RULES AND REGULATIONS PERTAINING TO

PHARMACISTS, PHARMACIES AND MANUFACTURERS,

WHOLESALERS AND DISTRIBUTORS

(R5-19-PHAR)

STATE OF RHODE ISLAND AND PROVIDENCE PLANTATIONS

Department of Health

Board of Pharmacy

March 1985

***As Amended*:**

May 1986
August 1986
April 1987
April 1988
October 1988 (E)
January 1989
September 1989 (E)
December 1989
May 1990
October 1990 (T)
September 1992 (E)
February 1993 (E)
April 1993
November 1993
February 1994
July 1996
July 1997
February 2000
July 2000 (E)
November 2000 (E)
December 2000
April 2001
August 2001 (E)
December 2001 (E)
January 2002 (re-filing in accordance with the provisions of section 42-35-4.1 of the Rhode Island General Laws, as amended)

NOTE: "Emergency" amendments appear in underlining and ~~strikeouts.~~

INTRODUCTION

These amended rules and regulations are promulgated pursuant to the authority conferred under section 5-19-6 of the General Laws of Rhode Island, as amended, and are established for the purpose of adopting administrative procedures and pharmaceutical practices consistent with current standards of practice.

Furthermore, pursuant to the provisions of section 42-35-3(c) of the General Laws of Rhode Island, as amended, the following issues have been given consideration in arriving at the amended regulations: (a) alternative approaches to the regulations; (b) duplication or overlap with other state regulations; and (c) significant economic impact which would be placed on pharmacies, pharmacists and manufacturers, wholesalers and distributors.

No alternative approaches, overlap or significant adverse economic impact was identified. Consequently, the rules and regulations are adopted in the best interest of the public health, safety and welfare.

These amended rules and regulations shall supersede all previous *Rules and Regulations Pertaining to Pharmacists, Pharmacies and Manufacturers, Wholesalers and Distributors* promulgated by the Rhode Island Department of Health and the Board of Pharmacy and filed with the Secretary of State.

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PART I ***DEFINITIONS***

Section 1.0 ***Definitions***

Wherever used in these rules and regulations the following terms shall be construed as follows:

1.1 ***"Act"*** refers to Chapter 5-19 of the General Laws of Rhode Island, as amended, entitled, "Pharmacy."

1.2 ***"Adverse drug reaction"*** means any undesirable or unexpected medication related event that requires discontinuing a medication or modifying the dose, requires or prolongs hospitalization, results in disability, requires supportive treatment, is life-threatening or results in death, results in congenital anomalies, or occurs following vaccination.

1.3 ***"Authentication of product history"*** means, but is not limited to, identifying the purchasing source, the ultimate fate, and any intermediate handling of any component of a radiopharmaceutical.

1.4 ***"Automated storage and distribution devices"*** means a mechanical device that delivers drugs other than by administration, and uses automated data processing technology to:

1. provide effective storage and security of drugs contained in the device;

2. limit access to authorized individuals;

3. record the identity of all personnel who access the drugs stored within the device;

4. provide documentation of storage and removal of contents;

5. provide ongoing documentation that monitors proper delivery of drugs to ensure patient safety;

6. comply with Rhode Island General Laws and regulations.

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

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

1.7 ***"Board"*** means the Board of Pharmacy within the Department of Health established pursuant to section 5-19-2 of the Act.

1.8 **"*Change of ownership*"** means:

a. In the case of a pharmacy, manufacturer or wholesaler which is a partnership, the removal, addition, or substitution of a partner which results in a new partner acquiring a controlling interest in the partnership;

b. In the case of a pharmacy, manufacturer or wholesaler which is an unincorporated sole proprietorship, the transfer of the title and property to another person;

c. In the case of a pharmacy, manufacturer or wholesaler which is a corporation:

(i) A sale, lease exchange, or other disposition of all, or substantially all of the property and assets of the corporation; or

(ii) A merger of the corporation into another corporation; or

(iii) The consolidation of two or more corporations, resulting in the creation of a new corporation; or

(iv) In the case of a pharmacy, manufacturer or wholesaler which is a business corporation, any transfer of corporate stock which results in a new person acquiring a controlling interest in the corporation; or

(v) In the case of a pharmacy, manufacturer or wholesaler which is a nonbusiness corporation, any change in membership which results in a new person acquiring a controlling vote in the corporation.

1.9 ***"Clinic"*** means a health facility providing health care services to individuals associated with a college or university.

1.10 ***"Compounding"*** means the preparation, mixing, assembling, packaging or labeling of a drug or device:

1.10.1 as a result of a practitioner's prescription or initiative based on the prescriber/patient/pharmacist relationship in the course of professional practice, and includes the preparation of drugs or devices in limited quantities based upon documented histories of receiving valid prescriptions, and in anticipation of prescriptions based on routine, regularly-observed patterns; or

1.10.2 for the purpose of, as an incident to research, teaching, chemical analysis and not for sale or dispensing.

1.11 ***"Confidential information"*** means health care and other information maintained by the pharmacist in the patient's records, which is deemed confidential by virtue of the provisions of Chapter 5-37.3, and any other federal or state law.

1.12 ***"Contact hour"*** means a unit of measure of educational credit which is equivalent to approximately fifty (50) to sixty (60) minutes of participation in an organized learning experience.

1.13 ***"Continuing education"*** means accredited or approved post-licensure professional pharmaceutical education designed to maintain and improve competence in the practice of pharmacy, pharmacy skills, and preserve pharmaceutical standards for the purpose of protecting public health, safety, and welfare. Continuing education programs shall address topics and subject matter areas which are pertinent to the contemporary practice of pharmacy.

1.14 ***"Continuing education unit"*** (CEU) means a unit of measure of educational credit which is equivalent to ten (10) hours.

1.15 ***"Counseling"*** means the oral communication by the pharmacist of information, as defined in the rules of the Board, to the patient or care giver, in order to improve therapy by ensuring proper use of drugs and devices.

1.16 ***"Deliver"*** or ***"Delivery"*** means the actual, constructive, or attempted transfer of a drug or device from one person to another, whether or not for a consideration.

1.17 ***"Device"*** means an instrument, apparatus, and contrivance, including their components, parts and accessories, intended:

1.17.1 for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in humans or other animals; or

1.17.2 to affect the structure or any function of the body of humans or other animals.

1.18 ***"Discontinuance"*** means the action of terminating by discontinuing, suspending, or revoking any registration for good and sufficient cause.

1.19 ***"Dispensary"*** shall have the same meaning as "clinic."

1.20 ***"Dispense"*** or ***"dispensing***" means the interpretation of a prescription or order for a drug, biological, or device and, pursuant to that prescription or order, the proper selection, measuring, compounding, labeling, or packaging necessary to prepare that prescription or order for delivery.

1.21 ***"Distribute"*** means the delivery of a drug other than by administering or dispensing.

1.22 ***"Drug"*** means:

1.22.1 articles recognized as drugs in the official United States Pharmacopeia, official Homeopathic Pharmacopeia of the United States, or Official National Formulary, or any supplement to any of them; and

1.22.2 articles intended for the use in the diagnosis, cure, mitigation, treatment, or prevention of disease in humans or other animals; and

1.22.3 articles (other than food) intended to affect the structure of any function of the body of humans or other animals; and

1.22.4 articles intended for use as a component of any article specified in sections 1.58.1 1.58.2 or 1.58.3 but does not include devices or their components, parts, or accessories.

1.23 ***"Drug Regimen Review"*** includes but is not limited to the following activities:

1.23.1 Evaluation of the prescriptions and patient records for:

a) known allergies;
b) rational therapy-contraindications;
c) reasonable dose and route of administration;
d) reasonable directions for use, and
e) evaluation of the prescriptions and patient records for duplication of therapy.

1.23.2 Evaluation of the prescriptions and patient records for interactions:

a) drug-drug;
b) drug-food;
c) drug-disease;
d) adverse drug reactions, and
e) idiosyncratic reactions.

1.23.3 Evaluations of the prescriptions and patient records for proper utilization (including over- and under-utilization), and optimum therapeutic outcomes.

1.24 ***"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.

1.25 ***"Drugs establishment"*** refers to any business eligible to hold a Federal Registration of Drug Establishment, issued by the Federal Food and Drug Administration of the United States Department of Health and Human Services (or a successor agency).

1.26 ***"Drugs, medicines and poisons"*** has the same meaning set forth in section 5-19-1 of the Act.

1.27 ***"Financial interest"*** means financial benefit gained by any practitioner with authority to prescribe drugs and includes such benefit derived by a spouse or dependent child.

1.28 ***"Foreign pharmacy graduate"*** is a pharmacist whose undergraduate pharmacy degree was conferred outside the United States by a pharmacy school listed in the World Directory of Schools of Pharmacy published by the World Health Organization. The United States, as used here, includes the fifty states, the District of Columbia, and Puerto Rico.

1.28.1 ***"FPGEC"*** means the Foreign Pharmacy Graduate Equivalency Commission.

1.28.2 ***"FPGEE"*** means the Foreign Pharmacy Graduate Equivalency Examination.

1.28.3 ***"TOEFL"*** is the Test of English as a Foreign Language, as given by the American College Testing (ACT), or its successor, and certified by the FPGEC.

1.28.4 ***"Test of Spoken English (TSE)"*** means the test of spoken English administered by the Educational Testing Service.

1.29 ***"Hospice care facility"*** means an inpatient setting where palliative and supportive services to the terminally ill and their families are provided.

1.30 ***"Hospital"*** means a facility with a governing body, an organized medical staff and a nursing service providing equipment and services primarily to inpatient care to persons who require definitive diagnosis and treatment for injury, illness or other disabilities or pregnancy, licensed pursuant to Chapter 23-17 of the Rhode Island General Laws, as amended.

1.31 ***"Institutional pharmacy"*** means any pharmacy located within any hospital, sanitorium, clinic or dispensary in which drugs are compounded or dispensed to its patients or patients of another licensed in-patient health care facility with whom it has a contract.

1.32 ***"Intern"*** means a graduate of an American Council on Pharmaceutical Education (ACPE) accredited program of pharmacy, or a student who is enrolled in at least the first year of a professional ACPE accredited program of pharmacy.

1.33 ***"Internal test assessment"*** means, but is not limited to, conducting those tests of quality assurance necessary to ensure the integrity of the test.

1.34 ***"Internship"*** means that period of training of an intern, under the direction of the preceptor, which is required for registration to engage in the practice of pharmacy.

1.35 ***"Investigational drug***" means any drug which has not been approved for use in the United States, but for which an investigational drug application has been approved by the Food and Drug Administration (FDA).

1.36 ***"Live hours"*** means hours acquired through attendance or participation at programs that provide for direct interaction between faculty and participants and may include lectures, symposia, live teleconferences or workshops.

1.37 ***"Manufacturer"*** means anyone who is engaged in manufacturing, preparing, propagating, compounding, processing, packaging, repackaging, or labeling of a prescription drug or poisons.

1.38 ***"Manufacturing"*** means the production, preparation, propagation, conversion or processing of a drug or device, either directly or indirectly, by extraction from substances of natural origin or

independently by means of chemical or biological synthesis, and includes any packaging or repackaging of the substances or labeling or relabeling of its container, and the promotion and marketing of such drugs and devices. Manufacturing also includes the preparation and promotion of commercially available products from bulk compounds for resale by pharmacists, practitioners, or other persons.

1.39 ***"Medical institution"*** means any hospital, santitorium, clinic or dispensary.

1.40 "***Medication error***" means any preventable event that may cause or lead to inappropriate medication use or patient harm, while the medication is in the control of the health care professional, patient, or consumer. Such events may be related to professional practice, health care products, procedures, and systems including, but not limited to: prescribing; order communication; product labeling, packaging and nomenclature; compounding; dispensing; distribution; administration; education; monitoring; and use.

1.41 ***"Medication orders"*** means a written, verbal or electronically transmitted order for drugs and devices from an authorized practitioner in this state for administration of a drug.

1.42 ***"Nonresident pharmacy"*** means a pharmacy located outside this state that ships, mails, or delivers prescription drugs and/or devices to a patient in this state.

