relating to the manufacturing, packaging, and labeling of drug products; and
 - (F) Has a working knowledge of the procedures and operations relating to aseptic compounding and parenteral admixture operations. [Eff and comp 12/24/92; comp 12/25/04] (Auth: HRS §461-4.5) (Imp: HRS §§461-9, 461-10, 461-11)

§16-95-87 Return or exchange of drugs prohibited. No prescription drug shall be accepted for return or exchange after such drug has been taken from the premises where dispensed or sold by prescription. [Eff and comp 12/24/92; comp 12/25/04] (Auth: HRS §461-4.5) (Imp: HRS §461-11)

Historical note: §16-95-87 is substantially identical to section 16-95-12. [Eff 5/15/64; am and ren §16-95-12, 6/22/81; R 12/24/92]

SUBCHAPTER 11

RECORD KEEPING REQUIREMENTS

§16-95-93 Records of dispensing. (a) Records of dispensing for original and refill prescriptions are to be made and kept by pharmacies for five years and shall include, but not be limited to, the following:

- (1) Quantity prescribed and quantity dispensed;
- (2) Date of dispensing;
- (3) Serial number or, if an institution, equivalent control system;
- (4) Identification of the pharmacist responsible for dispensing; and
- (5) Record of refills to date.

(b) An institutional pharmacy will have fulfilled the requirements of this section if the information required by paragraphs (1) to (4) of subsection (a) is kept on accurate patient profiles or medication administration records showing all drugs administered to the patient for five years; and the institutional facility keeps the original patient charts evidencing the prescription orders and medication administration records in the institutional facility's files for at least five years. [Eff and comp 12/24/92; comp 12/25/04] (Auth: HRS §461-4.5) (Imp: HRS §§461-10, 461-11, 461-13)

§16-95-94 Automated data processing systems. As an alternative to procedures set forth in §16-95-93, an automated data processing system may be employed for the record keeping system provided the following conditions have been met:

- (1) The automated data processing (ADP) system shall have the capability of producing hard copy documents of all drug orders of original and refilled prescription information. The hard copy

produced must be of a print size that is readable without the aid of any special device;

- (2) Information to be kept on the ADP system shall include, but not be limited to, the information required in §16-95-82, valid prescriptions, and §16-95-93, records of dispensing;
- (3) The pharmacist responsible for entries into the ADP system shall ensure that the information entered into the computer is accurate and complete;
- (4) The documentation used to satisfy the above requirements shall be provided to the pharmacy within seventy-two hours of the date of dispensing;
- (5) An auxiliary record keeping system shall be established for the documentation of refills in the event the ADP system is inoperative for any reason. The auxiliary system shall insure that all refills are authorized by the original prescription and that the maximum number of refills is not exceeded. When the ADP system is restored to operation, the information regarding drug orders and prescriptions filled and refilled during the inoperative period shall be entered in the ADP system within ninety-six hours;
- (6) Any pharmacy using an ADP system shall comply with all applicable state and federal laws and regulations; and
- (7) A pharmacy shall make arrangements with the supplier of data processing services or materials to assure that the pharmacy continues to have adequate and complete records for any drug order, prescription, and dispensing if the relationship with such supplier terminates for any reason. The pharmacy shall assure continuity in the maintenance of records. [Eff and comp 12/24/92; comp 12/25/04] (Auth: HRS §461-4.5) (Imp: HRS §§461-9, 461-10, 461-11, 461-12, 461-13)

§16-95-95 Security of records. To maintain the confidentiality of patient's prescriptions or drug orders, there shall exist adequate safeguards for security of the records whether kept manually or in an ADP system. [Eff and comp 12/24/92; comp 12/25/04] (Auth: HRS §461-4.5) (Imp: HRS §§461-9, 461-10, 461-11, 461-12, 461-13)

§16-95-96 Record keeping for wholesale prescription drug distributors.

(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) The wholesale distributor shall also maintain records to reflect:

(1) 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.

(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.

(2) Examination of materials.

(A) Documentation that each outside shipping container of prescription drugs was 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 shall be maintained. This examination shall be adequate to reveal container damage that would suggest possible contamination or other damage to the contents.

