

Note: The Effective Date of these Rules is August 15, 2003.

**BOARD OF PHARMACY
ADMINISTRATIVE RULES**

Adopted: August 15, 2003

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PART A. GENERAL INFORMATION

Section 1. The Board's Purpose

- 1.1 The Vermont Board of Pharmacy ("the Board") has been created and given powers by Vermont law, 26 V.S.A. Chapter 36. Its purpose is to protect the health, safety, and welfare of the public. The Board does this by setting standards for examining and licensing qualified applicants, by inspecting and licensing drug outlets, by defining standards and proper procedures for record keeping, and the safekeeping and proper dispensing of pharmaceuticals and legend drugs, and by regulating licensees and their practices.
- 1.2 The Board may not make any rule that limits the number of licensees or pharmacies in the state; nor may the Board require that nonprescription drugs be sold only by a pharmacist or under a pharmacist's supervision.

Section 2. Business Address

- 2.1 The Board is located at the Office of the Secretary of State, Office of Professional Regulation, Redstone Building, 26 Terrace Street, Montpelier, Vermont ("the Office"). The Board's mailing address is 109 State Street, Drawer 09, Montpelier, Vermont 05609-1106. The Office telephone numbers are 1-802-828-2363 or 1-802-828-2875. Copies of these rules and additional information about the Board may be obtained by contacting the Office or by accessing the Board's Web site at <http://www.vt.professionals.org>

Section 3. Board Members And Officers

- 3.1 The Board is composed of five licensed pharmacists, each with at least five years experience as a pharmacist in Vermont, and two members of the public. Public members of the Board shall have no financial interest in the field of Pharmacy, as defined in 26 V.S.A. §2022(13). Each member has been appointed by the Governor. The Board elects a chair, a secretary, and other officers from among its members. A list of the names and addresses of Board members and officers may be obtained from the Office.

Section 4. Hearings

- 4.1 The Board conducts hearings in accordance with the Administrative Rules for the Office of Professional Regulation and the provisions of the Vermont Administrative Procedure Act for contested cases, 3 V.S.A. §§ 801-816.

Section 5. Regular, Special, And Emergency Meetings

- 5.1 The Board holds at least two regular meetings a year. The chair or a majority of members may call a special or emergency meeting. A majority of members constitute a quorum for all meetings. Contact the Office for the date, time and location of scheduled meetings.

Section 6. Laws That Govern The Board

- 6.1 The Board is governed by the law in 26 V.S.A. Chapter 36, that establishes its responsibilities for setting standards, issuing licenses, and regulating the profession. In addition, the Board must comply with several other statutes, such as the "Law of Professional Regulation," (3 V.S.A. §§121-131), the "Administrative Procedure Act" (3 V.S.A. §§ 801-849), the "Right to Know Law" (1 V.S.A. §§ 311-314), and the "Access to Public Records Law" (1 V.S.A. §§ 315-320). These laws establish rights for applicants, licensees, and the public.
- 6.2 Most town clerks and libraries have copies of the Vermont Statutes Annotated, which contain the complete text of these laws. The Vermont Statutes Annotated may also be accessed through the Internet at <http://www.leg.state.vt.us>.
- 6.3 The profession of pharmacy is governed by other state and federal laws including the Generic Drug Law; Food, Drug, and Cosmetic Acts; the Health Insurance Portability and Accountability Act of 1996 (HIPAA); laws and regulations governing the use of alcohol; Federal Controlled Substance Act, 21 U.S.C. §801 et seq.; Vermont Regulated Drug Act, 18 V.S.A. §§ 4201-4248, and postal regulations to be followed when shipping legend drugs.

Section 7. Rules Of The Board

- 7.1 The Board is authorized to make these Rules under 26 V.S.A. §2032. These Rules govern Board proceedings and have the effect of law. The Board reviews these rules periodically and revises them as needed.

Section 8. Abbreviations And Definitions

- 8.1 **Abbreviations.** As used in these rules:
- 8.1.1 ACPE: American Council on Pharmaceutical Education
- 8.1.2 CCAPP: Canadian Council for Accreditation of Pharmacy Programs
- 8.1.3 DEA: Drug Enforcement Administration.
- 8.1.4 FDA: Food and Drug Administration.
- 8.1.5 MPJE: Multistate Pharmacy Jurisprudence Examination.