1.43 ***"Nuclear pharmacy"*** means a pharmacy providing radiopharmaceutical services.

1.44 ***"Nuclear/radiologic pharmacy practice"*** refers to a patient-oriented service that embodies the scientific knowledge and professional judgment required to improve and promote health through the assurance of the safe and efficacious use of radiopharmaceuticals and other drugs.

1.45 "***Nursing facility"*** means a place, however named, or an identifiable unit or distinct part thereof that provides 24-hour inresident nursing, therapeutic, restorative or preventive and supportive nursing care services for two (2) or more residents unrelated by blood or marriage whose condition requires continuous nursing care and supervision.

1.46 ***"Parenteral pharmacy practice"*** refers to admixtures of sterile parenteral solutions and dispensing of same intended for administration to patients in health care facilities and in the home.

1.47 ***"Patient profile"*** means a patient record system that is maintained by all pharmacies for patients for whom prescriptions are dispensed. The patient profile shall provide for the immediate retrieval of information necessary for the dispensing pharmacist to identify previously dispensed drugs at the time a prescription is presented for dispensing.

1.48 ***"Person"*** means any individual, trust or estate, partnership, corporation (including associations, joint stock companies) state or political subdivision or instrumentality of the state.

1.49 ***"Pharmaceutical care"*** is the provision of drugs and other pharmaceutical services intended to achieve outcomes related to cure or prevention of a disease, elimination or reduction of a patient's

symptoms, or arresting or slowing of a disease process. Pharmaceutical Care includes the judgment of a pharmacist in dispensing an equivalent drug or device in response to a prescription, after appropriate communication with the prescriber and the patient.

1.50 ***"Pharmacist"*** means an individual registered to engage in the practice of pharmacy in this state pursuant to section 5-19-19 of the Act.

1.51 ***"Pharmacy"*** or ***"drug store***", hereinafter referred to as "pharmacy" means that portion or part of a premises where prescriptions are compounded and dispensed, including that portion utilized for the storage of prescription drugs or legend drugs.

1.52 ***"Pharmacy and therapeutics committee"*** means the active standing committee in the hospital, nursing or hospice care facility which is the organizational line of communication and liaison between the medical and pharmacy staff which acts to review and promote rational drug therapy and utilization in the licensed facility.

1.53 ***"Pharmacy technician"*** means supportive personnel utilized in pharmacies whose responsibilities are to provide nonjudgmental technical services concerned with the preparation of legend drugs under the direct supervision and responsibility of a pharmacist.

1.54 ***"Practice of pharmacy"*** means the interpretation, evaluation and dispensing of prescription drug orders; participation in drug and device selection; drug regimen reviews; provision of patient counseling and the provision of those acts or services necessary to provide pharmaceutical care; and the responsibility for compounding and/or labeling of drugs and devices (except labeling by a manufacturer, repackager, or distributor of non-prescription drugs and commercially packaged legend drugs and devices).

1.55 ***"Practitioner"*** means a physician, dentist, veterinarian, nurse or other person duly authorized by law in the state in which they practice to prescribe drugs.

1.56 ***"Preceptor"*** means a pharmacist registered to engage in the practice of pharmacy in this state, or another jurisdiction who is in good standing in said state or jurisdiction and who has the responsibility for training interns.

1.57 ***"Prescription"*** means an order for drugs or devices from an authorized practitioner which is dispensed to or for an ultimate user.

1.58 ***"Prescription drug"*** or ***"legend drug"*** means a drug which, under federal law, is required, prior to being dispensed or delivered, to be labeled with either of the following statements:

1.58.1 Rx only;

1.58.2 "Caution: Federal law restricts this drug to use by, or on the order of, a licensed veterinarian"; or

1.58.3 A drug which is required by any applicable federal or state law or rule to be dispensed pursuant only to a prescription, or is restricted to use by practitioners only, and includes finished dosage forms and active ingredients subject to section 503 (b) of the federal food, drug, and cosmetic act, including all medical gases.

1.59 ***"Prospective drug review"*** means a review of the patient's drug therapy record and prescription, as established in the rules of the Board, prior to dispensing the drug as part of a drug regimen review.

1.60 ***"Qualified licensed professional"*** means a non-pharmacist individual (such as physician, nurse, or technologist) who possesses a current state license, if applicable, and who has sufficient training and experience to safely handle and dispense radiopharmaceuticals as defined by the respective requirements of the Nuclear Regulatory Commission and Chapter 23-1.3 of the General Laws of Rhode Island, as amended.

1.61 A ***"qualified nuclear pharmacist"*** means a currently registered pharmacist in the state of Rhode Island, who is certified as a nuclear pharmacist by the U.S. Nuclear Regulatory Commission, or who meets the following standards:

1.61.1 Minimum standards of training for "authorized user status" of radioactive material (reference 1);

1.61.2 Completed a minimum of 200 contact hours of instruction in nuclear pharmacy and the safe handling and the use of radioactive materials from a program approved by the Board, with emphasis in the following areas:

a) radiation physics and instrumentation;
b) radiation protection;
c) mathematics of radioactivity;
d) radiation biology;
e) radiopharmaceutical chemistry.

1.61.3 Attain a minimum of 500 hours of clinical nuclear pharmacy training under the supervision of a qualified nuclear pharmacist.

1.62 ***"Reasonable effort"*** includes collecting patient information with printed data forms provided to the patient by the pharmacist, the pharmacist interviewing the patient to develop a patient's medication history, or similar patient-pharmacist interactions where the pharmacist assumes responsibility to collect, record, and maintain information necessary to properly dispense a prescription and counsel a patient. Collection of patient information may be appropriately delegated by the responsible pharmacist.

1.63 ***"Radiopharmaceutical quality assurance"*** means, but is not limited to, the performance of appropriate chemical, biological, and physical tests on potential radiopharmaceuticals and the interpretation of the resulting data to determine their suitability for use in humans and animals, including internal test assessment, authentication of product history and the keeping of proper records.

1.64 ***"Radiopharmaceuticals"*** are radioactive drugs as defined by the FDA and regulated pursuant to Chapter 23-1.3 of the Rhode Island General Laws, as amended.

1.65 ***"Radiopharmaceutical service"*** means, but is not limited to, the procurement, storage, handling, preparation, labeling, quality assurance testing, dispensing, delivery, record keeping, and disposal of radiopharmaceuticals and other drugs.

1.66 ***"Recognized provider"*** means any person, corporation or association approved either by the Board, the American Council on Pharmaceutical Education (ACPE), or American Medical Association (AMA) Category I Programs, to conduct continuing education programs.

1.67 ***"Retail pharmacy"*** means any pharmacy where drugs are compounded, dispensed, stored or sold or where prescriptions are filled or dispensed to the general public.

1.68 ***"Retrospective drug review"*** means the monitoring for therapeutic appropriateness, over-utilization and under-utilization, appropriate use of generic products, therapeutic duplication, drug-disease contraindications, drug-drug interactions, incorrect dosage or duration of drug treatment, and clinical abuse/misuse after the drug has been dispensed.

1.69 ***"Sanitorium***" means any nursing facility, or hospice providing inpatient services, licensed pursuant to Chapter 23-17 of the Rhode Island General Laws, as amended.

1.70 ***"A single-unit container"***, as used in section 8.2.1, is the one that is designed to hold a quantity of drug intended for administration as a single dose, or a single finished device, intended for use promptly after the container is opened. Preferably, the immediate container, and/or the outer container or protective packaging, shall be designed as to show evidence of any tampering with the contents. Each single-unit container shall be labeled to indicate the identity, quantity, and/or strength, name of manufacturer, lot number, and expiration date of the article.

1.71 ***"Unit-dose container"*** is a single-unit container for articles intended for administration by other than parenteral route as a single dose, direct from the container. Each unit-dose container shall be labeled to indicate the identity, quantity, and/or strength, name of the manufacturer, and lot number of the article.

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

1.72.1 intracompany sales;

1.72.2 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 its own use from the group purchasing organization or from other hospitals or health care entities that are members of such organizations;

1.72.3 the sale, purchase or trade of a drug of an offer to sell, purchase, or trade a drug by a charitable organization to a non-profit affiliate of the organization to the extent otherwise permitted by law;

1.72.4 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, voting rights, by contract or otherwise;

1.72.5 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 transfers of prescription drugs by a retail pharmacy to another retail pharmacy to alleviate a temporary shortage;

1.72.6 the sale, purchase, or trade of a drug, an offer to sell, purchase, or trade a drug, or the dispensing of a drug pursuant to a prescription.

1.72.7 the lawful distribution of drug samples by manufacturers' representatives or distributors' representatives.

1.72.8 the sale, purchase, or trade of blood and blood components intended for transfusion.

1.73 ***"Wholesale distributor"*** means anyone engaged in wholesale distribution of 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, and retail pharmacies that conduct wholesale distribution.

PART II *PHARMACISTS/REGISTRATION REQUIREMENTS*

Section 2.0 *Registration Requirement*

2.1 No person, unless a registered pharmacist shall retail, compound or dispense drugs, medicine or poisons, except as provided pursuant to statutory provisions of sections 5-19-19 and 5-19-36 of the Act.

Section 3.0 *Qualifications for Registration*

3.1 Pursuant to the provisions of section 5-19-10 of the Act, every person in order to be a registered pharmacist shall:

3.1.1 a) be of good moral character and temperate habits;

b) be over eighteen (18) years of age;

c) have graduated from a first professional degree program in pharmacy which is:

i. authorized to confer degrees in the state in which it is located;

ii. accredited by the American Council on Pharmaceutical Education; and

iii. approved by the Board.

d) If the applicant is a foreign pharmacy graduate, he/she shall have obtained full certification from the FPGEC.

e) have satisfactorily completed the internship in accordance with section 6.0 herein; and

f) have successfully passed such examination as the Board may require in accordance with section 5.0 herein.

g) who shall not have been convicted of any felony for violations involving controlled substances subject to waiver by the Board upon presentation of satisfactory evidence that such conviction does not impair the ability of the person to conduct with safety to the public the practice of pharmacy.

Section 4.0 *Application for Registration and Fee*

4.1 Application for registration shall be made on forms provided by the Board and which may be obtained at:

The Rhode Island Department of Health
Three Capitol Hill, Room 205

Providence, Rhode Island 02908

Said forms shall be completed and signed by the applicant, notarized, and submitted to the Board no later than thirty (30) days prior to the scheduled date of examination. Such application shall be accompanied by the following documents and fee (non-returnable):

a) a notarized true copy of certificate of birth;

b) one (1) unmounted recent photograph, head and shoulders, front view, approximately 2 x 3 inches in size, of the applicant. Such photograph, must be certified by a member of the faculty of the college of pharmacy at which the applicant matriculated;

c) proof of graduation from an accredited college of pharmacy;

d) the application fee of one hundred dollars ($100.00) per check or money order (non-refundable), made payable to the General Treasurer, State of Rhode Island;

e) the application for NAPLEX Examination which will be submitted to the National Association of Boards of Pharmacy;

f) the current application fee for NAPLEX Examination of two hundred fifty dollars ($250.00) per money order, bank draft, or certified check, made payable to NABP Licensure Examination. Personal checks or cash will not be accepted; and

g) the current application fee for the Multistate Jurisprudence Examination of $85.00, per money order, bank draft or certified check, made payable to the NABP Licensure Exam. Personal checks or cash will not be accepted.

4.2 Application and supporting documents shall be verified and reviewed by the Board.

4.3 No applicant shall be approved or accepted for examination until he/she has met all requirements of internship as set forth in section 6.0 herein. Affidavit of internship hours shall be submitted to the Board prior to application for registration.

4.4 Applications shall be completed (including the submission of all supporting documents) within six (6) months of the date of initial submission. Any application that is not completed within this six (6) month time frame shall be deemed to be invalid, shall be denied, and the applicant shall be required to submit a new application.

Section 5.0 ***Examination For Registration***

5.1 ***By Examination:***

Applicants shall be required to pass written and practical examinations (conducted in English) as the Board deems most practical and expeditious to test the applicant's knowledge and skills to engage in the practice of pharmacy in this state, pursuant to section 5-19-13 of the Act.