(B) Documentation that each outgoing shipment of prescription drugs was inspected carefully to confirm the identity of the drugs and to ensure that no prescription drugs were delivered that have been damaged in storage or held under improper conditions shall be maintained

- (3) Returned, damaged, outdated, deteriorated, misbranded, and adulterated prescription drugs.
 - (A) Prescription drugs that are damaged, outdated, deteriorated, misbranded, or adulterated shall be physically separate 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, 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.
- (c) 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.
- (d) 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. [Eff and comp 12/24/92; comp 12/25/04] (Auth: HRS §461-4.5) (Imp: Act 196, SLH 1992)

SUBCHAPTER 12

ADVERTISING PRACTICES

§16-95-101 Procedures to advertise prescription drugs. (a) Advertising of prescription drugs is to provide the public with information in a manner consistent with public health and safety. Prescription drug advertising is for the purpose of providing information and not to create a demand for drugs. A pharmacy, if it chooses to advertise, will advertise prescription prices, drugs, and reference to prescription prices and drugs in accordance with this section:

- (1) A pharmacy may post its prices for prescription drugs on a prescription price poster. The form of such posting shall be legible.
 - (2) A pharmacy may advertise prescription prices by publication or display in any media. For purposes of this section, "media" includes, but is not limited to, newspapers, magazines, calling cards, and directories, including all listings in telephone directories.
 - (3) Any advertisement for prescription drugs shall be made in three commonly prescribed quantities.
 - (4) Any advertisement for prescription drugs shall contain the brand name of that drug.
 - (5) Any advertisement for prescription drugs or prices shall be truthful, reasonable, fully informative, and understandable to the public and shall not be false or misleading.
 - (6) Any advertisement for prescription drugs shall state the time period during which the prices advertised will be effective.
- (b) The price for prescription drugs advertised shall not be below cost as defined in section 481-3, HRS, as amended.
- (c) A pharmacist or the pharmacist's agent upon request however communicated to the pharmacist shall give the current price for any drug sold at the pharmacist's pharmacy for informational purposes only and such price quoted shall not be false or misleading but must be truthful, reasonable, informative, and understandable to the public. [Eff and comp 12/24/92; comp 12/25/04] (Auth: HRS §461-4.5) (Imp: HRS §§461-4.5, 461-21)

Historical note: The substance of this section is substantially identical to sections 16-95-5, 16-95-6 and 16-95-7. [Eff 5/16/64; 9/1/74; am 2/3/78; am and ren §§16-95-5, 16-95-6, 16-95-7, 6/22/81; R 12/24/92]

§16-95-102 Procedures to advertise related pharmacy services.

Advertising of related pharmacy services is to provide the public with information in a manner consistent with public health and safety and shall be truthful, reasonable, fully informative, and understandable to the public and shall not be false or misleading. A pharmacy may advertise that it performs the following services:

- (1) Personal medication record. To qualify as providing this service, a system must be maintained which enables the immediate retrieval of information concerning individual pharmacy patients which is of sufficient scope to enable a determination by the pharmacist of rational drug utilization. In accomplishing this purpose the design and use of the system must be to ascertain and record all patient information necessary to assist the pharmacist in avoiding adverse drug reactions, drug-drug interactions, and inappropriate use of drugs.
- (2) Professional consultation with patient and doctor. The availability of patient consultation means that the pharmacist routinely informs the patient, either directly or indirectly, on what the patient is taking, how to take it, what to expect, what special precautions should be observed, and how the medication is to be properly stored. This service is to assure that the patient understands the proper use of the drug and that the physician's intentions will materialize in a drug regimen of optimal effectiveness, safety, and duration. Doctor or prescriber consultation denotes the availability and practice of pharmacists acting as drug information specialists who discuss with prescribers drug effect, interactions, side effects, and drugs of choice for diseased conditions.
- (3) "Emergency prescription service" means the providing of pharmaceutical services, which includes prescription dispensing, at any time after usual pharmacy hours. This means that a pharmacist is available, can be readily contacted, and will respond with reasonable expediency at any hour, day or night, in a manner consistent with security and personal safety.

