Rhode Island Department of Health

NOTICE OF PUBLIC HEARING

The Director of the Rhode Island Department of Health has under consideration proposed ***Rules and Regulations Pertaining to Pharmacists, Pharmacies and Manufacturers, Wholesalers, and Distributors (R5-19.1-PHAR)*** promulgated pursuant to the authority conferred under Chapters 5-37.7 and 42-35 of the Rhode Island General Laws, as amended. The purpose of the proposed changes is to insert a new §21.10 regarding emergency dispensing of pharmaceuticals.

Notice is hereby given in accordance with the provisions of Chapter 42-35 of the Rhode Island General Laws, as amended, that the Director will hold a public hearing on the above mentioned matter, in the **AUDITORIUM** of the Rhode Island Department of Health (on the lower level of the Cannon Building), Three Capitol Hill, Providence, Rhode Island on **THURSDAY, 10 DECEMBER 2009 at 1:00 p.m.** at which time and place all persons interested therein will be heard. The seating capacity of the room will be enforced and therefore the number of persons participating in the hearing may be limited at any given time by the hearing officer, in order to comply with safety and fire codes.

In the development of the rules and regulations, consideration was given to the following: (1) alternative approaches; and (2) overlap or duplication with other statutory and regulatory provisions. No alternative approach, duplication, or overlap was identified based upon available information.

For the sake of accuracy, it is requested that statements to be made relative to any aspect of the regulations, including alternative approaches or overlap, be submitted in writing at the time of the hearing or mailed prior to the hearing date to: David R. Gifford, M.D., M.P.H., Director, Rhode Island Department of Health, #401 Cannon Building, 3 Capitol Hill, Providence, Rhode Island 02908-5097.

Copies of the regulations are available for public inspection in the Cannon Building, Room #201, Rhode Island Department of Health, 3 Capitol Hill, Providence, Rhode Island, on the Department's website: www.health.ri.gov/hsr/regulations/index.php or the Secretary of State's website: http://www.sec.state.ri.us/rules/, by calling 401-222-7767 or by e-mail to Bill.Dundulis@health.ri.gov

The Department of Health is accessible to the handicapped. If communication assistance (readers/ interpreters/captioners) is needed, or any other accommodation to ensure equal participation, please call 401-222-7767 or RI Relay 711 at least three (3) business days prior to the meeting so arrangements can be made to provide such assistance at no cost to the person requesting.

Signed this 4th day of November 2009

David R. Gifford, M.D., M.P.H. , Director of Health

PUBLIC HEARING DRAFT – REVISED 3 NOVEMBER 2009

RULES AND REGULATIONS PERTAINING TO PHARMACISTS, PHARMACIES AND MANUFACTURERS, WHOLESALERS AND DISTRIBUTORS

[R5-19.1-PHAR]

STATE OF RHODE ISLAND AND PROVIDENCE PLANTATIONS

DEPARTMENT OF HEALTH

March 1985

As Amended:

May 1986
August 1986
April 1987
April 1988
October 1988 (E)
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July 1996
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December 2000
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December 2002
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July 2007
January 2008
April 2009
July 2009 (E)
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December 2009 (Proposed)

COMPILER'S NOTES:
Additions: Underlined
Proposed Deletions: ~~Strikeouts~~

INTRODUCTION

These amended *Rules and Regulations* *Pertaining to Pharmacists, Pharmacies and Manufacturers, Wholesalers and Distributors* [*R5-19.1-PHAR*] are promulgated pursuant to the authority conferred under ~~section~~ §5-19.1-5 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~~ were given consideration in arriving at the amended regulations:

(a) Alternative approaches to the regulations; and

(b) Duplication or overlap with other state regulations.

Based on the available information, no known alternative approach~~es~~, duplication or overlap was identified. ~~Consequently, the rules and regulations are adopted in the best interest of the public health, safety and welfare.~~

Upon promulgation of these amendments, 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 5-19.1 of the General Laws of Rhode Island, as amended, entitled, "Pharmacies."

1.2 ***"Administer***", or "***administration***", as used herein, means the direct application of non-controlled medications to the body of a patient or research subject by a practitioner by injection, inhalation, ingestion, or any other means.

1.3 ***"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.

1.4 "***Assisted living residence licensed at the M-1 level***" means a publicly or privately operated residence that provides directly or indirectly by means of contracts or arrangements personal assistance to meet the resident's changing needs and preferences, including central storage and/or administration of medications, lodging, and meals to two (2) or more adults who are unrelated to the licensee or administrator, excluding however, any privately operated establishment or facility licensed pursuant to Chapter 23-17 of the General Laws of Rhode Island, as amended, and those facilities licensed by or under the jurisdiction of the Department of Mental Health, Retardation and Hospitals, the Department of Children, Youth, and Families, or any other state agency. Assisted living residences include sheltered care homes, and board and care residences, or any other entity by any other name providing the above services which meet the definition of assisted living residence.

1.5 ***"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.

1.6 ***"Automated dispensing system"*** means a computerized system for dispensing prepackaged medications in manufacturer labeled, unit-of-use doses.

1.7 ***"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.

1.8 ***"Batch compounding"*** means the act of compounding multiple containers/doses of a drug product or other material with uniform character and quality, within specified limits, that are

prepared in anticipation of physician/prescription drug orders or approved protocol/procedure based on routine, regularly observed prescribing patterns.

1.9 ***Biological product"***" means a virus, therapeutic serum, toxin, antitoxin, vaccine, blood, blood component or derivative, allergenic product, or analogous product, or arsphenamine or derivative of arsphenamine (or any other trivalent organic arsenic compound), applicable to the prevention, treatment, or cure of a disease or condition of human beings.

1.10 ***"Blister packages"*** means multi-dose containers of a specific medication repackaged by the pharmacy in accordance with section 13.7 herein and intended for a specific patient.

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

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

1.13 ***"Board"*** means the Board of Pharmacy within the Department of Health established pursuant to section 5-19.1-3 of the Act.

1.14 "***Call center operation***" means any operation that functions as a shared order processing facility but is not licensed as a pharmacy.

1.15 "***Central fill pharmacy"*** means the pharmacy that fills the prescription order for delivery in accordance with an agreement with a delivery pharmacy.

1.16 **"*Change of ownership*"** means:

a. In the case of a pharmacy, manufacturer or wholesaler which is a partnership 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 a 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.

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

1.18 "***Collaborative pharmacy practice***" is that practice of pharmacy whereby a pharmacist with advanced training and experience relevant to the scope of collaborative practice agrees to work in collaboration with one or more physicians for the purpose of drug therapy

management of patients, such management to be pursuant to a protocol or protocols authorized by the physician(s) and subject to conditions and/or limitations as set forth by the Department. A health care professional who has prescribing privileges and is employed by a collaborating physician may be in such an agreement.

1.19 ***"Collaborative practice agreement"*** is a written and signed agreement, entered into voluntarily, between a pharmacist with advanced training and experience relevant to the scope of collaborative practice and one or more physicians that defines the collaborative pharmacy practice in which the pharmacist and physician(s) propose to engage. Collaborative practice agreements shall be made in the best interest of public health.

1.20 "***Collaborative Practice Committee***" shall consist of six (6) individuals: three (3) individuals to be appointed by the Board of Pharmacy from nominees provided by the Rhode Island Pharmacists Association; three (3) individuals to be appointed by the Board of Medical Licensure and Discipline from nominees provided by the Rhode Island Medical Society. The Collaborative Practice Committee shall advise the Director on all issues pertinent to the regulation of collaborative practice agreements.

1.21 ***"Compounded sterile preparations (CSPs)"*** means a sterile drug or nutrient compounded in a licensed pharmacy or other healthcare-related facility pursuant to the order of a licensed prescriber; the article may or may not contain sterile products.

1.22 ***"Compounding"*** shall be the act of combining two (2) or more ingredients as a result of a practitioner's prescription or medication order occurring in the course of professional practice based upon the individual needs of a patient and a relationship between the practitioner, patient, and pharmacist. Compounding does not mean the routine preparation, mixing or assembling of drug products that are essentially copies of a commercially available product. Compounding shall only occur in the pharmacy where the drug or device is dispensed to the patient or caregiver and includes the preparation of drugs or devices in anticipation of prescription orders based upon routine, regularly observed prescribing patterns.

1.23 ***"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.

1.24 ***"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.

1.25 ***"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.

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

1.27 "***Controlled substance***" means a drug or substance, or an immediate precursor of such drug or substance, so designated under or pursuant to the provisions of Chapter 21-28 of the Rhode Island General Laws, as amended.

1.28 ***"Correctional facility"*** means any facility in this state for the confinement or rehabilitation of offenders or individuals charged with or convicted of criminal offenses.

1.29 ***"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.

1.30 ***"Deliver"*** or ***"Delivery"*** means the actual, constructive, or attempted transfer from one (1) person to another of a drug or device whether or not there is an agency relationship.

1.31 "***Department***" means the Rhode Island Department of Health.

1.32 "***Digital signature***" means an electronic signature based upon cryptographic methods of originator authentication, and computed by using a set of rules and a set of parameters that identify the signer so that the integrity of the data can be verified.

1.33 ***"Delivery pharmacy***" means the pharmacy that delivers the filled prescription medication to the patient.

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

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

1.34.2 to affect the structure or any function of the body of man or other animals.

1.35 ***Director"*** means the Director of the Rhode Island state Department of Health.

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

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

1.38 ***"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 or administration.

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

1.40 ***"Drug"*** means:

1.40.1 articles recognized in the official United States Pharmacopeia, or the official Homeopathic Pharmacopeia of the United States;

1.40.2 substances intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals;

1.40.3 substances (other than food) intended to affect the structure of any function of the body of man or other animals;

1.40.4 substances intended for use as a component of any substances specified in subsections 1.40.1, 1.40.2, 1.40.3 of this section and sections1.96.1, 1.96.2, or 1.96.3 but not including devices or their component parts or accessories.

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

1.41.1 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.

1.41.2 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.

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

1.42 ***"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.

1.43 ***"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).

1.44 ***"Drugs, medicines and poisons"*** has the same meaning set forth in section 5-19.1-2 (10) of the Act.

1.45 ***"Drug therapy management"*** means the review, in accordance with a collaborative practice agreement, of drug therapy regimen(s) of patients by a pharmacist for the purpose of rendering advice to one (1) or more physicians that are party to the agreement, or their physician designees, regarding adjustment of the regimen. Decisions involving drug therapy management shall be made in the best interests of the patient. In accordance with a collaborative practice agreement, drug therapy management may include:

(1) Modifying and managing drug therapy;

(2) Collecting and reviewing patient histories;

(3) Obtaining and checking vital signs, including pulse, temperature, blood pressure, and respiration; and

(4) Under the supervision of, or in direct consultation with a physician, ordering and evaluating the results of laboratory tests directly related to drug therapy when performed in accordance with approved protocols applicable to the practice setting and providing such evaluation does not include any diagnostic component.

1.46 *"**Electronic signature**"* means an electronic sound, symbol, or process attached to or logically associated with a record and executed or adopted by a person with the intent to sign the record.

1.47 ***"Electronic transmission prescription"*** means any prescription, other than an oral or written prescription, that is electronically transmitted from a practitioner authorized to prescribe to a pharmacy without alteration by a third party unless authorized by the prescribing practitioner or from one pharmacy to another pharmacy.

1.48 "***Equivalent and interchangeable"*** means having the same generic name, dosage form, and labeled potency, meeting standards of the United States Pharmacopoeia or National Formulary, or their successors, if applicable, and not found in violation of the requirements of the United States Food and Drug Administration, or its successor agency, or the Rhode Island Department of Health.

1.49 ***"Facsimile (FAX) prescription"*** means a written prescription or order that is transmitted by an electronic device that sends the exact image to the receiver (pharmacy) in a hard copy form.

1.50 ***"FDA-approved product***" means any drug or device that has received United States Food and Drug Administration (FDA) approval, including being manufactured in an FDA-approved facility.

1.51 ***"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.

1.52 ***"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.

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

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

1.52.3 ***"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.

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

1.53 ***"High-risk compounded sterile products"*** means products compounded under conditions that are at a high risk of becoming contaminated with an infectious microorganism. High risk conditions shall include: using non-sterile ingredients or a non-sterile device in the preparation of the final product; sterile contents that lack effective antimicrobial preservatives and packaging containers that are exposed to air quality inferior to ISO Class 5 before sterilization; procedures such as weighing and mixing conducted in air quality inferior to ISO Class 7; the chemical purity and content strength of ingredients used are not verified to meet their original or compendial specifications in packages of bulk ingredients.

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

1.55 ***"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.

1.56 ***"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.

1.57 ***"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 or a graduate of a foreign college of pharmacy who has obtained full certification from the FPGEC (Foreign Pharmacy Graduate Equivalency Commission) administered by the National Association of Boards of Pharmacy.

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

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

1.60 ***"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).

1.61 "***ISO"*** means the International Organization for Standardization of reference 7 herein.

1.62 ***"Legend drugs"*** means any drugs which are required by any applicable federal or state law or regulation to be dispensed on prescription only or are restricted to use by practitioners only.

1.63 "***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.

1.64 ***"Low-risk compounded sterile products"*** means a product compounded with aseptic manipulations entirely within ISO Class 5 or better air quality using no more than three (3) sterile ingredients added to one (1) package.

1.65 "***Manipulations"*** means aseptically opening ampuls, penetrating sterile stoppers on vials with sterile needles and syringes, and transferring sterile liquids in sterile syringes to sterile administration devices, package containers of other sterile products, and containers for storage and dispensing.

1.66 "***Manufacture***" means the production, preparation, propagation, compounding, or processing of a drug or other substance or device or the packaging or repackaging.

