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## TITLE 216 - DEPARTMENT OF HEALTH

### CHAPTER 40 - PROFESSIONAL LICENSING AND FACILITY REGULATION

#### SUBCHAPTER 15 - PHARMACY

PART 1 – Pharmacists, Pharmacies, and Manufacturers, Wholesalers, and Distributors

#### 1.1 Authority

These regulations are promulgated pursuant to the authority conferred by R.I. Gen. Laws § 5-19.1-5(6), for the purpose of establishing administrative procedures and pharmaceutical practices consistent with current standards of practice.

#### 1.2 Definitions

A. Wherever used in this Part the following terms shall be construed as follows:

1. "ACPE" means Accreditation Council for Pharmacy Education.
2. "Act" means [R.I. Gen. Laws Chapter 5-19.1](#) entitled, "Pharmacies."
3. "Active Ingredient" means any component that provides pharmacological activity or other direct effect in the diagnosis, cure, mitigation, treatment, or prevention of disease, or to affect the structure or any function of the body of man or animals.
4. "Actively reports" means reporting all dispensing errors and analyses of such errors to a patient safety organization as soon as practical but no later than thirty (30) days of identification of the error.
5. "Administer" or "Administration" means the direct application of - medications to the body of a patient or research subject by a practitioner by injection, inhalation, ingestion, or any other means.
4. "Actively reports" means reporting all dispensing errors and analyses of such errors to a patient safety organization as soon as practical but no later than thirty (30) days of identification of the error.

65. “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.
76. “Assisted living residence licensed at the M-1 level” or “Assisted living residence” 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 six (6) or more adults who are unrelated to the licensee or administrator, excluding however, any privately operated establishment or facility licensed pursuant to [R.I. Gen. Laws Chapter 23-17](#) and those facilities licensed by or under the jurisdiction of the Department of Behavioral Healthcare, Developmental Disabilities and Hospitals, the Department of Children, Youth, and Families, or any other state agency. Assisted living residences include sheltered care homes, board and care residences, and any other entity by any other name providing the above services.
87. "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.
9. “Auto Substitute” means the replacing of the prescribed product with either a generic product, another brand of the prescribed product, a product with the same active ingredient but different inactive ingredients, or a different drug within the same therapeutic class as the prescribed product, dispensing of either the prescribed product, or a replacement with a generic or another brand without being required to obtain inform the patient or prescriber authorization.
108. “Automated dispensing system” means a computerized system for dispensing prepackaged medications in manufacturer labeled, unit-of-use doses.
119. “Automated filling system” means an automated system used within a pharmacy to assist in filling a prescription drug order by selecting, labeling, filling, or sealing medication for dispensing. An “automated filling system” shall not include automated devices used solely to count medication or vacuum tube drug delivery systems.

120. “Automated pharmacy system” means a mechanical system, located within or adjacent to the prescription department, or at a remote location, that performs operations or activities, other than compounding or administration, relative to storage, packaging, dispensing, or distribution of medication, and which collects, controls, and maintains all transaction information.
131. “Automated storage and distribution devices” means a mechanical device that delivers drugs other than by administration, and uses automated data processing technology to:
- a. Provide effective storage and security of drugs contained in the device;
  - b. Limit access to authorized individuals;
  - c. Record the identity of all personnel who access the drugs stored within the device;
  - d. Provide documentation of storage and removal of contents;
  - e. Provide ongoing documentation that monitors proper delivery of drugs to ensure patient safety;
  - f. Comply with Rhode Island General Laws and regulations.
142. “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.
153. “Beyond use dating” means:
- a. The date or time beyond which a drug preparation is not recommended to be dispensed, administered, stored, or transported.
  - b. Beyond Use Dating shall be determined from the date and time the drug preparation is compounded. Administration times (also known as “hang times”) shall not exceed twenty-four (24) hours from the established beyond use dating on the dispensed product unless shorter administration times are required by the manufacturer’s specifications/literature.

164. "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 as defined in the "Public Health Service Act," 42 U.S.C. § 262.
175. "Biosimilar" means a product is a biological product that is approved based on a showing that it is highly similar to an FDA-approved biological product, known as a reference product, and has no clinically meaningful differences in terms of safety and effectiveness from the reference product. Only minor differences in clinically inactive components are allowable in biosimilar products.
186. "Blister packages" means multi-dose containers of a specific medication repackaged by the pharmacy in accordance with § 1.1.7 of this Part and intended for a specific patient.
197. "Blood" means whole blood collected from a single donor and processed either for transfusion or further manufacturing.
2048. "Blood component" means that part of blood separated by physical or mechanical means.
2149. "Board" means the Board of Pharmacy within the Department of Health established pursuant to R.I. Gen. Laws § [5-19.1-3](#) .
220. "Call center operation" means any operation that functions as a shared order processing facility but is not licensed as a pharmacy.
234. "Central fill pharmacy" means the pharmacy that fills the prescription order for delivery in accordance with an agreement with another pharmacy or pharmacies.
242. "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:
- d. A sale, lease exchange, or other disposition of all, or substantially all of the property and assets of the corporation; or
- e. A merger of the corporation into another corporation; or
- f. The consolidation of two or more corporations, resulting in the creation of a new corporation; or
- g. 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
- h. 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.

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

**264.** "Collaborative pharmacy practice" is that practice of pharmacy pursuant to R.I. Gen. Laws Chapter 5-19.2 whereby one or more licensed pharmacist(s), with advanced training and experience relevant to the scope of collaborative practice, agrees to work in collaboration with one or more physician(s) 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.

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

**286.** "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; and

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.

**297.** “Complex non-sterile drug preparation” means:

- a. A compounded drug preparation which requires special training, special environment, special facilities, or equipment.
- b. Compounding techniques and procedures that may present an elevated risk to the compounder or the patient.
- c. Complex Non-Sterile Drug Preparation shall be consistent with the category of complex non-sterile compounding described in current USP chapter 795.

**3028.** “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.

**3129.** “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, reconstitution or assembling of drug products that are essentially copies of a commercially available product. Pharmacy compounding includes the preparation of drugs or devices pursuant to a prescription or medication order or in anticipation of prescription or medication orders based upon routine, regularly observed prescribing patterns.

**320.** “Compounding accountability document” means:

- a. Formulation of the compounded product.
- b. Lot numbers, expiration dates, and beyond use dates of all chemicals used in the preparation of the finished compounded product.
- c. Initials to identify pharmacist and technician involved in the preparation of the finished compounded product.

331. "Confidential information" means healthcare and other information maintained by the pharmacist in the patient's records, which is deemed confidential by virtue of the provisions of [R.I. Gen. Laws Chapter 5-37.3](#), and any other federal or state law.
342. "Contact hour" means a unit of measure of educational credit as defined by ACPE.
353. "Consultant pharmacist" means a pharmacist licensed to engage in the practice of pharmacy in this state who is responsible for developing, coordinating, and supervising pharmaceutical services in a nursing facility, assisted living residence, medical institution, or hospice care facility.
364. "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.
375. "Continuing education unit" (CEU) means a unit of measure of educational credit which is equivalent to ten (10) hours.
386. "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 [R.I. Gen. Laws Chapter 21-28](#).
397. "Correctional facility" means any facility in the State of Rhode Island for the confinement or rehabilitation of offenders or individuals charged with or convicted of criminal offenses.
4038. "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.
39. ["COVID-19" means the disease caused by the novel coronavirus SARS-CoV2.](#)
40. "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.
410. "Department" means the Rhode Island Department of Health.

421. "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.
432. "Delivery pharmacy" means the pharmacy that delivers the filled prescription medication to the patient.
443. "Device" means an instrument, apparatus, and contrivances, including their components, parts and accessories, intended:
- a. For use in the diagnosis, cure, mitigation, treatment, or prevention of disease in humans or other animals; or
  - b. To affect the structure or any function of the body of man or other animals.
454. "Director" means the Director of the Rhode Island state Department of Health or his or her subordinates to whom the Director has delegated the powers and duties vested in the Director by these regulations. The terms Department or Director may be used interchangeably unless clearly indicated otherwise by the context of the sentence in which It appears. -
465. "Discontinuance" means the action of terminating by discontinuing, suspending, or revoking any license for good and sufficient cause.
476. "Dispensary" shall have the same meaning as "clinic."
487. "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.
498. "Dispense as written" means the prescriber's instructions regarding authorization for substitution of with generic equivalents or ordering of the specific prescribed medication with instructions on the prescription to dispense the specific prescribed medication stating "DO NOT SUBSTITUTE."
50. "Dispensing error" means one or more of the following discovered after the final verification by the pharmacist and after receipt of the drug by the patient:
- a. Variation from the prescriber's prescription drug order, including but not limited to:



- (1) Incorrect drug;
  - (2) Incorrect drug strength;
  - (3) Incorrect dosage form;
  - (4) Incorrect patient; or
  - (5) Inadequate or incorrect packaging, labeling, or directions.
- b. Failure to exercise professional judgment in identifying and managing:
- (1) Known therapeutic duplication;
  - (2) Known drug-disease contraindications;
  - (3) Known drug-drug interactions;
  - (4) Incorrect drug dosage or duration of drug treatment;
  - (5) Known drug-allergy interactions;
  - (6) A clinically significant, avoidable delay in therapy; or
  - (7) Any other significant, actual, or potential problem with a patient's drug therapy.
- c. Delivery of a drug to the incorrect patient.
- d. Variation in bulk repackaging or filling of automated devices, including but not limited to:
- (1) Incorrect drug;
  - (2) Incorrect drug strength;
  - (3) Incorrect dosage form; or
  - (4) Inadequate or incorrect packaging or labeling.

**5149.-** \_\_\_\_\_ "Dispensing error analysis" means a review of the findings collected and documented on each dispensing error, assessment of the cause and any factors contributing to the dispensing error, and any recommendation for remedial action to improve pharmacy systems and workflow processes to prevent or reduce future errors.

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

531. "Drug" means:

- a. Articles recognized in the official United States Pharmacopeia, or the official Homeo-pathic Pharmacopeia of the United States;
- b. Substances intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man, woman or other animals;
- c. Substances (other than food) intended to affect the structure of any function of the body of man, woman or other animals;
- d. Substances intended for use as a component of any substances specified here above or as a "Prescription drug" or "Legend drug" defined in these Regulations, but not including devices or their component parts or accessories.

542. "Drug regimen review" includes but is not limited to the following activities:

- a. Evaluation of the prescriptions and patient records for:
  - (1) Known allergies;
  - (2) Rational therapy-contraindications;
  - (3) Reasonable dose and route of administration;
  - (4) Reasonable directions for use, and
  - (5) Evaluation of the prescriptions and patient records for duplication of therapy.
- b. Evaluation of the prescriptions and patient records for interactions:
  - (1) Drug-drug;
  - (2) Drug-food;
  - (3) Drug-disease;
  - (4) Adverse drug reactions, and
  - (5) Idiosyncratic reactions.

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

**553.** "DEM" means the Rhode Island Department of Environmental Management.

**564.** "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.

**575.** "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).

**586.** "Drug " has the same meaning set forth in R.I. Gen. Laws § [5-19.1-2\(k\)](#).

**597.** "Drug therapy management" means the review, in accordance with a collaborative practice agreement, of drug therapy regimen or regimens of patients by one or more licensed pharmacist(s) for the purpose of initiating, adjusting, monitoring, or discontinuing 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:

- a. Initiating, adjusting, monitoring, or discontinuing drug therapy;
- b. Collecting and reviewing patient histories;
- c. Obtaining and checking vital signs, including pulse, height, weight, temperature, blood pressure, and respiration; and
- d. 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.

**6058.** "Electronic medical record" (eMAR) is an electronically stored report that serves as a record of the drugs administered to a patient at a facility by a health care professional. The eMAR is a part of a patient's permanent record on his/her medical chart.

**6159.** "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.

620. "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.
634. "Emergency drug kit" means a select supply of drugs and/or biologicals located at a nursing facility, assisted living residence, medical institution, or hospice care facility, except as prohibited by other statutes or regulations, for the immediate administration to patients upon the medical order of an authorized prescriber.
642. "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.
653. "Executive Orders" means Executive Order 20-02 (Declaration of Disaster) and 20-18 (Extension of Declaration of Disaster) issued by the Governor of Rhode Island.
66. "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.
674. "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.
685. "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.
696. "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.
- a. "FPGEC" means the Foreign Pharmacy Graduate Equivalency Commission.

- b. "FPGEE" means the Foreign Pharmacy Graduate Equivalency Examination.
- c. "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 FPGECE.
- d. "Test of Spoken English (TSE)" means the test of spoken English administered by the Educational Testing Service.

7067. "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.

7168. "Hazardous drug" means any drug identified on the NIOSH or DEM lists that has the potential to cause carcinogenicity, teratogenicity, developmental toxicity, reproductive toxicity in humans, organ toxicity at low dose in humans or animals, genotoxicity, or new drugs that mimic existing hazardous drugs in structure or toxicity.

7269. "Hospice care facility" means an inpatient setting where palliative and supportive services to the terminally ill and their families are provided.

730. "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 [R.I. Gen. Laws Chapter 23-17](#).

741. "Immunizing pharmacist" means a pharmacist who is certified to administer adult and pediatric vaccinations in accordance with these regulations.

752. "Institutional pharmacy" means any pharmacy

- a. Located within or

- b. Off-site and contracted with any hospital, clinic or dispensary in which drugs are compounded or dispensed to its patients or patients of another licensed in-patient healthcare facility with whom it has a contract.

763. "Interchangeable biological product" means biosimilar to an FDA-approved reference product and meets additional standards for interchangeability. An interchangeable biological product may be substituted for the reference product by a pharmacist without the intervention of the health care provider who prescribed the reference product.

774. "Intern" means a graduate of an Accreditation Council for Pharmaceutical Education (ACPE)-accredited program of pharmacy, or a student enrolled in 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.

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

796. "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.

8077. "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).

8178. "ISO" means an air quality classification from the International Organization for Standardization.

8279. "Legend drugs" means any drugs that 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.

830. "Limited-function test" means those tests listed in the Federal Register under the Clinical Laboratory Amendments of 1988 (CLIA) as waived tests.

841. "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.

- 852.** “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.
- 863.** “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.
- 874.** “Manufacture” means the production, preparation, propagation, compounding, or processing of a drug or other substance or device or the packaging or repackaging.
- 885.** “Manufacturer” means anyone who is engaged in manufacturing, preparing, propagating, compounding, processing, packaging, repackaging, or labeling of a prescription drug or poisons.
- 896.** “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.
- 9087.** “Medical institution” means any hospital, clinic or dispensary.
- 9188.** “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 healthcare professional, patient, or consumer. Such events may be related to professional practice, healthcare 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.
- 9289.** “Medication administration record” (MAR) is a report that serves as a record of the drugs administered to a patient at a facility by a health care professional. The MAR is a part of a patient's permanent record on their medical chart.