Should the pharmacy choose to advertise the performance of the foregoing services, it must conform with the definition of that service as herein

set forth. [Eff and comp 12/24/92; comp 12/25/04] (Auth: HRS §461-4.5) (Imp: HRS §461-4.5)

Historical note: The substance of this section is based substantially on section 16-95-5. [Eff 5/16/64; am 2/3/78; am and ren §16-95-5, 6/22/81; R 12/24/92]

§16-95-103 Advertising of controlled substances prohibited. No person shall advertise or promote to the public in any manner the sale of a Scheduled II, III, IV, or V controlled substance as defined in the Federal Controlled Substances Act and the rules promulgated thereunder as well as any other controlled substances as defined in chapter 329, HRS, as amended, and the rules promulgated thereunder by the state department of health. [Eff and comp 12/24/92; comp 12/25/04] (Auth: HRS §461-4.5) (Imp: HRS §461-4.5)

Historical note: The substance of this section is substantially identical to section 16-95-8. [Eff 9/1/74; am 2/3/78; am and ren §16-95-8, 6/22/81; R 12/24/92]

SUBCHAPTER 13

DISCIPLINARY SANCTIONS, APPLICATION DENIAL, HEARINGS, ADMINISTRATIVE PRACTICE AND PROCEDURE

§16-95-110 Grounds for revocation, suspension, refusal to renew or restore, denial, or conditioning of license or permit. (a) In addition to any other acts or conditions provided by law, the board may revoke, suspend, refuse to renew or restore, deny, or condition a license or permit for any one or more of the following acts or omissions:

- (1) Procuring a license or permit through misrepresentation or deceit;
- (2) Failing to meet or maintain the requirements or conditions necessary to qualify for license or permit;
- (3) Conviction of, or pleading nolo contendere to a crime that is substantially related to the qualification, functions, or duties of a pharmacist;
- (4) Committing any act or omission in the practice of pharmacy or wholesale distribution which constitutes dishonesty, fraud, or misrepresentation with the intent to substantially benefit the pharmacist or wholesale distributor or with the intent to substantially injure another person;

§16-95-110

- (5) Aiding or abetting an unlicensed person to directly or indirectly evade chapter 461, HRS, or this chapter;
- (6) Failing to maintain records or to make accessible any records as required in subchapter 11;
- (7) Violating any provisions of the department of health or department of public safety;
- (8) Accepting returns or exchanges of prescription drugs after such drugs had been taken from the premises where it was dispensed or sold by a prescription;
- (9) Dispensing a different drug or brand in place of the drug or brand prescribed without the express consent of the person prescribing;
- (10) Failing to comply with the state's drug formulary or substitution laws as set forth in part VI of chapter 328, HRS;
- (11) Professional misconduct, gross carelessness, or manifest incapacity;
- (12) Violation of any state or federal drug, controlled substance, or poison law;
- (13) False, fraudulent, or deceptive advertising;
- (14) Making a false statement on any document submitted or required to be filed by this chapter;
- (15) Habitual intemperance or addiction to the use of habit-forming drugs;
- (16) Violating the provisions of chapter 461, HRS, this chapter, or any order of the board.

(b) The board may also fine or impose conditions or limitations upon a license or permit after a hearing conducted in accordance with chapter 91, HRS. The violation of any condition or limitation on a license or permit may be cause to impose additional sanctions against the licensee or permittee. Any fine imposed by the board after a hearing in accordance with chapter 91, HRS, shall be no less than \$100 and no more than \$1,000 for each violation, and each day of violation may be deemed a separate violation. [Eff and comp 12/24/92; comp 12/25/04] (Auth: HRS §461-4.5) (Imp: HRS §§461-4.5, 461-17, 461-21, 461-22, Act 196, SLH 1992)

§16-95-111 Denial. In the event an application for the issuance of a license or permit or for the reinstatement thereof is denied, the board shall notify the applicant by letter of the board's action which shall include a concise

statement of the reasons therefor and a statement informing the applicant of the applicant's right to a hearing if the applicant so desires. [Eff and comp 12/24/92; comp 12/25/04] (Auth: HRS §461-4.5) (Imp: HRS §§461-8, 461-14, 461-21, 461-22)

Historical note: The substance of this section is substantially identical to section 16-95-27. [Eff 5/16/64; am and ren §16-95-27; 6/22/81; R 12/24/92]

§16-95-112 Demand for hearing; proceedings upon demand for hearing.

(a) Any person whose application for a license or permit or whose application for the reinstatement of a license or permit has been denied by the board shall be entitled to a hearing, provided that a demand for a hearing is filed with the board within sixty days of the date of denial of the application.