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

1.68 ***"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.

1.69 ***"Medical institution"*** means any hospital, sanitorium, clinic or dispensary.

1.70 "***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.

1.71 ***"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.

1.72 ***"Medium-risk compounded sterile products"*** means a product compounded under low-risk conditions with the addition of at least one of the following conditions: compounding a CSP that will be administered to either multiple patients or to one (1) patient on multiple occasions; and the compounding process involves complex aseptic manipulations or an unusually long duration.

1.73 ***"Multi-drug single-dosing container"*** means a container that is a customized single-dosing package labeled by a pharmacy for a specific patient, and such package contains one (1) or more solid, oral dosage form drugs to be administered to or taken by a specific patient at the same dosage time from a single container.

1.74 "***Nonlegend"*** or "***nonprescription drugs***" means any drugs which may be lawfully sold without a prescription.

1.75 ***"Nonresident pharmacy"*** means a pharmacy located outside this state in any state in the United States or any province of Canada that ships, mails, or delivers prescription drugs and/or devices to a patient or person in this state.

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

1.77 ***"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.

1.78 "***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.

1.79 ***"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.

1.80 ***"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.

1.81 ***"Perforated unit-dose blister packages"*** means unit-dose containers of a specific medication prepared in multi-dose containers by the manufacturer or pharmacy that includes the identity, quantity and strength of the product, name of the manufacturer, lot number and expiration date and labeled by the pharmacy for a specific patient.

1.82 ***"Person"*** means an individual, corporation, government, subdivision or agency, business trust, estate, trust, partnership or association, or any other legal entity.

1.83 "***Pharmaceutical assistance program (PAP) medication***" means a non-controlled manufacturer-prepared medication that is shipped to a practitioner for a specific "medically indigent" patient, generally defined as those with low income, without insurance, and ineligible for public programs.

1.84 ***"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 and interchangeable drug or device in response to a prescription, after appropriate communication with the prescriber and the patient.

1.85 ***"Pharmacist"*** means an individual licensed to engage in the practice of pharmacy in this state pursuant to section 5-19.1-14 of the Act.

1.86 "***Pharmacist-in-charge***" means a pharmacist licensed in this state is designated by the owner as the person responsible for the operation of a pharmacy in conformance with all laws and regulations pertinent to the practice of pharmacy and who is personally in full and actual charge of such pharmacy and personnel.

1.87 "***Pharmacist with advanced training and experience relevant to the scope of collaborative practice***" means, a licensed pharmacist in this state with post-graduate educational training. Such training shall include, but not limited to, residency training, board certification, certification from an accredited professional organization educational institution, or any other continuing education provider approved by the Director of Health, relevant to the proposed scope of the collaborative practice agreement.

1.88 ***"Pharmacy"*** means that portion or part of a premises where prescriptions are compounded and dispensed, including that portion utilized for the storage of prescription or legend drugs.

1.89 ***"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.

1.90 ***"Pharmacy technician"*** means an individual who meets minimum qualifications established by the Board, which are less than those established by the Act as necessary for licensing as a pharmacist; and works under the direction and supervision of a licensed pharmacist. There shall be two levels of licensure for pharmacy technicians: 1. Pharmacy technician I; and 2.

Pharmacy technician II. (See also section 23.10 herein). As used herein, a "pharmacy technician II" is one who is licensed by the Board as a pharmacy technician and who is also currently certified by the Pharmacy Technician Certification Board (PTCB) of the American Pharmacists' Association or other national certifying organization as may be approved by the Board.

1.91 ***"Practice of pharmacy"*** means the interpretation, evaluation and implementation of medical orders; including the performance of clinical laboratory tests provided such testing is conducted in conformity with the federal Clinical Laboratories Improvement Act, as amended, 42 USCS section 26; the dispensing of prescription drug orders; participation in drug and device selection; drug regimen reviews and drug or drug related research; the administration of adult immunizations pursuant to a valid prescription or physician-approved protocol and in accordance with training requirements, as promulgated herein; provision of patient counseling and the provision of those acts or services necessary to provide pharmaceutical care; and the responsibility for the supervision for compounding and labeling of drugs and devices (except labeling by a manufacturer, repackager, or distributor of non-prescription drugs and commercially packaged legend drugs and devices) proper and safe storage of drugs and devices, and maintenance of proper records for them. Nothing in this definition shall be construed to limit or otherwise affect the scope of practice of any other profession.

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

1.93 ***"Preceptor"*** means a pharmacist licensed to engage in the practice of pharmacy in this state who has the responsibility for training interns.

1.94 ***"Prescription"*** means an order for drugs or devices issued by the practitioner duly authorized by law in the state in which he practices to prescribe drugs or devices in the course of his or her professional practice for a legitimate medical purpose.

1.95 ***"Prescription sample"*** means a complimentary drug packaged in accordance with federal and state statutes and provided to a licensed practitioner free of charge by manufacturers.

1.96 "***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:

1.96.1 Rx only;

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

1.96.3 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.

1.97 "***Product liability***", as used herein, means insurance coverage protecting the Canadian pharmacy against legal liability resulting from a defective condition causing bodily injury, or damage, to any individual or entity, associated with the use of the product.

1.98 ***"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.

1.99 ***"Qualified licensed professional"*** means a non-pharmacist individual (such as physician, nurse, physician assistant 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.

1.100 A ***"qualified nuclear pharmacist"*** means a currently licensed 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:

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

1.100.2 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.

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

1.101 ***"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.

1.102 ***"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.

1.103 ***"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.

1.104 ***"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.

1.105 ***"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.

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

1.107 ***"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.

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

1.109 ***"Shared order filling***" means that the functions of: preparation, packaging, compounding, or labeling of an order or any combination of these functions by an authorized person located at a pharmacy on behalf of and at the request of another pharmacy; and returning the filled order to the requesting pharmacy for delivery to the patient or patient's agent or, at the request of the delivery pharmacy, directly delivering the filled order to the patient.

1.110 "***Shared order processing"*** means that the functions of: interpreting and entering the order, performing drug utilization reviews, claim adjustments, refill authorizations, or therapeutic interventions, or any combination of these functions are performed in accordance with Chapter 5-19.1 of the Rhode Island General Laws, as amended, and the regulations contained herein and are performed at a licensed pharmacy at the request of, and on behalf of, another pharmacy.

1.111 "***Shared services pharmacy"*** means both central fill and delivery pharmacies that have the same owner, or have a written contract outlining the services provided and the shared responsibilities of each party in accordance with Chapter 5-19.1 of the Rhode Island General Laws, as amended, and the regulations contained herein; and that participate in shared order filling or shared order processing, or both.

1.112 "***Substance abuse facility"*** means a facility licensed by the state Department of Mental Health, Retardation, and Hospitals that includes residential treatment services and detoxification services.

1.113 ***"Supply***" means the delivery of a non-controlled medication to a patient by a practitioner by one of the following methods and in accordance with the requirements stated herein:

- pre-packaged prescription sample medication;
- automated dispensing system;
- administration of a stock medication;
- dispensing of a manufacturer-prepared PAP medication;
- dispensing of oral and transdermal contraceptives.

1.114 ***"Unit-dose container"*** is one that is designed to hold a quantity of drug intended for use as a single dose and used promptly after the container is opened. The immediate container, and/or the outer container or protective packaging shall be designed to show evidence of any tampering with the contents. Each individual container shall be fully identifiable containing

a single dose of a single entity and shall protect the integrity of the dosage form. Labeling shall be in accordance with USP standards compendia and federal and state law and shall include the identity, quantity, and strength of the product, name of the manufacturer, and lot number and expiration date of the article.

1.115 "***USP***" means the United States Pharmacopeia of reference 5 herein.

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

1.116.1 intracompany sales;

1.116.2 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;

1.116.3 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;

1.116.4 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;

1.116.5 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;

1.116.6 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.

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

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

1.116.9 every hospital licensed in accordance with Chapter 23-17 of the Rhode Island General Laws, as amended, that is required to restock supplies listed by the Director of Health that are used by a licensed emergency medical services provider in transporting emergency patients to such hospital, pursuant to section 23-4.1-7.1 of the Rhode Island General Laws, as amended.

1.116.10 every hospital licensed in accordance with Chapter 23-17 of the Rhode Island General Laws, as amended, that accepts vaccine from the Department and distributes such vaccine as part of the Department's immunization program.

1.117 ***"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.

1.118 "***Wholesaler"*** shall mean a person who buys drugs or devices for resale and distribution to corporations, individuals, or entities other than consumers.

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PART II ***Pharmacists/Licensure Requirements***

Section 2.0 ***Licensure Requirement***

2.1 No person, unless a licensed pharmacist shall retail, compound or dispense drugs, medicine or poisons, except as provided pursuant to statutory provisions of section 5-19.1-8 of the Act.

Authorized Practices

2.2 In accordance with section 5-19.1-22 of the Rhode Island General Laws, as amended, nothing in the Act or the rules and regulations herein shall apply to any practitioner with authority to prescribe who does not keep open shop for the retailing, dispensing of medicines and poisons, nor prevent him or her from administering or supplying to his patients such articles as he or she may deem fit and proper.

2.3 Nothing in the Act or the rules and regulations herein shall apply to, nor in any manner interfere with the business of a general merchant in selling and distributing non-narcotic, nonprescription medicines or drugs which are prepackaged, fully prepared by the manufacturer for use by the consumer, and labeled in accordance with the requirements of the state and federal food and drug acts.

Section 3.0 ***Qualifications for Licensure: Pharmacists***

3.1 Pursuant to the provisions of section 5-19.1-14 of the Act, every person in order to be a licensed pharmacist shall:

3.1.1 a) have satisfied the Board that he or she is of good moral and professional character;

b) be at least eighteen (18) years of age;

c) hold a baccalaureate degree in pharmacy or a doctor of pharmacy degree granted by a school or college of pharmacy program that is accredited by the American Council on Pharmaceutical Education; or be a graduate of a foreign college who wishes to be examined for licensure as a pharmacist in this state and who shall provide evidence of successful completion of the FPGEC Certification Program.

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

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

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

f) 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.

g) meet such additional requirements as may be established in regulations.

Section 4.0 ***Application for Licensure and Fee***

4.1 Application for licensure shall be made on forms provided by the Department 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 Department no sooner than thirty (30) days prior to the scheduled date of graduation. 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 seventy dollars ($170.00) per check or money order (non-refundable), made payable to the General Treasurer, State of Rhode Island.

4.2 Application and supporting documents shall be verified and reviewed by the Department. Eligibility for examinations shall not be granted until after the applicant's date of graduation.

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 Department prior to application for licensure.

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 Licensure***

5.1 ***By Examination*:**

Applicants shall be required to pass a written examination (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 5-19.1-14 of the Act.

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

a) The North American Pharmacists Licensure Examination (NAPLEX) or its successor examination of the National Association of Boards of Pharmacy (NABP) which may be:

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

ii. administered in another state by the licensing authority of the respective state, and provided the requirements of section 5.1.2 herein on transfer of grades are met; and

b) The Multistate Pharmacy Jurisprudence Examination (MPJE) with a passing grade as determined by NABP.

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 licensure 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 licensure in this state must submit an application for licensure to the Department 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 NAPLEX Examination, and/or the Multistate Pharmacy Jurisprudence Examination (MPJE), such applicant shall be entitled to re-examination(s) in accordance with NABP guidelines. However, 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 Department and accompanied by the required fees in accordance with section 4.1 herein.

5.3 ***Without Examination by Reciprocity***

The Department shall, without examination other than those required in section 5.1 (above) relating to the practice of pharmacy, license as a pharmacist any individual who has been duly licensed by examination as a pharmacist under the laws of another state, territory or possession of the United States, if, in the opinion of the Board, the applicant meets the qualifications required of professional pharmacists in this state.

5.3.1 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;

5.3.2 The applicant shall have passed the Multistate Pharmacy Jurisprudence Examination and the examination of the National Association of Boards of Pharmacy in accordance with the provisions of section 5.1.1 herein.

5.3.3 The applicant shall submit to the Department the Official Transfer of Pharmaceutic Licensure Application of the NABP, a notarized copy of his/her birth certificate, and the one-hundred seventy dollar ($170.00)) application fee.

Temporary Ninety (90) Day License

5.4 In accordance with section 5-19.1-8 of the Rhode Island General Laws, as amended, persons who provide acceptable evidence of being currently licensed by examination or endorsement under the laws of other states of the United States and the District of Columbia, shall not be prevented from practicing in this state for a period of ninety (90) days from the date on the application receipt, provided that they become duly licensed in this state within ninety (90) days. This original privilege to work ninety (90) days shall not be extended or renewed and shall only be granted to an applicant on a one-time basis.

5.4.1 The licensing agency in each state in which the applicant holds or has held a registration or license shall submit to the Board a statement confirming the applicant to be or have been in good standing in that state.

Section 6.0 ***Internship: Pharmacy Interns***

General Requirements

6.1 Any person who is a graduate of an accredited program of pharmacy or who is a student enrolled in at least the first year of a professional program of an accredited program of pharmacy, or any graduate of a foreign college of pharmacy who has obtained FPGEC certification, may file with the Department an application for licensure as a pharmacy intern. He or she shall be required to furnish such information as the Board may prescribe and, simultaneously with the filling of said application, shall pay to the Department a fee of twenty dollars ($20.00).

6.2 All licenses issued to pharmacy interns shall be valid for a period of one (1) year, but in no instance shall the license be valid if the individual is no longer making timely progress toward graduation.

6.3 No pharmacy student may serve an internship with a preceptor without holding a valid pharmacy intern license from the Board.