5.1.1 For written examination the Board requires applicants to successfully pass, the following examinations:

a) The Integrated Examination of the National Association of Boards of Pharmacy which may be:

i. administered in this state with the passing grade as determined by NAPLEX and approved by the Board; or

ii. administered in another state by the licensing authority of the respective state, provided said examination was administered on the same date as the scheduled examination date in this state and provided the requirements of section 5.1.2 herein on transfer of grades are met; and

b) The Multistate Jurisprudence Examination with a passing grade of not less than seventy-five percent (75%).

5.1.2 ***Transfer of Grades***

a) Applicants wishing to participate in the National Association of Boards of Pharmacy Transfer of Scores Program must comply with all the requirements of the National Association of Boards of Pharmacy regarding the transfer of scores including but not limited to the submission to the National Association of Boards of Pharmacy the completed and signed NAPLEX SCORE TRANSFER FORM with accompanying fee (non-refundable).

b) For individuals seeking registration in Rhode Island, the Board of Pharmacy will only accept scores submitted directly by the National Association of Boards of Pharmacy. Furthermore, each individual seeking registration in this state must submit an application for registration to the Board in accordance with section 4.0 herein and must meet all other statutory and regulatory requirements herein.

c) Applicants participating in the Transfer of Scores Program shall complete the Multistate Jurisprudence Examination, as described in section 5.1.1(b) herein within six months of application to the Rhode Island Board of Pharmacy.

5.2 ***Re-Examination***

In case of failure of any applicant to satisfactorily pass the Integrated NAPLEX Examination, and/or the Rhode Island Jurisprudence Examination, such applicant shall be entitled to re-examination(s) at such time and place as the next scheduled regular examinations. An applicant who twice fails any licensing examination shall not be eligible for further examination until the applicant has satisfactorily completed additional preparation as directed and approved by the Board. This condition on eligibility also applies to each third and subsequent failure.

Application for re-examination shall be submitted to the Board and accompanied by the required fees in accordance with section 4.1 herein.

5.3 ***Without Examination by Reciprocity***

A registration to engage in the practice of pharmacy in this state may be issued without examination to an applicant who has been duly registered or licensed by examination in another state provided:

a) such state gives reciprocity to pharmacists registered by examination in this state;

b) the Board of Pharmacy in each state in which the applicant holds or has held a registration or license submits to the Board in this state a statement confirming the applicant to be or have been in good standing;

c) the applicant has passed the Multistate Jurisprudence Examination and the Integrated Examination of the National Association of Boards of Pharmacy in accordance with the provisions of section 5.1.1 herein.

Said applicant must submit, at least thirty (30) days prior to the next scheduled Board meeting date, the registration application form with supporting documents as required in section 4.0 and 5.3 herein, including the registration fee of one hundred dollars ($100.00) check or money order (non-refundable), made payable to the General Treasurer, State of Rhode Island.

Section 6.0 ***Internship***

6.1 Prior to commencing internship the applicant must obtain a limited license from the Department. A limited license shall be granted to an applicant who is:

1. eighteen (18) years of age or older;

2. of good moral character;

3. enrolled in at least the first year of a professional program of an accredited college of pharmacy.

4. Foreign graduates as defined in this section shall have obtained a FPGEC certification prior to commencing internship.

6.2 ***Internship***

The internship required of applicants for registration as pharmacists shall consist of fifteen hundred (1500) hours and shall be carried out under the supervision of a U.S. registered pharmacist who shall act as a preceptor.

~~a)~~ ~~A maximum of seven hundred fifty (750) hours shall be accrued in an experiential learning pharmacy practice course offered by an accredited college of pharmacy; and~~

~~b) The remaining seven hundred and fifty (750) hours of the internship shall be carried out under the supervision of a registered pharmacist who shall act as a preceptor who is an employee of the business or institution that operated the pharmacy.~~

Applicants seeking registration as a pharmacist by reciprocity (section 5.3 herein) shall have satisfied the requirements of internship in the state of initial licensure.

~~6.3 The Board, after review, may accept alternate programs of instruction as equivalents to the requirements of section 6.2(b) above, provided, however, that one-half (1/2) of internship hours accrued outside an educational pharmacy practice course must be performed in a registered pharmacy.~~

~~6.4~~ 6.3 Prior to application for examination, the pharmacy intern shall submit, on forms provided by the Board, verification of his/her practical experience under the supervision of a registered pharmacist as defined in section 6.2(b) herein.

Section 7.0 ***Issuance and Renewal of Registration***

7.1 Upon completion of the aforementioned requirements, a registration shall be issued by the Board to an applicant found to have satisfactorily met all the requirements herein. Said registration unless sooner suspended or discontinued shall expire annually on the first (1st) day of July.

7.2 Every person registered as a pharmacist in this state who desires to renew his or her license shall file such renewal application annually with the Board by the first (1st) day of July. Said renewal shall be duly executed together with renewal fee of fifty dollars ($50.00) per check or money order (non-refundable), made payable to the General Treasurer, State of Rhode Island. Upon receipt of such application and payment of such fee, the accuracy of the application shall be verified and a registration renewal shall be granted effective for one (1) year unless sooner suspended or discontinued.

7.3 Any person who allows his or her license to lapse by failing to renew it on or before the first (1st) day of July of each year, may be reinstated upon filing an application with payment of renewal fee of fifty dollars ($50.00) per check or money order (non-refundable), made payable to the General Treasurer, State of Rhode Island.

7.3.1 Any pharmacist registration that has lapsed, been revoked or suspended and the pharmacist has not practiced pharmacy, as defined by the Board, for three (3) years requires that he/she take and pass the same examinations required for initial registration.

7.4 ***Continuing Education***

Pursuant to the provisions of section 5-19-6 of the General Laws of Rhode Island, as amended, any pharmacist, registered to practice pharmacy in Rhode Island, who seeks annual registration renewal, shall be required to have satisfactorily completed at least fifteen (15) hours (1.5 continuing education units) of continuing education courses sponsored by a recognized provider. Furthermore, five (5) hours or 0.5 continuing education units of the required fifteen (15) hours of continuing education must be live hours. In addition:

a) For the first year of registration following graduation from a college of pharmacy, a pharmacist shall not be subject to the continuing education requirements herein; and

b) In emergency or hardship cases, a registered pharmacist may apply to the Board on forms provided by the Board for an exemption from the continuing education requirements herein.

7.4.1 The annual application for registration renewal shall include affidavits signed by the applicant attesting to the fact that he or she has satisfactorily completed an approved course(s) of continuing education provided by a recognized provider, as defined herein. Furthermore:

i. Certificates of continuing education courses must be retained and safeguarded by each pharmacist for review by the Board, if required and requested. Such certificate need not be submitted with the application for registration renewal; however, documentation must be retained for two (2) years following the date of completion of the course.

ii. Any pharmacist whose license has not been renewed for one or more years must demonstrate compliance with continuing education regulations for the registration period immediately prior to application.

iii. Pharmacists failing to comply with the requirements of this section of the rules and regulations shall not be granted license renewal.

7.4.2 ***Recognized Provider***

A "recognized provider" is any person, group or organization approved by the Board as responsible and competent to provide continuing education courses and includes providers accredited by an appropriate national, regional or state accreditation agency. Any provider approved the American Council on Pharmaceutical Education (ACPE), the board of pharmacy in another state or jurisdiction, or the provider of American Medical Association (AMA) Category I programs shall be considered recognized providers.

Any applicant requesting status as a Board-approved provider of a continuing education program shall make application within thirty (30) days after the completion of the course. Any provider wishing to include the statement "Approved by the Rhode Island Board of Pharmacy" in program literature must submit the application for approval at least forty-five (45) days prior to the program. No provider shall state that the provider or program is Board-approved until the provider receives written approval from the Board. The applicant must provide documentation that the following criteria have been met:

1. ***Promotional Announcements and Literature:*** All literature including brochures, advertisements and announcements should include the following items:

- Educational goals and learning objectives;
- Nature of the target audience that would benefit from participation;

- Faculty members and their credentials;
- Schedule of educational activities;
- Amount of CEUs assigned;
- Description of requirements established by provider for successful completion of continuing education program;
- Financial sponsorship/program support.

2. ***Continuing Education Credit:*** shall be determined by the provider in advance of the program. The minimum unit of credit awarded for any continuing education program is one (1) contact hour (0.1 CEU).

3. ***Certificates of Credit:*** certificates shall be provided to each participant in the program and must include:

   - The name of the participant;
   - Title and date of the program;
   - Name of the approved provider;
   - Amount of credit approved.

4. The provider shall select an appropriate number of competent faculty for each continuing education program.

5. ***Educational Program Development:***

   Continuing education programs shall address topics and subject matter areas that are pertinent to the contemporary practice of pharmacy that include, but are not limited to: the social, economic, behavioral, legal, administrative and managerial aspects of pharmacy practice and health care; the properties and actions of drugs and dosage forms; the etiology, characteristics, therapeutics and prevention of disease states; the pharmaceutical monitoring and management of patient therapy; and other information unique to specialized types of pharmacy practice.

   If topics are not exclusively specific to pharmacy, the provider shall take appropriate steps to assure that the core content is explicitly related to the contemporary practice of pharmacy.

   Educational goals and learning objectives shall reflect the relationship of the program topic or content to contemporary practice of pharmacy.

   Each continuing education activity shall be designed to explore one subject or a group of closely-related subjects.

6. ***Program Evaluation:***

Providers shall establish a mechanism for allowing participants to assess their achievement with the program's learning objectives.

Providers shall develop and implement a program evaluation component for each program, whereby each participant may have the opportunity to evaluate the continuing education activity.

B. Certification of completion of course(s) shall be furnished by the "recognized providers" to each participant who satisfactorily completed the approved continuing education course(s).

7.4.3 ***Continuing Education Credit For Postgraduate Pharmacy Curriculum/Program***

A registered pharmacist who is enrolled in a postgraduate doctor of pharmacy program shall be awarded CEUs for satisfactory completion of courses within said curriculum or program, provided that the sponsor of the postgraduate curriculum or program is an accredited college of pharmacy. A registered pharmacist enrolled in other postgraduate pharmacy programs may seek continuing education credit provided that the application satisfies all requirements under this section and provided further that the course provides instruction in one (1) or more of the following areas: pharmacy, pharmaceutical sciences, pharmacy practice or pharmacy law.

Students seeking continuing education credit for postgraduate pharmacy education must maintain official course transcripts for two (2) years after completion of the course work.

Section 8.0 ***Return or Exchange of Drugs, Etc.***

8.1 The Board, with the approval of the Director of Health, of the Rhode Island State Department of Health, hereby declares it to be its policy and intent, and the purpose of this rule, to protect the public health and safety, and to conform with the Rhode Island Food, Drugs and Cosmetics Act, and in particular, but without limitation of such purpose, to ensure that the public shall receive drugs, medicines, sick room supplies, and items for personal hygiene, with the assurance of safety and efficacy in their use.

8.2 Drugs, medicines, sick room supplies, and items for personal hygiene, shall not be accepted for return or exchange by any pharmacist, after such drugs, medicines, sick room supplies, or items for personal hygiene have been taken from the premises where sold, distributed, or dispensed, except under the following conditions:

8.2.1 ***Single Unit Container:*** the pharmacist or pharmacy may accept for return, single unit containers from the ultimate users to whom the medication was dispensed, provided the pharmacist or pharmacy was the provider of the particular single unit container, and the ultimate user is a patient in a hospital;

8.2.2 ***Recording:*** the pharmacist must maintain a record of the receipt of each drug, medicine, or device showing the date received, the prescription number for which the material was

acquired, and the identity, quantity, and/or strength, and the name of the manufacturer. Such records shall be kept on file in the pharmacy for a period of two (2) years;

8.2.3 ***Sick Room Supplies/Equipment:*** a pharmacist may accept for return sick room supplies/equipment provided such can be sanitized. If the surfaces of the sick room supplies or equipment cannot be cleansed or sterilized, the articles are not returnable. However, sick room supplies are not to be construed to mean nor include hospital beds, wheel chairs, crutches and such other major equipment used in the care and treatment of the sick and injured.