(b) If a demand for hearing is filed within the time prescribed, the board shall order a hearing in accordance with chapter 91, HRS, relating to contested cases and unless the context otherwise requires, the rules set forth in chapter 16-201, Hawaii Administrative Rules, the rules of practice and procedure of the department. [Eff and comp 12/24/92; comp 12/25/04] (Auth: HRS §461-4.5) (Imp: HRS §§91-9, 91-9.5, 91-10, 91-11, 91-12, 461-4.5, 461-21)

Historical note: The substance of this section is substantially identical to sections 16-95-28 and 16-95-29. [Eff 5/16/64; am and ren §§16-95-28, 16-95-29, 6/22/81; R 12/24/92]

§16-95-113 Administrative practice and procedure. The rules of practice and procedure for pharmacies and pharmacists shall be as provided in chapter 16-201, the rules of practice and procedure of the department as adopted, and as may subsequently be amended, which are incorporated by reference and made a part of this chapter. [Eff and comp 12/24/92; comp 12/25/04] (Auth: HRS §461-4.5) (Imp: HRS §§91-2, 461-4.5)

SUBCHAPTER 14

ORAL TESTIMONY

§16-95-118 Oral testimony. (a) The board shall accept oral testimony on any item which is on the agenda, provided that the testimony shall be subject to the following conditions:

- (1) Each person seeking to present oral testimony is requested to notify the board not later than forty-eight hours before the meeting, and at that time to state the item on which testimony is to be presented;
- (2) The board may request that any person providing oral testimony submit the remarks, or a summary of the remarks, in writing to the board;
- (3) The board may rearrange the items on the agenda for the purpose of providing for the most efficient and convenient presentation of oral testimony;
- (4) Persons presenting oral testimony at the beginning of the testimony shall identify themselves and the organization, if any, that they represent;
- (5) The board may limit oral testimony to a specified time period but in no case shall the period be less than five minutes, and the person testifying shall be informed prior to the commencement of the testimony of the time constraints to be imposed; and
- (6) The board may refuse to hear any testimony which is irrelevant, immaterial, or unduly repetitious to the agenda item on which it is presented.

(b) Nothing in this section shall require the board to hear or receive any oral or documentary evidence from a person on any matter which is the subject of another proceeding pending subject to the hearings relief, declaratory relief, or rule relief provisions of chapter 16-201.

(c) Nothing in this section shall prevent the board from soliciting oral remarks from persons present at the meeting or from inviting persons to make presentations to the board on any particular matter on the board's agenda. [Eff and comp 12/24/92; comp 12/25/04] (Auth: HRS §461-4.5) (Imp: HRS §§92-3, 461-4.5)

SUBCHAPTER 15

FEES

§16-95-123 Fees established. The fees are as established in chapter 16-53. The fees for wholesale prescription drug distributors license shall be the same fees as established for a pharmacy in chapter 16-53. [Eff and comp 12/24/92; comp 12/25/04] (Auth: HRS §461-4.5) (Imp: HRS §§461-4.5, 26-9)

§16-95-124 Form of fee. The fees, if in the form of a money order or check, shall be made payable to the department of commerce and consumer affairs. [Eff and comp 12/24/92; comp 12/25/04] (Auth: HRS §461-4.5) (Imp: HRS §461-4.5)

§16-95-125 Dishonored checks considered failure to meet requirements. The dishonoring of any check upon first deposit shall be considered a failure to meet requirements. [Eff and comp 12/24/92; comp 12/25/04] (Auth: HRS §461-4.5) (Imp: HRS §461-4.5)

SUBCHAPTER 16

EMERGENCY CONTRACEPTION COLLABORATIVE AGREEMENT

§16-95-130 Emergency contraception written collaborative agreement.
(a) Each arrangement between a licensed pharmacist and a licensed physician relating to the distribution to a patient of emergency contraception drugs shall be documented in a signed collaborative agreement in accordance with the form attached hereto as Exhibit "A" and made a part of this chapter. The agreement shall be delivered to the department by the licensed pharmacist within seven days of the execution of the agreement by the pharmacist and the physician.

(b) Before a pharmacist may participate in the collaborative agreement, the pharmacist shall have completed an emergency contraception training course approved by the American Council of Pharmaceutical Education (ACPE), curriculum-based programs from an ACPE-accredited college of pharmacy, applicable state or local health department programs, or programs recognized by the board of pharmacy. Training shall include procedures listed

in Exhibit "A", the management of the sensitive communications often encountered in emergency contraception, providing service to minors, quality assurance, referral for additional services, documentation, and a crisis plan if the pharmacy operations are disrupted by individuals opposing the emergency contraception.