9390. "Medication orders" or "Orders" means a written, verbal or electronically transmitted order for drugs and devices from an authorized practitioner in the State of Rhode Island for the dispensing and administration of a drug.
944. "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.
952. "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.
963. "NABP" means National Association of Boards of Pharmacy
974. "NIOSH" means National Institute for Occupational Safety and Health
985. "Nonlegend" or "Nonprescription drugs" means any drugs that may be lawfully sold without a prescription.
996. "Nonresident pharmacy" means a pharmacy located outside Rhode Island in any state in the United States or any province or territory of Canada that ships, mails, or delivers prescription drugs and/or devices to a patient or person in Rhode Island.
10097. "Nuclear pharmacy" means a pharmacy providing radiopharmaceutical services.
10198. "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.
10299. "Nursing facility" means a place, however named, or an identifiable unit or distinct part thereof that provides twenty-four (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.
1030. "Outsourcing facility" means a facility at one geographic location or address that is engaged in the compounding of sterile drugs, has elected



to register as an outsourcing facility, and complies with all of the requirements of section 503B of the federal Food, Drug, and Cosmetic Act.

1041. "Parenteral pharmacy practice" refers to admixtures of sterile parenteral solutions and dispensing of same intended for administration to patients in healthcare facilities and in the home.
1052. "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.
1063. "Patient safety organization" (PSO) means an organization that has as its primary mission continuous quality improvement under the Patient Safety and Quality Improvement Act of 2005 (Pub. L. 109-41) and is credentialed by the Agency for Healthcare Research and Quality.
1074. "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.
1085. "Person" means an individual, corporation, government, subdivision or agency, business trust, estate, trust, partnership or association, or any other legal entity.
1096. "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.
1107. "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 patient.
1108. "Pharmaceutical organization" means any profit or non-profit organization that advocates, lobbies, solicits business, or provides support

services to any private or public sector organization, or business within the various disciplines of the pharmacy profession, including but not limited to state pharmacy associations, national pharmacy associations, accrediting organizations and suppliers.

11209. "Pharmacist" means an individual licensed to engage in the practice of pharmacy in the State of Rhode Island pursuant to R.I. Gen. Laws § [5-19.1-14](#).
1130. "Pharmacist care services" is the provision by a Pharmacist of patient care activities within this State or into this State, as defined by this Part, with or without the Dispensing of Drugs or Devices, intended to achieve outcomes related to the cure or prevention of a disease, elimination or reduction of a patient's symptoms, or arresting or slowing of a disease process.
1141. "Pharmacist-in-charge" means a pharmacist licensed in the State of Rhode Island 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.
1152. "Pharmacist with advanced training and experience relevant to the scope of collaborative practice" means, a licensed pharmacist in the State of Rhode Island with post-graduate educational training. Such training shall include, but not be limited to, residency training; board certification; certification from an accredited professional organization educational institution; or any other continuing education provider or employer sponsored training approved by the Director relevant to the proposed scope of the collaborative practice agreement.
1163. "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.
1174. "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.
1185. "Pharmacy technician" means an individual who meets minimum qualifications established by the Board, that are less than those established by the Act as necessary for licensing as a pharmacist; and

who work under the direction and supervision of a licensed pharmacist. There shall be two levels of licensure for Pharmacy Technicians:

- a. Pharmacy Technician I; and
- b. Pharmacy Technician II. (See also § 1.1.10 of this Part). As used in these Regulations, 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.

1196. "Practice of pharmacy" means the interpretation, evaluation and implementation of medical orders; the dispensing of prescription drug orders; participation in drug and device selection; drug regimen reviews and drug or drug related research as well as medication therapy management (MTM); the participation in collaborative practice; the administration of medications; the administration of immunizations pursuant to a valid prescription or prescriber-approved protocol and in accordance with regulations, to include training requirements, as promulgated by the Department; 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 and the performance of clinical laboratory tests provided such testing is limited to limited-function tests as defined in this Part. Nothing in this definition shall be construed to limit or otherwise affect the scope of practice of any other profession.

12017. "Practitioner" means a physician, physician assistant, dentist, veterinarian, nurse or other person duly authorized by law in the state in which he/she practices to prescribe drugs.

12118. "Preceptor" means a pharmacist licensed to engage in the practice of pharmacy in the State of Rhode Island or a licensed pharmacist in the USA who has the responsibility for training interns.

12219. "Prescription" means an order for drugs or devices issued by the practitioner duly authorized by law in the state in which he/she practices to prescribe drugs or devices in the course of his or her professional practice for a legitimate medical purpose.

1230. "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.
1241. "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:
- a. "Rx only";
  - b. "Caution: Federal law restricts this drug to use by, or on the order of, a licensed veterinarian"; or
  - c. 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 § 503(b) of the federal Food, Drug, and Cosmetic Act, including all medical gases.
1252. "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.
1263. "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.
1274. "PTCB" means Pharmacy Technician Certification Board.
1285. "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 Rhode Island Rules and Regulations for the Control of Radiation healthcare and [R.I. Gen. Laws Chapter 23-1.3](#).
1296. "Qualified nuclear pharmacist" means a currently licensed pharmacist in the state of Rhode Island, who is identified as an Authorized Nuclear Pharmacist on a radioactive materials license issued pursuant to Subpart C.8 of the "Rules and Regulations for the Control of Radiation [R23-1.3-RAD]" or equivalent regulations of the U.S. Nuclear Regulatory Commission or another Agreement State.

13027. "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.
13128. "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.
13229. "Radiopharmaceuticals" are radioactive drugs as defined by the FDA and regulated pursuant to [R.I. Gen. Laws Chapter 23-1.3](#) and the "Rules and Regulations for the Control of Radiation [R23-1.3-RAD]".
1330. "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.
1341. "Recognized provider" means any person, corporation or association approved either by the Board, the Accreditation Council for Pharmaceutical Education (ACPE), or American Medical Association (AMA) Category I Programs, to conduct continuing education programs.
1352. "Restricted pharmacy" is a facility established pursuant to R.I. Gen. Laws § [5-19.1-10](#), and the provisions of the Employee Retirement Income Security Act of 1974, 29 U.S.C. § 1001 *et seq.*, for the purposes of dispensing drugs to the beneficiaries of any trust, fund, pension plan, combination plan, or profit sharing plan.
1363. "Retail pharmacy" means any pharmacy where drugs are compounded, dispensed, stored or sold or where prescriptions are filled or dispensed to the general public.
1374. "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.

1385. “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, or an alternate location of the patient’s choosing.

1396. “Shared order processing” means that the functions of: interpreting and entering the order, performing drug utilization reviews, refill authorizations, or therapeutic interventions, or any combination of these functions are performed in accordance with the Act and these Regulations, and are performed at a licensed pharmacy at the request of, and on behalf of, another pharmacy.

14037. “Shared pharmacy services” means a system that allows a participating Pharmacist or Pharmacy pursuant to a request from another participating Pharmacist or Pharmacy to process or fill a Prescription Drug Order, which may include preparing, packaging, Labeling, Compounding for specific patients, Dispensing, performing Drug Utilization Reviews, reviewing therapeutic interventions, and/or reviewing institutional facility orders.

14138. “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 the Act and this Part, and that participate in shared order filling or shared order processing, or both.

14239. “Sterile compounding” means any manipulation of a sterile or non-sterile product intended to produce a sterile final product.

1430. “Substance abuse facility” means a facility licensed by the state Department of Behavioral Healthcare, Developmental Disabilities and Hospitals that includes residential treatment services and detoxification services.

1441. “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:

- a. Pre-packaged prescription sample medication;

- b. Automated dispensing system;
- c. Administration of a stock medication;
- d. Dispensing of a manufacturer-prepared pap medication;
- e. Dispensing of oral and transdermal contraceptives.

1452. "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.

1463. "USP" means the United States Pharmacopeia.

1474. "Wholesale distribution" means distribution of prescription drugs to person other than a consumer or patient, but does not include:

- a. Intracompany sales;
- b. The purchase or other acquisition by a hospital or other healthcare 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 healthcare entities that are members of such organizations;
- c. The sale, purchase or trade of a drug or 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;
- d. The sale, purchase, or trade of a drug or an offer to sell, purchase, or trade a drug among hospitals or other healthcare 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;
- e. 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;

- f. 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.;
- g. The lawful distribution of drug samples by manufacturers' representatives or distributors' representatives;
- h. The sale, purchase, or trade of blood and blood components intended for transfusion;
- i. Every hospital licensed in accordance with [R.I. Gen. Laws Chapter 23-17](#) 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 [R.I. Gen. Laws § 23-4.1-7.1](#).
- j. Every hospital licensed in accordance with [R.I. Gen. Laws Chapter 23-17](#) that accepts vaccine from the Department and distributes such vaccine as part of the Department's immunization program.

1485. "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.

1496. "Wholesaler" means a person who buys drugs or devices for resale and distribution to corporations, individuals, or entities other than consumers.

### **1.3 Code of Professional Conduct for Pharmacists and Pharmacies**

- A. A pharmacist-in-charge, registered pharmacist, pharmacy, or anyone acting on behalf of a pharmacy or pharmacy department shall follow the Code of Professional Conduct to include, but not be limited to the following:
  - 1. A pharmacist-in-charge, registered pharmacist, pharmacy, or anyone acting on behalf of a pharmacy or pharmacy department shall at all times conduct professional activities in conformity with federal, state and municipal laws, ordinances and/or regulations, including the regulations of the Board.



2. A pharmacist-in-charge, registered pharmacist, pharmacy, or anyone acting on behalf of a pharmacy or pharmacy department shall not dispense drugs, devices, or other substances in a manner which is intended, either directly or indirectly, to circumvent the law.
3. A pharmacist-in-charge, registered pharmacist, pharmacy, or anyone acting on behalf of a pharmacy or pharmacy department shall observe the standards of the current United States Pharmacopoeia in addition to State laws and regulations.
4. While on duty, a pharmacist-in-charge, registered pharmacist, pharmacy, or anyone acting on behalf of a pharmacy or pharmacy department shall be responsible for the proper preservation and security of all drugs in the pharmacy or pharmacy department, including the proper refrigeration and storage of said drugs.
5. A pharmacist-in-charge, registered pharmacist, pharmacy, or anyone acting on behalf of a pharmacy or pharmacy department shall not engage in any fraudulent or deceptive act
6. A pharmacist-in-charge, registered pharmacist, pharmacy, or anyone acting on behalf of a pharmacy or pharmacy department shall not in any way aid or abet the unlawful practice of pharmacy.
7. A pharmacist-in-charge, registered pharmacist, pharmacy, or anyone acting on behalf of a pharmacy or pharmacy department shall not knowingly dispense or distribute expired, outdated or otherwise substandard drugs or devices or counterfeit drugs or devices to any person or entity.
8. A pharmacist-in-charge, registered pharmacist, pharmacy, or anyone acting on behalf of a pharmacy or pharmacy department shall not knowingly dispense or distribute drugs or devices to any person or entity who is not licensed or legally authorized to receive such drugs or devices.
9. A pharmacist-in-charge, registered pharmacist, pharmacy, or anyone acting on behalf of a pharmacy or pharmacy department may dispense prescription drugs by mail or common carrier in a manner consistent with federal and state laws and regulations, including the regulations of the Board. All pharmacists shall have available sufficient information to contact the patient and the prescribing practitioner.
10. A pharmacist, pharmacy, pharmacy department, pharmaceutical organization or pharmacy corporation shall not provide any practitioner



is necessary to dispense medication before the medication can be delivered to the island. The waiver shall be subject to the following provisions:

1. Medication to be dispensed shall be limited to legend drugs included in a written policy established by the Block Island Health Center. A full instruction on the use of the product in plain language shall be provided to the patient.
2. The Block Island Health Center shall keep a written log of all medications dispensed pursuant to the waiver authorized by this Part. The dispensing log shall contain, as a minimum, the following information:
  - a. The name of the prescriber;
  - b. The full name of the patient;
  - c. The name of the drug dispensed in accordance with [R.I. Gen. Laws Chapter 21-31](#);
  - d. Quantity and strength of the drug dispensed; and
  - e. The date of dispensing.
3. Copies of the dispensing logs shall be maintained for twenty-four (24) months from the date the legend drug was dispensed and shall be made available to the Department upon request.
4. Each medication dispensed pursuant to the waiver authorized by this Part shall have a label attached which meets the requirements of § 1.5.17(A) of this Part.
5. When required, the healthcare provider who dispenses medication pursuant to the waiver authorized by § 1.4.1 of this Part shall be responsible for ensuring that all necessary data is entered into the Department's Prescription Monitoring Program (PMP) database in accordance with the rules and regulations for the Prescription Drug Monitoring Program (Part 20-20-3 of this Title).
6. Any waiver utilized pursuant to this Part shall not relieve the licensed healthcare provider of record-keeping or other requirements of this Part.

#### **1.4.2 Authorized Practices**

- A. In accordance with R.I. Gen. Laws § [5-19.1-22](#), nothing in the Act or this Part shall apply to any practitioner with authority to prescribe who does not maintain

an 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.

- B. Nothing in the Act or this Part 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.

#### **1.4.3 Qualifications for Licensure: Pharmacists**

- A. In addition to the provisions of R.I. Gen. Laws § [5-19.1-14](#), every person in order to be a licensed pharmacist shall:
1. If the applicant is a foreign pharmacy graduate, have obtained full certification from the FPGEC.
  2. Have satisfactorily completed the internship in accordance with § 1.4.14 of this Part; and
  3. Have successfully passed such examination as the Board and the Director may require in accordance with § 1.4.5(A) of this Part.
  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 practice of pharmacy.
  5. Obtain and report an eProfile number from NABP.
  6. Meet such additional requirements as may be established in this Part.

#### **1.4.4 Application for Licensure and Fee**

- A. 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 103

Providence, Rhode Island 02908

1. Said forms shall be completed and signed by the applicant, 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 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 as set forth in the Fee Structure for Licensing, Laboratory and Administrative Services Provided by the Department of Health (Part 10-05-2 of this Title).
- B. 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.
- C. No applicant shall be approved or accepted for examination until he/she has met all requirements of internship as set forth in § 1.4.14 of this Part. Affidavit of internship hours shall be submitted to the Department prior to application for licensure.
- D. 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. No fees shall be refunded.

#### **1.4.5 Examination for Licensure**

- A. 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 the State of Rhode Island, pursuant to R.I. Gen. Laws § [5-19.1-14](#).
  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:
  - (1) Administered in the State of Rhode Island with the passing grade as determined by NABP and approved by the Board; or
  - (2) Administered in another state by the licensing authority of the respective state, and provided the requirements of § 1.4.5(B) of this Part on transfer of grades are met; and
- b. The Multistate Pharmacy Jurisprudence Examination (MPJE) with a passing grade as determined by NABP.

**B. Transfer of Grades**

- 1. 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).
- 2. 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 the State of Rhode Island must submit an application for licensure to the Department in accordance with § 1.4.12 of this Part and must meet all other statutory and regulatory requirements in this Part.
- 3. Applicants participating in the Transfer of Scores Program shall complete the Multistate Jurisprudence Examination, as described in § 1.4.5(A) of this Part, within six months of application to the Rhode Island Board of Pharmacy.

**1.4.6 Re-Examination**

- A. 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.

- B. Application for re-examination shall be submitted to the Department and accompanied by the required fees in accordance with § 1.4.4 of this Part.

#### **1.4.7 Without Examination by Reciprocity**

- A. The Department shall, without examination other than those required in § 1.4.5 of this Part 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 the State of Rhode Island.
  - 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 the State of Rhode Island a statement confirming the applicant to be or have been in good standing.
  - 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 § 1.4.5 of this Part.
  - 3. The applicant shall submit to the Department the Official Transfer of Pharmaceutic Licensure Application of the NABP, a copy of his/her birth certificate, and the application fee as set forth in the Fee Structure for Licensing, Laboratory and Administrative Services Provided by the Department of Health (Part 10-05-2 of this Title).