6.4 To assure adequate practical instruction, pharmacy internship experience as required under the Act and the rules and regulations herein shall be obtained after licensure as a pharmacy intern by practice in any licensed pharmacy or other program meeting the requirements promulgated herein, and shall include such instruction in the practice of pharmacy as the Board shall prescribe.

6.5 Licensed pharmacy interns shall practice only under the immediate supervision of a licensed pharmacist.

Limited License

6.6 No pharmacy students enrolled in not less than the first year of a professional program of an accredited college of pharmacy may serve an internship in this state with a preceptor without holding a valid limited license by the Board of Pharmacy pursuant to the provisions of section 5-19.1-15 of the General Laws of Rhode Island, as amended.

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

1. is eighteen (18) years of age or older;
2. has satisfied the Board that he or she is of good moral and professional character;
3. is enrolled in at least the first year of a professional program of an accredited college of pharmacy.

Foreign Graduates:

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

Application and Fee

6.8 Application for limited licensure shall be made on forms provided by the Department 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 Department prior to accruing any hours. 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 first year of a professional program of an accredited college of pharmacy, and signed by the Dean of the College of Pharmacy or his appointed designee;

c) the application fee of twenty dollars ($20.00) made payable by check or money order to the General Treasurer, State of Rhode Island.

Issuance of Limited License

6.9 The application and credentials of the applicant shall be reviewed and verified by the Department. 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 28.0 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 license fee of twenty dollars ($20.00) made payable by check or money order to the General Treasurer, State of Rhode Island. A limited license is not transferable.

6.10 Every graduate of an approved school of pharmacy functioning as a pharmacy intern who has filed with the Board a completed application, with supporting documents of credentials, for licensure as a pharmacist, may upon receiving a receipt from the Board for said application and documents, function as a pharmacy intern, until such time as a license is received from the Department and in each case he/she shall be supervised by a registered pharmacist licensed in this state.

Internship

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

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

6.12 Prior to application for examination, the pharmacy intern shall submit, on forms provided by the Department, verification of his/her practical experience under the supervision of a licensed pharmacist. Any hours accrued prior to the issuance of the limited license shall not be accepted as part of the internship requirement.

Duties and Responsibilities of Pharmacy Interns

6.13 Pharmacy interns may perform only those tasks in which they have proficiency, in the professional judgment of the pharmacist-in-charge, but in no case, shall ever exceed what is permitted by regulation or law.

6.14 A pharmacy intern may not perform a final review or exercise final decision-making with respect to any of the following without the prior review and approval of the licensed pharmacist: drug utilization review; clinical conflict resolution, prescriber contact concerning prescription drug order clarification or therapy modification; or dispensing process validation.

6.15 A pharmacy intern shall wear a name tag that indicates the intern's name and the intern's licensure designation.

Section 7.0 ***Issuance and Renewal of the Pharmacist License***

7.1 Upon completion of the aforementioned requirements, a license shall be issued by the Department to an applicant found to have satisfactorily met all the requirements herein. Said license unless sooner suspended or discontinued shall expire annually on the thirtieth {30th} day of June.

7.2 Every person licensed as a pharmacist in this state who desires to renew his or her license shall file such renewal application annually with the Department by the first (1st) day of July. Said renewal shall be duly executed together with renewal fee of ninety ($90.00) dollars 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 license 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 the renewal fee of ninety ($90.00) dollars per check or money order (non-refundable), made payable to the General Treasurer, state of Rhode Island.

7.3.1 Any pharmacist license 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 licensure.

7.4 ***Continuing Education***

Pursuant to the provisions of section 5-19.1-14 of the General Laws of Rhode Island, as amended, any pharmacist, licensed to practice pharmacy in Rhode Island, who seeks annual licensure 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 licensure following graduation from a college of pharmacy, a pharmacist shall not be subject to the continuing education requirements herein, with the exception of the continuing education requirement contained in section 23.7 herein; and

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

7.4.1 The annual application for license 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 Department, if required and requested. Such certificate need not be submitted with the application for licensure 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 licensure 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 licensed 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 licensed 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***

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 a) The pharmacist or pharmacy may accept for return and redispensing, unit dose packages from the ultimate users to whom the medication was dispensed; provided the pharmacist deems that, in his/her professional judgment, the medication has not been tampered with, and that manufacturer-applied safety features and storage integrity have been maintained; and provided that the pharmacist or pharmacy was the provider of the particular unit dose packages; and the ultimate user is a patient in a hospital, licensed health care facility, assisted living residence licensed at the M-1 level that provides central storage of medications, or state correctional facility;

b) The pharmacist may accept for return and redispensing by re-labeling only full, unopened blister packages of medication dispensed to patients or residents of a licensed health care facility, an assisted living residence licensed at the M-1 level, or state correctional facility within fourteen (l4) days of date of dispensing. However, partial containers of perforated unit-dose blister packages with patient-specific labeling may be returned in accordance with section 8.2.1 a) herein.

c) No pharmacy shall accept for return any drug defined as a controlled substance, pursuant to Chapter 21-28 of the Rhode Island General Laws, as amended, or 21 CFR Part 1300 to End. The preceding requirements shall not apply to drugs supplied to hospital inpatients.

8.2.2 ***Recording*:** the retail pharmacy shall maintain a record of the receipt of each drug, medicine, or device showing the prescription number for which the material was acquired, and quantity. 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 ***Multi-drug Single-Dosing Systems***

General Requirements

8.3.1 Requirements related to the utilization of multi-drug single-dosing containers include the following:

a) The number of drugs placed in one package cannot exceed the capacity of the container in order to prevent damage to the individual dosage forms;

b) The total quantity of drugs dispensed may not exceed a maximum of a thirty-four (34) day supply;

c) The multi-drug single-dosing container may include controlled medications from Schedule IV if such medications are prescribed for the patient on a routine, customary basis;

d) The labels must be of sufficient size to properly and clearly label each container of a thirty-four (34) day or less drug supply with all information required by state and federal law and rules;

e) The integrity of each individual multi-drug single-dosing container shall be maintained until the last drug dose is administered to or taken by the patient.

8.3.2 A multi-drug single-dosing container shall be designed to prevent the container from being re-closed, designed to show evidence of having been opened, and designed in such a manner that the label cannot be altered.

8.3.3 Once a multi-drug single-dosing container has been properly labeled and dispensed to a patient, and said container is returned to the pharmacy for any reason, the drugs packaged in such container shall be considered adulterated and shall not be returned to the pharmacy stock. Provided, however, drugs in multi-drug single-dosing containers may be redispensed to the same patient to whom the drugs were originally dispensed.

8.3.4 Whenever a drug(s) in a multi-drug single-dosing container has/have been discontinued, the remaining container(s) may be returned to the dispensing pharmacy for the removal of the discontinued drug(s) for destruction. Under no circumstances shall any of the remaining or discontinued drug(s) be returned to the drug stock of the pharmacy or dispensed to any patient other than the patient to whom the drugs were originally dispensed.

8.3.5 Nothing contained in these regulations is meant to prevent a nurse or a patient-specified caregiver from removing a discontinued drug(s) from a container at the time of administration in order to be wasted as directed by a pharmacist or from retaining up to a seventy-two (72) hour supply of the continued drug(s) in the original container in order to maintain a patient on his or her continuing drug administration schedule.

Labeling Requirements

8.3.6 Each individual, customized, multi-drug single-dosing container shall bear a label, which, at a minimum, contains the following:

a) The name of the patient;

b) The name of the prescribing practitioner of each drug;

c) The identifying serial number assigned to the prescription drug order for each drug contained therein;

d) The name, strength, exact physical description, and total quantity of each drug contained therein;

e) The directions for use, and/or time of administration or time to be taken for each individual multi-drug single-dosing container;

f) Either the dispensing or preparation date, as well as a beyond-use (expiration) date for each drug contained in the multi-drug single-dosing container. The expiration date of each drug included therein shall not be longer than one (1) year from the date of preparation of the multi-drug single-dosing container. All drugs shall be packaged in accordance with USP standards.

8.3.7 The name, address, and telephone number of the pharmacy issuing the multi-drug single dosing container and any cautionary statements necessary for the proper administration or storage of the medication shall appear on the individualized patient container.

Exclusions

8.3.8 Multi-drug single-dosing containers shall not include drug(s) that have the following characteristics:

a) USP-DI monograph or official labeling requires dispensing in the original container;

b) Are incompatible with packaging components or with each other;

c) Require special packaging;

d) Are controlled medications from Schedules II and III.

Requirements for Nursing Facilities and Assisted Living Residences

8.3.9 Requirements related to the utilization of multi-drug single-dosing containers in a nursing facility or assisted living residence include the following:

a) The name, address, and telephone number of the pharmacy issuing the multi-drug single dosing container and any cautionary statements necessary for the proper administration or storage of the medication shall appear on the medication administration record (MAR).

8.3.10 In a nursing facility or assisted living residence licensed at the M-1 level, only a nurse, other licensed person acting within his/her scope of practice, or selected non-licensed personnel who have satisfactorily completed a State Approved Course

in Drug Administration and have demonstrated competency in accordance with the state-approved protocol in drug administration shall remove a discontinued drug(s) from a container in order to be wasted in accordance with policies and procedures of the facility.

Prescriptions

8.4 A prescription shall contain the following information, at a minimum:

1. full name and street address of the patient;
2. name, address, and if required by law or rules of the Board, DEA registration number of the prescribing practitioner;
3. date of issuance;
4. name, strength, dosage form and quantity of drug prescribed;
5. directions for use;
6. refills authorized, if any;
7. if a written prescription, prescribing practitioner's signature;
8. if an electronically transmitted prescription, prescribing practitioner's electronic or digital signature;
9. if a hard copy prescription generated from facsimile, prescribing practitioner's electronic or manual signature. For those with electronic signatures, such prescription shall be applied to paper that utilizes features that will ensure the prescription is not subject to any form of copying and/or alteration.
10. Oral prescriptions shall be reduced promptly to writing and stored either electronically or in hard copy format.

8.4.1 ***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.

8.4.2 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, 5-19.1 and such other applicable statutory requirements.

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

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;

   i. In compliance with federal requirements, the transmission of prescriptions for controlled substances by technological devices shall consist of a copy of the original prescription that has been signed by the licensed prescriber.

   ii. In compliance with federal requirements, an electronic signature by the licensed prescriber for controlled substance prescriptions is prohibited.

b) Unless otherwise prohibited by law, prescriptions may be transmitted by electronic means or facsimile from the prescriber as defined in section 21-31-2(s) of the Rhode Island General Laws, as amended, for transmission of prescriptions to the dispensing pharmacy. The facsimile copy of the prescription may serve as the hard copy of the prescription except for prescription orders for Schedule II drugs in accordance with the provisions of Chapter 21-28 of the Rhode Island General Laws, as amended.

c) In addition to all other information required to be included on a prescription, an electronically transmitted prescription and facsimile prescriptions shall include the date of transmission, and the identity of the receiving pharmacy.

d) A pharmacy receiving an electronic transmission prescription shall either receive the prescription in hard copy form or have the capacity to retrieve a hard copy of the prescription from the pharmacy's computer memory.

e) The patient shall have the right to choose the manner in which his/her prescription is transmitted to the pharmacy.

f) The patient shall have the right to choose the pharmacy to which his/her prescription is transferred.

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

h) Technological devices shall not be used to circumvent documentation, verification, or any provisions of Chapter 5-19.1 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.

i) Technological devices shall be located within the pharmacy.

Emergency Prescription Refill

8.5 In the event a pharmacist receives a request for a prescription refill and the pharmacist is unable to readily obtain refill authorization from the prescriber, the pharmacist may dispense a one-time emergency refill of up to a 72-hour supply of the prescribed medication, providing that:

(1) The prescription is not for a drug in schedule II appearing in Chapter 21-28 of the Rhode Island General Laws, as amended;

(2) The medication is essential to the maintenance of life or to the continuation of therapy of a chronic condition;

(3) In the pharmacist's professional judgment, the interruption of therapy might reasonably produce undesirable health consequences or may cause physical or mental discomfort; and

(4) The dispensing pharmacist notifies the prescriber of the emergency dispensing within a reasonable time after such dispensing.

(5) For medications that are pre-packaged in a unit-of-use container that do not conform with a seventy-two (72) hour supply, the pharmacist shall dispense the smallest unit of use to the patient.

(6) For an emergency prescription refill, there shall be appropriate documentation in the patient profile or on the hard copy of the prescription that an emergency refill has been dispensed.

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PART III ***Pharmacies: Licensure Requirements***

Section 9.0 ***Licensure Requirements: Pharmacies***

9.1 Pursuant to section 5-19.1-9 of the Act, no person shall conduct, maintain, or operate a pharmacy in this state 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 ***Restricted Pharmacies*****:** Pursuant to section 5-19.1-10 of the Act, upon application of the plan administrator or trustee of any trust, fund, pension plan, combination plan, or profit sharing plan, which is subject to the provisions of the Employee Retirement Income Security Act of 1974, 29 U.S.C. sec 1001 et seq., the Board may license a facility, hereinafter called a restricted pharmacy, for the purpose of dispensing pharmacy services to beneficiaries; provided, however, that no such license shall be granted unless the said trust, fund or plan demonstrates to the satisfaction of the Board that it is associated with another such trust, fund or plan already licensed in another state to own and operate a restricted pharmacy for the purpose of dispensing pharmacy services to its beneficiaries. Charges for such serviced shall be determined by the trustee or plan administrator. A restrictive pharmacy may, after written notice to the Board, limit its operation to a specific schedule of drugs.

9.2.1 Nothing in this section shall prohibit a restricted pharmacy from accepting or filling prescriptions by mail; provided, that the prescribing physician is verified, according to the procedures established by Chapter 5-37 of the Rhode Island General Laws, as amended, as licensed to practice in this state or in any New England state.