8.3 ***Prescriptions***

8.3.1 ***Prescription Refill Information***

a. No pharmacist shall fill or refill any prescription after one (1) year from the date of issuance by the practitioner without authorization from the practitioner.

b. A pharmacist may refill a prescription for a patient written by a practitioner who has expired or has had his/her license to practice or controlled substance registration revoked, suspended, or discontinued, for a period not to exceed ninety (90) days, if the prescription was written by the practitioner prior to his/her death or action against license and the prescription contains authorizations for refills.

8.3.2 Pharmacists shall only compound prescriptions for a drug product(s) not included in the official compendium (The U.S. Pharmacopoeia, N.F.) if the prescription clearly delineates in writing all the ingredients to be included in the drug product. All such prescriptions, drugs and ingredients must conform to the requirements of Chapters 21-31, 21-28, 5-19 and such other applicable statutory requirements.

8.3.3 Technological devices for the transmission or communication of prescriptions between licensed prescribers and pharmacists may be used in accordance with the following guidelines:

a) The transmission of prescriptions for controlled substances shall be in compliance with the provisions of Chapters 21-28 ("Controlled Substances Act") and 5-37.3 ("Confidentiality of Health Care Information Act") of the General Laws of Rhode Island, as amended, and all other federal or state laws;

b) The pharmacist shall exercise professional judgement regarding the accuracy or authenticity of the transmitted prescription consistent with existing laws and regulations;

c) The use of technological devices for the transmission of prescription orders shall occur only at the option of the patient, or the patient's agent, to a pharmacy of the patient's choice;

d) Technological devices shall not be used to circumvent documentation, verification, or any provisions of Chapter 5-19 of the General Laws of Rhode Island, as

amended. Neither shall they be used to commit any other action that may be deemed unprofessional conduct.

e) Technological devices shall be located within the pharmacy.

PART III *PHARMACIES: REGISTRATION REQUIREMENTS*

Section 9.0 *Registration Requirement*

9.1 ***Retail Pharmacies:*** Pursuant to section 5-19-20 of the Act, no person shall conduct, maintain or operate a pharmacy or any open shop or store for the purpose of retailing, compounding or dispensing drugs, medicines or poisons, without first obtaining and having in force a pharmacy license in accordance with the statutory provisions of the Act, and the regulatory requirements herein.

9.2 ***Pharmacies Within Medical Institutions:*** Pursuant to section 5-19-28 of the Act, no person shall operate, conduct, maintain, open or establish a pharmacy within any hospital, sanitorium, clinic or dispensary, in which drugs, medicines and poisons are compounded or dispensed without obtaining a license in accordance with the statutory provision of the Act, and the regulatory requirements herein.

Section 10.0 *Application For License and Fee*

10.1 Application for a license (retail pharmacy, or pharmacy within a medical institution) to conduct, maintain or operate a pharmacy in this state shall be made in writing on forms provided by the Board and shall be submitted to the Board at least thirty (30) days prior to the expected operating date of the establishment for the transaction of business as a pharmacy.

10.2 The initial application must include the following:

a) name and address of owner and/or manager;

b) name of pharmacist having supervision over the conduct and maintenance of the pharmacy or drug store;

c) proposed location and address of place of business and blueprint or drawings of proposed floor plans;

d) the initial registration fee of one hundred dollars ($100.00) per check or money order (non-refundable), made payable to the General Treasurer, State of Rhode Island; and

e) such other information as the Board may deem necessary.

10.3 Applications for license renewal shall be made on forms provided by the Board and shall include such information as the Board may require, and the application must be accompanied by the license renewal fee of fifty dollars ($50.00) per check or money order (non-refundable), made payable to the General Treasurer, State of Rhode Island.

Section 11.0 ***Issuance and Renewal of License***

11.1 Upon receipt of an application for a license the Board shall issue a license or renewal thereof for a period of one (1) year if the applicant meets the statutory and regulatory requirements herein. Said license, unless sooner suspended or discontinued, shall expire annually on the first (1st) of July following its issuance and may be renewed from year to year upon submission of application and license renewal fee. The Board shall use the following criteria in determining ownership interest:

11.1.1 The Board of Pharmacy shall refuse to grant any pharmacy license to any person who is a practitioner authorized to prescribe medications or to any partnership, corporation or other entity in which practitioners authorized to prescribe medications maintain a financial interest which, in the aggregate, exceeds ten percent (10%) of the total ownership of said entity or of the subject pharmacy or drug store.

11.1.2 On and after July 1, 1994, good and sufficient cause shall exist for the refusal to renew and/or for the revocation of any pharmacy license, if, after hearing, the Board of Pharmacy determines that:

(a) Practitioners, spouse (if not estranged) or any dependent child or business associate of the person with authority to prescribe medications maintain a financial interest, which, in the aggregate, exceeds ten percent (10%) of the total ownership of the subject pharmacy, drug store or licensee; or

(b) More than forty percent (40%) of the prescriptions filled by the subject pharmacy or drug store within any three (3) month period beginning on or after July 1, 1994 were issued by practitioners with any ownership interest in a drug store or licensee.

i. The registrant of said pharmacy shall furnish and deliver to the Board, upon request, all dispensing reports, and any other required documents necessary to determine the percentage of prescriptions filled.

11.2 A license shall be issued to a pharmacy or drug store in the name of the registered pharmacist who has supervision over the conduct and maintenance of the pharmacy. The license shall be issued to the specific pharmacist for a specific location and shall not be transferable.

11.2.1 No pharmacist shall be allowed to register more than one pharmacy at the same time.

11.3 A license issued hereunder is the property of the state and loaned to such licensee. It shall be kept posted in a conspicuous place in the registered pharmacy.

11.3.1 The name of the pharmacist registering a pharmacy, and the name of each pharmacist in attendance, shall be conspicuously displayed in the pharmacy.

Section 12.0 ***Change of Ownership, Operation, Location and/or Registrant (Supervisory Pharmacist)***

12.1 When a change of ownership, or operation, or location or when discontinuation of services is contemplated, the person owning the pharmacy or the registrant (supervising pharmacist) shall notify the Board in writing at least fourteen (14) days prior to proposed action.

12.2 Furthermore, every registrant of a pharmacy shall give the Board fourteen (14) days notice in writing prior to terminating services as a registrant of a pharmacy. The person, owning such pharmacy, shall give like notice prior to terminating services as a registrant of a pharmacy.

12.3 When there is a change in ownership, operation, location and/or registrant (supervising pharmacist) the license shall immediately become void and shall be delivered by the registrant pharmacist to the Board.

12.3.1 The Board, or its designee, reserves the right to extend the expiration date of such license, allowing the pharmacy to operate but under conditions stipulated by the Board for such time as shall be required for the processing of a new application.

12.3.2 The new applications must be filed in accordance with the provisions of section 10.0 herein and be accompanied by the registration fee pursuant to section 5-19-31 of the Act.

12.4 ***Pharmacy renovations or remodeling***: Any renovations or remodeling of an existing pharmacy shall not be considered a change of location.

Section 13.0 ***Retail Pharmacy: General Requirements***

13.1 ***Personnel:*** A registered pharmacist shall be in the pharmacy at all times during the hours of operation to operate and manage the pharmacy. The pharmacist(s) shall be subject to all the statutory and regulatory provisions herein pertaining to the practice of pharmacy.

13.2 ***Security:*** Every pharmacy must have and maintain proper security to limit accessibility of unauthorized personnel on the premises and to safeguard against the diversion of drugs, biologicals and medications.

13.3 ***Facilities, Equipment and Stock***: Every pharmacy must be properly secured, equipped with facilities, apparatus, utensils, the current edition of the U.S. Pharmacopeia/National Formulary, and a representative stock of pharmaceuticals, chemicals, drugs and preparations, so that prescriptions can be properly filled.

13.4 ***Space:*** The pharmacy shall be adequate in size and space to enable the pharmacist(s) to discharge all pharmaceutical functions and duties in a safe and effective manner, and to contain all required equipment, utensils, storage areas, including prescription compounding counter, and an area with adequate privacy to conduct patient counseling.

a) The surface of the prescription counter shall not be less than twenty-four (24) inches in width, not less than sixteen (16) square feet in unobstructed working space for one pharmacist, and not less

than twenty-four (24) square feet of total working space for two or more pharmacists on duty at any one time.

b) The pharmacy shall be equipped with proper sanitary appliances and kept in a clean, sanitary and orderly manner.

c) Any new pharmacy shall have an area of not less than 250 square feet.

Section 14.0 ***Institutional Pharmacy: General Requirements***

Personnel

14.1 The institutional pharmacy shall be directed by a registered pharmacist, hereinafter referred to as the registrant, who shall be responsible for meeting the requirements set forth by federal and state law, this section, and other applicable regulations of the Board. The registrant shall be thoroughly familiar with the specialized functions of institutional pharmacy practice.

14.2 The registrant shall be assisted by a sufficient number of pharmacists and supportive personnel to operate such pharmacy competently, safely, and to meet the needs of the patients of the medical institution. A registered pharmacist shall be in the institution at all times during the hours of pharmacy scheduled operation to operate and manage the pharmacy.

14.3 The registrant shall ensure that an adequate number of qualified, competent and trained pharmacists are employed. The registrant shall develop and implement written policies and procedures to specify the duties to be performed by such pharmacists.

14.4 The registrant shall ensure that a sufficient number of qualified, trained, competent and adequately supervised supportive personnel are employed to provide technical services, as well as ensuring that all such functions and activities are performed competently, safely, and without risk of harm to patients. The relationship between the supervising pharmacist and the supportive personnel shall be such that the pharmacist is fully aware of and responsible for all activities involved in the preparation and dispensing of medications prior to the release to the patient, including the maintenance of appropriate records.

Physical Requirements

14.5 An institutional pharmacy shall have sufficient floor space allocated to it to ensure that drugs are prepared in sanitary, well-lighted and enclosed places. It shall have sufficient equipment, supplies and physical facilities for proper compounding, dispensing and storage of drugs, including parenteral preparations and for the provision of pharmaceutical care. All work surfaces shall be free of equipment, supplies, records and labels unrelated to the preparation of medications. The equipment and physical facilities shall include, but are not limited to, the following:

a) Compounding and dispensing areas;

b) Physically separate parenteral solution additive area when solutions are compound in the pharmacy as described in section 15.4;

c) Receiving and storage areas;

d) Packaging and repackaging areas;

e) Office space sufficient to allow for administrative functions without interference with the safe compounding and dispensing of medications and security of the pharmacy.

After-hours Pharmacy Services

14.6 The registrant shall establish policies and procedures for the provision of a limited supply of medications for filling of urgent orders to patients of the medical institution after the scheduled hours of operation of the pharmacy. The pharmacist in charge shall provide for the provision of pharmaceutical care after normal working hours by use of an "on call" pharmacist accessible to the medical institution after hours. The institutional pharmacy may enter into a contractual arrangement with another pharmacy or pharmacist for the provision of such services. Medications may be accessed from a pharmacy-designated area. The policies and procedures shall address:

a) A list of those individuals authorized by the registrant to remove medications from the pharmacy-designated area.

b) A list of medications authorized for removal from the pharmacy-designated area determined by the registrant, or designee, and the medical staff of the medical institution. The pharmacist in charge shall limit the number of medications, quantity and dosage forms to maximize patient safety. Medications shall be removed from the designated area in unit-of-use packaging, whenever possible. If a non-unit-dosed medication is needed when the pharmacy is closed, the bulk medication container shall be signed out. When the pharmacy re-opens, the pharmacist shall retrieve the bottle and dispense the necessary amount of medication. The bottle shall be returned to the pharmacy within twenty-four (24) hours after the pharmacy re-opens.

c) documentation of medications removed from the pharmacy-designated area, which shall include, but not be limited to, medication name, strength, signature of authorized person removing medications, quantity and name of patient.

d) methods for performing a periodic review of those policies and procedures.