#### **1.4.8 Temporary Ninety (90) Day License**

- A. In accordance with R.I. Gen. Laws § [5-19.1-8](#) 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 the State of Rhode Island for a period of ninety (90) days from the date on the application receipt, provided that they become duly licensed in the State of Rhode Island 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.
- B. 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.

#### **1.4.9 Internship: Pharmacy Interns**

## A. General Requirements

1. Any person who is a graduate of an accredited program of pharmacy or who is a student enrolled in 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 Department may prescribe and, simultaneously with the filling of said application, shall pay to the Department a fee as set forth in the Fee Structure for Licensing, Laboratory and Administrative Services Provided by the Department of Health (Part 10-05-2 of this Title).
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.
3. No pharmacy student may serve an internship with a preceptor without holding a valid limited license from the Board.
4. To assure adequate practical instruction, pharmacy internship experience as required under the Act and this Part shall be obtained after licensure as a pharmacy intern by practice in any licensed pharmacy or other program meeting the requirements promulgated in this Part, and shall include such instruction in the practice of pharmacy as the Board shall prescribe.
5. Licensed pharmacy interns shall practice only under the immediate supervision of a licensed pharmacist.

### 1.4.10 Limited License

- A. No pharmacy student enrolled in a professional program of an accredited college of pharmacy may serve an internship in the State of Rhode Island with a preceptor without holding a valid limited license by the Board of Pharmacy pursuant to the provisions of R.I. Gen. Laws § [5-19.1-15](#).
- B. 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 a professional program of an accredited college of pharmacy.



#### **1.4.11 Foreign Graduates**

Foreign graduates shall have obtained full FPGEC certification prior to commencing internship.

#### **1.4.12 Application and Fee**

- A. 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 103

Providence, Rhode Island 02908

1. 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 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 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 as set forth in the Fee Structure for Licensing, Laboratory and Administrative Services Provided by the Department of Health (Part 10-05-2 of this Title).
2. Foreign Interns: The license application requirement of a documented social security number (SSN) may only be waived for the initial license year. Subsequent license renewal shall require a documented SSN. A foreign pharmacy intern may practice under a limited license without a registered SSN at the discretion of the preceptor.

#### **1.4.13 Issuance of Limited License**

- A. 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 § 1.4.2 of this Part, shall expire annually on the first (1<sup>st</sup>) 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 as set forth in the Fee Structure for Licensing, Laboratory and Administrative Services Provided by the Department of Health (Part 10-05-2 of this Title).

- B. A limited license is not transferable.
- C. 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 for no more than one (1) year from the date of graduation from an ACPE-accredited college of pharmacy, and in each case he/she shall be supervised by a registered pharmacist licensed in the State of Rhode Island.

#### **1.4.14 Internship**

- A. The internship required of applicants for licensure as pharmacists shall consist of fifteen hundred (1,500) hours, and shall be carried out under the supervision of a U.S. registered or licensed pharmacist who shall act as a preceptor.
- B. Applicants seeking licensure as a pharmacist by reciprocity (§ 1.4.6 of this Part) shall have satisfied the requirements of internship in the state of initial licensure.
- C. 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.

#### **1.4.15 Duties and Responsibilities of Pharmacy Interns**

- A. 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.
- B. 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, or dispensing process validation.

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

#### **1.4.16 Issuance and Renewal of the Pharmacist License**

- A. 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 shall expire on the thirtieth (30th) of June each year unless sooner suspended or discontinued.
- B. Every person licensed as a pharmacist in the State of Rhode Island who desires to renew his or her license shall file such renewal application with the Department by the thirtieth (30th) day of June each year. Said renewal shall be duly executed together with the renewal fee as set forth in the Fee Structure for Licensing, Laboratory and Administrative Services Provided by the Department of Health (Part 10-05-2 of this Title).
  - 1. 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 up to two (2) years unless sooner suspended or discontinued.
- C. Every person licensed as a pharmacist in this state who desires to renew his or her license must obtain an eProfile number from the national association of boards of pharmacy.
- D. Any person who allows his or her license to lapse by failing to renew it on or before the thirtieth (30st) day of June of each year may be reinstated upon filing an application with payment of the renewal fee as set forth in the Fee Structure for Licensing, Laboratory and Administrative Services Provided by the Department of Health (Part 10-05-2 of this Title).
  - 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.

#### **1.4.17 Continuing Education**

- A. Pursuant to the provisions of R.I. Gen. Laws § [5-19.1-14](#), any pharmacist, licensed to practice pharmacy in Rhode Island, who seeks 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 between January 1st and December 31st of each calendar year. One (1) hour or 0.1 continuing education units of the required fifteen (15)

hours of continuing education between January 1st and December 31st of each calendar year shall be in the area of the law as classified by ACPE. Furthermore, five (5) hours or 0.5 continuing education units between January 1st and December 31st of each calendar year must be live hours. In addition:

1. Immunizing pharmacists shall complete one (1) hour or 0.1 continuing education units of the required fifteen (15) hours of continuing education.
2. Any pharmacist participating in a collaborative pharmacy practice agreement shall earn at least five (5) additional contact hours or 0.5 continuing education units of board-approved continuing education that addresses areas of practice generally related to collaborative practice agreements 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.
3. 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 this Part, 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.
4. For the first year of licensure following graduation from a college of pharmacy, a pharmacist shall not be subject to the continuing education requirements of this Part, with the exception of the continuing education requirement contained in § 1.11.1(B)(7) of this Part; and
5. 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 of this Part.
6. 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 in this Part. Furthermore:
  - a. 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.

- b. Any pharmacist whose license has not been renewed for one (1) or more years must demonstrate compliance with continuing education regulations for the licensure period immediately prior to application.
- c. Pharmacists failing to comply with the requirements of § 1.4.17(A) (6) of this Part.

#### **1.4.18 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 Accreditation Council for 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.

#### **1.4.19 Continuing Education Credit for Postgraduate Pharmacy Curriculum/Program**

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

#### **1.4.20 Return or Exchange of Drugs**

- A. The Board, with the approval of the Director 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.

- B. 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.
1. Prescription Drugs. Unused prescription drugs may be accepted by wholesalers or pharmacies, from which they were purchased, for return from nursing facilities, assisted living residences, residential care facilities, community health organizations and state correctional facilities that centrally store prescription drugs and are licensed at the M1 licensure level by the Department, within forty-five (45) days of dispensing.
    - a. The wholesaler or pharmacy to which the following categories of prescription drugs are returned may repackage, restock, and redistribute such medication:
      - (1) Unopened sections of blister pack prescription medication, with seal intact;
      - (2) Unopened unit-dose containers of liquids with the safety seal intact;
      - (3) Unopened unit-dose containers of powders for oral solution with safety seal intact; and
      - (4) Unused injectables, with safety seal intact.
    - b. Exceptions. Notwithstanding the provisions of § 1.4.20(B)(1) of this Part, the unused prescription drug shall not be accepted, repackaged or redispensed if:
      - (1) The prescription drug is expired or beyond use date;
      - (2) The pharmacist accepting or redispensing the drug, in his or her judgment has reason to believe that the prescription drug is adulterated, mislabeled, or has been improperly stored;
      - (3) The prescription drug is defined as controlled substances in [R.I. Gen. Laws § 21-28-1.02](#); or

- (4) It is a drug that can only be dispensed to a patient registered with the drug's manufacturer in accordance with federal Food and Drug Administration requirements.
2. Recording: The wholesaler or 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.
3. The wholesaler or pharmacy shall be required to reimburse or credit the purchaser for any such returned prescription drugs at original invoice price plus a restocking fee not to exceed five dollars (\$5.00).
4. 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.

#### **1.4.21 Multi-drug Single-Dosing Systems**

##### **A. General Requirements**

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 multi-drug single-dosing container may include controlled medications from Schedule IV and V if such medications are prescribed for the patient on a routine, customary basis;
  - c. The labels must be of sufficient size to properly and clearly label each container with all information required by state and federal law and rules
  - d. 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.

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.
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.
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.
5. Nothing contained in this Part 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.

#### B. Labeling Requirements

1. 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.
  2. 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.
- C. Exclusions. Multi-drug single-dosing containers shall not include drug(s) that have the following characteristics:
  1. USP-DI monograph or official labeling requires dispensing in the original container;
  2. Are incompatible with packaging components or with each other;
  3. Require special packaging;
  4. Are controlled medications from Schedules II and III.
- D. Requirements for Nursing Facilities and Assisted Living Residences
  1. 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).
  2. 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.

- E. Prescriptions. 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 is generated from a facsimile or a prescribing practitioner's electronic or manual signature, 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.

#### **1.4.22 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.
- C. 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

[R.I. Gen. Laws Chapters 21-31, 21-28, 5-19.1](#) and such other applicable statutory requirements.

#### **1.4.23 Electronic Transmission**

- A. Technological devices for the transmission or communication of prescriptions between licensed prescribers and pharmacists may be used in accordance with the following requirements:
1. The transmission of prescriptions for controlled substances shall comply with the provisions of [R.I. Gen. Laws Chapters 21-28](#) ("Controlled Substances Act"), 21 C.F.R. § 1306.08, R.I. Gen. Laws § [5-37.3](#) ("Confidentiality of Healthcare Information Act"), and all other federal or state laws.
  2. Unless otherwise prohibited by law, prescriptions may be transmitted by electronic means or facsimile from the prescriber as defined in R.I. Gen. Laws Chapters 21-28 and 21 C.F.R. § 1306.08, 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 [R.I. Gen. Laws Chapters 21-28](#).
  3. 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.
  4. A pharmacy receiving an electronic transmission prescription shall either receive the prescription in hard copy form or have the capacity to retrieve an electronic copy of the prescription from the pharmacy's computer memory.
  5. The patient shall have the right to choose the manner in which his/her prescription is transmitted to the pharmacy.
  6. The patient shall have the right to choose the pharmacy to which his/her prescription is transferred.
  7. The pharmacist shall exercise professional judgment regarding the accuracy or authenticity of the transmitted prescription consistent with existing laws and regulations
  8. Technological devices shall not be used to circumvent documentation, verification, or any provisions of the Act. Neither shall they be used to commit any other action that may be deemed unprofessional conduct.

9. Technological devices shall be located within the pharmacy.

#### **1.4.24 Emergency Prescription Refill**

- A. 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 seventy-two (72)-hour supply of the prescribed medication, providing that:
  1. The prescription is not for a drug in schedule II appearing in [R.I. Gen. Laws Chapter 21-28](#)
  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.

### **1.5 Pharmacies: Licensure Requirements**

#### **1.5.1 Licensure Requirements: Pharmacies**

- A. Pursuant to R.I. Gen. Laws § [5-19.1-9](#), no person shall conduct, maintain, or operate a pharmacy in the State of Rhode Island without first obtaining and having in force a pharmacy license in accordance with the statutory provisions of the Act and the regulatory requirements of this Part.
- B. Restricted Pharmacies: Pursuant to R.I. Gen. Laws § [5-19.1-10](#), 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. § 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.

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 [R.I. Gen. Laws Chapter 5-37](#), as licensed to practice in the State of Rhode Island or in any New England state.
- C. 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 Healthcare Workers, in Licensed Healthcare Facilities, and by Other Persons, Firms, or Corporations Licensed or Registered by the Department (Part 20-15-3 of this Title).
- D. 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.
- E. All pharmacies shall maintain an adequate number of pharmacists and pharmacy technicians to meet pharmacy workload demands, provide for adequate rest periods for personnel, and maintain public safety. Pharmacy staffing information shall be provided to the Department upon request, including but not limited to number of pharmacists and pharmacy technicians, prescription volume, pharmacy hours of operation, and staff schedules.

### **1.5.2 Application for License and Fee**

- A. Application for a license (retail pharmacy, pharmacy within a medical institution, or restricted pharmacy) to conduct, maintain or operate a pharmacy in the State of Rhode Island 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.
- B. The initial application must include the following:

1. Name and address of owner and/or manager and a notarized declaration of ownership and location
  2. Name of pharmacist-in-charge of the pharmacy
  3. Proposed location and address of place of business and blueprint or drawings of proposed floor plans
  4. For all pharmacies, the initial licensure fee as set forth in the Fee Structure for Licensing, Laboratory and Administrative Services Provided by the Department of Health (Part 10-05-2 of this Title);
  5. An eProfile number from the national association of boards of pharmacy.
  6. Pharmacies that compound sterile products shall provide an inspection report performed by the Board of Pharmacy from the pharmacy's home state, an independent organization such as NABP, or other similar agency as approved by the Board. Inspection shall be:
    - a. At the expense of the applicant;
    - b. Performed as a condition of initial licensure and annually thereafter; and
    - c. As deemed necessary by the Department to protect the public health and safety.
  7. Such other information as the Board may deem necessary.
- C. 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 as set forth in the Fee Structure for Licensing, Laboratory and Administrative Services Provided by the Department of Health (Part 10-05-2 of this Title).

### **1.5.3 Issuance and Renewal of License**

- A. 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 requirements of the Act and this Part. Said license, unless sooner suspended or discontinued, shall expire annually on the thirtieth (30<sup>th</sup>) day of September following its issuance and may be renewed from year to year upon submission of application and license renewal fee. The applicant for renewal must obtain and submit an eProfile from the national association of boards of pharmacy.

- B. 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.
  - 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.
- C. A license issued under this Part is the property of the State of Rhode Island and loaned to such licensee. It shall be kept posted in a conspicuous place in the licensed pharmacy.
  - 1. The name of the pharmacist-in-charge shall be conspicuously displayed in the pharmacy.

#### **1.5.4 Change of Ownership and/or Location**

- A. 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.
- B. 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.
- C. When there is a change in ownership and/or location, the license shall immediately become void and shall be delivered to the Department.
  - 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.
  - 2. The new applications must be filed in accordance with the provisions of § 1.5.2 of this Part and be accompanied by the initial licensure fee pursuant to R.I. Gen. Laws § [5-19.1-9](#) and as set forth in the Fee Structure for Licensing, Laboratory and Administrative Services Provided by the Department of Health (Part 10-05-2 of this Title).
- D. Pharmacy renovations or remodeling: Any renovations or remodeling of an existing pharmacy shall not be considered a change of location.

- E. Patient records shall be retained and shall be capable of being retrieved, in a reasonable time period, for no less than two (2) years after a change of ownership is completed.

### **1.5.5 General Requirements: All Pharmacies**

- A. 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 of this Part pertaining to the practice of pharmacy.
  - 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.
  - 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.
  - 3. The pharmacist-in-charge of any pharmacy licensed in the State of Rhode Island and located in the State of Rhode Island or in another state, shall be licensed as a registered pharmacist in the state where the pharmacy is located.
  - 4. 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.
  - 5. The owner shall develop and implement written policies and procedures to specify the duties to be performed by such pharmacists.