9.3 Any pharmacy that utilizes latex gloves shall do so in accordance with the provisions of the ***Rules and Regulations Pertaining to the Use of Latex Gloves by Health Care Workers, in Licensed Health Care Facilities, and by Other Persons, Firms, or Corporations Licensed or Registered by the Department*** promulgated by the Department of Health.

9.4 A mechanism shall be in place to verify current licensure for every individual within the pharmacy who is licensed, certified, or registered by the state of Rhode Island. Documentation of current licensure shall be maintained by the pharmacy.

Section 10.0 ***Application For License and Fee***

10.1 Application for a license (retail pharmacy, pharmacy within a medical institution, or restricted pharmacy) to conduct, maintain or operate a pharmacy in this state shall be made in writing on forms provided by the Department and shall be submitted to the Department 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 and a notarized declaration of ownership and location;

b) name of pharmacist-in-charge of the pharmacy;

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

d) for all pharmacies, the initial licensure fee of one hundred seventy dollars ($170.00) 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 Department and shall include such information as the Board may require, and the application must be accompanied by the license renewal fee of ninety ($90.00) dollars by 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 thirtieth {30th} day of September following its issuance and may be renewed from year to year upon submission of application and license renewal fee.

11.2 A license shall be issued to a pharmacy in the name of the owner of the pharmacy. The license shall be issued for a specific location and shall not be transferable.

11.2.1 No pharmacist shall be a pharmacist-in-charge at more than one pharmacy at the same time. Provided, however, a pharmacist may be designated as the pharmacist-in-charge at a maximum of two (2) pharmacies for a period not to exceed sixty (60) days for the purpose of transitioning to a new pharmacist-in-charge.

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 licensed pharmacy.

11.3.1 The name of the pharmacist-in-charge shall be conspicuously displayed in the pharmacy.

Section 12.0 ***Change of Ownership and/or Location***

12.1 When a change of ownership or location or when discontinuation of services is contemplated, the owner shall notify the Department in writing at least fourteen (14) days prior to the proposed action.

12.2 The pharmacy owner shall give the Department fourteen (14) days notice in writing prior to terminating services of a pharmacist-in-charge of a pharmacy, unless the pharmacist-in-charge vacates the position without notice. In this instance, the Department shall be notified in writing immediately of the change in pharmacist-in-charge.

12.3 When there is a change in ownership and/or location, the license shall immediately become void and shall be delivered to the Department.

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 initial licensure fee pursuant to section 5-19.1-9 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.

12.5 Patient records shall be retained and shall be capable of being retrieved for no less than two (2) years after a change of ownership is completed.

Section 13.0 ***General Requirements: All Pharmacies***

13.1 ***Personnel*:** A licensed pharmacist shall be physically accessible at the address listed on the license in order to operate and manage the pharmacy at all times during the hours of operation when the pharmacy is open to the public. The pharmacist(s) shall be subject to all the statutory and regulatory provisions herein pertaining to the practice of pharmacy.

13.1.1 The owner shall ensure that a sufficient number of qualified, trained, competent and adequately supervised pharmacists and 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.

13.1.2 The pharmacy shall be directed by a licensed pharmacist, hereinafter referred to as the pharmacist-in-charge, 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 pharmacist-in-charge shall be thoroughly familiar with the specialized functions of pharmacy practice.

13.1.3 The pharmacist-in-charge shall ensure that a sufficient number of pharmacists and supportive personnel are available to operate such pharmacy competently, safely, and to meet the needs of patients. All pharmacists shall be properly identified by name and licensure designation.

13.1.4 The owner shall develop and implement written policies and procedures to specify the duties to be performed by such pharmacists.

13.1.5 The pharmacist-in-charge of a pharmacy shall be responsible for no less than the following:

a) provide to the Department a beginning inventory of all controlled substances, Schedules II-V, upon commencement of duties, and an ending inventory of same upon termination of duties as pharmacist-in-charge;

b) maintain adequate controls to prohibit the diversion of controlled substances and promptly execute DEA Form 106 (or its successor form) to the Drug Enforcement Administration and the Department in the event of a theft or loss of a controlled substance;

c) report prescription forgeries, or attempted forgeries, as deemed necessary in the professional judgment of the pharmacist-in-charge, to the appropriate law enforcement authorities;

d) ensure that the pharmacy dispensing area and equipment is in clean and orderly condition, that all licenses and registrations are current, that the "top ten" list and prices are conspicuously posted, and that the expiration dates of the pharmaceutical stock are periodically checked to ensure that no expired medications are dispensed;

e) remove all controlled and non-controlled drugs from any pharmacy or institution upon sale or closure of the facility;

f) comply with the *Rules and Regulations Governing the Disposal of Legend Drugs (R21-31-LEG)* promulgated by the Department of Health, to utilize an alternative drug destruction mechanism for expired, excess/undesired controlled substances consistent with all federal and state laws and regulations;

g) contact the Department whenever a concern arises that would affect the pharmacy's practice;

h) ensure adherence to all policies and procedures for the operation of the pharmacy in accordance with the Act and the rules and regulations herein;

i) be administratively responsible for the overall operation and conduct of the 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, adequate reference materials relevant to the practice site, and a representative stock of pharmaceuticals, chemicals, drugs and preparations, so that prescriptions can be properly filled.

13.3.1 Each pharmacy shall adhere to written policies and procedures that require all stocks of medications to be inspected routinely for outdated, unusable or mislabeled products. Any outdated, unusable, or mislabeled medication or products shall be segregated to ensure that no such medications or products are dispensed.

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. The pharmacy

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

Pharmaceutical Services

Drug Recall

13.5 The pharmacist-in-charge shall ensure that 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

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

a) The pharmacist-in-charge 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

13.7 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.

13.8 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

13.9 The pharmacist-in-charge 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.

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

13.9.2 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.

13.9.3 Investigational drugs shall be segregated from commercial products.

13.9.4 The pharmacist-in-charge shall be responsible for the provision of staff education regarding investigational drugs.

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

13.10 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

13.11 ***Medication Use Evaluation Program***: The pharmacist-in-charge 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). ADRs deemed to be significant by the pharmacist shall be reported to the FDA's MedWatch Program. Vaccine-related adverse events shall be reported to the CDC.

13.12 ***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.

13.13 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.

13.14 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.

13.15 ***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.

Patient Counseling

13.16 After receipt of a new prescription and following a review of the patient's record, a pharmacist or pharmacy intern, as defined in Chapter 5-19.1, 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, by telephone or electronic means, 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 judgment of the pharmacist. Such elements may include the following:

a) the name and description of the drug;

b) the dosage form, dose, route of administration, dosing schedule, and duration of drug therapy;

c) intended use of the drug and expected action;

d) special directions and precautions for preparation, administration, and use by the patient;

e) 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;

f) techniques for self-monitoring drug therapy;

g) proper storage;

h) prescription refill information;

i) action to be taken in the event of a missed dose; and

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

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

13.18 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.

13.19 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.

Prescription Transfer

13.20 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, or supportive personnel, as permitted, 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, or supportive personnel, as permitted, 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, or supportive personnel, as permitted, 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.

13.21 ***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.

Necessity of Prescription Label

13.22 In accordance with section 5-19.1-18 of the Act, to every box, bottle, jar, tube or other container of a prescription which is dispensed, a label shall be attached, the contents of which shall include:

- the name of the prescriber;
- the full name of the patient;
- the name and address of the pharmacy;
- the name of the drug dispensed in accordance with Chapter 21-31 of the Rhode Island General Laws, as amended;
- quantity and strength of the drug dispensed;
- the date of dispensing;
- the prescription number;
- the expiration date of the prescription in accordance with section 13.21 herein;
- a full instruction on the use of the product in plain language.

13.22.1 Said label shall be printed, typed, or a combination of printed and typed, but shall not be handwritten, except in the case of an emergency.

13.22.2 No person shall alter, deface, or remove any label so affixed.

13.22.3 The requirements of this section shall not apply to an order to dispense a drug for immediate administration to a licensed hospital, nursing facility, or hospice facility in-patient.

Generic Substitutions

13.23 Pharmacists when dispensing a prescription shall, unless requested otherwise by the individual presenting the prescription in writing, substitute drugs containing all the same active chemical ingredients of the same strength, quantity, and dosage form as the drug requested by the prescriber from approved prescription drug products in accordance with the provisions of sections 21-31-16 and 21-31-15 (l)(1) of the Rhode Island General Laws, as amended, unless ordered by the prescribing physician to dispense as brand name necessary on the prescription form, or if the prescriber gives oral direction to that effect to the dispensing pharmacist.

13.23.1 The requirements of this section shall not apply to an order to dispense a drug for immediate administration to a licensed hospital, nursing facility or hospice facility in-patient.

13.23.2 The pharmacist shall make a product selection from approved prescription drug products and shall pass the savings on to the ultimate consumer. When a drug product selection is made, the pharmacist shall indicate the product dispensed on the written prescription or on the oral prescription, which has been reduced to writing or product information may be maintained on a computerized system if information is readily retrievable.

Central Database -- Operation

13.24 In accordance with section 5-19.1-17 of the Act, pharmacies operated by a person pursuant to the Act may refill prescriptions which have been previously dispensed by an affiliated pharmacy, provided, that prior to dispensing a refill the pharmacy refilling the prescription verifies the appropriateness of the refill through a centralized database.

13.24.1 Clinic pharmacies operated by a health maintenance organization licensed under Chapter 27-41 of the Rhode Island General Laws, as amended, and the Act may refill prescriptions which have been previously dispensed by another health maintenance organization clinic pharmacy, provided that prior to dispensing a refill the pharmacy refilling the prescription verifies the appropriateness of the refill through a centralized database of that health maintenance organization.

13.24.2 Disclosure of prescription information to any other person(s) other than agents of properly licensed pharmacies pursuant to sections 13.24 or 13.24.1 (above) is prohibited.

13.24.3 Disclosure of prescription information is permitted only to those directly involved in patient care consistent with Chapter 5-37.3 of the Rhode Island General Laws, as amended, the "Health Care Communications and Information Act" and other applicable federal and state laws.

13.24.4 The disclosure of prescription information to researchers may only be authorized in accordance with federal policy for the protection of human subjects.

Product Selection

13.25 A pharmacist may alter the prescribed dosage form of a medication, if in the professional judgment of the pharmacist, the form dispensed meets the bio-equivalency of the dose prescribed and it is appropriate for the patient.

Poison Prevention Packaging

13.26 All drugs and substances cited in the federal poison prevention packaging act regulations of reference 4 herein shall be packaged and dispensed in accordance with said regulations.

13.26.1 Documentation shall be maintained by the pharmacy to record those instances when a non-child-resistant safety cap container has been requested by a consumer.

Section 14.0 ***General Requirements: Retail Pharmacies***

14.1 ***Space*:** Any new pharmacy shall have an area of not less than 250 square feet.

List of Drugs Posted

14.2 Each pharmacy:

(1) Shall conspicuously display the list of the ten (10) prescribed health maintenance prescription drugs compiled by the Director at or adjacent to the place in the pharmacy where prescriptions are presented for compounding and dispensing;

(2) Shall, upon request, provide to a consumer who possesses a prescription for any listed prescription drug, the current selling price of that drug; and

(3) May change the current selling price and the posting of that price on the list at any time.

14.3 Each pharmacy shall post, in a clear and legible form, on that list, the current selling price of each prescription drug listed. Current selling price means the actual price to be paid by a retail purchaser to the pharmacy for any prescription drug listed at the usual strength and amount listed.

14.4 The requirements of this section do not apply to an order to dispense a drug for immediate administration to a hospital patient.

Section 15.0 ***General Requirements: Institutional Pharmacies***

Physical Requirements

15.1 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 19.0;

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

15.2 The pharmacist-in-charge 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 pharmacist-in-charge to remove medications from the pharmacy-designated area.

b) a list of medications authorized for removal from the pharmacy-designated area determined by the pharmacist-in-charge 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

15.3 The pharmacist-in-charge shall establish policies and procedures relating to the procurement, distribution and control of all drug products used in the medical institution.

Medication Orders

15.3.1 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.

15.3.2 A licensed pharmacist in the institutional pharmacy shall review all medication orders for appropriateness upon receipt in the pharmacy prior to dispensing, 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.

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

Medication Storage and Security

15.3.4 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.

15.3.5 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.

15.3.6 Each pharmacy shall adhere to written policies and procedures that require all stocks of medications to be inspected routinely for outdated, unusable or mislabeled products.

15.3.7 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.

15.3.8 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.

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

Labeling

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

15.3.11 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 pharmacist-in-charge shall develop policies and procedures for preparation and labeling.

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

Records

15.3.13 The pharmacist-in-charge 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 two (2) years. 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

15.3.14 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.

15.3.15 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

15.3.16 The pharmacist-in-charge and medical staff shall establish policies and procedures for the dispensing of medications from the emergency room.

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

15.3.16.2 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

15.4 The pharmacist shall review the appropriateness of the choice of medications for the patient and the patient's therapeutic regimen, pursuant to section 13.13 of these regulations.

15.4.1 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.

15.4.2 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.

15.4.3 ***Medication Use Evaluation Program*:** The pharmacist-in-charge 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:

15.4.3.1 ***Adverse Drug Reactions (ADR)*:**. ADR's that the pharmacist deems to be significant shall be reported to the FDA's MedWatch Program. Vaccine-related adverse events shall be reported to the CDC.

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

15.4.3.3 ***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.