(c) By executing the collaborative agreement, both the physician and pharmacist agree and acknowledge that:

- (1) They accept the responsibility for the distribution of the emergency contraception drugs and that the licensed pharmacist shall dispense only certain drugs approved for emergency contraception by the United States Food and Drug Administration. The currently approved drugs are listed in the attached Exhibit "B" and made a part of this chapter. Plan B®, an oral contraceptive manufactured by Women's Capital Corporation (or generic equivalent), shall be the preferred drug therapy. Other drugs listed in Exhibit "B" may be dispensed instead of Plan B® in the following circumstances:
 - (A) Plan B® is unavailable;
 - (B) Plan B® is not covered under the patient's health insurance plan and another drug listed in Exhibit "B" is covered; or
 - (C) The patient chooses another listed drug after the pharmacist advises the patient that side effects are usually less with Plan B®.

The list of approved drugs in Exhibit "B" also shall include adjunctive drugs for treatment of nausea and vomiting that may be associated with emergency contraceptives;

- (2) The licensed pharmacist shall provide the patient with drug information concerning dosage, potential adverse side effects, and follow-up contraceptive care;
- (3) The collaborative agreement shall be effective for a period of at least two years from the date of its delivery to the department, unless rescinded in writing earlier by either the physician or the pharmacist, with written notice to the other and the department, or unless the pharmacy board invalidates the agreement or changes the terms of the agreement. After the two year period, the agreement shall continue to be valid from month to month unless rescinded, invalidated, or changed as provided herein. The licensed pharmacist or the licensed physician, who rescinds the agreement, shall notify the department within three business days of the rescission. At the time the collaborative agreement is

rescinded, the licensed pharmacist shall not have prescriptive authority to dispense emergency contraceptives until another collaborative agreement with a physician is completed and delivered to the department; and

- (4) Each drug therapy prescription authorized by the physician and dispensed by the pharmacist shall be documented in a patient profile.
- (d) Additionally, the collaborative agreement between the licensed pharmacist and licensed physician shall include:
 - (1) The name, address, and phone number of the licensed pharmacist and pharmacy and the signature of the licensed pharmacist;
 - (2) The name, address, and phone number of the licensed physician and the signature of the licensed physician;
 - (3) The purpose of the collaborative agreement, which is to permit emergency contraception drug therapy within one hundred and twenty hours of the patient having unprotected sexual contact and to ensure that the patient receives appropriate information from the licensed pharmacist regarding the drug therapy;
 - (4) The procedures, delineated in Exhibit "A", to be followed by the licensed pharmacist when the patient requests drug therapy, including any applicable referrals;
 - (5) Any limitation agreed upon by both the licensed pharmacist and the licensed physician including, but not limited to, approved drugs that may not be prescribed to the patient or whether the licensed pharmacist's or the licensed physician's decision shall control in the event of a disagreement on the prescription for a patient;
 - (6) A provision that the licensed pharmacist shall refer the patient to the licensed physician;
 - (7) A statement that the label placed on the drug therapy product shall contain the names of both the pharmacist and the physician signers of this Agreement;
 - (8) An informed consent, included in Exhibit "A", to be used by the licensed pharmacist to inform the patient about the emergency contraception drug therapy. The informed consent shall be signed by both the licensed pharmacist and the patient; and
 - (9) A screening checklist for emergency contraception pills, included in Exhibit "A", to be filled in by the patient and signed by both the licensed pharmacist and the patient.

(e) Any modification to an existing collaborative agreement previously delivered to the department shall be submitted also to the department by the licensed pharmacist at least ten working days prior to the intended implementation of the changed collaborative agreement.

(f) The board of pharmacy shall have the authority to reject a collaborative agreement if the board determines that the collaborative agreement is not in compliance with this section or is not in the best interests of the patient.

(g) The form of the collaborative agreement, the informed consent form, and the screening checklist for emergency contraception drugs attached as Exhibit "A" hereto, shall be made available to licensed pharmacists and licensed physicians. [Eff and comp 12/25/04] (Auth: HRS §461-4.5) (Imp: HRS §461-1)

Amendments to and compilation of chapter 16-95, Hawaii Administrative Rules, on the Summary page dated September 28, 2004, were adopted on September 28, 2004, following a public hearing held on September 28, 2004, after public notice was given in the Honolulu Star-Bulletin, The Garden Island, Hawaii Tribune-Herald, West Hawaii Today, and The Maui News on August 27, 2004.