6. 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 for Disposal of Drugs (Part 20-20-1 of this Title), 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 this Part;
  - i. Be administratively responsible for the overall operation and conduct of the pharmacy.
- B. Nothing in this Part shall prohibit a pharmacist from practicing pharmacy and providing pharmaceutical care outside of a pharmacy, including into Rhode Island, if the following conditions are met:

1. The pharmacist is licensed in Rhode Island or an employee of a non-resident pharmacy licensed in Rhode Island;
2. The pharmacist has real-time electronic access to prescription records, patient profiles, or other relevant medical information and appropriately reviews the information;
3. Such records are protected from unauthorized access and use; and
4. The pharmacist maintains the records or other patient-specific information created, collected, or used electronically.

#### **1.5.6 Security**

- A. 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.
- B. Each pharmacy shall, at least while closed, utilize an alarm or other comparable monitoring system.
- C. The Board shall deem additional security requirements necessary for the protection of the pharmacy and of the public.
- D. The pharmacy shall place security cameras at multiple vantage points in the drug storage area within the pharmacy, including other adjacent areas of the building and pharmacy as deemed necessary by the Department and Board, which actively record and store video data for a minimum of 30 (thirty) days.
- E. The pharmacy shall establish policies and procedures to address disasters and emergencies in order to protect the integrity of drugs and prevent unauthorized access to prescription medication.

#### **1.5.7 Facilities, Equipment and Stock**

- A. 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.
- B. 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.

### **1.5.8 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 as well as other practice of pharmacy functions defined in this Part. The pharmacy shall be equipped with proper sanitary appliances and kept in a clean, sanitary and orderly manner.

### **1.5.9 Pharmaceutical Services - Drug Recall**

- A. 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:
1. A process for review of documents (i.e., prescriptions, drug orders, etc.) of the recalled lots.
  2. Notification to the recipients and prescribers of the recalled product, when appropriate.
  3. Personal inspection of all areas where drugs are stored to determine presence of recalled products.
  4. Quarantine of all recalled products to be marked "Quarantined-Do Not Use" until returned to manufacturer.
  5. Maintenance of written log of all recalls, the actions taken, and the results.

### **1.5.10 Emergency Kits**

- A. Drugs and devices may be provided in emergency kits for use by authorized personnel in nursing facilities, assisted living residences, medical institutions, or hospice care facilities (collectively "institutions") provided that:
1. The pharmacist-in-charge or designee, and the qualified health care staff shall jointly determine the drugs to be included in the kit by identity and quantity.
  2. 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.

3. 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.
4. All drugs within the emergency kit shall be labeled, if applicable, with the name, strength, lot number, manufacturer and expiration date.
5. 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.
6. 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.
7. The pharmacy may use automated storage and distribution devices as an emergency kit so long as the automated storage and distribution device complies with the provisions of this section.

#### **1.5.11 Repackaging**

- A. Drugs which are repackaged within a pharmacy for subsequent dispensing or administration shall be labeled to include:
  1. The generic or trade name, strength, and quantity of drug
  2. 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
  3. 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.
- B. 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.

- C. A pharmacy may repackage a patient's previously dispensed medication provided that the pharmacy implements policies and procedures that include but are not limited to the following requirements:
1. The patient or patient's responsible party requests that the pharmacy repackage the medication for ease of administration in unit dose containers.
  2. The pharmacy receiving the previously dispensed medication records the prescription medication received, all label information, and stores the medication separate from the pharmacy's inventory.
  3. The medication is repackaged in an appropriate USP approved multi-unit, unit-of-use, or single-unit dose container.
  4. The pharmacy records the previously repackaged medication quantity, includes all information on the original prescription label, and a pharmacist verifies the medication that was repackaged is correctly labeled by the pharmacy.

#### **1.5.12 Investigational Drugs**

- A. The pharmacist-in-charge and the medical staff shall be responsible for developing policies and procedures for ensuring proper labeling pursuant to [R.I. Gen. Laws Chapter 21-31](#), storage, distribution, administration and control of investigational drugs.
1. Investigational drugs shall be relabeled "For Investigational Use Only."
  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.
  3. Investigational drugs shall be segregated from commercial products.

4. The pharmacist-in-charge shall be responsible for the provision of staff education regarding investigational drugs.
  5. Prior to dispensing, any investigational drug, dose and treatment schedule should be verified against the protocol.
- B. Any information pertaining to potential adverse effects, precautions, compounding and preparation requirements, etc., of the investigational drug shall be reviewed by the pharmacist.

### **1.5.13 Adverse Drug Reactions (ADRs) and Medication Errors**

- A. Medication Use Evaluation Program:
1. 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 using VAERS and adverse events involving Dietary Supplements shall be reported to <https://www.safetyreporting.hhs.gov>.
- B. Patient Profile
1. 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 (12) 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.
- C. 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.
- D. The patient record shall be maintained for a period of not less than two (2) 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.
- E. Prospective Drug Review
1. 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.
  2. 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.
- F. Continuous quality improvement programs.

1. Notwithstanding practices constituting unprofessional practice indicated in this Part, any pharmacy that actively reports dispensing errors and the analysis of such errors to a patient safety organization shall be deemed in compliance with this section.
2. Pharmacies not actively reporting to patient safety organizations shall implement a program for continuous quality improvement in compliance with this section.
  - a. Notification requirements:
    - (1) A pharmacy intern or pharmacy technician who identifies or learns of a dispensing error shall immediately notify a pharmacist on duty of the dispensing error.
    - (2) A pharmacist on duty shall appropriately respond to the dispensing error in a manner that protects the health and safety of the patient.
    - (3) A pharmacist on duty shall immediately notify the patient or the person responsible for administration of the drug to the patient and communicate steps to avoid injury or mitigate the error if the patient is in receipt of a drug involving a dispensing error that may cause patient harm or affect the efficacy of the drug therapy. Additionally, reasonable efforts shall be made to determine if the patient self-administered or was administered the drug involving the dispensing error. If it is known or reasonable to believe the patient self-administered or was administered the drug involving the dispensing error, the pharmacist shall immediately assure that the prescriber is notified.
  - b. Documentation and record requirements; remedial action:
    - (1) Documentation of the dispensing error must be initiated as soon as practical, not to exceed three days from identifying the error. Documentation shall include, at a minimum, a description of the event that is sufficient to allow further investigation, categorization, and analysis of the event.
    - (2) The pharmacist-in-charge or designee shall perform a systematic, ongoing analysis, as defined in these regulations, of dispensing errors. An analysis of each dispensing error shall be performed within 30 days of identifying the error.



- (3) The pharmacist-in-charge shall inform pharmacy personnel of changes made to pharmacy policies, procedures, systems, or processes as a result of the analysis.
- (4) Documentation associated with the dispensing error need only to be maintained until the systematic analysis has been completed. Prescriptions, dispensing information, and other records required by federal or state law shall be maintained accordingly.
- (5) A separate record shall be maintained and available for inspection to ensure compliance with this section for 12 months from the date of the analysis of dispensing errors and shall include the following information:
  - (AA) Dates the analysis was initiated and completed;
  - (BB) Names of the participants in the analysis;
  - (CC) General description of remedial action taken to prevent or reduce future errors; and

#### **1.5.14 Patient Counseling**

- A. After receipt of a new prescription and following a review of the patient's record, a pharmacist or pharmacy intern, as defined in the Act, 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:
  - 1. The name and description of the drug;
  - 2. The dosage form, dose, route of administration, dosing schedule, and duration of drug therapy;
  - 3. Intended use of the drug and expected action;
  - 4. Special directions and precautions for preparation, administration, and use by the patient;

5. 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;
  6. Techniques for self-monitoring drug therapy;
  7. Proper storage;
  8. Prescription refill information;
  9. Action to be taken in the event of a missed dose; and
  10. Pharmacist comments relevant to the individual's drug therapy, including any other information peculiar to the specific patient or drug.
- B. Alternative forms of patient information shall be used, when deemed necessary in the professional judgment of the pharmacist, to supplement patient counseling when appropriate. Examples to include written information leaflets, pictogram labels, video programs, etc.
- C. Patient counseling and patient profiles, as described above and defined in this act shall not be required for inpatients of a hospital or institution, or any other licensed health-care facility, where other licensed healthcare professionals are authorized to administer the drugs.
- D. A pharmacist shall not be required to counsel a patient or care giver when the patient or care giver refuses such consultation. Such refusal shall be documented in writing.

#### **1.5.15 Prescription Transfer**

- A. Prescriptions may be transferred for the purposes of filling or refilling between pharmacies by any means either verbally, electronically, or via fax provided that the pharmacies adhere to the following requirements:
1. The prescription is for a drug that is lawfully able to be filled.
  2. The pharmacist, or supportive personnel, as permitted, transferring the prescription cancels the original prescription in his/her records, and indicates in the prescription record 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 or supportive personnel.

3. The pharmacist, or supportive personnel, as permitted, receiving the transferred prescription shall:
    - a. Note that it is a transferred prescription.
    - b. Record all of the following information in the prescription records, in addition to other information required by law:
      - (1) Date of issuance of the original prescription
      - (2) Original number of refills authorized on prescription
      - (3) Complete refill record from original prescription
      - (4) Number of valid refills remaining.
    - c. File number of the original prescription.
    - d. Name of the pharmacy and pharmacist or supportive personnel from whom the prescription was transferred.
  4. A pharmacist, or supportive personnel, as permitted, may transfer a prescription to another pharmacist or supportive personnel employed by the same corporation without regard to the requirements of §§ 1.5.15(A) (2) and (3) of this Part, provided that both have access to the same computerized prescription transfer system which contains the prescription and refill records and incorporates procedures to prevent unauthorized refills.
  5. If the prescription is for a controlled substance in Schedules III, IV, or V, the pharmacies shall comply with 21 C.F.R. § 1306.26.
- B. The requirements of §§ 1.5.15(A)(2) through (4) of this Part are excepted when an offsite pharmacy that provides pharmaceutical services to a nursing facility, assisted living residence, mental health institution, medical institution, hospital, or hospice care facility pursuant to a valid medication order or prescription directly transmits and shares the quantity of a prescription or medication order with another pharmacy if:
1. The transmission and sharing of the prescription or medication order is for the limited purpose of ensuring that drugs or devices are attainable to meet the immediate needs of patients for up to a seventy-two (72) hour supply or the originating pharmacy cannot provide services for the institutional facility on an ongoing basis due to a state of emergency

declared by an authorized government official or agency or unforeseen circumstances requiring that the pharmacy temporarily cease operations;

2. The originating pharmacy obtains consent from the facility, home health agency or hospice agency to share the pharmacy services for its residents;
3. The originating pharmacy provides a copy of a valid verbal, electronic, or written prescription or medication order to the receiving pharmacy prior to dispensing by the receiving pharmacy; and
4. The receiving pharmacy maintains responsibility for performing all requirements under applicable pharmacy statutes and regulations when dispensing the portion of the prescription or medication order.

#### **1.5.16 Beyond-Use Dating on Labels**

- A. 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:
  1. 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
  2. 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.

#### **1.5.17 Necessity of Prescription Label**

- A. In accordance with R.I. Gen. Laws § [5-19.1-18](#), 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:
  1. The name of the prescriber;
  2. The full name of the patient;
  3. The name and address of the pharmacy;
  4. The name of the drug dispensed in accordance with [R.I. Gen. Laws Chapter 21-31](#);

5. Quantity and strength of the drug dispensed;
  6. The date of dispensing;
  7. The prescription number;
  8. The expiration date of the prescription in accordance with § 1.5.16 of this Part; and
  9. A full instruction on the use of the product in plain language.
- B. 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.
- C. No person shall alter, deface, or remove any label so affixed.
- D. 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.

#### **1.5.18 Generic Substitutions**

- A. 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 [R.I. Gen. Laws §§ 21-31-16](#) and [21-31-15\(l\)\(1\)](#), 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.
- B. The requirements of § 1.5.18(A) of this Part shall not apply to an order to dispense a drug for immediate administration to a licensed hospital, nursing facility or hospice facility in-patient.
- C. 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.

#### **1.5.19 Biosimilar Interchange**

- A. Pharmacists when dispensing a biological product shall, unless requested otherwise by the patient, interchange with a less expensive product that is a highly similar product to the FDA-approved biological product, known as a reference product, which has no clinically meaningful differences in terms of safety and effectiveness from the reference product, and the FDA has:
1. Licensed and determined meets the standards for interchangeability pursuant to 42 U.S.C. § 262(k)(4) or lists of licensed, biological products with reference product exclusivity and biosimilarity or interchangeability evaluations; or
  2. Determined is therapeutically equivalent as set forth in the latest edition of or supplement to, the United States Food and Drug Administration's Approved Drug Products with Therapeutic Equivalence Evaluations.

#### **1.5.20 Central Database – Operation**

- A. In accordance with R.I. Gen. Laws § [5-19.1-17](#), 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.
- B. Clinic pharmacies operated by a health maintenance organization licensed under [R.I. Gen. Laws Chapter 27-41](#) 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.
- C. Disclosure of prescription information to any other person(s) other than agents of properly licensed pharmacies pursuant to §§ 1.5.20(A) and (B) of this Part is prohibited.
- D. Disclosure of prescription information is permitted only to those directly involved in patient care consistent with [R.I. Gen. Laws Chapter 5-37.3](#), the "Healthcare Communications and Information Act" and other applicable federal and state laws.
- E. The disclosure of prescription information to researchers may only be authorized in accordance with federal policy for the protection of human subjects.

#### **1.5.21 Product Selection**

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.

#### **1.5.22 Poison Prevention Packaging**

- A. All drugs and substances cited in the federal poison prevention packaging act regulations shall be packaged and dispensed in accordance with said regulations.
- B. 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.

#### **1.5.23 Product Verification**

Verification by a pharmacist of a filled prescription must include a verification of the prescription label and product against the original or scanned prescription.

#### **1.5.24 Therapeutic Substitution**

- A. Therapeutic substitutions by pharmacists are permitted in situations requiring compliance with a formulary prepared by the pharmacy and therapeutics committee, and agreed to by the staff physicians of the facility:
  - 1. In a hospital, licensed pursuant to [R.I. Gen. Laws Chapter 23-17](#); or
  - 2. In a nursing facility, medical institution, or hospice care facility with contracted pharmaceutical services pursuant to § 1.6.1 of this Part and licensed under [R.I. Gen. Laws Chapter 23-17](#).

#### **1.5.25 Return to Stock of Undelivered Medications**

- A. Prescriptions that have not been picked up by or delivered to patients may be returned to stock. The pharmacist shall be responsible for the development of written policies and procedures that shall include, but not be limited to, the following:
  - 1. Drugs returned to stock have been maintained to assure their integrity
  - 2. No drug returned to stock have expirations dates that exceed twelve (12) months from the date of dispensing of original prescription

3. Patient information on prescription labels have been redacted to protect patient confidentiality; and
4. Given a manufacturer or FDA recall for a drug product, pharmacist shall assume products held in containers without lot numbers are included in the recall and proceed accordingly.

#### **1.5.26 General Requirements: Retail Pharmacies**

- A. Space. Any new pharmacy shall have an area of not less than two hundred and fifty (250) square feet.
- B. List of Drugs Posted. 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.
- C. 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.
- D. The requirements of this section do not apply to an order to dispense a drug for immediate administration to a hospital patient.

#### **1.5.27 General Requirements: Institutional Pharmacies**

- A. Physical Requirements. 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:
  1. Compounding and dispensing areas;



2. Physically separate parenteral solution additive area when solutions are compound in the pharmacy as described in § 1.7 of this Part;
3. Receiving and storage areas;
4. Packaging and repackaging areas;
5. Office space sufficient to allow for administrative functions without interference with the safe compounding and dispensing of medications and security of the pharmacy.