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PART IV *Specialized Pharmacy Practice*

Section 16.0 *Pharmaceutical Services: Nursing and Hospice Care Facilities*

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

16.1.1 Unless the nursing or hospice care facility operates a licensed pharmacy and employs a director of pharmacy services, the nursing or hospice care facility shall have a written agreement with a licensed pharmacy to provide pharmaceutical services. The pharmacist-in-charge of the pharmacy shall supervise the entire spectrum of pharmaceutical services in the nursing or hospice care facility.

16.1.2 The pharmacy and therapeutics committee, or its equivalent, shall consist of not less than a licensed 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.

16.1.3 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:

- υ receive a valid medication or prescription order prior to the dispensing of any drug.
- υ 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.
- υ ensure that each cabinet, cart or other area utilized for the storage of drugs is locked and accessible only to authorized personnel.
- υ 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:

- υ review the drug and biological regimen of each resident monthly.
- υ report any irregularities to the attending physician and director of nurses. Reports shall show evidence of review and response; and
- υ 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.

16.1.4 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.

Section 17.0 ***Pharmaceutical Services: Nuclear/Radiologic Pharmacies***

17.1 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.

Policies and Procedures

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

17.3 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).*

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

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

17.6 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.

Personnel

17.7 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.

17.8 The nuclear pharmacy area shall be secured from unauthorized personnel.

Physical Requirements

17.9 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.

Section 18.0 ***Nonresident Pharmacies***

18.1 ***Licensure*** - In order to ship, mail, or deliver prescription drugs and/or devices to a patient in this state, a non-resident pharmacy must be licensed by the Board and shall comply with all statutory and regulatory requirements as stated herein.

18.2 ***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, or by international certified mail, return receipt requested, postage prepaid, at the address of such nonresident pharmacy as designated on the pharmacy's application for licensure in this state. If any such pharmacy is not licensed in this state, service on the Secretary of State in this state only shall be sufficient service.

18.3 ***Conditions of Licensure*** - As conditions of licensure, the nonresident pharmacy must comply with the following:

a) maintain, at all times a valid unexpired license, permit or registration to operate the pharmacy in compliance with the laws of the state or province of Canada in which it is located;

b) provide a description of any final disciplinary action(s) by licensing boards in other states or provinces of Canada; and

c) provide all information requested by the Board.

18.4 A pharmacy license will be issued to the owner who meets the requirements established pursuant to the Act and the rules and regulations herein. The owner of each pharmacy shall receive a license of location, which shall entitle the owner to operate such pharmacy at the location specified, or such other temporary location as the director may approve, for the period ending on 30 September. Each such owner shall at the time of filing provide proof of

payment of such fee, file with the Department on a provided form, a declaration of ownership and location. Such declaration of ownership and location so filed as aforesaid shall be deemed presumptive evidence of ownership of the pharmacy mentioned therein.

18.5 A license shall be issued to the owner and premise listed on the form and shall not be transferred. A license issued hereunder shall be the property of the state and loaned to the licensee, and it shall be kept posted in a conspicuous place on the licensed premises. If a change in owner or premise listed in said firm occurs, the license becomes null and void.

18.6 It shall be the duty of the owner to immediately notify the Department of any proposed change of location or ownership.

18.7 In the event such license fee remains unpaid on the date due, no renewal or new license shall be issued except upon payment of the license renewal fee.

18.8 ***Reports and Complaints*** - Upon receipt of a complaint against the non-resident pharmacy, the Department shall forward the complaint to the state or Canadian provincial boards where the non-resident pharmacy is licensed.

Canadian Pharmacies[1]

18.9 A Canadian pharmacy seeking licensure in Rhode Island shall, as a condition of licensure, comply at all times with the following requirements:

a) shall only ship into Rhode Island products that have been approved by the United States Food and Drug Administration (FDA);

b) shall provide written documentation acceptable to the Board that the Canadian pharmacy's importation of prescription drugs to Rhode Island residents is in compliance with all FDA and other applicable federal laws and regulations;

c) shall provide a certificate of insurance in the name of the Department as certificate holder showing evidence of five million dollars ($5,000,000) of product liability insurance or other equivalent means of security acceptable to the Board.

1) The product liability insurance policy shall include U.S. territories and shall be issued by an insurer that maintains at least an "A" rating from A.M. Best and a financial size category of at least Class "X".

2) Failure to maintain product liability insurance shall result in the revocation of the Canadian pharmacy's license to do business in Rhode Island.

3) The product liability insurance policy shall include a provision that stipulates that the Director shall be notified of the cancellation or failure to renew the insurance. Further, the policy shall be required to continue in effect for ten (10) days after written notice of the cancellation is given to the Director of the cancellation or

[1] **Compiler's Note:** During preparation of the April 2009 amendments for filing with the Secretary of State, it was discovered that two consecutive paragraphs were both designated as §18.9 c). The second paragraph was re-designated as §18.9 d). Subsequent §§ 18.9 d) – 18.9 i) were redesignated as §§ 18.9 e) – 18.9 j) respectively.

termination of the product liability insurance policy by the issuing insurance company or companies in addition to any other notices which may be required by law.

d) shall not perform therapeutic substitution (i.e., substitution of medications within a class) without the approval of the prescriber;

e) shall provide patients with an opportunity to discuss matters that will enhance or optimize drug therapy with each patient or care giver of such patient. Such discussion, by telephone, electronic, or other acceptable means, shall include appropriate elements of patient counseling, as is appropriate for the patient in the professional judgment of the pharmacist.

f) shall provide for the secure and confidential storage of confidential patient health care information with restricted access, including policies and procedures implemented to protect the integrity and confidentiality of patient health care information. Except as provided in Chapter 5-37.3 of the Rhode Island General Laws, as amended, or as specifically provided by state and federal law, a patient's confidential health care information shall not be released or transferred without the written authorization of the patient or his or her authorized representative, on a consent form meeting the requirements set forth in Chapter 5-37.3 of the Rhode Island General Laws, as amended. Further, under no circumstances shall a patient's confidential health care information be provided to a third party for marketing, fundraising, or research purposes. Any one who violates the provisions of Chapter 5-37.3 of the Rhode Island General Laws, as amended, may be held liable for actual and exemplary damages and other penalties set forth in section 5-37.3-9 of the Rhode Island General Laws, as amended;

g) shall provide and maintain all appropriate inventory controls in order to detect and document any theft, counterfeiting, or diversion of drugs or devices;

h) shall have a procedure in place for handling recalls and withdrawals of drugs and devices, including the tracking of lot numbers, consistent with the requirements of section 25.0 herein. Such procedure shall be adequate to deal with recalls and withdrawals due to:

   1) any action initiated at the request of the U.S. FDA or any other federal, state, or local law enforcement or other governmental agency, including the Board;

   2) any volunteer action by the manufacturer to remove defective or potentially defective drugs or devices from the market; or

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

i) shall provide the patient with written documentation that indicates the country(ies) where the patient's medication(s) were manufactured;

j) shall ensure that all drug labels are written in English and meet all requirements set forth in Rhode Island law.

18.10 A non-resident Canadian pharmacy shall not ship, mail, deliver, or otherwise dispense to a Rhode Island patient any of the following:

a) a controlled substance as defined in section 21-28-1.02 (7) of the Rhode Island General Laws, as amended;

b) a biological product as defined herein;

c) an infused drug including peritoneal dialysis solution;

d) an intravenously injected drug;

e) a drug that is inhaled during surgery;

f) a parenteral drug;

g) a drug manufactured through one or more biotechnology processes including: 1) a therapeutic DNA plasmid product; 2) a therapeutic synthetic peptide product of not more than forty (40) amino acids; 3) a monoclonal antibody product for in-vivo use; and 4) a therapeutic recombinant DNA-derived product.

h) a drug required to be refrigerated at any time during manufacturing, packaging, processing, or holding;

i) a photoreactive drug.

18.11 The Canadian pharmacy shall provide the name and address of a Rhode Island resident upon whom notices or orders of the Department or process affecting the Canadian pharmacy may be served.

18.12 As a condition of licensure, a Canadian pharmacy shall agree that the statutes and regulations of the State of Rhode Island will apply to all matters. Further, the Canadian pharmacy agrees that exclusive jurisdiction for any dispute with any Rhode Island citizen resides in the courts of the State of Rhode Island and further agrees and expressly consents to the exercise of personal jurisdiction in the courts of the State of Rhode Island in connection with any dispute, including any claim involving any Rhode Island citizen.

Section 19.0 ***Compounding of Pharmaceuticals***

General Requirements: Non-sterile and Sterile Compounding

19.1 A pharmacist/patient/prescriber relationship shall exist in order for a pharmacist to prepare compounds that are not commercially available.

19.2 Pharmacists engaged in compounding shall operate in conformity with all applicable state and federal laws and regulations regulating the practice of pharmacy.

19.3 The regulations contained in this section shall not apply to the preparation of medications by licensed health care professionals in emergency situations for immediate administration to patients.

19.4 A practitioner's prescription shall be required for the compounding of all pharmaceuticals.

19.5 Retail pharmacies shall only prepare compounded preparations in limited quantities (i.e., stock preparation, batch processing) prior to receiving a valid prescription based on a history of receiving valid prescriptions that have been generated solely within an established pharmacist/patient/practitioner relationship, provided that the prescriptions are maintained on file for all such products prepared at the pharmacy.

19.5.1 Hospital and institutional pharmacies shall only prepare compounded preparations in limited quantities (i.e., batch compounding) in anticipation of receiving a valid practitioner order/prescription or as part of an established hospital or institutionally approved protocol/procedure. Such anticipated compounding shall be based upon a history of receiving valid practitioner orders/prescriptions/protocol/procedure that have been generated solely within an established pharmacist/patient/practitioner relationship provided that the practitioner order/prescription/protocol/procedure is maintained on file in the pharmacy or in the patient's medical record for all such products prepared at the pharmacy.

19.6 All compounded products shall be labeled with the following information:

a) complete list of active ingredients (components) (Abbreviations may be included);

b) the assigned beyond-use date.

19.7 All compounded products shall be stored under conditions dictated by composition and stability characteristics (e.g., in a clean, dry place, on a shelf, or in the refrigerator) to ensure strength, quality, and purity.

19.8 Pharmacists shall not offer pharmaceutically prepared compounded preparations to other state-licensed persons or commercial entities for subsequent resale.

19.9 Compounding personnel shall be responsible for ensuring that compounded preparations are accurately identified, measured, diluted, and mixed; are correctly packaged, sealed, labeled, stored, dispensed, and distributed. Ingredients shall be of the correct identity, quality, and purity. Appropriate cleanliness shall be maintained. Proper labeling and supplementary instructions for the clinical administration of CSPs shall be provided by a pharmacist. Beyond-use dates shall be assigned based upon professional judgment.

19.10 Bulk and active ingredients used in the preparation of low risk and medium risk CSPs, and non-sterile compounded products shall be USP or National Formulary (NF) certified or shall be accompanied by a certificate of analysis for inspection by the Department upon request.

General Requirements-- All Risk Levels: Sterile Compounding

19.11 The pharmacist-in-charge shall ensure the following activities are accomplished for all compounding risk levels:

a) All CSPs shall be prepared in a manner that maintains sterility and minimizes the introduction of particulate matter;

b) All CSPs shall be accurately identified, measured, diluted, and mixed; and are correctly purified, sterilized, packaged, sealed, labeled, stored, dispensed, and distributed as

appropriate for the risk level. This requirement includes maintaining appropriate cleanliness and providing labeling and supplementary instructions for the proper clinical administration of CSPs;

c) Through appropriate information sources, specific CSPs maintain their labeled strength according to USP guidelines until their beyond-use dates;

d) A written quality assurance procedure includes the following in-process checks that are applied, as is appropriate, to specific CSPs: accuracy and precision of measuring and weighing; the requirement for sterility; methods of sterilization and purification; safe limits and ranges for strength of ingredients; bacterial endotoxins, particulate matter, and pH; labeling and storage requirements.

e) Upon discovery of potential contamination, the pharmacist-in-charge shall immediately notify any patient(s) to whom a potentially contaminated CSP was administered. In an institutional setting, the pharmacist-in-charge shall immediately notify the patient's physician of the potential risk. Positive sterility test results shall prompt a rapid and systematic investigation of aseptic techniques, environmental controls, and other sterility assurance controls to identify sources of contamination and correct problems in the methods or processes.

19.12 ***Low Risk CSPs*** shall have quality assurance practices that shall include, at a minimum: routine disinfections and air quality testing of the direct compounding environment; visual confirmation that personnel are properly garbed; orders reviewed to ensure the correct identity and amount of the ingredients used; and a visual inspection of the CSP to ensure proper labeling, accuracy and the absence of particulate matter and leakage. In addition, personnel shall be required to complete a media-fill, or equivalent test, on an annual basis.

19.12.1 In the absence of sterility testing, storage periods (before administration) shall not exceed the following: low risk products shall be properly stored and shall be exposed for no more than forty-eight (48) hours at a controlled room temperature, for no more than fourteen (14) days under refrigeration and for no more than forty-five (45) days in a solid frozen state at minus twenty (-20) degrees Centigrade or colder.

19.13 ***Medium Risk CSPs*** shall have quality assurance practices that include all of the low-risk CSP conditions. Personnel who are authorized to compound medium-risk CSPs shall also perform a more challenging media-fill test that represents medium-risk level compounding on an annual basis.

19.13.1 In the absence of sterility testing, storage periods (before administration) shall not exceed the following: medium risk products shall be properly stored and shall be exposed for no more than thirty (30) hours at controlled room temperature, for no more than nine (9) days under refrigeration and for no more than forty-five (45) days in a solid frozen state at minus twenty (-20) degrees Centigrade or colder.