Medication Distribution and Control

14.7 The registrant shall establish policies and procedures relating to the procurement, distribution and control of all drug products used in the medical institution.

Medication Orders

14.7.1 Medications are to be prescribed, dispensed and administered only upon orders of authorized practitioners and medication orders transmitted to the pharmacy in an appropriate manner.

14.7.2 A registered pharmacist in the institutional pharmacy shall review all medication orders for

appropriateness within twenty-four (24) hours, except orders initiated in the operating room, emergency room, procedural rooms, and ambulatory care centers. Medication orders written when the pharmacy is closed shall be reviewed within twenty-four (24) hours after the pharmacy re-opens.

14.7.3 All patient medication orders shall be contained in the patient's medical record.

Medication Storage and Security

14.7.4 All areas designated for medication storage shall have and shall maintain proper security to limit accessibility of unauthorized personnel on the premises and to safeguard against diversion of drugs, biologicals and medications.

14.7.5 All medications shall be stored in designated areas under proper conditions of sanitation, temperature, light, moisture, ventilation, and segregation to ensure medication integrity. Medications shall be stored in accordance with medication labeling pursuant to the federal and state Food Drug and Cosmetic Acts.

14.7.6 All stocks of medications shall be inspected routinely to ensure the absence of outdated, unusable or mislabeled products.

14.7.7 Floor stock of medications shall be limited to medications for emergency use, non-legend medications that are routinely used, and limited medications as designated by the facility.

14.7.8 All medication areas including auxiliary drug supplies, unit dose carts and emergency kits, shall remain secured at all times. All medications must be adequately secured to restrict access by unauthorized personnel.

14.7.9 Sample medications shall be procured, stored, dispensed and/or donated to charitable institutions in accordance with the federal Food Drug and Cosmetic Act.

Labeling

14.7.10 All drugs dispensed within a medical institution shall be labeled and identified up to the point of administration.

14.7.11 Whenever a drug is added to a parenteral admixture, it shall be labeled with a supplementary label indicating the name and amount of the drug added, expiration date and expiration time, if applicable. For admixtures prepared outside the pharmacy, the registrant shall develop policies and procedures for preparation and labeling.

14.7.12 Labels for outpatient medications shall comply with section 21-31-15(l)(l) of the Rhode Island General Laws, as amended.

Records

14.7.13 The registrant shall develop a system of daily accountability for medication compounding and dispensing that shall permit the identification of the responsible pharmacist. Readily retrievable records of accountability shall be maintained for at least one (1) year. At a minimum, this system shall identify all personnel who perform these activities and the pharmacist responsible for:

a) interpretation and appropriateness of new medication orders;

b) profile entry of new medication orders;

c) dispensing of new medication orders including "stat" doses;

d) daily cart fills;

e) compounding medications; and

f) periodically assessing the quality of pharmacy procedures for preparation and release of drugs for replenishment of floor stock, ancillary drug supplies, emergency kits and automated dispensing devices in locations outside the pharmacy.

Patient's Personal Medications

14.7.14 Medications brought into the hospital by patients may only be administered pursuant to a written order. Prior to administration, medications shall be identified by a prescribing practitioner or a pharmacist.

14.7.15 In the case that the medications are not to be used during the patient's hospitalization, every attempt shall be made to give the medications to the patient's family or caregiver. If this is not possible, the pharmacy shall package and seal the medications and store the medications in a secure location until such time that the patient is discharged. No medication shall be retained by the medical institution for longer than thirty (30) days after the patient's discharge and shall be disposed of in accordance with the policy of the medical institution.

Emergency Outpatient Medications

14.7.16 The registrant and medical staff shall establish policies and procedures for the dispensing of medications from the emergency room.

14.7.16.1 Only a licensed prescriber shall be authorized to dispense medications to patients in an emergency situation.

14.7.16.2 Emergency medications shall be labeled in accordance with section 21-31-15(l)(l) of the Rhode Island General Laws, as amended.

Monitoring Drug Therapy

14.8 The pharmacist shall review the appropriateness of the choice of medications for the patient and the patient's therapeutic regimen, pursuant to section 15.15 of these regulations.

14.8.1 Pharmacists shall have access to the following information:

1. admission diagnosis;
2. age, weight, height and sex;
3. history of allergies and/or previous adverse drug reactions;
4. current and discontinued medications;
5. co-morbid disease states;
6. pertinent laboratory information.

14.8.2 The pharmacist shall review each medication order and, in the case of an identified, significant problem or opportunity for improvement, the pharmacist shall contact the prescribing practitioner. All such communications shall be documented electronically or in writing. Pharmacy interventions shall be reviewed with appropriate staff committees on a routine basis.

14.8.3 ***Medication Use Evaluation Program:*** The registrant and medical staff shall establish policies and procedures to increase the effectiveness and minimize the risk of drug use. Policies and procedures shall include defining, monitoring, detecting, reporting and reviewing the following:

14.8.3.1 ***Adverse Drug Reactions (ADR):***. Serious ADR's shall be reported to the FDA's MedWatch Program. Vaccine-related adverse events shall be reported to the CDC.

14.8.3.2 ***Medication Errors***: Special consideration shall be given to measures to prevent medication administration errors associated with preparing parenteral and sterile products.

14.8.3.3 ***Medication Use Evaluation:*** The system shall identify, and resolve actual and potential medication-related problems, and prevent potential medication problems that could interfere with optimum patient outcomes from medication therapy.

Section 15.0 ***Pharmacy Practice***

Pharmaceutical Services: Nursing and Hospice Care Facilities

15.1 Any registered pharmacy or registered pharmacist that provides pharmaceutical services by contract to a nursing or hospice facility shall comply with the following regulations:

15.1.1 Unless the nursing or hospice care facility operates a registered pharmacy and employs a director of pharmacy services, the nursing or hospice care facility shall have a written agreement with a registered pharmacy to provide pharmaceutical services. The registrant of

the pharmacy shall supervise the entire spectrum of pharmaceutical services in the nursing or hospice care facility.

15.1.2 The pharmacy and therapeutics committee, or its equivalent, shall consist of not less than a registered pharmacist, a registered nurse, a physician and the administrator or a representative from administration and shall review all policies and procedures for the provision of pharmaceutical services to patients.

15.1.3 The pharmacist shall be responsible for the development of written policies and procedures that shall include, but not be limited to, the following:

a) Procedures for administering the services outlined in the written agreement with the facility.

b) Policies and procedures necessary to ensure the safe use, administration, control and accountability of all drugs throughout the nursing or hospice facility in compliance with federal and state laws. The pharmacist shall:

- receive a valid medication or prescription order prior to the dispensing of any drug.
- ensure that the drugs for each patient are kept and stored in the originally received containers and that the medication of one patient shall not be transferred to another patient.
- ensure that each cabinet, cart or other area utilized for the storage of drugs is locked and accessible only to authorized personnel.
- provide for the timely delivery of drugs and biologicals from the pharmacy so a practitioner's orders for drug therapy can be implemented without undue delay.

c) Policies and procedures outlining the return or destruction on-site of wastage for all controlled substances and the proper disposal of legend drugs.

d) Policies governing appropriate storage of medications, an effective drug recall procedure, and labeling of all prescription drugs and biologicals in accordance with federal and state requirements.

e) For nursing facilities, policies and procedures governing patient drug regimen reviews, that shall include procedures for reporting irregularities, and documenting that such reviews have been performed. The contracted pharmacy consultant shall review all medication orders or prescription orders with information on the patient profiles. The consultant pharmacist shall:

- review the drug and biological regimen of each resident monthly.

- report any irregularities to the attending physician and director of nurses. Reports shall show evidence of review and response; and

- document in writing the performance of such review, which documentation shall be kept on file by the facility and shall be made accessible to inspectors upon request.

15.1.4 A unit dose drug dispensing system or automated dispensing device may be utilized for the dispensing of drugs to patients in a licensed hospital, nursing facility or hospice facility. Such systems or devices shall be utilized in accordance with regulations herein.

Nuclear/Radiologic Pharmacies

15.2 The practice of nuclear/radiologic pharmacy is hereby recognized as a specialty of pharmacy practice, regulated by the Board. This section applies only to pharmacies which are preparing and distributing, or redistributing radioactive material, not simply handling such material.

15.2.1 ***Policies & Procedures***

a) These rules and regulations herein shall not apply to a nuclear medicine department within a medical institution which is licensed by another agency.

b) Nuclear pharmacies shall maintain records of acquisition, inventory, and disposition of all radioactive drugs and other radioactive materials, in accordance with the provisions of the *Rules and Regulations for the Control of Radiation (R23-1.3RAD).*

c) All pharmacies handling radiopharmaceuticals shall provide a radioactive storage and product decay area. Detailed floor plans shall be submitted to the Board and the state Office of Occupational and Radiological Health before approval of the license.

d) Radiopharmaceuticals are to be dispensed only upon a prescription drug order, from a practitioner authorized to possess, use and administer radiopharmaceuticals.

e) The permit to operate a nuclear pharmacy is conditional upon an approved state Office of Occupational and Radiological Health license. Copies of the Office of Occupational and Radiological Health inspection reports shall be made available upon request for Board inspection.

15.2.2 ***Personnel***

a) A license to operate a pharmacy providing radiopharmaceutical services shall only be issued to a qualified nuclear pharmacist. All personnel performing tasks in the preparation and distribution of radioactive drugs shall be under the direct supervision of a qualified nuclear pharmacist. A qualified nuclear pharmacist shall be responsible for all operations of the

pharmacy and shall be in personal attendance at all times that the pharmacy is open for business.

b) The nuclear pharmacy area shall be secured from unauthorized personnel.

15.2.3 ***Physical Requirements***

a) Nuclear pharmacies shall have adequate space and equipment, commensurate with the scope of services required and provided, meeting minimal space requirements established for all pharmacies in the state or as otherwise defined by the Board.

15.3 ***Nonresident Pharmacy***

15.3.1 ***Registration*** - In order to ship, mail, or deliver prescription drugs and/or devices to a patient in this state, a non-resident pharmacy must register with the Board.

15.3.2 ***Agent of record*** - Each nonresident pharmacy that ships, mails, or delivers prescription drugs and/or devices to a patient in this state shall designate a resident agent in this state for service of process. Any such nonresident pharmacy that does not so designate a registered agent and that ships, mails, or delivers prescription drugs and/or devices in this state, shall be deemed an appointment by such nonresident pharmacy of the Secretary of State to be its true and lawful attorney upon whom may be served all legal process in any action or proceeding against such pharmacy growing out of or arising from such delivery. A copy of any such service of process shall be mailed to the nonresident pharmacy by the complaining party by certified mail, return receipt requested, postage prepaid, at the address of such nonresident pharmacy as designated on the pharmacy's application for registration in this state. If any such pharmacy is not registered in this state, service on the Secretary of State in this state only shall be sufficient service.

15.3.3 ***Conditions of Registration*** - As conditions of registration, the nonresident pharmacy must comply with the following:

a) be registered and in good standing in the state in which located, and

b) provide all information requested by the Board.

15.3.4 ***Reports and Complaints*** - Upon receipt of a complaint against the non-resident pharmacy, the Board shall forward the complaint to the state boards where the non-resident pharmacy is licensed.

Compounding of Sterile Pharmaceuticals

15.4 The regulations that follow do not apply to the preparation of medications by pharmacists, nurses or physicians in emergency situations for immediate administration to patients.

General Requirements

15.4.1 Products intended for parenteral administration or ophthalmic instillation shall be compounded using aseptic technique.