B. After-hours Pharmacy Services. 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:

1. A list of those individuals authorized by the pharmacist-in-charge to remove medications from the pharmacy-designated area.
2. 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.
3. 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.
4. Methods for performing a periodic review of those policies and procedures.

C. Medication Distribution and Control. 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.

1. Medication Orders

- a. 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.
- b. 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.
- c. All patient medication orders shall be contained in the patient's medical record.
- d. Medication orders shall contain:
  - (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 of drug prescribed;
  - (5) Directions for use;
  - (6) If a written prescription, prescribing practitioner's signature;
  - (7) If an electronically transmitted prescription, prescribing practitioner's electronic signature or type written signature; and
  - (8) Oral prescriptions shall be reduced promptly to writing by the pharmacist or intern and stored either electronically or in hard copy format.
- e. Medication orders for controlled substances must comply with all applicable federal and state laws.

- f. A valid medication order may be transmitted to a licensed pharmacy by the following means:
- (1) Delivery of the original, signed written medication order.
  - (2) Electronically by a nurse or authorized agent of the prescriber in a hospital, nursing facility, medical institutions, or hospice care facilities via a secure, interoperable information technology system that exchanges data accurately, effectively and in compliance with applicable laws.
  - (3) Verbally by an authorized prescriber or the prescriber's authorized designated agent. For the purposes of this section, nurses in nursing facilities shall be considered authorized designated agents.
  - (4) Via facsimile by a prescriber or the prescriber's authorized designated agent. If the order was initially received verbally, the transmitted document shall include the name of the prescriber, the name of the agent who received and transcribed the medication order.

2. Medication Storage and Security

- a. 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.
- b. 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.
- c. 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.
- d. 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.

- e. 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.
  - f. Sample medications shall be procured, stored, dispensed and/or donated to charitable institutions in accordance with the federal Food Drug and Cosmetic Act.
3. Labeling
- a. All drugs dispensed within a medical institution shall be labeled and identified up to the point of administration.
  - b. 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.
  - c. Labels for outpatient medications shall comply with [R.I. Gen. Laws § 21-31-15\(l\)\(l\)](#).
4. Records. 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.

5. Patient's personal medications may be administered to the patient in the event that the hospital does not stock the medication, and shall be arranged per hospital policy.
6. Emergency Outpatient Medications
  - a. The pharmacist-in-charge and medical staff shall establish policies and procedures for the dispensing of medications from the emergency room.
    - (1) Only a licensed prescriber shall be authorized to dispense medications to patients in an emergency situation.
    - (2) Emergency medications shall be labeled in accordance with [R.I. Gen. Laws § 21-31-15\(l\)\(l\)](#).
7. Monitoring Drug Therapy. The pharmacist shall review the appropriateness of the choice of medications for the patient and the patient's therapeutic regimen, pursuant to § 1.5.13(C) of this Part.
  - a. 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.
  - b. 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.
  - c. 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:

- (1) Adverse Drug Reactions (ADR): ADRs 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.
- (2) Medication Errors: Special consideration shall be given to measures to prevent medication administration errors associated with preparing parenteral and sterile products.
- (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.

## **1.6 Specialized Pharmacy Practice**

### **1.6.1 Pharmaceutical Services: Nursing, Hospice Care, and Correctional Facilities**

- A. Any licensed pharmacy or licensed pharmacist that provides pharmaceutical services by contract to a nursing, hospice, or correctional facility shall comply with the following requirements:
  1. Unless the nursing, hospice care, or correctional facility operates a licensed pharmacy and employs a director of pharmacy services, the nursing, hospice care, or correctional facility shall have a written agreement with a licensed resident or non-resident pharmacy to provide pharmaceutical services. The pharmacist-in-charge of the pharmacy shall supervise the entire spectrum of pharmaceutical services in the nursing, hospice care, or correctional facility.
    - a. If pharmaceutical services are provided by a non-resident pharmacy in a correctional facility, a state licensed pharmacist shall supervise those services.
  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.

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, hospice care, or correctional facility in compliance with federal and state laws. The pharmacist shall:
    - (1) Ensure that a valid medication or prescription order is received prior to the dispensing of any drug pursuant to § 1.5.27(C) of this Part.
    - (2) 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.
    - (3) Ensure that each cabinet, cart or other area utilized for the storage of drugs is locked and accessible only to authorized personnel.
    - (4) 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. The pharmacist shall:
    - (1) Report any irregularities to the attending physician, medical director, and director of nurses. Reports shall show evidence of review and response; and
    - (2) 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.

- f. For nursing facilities, policies and procedures governing patient drug regimen reviews shall include procedures for reporting irregularities, and documenting that such reviews have been performed. The contracted pharmacy consultant shall review all medication orders or prescription orders with information on the patient profiles. The consultant pharmacist shall review the drug and biological regimen of each resident monthly.
4. A unit dose drug dispensing system or automated storage and distribution device may be utilized for the dispensing of drugs to patients in a licensed hospital, nursing, hospice care, or correctional facility. Such systems or devices shall be utilized in accordance with this Part.
5. Secure Delivery Area: Filled prescriptions may be delivered to health care facilities by pharmacy employees or authorized agents. Prescription medication may be accepted for delivery from a pharmacy during normal business hours under the general supervision of a pharmacist. However, when the pharmacy is closed for business prescription medication may only be accepted for delivery or dropped off at the pharmacy if:
  - a. The prescriptions are placed in a secured delivery area equipped with adequate security, including an alarm or comparable monitoring system, to prevent unauthorized entry, theft and diversion;
  - b. The secured delivery area appropriately safeguards product integrity in accordance with USP-NF requirements;
  - c. The secured delivery area is on the same premises as the pharmacy that filled the prescriptions;
  - d. The pharmacy and the approved agent solely have access to the secure delivery area;
  - e. The pharmacy maintains records of all persons who have accessed the secured delivery area and each prescription stored and removed for delivery;
  - f. The pharmacy maintains written policies and procedures for secured delivery area storage and removal of prescriptions;
  - g. A pharmacist or a pharmacy, by means of its agent, may accept the return of the following drugs or devices to the secured delivery area:



- (1) Emergency kits;
- (2) Prescriptions that were unsuccessfully delivered by the pharmacy, a pharmacist, or its agent; and
- (3) Those deemed qualified for return pursuant to the requirements of this Part.

### **1.6.2 Pharmaceutical Services: Nuclear/Radiologic Pharmacies**

- A. The practice of nuclear/radiologic pharmacy is hereby recognized as a specialty of pharmacy practice, regulated by the Department and the Board. This section applies only to pharmacies which are preparing and distributing, or redistributing radioactive material, not simply handling such material.
- B. Policies and Procedures
  1. This Part shall not apply to a nuclear medicine department within a medical institution which is licensed by another agency.
  2. 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 [R23-1.3-RAD]."
  3. All pharmacies handling radiopharmaceuticals shall provide a radioactive storage and product decay area. Detailed floor plans shall be submitted to the Department and the Rhode Island Radiation Control Agency before approval of the license.
  4. Radiopharmaceuticals are to be dispensed only upon a prescription drug order, from a practitioner authorized to possess, use and administer radiopharmaceuticals.
  5. The permit to operate a nuclear pharmacy is conditional upon an approved Rhode Island Radiation Control Agency license. Copies of the Rhode Island Radiation Control Agency inspection reports shall be made available upon request for Board inspection.
- C. Personnel
  1. 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.

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

D. Physical Requirements

1. 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.

**1.6.3 Nonresident Pharmacies**

- A. Licensure: In order to ship, mail, or deliver prescription drugs and/or devices to a patient in Rhode Island, a non-resident pharmacy must be licensed by the Board and shall comply with all statutory requirements and this Part.
- B. Agent of record: Each nonresident pharmacy that ships, mails, or delivers prescription drugs and/or devices to a patient in Rhode Island shall designate a resident agent in Rhode Island 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 Rhode Island, shall be deemed an appointment by such nonresident pharmacy of the Rhode Island 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 Rhode Island. If any such pharmacy is not licensed in Rhode Island, service on the Rhode Island Secretary of State only shall be sufficient service.
- C. Conditions of Licensure: As conditions of licensure, the nonresident pharmacy must comply with the following:
  1. Maintain, at all times a valid unexpired license, permit or registration to operate the pharmacy in compliance with the laws of any other state in the United States or any province or territory of Canada in which it is located;

2. Provide a description of any final disciplinary action(s) by licensing boards in other states in the United States, United States territories or possessions, or any provinces or territories of Canada; as defined as discipline in those states, provinces, or territories and
  3. Provide all information requested by the Board.
- D. A pharmacy license will be issued to the owner who meets the requirements established pursuant to the Act and this Part. 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 September 30 of the current licensing cycle. 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 filed with the Department shall be deemed presumptive evidence of ownership of the pharmacy specified on the license.
- E. A license shall be issued to the owner and premise listed on the form and shall not be transferred. A license issued pursuant to this Part shall be the property of the Department 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.
- F. It shall be the duty of the owner to immediately notify the Department of any proposed change of location or ownership.
- G. 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.
- H. Reports and Complaints - Upon receipt of a complaint against the non-resident pharmacy, the Department shall forward the complaint to the other state (in the United States) or Canadian provincial or territorial boards where the non-resident pharmacy is licensed.

#### **1.6.4 Canadian Pharmacies**

- A. A Canadian pharmacy seeking licensure in Rhode Island shall, as a condition of licensure, comply at all times with the following requirements:
1. Only ship into Rhode Island products that have been approved by the United States Food and Drug Administration (FDA)
  2. 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

3. 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.
  - a. 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”.
  - b. Failure to maintain product liability insurance shall result in the revocation of the Canadian pharmacy’s license to do business in Rhode Island.
  - c. 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 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.
4. Not perform therapeutic substitution (i.e., substitution of medications within a class) without the approval of the prescriber;
5. 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.
6. Provide for the secure and confidential storage of confidential patient healthcare information with restricted access, including policies and procedures implemented to protect the integrity and confidentiality of patient healthcare information. Except as provided in [R.I. Gen. Laws Chapter 5-37.3](#) or as specifically provided by state and federal law, a patient's confidential healthcare 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 [R.I. Gen. Laws Chapter 5-37.3](#). Further, under no

circumstances shall a patient's confidential healthcare information be provided to a third party for marketing, fundraising, or research purposes. Any one who violates the provisions of [R.I. Gen. Laws Chapter 5-37.3](#) may be held liable for actual and exemplary damages and other penalties set forth in [R.I. Gen. Laws Chapter 5-37.3](#).

7. Provide and maintain all appropriate inventory controls in order to detect and document any theft, counterfeiting, or diversion of drugs or devices.
  8. 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 § 1.13 of this Part. Such procedure shall be adequate to deal with recalls and withdrawals due to:
    - a. 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;
    - b. Any volunteer action by the manufacturer to remove defective or potentially defective drugs or devices from the market; or
    - c. Any action undertaken to promote public health and safety by the replacing of existing merchandise with an improved product or new package design.
  9. Provide the patient with written documentation that indicates the country(ies) where the patient's medication(s) were manufactured.
  10. Ensure that all drug labels are written in English and meet all requirements set forth in Rhode Island law and this Part.
- B. A non-resident Canadian pharmacy shall not ship, mail, deliver, or otherwise dispense to a Rhode Island patient any of the following:
1. A controlled substance as defined in [R.I. Gen. Laws § 21-28-1.02\(7\)](#);
  2. A biological product as defined in this Part;
  3. An infused drug including peritoneal dialysis solution;
  4. An intravenously injected drug;
  5. A drug that is inhaled during surgery;
  6. A parenteral drug;

7. A drug manufactured through one or more biotechnology processes including:
    - a. A therapeutic DNA plasmid product;
    - b. A therapeutic synthetic peptide product of not more than forty (40) amino acids;
    - c. A monoclonal antibody product for in-vivo use; and
    - d. A therapeutic recombinant DNA-derived product.
  8. A drug required to be refrigerated at any time during manufacturing, packaging, processing, or holding;
  9. A photoreactive drug.
- C. 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.
- D. 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.

## **1.7 Compounding of Pharmaceuticals**

- A. General Requirements: Non-sterile and Sterile Compounding
1. A pharmacist/patient/prescriber relationship shall exist in order for a pharmacist to prepare compounds that are not commercially available, except as applied to Outsourcing Facilities.
  2. Pharmacists, interns, or Technician IIs engaged in compounding shall operate in conformity with all applicable state and federal laws and regulations regulating the practice of pharmacy.
  3. The requirements in § 1.7 of this Part shall not apply to the preparation of medications by licensed healthcare professionals in emergency situations for immediate administration to patients.

4. A practitioner's prescription shall be required for the compounding of all pharmaceuticals except as applied to Outsourcing Facilities.
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.
  - a. 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.
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.
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.
8. Pharmacists shall not offer pharmaceutically prepared compounded preparations to other state-licensed persons or commercial entities for subsequent resale, except as applied to Outsourcing Facilities.
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 determined

based upon current USP standards and documented testing or literature and professional judgment.

10. Bulk and active ingredients used in the preparation of compounded sterile products (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.
- B. General Requirements-- All Risk Levels: Sterile Compounding. The pharmacist-in-charge shall ensure the following activities are accomplished for all sterile compounding as outlined in current USP standards: 1. All CSPs shall be prepared in a manner that maintains sterility and minimizes the introduction of particulate matter;
- a. All CSPs shall be accurately identified, measured, diluted, and mixed; and are correctly purified, sterilized, packaged, sealed, labeled, stored, dispensed, and distributed as appropriate. This requirement includes maintaining appropriate cleanliness and providing labeling and supplementary instructions for the proper clinical administration of CSPs;
  - b. Through appropriate information sources, specific CSPs maintain their labeled strength according to USP guidelines until their beyond-use dates;
  - c. 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;
  - d. 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.



2. 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. In the absence of sterility testing, storage periods (before administration) shall not exceed current USP requirements.
3. 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. In the absence of sterility testing, storage periods (before administration) shall not exceed current USP requirements.
4. 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. In the absence of sterility testing, storage periods (before administration) shall not exceed current USP requirements.

C. Responsibilities of Compounding Personnel: Sterile Compounding

1. The pharmacist-in-charge shall be responsible for the overall operation of the compounding pharmacy.
  - a. The compounding pharmacist shall be responsible for assigning the appropriate risk level (low, medium, or high) to each individual product.
2. CSPs shall be prepared in a manner that maintains sterility and minimizes the introduction of particulate matter.
3. 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.
4. The pharmacist-in-charge shall ensure the following are achieved:
  - a. Compounding personnel shall have demonstrated competencies on file at least annually for low- and medium-risk level compounding

and semi-annually for high-risk level compounding, and shall be adequately educated and trained to perform and document duties in accordance with USP requirements to include, but not be limited to, the following:

- (1) Perform antiseptic hand cleansing and disinfection of non-sterile compounding surfaces;
  - (2) Select and appropriately don protective garments and equipment;
  - (3) Use laminar flow clean-air hoods, barrier isolators, biological safety cabinets and other contamination control devices;
  - (4) Identify, weigh, and measure ingredients; and
  - (5) Manipulate sterile products aseptically.
  - (6) Personnel who prepare CSPs shall be trained conscientiously and skillfully by expert personnel and through audio-video instructional sources, and professional publications in the theoretical principles and practical skills of aseptic manipulations and in achieving and maintaining ISO Class 5 environmental conditions before they begin to prepare CSPs.
- 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.