19.14 ***High-Risk CSPs*** shall have quality assurance practices that include all of the low-risk CSP conditions. Personnel who are authorized to compound high-risk CSPs shall also perform a media-fill test that represents high-risk level compounding on a semi-annual basis.

19.14.1 In the absence of sterility testing, storage periods (before administration) shall not exceed the following: high risk products subjected to terminal sterilization shall be passed through a filter with porosity not larger than 1.2 microns to remove particulate matter. Filtration sterilization of high-risk CSPs shall be performed with a sterile 0.22 micron porosity filter entirely within an ISO Class 5 environment. Products shall be properly stored and shall be exposed for no more than twenty-four (24) hours at controlled room temperature, for no more than three (3) days under refrigeration and for no more than forty-five (45) days in a solid frozen state at minus twenty (-20) degrees Centigrade or colder. Any CSPs not able to be filtered shall be subject to terminal sterilization by alternate sterilization processes.

Responsibilities of Compounding Personnel: Sterile Compounding

19.15 The pharmacist-in-charge shall be responsible for the overall operation of the compounding pharmacy.

19.15.1 The compounding pharmacist shall be responsible for assigning the appropriate risk level (i.e., low, medium, or high) to each individual product.

19.16 CSPs shall be prepared in a manner that maintains sterility and minimizes the introduction of particulate matter.

19.17 Pharmacies that compound CSPs shall implement a formal quality assurance program for monitoring, evaluating, correcting, and improving the activities, systems and processes that support the preparation of CSPs.

19.18 The pharmacist-in-charge shall ensure the following are achieved:

a) Compounding personnel shall be adequately educated and trained to perform and document the following duties:
   i. Perform antiseptic hand cleansing and disinfection of non-sterile compounding surfaces;
   ii. Select and appropriately don protective garments and equipment;
   iii. Use laminar flow clean-air hoods, barrier isolators, biological safety cabinets and other contamination control devices;
   iv. Identify, weigh, and measure ingredients; and
   v. Manipulate sterile products aseptically.

b) Opened or partially used multi-dose packages of ingredients for subsequent use in CSP shall be properly stored in the compounding area. Such packages shall not be used when visual inspection detects unauthorized breaks in the container, closure, and seal; when the contents do not possess the expected appearance, aroma, or texture, when the contents do not pass identification tests specified by the compounding facility; and when either the beyond-use or expiration date has been exceeded. Single use containers of ingredients for subsequent use in CSP shall be discarded within six (6) hours.

c) Measuring, mixing, sterilizing, and purifying devices shall be clean, appropriately accurate, and effective for their intended use.

d) Packaging selected for CSPs shall be appropriate to preserve the sterility and strength until the beyond-use-date.

e) CSP labels shall list the names and amounts or concentrations of all active ingredients. Before being dispensed, and/or administered, the clarity of the solutions shall be visually confirmed, where appropriate. The identity and amounts of ingredients, procedures to prepare and sterilize CSPs, and specific release criteria shall be reviewed to ensure accuracy and completeness.

Personnel Training and Evaluation in Aseptic Manipulation Skills: Sterile Compounding

19.19 The pharmacist-in-charge shall ensure that personnel who prepare CSPs shall have documented training that may include, but not be limited to: audio-video instructional sources, and professional publications in the theoretical principles and practical skills of aseptic manipulations before preparing CSPs. The pharmacist-in-charge shall ensure that compounding personnel have demonstrated competencies on file at least annually for *low*- and *medium*-risk level compounding and semi-annually for *high*-risk level compounding.

Facility Requirements: Sterile Compounding

The provisions of section 19.20 up through and including section 19.28 shall take effect on **July 1, 2008**.

19.20 Pharmacies that engage in the pharmaceutical preparation of CSPs shall have a specifically designed and adequate space for the orderly placement of equipment and the materials used to prepare sterile preparations. This area shall be separate and distinct from other areas within the pharmacy and no other activity other than the preparation of sterile products shall occur in this area.

19.21 Pharmacies shall employ the use of either laminar airflow workbenches (LAFWs) or a barrier isolator system to prepare CSPs. These devices shall be located within a buffer or clean-room area that maintains at least an ISO Class 7 environment. Pharmacies choosing to utilize a barrier isolator system shall not be required to locate these in such a buffer air quality area.

19.22 Pharmacies that compound cytotoxic preparations shall utilize, at a minimum, a vertical flow Class II biological safety cabinet to compound these products.

19.23 A supply of bulk drugs and other materials used for the scheduled preparation of sterile CSPs (i.e., needles, syringes, bags, and transfer tubing) may be stored in an anteroom area. A demarcation line or barrier shall identify the separation of the buffer or clean room area from the anteroom area.

19.24 Hand sanitizing and gowning activities shall occur in the anteroom area.

Environmental Monitoring: Sterile Compounding

19.25 Certification that each LAFW, barrier isolator, and biological safety cabinet is working properly and meets the air quality requirement of ISO Class 5 shall be conducted every six (6) months and whenever the LAFW, barrier isolator, or biological safety cabinet is relocated. Such certification shall be performed and documented by qualified operator(s) using current state-of-the-art electronic air sampling.

19.26 The air quality of the buffer or clean room and the anteroom area shall be in conformity with ISO Class 7 and ISO Class 8 requirements, as appropriate. Certification inspections shall be conducted every six (6) months and whenever renovations occur. Such certification shall be performed and documented by a qualified operator(s).

19.27 The pharmacist-in-charge shall be responsible for reviewing and maintaining the certification records required in sections 19.24 and 19.25 above for a period of no less than two (2) years.

19.28 A written plan and schedule for the environmental monitoring procedures for viable micro organisms shall be established and followed. The plan shall be adequate to evaluate the various controlled air environment areas (LAFW, barrier isolators, biological safety cabinets, buffer or clean room, and anteroom) of the designated sterile compounding area(s). For sterile compounding areas used for *low*- and *medium*-risk preparations, a minimum monthly evaluation shall be required. For sterile compounding areas used for *high*-risk preparations, a weekly evaluation shall be required.

Variance Procedure

19.29 Any compounding pharmacy that is temporarily unable to meet the requirements of *USP* or sections 19.20, 19.22, 19.23, 19.24, 19.25, 19.26, or 19.27 of these regulations may apply to the Board for a variance.

19.30 Variances may be granted at the discretion of the Board upon good cause shown as long as the compounding is performed in an ISO 5 environment. Variances will be granted to the minimum amount necessary. Variances will be granted for a compliance date certain. If the date certain cannot be met, a new request for a variance shall be made to the Board.

Equipment: Sterile Compounding

19.31 Written procedures outlining required calibration, annual maintenance, monitoring for proper function, and controlled procedures for use shall be established and followed for all equipment, apparatus, and devices used in the preparation of CSPs. Results from calibration, annual maintenance reports, and routine maintenance shall be kept on file for the lifetime of the equipment.

Record Keeping Requirements: Sterile Compounding

19.32 All records required to be retained under these rules and regulations, or copies of such records, shall be readily retrievable for inspection by the Department during the retention period at the establishment where activities described in such records occurred.

19.33 Records required under these rules and regulations may be retained either as the original records or as true copies, such as photocopies, microfilm, microfiche, or other accurate reproductions of the original records.

Radiopharmaceuticals As CSPs

19.34 Compounding of radiopharmaceuticals for positron emission tomography (PET) shall be performed in accordance with the *Radiopharmaceuticals for Positron Emission Tomography-USP Compounding 823* of reference 5 herein.

19.35 For the purposes of this section, the following shall be designated *low-risk level CSPs*: (1) radiopharmaceutical dosage units with volumes of fifteen (15) mL and less and expiration times of twenty-four (24) hours and shorter, such as those prepared from eluates from technetium-99m/molybdenum 99 generator systems; and (2) commercially manufactured cyclotron radiopharmaceuticals that contain preservatives and bear expiration times of seventy-two (72) hours or shorter.

19.36 Radiopharmaceuticals shall be compounded using appropriately shielded vials and syringes in a properly functioning and certified vertical LAFW, Class II Type B2 BSC, or other suitable containment device (e.g., CAI) located in an ISO Class 8 or cleaner air environment to permit compliance with special handling, shielding, and negative air flow requirements.

19.37 Multiuse radiopharmaceutical vials, compounded with technetium-99m, exposed to ISO Class 5 environment and punctured by needles with no direct contact contamination may only be used up to twenty-four (24) hours post compounding.

19.38 Notwithstanding section 19.20 herein, nuclear pharmacies may use an electronic dose calibrator within the LAFW to assay non-sterile oral capsules to measure the quantity of radioactive materials being handled and/or dispensed.

Section 20.0 ***Automated Storage and Distribution Devices***

20.1 Automated storage and distribution devices may be utilized by nursing or hospice care facilities who maintain contracts for pharmaceutical services with licensed pharmacies and which provide contractual pharmaceutical services to patients in long term care facilities; or licensed pharmacies, in the case of prescriptions available for delivery; and shall comply with the following provisions:

20.1.1 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.

20.2 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.

20.3 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 Department. 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 pharmacist-in-charge 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.

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

20.5 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.

20.6 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.

20.7 The pharmacist-in-charge 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, and provides a method to identify the patient and to release that patient's prescriptions correctly.

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 licensed pharmacist.

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

f) Assure that a pharmacist is available at all times to fulfill any patient counseling as required by law and regulation during the operating hours of the pharmacy or telephonically during any hours that prescriptions are available for pick-up.

g) If an automated self-serve prescription delivery kiosk is located at the pharmacy, the kiosk shall be located either in a wall of a properly licensed pharmacy or within twenty (20) feet of a properly licensed pharmacy. The automated storage/distribution system shall be secured against a wall or floor in such a manner as to prevent the unauthorized removal of the system.

20.8 The pharmacist-in-charge shall establish policies and procedures for the process of dispensing and/or administering medications pursuant to a medication order.

Section 21.0 ***Provision of Medications by Non-Pharmacists***

Samples

21.1 A practitioner, or his/her authorized agent, may supply prescription sample medications to his/her patients.

Automated Dispensing Systems

21.2 A practitioner may dispense legend medications, excluding controlled substances, in accordance with his/her scope of practice, through the use of an automated dispensing system. The practitioner shall perform drug utilization review prior to the medication being dispensed.

21.3 If a practitioner utilizes an automated dispensing system for dispensing medications to his/her patients, the following requirements shall apply:

a) Entering the patient's medication order into the system shall be done by the practitioner;

b) Labeling of medication containers shall be in accordance with all applicable state and federal statutes and regulations;

c) Loading medication into the automated system shall be the responsibility of the

practitioner.

Pharmaceutical Assistance Program (PAP) Medications

21.4 PAP medications may be dispensed from stock supplies provided that the following requirements are met:

a) Packaging and labeling of medication containers shall be in accordance with all applicable state and federal statutes and regulations;

b) Practitioner performs drug utilization review and dispensing process validation ("final check") prior to the medication being dispensed.

21.5 Delivery of the PAP medication to the patient may be delegated by the practitioner.

Stock Medications

21.6 In a health care settings where the facility or practitioner does not hold an institutional pharmacy license, administration of stock medications is permitted. The practitioner shall perform drug utilization review and medication validation ("final check") prior to the medication being administered. Provided, however, the practitioner may delegate the medication validation ("final check") to the registered nurse administering the medication.

21.7 In substance abuse facilities, that include detoxification services and residential treatment services, stock medications shall be administered in accordance with a protocol approved by the Board.

21.8 In a health care settings where the facility or practitioner does not hold an institutional pharmacy license, dispensing of stock medications shall be prohibited.

Oral Contraceptives

21.9 In entities receiving Title X funding for family planning services pursuant to 42 Code of Federal Regulations Part 59, Subpart A and Section 1001 of the Public Health Services Act (42 United States Code 300), any practitioner may authorize a registered nurse to dispense oral and transdermal contraceptives to his/her patients for the purposes of birth control, pursuant to criteria established by the Board.

Emergency Dispensing of Pharmaceuticals

21.10 Notwithstanding any other provision of these regulations to the contrary, any practitioner authorized to deliver health care services at a facility licensed pursuant to the *Rules and Regulations for Licensing Organized Ambulatory Care Facilities* [*R23-17-OACF*] may dispense pharmaceuticals provided by the Director only during a period covered by a federal or state emergency declaration. However, all such emergency dispensing shall only be performed in accordance with specific written protocols provided by the Director for these pharmaceuticals.

Section 22.0 ***Central Fill Operations***

22.1 A shared services pharmacy shall be licensed by the Board as either a resident or non-resident pharmacy.

22.2 Shared services pharmacies shall meet no less than the following requirements:

22.2.1 Share a common electronic file or appropriate technology to allow access to sufficient information necessary to fill, refill, or perform shared services in conformity with Chapter 5-19.1 of the Rhode Island General Laws, as amended, and the regulations contained herein;

22.2.2 Report to the Board, as soon as practical, the results of any disciplinary action taken against a shared services pharmacy by an alternate jurisdiction;

22.2.3 Maintain a mechanism for tracking the order during each step of the processing and filling functions performed at the pharmacy;

22.2.4 Maintain a mechanism for identifying on the prescription label the names of the delivery and central fill pharmacies involved in filling the order;

22.2.5 Provide adequate security to protect the confidentiality and integrity of patient information, in accordance with all applicable federal and state laws and regulations;

22.2.6 Ensure that all controlled medications not claimed at the delivery pharmacy are returned to the central fill pharmacy within thirty (30) days;

22.2.7 Ensure that patient counseling is performed in accordance with all applicable regulations.

22.2.8 Ensure that the pharmacist-in-charge at each shared services pharmacy shall be responsible for all storage and shipping procedures to ensure drug integrity and to prohibit drug tampering.