15.4.2 The registrant of a pharmacy or dispensing practitioner shall be responsible for establishing policies and procedures for the compounding, dispensing and delivery of sterile products, which shall include, but not be not be limited to, the following:

a) Personnel qualifications including initial and follow-up training and method of periodic re-evaluation of qualifications and performance;

b) Scope of compounding performed at the pharmacy and proper procedures for compounding to include maintaining suitable environmental conditions in the compounding area, wearing appropriate garb to reduce particulate matter and contamination of work area, performing aseptic procedures;

c) Procedures for maintaining and monitoring proper operating conditions for all equipment used in sterile compounding;

d) Guidelines for patient or caretaker education if products are dispensed for home use to include instructions concerning proper storage, aseptic manipulation of the product, proper administration and use of devices if applicable, recognizing signs of instability or incompatibility, and procedures in case of an emergency with the product;

e) Guidelines for assignment of beyond-use dates for all compounded sterile products and justification for any date chosen that exceeds the standard set forth in this regulation;

f) Separate procedures for handling cytotoxic drugs, if applicable, to include protective apparel; disposal procedures consistent with applicable local, state and federal requirements; procedures for handling spills; special packaging and labeling requirements and delivery to minimize risks of accidental spills, in accordance with federal Occupational Safety and Health Administration (OSHA) standards;

g) If applicable, separate procedures for compounding sterile products using non-sterile components or open system transfer techniques and for end-product sterilization of these products.

Physical and Equipment Requirements Preparing Sterile Products

15.4.3 The sterile compounding area shall be of sufficient size to accommodate a laminar airflow hood and to provide for the proper storage of drugs and supplies used in aseptic processing.

15.4.4 The sterile compounding area where parenteral products are routinely prepared shall be

isolated from other areas and other pharmacy functions.

15.4.5 Sterile compounding shall be performed with a laminar flow hood or other appropriate environmental control device capable of maintaining, during normal activity, at least Class 100 conditions in the work area where sterile compounding is performed. Compounding of cytotoxic preparations shall be performed in a vertical flow Class II biological safety cabinet.

15.4.6 The sterile compounding area shall contain supplies adequate for the aseptic preparation of sterile products including, but not limited to:

a) antibacterial soap;

b) hot and cold water supply easily accessible to the sterile compounding area for hand washing prior to aseptic compounding;

c) appropriate apparel for personnel performing sterile compounding;

d) suitable disposal containers for used needles, syringes, etc. and, if applicable, containers for cytotoxic waste and medical wastes.

15.4.7 The sterile compounding area shall have sufficient current reference materials related to sterile products consistent with the policy and procedure manual and with the types of products prepared.

15.4.8 The sterile compounding area shall have equipment necessary for maintaining and monitoring required temperature storage conditions both in the pharmacy or designated compounding area and during delivery to the patient, if applicable.

Labeling Requirements

15.4.9 In addition to other applicable labeling requirements for prescriptions under the rules and regulations herein and Chapter 21-31 of the Rhode Island General Laws, as amended ("Food, Drug and Cosmetic Act"), the label of a compounded sterile product shall include all active ingredient names, strengths, amounts and concentrations, when applicable and for IV infusion shall include the name of all solutions.

15.4.10 The label of a compounded sterile product shall include an appropriate beyond-use date and time, if applicable, and the required storage conditions to assure product integrity for that time period. Unless otherwise specified and justification provided in the policy and procedure manual, the expiration date for unpreserved sterile products prepared aseptically in a closed system for a single patient shall bear a maximum beyond-use date, including administration as follows:

a) Twenty-eight (28) hours if stored at controlled room temperature;

b) Seven (7) days if stored under refrigeration; and

c) Thirty (30) days if stored under freezing conditions.

15.4.11 The label of other compounded sterile products shall bear an appropriate beyond-use date, not to exceed six (6) months from the date of preparation.

15.4.12 If the product is for home or other outpatient use, the label shall bear the prescribed administration regimen including rate and route of administration and any device-specific instructions.

15.4.13 The label shall bear any appropriate auxiliary labeling, including precautions for cytotoxic drugs.

Quality Assurance

15.4.14 The registrant of the pharmacy or the dispensing practitioner who compounds sterile products shall be responsible for maintaining and updating the policy and procedure manual as set forth in sections 15.4.1 and 15.4.2 in accordance with current acceptable standards and for ensuring compliance with the policy and procedure manual.

15.4.15 All laminar flow hoods or other environmental control devices shall be certified according to accepted standards for operational efficiency at least annually.

15.4.16 Laminar flow hoods or other automatic compounding devices shall be maintained in accordance with manufacturing recommendations for maintenance and certification.

Recordkeeping Requirements

15.4.17 In addition to other required records, the following additional records shall be maintained for sterile compounding:

a) Compounding records maintained on or with the original prescription or medication order, or in a log format which can be cross-referenced with the prescription, or in an automated data processing system which contains the same information required in a manual system and is capable of producing a hard copy print-out of a two (2) year history of prescription compounding and dispensing upon request within seventy-two (72) hours. In addition to medication order/prescription information, the records shall include the following information:

i. date of sterile compounding;

ii. beyond-use date assigned to the sterile product;

iii. signature, initials or electronic identification of pharmacist compounding, or of both the non-pharmacist compounding and pharmacist checking the compounding of the sterile product, and;

b) Record documenting certification of clean room or laminar flow hoods.

c) If sterile products are provided to a patient's residence, a record documenting training of the patient or caregiver (or both) in the proper storage and use of the product and any devices used to administer the medications shall be maintained.

Automated Storage and Distribution Devices

15.5 Automated storage and distribution devices may be utilized by nursing or hospice care facilities who maintain contracts for pharmaceutical services with registered pharmacies and which provide contractual pharmaceutical services to patients in long term care facilities and shall comply with the following provisions:

15.5.1 Documentation as to type of equipment, serial numbers, content, policies and procedures and location shall be maintained on-site in the pharmacy. Such documentation shall include:

a) name and address of the pharmacy where the automated pharmacy system is being used;

b) manufacturer's name and model;

c) description of how the device is used;

d) quality assurance procedures to determine continued appropriate use of the automated device;

e) policies and procedures for system operation, safety, security, accuracy, patient confidentiality, access and malfunction.

15.5.2 Automated storage and distribution devices shall have adequate security systems and procedures to prevent unauthorized access, to comply with federal and state regulations and maintain patient confidentiality.

15.5.3 Records and/or electronic data kept by automated storage and distribution devices shall meet the following requirements:

a) All events involving the contents of the automated pharmacy system shall be recorded electronically;

b) Records shall be maintained by the pharmacy and shall be readily available to the Board. Such records shall include:

i) identity of system accessed;
ii) identification of the individual accessing the system;

iii) type of transaction;
iv) name, strength, dosage form, and quantity of the drug accessed;
v) name of the patient for whom the drug was accessed;
vi) such additional information as the registrant may deem necessary.

c) A record of medications filled/stocked into an automated pharmacy system shall be maintained and shall include identification of the persons filling/stocking and checking for accuracy.

15.5.4 All containers of medications stored in the automated pharmacy system shall be packaged and labeled in accordance with federal and state laws and regulations.

15.5.5 The automated pharmacy system shall provide a mechanism for securing and accounting for medications removed from and subsequently returned to the automated pharmacy system, in accordance with existing regulations.

15.5.6 The automated pharmacy system shall provide a mechanism for storing and accounting for wasted medications or discarded medications in accordance with existing state and federal law.

Responsibilities of Registrant

15.5.7 The registrant shall establish policies and procedures that shall:

a) Assure that the automated pharmacy system is in good working order and accurately dispenses the correct strength, dosage form, and quantity of the drug prescribed while maintaining appropriate record-keeping and security safeguards.

b) Assure access to medications for the purposes of administration by authorized licensed personnel only.

c) Authorize individuals and determine levels of access to automated storage and distribution devices and ensure security of the system;.

d) Assure that the filling/stocking of all medications in the system shall be accomplished by qualified personnel under the supervision of a registered pharmacist.

e) Implement an ongoing quality assurance program that monitors compliance to the established polices and procedures of the automated pharmacy system.

15.5.8 The registrant shall establish policies and procedures for the process of dispensing and/or administering medications pursuant to a medication order.

Drug Recall

15.6 The registrant shall develop a written procedure to handle drug product recalls. The procedure shall

include, but is not limited to, the following:

a) A process for review of documents (i.e., prescriptions, drug orders, etc.) of the recalled lots.

b) Notification to the recipients and prescribers of the recalled product, when appropriate.

c) Personal inspection of all areas where drugs are stored to determine presence of recalled products.

d) Quarantine of all recalled products to be marked "Quarantined-Do Not Use" until returned to manufacturer.

e) Maintenance of written log of all recalls, the actions taken, and the results.

Emergency Kits

15.7 Drugs and devices may be provided in emergency kits for use by authorized personnel provided that:

a) The registrant, or designee, and the medical staff of the medical institution jointly determine the drugs to be included in the kit by identity and quantity. Drugs included in the kit shall be limited to those for emergency use only and are not to be used for any other purpose.

b) The emergency kit shall be sealed with a non-reusable, easily removable seal to prevent unauthorized access, and to ensure a proper environment for preservation of the drugs.

c) The exterior of the emergency kit shall be labeled so as to clearly indicate that it is an emergency drug kit. A listing of the drugs contained therein including name, strength and quantity of each drug or device shall be attached. Each emergency kit shall be inspected by a pharmacist or his designee monthly to check for expiration dates and the integrity of the seal.

d) All drugs within the emergency kit shall be labeled, if applicable, with the name, strength, lot number, manufacturer and expiration date.

e) Drugs and devices shall be removed from the emergency kit for administration to a patient only pursuant to a valid physician's order, by personnel authorized by the medical institution.

f) The pharmacy shall be notified whenever an emergency kit is opened. The pharmacist or designee shall re-stock, reseal and return the kit to the unit within a reasonable length of time.

Repackaging

15.8 Drugs which are repackaged within a pharmacy for subsequent dispensing or administration shall be labeled to include:

a) the generic or trade name, strength, and quantity of drug;

b) control number assigned by the pharmacy which corresponds to the identification of the manufacturer, manufacturer's expiration date, lot number of the drug, quantity repackaged, date repackaged and pharmacist responsible for repackaging;

c) The expiration date of the drug being repackaged shall be one (1) year from the date the drug is repackaged or the expiration date on the manufacturer's container, whichever is earlier.

15.9 The pharmacy shall have and use facilities, personnel, operational practices, packaging material, and control procedures to assure that the purity, integrity, safety, and effectiveness of the drugs are not affected by such repackaging. All repackaging must be performed by or under the supervision of a pharmacist.

Investigational Drugs

15.10 The registrant and the medical staff shall be responsible for developing policies and procedures for ensuring proper labeling pursuant to Chapter 21-31 of the Rhode Island General Laws, as amended, storage, distribution, administration and control of investigational drugs.

15.10.1 Investigational drugs shall be relabeled "For Investigational Use Only."

15.10.2 A perpetual inventory record for investigational drugs shall be maintained. The record shall contain:

a) drug's name, dosage form and strength, lot number, expiration date;

b) name, address, telephone number of the sponsor;

c) protocol number;

d) information on disposition of the drug;

e) recording dispenser's initials.

15.10.3 Investigational drugs shall be segregated from commercial products.

15.10.4 The registrant shall be responsible for the provision of staff education regarding investigational drugs.

15.10.5 Prior to dispensing, any investigational drug, dose and treatment schedule should be verified against the protocol.

15.11 Any information pertaining to potential adverse effects, precautions, compounding and preparation requirements, etc., of the investigational drug shall be reviewed by the pharmacist.

Adverse Drug Reactions (ADRs) and Medication Errors

15.12 ***Medication Use Evaluation Program:*** The registrant shall establish policies and procedures to increase the effectiveness and minimize the risk of drug use. Policies and procedures shall include defining, monitoring, detecting, reporting and reviewing medication errors and adverse drug reactions (ADRs). Serious ADRs shall be reported to the FDA's MedWatch Program. Vaccine-related adverse events shall be reported to the CDC.

15.13 ***Patient Profile*** - A patient record system shall be maintained by all pharmacies for patients for whom prescriptions are dispensed. The patient record system shall provide for the immediate retrieval of information necessary for the dispensing pharmacist to identify previously dispensed drugs at the time a prescription is presented for dispensing. The pharmacist shall make a reasonable effort to obtain, record, and maintain the following information:

a) full name of the patient for whom the drug is intended;

b) address and telephone number of the patient;

c) patient's age or date of birth;

d) patient's gender;

e) a list of all prescriptions obtained by the patient at the pharmacy maintaining the patient record during the twelve months immediately preceding the most recent entry showing the name of the drug or device, prescription number, name and strength of the drug, the quantity and date received, and the name of the practitioner, and

f) Pharmacist comments relevant to the individual's drug therapy and drug allergies, including any other information peculiar to the specific patient or drug.