They shall take effect ten days after filing with the Office of the Lieutenant Governor.

/s/ Valerie M. K. Matsunaga
VALERIE MATSUNAGA
Chairperson, Board of Pharmacy

APPROVED AS TO FORM: Date 11/9/04

/s/ James F. Nagle
Deputy Attorney General

APPROVED: Date 11/17/04

/s/ Mark E. Recktenwald
MARK E. RECKTENWALD
Director of Commerce and Consumer Affairs

APPROVED: Date 12/14/04

/s/ Linda Lingle
LINDA LINGLE
Governor of Hawaii

DEPARTMENT OF COMMERCE AND CONSUMER AFFAIRS

Amendment and Compilation of Chapter 16-95
Hawaii Administrative Rules

September 28, 2004

SUMMARY

1. §16-95-130 is added.
2. Chapter 95 is compiled.

This material can be made available for individuals with special needs. Please call the Program Specialist, Professional and Vocational Licensing Division, DCCA, at 586-2692, to submit your request.

Effective 12/25/04

EXHIBIT "A"

This Emergency Contraception Drug Therapy collaborative Agreement was developed using the collaborative agreements of Washington and California, who developed their guidelines from the American College of Obstetricians and Gynecologists and the World Health Organization and physicians, pharmacists and nurses. This Agreement has been approved by the Board of Pharmacy, State of Hawaii.

Emergency Contraception Drug Therapy Collaborative Agreement

As a licensed physician authorized to prescribe medications in the State of Hawaii, I authorize the licensed pharmacist _____ to initiate emergency contraception drug therapy according to the terms and conditions that follows and according to Hawaii Administrative Rule §16-95-130. This Agreement provides written terms and conditions for initiating emergency contraception drug therapy in accordance with the laws and rules of the State of Hawaii. This agreement shall be delivered to the Department of Commerce and Consumer Affairs within seven (7) days of the execution of the agreement by the licensed pharmacist and the licensed physician. Any modification to an existing collaborative agreement previously delivered to the Department shall be delivered also to the Department by the licensed pharmacist at least ten working days prior to the intended implementation of the changed collaborative agreement.

Purpose: Permit the use of drug therapy within 120 hours of the patient having unprotected sexual contact and to ensure the patient receives adequate information to successfully complete drug therapy.

Procedures: When the patient's pharmacist requests drug therapy, the pharmacist shall assess the need for drug therapy and/or referral for contraceptive care and reproductive health care. The pharmacist shall determine the following:

1. The date of the patient's last menstrual period to rule out established pregnancy;
2. Whether the elapsed time since unprotected intercourse is less than 120 hours;
3. Whether the patient has been a victim of sexual assault; and
4. That the patient is at least 14 years of age.

Referrals: The licensed pharmacist shall refer the patient to the licensed physician for follow-up. If drug therapy services are not available at the pharmacy, the pharmacist shall refer the patient to another licensed pharmacist. Also, the pharmacist shall refer the patient to see either a medical doctor or family planning clinic provider if:

- A. The pharmacist cannot rule out that the patient is pregnant or if the elapsed time since the patient having unprotected intercourse is greater than 120 hours;
- B. The pharmacist is concerned that the patient may have been exposed to a sexually transmitted disease;
- C. The patient does not have a regular contraceptive method; and
- D. The patient does not have a health care provider and needs free or low cost family planning services.

If the pharmacist is concerned that the patient may have contracted a sexually transmitted disease through unprotected sexual activity and/or if the patient indicates that she has been sexually assaulted, the pharmacist may recommend referral to a medical doctor, a family planning clinic, a sexual assault treatment center, the police, or multiple referrals to these entities as the pharmacist may deem appropriate, while providing drug therapy.

While drug therapy can be used repeatedly without serious health risks, patients who request drug therapy shall be referred to a medical doctor or family planning clinic provider for consideration of the use of a regular contraceptive method.

Drug Therapy product selection: The pharmacist shall provide medication from a list of drugs approved for emergency contraception by the United States Food and Drug Administration ("FDA") listed in Exhibit "B" and agreed upon as part of this collaborative Agreement. Plan B® shall be the preferred drug therapy. The list shall include emergency contraceptives and adjunctive medications for treatment of nausea and vomiting associated with emergency contraceptives. The list shall be maintained at the pharmacy and shared by all participants in the agreement. Along with the medication, the pharmacist shall provide drug information concerning dosage, potential adverse effects, and follow-up contraceptive care.