22.3 Any pharmacy participating in shared order processing or shared order filling shall adopt a policy/procedures manual that shall be maintained at each shared services pharmacy and shall describe methods by which the pharmacies shall achieve compliance with Chapter 5-19.1 of the Rhode Island General Laws, as amended, and the regulations contained herein while engaging in shared services.

22.4 Prior to filling patients' prescriptions, the delivery pharmacy shall provide a one-time written notification to patients informing them that their prescription medications may be processed at an alternate site. Signage conspicuously displayed at the delivery pharmacy notifying patients that their prescription medications may be processed at an alternate site shall meet this requirement for patient notification.

22.5 A call center operation may perform the functions listed in sections 22.2.1, 22.2.2, 22.2.3, 22.2.5, 22.2.7 (as appropriate), and 22.3 above.

22.6 No person shall perform the duties of a pharmacist or pharmacy technician unless the person is licensed to do so by the Department under the provisions of the Act and these regulations.

Section 23.0 ***Administration of Immunizations by Pharmacists***

23.1 An immunizing pharmacist shall follow a written protocol from a prescriber or have obtained a valid prescription for immunization administration to a patient.

Qualifications

23.2 A pharmacist may administer immunizations to persons who are at least eighteen (18) years of age, as provided herein.

23.3 A pharmacist may administer any immunization available in accordance with manufacturers' guidelines and established guidelines issued by the Centers for Disease Control and Prevention's (CDC) Advisory Committee on Immunization Practices (ACIP) for administration to adult patients.

23.4 A pharmacist who is administering immunizations to a student eighteen (18) years of age or older shall do so in accordance with the Department's immunization regulations of references 8 and 9 herein.

23.5 A pharmacist may administer immunizations if the pharmacist has completed either: 1. immunization training within an accredited college of pharmacy program and possesses documentation of same; or 2. a twenty (20) hour course of training recognized by the Board and in accordance with the following:

23.5.1 The course of study for the training program shall include current guidelines and recommendations of the Centers for Disease Control and Prevention and the American Pharmacists Association.

23.5.2 The training course of study shall include, at a minimum, the following components:

a) mechanisms of action of immunizations, contraindications, drug interactions, and monitoring after immunizations administration;

b) immunization schedules;

c) immunization screening questions, informed consent, recordkeeping, registries and state/federal reporting mechanisms;

d) vaccine storage and handling in accordance with the guidelines of reference 10 herein;

e) biohazard waste disposal;

f) sterile techniques;

g) establishing protocols and standing orders;

h) immunization coalitions and other community resources available;

i) identifying, managing, and responding to adverse events associated with immunization administration;

j) mechanism for reporting adverse events to the Vaccine Adverse Event

Reporting System (VAERS);

k) reimbursement procedures and immunization coverage by federal, state, and local entities;

l) administration techniques.

23.6 The pharmacist shall possess evidence of current basic cardiopulmonary resuscitation (CPR) training issued by the American Heart Association, the American Red Cross, or other such similar training organization.

23.7 The pharmacist shall complete at least one (1) hour of continuing education in the area of immunizations each year.

23.8 No pharmacist may delegate the administration of immunizations to another person, except for a licensed intern who has completed a recognized immunization certificate training program and who is practicing under the direct supervision of an immunizing pharmacist.

Immunization Administration Policies and Procedures

23.9 All immunizing pharmacists shall adhere to written policies and procedures that include no less than the following:

23.9.1 A statement of the procedures, decision criteria, or plan the pharmacist will follow when exercising the administration authority, including when to refer the patient to the physician/prescriber.

23.9.2 A statement of the procedures for emergency situations.

23.9.3 A statement of record keeping and documentation procedures.

23.9.4 A statement related to the handling and disposal of used or contaminated equipment and supplies.

23.9.5 A statement requiring that the pharmacy give the appropriate Vaccine Information Statement (VIS) to the patient or legal representative with each dose of immunization covered by these forms.

23.9.6 A statement that the pharmacy report adverse events to the Vaccine Adverse Events Reporting System (VAERS) and to the primary care provider, as identified by the patient.

23.9.7 If a patient is immunized pursuant to a valid prescription, a notation of such prescription shall be made in the patient's pharmacy profile.

Prescriber Protocols

23.10 Prior to administering immunizations to adults, pharmacists who have not obtained a valid prescription for immunization administration shall follow written protocols established between the pharmacist and a protocol prescriber.

23.11 The protocol shall include, at a minimum:

23.11.1 A statement identifying the person authorized to prescribe drugs who has delegated the activity;

23.11.2 A statement identifying the individual pharmacist(s) authorized to administer immunizations and a copy of said pharmacist's documentation of completion of the recognized immunization training program;

23.11.3 A statement identifying the routes and types of immunizations that the pharmacist is authorized to administer (e.g., injectable and nasally administered).

23.12 The protocol shall be reviewed no less than every two (2) years by the prescriber and the immunizing pharmacist.

23.13 The immunizing pharmacist shall provide written notification of a patient's immunization to the primary care provider, if known, within fourteen (14) days.

Record-Keeping and Reporting

23.14 A pharmacist who administers any immunization shall maintain the following information in the pharmacy records regarding each immunization administration:

a) Patient's name, address, and date of birth;

b) Date of the administration and site of injection of the immunization;

c) Name, dose, manufacturer, lot number, and expiration date of the immunization;

d) Name and address of the patient's primary health care provider, as identified by the patient, if known;

e) Name or identifiable initials of the immunizing pharmacist and intern, if applicable;

f) Publication date of the Vaccine Information Statement (VIS):

g) Date that the VIS was provided to the patient.

23.15 The immunization records shall be maintained for no less than five (5) years in accordance with all applicable state and federal statutes and regulations pertaining to confidentiality.

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PART V ***Pharmacy Technicians and Collaborative Pharmacy Practice***

Section 24.0 ***Pharmacy Technicians***

General Requirements

24.1 In accordance with section 5-19.1-16 of the Rhode Island General Laws, as amended, a pharmacy technician license will be issued to any individual who meets the requirements established under the Act and the rules and regulations contained herein.

24.2 No person shall perform the duties set forth in sections 24.14, 24.15, 24.16, and 24.17 herein unless such person is licensed as a pharmacy technician.

24.3 There shall be two (2) levels of licensure for a pharmacy technician: pharmacy technician **I** and pharmacy technician **II**.

24.4 The pharmacy technician shall file with the Department an application for licensure (see below) and shall be required to furnish such information as the Board may prescribe and, simultaneously with the filing of said application, shall pay to the Department the required non-refundable fee of forty dollars ($40.00).

24.5 All licenses issued to pharmacy technicians shall be valid for a period of one {1} year.

24.6 No individual may serve as a pharmacy technician without holding a valid pharmacy technician license from the Board.

24.7 A pharmacy technician shall wear a name tag that indicates the technician's name and the appropriate licensure designation.

"Grandfather" Provision

24.8 Individuals who are currently licensed as pharmacy technician trainees on or before July 1, 2007 shall be licensed by the Board as pharmacy technician **I**s.

Licensure by Endorsement

24.9 A pharmacy technician currently licensed or registered and in good standing in another state or jurisdiction may be licensed by the Board. Provided, however, the requirements for licensure or registration in the state of original and current licensure shall be equivalent to the requirements established by the Board.

Exemption for High-School Career Exploration Programs

24.10 High school students working in pharmacies as part of school or community sponsored career exploration programs shall be exempt from the requirements of this section and shall not be required to be licensed as pharmacy technicians.

Licensure of Pharmacy Technicians

24.11 There shall be two (2) levels of licensure for pharmacy technicians. An applicant for licensure as a pharmacy technician shall be licensed as one of the following:

24.11.1 Pharmacy technician **I**: person licensed as a pharmacy technician who performs any pharmacy function or duties under the supervision of a pharmacist. The pharmacy technician I license shall be employer-specific.

24.11.2 Pharmacy technician **II**: pharmacy technician who is licensed by the Board and who performs any pharmacy functions and duties under the supervision of a pharmacist.

Qualifications

Pharmacy Technician I

24.12 An applicant for licensure as a pharmacy technician **I** must:

24.12.1 have satisfied the Board that he or she is of good moral and professional character;

24.12.2 be 18 years of age or older with the exception of those high school students working in pharmacies as part of school or community sponsored career exploration programs;

24.12.3 be a high-school graduate or the equivalent, or currently enrolled in a high school or vocational training program that awards such degree or certificate;

24.12.4 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 **I**;

24.12.5 be currently enrolled in or successfully completed a Board-approved pharmacy technician **I** training program defined in section 24.19 herein.

Pharmacy Technicians II

24.13 An applicant for licensure as a pharmacy technician **II** must:

24.13.1 have satisfied the Board that he or she is of good moral and professional character;

24.13.2 be 18 years of age or older;

24.13.3 be a high-school graduate or the equivalent;

24.13.4 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.

24.13.5 have successfully completed one of the Board-approved pharmacy technician training programs and/or successfully completed an examination as defined in section 24.18 herein.

Duties and Responsibilities

Pharmacy Technician I

24.14 A pharmacy technician **I** may perform only those tasks for which he/she has been trained and in which there is proficiency as determined by the pharmacist-in-charge, but in no case, shall ever exceed what is permitted by regulation, law or scope of practice, and as set forth below:

24.14.1 A pharmacy technician **I** may request refill authorizations for patients from a prescriber who uses a voice mail response system and/or when an agent of the prescriber transcribes the requested information for a follow-up phone call to the pharmacy after reviewing the request with the prescriber. The pharmacy technician **I** may accept authorization for refills from the prescriber or prescriber's agent provided that no information has changed from the previous prescription.

24.14.2 A pharmacy technician **I** may not perform drug utilization review; clinical conflict resolution, prescriber contact concerning prescription drug order clarification or therapy modification; patient counseling or dispensing process validation; or receive new prescription drug orders or conduct prescription transfers.

Pharmacy Technician II

24.15 A pharmacy technician **II** may perform only those tasks for which he/she has been trained and in which there is proficiency as determined by the pharmacist-in-charge, but in no case, shall ever exceed what is permitted by regulation, law, or scope of practice. In addition to performing the duties and responsibilities stipulated above for pharmacy technician **I**, a pharmacy technician **II** may perform the following duties:

24.15.1 A pharmacy technician **II** may request refill authorizations from the prescriber or prescriber's agent and, with the approval of the pharmacist on duty, receive new prescription information and changes to prescriptions from the prescriber or agent, except where otherwise prohibited by federal or state laws and regulations.

24.16 When a licensed pharmacist is not physically accessible at the address listed on the license, there shall be a sign posted that a licensed pharmacist is not available and that the pharmacy is not opened to the public. Such sign shall be legible and easily viewed by patients or customers. In this circumstance, only pharmacy technician **II**(s) may be present in the pharmacy and the pharmacy shall be closed to the public.

24.17 With the approval of the pharmacist-in-charge, a pharmacy technician **II** may be present in the pharmacy without a pharmacist present in order to prepare medications and to perform other duties and activities as authorized by statute, regulation, and the pharmacy technician **II** 's scope of practice. Provided, however, a pharmacy technician **II** may not perform drug utilization review; clinical conflict resolution; therapy modification; patient counseling; or dispensing process validation.

Board-approved Training Programs for Pharmacy Technician IIs

24.18 Training programs for pharmacy technicians **II**s that are approved by the Board include:

24.18.1 a pharmacy technician training program accredited by the ***American Society of Health-System Pharmacists***;

24.18.2 a pharmacy technician training program provided by a branch of the ***United States Armed Services or the U.S. Public Health Service***;

24.18.3 a pharmacy technician training program offered by a secondary educational institution that has been approved by the Rhode Island Board of Regents or their designees; or a pharmacy technology degree/certificate awarded by a college or university accredited by a regional accrediting authority;

24.18.4 a training program that includes successful completion of a nationally-recognized certification examination acceptable to the Board, including, but not limited to, the Pharmacy Technician Certification Examination (PTCE) or the Institute for Certification of Pharmacy Technicians "ExCPT" examination.

Board-approved Training Programs for Pharmacy Technician Is

24.19 Training programs for pharmacy technicians **I**s that are approved by the Board include:

24.19.1 ***an employer-based pharmacy technician training program*** that includes theoretical and practical instruction as described herein;

1) Said employer-based pharmacy technician training program shall:

a) include written guidelines, policies, and procedures that define the specific tasks the technician shall be expected to perform that include but are not limited to the following;

- orientation;
- job descriptions;
- communication techniques;
- laws and rules;
- security and safety;
- prescription drugs;
- basic pharmaceutical nomenclature;
- dosage forms;
- drug orders;
- prescribers;
- directions for use;
- commonly-used abbreviations and symbols;
- number of dosage units;
- strengths and systems of measurement;

- routes of administration;
- frequency of administration;
- interpreting directions for use;
- drug order preparation;
- creating or updating patient medication records;
- entering drug order information into the computer or typing the label in a manual system;
- selecting the correct stock bottle;
- accurately counting or pouring the appropriate quantity of drug product;
- selecting the proper container;
- affixing the prescription label;
- affixing auxiliary labels, if indicated; and
- preparing the finished product for inspection and final check by pharmacists.

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

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

3) The pharmacist-in-charge shall certify that the pharmacy technician has successfully completed the training program. Documentation of the training shall be maintained at the pharmacy by the pharmacist-in-charge.

24.19.2 Any other training program as approved by the Board.

24.20 In specialty pharmacies (e.g., compounding pharmacies), the pharmacist-in-charge shall ensure that pharmacy technicians receive any training necessary to perform specialty functions and duties. Such training shall be documented by the pharmacist-in-charge.