15.14 The pharmacist shall make a reasonable effort to obtain from the patient or the patient's agent any known allergies, drug reactions, idiosyncrasies, and chronic conditions of the patient and the identity of any other drugs, including over-the-counter drugs, or devices currently being used by the patient which may relate to prospective drug review, and shall record this information in the patient's profile.

15.15 The patient record shall be maintained for a period of not less than two years from the date of the last entry in the patient profile record. This record may be a hard copy or in a computerized form.

15.16 ***Prospective Drug Review*** - A pharmacist shall review the patient record and each prescription presented for dispensing for purposes of promoting therapeutic appropriateness by identifying:

a) over-utilization or under-utilization;

b) therapeutic duplication;

c) drug-disease contraindications;

d) drug-drug interactions;

e) incorrect drug dosage or duration of drug treatment;

f) drug-allergy interactions;

g) clinical abuse/misuse;

h) food-drug interaction.

Upon recognizing any of the above, the pharmacist shall take appropriate steps to avoid or resolve the problem which shall, if necessary, include consultation with the practitioner or other appropriate persons.

15.17 ***Patient Counseling***

a) After receipt of a new prescription and following a review of the patient's record, a pharmacist or other licensed personnel, as defined in Chapter 5-19, shall initiate discussion of matters which will enhance or optimize drug therapy with each patient or care giver of such patient. Such discussion shall be in person whenever practicable, or by telephone, and shall include appropriate elements of patient counseling, as is appropriate for the patient in the professional judgment of the pharmacist. The offer to counsel may be delegated by the pharmacist. Nothing in this section will prohibit a pharmacist from counseling a patient on a refill prescription when deemed necessary in the professional judgement of the pharmacist. Such elements may include the following:

i. the name and description of the drug;

ii. the dosage form, dose, route of administration, dosing schedule, and duration of drug therapy;

iii. intended use of the drug and expected action;

iv. special directions and precautions for preparation, administration, and use by the patient;

v. common severe side or adverse effects or interactions and therapeutic contraindications that may be encountered, including their avoidance, and the action required if they occur;

vi. techniques for self-monitoring drug therapy;

vii. proper storage;

viii. prescription refill information;

ix. action to be taken in the event of a missed dose; and

x. pharmacist comments relevant to the individual's drug therapy, including any other information peculiar to the specific patient or drug.

b) Alternative forms of patient information shall be used, when deemed necessary in the professional judgement of the pharmacist, to supplement patient counseling when appropriate. Examples to include written information leaflets, pictogram labels, video programs, etc.

c) Patient counseling and patient profiles, as described above and defined in this act shall not be required for inpatients of a hospital or institution, or any other licensed health-care facility, where other licensed health care professionals are authorized to administer the drugs.

d) A pharmacist shall not be required to counsel a patient or care giver when the patient or care giver refuses such consultation. Such refusal shall be documented in writing.

15.18 ***Prescription Transfer***

Prescriptions may be transferred between pharmacies provided that the pharmacies adhere to the following requirements for transferring prescriptions between pharmacies:

a) The prescription is for a drug that is lawfully able to be refilled.

b) The drug is not a Schedule II controlled substance.

c) An original or new prescription is not required from the prescriber by law.

d) The pharmacist transferring the prescription cancels the original prescription in his/her records, and indicates on the prescription records to whom the prescription was transferred, including the name of the pharmacy, the date of the transfer, and the name or initials of the transferring pharmacist.

e) The pharmacist receiving the transferred prescription shall:

1. Note on the prescription that it is a transferred prescription.

2. Record all of the following information on the prescription records, in addition to other information required by law:

i. Date of issuance of the original prescription;

ii. Date of original filling of prescription;

iii. Original number of refills authorized on prescription;

iv. Complete refill record from original prescription;

v. Number of valid refills remaining.

3. Note the location and file number of the original prescription.

4. Note the name of the pharmacy and pharmacist from whom the prescription was transferred.

f) A pharmacist may transfer a prescription to another pharmacist employed by the same corporation without regard to the requirements of sections (d) and (e) herein, provided that both pharmacists have access to the same computerized prescription transfer system which contains the prescription and refill records and incorporates procedures to prevent unauthorized refills.

g) If the prescription is for a controlled substance in Schedules III, IV, or V, the pharmacies shall comply with the *Code of Federal Regulations* (CFR) 1306.26.

15.19 ***Beyond-Use Dating on Labels:*** It shall be the responsibility of the dispenser, taking into account the nature of the drug repackaged, the characteristics of the container, and the storage conditions to which the article may be subject, to determine a suitable beyond-use date to be placed on the label. In addition:

a) the maximum beyond-use date that may be placed on the prescription container label shall be one (1) year from the date the drug is dispensed or the expiration date on the manufacturer's container, whichever is earlier;

b) where an expiration date on a product is dated only by the month and year, the intended expiration date shall be considered to be the last day of the stated month.

PART IV ***REGISTRATION OF MANUFACTURERS, WHOLESALERS, & DISTRIBUTORS***

Section 16.0 ***Registration Requirements***

16.1 Pursuant to the provisions of sections 5-19-26 and 5-19-27 of the Act, every wholesale distributor and/or manufacturer, wherever located, who engages in wholesale distribution into, out of, or within this state, must be registered by the Board in accordance with the laws and regulations of this state, before engaging in wholesale distribution of prescription drugs.

16.1.1 ***Wholesale Distributors and/or Manufacturers*** - The Board requires the following from each wholesale drug distributor or manufacturer as part of the initial licensing procedure, and as part of any renewal of such license;

a) The name, full business address, and telephone number of the licensee;

b) All trade or business names used by the licensee;

c) Addresses, telephone numbers, and the names of contact persons for the facility used by the license for the storage, handling and distribution of prescription drugs;

d) The type of ownership or operation (i.e. partnership, corporation or sole proprietorship;

e) The names(s) of the owner and/or operator of the licensee, including:

1. If a person, the name of the person;

2. If a partnership, the name of each partner, and the name of the partnership;

3. If a corporation, the name and title of each corporate officer and director, the corporate names, and the name of the state of incorporation, and the name of the parent company, if any; and

4. If a sole proprietorship, the full name of the sole proprietor, and the name of the business entity.

16.1.2 Where operations are conducted at more than one location by a single wholesale distributor, each such location distributing into the state shall be registered by the Board.

16.1.3 Changes in any information required by this section shall be submitted to the Board within fifteen (15) days of change.

16.2 The license will be issued upon receipt of the required fee in accordance with section 5-19-31 of the Act.

16.3 ***Minimum Qualifications***

16.3.1 The Board will consider the following factors in determining eligibility for registration of persons who engage in the wholesale distribution or manufacturing of prescription drugs:

a) Engaging in any unprofessional conduct as defined in section 19.0.

b) Any felony convictions of the applicant under federal, state or local laws;

c) The applicant's professional qualifications and past experience in the manufacture or distribution of prescription drugs, including controlled substances;

d) The furnishing by the applicant of false or fraudulent material in any application made in connection with drug manufacturing or distribution;

e) Suspension or revocation by federal, state or local government of any license currently or previously held by the applicant for the manufacture or distribution of any drugs, including controlled substances;

f) Compliance with licensing requirements under previously granted licenses, if any;

g) Compliance with the requirements to maintain and/or make available to the state licensing authority or the federal, state, or local law enforcement officials those records to be maintained by wholesale drug distributors and manufacturers, and

h) Any other factors or qualifications the Board considers relevant to, and consistent with, the public health and safety.

16.4 ***Personnel***

16.4.1 The registered wholesale distributor or manufacturer shall employ adequate personnel with the education and experience necessary to safely and lawfully engage in the wholesale distribution and/or manufacturing of drugs.

16.5 Storage and handling of prescription drugs and the establishment and maintenance of prescription drug distribution records by wholesale drug distributors and their officers, agents, representatives, and employees:

16.5.1 ***Facilities***

a) All facilities at which prescription drugs are stored, warehoused, handled, held, offered, marketed, or displayed shall:

1) Be of suitable size and construction to facilitate cleaning, maintenance, and proper operations;

2) Have storage areas designed to provide adequate lighting, ventilation, temperature, sanitation, humidity, space, equipment, and security conditions;

3) Have a quarantine area for storage of prescription drugs that are outdated, damaged, deteriorated, misbranded, or adulterated, or that are in immediate or sealed, secondary containers that have been opened;

4) Be maintained in a clean and orderly condition, and

5) Be free from infestation by insects, rodents, birds, or vermin of any kind.

16.5.2 ***Security***

a) All facilities used for wholesale drug distribution and/or manufacturing shall be secure from unauthorized entry.

1) Access from outside the premises shall be kept to a minimum and be well-controlled.

2) The outside perimeter of the premises shall be well-lighted.

3) Entry into areas where prescription drugs are held shall be limited to authorized personnel.

b) All facilities shall be equipped with an alarm system to detect entry after hours.

c) All facilities shall be equipped with a security system that will provide suitable protection against theft and diversion. When appropriate, the security system shall provide protection against theft or diversion that is facilitated or hidden by tampering with computers or electronic records.

16.5.3 ***Storage:*** All prescription drugs shall be stored at appropriate temperatures and under appropriate conditions in accordance with requirements, if any, in the labeling of such drugs or with the requirements in the current edition of an official compendium, such as the United States Pharmacopeia, and National Formulary, or their successor agency.

1) 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.

2) Appropriate manual, electro-mechanical, or electronic temperature and humidity recording equipment, devices and/or logs shall be utilized to document proper storage or prescription drugs.

3) The record keeping requirements in section 16.5.6 shall be followed for all stored drugs.

4) Storage shall not include temporary or incidental possession for the purpose of delivery and/or shipment of prescription drugs.

16.5.4 ***Examination of Materials***

a) Upon receipt, each outside shipping container shall be visually examined for identity and to prevent the acceptance of contaminated prescription drugs, or prescription drugs that are otherwise unfit for distribution. This examination shall be adequate to reveal container damage that would suggest possible contamination or other damage to the contents.

b) The contents of each outgoing shipment shall be carefully inspected for identity of the prescription drug products, and to ensure that there is no delivery of prescription drugs that have been damaged in storage or held under improper conditions.

c) The record keeping requirements in section 16.5.6 shall be followed for all incoming and outgoing prescription drugs.

16.5.5 ***Returned, Damaged and Outdated Prescription Drugs***

a) Prescription drugs that are outdated, damaged, deteriorated, misbranded, or adulterated shall be quarantined and physically separated from other prescription drugs until they are destroyed or returned to their supplier.

b) Any prescription drugs whose immediate or sealed outer or sealed secondary containers have been opened or used, shall be identified as such, and shall be quarantined and physically separated from other prescription drugs until they are either 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 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 drug distributor shall consider, among other things, the conditions under which the drug has been held, stored, or shipped before or during its return, and the condition of the drug and its container, carton, or labeling, as a result of storage or shipping.

d) The record keeping requirements in this section 16.5.6 shall be followed for all outdated, damaged, deteriorated, misbranded, or adulterated prescription drugs.

16.5.6 ***Record keeping***

a) Wholesale drug distributors and/or manufacturers shall establish and maintain inventories and records of all transactions regarding the receipt and distribution of prescription drugs. These records shall include the following information:

1) The source of the drugs, including the name and principal address of the seller or transferor, and the address of the location from which the drugs were shipped;

2) The identity and quantity of the drugs received and distributed or disposed of, and

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

b) Inventories and records shall be made available for inspection and photocopying by any authorized official of any governmental agency charged with enforcement of these regulations for a period of two years following disposition of the drugs.

c) Records described in this section that are kept at the inspection site, or that can be immediately retrieved 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 (2) working days of a request by an authorized official of any governmental agency charged with enforcement of these regulations.