D. Facility Requirements: Sterile Compounding

1. 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 in accordance with current USP guidelines. 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.
2. 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 locate these in accordance with current USP requirements.
3. Pharmacies that compound cytotoxic preparations shall do so in accordance with current USP requirements..
4. 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 current USP required barrier shall identify the separation of the buffer or clean room area from the anteroom area.
5. Hand sanitizing and gowning activities shall occur in the anteroom area.

E. Environmental Monitoring: Sterile Compounding

1. 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.
2. 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).

3. The pharmacist-in-charge shall be responsible for reviewing and maintaining the certification records required in §§ 1.7(D)(5) and (E)(1) of this Part for a period of no less than two (2) years.
4. 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.
5. When above action level results for viable sampling are discovered, the pharmacy shall keep records of viable sampling reports and remediation actions and have such records readily retrievable for Board inspection for a period of two (2) years.
6. The pharmacy shall follow current USP requirements relating to cleaning and disinfecting of all affected sterile compounding environments and shall immediately conduct environmental monitoring testing once cleaning and disinfecting is complete.
7. The pharmacy shall not continue to conduct sterile compounding activities if above action level results are not corrected after complete cleaning and retesting in affected ISO 5 primary engineering controls and ISO 7 or lower classified rooms and shall arrange for practical alternatives to continue safe sterile compounding activities including but not limited to alternate locations for sterile compounding. Sterile compounding shall not continue when repeated above action level results occur in primary engine controls or ISO 7 or lower rooms.
8. The pharmacy shall ensure that patients receiving compounded sterile products shall not be exposed to risks of infection resulting from the commencement of sterile compounding activities in environments with above action level results for fungal or bacterial contamination in the air or on surfaces in ISO 7 or lower certified rooms or primary engineering controls.

F. Variance Procedure

1. Any compounding pharmacy that is temporarily unable to meet the requirements of USP or §§ 1.7(D)(1) through (5) or 1.7(E)(1) through (3) of this Part may apply to the Board for a variance.
2. 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.

### **1.7.1 Equipment: Sterile Compounding**

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.

### **1.7.2 Record Keeping Requirements: Sterile Compounding**

- A. All records required to be retained under this Part, 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.
- B. Records required under this Part may be retained either as the original records or as true copies, such as photocopies, microfilm, microfiche, electronic image or other accurate reproductions of the original records.

### **1.7.3 Radiopharmaceuticals As CSPs**

- A. Compounding of radiopharmaceuticals for positron emission tomography (PET) shall be performed in accordance with the current applicable USP guidance.
- B. For the purposes of § 1.7 of this Part, 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.

- C. 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.
- D. 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.
- E. Notwithstanding § 1.7(D)(1) of this Part, 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.

## **1.8 Automated Storage and Distribution Devices**

### **1.8.1 Automated Storage and Distribution Devices**

- A. Automated storage and distribution devices may be utilized by nursing facilities, medical institutions, assisted living, rehabilitation, hospitals, hospice care or correctional facilities who maintain contracts for pharmaceutical services with licensed pharmacies and which provide contractual pharmaceutical services to patients or licensed pharmacies, in the case of prescriptions available for delivery; and shall comply with the following provisions:
  - 1. Drugs stored in an automated storage and distribution device servicing nursing facilities, medical institutions, assisted living, rehabilitation centers, hospitals, hospice care or correctional facilities are part of the inventory of the pharmacy providing pharmaceutical services to that facility.
  - 2. 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 storage and distribution device 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.
- 3. 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.
- 4. 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 storage and distribution device shall be recorded electronically
  - b. Records shall be maintained by the pharmacy and shall be readily available to the Department. Such records shall include:
    - (1) Identity of system accessed;
    - (2) Identification of the individual accessing the system;
    - (3) Type of transaction;
    - (4) Name, strength, dosage form, and quantity of the drug accessed;
    - (5) Name of the patient for whom the drug was accessed;(6) Such additional information as the pharmacist-in-charge may deem necessary.
  - c. A record of medications filled/stocked into an automated storage and distribution device shall be maintained and shall include identification of the persons filling/stocking and checking for accuracy.
- B. All containers of medications stored in the automated storage and distribution device shall be packaged and labeled in accordance with federal and state laws and regulations.
- C. The pharmacy operating an automated storage and distribution device shall provide a mechanism for securing and accounting for medications removed from and subsequently returned to the automated storage and distribution device in accordance with existing regulations.
- D. The automated storage and distribution device shall provide a mechanism for storing and accounting for wasted medications or discarded medications in accordance with existing state and federal law.

- E. The pharmacist-in-charge shall establish policies and procedures that shall:
1. Assure that the automated storage and distribution device 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.
  2. 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.
  3. Authorize individuals and determine levels of access to automated storage and distribution devices and ensure security of the system.
  4. Assure that the filling/stocking of all medications in the system shall be accomplished by qualified personnel as defined by pharmacy policy and procedure.
  5. Implement an ongoing quality assurance program that monitors compliance to the established policies and procedures of the automated pharmacy system.
  6. 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.
  7. 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.
- F. The pharmacist-in-charge shall establish policies and procedures for the process of dispensing and/or administering medications pursuant to a medication order.

## **1.9 Provision of Medications by Non-Pharmacists**

- A. Samples
1. A practitioner, or his/her authorized agent, may supply prescription sample medications to his/her patients.
- B. Automated Dispensing Systems



1. 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.
2. 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.

C. Pharmaceutical Assistance Program (PAP) Medications

1. 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.
2. Delivery of the PAP medication to the patient may be delegated by the practitioner.

D. Stock Medications

1. In a hospital, nursing facility, medical institution, clinic, assisted living residence, or hospice care facility 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.

2. 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.

E. Oral Contraceptives

1. In entities receiving Title X funding for family planning services pursuant to 42 C.F.R. § 59(A)(1001) of the Public Health Services Act (42 U.S.C. 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.

F. Emergency Dispensing of Pharmaceuticals

1. Notwithstanding any other provision of this Part to the contrary, any practitioner authorized to deliver healthcare services at a facility licensed pursuant to the “Rules and Regulations for the Licensing of Organized Ambulatory Care Facilities” 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.
2. Notwithstanding any other provision of this Part to the contrary, any practitioner in a hospital emergency department who treats a patient for sexual assault, needle stick or other incident involving potential exposure to Human Immunodeficiency Virus (HIV) may provide the patient with up to the entire recommended course of medication for prophylaxis against potential HIV exposure. Any such dispensing of HIV prophylaxis medication shall be conducted in accordance with protocols established by the hospital’s institutional pharmacy, and shall include written instructions to be given to the patient regarding the use of the medication, which shall contain, as a minimum, the information required by §§ 1.9(G) (1)(a) through (f) of this Part.

G. Distribution of Remaining Doses of Prescriptions Drugs

1. A practitioner in a hospital emergency room, hospital clinic or ambulatory surgical center who administers to a patient a single dose of a medication from a multi-dose unit of use package may distribute any remaining doses of the prescription drug to the patient, provided the practitioner gives the patient sufficient instructions regarding the prescription drug, which instructions may include, but not be limited to:
  - a. The name and description of the drug;

- b. Intended use of the drug and expected action;
  - c. Special directions and precautions for preparation, administration, and use by the patient;
  - d. 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;
  - e. Proper storage; and
  - f. Action to be taken in the event of a missed dose.
2. For the purposes of § 1.9(G) of this Part, “sufficient instructions” shall include the receipt by the patient of appropriate written information such as a drug monograph.
3. A label shall be affixed to each dispensed medication that shall include:
  - a. The full name of the patient;
  - b. The name of the prescriber;
  - c. The name of the drug dispensed;
  - d. Quantity and strength of the drug dispensed;
  - e. Date of dispensing; and
  - f. Directions for use.
4. Medication dispensing and labeling shall be limited to prescribers only and may not be delegated to other personnel.
5. In a hospital setting, the pharmacist/pharmacy shall be responsible to determining which medicines can be dispensed from the Emergency Department and/or hospital clinic in this manner.
6. Under no circumstances shall any drug designated as a controlled substance pursuant to [R.I. Gen. Laws Chapter 21-28](#), be dispensed to a patient by a practitioner in a hospital emergency room or ambulatory surgery center.

## 1.10 Central Fill Operations

- A. A shared services pharmacy shall be licensed by the Board as either a resident or non-resident pharmacy.
- B. Shared services pharmacies shall meet no less than the following requirements:
  - 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 the Act and this Part;
  - 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;
  - 3. Maintain a mechanism for tracking the order during each step of the processing and filling functions performed at the pharmacy;
  - 4. Maintain a mechanism for placing a unique identifier, identifying on the prescription label the names of the delivery and central fill pharmacies involved in filling the order;
  - 5. Provide adequate security to protect the confidentiality and integrity of patient information, in accordance with all applicable federal and state laws and regulations;
  - 6. Ensure that all controlled medications not claimed at the delivery pharmacy are returned to the central fill pharmacy within thirty (30) days;
  - 7. Ensure that patient counseling is performed in accordance with all applicable regulations;
  - 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.
- C. 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 the Act and this Part while engaging in shared services.
- D. 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.

- E. A call center operation may perform the functions listed in §§ 1.10(B)(1) through (3), (5), (7) of this Part (as appropriate), and § 1.10(C) of this Part.
- F. 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 this Part.

## **1.11 Administration of Immunizations and Performance of Limited-Function Tests by Pharmacists**

### **1.11.1 Administration of Immunizations**

- A. An immunizing pharmacist shall follow a written protocol from a prescriber or have obtained a valid prescription for immunization administration to a patient.
- B. Qualifications
  - 1. A pharmacist may administer immunizations to persons who are at least eighteen (18) years of age, as provided in § 1.11 of this Part.
  - 2. A pharmacist may administer influenza vaccine to a person between the ages of nine (9) and eighteen (18) years old inclusive.
  - 3. A pharmacist may administer any immunization, pursuant to §§ 1.11(B)(1) and (2) of this Part, available in accordance with manufacturers' guidelines or established guidelines issued by the Centers for Disease Control and Prevention's (CDC) Advisory Committee on Immunization Practices (ACIP) or American Academy of Pediatrics (AAP) for administration to patients.
  - 4. A pharmacist who is administering immunizations to a student eighteen (18) years of age or older shall do so in accordance with the regulations for Immunization and Communicable Disease Testing in Preschool, School, Colleges or Universities (Part 30-05-3 of this Title).
  - 5. A pharmacist may administer immunizations if the pharmacist has completed either:
    - a. Immunization training within an accredited college of pharmacy program and possesses documentation of same; or

- b. A twenty (20) hour course of training recognized by the Board and in accordance with the following:
  - (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.
  - (2) The training course of study shall include, at a minimum, the following components:
    - (AA) Mechanisms of action of immunizations, contraindications, drug interactions, and monitoring after immunizations administration;
    - (BB) Immunization schedules;
    - (CC) Immunization screening questions, informed consent, recordkeeping, registries and state/federal reporting mechanisms;
    - (DD) Vaccine storage and handling in accordance with the guidelines of the U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, Advisory Committee on Immunization Practices Recommendations and Guidelines;
    - (EE) Biohazard waste disposal;
    - (FF) Sterile techniques;
    - (GG) Establishing protocols and standing orders;
    - (HH) Immunization coalitions and other community resources available;
    - (II) Identifying, managing, and responding to adverse events associated with immunization administration;
    - (JJ) Mechanism for reporting adverse events to the Vaccine Adverse Event Reporting System (VAERS);
    - (KK) Reimbursement procedures and immunization coverage by federal, state, and local entities;
    - (LL) Administration techniques.

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.
7. The pharmacist shall complete at least one (1) hour of continuing education in the area of immunizations each year.
8. A pharmacist shall not delegate the administration of immunizations to another person, except;
  - a. A licensed pharmacy intern who has completed a recognized immunization certificate training program and holds a current basic cardiopulmonary resuscitation (CPR) training certificate, shall carry out the same functions as an immunizing pharmacist pursuant to this Part and shall do so under the direct supervision and with the authorization of an immunizing pharmacist.
  - b. A technician II who has completed a recognized certificate training course on appropriate immunization administration technique and holds a current basic cardiopulmonary resuscitation (CPR) training certificate, shall be permitted to administer vaccinations under the direct supervision and with the authorization of an immunizing pharmacist when;
    - (1) The immunizing pharmacist has completed all of the requirements pursuant to § 1.11 of this Part prior to administration of the vaccination.
    - (2) The immunizing pharmacist is on the premises for post-immunization monitoring of the patient.

C. Immunization Administration Policies and Procedures: All immunizing pharmacists shall adhere to written policies and procedures that include no less than the following:

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.
2. A statement of the procedures for emergency situations.
3. A statement of record keeping and documentation procedures.
4. A statement related to the handling and disposal of used or contaminated equipment and supplies.

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.
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.
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.

D. Prescriber Protocols

1. Prior to administering immunizations to adults, pharmacists who have not obtained a valid prescription for immunization administration shall follow written protocols established between either a pharmacy or individually by a pharmacist and a protocol prescriber.
2. The protocol shall include, at a minimum:
  - a. A statement identifying the person authorized to prescribe drugs who has delegated the activity;
  - b. A statement identifying either the pharmacy or the individual pharmacist(s) authorized to administer immunizations and a copy of said pharmacist's documentation of completion of the recognized immunization training program;
  - c. A statement identifying the routes and types of immunizations that a pharmacist is authorized to administer (e.g., injectable and nasally administered).
3. The protocol shall be reviewed no less than every two (2) years by the prescriber and an immunizing pharmacist.
4. An immunizing pharmacist shall provide written notification of a patient's immunization to the primary care provider, if known, within seven (7) days.

E. Record-Keeping and Reporting

1. The 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 healthcare provider, as identified by the patient, if known;
  - e. Name or identifiable initials of the immunizing pharmacist, intern or technician II if applicable;
  - f. Publication date of the Vaccine Information Statement (VIS);
  - g. Date that the VIS was provided to the patient.
2. The immunization records shall be maintained for no less than two (2) years in accordance with all applicable state and federal statutes and regulations pertaining to confidentiality.
  3. Pharmacists authorized to administer influenza immunizations to individuals between the ages of nine (9) and eighteen (18) years, inclusive, shall be required to electronically report to the Department all immunizations administered within seven (7) days of administration in the format and for the populations required by the Department.