Application

24.21 Application for licensure as a pharmacy technician **I** or **II** shall be made on the form provided by the Department that 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 and accompanied by the non-refundable, non-returnable fee of forty dollars ($40.00).

24.21.1 On the above application, the pharmacist-in-charge 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.

24.22 Each pharmacy technician **I** applicant shall specify the name of the employer on the application and shall notify the Department when there is a change in employer.

Issuance of License

24.23 Each license, unless sooner suspended or discontinued for due cause in accordance with section 27.0 herein, shall expire annually on the thirtieth {30th} day of June.

24.24 Said license shall be renewed annually.

24.25 Every person licensed as a pharmacy technician in this state who desires to renew his or her license shall file such renewal application annually with the Department by the first (1st) day of July. Said renewal shall be duly executed together with renewal fee of forty dollars ($40.00) paid by check or money order (non-refundable and non-returnable), made payable to the General Treasurer, State of Rhode Island.

24.26 A pharmacy technician **I** and **II** license shall not be transferable.

Section 25.0 ***Collaborative Pharmacy Practice***

25.1 A pharmacist may engage in collaborative pharmacy practice pursuant to a collaborative practice agreement. Any pharmacist desiring to engage in collaborative pharmacy practice shall execute an agreement which shall include, but not be limited to, the following:

1. Identification and signatures of parties to the agreement, as well as dates of signing;
2. A provision that allows either party to cancel the agreement by written notification;
3. Site and setting where the collaborative practice is to take place;
    a. The agreement shall specify the site and setting where the collaborative practice occurs. All services provided pursuant to a collaborative practice agreement shall be performed in a setting that ensures patient privacy and confidentiality.

Informed Consent Procedures

4. The agreement shall specify the procedures for obtaining an informed consent from each patient involved in services pursuant to a collaborative practice agreement.
5. Informed consent shall include patients' consent to release all medical information from the prescribing health care provider or physician to pharmacist and pharmacist to prescribing health care provider or physician.
6. Informed consent shall include provision to allow the patient to withdraw from collaborative practice at anytime.

Qualification of Pharmacist and Participating Practitioners

7. The agreement shall specify the qualifications of all participants in the collaborative

practice agreement. Any pharmacist participating in the collaborative pharmacy practice shall comply with section 25.6 of these regulations.

8. Role of any employed health care professional with prescriptive privileges participating in the collaborative practice;

Scope of Conditions or Diseases to be Managed

9. A detailed description of the types of diseases, drugs or drug categories involved, drug therapies management allowed in each case;
10. Agreements may only be used for conditions or diseases with generally accepted standards of care;
11. The scope of the agreement shall not include research, clinical or investigational trials;
12. The agreement shall include only the conditions or diseases to be managed that meet the qualifications and scope of practice for each party to the agreement.

Practice Protocols

13. The practice protocol shall contain a statement by the physician that describes the activities the pharmacist is authorized to engage in, including:
    a. The procedures, decision criteria, or plan the pharmacist shall follow when providing drug therapy management;
    b. The procedures the pharmacist shall follow for documentation; and
    c. The procedures the pharmacist shall follow for reporting activities and results to the physician or the prescribing health care provider caring for the patient.
14. A provision that allows the physician to override a collaborative practice decision made by the pharmacist when appropriate;
15. A provision for regular review and revision to reflect changes in standards of care;
16. A provision that allows either party to cancel the agreement by written notification;
17. An effective date.

Risk Management Activities

18. The agreement shall provide for a plan for measuring and ensuring quality.
19. The agreement shall include proof that liability insurance is maintained by all parties.

Outcomes Measurements

20. The agreement shall include a method to monitor compliance and clinical outcomes.

25.1.1 The pharmacist shall submit a copy of the agreement to the Board prior to the commencement of collaborative pharmacy practice.

25.2 Amendments to the agreement must be documented, signed, and dated.

25.3 The pharmacist shall initiate drug therapy management for a particular patient pursuant to a medical order from the physician or the prescribing health care provider caring for the patient.

25.4 The pharmacist shall have adequate access to the patient's history, disease states, drug therapy and laboratory and procedure results.

25.5 An agreement shall be valid for a period not to exceed two (2) years. The signatories shall implement a procedure for reviewing and, if necessary, revising the procedures and protocols of a collaborative agreement at least every two (2) years.

25.6 A pharmacist with advanced training and experience relevant to the scope of collaborative practice shall be a licensed pharmacist in this state with post-graduate educational training relevant to the scope of the collaborative practice agreement. Such training shall include residency training, board certification or certification from an accredited professional organization, educational institution, or continuing education provider. The pharmacist shall meet one of the following qualifications:

1. has successfully completed certification from the Board of Pharmaceutical Specialties, or has completed an American Society of Health System Pharmacists (ASHP) or other accredited residency program in the area of practice covered by the agreement. If the residency program is not in the area of practice covered by the agreement, the pharmacist shall complete a continuing education provider certificate program in the area of practice covered by the agreement; or
2. has successfully completed the course of study and holds the academic degree of Doctor of Pharmacy and has two (2) years of professional experience and has completed an American Council of Pharmaceutical Education (ACPE), Continuing Medical Education (CME), or other continuing education provider certificate program in the area of practice covered by the agreement; or
3. has successfully completed the course of study and holds the academic degree Bachelor of Science in Pharmacy and has three (3) years of professional experience and has completed one (1) ACPE or other continuing education provider certificate programs with at least one (1) program in the area of practice covered by the agreement.

25.7 Any pharmacist participating in a collaborative pharmacy practice agreement shall earn five (5) of the fifteen (15) hours required in section 7.4 herein in the area of practice covered by the agreement each year and shall maintain documentation of these hours at the practice site to be made available for inspection by the Boards of Medical Licensure and Discipline and Pharmacy.

25.8 Any pharmacist who has not participated in a collaborative pharmacy practice arrangement for a period of two (2) years and seeks to enter into such an arrangement, must have obtained and/or maintained the certification set forth in subsections 25.6 (2) or (3), as applicable, or have earned fifteen (15) hours of relevant continuing education within the prior year in the area of practice covered by the agreement.

Recordkeeping Requirements

25.9 Signatories to an agreement shall keep a copy of the agreement on file at their primary place(s) of practice.

25.10 An order for a specific patient from the prescribing physician or the prescribing health care provider caring for the patient authorizing the implementation of drug therapy management pursuant to the agreement shall be noted in the patient's medical record and kept on file by the pharmacist.

25.11 A copy of the informed written consent from the patient shall be maintained in the patient's medical record and kept on file along with the practitioner's order by the pharmacist in a readily retrievable manner.

Administration of Immunizations

25.12 Nothing in this section shall prohibit a pharmacist from administering immunizations, if done so in accordance with the requirements of section 23.0 herein.

Hospital Pharmacists

25.13 Nothing in Chapter 5-19.2 shall be construed to prohibit hospital pharmacists from participating in drug therapy management by protocol approved by the president of the hospital medical staff and the director of pharmacy for the care and treatment of patients.

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PART VI *Licensure of Manufacturers, Wholesalers, and Distributors*

Section 26.0 *Licensure Requirements*

26.1 Pursuant to the provisions of sections 5-19.1-12 and 5-19.1-13 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 licensed by the Board in accordance with the laws and regulations of this state, before engaging in wholesale distribution of prescription drugs.

26.2 ***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 owner;

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

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 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.

f) the FDA manufacturing license number;

g) The initial licensure fee of one-hundred seventy dollars ($170.00) and/or the license renewal fee of one hundred thirty dollars ($130.00) paid by check or money order (non-refundable), made payable to the General Treasurer, State of Rhode Island.

26.3 Where operations are conducted at more than one location by a single wholesale distributor, each such location distributing into the state shall be licensed by the Board. Each board of pharmacy in the state(s) in which the applicant holds a registration or license shall submit to the Department in this state a statement confirming the applicant holds a current license in good standing in said state.

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

26.5 The license will be issued upon receipt of the required fee in accordance with sections 5-19.1-12 and 5-19.1-13 of the Act.

Minimum Qualifications

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

a) Engaging in any unprofessional conduct as defined in section 27.0;

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.

Personnel

26.7 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.

26.8 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:

Facilities

26.9 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.

Security

26.10 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.

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

26.12 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.

26.13 ***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 sections 26.21, 26.22, and 26.23 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.

Examination of Materials

26.14 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.

26.15 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.

26.16 The record keeping requirements in sections 26.21, 26.22, and 26.23 shall be followed for all incoming and outgoing prescription drugs.

Returned, Damaged and Outdated Prescription Drugs

26.17 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.

26.18 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.

26.19 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.

26.20 The record keeping requirements in this sections 26.21, 26.22, and 26.23 hall be followed for all outdated, damaged, deteriorated, misbranded, or adulterated prescription drugs.

Record keeping

26.21 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.

26.22 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.

26.23 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.

26.24 ***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.

26.25 ***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.

26.26 ***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.

26.27 ***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.

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PART VII *Violations, Sanctions and Severability*

Section 27.0 *Grounds For Denial or Discontinuation of License*

27.1 In accordance with the provisions of section 5-19.1-21 of the Rhode Island General Laws, as amended, the Board, with the approval of the Director, may deny, suspend, revoke or otherwise discipline the licensee upon proof that:

(1) The license was procured through fraud, misrepresentation or deceit;

(2) The licensee has violated any of the laws of this state or the United States relating to the practice of pharmacy, drugs, controlled substances, cosmetics, or nonprescription drugs, or has violated any of the rules and regulations of the Board or has been convicted of a felony;

(3) A court of competent jurisdiction has determined a pharmacist to be mentally incompetent, the pharmacist shall automatically have his or her license suspended by the Board upon the entry of the judgment, regardless of the tendency of an appeal;

(4) The licensee has dependence upon controlled substances, habitual drunkenness, or rendering professional services while the licensee is intoxicated or incapacitated by the use of drugs;

(5) The licensee made and/or filed false reports or records;

(6) The licensee's conduct is incompetent, or negligent which shall include, but not be limited to, any departure from or failure to conform to the minimal standards acceptable and prevailing pharmacy practice as determined by the Board;

(7) The licensee has been found guilty in another state of conduct, which, if committed in Rhode Island, would constitute grounds to deny, revoke or suspend or otherwise discipline a licensee;

(8) The licensee has violated or permitted the violation of any provision of any state or federal law, rule or regulation governing the possession, use, distribution or dispensing of drugs, including, but not limited to, the violation of any provision of the Act, title 21-28, title 21-31, or rule or regulation of the Board;

(9) The licensee has knowingly allowed any unlicensed person to take charge of a pharmacy or engage in the practice of pharmacy;

(10) The pharmacist has compounded, dispensed or caused the compounding or dispensing of any drug or device which contains more or less than the equivalent quantity of ingredient or ingredients specified by the person who prescribed such drug or device; provided, however, that nothing herein shall be construed to prevent the pharmacist from exercising professional judgment in the preparation or providing of such drugs or devices;

(11) The licensee has engaged in unprofessional conduct by failing to maintain the standards of practice or by such other conduct as prescribed in regulation;

(12) On or after July 6, 1993, the Board shall refuse to grant any pharmacy license to any individual 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 the entity or of the subject pharmacy or drug store;

(13) On or 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 determines that:

(i) Practitioners 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

(ii) More than forty percent (40%) of the prescription 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 the subject pharmacy, drug store, or licensee;

A. The pharmacist-in-charge of said pharmacy shall furnish and deliver to the Department, upon request, all dispensing reports, and any other required documents necessary to determine the percentage of prescriptions filled.

(14) To have been convicted of a violation, plead Nolo Contendere, or entered a plea bargain to any federal, state, or local statute, regulation, or ordinance.

Unlawful Practices

27.2 Any person who shall take or use or exhibit in or upon any place of business, or advertise in a newspaper, telephone directory, or other directory, or by electronic media, or in any other manner, the title of pharmacist, pharmacy intern, druggist, pharmacy, drug store, medicine store, drug department, drugs, drug sundries, or any title or name of like description or import without continuously and regularly employed in his or her shop, store or place of business, during business hours of the pharmacy, a pharmacist duly licensed under the Act and the rules and regulations herein shall be guilty of a misdemeanor, and each and every day that such prohibited practice continues shall be deemed a separate offense.

Section 28.0 ***Violations and Sanctions***

28.1 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 5-19.1-27 of the Act.

28.2 Any licensed 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 licensure, and the Board of Pharmacy shall thereupon discontinue his/her license.

Section 29.0 ***Variance Procedure***

29.1 The Department may grant a variance from the provisions of a rule or regulation in a specific case if it finds that a literal enforcement of such provision will result in unnecessary hardship to the applicant and that such a variance will not be contrary to the public interest and/or health and safety of the public.

Variances may be granted only for the provisions of Part IV herein and shall be for a limited period of time, generally not to exceed one (1) year.

29.2 A request for a variance shall be filed by an applicant in writing, setting forth in detail the basis upon which the request is made.

29.2.1 Upon the filing of each request for variance with the Department, and within a reasonable time thereafter, the Department shall notify the applicant by certified mail of its approval or in the case of a denial, a hearing date, time and place may be scheduled if the person appeals the denial.

29.3 At a hearing held in furtherance of an appeal from a denial for a variance in accordance with section 29.2.1 above, the applicant shall present his case to the Director or his designee for quasi-judicial matters, and shall have the burden of persuading the Director or his designee as aforesaid, through the introduction of clear and convincing evidence, that a literal enforcement of the rules will result in unnecessary hardship, and that a variance will not be contrary to the public interest and/or health and safety of the public.

Section 30.0 ***Rules Governing Practices and Procedures***

30.1 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 5-19.1of the General Laws of Rhode Island, as amended, shall be held in accordance with the *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 31.0 ***Severability***

31.1 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.

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