16.5.7 ***Written policies and procedures*:** Wholesale drug distributors and/or manufacturers shall establish, maintain and adhere to written policies and procedures, which shall be followed for the receipt, security, storage, inventory, and distribution of prescription drugs, including policies and procedures for identifying, recording, and reporting losses or thefts, and for correcting all errors and inaccuracies in inventories. Wholesale drug distributors and/or manufacturers shall include in their written policies and procedures the following:

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

b) A procedure to be followed for handling recalls and withdrawals of prescription drugs. Such procedure shall be adequate to deal with recalls and withdrawals due to:

1) Any action initiated at the request of the Food and Drug Administration or other federal, state or local law enforcement or other government agency, including the Board;

2) Any voluntary action by the manufacturer to remove defective or potentially defective drugs from the market, or

3) Any action undertaken to promote public health and safety by replacing of existing merchandise with an improved product or new package design.

c) A procedure to ensure that wholesale drug distributors and/or manufacturers prepare for, protect against, and handle any crisis that affects security for operation of any facility in the event of strike, fire, flood, or other natural disaster, or other situations of local, state, or national emergency.

d) A procedure to ensure that any outdated prescription drugs shall be segregated from other drugs and either returned to the manufacturer or destroyed. This procedure shall provide for written documentation of the disposition of outdated prescription drugs. This documentation shall be maintained for two years after disposition of the outdated drugs.

16.5.8 ***Responsible persons***: Wholesale drug distributors shall establish and maintain lists of officers, directors, managers, and other persons in charge of wholesale drug distribution, storage, and handling, including a description of their duties, and a summary of their qualifications.

16.5.9 ***Compliance with federal, state and local laws:*** Wholesale drug distributors and/or manufacturers shall operate in compliance with applicable federal, state and local laws and regulations.

a) Wholesale drug distributors and/or manufacturers shall permit the Board and authorized federal, state and local law enforcement officials to enter and inspect their premises and delivery vehicles, and to audit their records and written operating procedures, at reasonable times, and in a reasonable manner, to the extent authorized by law.

b) Wholesale drug distributors and/or manufacturers that deal in controlled substances shall register with the Department of Health, and with the Drug Enforcement Administration (DEA), and shall comply with all applicable state, local and DEA regulations.

16.5.10 ***Salvaging and reprocessing:*** Wholesale drug distributors and/or manufacturers shall be subject to the provisions of any applicable federal, state, or local laws or regulations that relate to prescription drug product salvaging or reprocessing, including Chapter 21, parts 207, 210(d), 211 of the Code of Federal Regulations.

PART V *LIMITED REGISTRATION FOR PHARMACY STUDENTS*

Section 17.0 *General Requirements*

17.1 No pharmacy students enrolled in not less than the third year in a recognized college of pharmacy may serve an internship in this state with a preceptor without holding a valid limited registration by the Board of Pharmacy pursuant to the provisions of section 5-19-13.1 of the General Laws of Rhode Island, as amended.

17.2 *Application and Fee*

Application for limited registration shall be made on forms provided by the Board and which may be obtained at:

The Rhode Island Department of Health
Three Capitol Hill, Room 205
Providence, Rhode Island 02908

Said forms shall be completed and signed by the applicant and submitted to the Board no later than thirty (30) days prior to the scheduled date of the Board meeting. Such application shall be accompanied by the following documents and fee (non-returnable and non-refundable):

a) a notarized copy of certificate of birth to verify that the applicant is eighteen (18) years of age or older;

b) documented evidence that the student is enrolled in no less than the third (3rd) year in a recognized college of pharmacy, and signed by the Dean of the College of Pharmacy or his appointed designee;

c) the application fee of ten dollars ($10.00) made payable by check or money order to the General Treasurer, State of Rhode Island.

17.3 *Issuance of Limited License*

The application and credentials of the applicant shall be reviewed and verified by the Board. Applicants found to meet the requirements herein shall be issued a limited license. Said license unless sooner suspended or discontinued for due cause in accordance with section 19.0 herein, shall expire annually on the first (1st) day of July. Said license may be renewed annually, subject to the applicant meeting the requirements herein, and upon submission of the annual registration fee of ten dollars ($10.00) made payable by check or money order to the General Treasurer, State of Rhode Island. A limited license is not transferable.

PART VI

Section 18.0 *PHARMACY TECHNICIANS*

The Board of Pharmacy does not recognize the certification or licensing of pharmacy technicians. However, no pharmacy technician shall work in a pharmacy in this state without first enrolling with the Board.

18.1 *Enrollment of Pharmacy Technicians*

An applicant for enrollment as a pharmacy technician must:

18.1.1 be 18 years of age or older;

18.1.2 be a high-school graduate or the equivalent;

18.1.3 not have been convicted of any felony for violations involving controlled substances subject to waiver by the Board upon presentation of satisfactory evidence that such conviction does not impair the ability of the person to conduct with safety to the public the duties of a pharmacy technician.

18.2 *Application*

18.2.1 Application for enrollment as a pharmacy technician shall be made on the form provided by the Board, which may be obtained at:

The Rhode Island Department of Health
Three Capitol Hill, Room 205
Providence, RI 02908

Said form shall be completed and signed by the applicant.

18.2.2 On the above application, the pharmacy registrant shall also attest to the following:

a) that the applicant will receive documented on-the-job training with the duties of employment; and

b) that the applicant will only be assigned duties for which competency has been demonstrated; and

c) that the registrant has complied with the requirements of the Code of Federal Regulations, Part 21, sections 1301.76 ("Other Security Controls for Practitioners"), 1301.90 ("Employee Screening Procedures") and 1301.93 ("Sources of Information for Employee Checks").

18.3 ***Issuance of Enrollment***

18.3.1 Said enrollment shall specify the locations of employment of the applicant. Termination of that employment voids the enrollment, and the technician must re-enroll before working with a new employer.

18.3.2 If the pharmacy technician is working at more than one location for the same employer, only one (1) enrollment is required.

18.3.3 Said enrollment, unless sooner suspended or discontinued for due cause in accordance with section 19.0 herein, shall expire annually on the first (1st) day of July.

18.3.4 Said enrollment shall be renewed annually.

18.3.5 A pharmacy technician enrollment is not transferable.

18.3.6 It shall be the responsibility of the pharmacy registrant to ensure that each pharmacy technician is properly enrolled.

18.4 ***Training of Pharmacy Technicians***

18.4.1 Pharmacy technicians shall complete a training program at the pharmacy of employment or in a program conducted by the employer.

18.4.2 The training program shall:

a) be approved by the registrant pharmacist;

b) be based on the needs of the individual pharmacy;

c) include written guidelines that define the specific tasks the technician shall be expected to perform;

d) stipulate how the technician's competency is to be assessed.

18.4.3 A copy of the training program shall be kept in the pharmacy at all times.

18.4.4 The registrant pharmacist shall certify that the pharmacy technician has successfully completed the training program.

18.4.5 Pharmacy technicians may perform only those tasks for which they have been trained and in which competency has been demonstrated, but in no case, shall ever exceed what is permitted by regulation or law.

PART VII *VIOLATIONS, SANCTIONS & SEVERABILITY*

Section 19.0 *Grounds For Denial or Discontinuation of Registration*

19.1 Good and sufficient cause for the discontinuance of, or refusal to grant or to renew any registration issued under the statutory provisions of the act and the regulations herein shall include, but not be limited to, the following acts herein defined as unprofessional conduct:

a) To obtain such registration by misrepresentation or fraud;

b) To use alcohol, controlled substances, or other agents to such an extent as to deprive a licensee of reasonable self-control, or in violation of any federal or state law;

c) To enter into an agreement, or an arrangement, with a practitioner for the compounding and/or dispensing of secret formula or coded prescriptions, or the acceptance of compensation from a practitioner or compensating a practitioner for referral of service;

d) To enter into an agreement, or an arrangement with a practitioner to promote the sale and distribution of drugs, medicines and poisons, to the economic advantage of any, or all of the parties to the agreement, or arrangement;

e) To permit an unregistered person to perform the functions reserved by law to a registered pharmacist;

f) To have been convicted of or plead nolo contendere to any court in the state of Rhode Island, or of any state, or of the United States, to any felony, or any violation of any state or federal Uniform Controlled Substance Act, or similar drug control statute;

g) To have become unfit, or incompetent, to practice pharmacy by reason of negligence, habits, or other causes;

h) To solicit, collect, accept, or dispense prescriptions for drugs, medicines and poisons at any location or establishment other than the registered pharmacy at which the prescriptions are to be filled or compounded. Provided, however, that this section shall not be construed as to prohibit the collection of the prescription, or the delivery of the prescribed drugs, medicines or poisons at the residence, office or place of employment of the person for whom the prescription was issued;

i) To have violated any of the provisions of any town or city ordinance, state or federal law, and/or the rules and regulations promulgated thereunder which pertain to the sale and distribution of drugs, medicines and poisons, and to the practice of pharmacy;

j) No pharmacist registered and practicing in this state shall advertise by written or spoken words of a character tending to deceive or mislead the public;

k) Making and filing false reports, records, or documents in connection with the practice of pharmacy or failing to keep records and provide records as required within a reasonable time;

l) Disregard of the standards of pharmacy practice or failure to maintain standards established by the pharmacy profession; and

m) Guilty of violating any of the provisions of the Act and/or the rules and regulations adopted thereunder, and

n) To have his or her license to practice pharmacy issued by any other properly-constituted licensing authority of any other state suspended or revoked or surrendered in lieu of suspension or revocation for acts or conduct which would constitute grounds for action under the provisions of Chapter 5-19 and/or the regulations promulgated thereunder.

o) To maintain a financial interest, which, in the aggregate, exceeds ten percent (10%) of the total ownership of the subject pharmacy, drug store or licensee, or to fill within any three (3) month period beginning on or after July 1, 1994, more than forty (40%) of the prescriptions filled by the subject pharmacy or drug store which were issued by practitioners with any ownership interest in the subject pharmacy, drug store, or licensee.

Section 20.0 ***Violations and Sanctions***

20.1 Every person, co-partnership or corporation who shall violate any of the provisions of this Act and the rules and regulations thereof shall, unless otherwise provided, be subject to such penalties as specified in section 5-19-34 of the Act.

20.2 Any registered pharmacist who shall have been convicted of a violation of the provisions of Chapter 28 of the Title 21 of the Congress of the United States approved October 27, 1970, as amended entitled "Comprehensive drug abuse prevention and control act of 1970" (Title 21, U.S.C. 84 stat. 1236), and all regulations pertaining thereto shall be deemed to have forfeited his/her right to registration, and the Board of Pharmacy shall thereupon discontinue his/her registration.

Section 21.0 ***Rules Governing Practices and Procedures***

21.1 Upon due notice in accordance with Chapter 42-35 of the Rhode Island General Laws, as amended (the Administrative Procedures Act), all hearings and reviews required under the provisions of Chapter 5-19 of the General Laws of Rhode Island, as amended, shall be held in accordance with the rules and regulations promulgated by the Rhode Island Department of Health entitled *Rules and Regulations of the Rhode Island Department of Health Regarding Practices and Procedures Before the Department of Health and Access to Public Records of the Department of Health (R42-35-PP).*

Section 22.0 ***Severability***

22.1 If any provisions of these rules and regulations or the application thereof to any person or circumstance shall be held invalid, such invalidity shall not affect the provisions or application of the rules and regulations which can be given effect, and to this end the provisions of the rules and regulations are declared to be severable.

REFERENCES

1. *Rules and Regulations for the Control of Radiation (R23-1.3-RAD)*, State of Rhode Island, Department of Health, June 1999 and subsequent amendments thereto.

2. "Guide for the Preparation of Applications for Nuclear Pharmacy Licenses." U.S. Nuclear Regulatory Commission, Office of Nuclear Regulatory Research, August 1985.

3. Office of the Federal Register, National Archives and Records Administration. *Code of Federal Regulations* Part 21, sections 1301.76, 1301.90 and 1301.93 (April 1, 1993), p. 30--31.

October 17, 2001
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