### **1.11.2 Limited-Function Tests**

- A. Performing a Limited-Function Test. A pharmacist may perform a limited-function test, as defined in this Part, only in accordance with instructions provided in the kit manufacturer's package insert, and in accordance with guidance published by the Centers for Disease Control and Prevention, Division of Laboratory Programs, Standards, and Services.
- B. Reporting Limited-Function Test Results.
  1. A report of a limited-function test shall contain, at a minimum, the following information:
    - a. Patient name;
    - b. Patient date of birth, sex and age;
    - c. Test performed;
    - d. Test results;

- e. Interpretation, according to instructions in the product insert;
  - f. Reference range of lab results;
  - g. Comments or qualifying statement, if applicable;
  - h. Date completed or reported; and
  - i. Name of pharmacist performing the test.
2. Upon receiving consent from the patient, a pharmacist performing a limited-function test shall report test results to the patient's primary care practitioner, if known, within a reasonable timeframe.
3. In the event that a patient with an abnormal test result does not have an existing relationship with a primary care practitioner, the pharmacist shall make efforts to refer the patient to a primary care practitioner practice, health center, or clinic.
4. The pharmacist shall inform the patient that the limited-function test results are intended for informational & educational purposes, rather than diagnostic purposes.
5. The requirements of this section shall not apply to tests performed through a collaborative practice agreement, as defined in this Part. C. Required Documents and Records. Each pharmacy where a pharmacist performs one or more limited-function tests shall maintain, at a minimum, the following:
  1. Name of test;
  2. Test procedures or site-specific work instructions;
  3. Records of testing materials used, test system and equipment function checks, and maintenance;
  4. Test results, including the results of any confirmatory or supplemental testing required by the kit manufacturer's package insert;
  5. Records of any test system failures, troubleshooting, and corrective action taken when problems are identified, including related communication with testing personnel;
  6. Unless a different interval is specified by applicable statute or regulation, records and documents required by this Part shall be maintained for three (3) years from the date of completion.

## 1.12 Pharmacy Technicians

### 1.12.1 Pharmacy Technicians

#### A. General Requirements

1. In accordance with R.I. Gen. Laws § [5-19.1-16](#), a Pharmacy Technician license will be issued to any individual who meets the requirements established under the Act and this Part.
2. No person shall perform the duties set forth in §§ 1.12.1(F)(1)(a) and (F)(2) of this Part unless such person is licensed as a Pharmacy Technician.
3. There shall be two (2) levels of licensure for a Pharmacy Technician: Pharmacy Technician I and Pharmacy Technician II.
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 as set forth in the Fee Structure for Licensing, Laboratory and Administrative Services Provided by the Department of Health (Part 10-05-2 of this Title).
5. All licenses issued to Pharmacy Technicians shall be valid for a period of one (1) year.
6. No individual may serve as a Pharmacy Technician without holding a valid Pharmacy Technician license from the Board.
7. A Pharmacy Technician shall wear a name tag that indicates the technician's name and the appropriate licensure designation.

#### B. Licensure by Endorsement

1. 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.

#### C. Exemption for High-School Career Exploration Programs

1. High school students working in pharmacies as part of school or community sponsored career exploration programs shall be exempt from

the requirements of § 1.12.1 of this Part and shall not be required to be licensed as Pharmacy Technicians.

D. Licensure of Pharmacy Technicians

1. 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:
  - a. Pharmacy technician I: A person licensed by the Board as a Pharmacy Technician I and who performs any pharmacy function or duties under the supervision of a pharmacist as defined in § 1.12.1(E)(1) of this Part.
  - b. Pharmacy technician II: A person licensed by the Board as a Pharmacy Technician II and who performs any pharmacy functions and duties under the supervision of a pharmacist as defined in § 1.12.1(E)(2) of this Part.

E. Qualifications

1. Pharmacy Technician I. An applicant for licensure as a Pharmacy Technician I must:
  - a. Have satisfied the Board that he or she is of good moral and professional character;
  - b. Be eighteen (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;
  - c. 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;
  - d. 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;
  - e. Be currently enrolled in or successfully completed a Board-approved Pharmacy Technician I training program defined in § 1.12.1(G) of this Part.

- f. Obtain an eProfile number from the national association of boards of pharmacy.
- 2. Pharmacy Technicians II. An applicant for licensure as a Pharmacy Technician II must:
  - a. Have satisfied the Board that he or she is of good moral and professional character;
  - b. Be eighteen (18) years of age or older;
  - c. Be a high-school graduate or the equivalent;
  - d. 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;
  - e. Have successfully passed a nationally-recognized certification examination acceptable to the Board, including, but not limited to, the Pharmacy Technician Certification Examination (PTCE) or the National Healthcare Association's "ExCPT" examination.
  - f. Obtain an eProfile number from the national association of boards of pharmacy.

F. Duties and Responsibilities

1. Pharmacy Technician I

- a. 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:

- (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.

- (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.

## 2. Pharmacy Technician II

- a. 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:
  - (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, transfer and receive new prescription information and changes to prescriptions from the prescriber or agent, except where otherwise prohibited by federal or state laws and regulations, provide immunizations, perform sterile and non-sterile compounding, and clarify prescription or medication orders.
- b. 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.
- c. 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.

## G. Board-approved Training Programs for Pharmacy Technician Is

1. Training programs for Pharmacy Technicians Is that are approved by the Board include:
  - a. 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:
      - (AA) 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:
        - (i) Orientation;
        - (ii) Job descriptions;
        - (iii) Communication techniques;
        - (iv) Laws and rules;
        - (v) Security and safety;
        - (vi) Prescription drugs;
        - (vii) Basic pharmaceutical nomenclature;
        - (viii) Dosage forms;
        - (ix) Drug orders;
        - (x) Prescribers;
        - (xi) Directions for use;
        - (xii) Commonly-used abbreviations and symbols;
        - (xiii) Number of dosage units;
        - (xiv) Strengths and systems of measurement;
        - (xv) Routes of administration;
        - (xvi) Frequency of administration;
        - (xvii) Interpreting directions for use;

- (xviii) Drug order preparation;
- (xix) Creating or updating patient medication records;
- (xx) Entering drug order information into the computer or typing the label in a manual system;
- (xxi) Selecting the correct stock bottle;
- (xxii) Accurately counting or pouring the appropriate quantity of drug product;
- (xxiii) Selecting the proper container;
- (xxiv) Affixing the prescription label;
- (xxv) Affixing auxiliary labels, if indicated; and
- (xxvi) Preparing the finished product for inspection and final check by pharmacists.

(BB) 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.

b. Any other training program as approved by the Board.

- 2. 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.

#### H. Application

- 1. 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 103

Providence, RI 02908

2. Said form shall be completed and signed by the applicant and accompanied by the non-refundable, non-returnable fee as set forth in the Fee Structure for Licensing, Laboratory and Administrative Services Provided by the Department of Health (Part 10-05-2 of this Title).
    - a. On the above application, the pharmacist-in-charge shall also attest to the following:
      - (1) That the applicant will receive documented on-the-job training with the duties of employment; and
      - (2) That the applicant will only be assigned duties for which competency has been demonstrated.
  3. 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.
- I. Issuance of License
1. Each license, unless sooner suspended or discontinued for due cause in accordance with § 1.15 of this Part shall expire annually on the thirtieth (30<sup>th</sup>) day of June.
  2. Said license shall be renewed annually.
  3. Every person licensed as a Pharmacy Technician in the State of Rhode Island who desires to renew his or her license shall file such renewal application annually with the Department on or before the thirtieth (30<sup>th</sup>) day of June. Said renewal shall be duly executed together with the renewal fee as set forth in the Fee Structure for Licensing, Laboratory and Administrative Services Provided by the Department of Health (Part 10-05-2 of this Title).
  4. Every person licensed as a Pharmacy Technician in this state must obtain an eProfile number from the national association of boards of pharmacy in order to renew their license.

5. A Pharmacy Technician II, licensed by national certification shall maintain his or her certification in order to renew said license.

J. Continuing Education Requirement

1. A Pharmacy Technician II who seeks annual licensure renewal shall be required to:
  - a. Satisfactorily complete at least ten (10) hours (1 continuing education unit) of continuing education courses, sponsored by a recognized provider between January 1st and December 31st of each year.
  - b. Maintain documentation of all required continuing education for a period of at least two (2) years from the date the training was completed.
2. A Pharmacy Technician I and II license shall be transferable to different practice locations within the State of Rhode Island.

### **1.13 Collaborative Pharmacy Practice**

- A. A pharmacist may engage in collaborative pharmacy practice pursuant to a collaborative practice agreement.
- B. 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.
- C. Informed Consent Procedures

1. The agreement shall specify the procedures for obtaining an informed consent from each patient involved in services pursuant to a collaborative practice agreement.
2. Informed consent shall include patients' consent to release all minimum necessary medical information between the parties.
3. Informed consent shall include provision to allow the patient to withdraw from collaborative practice at any time.

D. Qualification of Pharmacist and Participating Practitioners

1. 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 § 1.13(L) of this Part.
2. Role of any employed healthcare professional with prescriptive privileges participating in the collaborative practice shall include, but not be limited to, initiating, adjusting, monitoring, or discontinuing drug therapy.

E. Scope of Conditions or Diseases to be Managed

1. A detailed description of the types of diseases, drugs or drug categories involved, drug therapies management allowed in each case;
2. Agreements may only be used for conditions or diseases with generally accepted standards of care;
3. The scope of the agreement shall not include research, clinical or investigational trials;
4. 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.

F. Practice Protocols

1. The practice protocol shall contain a statement by the physician that describes the activities a pharmacist is authorized to engage in, including:
  - a. The procedures, decision criteria, or plan a pharmacist shall follow when providing drug therapy management;
  - b. The procedures a pharmacist shall follow for documentation; and

- c. The procedures a pharmacist shall follow for reporting activities and results to the physician or the prescribing healthcare provider caring for the patient.
  2. A provision that allows the physician to override a collaborative practice decision made by the pharmacist when appropriate
  3. A provision for regular review and revision to reflect changes in standards of care
  4. A provision that allows either party to cancel the agreement by written notification
  5. An effective date.
- G. Risk Management Activities
  1. The agreement shall provide for a plan for measuring and ensuring quality.
  2. The agreement shall include proof that liability insurance is maintained by all parties.
- H. Outcomes Measurements
  1. The agreement shall include a method to monitor compliance and clinical outcomes.
    - a. A pharmacist shall submit a copy of the agreement to the Board prior to the commencement of collaborative pharmacy practice.
- I. Amendments to the agreement must be documented, signed, and dated.
- J. A pharmacist shall initiate drug therapy management for a particular patient.
- K. A pharmacist shall have adequate access to the patient's history, vital signs including pulse, height, weight, temperature, blood pressure, and respiration, disease states, drug therapy and laboratory and procedure results.
- L. A pharmacist with advanced training and experience relevant to the scope of collaborative practice shall be a licensed pharmacist in the State of Rhode Island with a bachelor of science degree in pharmacy and post-graduate educational training or a doctor of pharmacy degree. Such training shall include, but not be limited to, residency training, board certification, certification from an accredited professional organization, educational institution, or any other continuing education provider approved by the Department relevant to the proposed scope

of the collaborative practice agreement. 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 Accreditation Council for 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.
- M. Any pharmacist participating in a collaborative pharmacy practice agreement shall earn at least five (5) additional contact hours or 0.5 continuing education units of board-approved continuing education that addresses areas of practice generally related to collaborative practice agreements 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
- N. 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 §§ 1.13(L)(2) or (3) of this Part, 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.
- O. Recordkeeping Requirements
1. Signatories to an agreement shall keep a copy of the agreement on file at their primary place(s) of practice.
  2. An order for a specific patient from the prescribing physician or the prescribing healthcare 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.

3. 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.

P. Administration of Immunizations

1. Nothing in this section shall prohibit a pharmacist from administering immunizations, if done so in accordance with the requirements of § 1.11 of this Part.

Q. Hospital Pharmacists

1. Nothing in [R.I. Gen. Laws 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.

## **1.14 Wholesalers Distributors, and Manufacturers**

### **1.14.1 Licensure Requirements**

A. General Licensure Requirements.

1. Pursuant to the provisions of R.I. Gen. Laws §§ 5-19.1-12 and 5-19.1-13:
  - a. If Rhode Island is the state in which a prescription drug is distributed or is the state from which or into which a prescription drug is distributed by a wholesale distributor, that wholesale distributor may not distribute in or into or out of Rhode Island unless each facility of such wholesale distributor is licensed in Rhode Island.
  - b. If Rhode Island is the state into which a prescription drug is shipped by a wholesale distributor, that wholesale distributor shall also be licensed as a wholesale distributor by the state from which that wholesale distributor ships.
  - c. If Rhode Island is the state in which a prescription drug is manufactured or is the state from which or into which a prescription drug of a manufacturer is shipped, this prescription drug may not be

manufactured in and/or shipped into or out of Rhode Island unless each facility of such manufacturer is licensed in Rhode Island.

2. Federal Licensure
  - a. A manufacturer shall also be licensed as a manufacturer by the Secretary of the U.S. Department of Health and Human Services, Food and Drug Administration;
3. The Board shall have the right to deny a license to an applicant if it determines that the granting of such a license would not be consistent with the public health and safety.
4. A wholesaler distributor or manufacturer license is only valid for the name, ownership and location listed on the license. Changes of name, ownership or location shall require a new license.
5. When wholesale distribution or manufacturing facility operations are conducted at more than one location, each location shall be licensed by the Board.
6. A wholesale distributor or manufacturer shall not operate from a place of residence.
7. A wholesale distributing or manufacturing facility shall be located apart and separate from any retail pharmacy licensed by the Board.
8. Changes in any information required for a wholesale distributor or manufacturer must be reported to the Board, in writing, within ten (10) days (e.g. facility manager, designated representative, telephone number, etc.).
9. Each wholesale distributor or manufacturer facility must publicly display all licenses and have readily available the most recent state and/or federal inspection reports.
10. Each wholesale distributor or manufacturer shall ship only to the address listed on the purchaser's license
11. Compliance with Federal, State and Local Laws. Each wholesale distributor or manufacturer shall operate in compliance with applicable federal, state and local laws and regulations.
  - a. Each wholesale distributor or manufacturer shall permit the Department, 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. Each wholesale distributor or manufacturer that deals in controlled substances shall register with the Department, and with the Drug Enforcement Administration (DEA), and shall comply with all applicable state, local and DEA regulations.

B. Wholesale Distributor Licensure

- 1. The Department and Board requires the following from each wholesale drug distributor as part of the initial licensing procedure, and as part of any renewal of such license:
  - a. The applicant's full name, full business address, and telephone number;
  - b. All trade or business names used by the applicant;
  - c. The type of ownership (e.g., individual, partnership, limited liability company or corporation);
  - d. Name(s) of the owner(s) of the applicant including:
    - (1) If a person; the name, address, social security number and date of birth;
    - (2) If other than a person; the name, address, and social security number and date of birth of each partner, limited liability company member, or corporate officer and corporate director, and the federal employer identification number [FEIN];
    - (3) If a corporation, the state of incorporation; and
    - (4) If a publicly traded corporation, the information in § 1.14.1(B)(1)(d) of this Part is not required for corporate officers and corporate directors.
  - e. Names of designated representatives and facility managers of the applicant, their Social Security numbers and date of birth;



- f. Proof of licensure by the U.S. Secretary of Health and Human Services, Food and Drug Administration and, if applicable, by the state where the applicant is located (home state);
- g. Upon the Board's written request, a list of all manufacturers, wholesale distributors, and dispensers for whom the manufacturer provides services at such facility;
- h. Any other information the Board deems necessary to protect the public health and safety; and
- i. The initial or renewal licensure fee as set forth in the Fee Structure for Licensing, Laboratory and Administrative Services Provided by the Department of Health (Part 10-05-2 of this Title).