Prescription labeling: The label placed on the drug therapy product shall contain the names of both the pharmacist and the physician signers of this Agreement.

Documentation: Each drug therapy prescription authorized by the physician and initiated by the pharmacist shall be documented in a patient profile.

Training: The pharmacist who participates in the drug therapy shall have 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. Training must include procedures listed above, the management of the sensitive communications often encountered in emergency contraception, service to minors, quality assurance, referral for additional services, documentation and a crisis plan if the pharmacy operations are disrupted by individuals opposing the emergency contraception.

Further, the pharmacist agrees to participate in the Emergency Contraception Hotline.

Term of the Agreement: This agreement shall be effective for a period of at least two years from the date of its delivery to the Department unless rescinded in writing earlier by either the physician or the pharmacist, with written notice to the other and to the Department, or unless the Pharmacy Board invalidates such Agreement or changes the terms of the agreement. After the two year period, the agreement shall continue to be valid month to month unless rescinded, invalidated, or changed as provided herein. The licensed pharmacist or the licensed physician, who rescinds the agreement, shall notify the Department within three business days of the rescission. At the time the collaborative agreement is rescinded, the licensed pharmacist shall not have prescriptive authority to dispense emergency contraceptives until another collaborative agreement with a physician is completed and delivered to the department.

Additional Terms or Limitations:

Physician's Name: _____

Street Address/City/State; Zip Code: _____

Phone Number: _____ MD License No.: _____

Physician's Signature: _____ Date: _____

Pharmacist's Name: _____

Street Address/City/State/Zip Code where Drug Therapy will occur (include name of pharmacy, pharmacy license number, pharmacist-in-charge and pharmacist-in-charge license number):

_____ Pharmacist License No.: _____

Phone Number: _____

Pharmacist's Signature: _____ Date: _____

Pharmacist-in-charge's Signature: _____ Date: _____

(Name of Pharmacy)

Informed Consent for Emergency Contraception Drug Therapy

Name of Patient: _____ Age: _____

Address: _____

Phone No.: _____

First day of last menstrual period: ___/___/___
Mo/Day/Year

Date of unprotected sexual intercourse: ___/___/___
Mo/Day/Year

If more than one exposure, give date and time of initial exposure: _____

Was this sexual intercourse the result of sexual assault? Yes ___ No ___

Before giving your consent, be sure that you understand both the pros and cons of Emergency Contraceptive Pills (ECPs). If you have any questions, we will be happy to discuss them with you. Do not sign your name at the end of this form until you have read and understood each statement and the pharmacist has answered your questions and can witness your signature. This information is confidential.

I understand that:

1. ECPs contain hormones that act to prevent pregnancy. These pills are taken after having unprotected sex (sex without birth control or birth control failure). They are to be used as an emergency treatment only and not as a routine method of contraception.
2. ECPs work by preventing or delaying the release of an egg from the ovary, preventing fertilization, or causing changes in the lining of the uterus that may prevent implantation of a fertilized egg. I understand that if I am already pregnant, ECPs will not stop or interfere with the pregnancy.
3. ECP treatment should be started within 5 days (120 hours) of unprotected sex.
4. ECPs are not 100 percent effective.
5. Reactions to the pills may include: nausea and vomiting, fatigue, dizziness, breast tenderness, early or late menstrual period.
6. I should see a physician if my period has not started within 3 weeks after treatment.
7. I should use condoms, spermicides, or a diaphragm, or continue taking birth control pills to prevent pregnancy if I have sex before my next period. After that, I should continue to use a method of contraception.
8. ECPs will not protect me from or treat sexually transmitted diseases and I should seek diagnosis and treatment if I am concerned because I have had sex with a new partner in the past month or my partner has had sex with someone else in the past month or my partner has a sexually transmitted disease.
9. I understand that it may be useful to share this treatment information with my regular health care provider. Therefore, I request and authorize the release of this information to the following designated provider:

Yes ___ No ___

10. Designated Provider's Name: _____

Patient's Signature: _____ Date: _____

Informed Consent for Emergency Contraception Drug Therapy Continued

Pharmacist's Signature: _____ Date: _____

Pharmacist only: Referral made to: _____

Rx No.: _____

Screening Checklist for Emergency Contraceptive Pills

Patient Name: _____ Today's Date: _____

Address: _____ Age: _____

These questions are to help us understand what you need right now.

- 1. Have you had unprotected sex during the last 5 days? Yes ___ No ___
- 2. On what day(s) did you have unprotected sex in the past 5 days?
Monday ___ Tuesday ___ Wednesday ___ Thursday ___ Friday ___ Saturday ___ Sunday ___
- 3. What time of day was the first unprotected sex in the past 5 days? ___ A.M. ___ P.M.
- 4. Have you had unprotected sex prior to the last five days? Yes ___ No ___
- 5. When was the first day of your last menstrual period? Date: _____
- 6. Are you currently using a method of birth control?
No method ___ Birth Control Pills ___
Condoms ___ Diaphragm _____
IUD _____ Other Method _____
Contraceptive Shot (Depo Provera®) ___
- 7. Did you have unprotected sex as a result of sexual assault (or, did anyone pressure you into having sex when you didn't want to?)
Yes ___ No ___
- 8. Would you like a pharmacist to call you in the next couple of weeks to see how you're doing?
Yes ___ No ___
If yes, what time of the day is best to call? ___ A.M. ___ P.M.

Patient's Signature: _____ Date: _____

For Pharmacist Use Only

Date and time of interview: _____ EC Provided: Yes ___ No ___

Referral made for (check all that apply):
Contraception follow-up ___ Evaluation for STD ___ Other medical evaluation ___
Pregnancy counseling ___ Assault Counseling ___ No referrals made _____

Date and time of callback: _____ Referrals made then? _____

Pharmacist's Signature: _____ Date: _____

EXHIBIT "B"

Brands and Doses

Of Oral Contraceptive Pills Used For Emergency Contraception

There are now two prepackaged emergency contraceptive pill products (dedicated emergency contraceptive pills) as well as 14 brands of birth control pills that can be used for emergency contraception.

Brand	Manufacturer	Pills per Dose (Treatment schedule is one dose ASAP after unprotected intercourse, and a second dose 12 hours later)	Ethinyl Estradiol per Dose (mcg)	Levonorgestrel per Dose (mg)*
<i>Dedicated Emergency Contraceptive Pills</i>				
Plan B	Women's Capital Corporation	1 white pill	0	0.75
Preven	Gynetics	2 blue pills	100	0.50
<i>Oral Contraceptive Pills</i>				
Levora	Watson	4 white pills	120	0.60
Levlen	Berlex	4 light-orange pills	120	0.60
Lo/Ovral	Wyeth-Ayerst	4 white pills	120	0.60*
Low-Ogestrel	Watson	4 white pills	120	0.60*
Nordette	Wyeth-Ayerst	4 light-orange pills	120	0.60
Alesse	Wyeth-Ayerst	5 pink pills	100	0.50
Aviane	Duramed	5 orange pills	100	0.50
Levlite	Berlex	5 pink pills	100	0.50
Ogestrel	Watson	2 white pills	100	0.50*
Ovral	Wyeth-Ayerst	2 white pills	100	0.50*
Tri-Levlen	Berlex	4 yellow pills	120	0.50
Triphasil	Wyeth-Ayerst	4 yellow pills	120	0.50
Trivora	Watson	4 pink pills	120	0.50

Adapted from RA Hatcher, et al, *Contraceptive Technology: Seventeenth Revised Edition*. New York NY: Ardent Media, 1998. Updated by Felicia Steward, MD 2001.

* This progestin in Ovral, Lo/Ovral, Low-Ogestrel, Ogestrel and Ovrette is norgestrel, which contains two isomers only one of which (levonorgestrel) is bioactive; the amount of norgestrel in each dose is twice the amount of levonorgestrel.

Anti-nausea Treatment Options for use with Emergency Contraception

Drug	Dose	Timing of Administration
<i>Non-prescription Drugs</i>		
Meclizine hydrochloride (Dramamine, Bonine)	One or two 25mg tablets	1 hour before first EC dose; repeat if needed in 24 hours
Diphenhydramine hydrochloride (Benadryl)	One or two 25mg tablets or capsules.	1 hour before first EC dose; repeat as needed every 4-6 hours.
Dimenhydrinate (Dramamine)	One or two 50mg tablets or 4- 8 teaspoons liquid	30 minutes to 1 hour before first ECP dose; repeat as needed every 4-6 hours.
Cyclizine hydrochloride (Marezine)	One 50mg tablet	30 minutes before first EC dose; repeat as needed every 4-6 hours.

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