C. Criteria for Renewal of Licensure for Wholesale Distributors

- 1. The Board shall consider, at a minimum, the following factors in determining the eligibility for, and renewal of, licensure of wholesale distributors:
  - a. Engaging in any unprofessional conduct as defined in § 1.15 of this Part;
  - b. Any finding by a law enforcement agency or regulatory agency that the applicant or any of its owners have violated any federal, state, or local laws or foreign laws;
  - c. Suspension, revocation or any other sanction against a license currently or previously held by the applicant or any of its owners for violations of state or federal laws;
  - d. Any finding that the applicant or any of its owners are guilty of or pleaded guilty or nolo contendere to violating federal, state, or local criminal laws;
  - e. The furnishing by the applicant of false or fraudulent material in any application;
  - f. Failure to maintain and/or make available to the Board or to federal, state, or local law enforcement officials those records required to be maintained by wholesale distributors;
  - g. Any licensee who has no record of wholesaler distributions during routine inspection may have its subsequent renewal application

referred to the Board for review and possible approval or disapproval, and such review may require the licensee to appear before the Board; and

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

#### D. Manufacturer Licensure

1. The Board requires the following from each manufacturer as part of the initial licensing procedure, and as part of any renewal of such license:
  - a. The applicant's full name, full business address, and telephone number;
  - b. All trade or business names used by the applicant;
  - c. The type of ownership (e.g., individual, partnership, limited liability company or corporation);
  - d. Name(s) of the owner(s) of the applicant including:
    - (1) If a person; the name, address, social security number and date of birth;
    - (2) If other than a person; the name, address, and social security number and date of birth of each partner, limited liability company member, or corporate officer and corporate director, and the federal employer identification number [FEIN];
    - (3) If a corporation, the state of incorporation; and
    - (4) If a publicly traded corporation, the information in § 1.14.1(D)(1)(d) is not required for corporate officers and corporate directors.
  - e. Names of designated representatives and facility managers of the applicant, their Social Security numbers and date of birth;
  - f. Proof of licensure by the U.S. Secretary of Health and Human Services, Food and Drug Administration and, if applicable, by the state where the applicant is located (home state);

- g. Upon the Board's written request, a list of all manufacturers, wholesale distributors and dispensers for whom the manufacturer provides services at such facility;
- h. Any other information the Board deems necessary to protect the public health and safety; and
- i. The initial or renewal licensure fee as set forth in the Fee Structure for Licensing, Laboratory and Administrative Services Provided by the Department of Health (Part 10-05-2 of this Title).

E. Criteria for Renewal of Licensure for Manufacturers

- 1. The Board shall consider, at a minimum, the following factors in determining the eligibility for, and renewal of, licensure of manufacturers:
  - a. Engaging in any unprofessional conduct as defined in § 1.15 of this Part;
  - b. Any finding by a law enforcement agency or regulatory agency that the applicant or any of its owners have violated any federal, state, or local laws or foreign laws;
  - c. Suspension, revocation or any other sanction against a license currently or previously held by the applicant or any of its owners for violations of state or federal laws;
  - d. Any finding that the applicant or any of its owners are guilty of or pleaded guilty or nolo contendere to violating federal, state, or local criminal laws;
  - e. The furnishing by the applicant of false or fraudulent material in any application;
  - f. Failure to maintain and/or make available to the Board or to federal, state, or local law enforcement officials those records required to be maintained by manufacturers;
  - g. Any licensee who has no record of manufacturing during routine inspection may have its subsequent renewal application referred to the Board for review and possible approval or disapproval, and such review may require the licensee to appear before the Board; and

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

#### **1.14.2 Operational Procedures**

- A. Diversion Detection and Prevention Plan. Each wholesale distributor or manufacturer shall have and follow a diversion detection and prevention plan that includes all prescription drugs.
- B. Written Policies and Procedures. Each wholesale drug distributor or manufacturer 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. Each wholesale distributor or manufacturer shall include, as a minimum, the following items in their written policies and procedures:
  - 1. 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.
  - 2. 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:
    - a. 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;
    - b. Any voluntary action by the manufacturer to remove defective or potentially defective drugs from the market, or
    - c. Any action undertaken to promote public health and safety by replacing of existing merchandise with an improved product or new package design.
  - 3. A procedure to ensure that each wholesale distributor or manufacturer prepares for, protects against, and handles 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.
  - 4. 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 (2) years after disposition of the outdated drugs.

C. Personnel. A wholesale distributor or manufacturer shall:

1. Establish and maintain for Board inspection a list of each partner, limited liability company member or corporate officer and corporate director, as well as designated representatives and facility managers, including a description of their duties and a summary of their qualifications;
2. Designate, in writing, a person to serve as the designated facility manager of the wholesale distributor or manufacturer (as appropriate) for each location licensed;
3. Not have as an owner, designated representative, facility manager, or supervising pharmacist anyone:
  - a. Convicted of any felony for conduct relating to compounding prescription drugs, any felony for violation of 21 U.S.C. §§ 331(i) or (k) or any felony for violation of 18 U.S.C. § 1365 relating to product tampering; or
  - b. Who has violated federal or state requirements for licensure that presents a threat of serious adverse health consequences or death to humans.
4. Employ adequate personnel with the education and experience necessary to safely and lawfully engage in acting as a wholesale distributor or manufacturer as applicable.

D. Facilities. Each wholesale distributor or manufacturer 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.

E. Security.

1. Each wholesale distributor or manufacturer shall be secure from unauthorized entry:
  - a. Access from outside the premises shall be kept to a minimum and be well-controlled;
  - b. The outside perimeter of the premises shall be well-lighted;
  - c. Entry into areas where prescription drugs are held shall be limited to authorized personnel.
2. Each wholesale distributor or manufacturer shall be equipped with an alarm system to detect entry after hours.
3. Each wholesale distributor or manufacturer 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.

F. 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 § 1.14.2(l) of this Part shall be followed for all stored drugs; and
4. Storage shall not include temporary or incidental possession for the purpose of delivery and/or shipment of prescription drugs.

G. Examination of Materials.

1. 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.
2. 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.
3. The record keeping requirements in § 1.14.2(l) of this Part shall be followed for all incoming and outgoing prescription drugs.

H. Salvaging, Reprocessing, Returned, Damaged and Outdated Prescription Drugs.

1. 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.
2. 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.
3. 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.
4. The record keeping requirements in § 1.14.2(l) of this Part shall be followed for all outdated, damaged, deteriorated, misbranded, or adulterated prescription drugs.
5. Salvaging and Reprocessing. Each wholesale distributor or manufacturer 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 21 C.F.R. Parts 207, 210(d), 211.

I. Record keeping.

1. Each wholesale distributor or manufacturer 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:
  - a. 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;
  - b. The identity and quantity of the drugs received and distributed or disposed of, and
  - c. The dates of receipt and distribution or other disposition of the drugs.
2. Inventories and records shall be made available for inspection and photocopying by any authorized official of any governmental agency charged with enforcement of this Part for a period of two (2) years following disposition of the drugs.
3. Records described in § 1.14.2(I) of this Part 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 this Part.

**1.15** ————COVID-19 Emergency Response Related to Pharmacy Practices and Procedures

- A. Notwithstanding any other provision of this Part to the contrary, the language of provisions elsewhere in this Part, during the pendency of the state of emergency declared by the governor for the State of Rhode Island on March 9, 2020 due to the dangers to health and life posed by COVID-19 virus in Rhode Island, the practice of pharmacy shall include and permit the practice of pharmacy will permit the following practices and procedures:-



1. Notwithstanding the provisions of § 1.4.24 of this Part, or any other provision of this Part to the contrary, Any pharmacist is authorized to dispense an emergency supply of prescribed medication of up to ninety (90) days for continuation of therapy. This provision shall not include apply to controlled substances.
2. Notwithstanding the provisions of § 1.5.18 of this Part, or any other provision of this Part to the contrary, Any pharmacist is authorized to auto-substitute a prescribed medication product without having to adhere to a dispense--as--written directive.
3. Notwithstanding the provisions of § 1.4.9 of this Part, or any other provision of this Part to the contrary, Any intern holding a valid, active intern license license as an intern from another state, as verified by the hiring pharmacy, will be permitted to work in any pharmacies located in Rhode Island upon verification of his or her out of state intern license by the hiring pharmacy.
4. Any immunizing pharmacist, immunizing intern, or immunizing technician II currently holding a basic cardiopulmonary resuscitation (CPR) training certificate as of March 1, 2020, shall be deemed to have a current CPR training certificate, as required in § 1.11.1 of this Part, notwithstanding the stated expiration date of the certification. Any pharmacy is permitted to waive the CPR certification requirements for immunizing pharmacists, interns and pharmacy technicians II set for in § 1.11.1(B)(6) and (8) of this Part.
5. Any pharmacy is authorized to permit pharmacists to work remotely, as operationally feasible and in accordance with applicable state and federal law, to conduct prescription data entry, prescription verification, clinical pharmacy, and other functions that are normally performed in a pharmacy- and are operationally feasible to be performed remotely.
6. Any pharmacy is authorized to permit pharmacy technicians to work remotely, as operationally feasible and in accordance with applicable state and federal law, as necessary to conduct order entry and other functions that are normally performed in a pharmacy.
7. Any pharmacy is authorized to suspend all identification/signature requirements in pharmacies to help prevent the spread of infection.
8. Any pharmacy is authorized to temporarily operate in an area not designated by permit subject to approval by the Director.

7. Notwithstanding the provisions of § 1.5.15 of this Part, or any other provision of this Part to the contrary, Any pharmacy is permitted to engage in unlimited transfers of prescribed medications between pharmacies prescriptions may transferred for any purposes between pharmacies and may be transferred an unlimited number of times.
8. Notwithstanding the provisions of § 1.5.27(C)(5) of this Part, or any other provision of this Part to the contrary, a hospital may refuse to store its patients' personal medications in its pharmacy and may direct that personal medications be stored securely in the patients' rooms or returned to the patients' homes. Patient personal Any hospital licensed under R.I. Gen. Laws § 23-17-4 is permitted to direct that a patient's home medications be brought back to the patient's home or stored in the patient's room in a secure manner if the patient's medications cannot be brought home. These home medications can also may be administered to the patient during thea hospital stay, if necessary.
9. Notwithstanding the provisions of § 1.7 of this Part, or any other provision of this Part to the contrary, Any pharmacy is compounding personnel are permitted to adhere to current recommendations from nationally of the Centers for Disease Control and Prevention (CDC) or other nationally recognized health care organizations public health agency for use of personal protective equipment (PPE) by personnel during non-hazardous sterile compounding for the purpose of conserving PPE resources.
10. Any infusion pharmacy licensed under R.I. Gen. Laws § 5-19-1 is Notwithstanding the provisions of § 1.7(E)(2) of this Part, or any other provision of this Part to the contrary, pharmacies that engage in the pharmaceutical preparation of CSPs are permitted to extend the period for certification inspections beyond six (6) months, clean room certification deadlines subject to approval by the Director.
11. Notwithstanding the provisions of § 1.6.1(3) of this Part, which sets forth certain responsibilities of licensed pharmacies and pharmacists providing pharmaceutical services by contract to nursing, hospice, or correctional facilities to be set forth in written policies and procedures, the responsibilities referenced in § 1.6.1(3)(e) and (f) of this Part are suspended Any nursing, hospice care, or correctional facility is permitted to waive all required on site actions for long term care consultation by pharmacists, other than clinical consultations required in § 1.6.1 of this Part.
12. Notwithstanding the provisions of § 1.5.3-(B) of this Part, in the event that ana hospital establishes an alternate hospital site (AHS) is established,

~~where outpatient medications will need to be dispensed to patients upon their discharge from the AHS, an extension of the license of any retail pharmacy license shall be owned by the hospital shall be extended to the AHS. The retail pharmacy license extension of the retail license shall become null and void terminate automatically upon closure of the AHS, or the conclusion of the state of emergency declared on March 9, 2020, whichever happens first. In accordance with § 1.5.3 of this Part, the retail pharmacy license extension shall not be transferable to any other site.~~

~~15. Notwithstanding the provisions of § 1.5.3 (B)(1) of this Part, a pharmacist may be a pharmacist in charge of more than one pharmacy at the same time during the establishment of an AHS during the COVID-19 public health emergency.~~

## **1.16** Violations, Complaints, and Sanctions

### **1.165.1** Grounds for Denial or Discontinuation of License

- A. The Board, with the approval of the Director, may deny, suspend, revoke or otherwise discipline the licensee upon proof of the conduct described in R.I. Gen. Laws § 5-19.1-21:
1. 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:
    - a. 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
    - b. More than forty percent (40%) of the prescription filled by the subject pharmacy or drug store within any three (3) month period were issued by practitioners with any ownership interest in the subject pharmacy, drug store, or licensee.
      - (1) 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.
- B. Penalties for unlawful practices are pursuant to R.I. Gen. Laws § [5-19.1-23](#).

## **1.165.2 Violations and Sanctions**

- A. 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 R.I. Gen. Laws § [5-19.1-27](#).
- B. 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" (21, U.S.C. § 84(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.
- C. A licensed pharmacist may decline to dispense a drug or device, pursuant to an order or prescription, on ethical, moral, or religious grounds only if the licensed pharmacist has previously notified the pharmacy owner, in writing, of the device(s), drug or class of drugs to which he or she objects, and the pharmacy owner can, without creating undue hardship, provide a reasonable accommodation of the licensed pharmacist's objection. The licensed pharmacy owner shall establish protocols to ensure that the patient has timely access to the prescribed drug or device despite the licensed pharmacist's refusal to dispense the prescription or order. For the purpose of this section, "reasonable accommodation" shall mean the pharmacy owner has demonstrated that they explored any available reasonable alternative means of accommodating the licensed pharmacist's ethical, moral, or religious objections, including the possibilities of excusing the licensed pharmacist from those duties or permitting those duties to be performed by another person, but is unable to reasonably accommodate the ethical, moral, or religious objections without undue hardship on the conduct of the pharmacy owner's business.

## **1.165.3 Complaints**

- A. Any person, pharmacist, business entity or public officer, including a licensee, may submit a complaint to the Board against any licensee or person believed to be engaged in activity which violates the Act or this Part.
- B. All complaints must be submitted to the Department by the complainant or an authorized representative of the complainant. A complaint must state the grounds for the complaint, including a statement of facts or circumstances upon which the complaining party relies for the charge. A complaint shall state the name, address, and telephone number or email address of the complainant or

representative to be contacted by the Board or its investigative designees for purposes of investigation or issuance of notice.

- C. Within twenty-one (21) calendar days of receipt of notice that a complaint has been filed, the licensee or person against whom the complaint has been filed must respond in writing to the Board and the Department.

#### **1.165.4 Variance Procedure**

- A. 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.
  - 1. Variances may be granted only for the provisions of §§ 1.6 through 1.11 of this Part and shall be for a limited period of time, generally not to exceed one (1) year.
- B. 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.
  - 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.
- C. At a hearing held in furtherance of an appeal from a denial for a variance in accordance with § 1.6.3(B)(1) of this Part, the applicant shall bear the burden of proof 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.

#### **1.165.5 Rules Governing Practices and Procedures**

Upon due notice in accordance with [R.I. Gen. Laws Chapter 42-35](#) (the Administrative Procedures Act), all hearings and reviews required under the provisions of the Act shall be held in accordance with the rules and regulations pertaining to Practices and Procedures Before the Rhode Island Department of Health (Part 10-05-4 of this Title).