8.1.6 NABP: National Association of Boards of Pharmacy.

8.1.7 NAPLEX: North American Pharmacy Licensure Examination.

8.2 Definitions. As used in these rules:

8.2.1 "Administer" means the direct application of a Drug to the body of a patient or research subject by injection, inhalation, ingestion, or any other means.

8.2.2 "Automated Pharmacy Systems" include, but are not limited to, mechanical systems which perform operations or activities, other than Compounding or Administration, relative to the storage, packaging, Dispensing, or Distribution of medications, and which collect, control, and maintain all transaction information.

8.2.3 "Beyond-Use Date" means a date determined by a Pharmacist and placed on a prescription label at the time of Dispensing that is intended to indicate to the patient or care giver a time beyond which the contents of the prescription are not recommended to be used.

8.2.4 "Board of Pharmacy" or "Board" means the Vermont Board of Pharmacy.

8.2.5 "Collaborative Pharmacy Practice" is that Practice of Pharmacy whereby one or more Pharmacists have jointly agreed, on a voluntary basis, to work in conjunction with one or more Practitioners under protocol whereby the Pharmacist may perform certain patient care functions authorized by the Practitioner or Practitioners under certain specified conditions and/or limitations.

8.2.6 "Compounding" means the preparation, mixing, assembling, packaging, or Labeling of a Drug or Device (I) as the result of a Practitioner's Prescription Drug Order or initiative based on the Practitioner/patient/Pharmacist relationship in the course of professional practice, or (ii) for the purpose of, or as an incident to, research, teaching, or chemical analysis and not for sale or Dispensing. Compounding also includes the preparation of Drugs or Devices in anticipation of Prescription Drug Orders based on routine, regularly observed prescribing patterns.

8.2.7 "Confidential Information" means information accessed, maintained by, or transmitted to the Pharmacist in the patient's records or which is communicated to the patient as part of Patient Counseling, which is privileged and may be released only to the patient or, as the patient directs, to those Practitioners, other authorized health care professionals, and other Pharmacists where, in the Pharmacist's professional judgment, such release is necessary to protect the patient's health and well being; and to such other Persons or governmental agencies authorized or required by law to receive such Confidential Information, regardless of whether such information is in the form of paper, preserved on microfilm, or is stored on electronic media.

8.2.8 "Deliver" or "Delivery" means the actual, constructive, or attempted transfer of a Drug or Device from one Person to another, whether or not for a consideration.

8.2.9 "Device" means an instrument, apparatus, implement, machine, contrivance, implant, or other similar or related article, including any component part or accessory, which is required under Federal law to bear the label, "Caution: Federal or State law requires Dispensing by or on the order of a physician."

8.2.10 "Dispense" or "Dispensing" means the interpretation, evaluation, and implementation of a Prescription Drug Order, including the preparation and Delivery of a Drug or Device to a patient or patient's agent in a suitable container appropriately labeled for subsequent Administration to, or use by, a patient.

8.2.11 "Distribute" means the Delivery of a Drug or Device other than by Administering or Dispensing.

8.2.12 "Drug" means:

- 1) articles recognized as Drugs in any official compendium, or supplement thereto, designated from time to time by the Board for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in humans or other animals;
- 2) articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in humans or other animals;
- 3) articles (other than food) intended to affect the structure or any function of the body of humans or

other animals; and

4) articles intended for use as a component of any articles specified in clause (1), (2), or (3) of this definition.

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

1) Evaluation of the Prescription Drug Order(s) and patient record(s) for:

- (I) known allergies;
- (ii) rational therapy-contraindications;
- (iii) reasonable dose and route of Administration; and
- (iv) reasonable directions for use.

2) Evaluation of the Prescription Drug Order(s) and patient record(s) for duplication of therapy.

3) Evaluation of the Prescription Drug Order(s) and patient record(s) for interactions:

- (I) Drug-Drug;
- (ii) Drug-food;
- (iii) Drug-disease; and
- (iv) adverse Drug reactions.

4) Evaluation of the Prescription Drug Order(s) and patient record(s) for proper utilization (including over- or under-utilization), and optimum therapeutic outcomes.

8.2.14 "Electronic Transmission" means transmission of information in electronic form or the transmission of the exact visual image of a document by way of electronic equipment.

8.2.15 "Emergency Situations," for the purposes of authorizing an oral Prescription Drug Order of a Schedule II controlled substance, means those situations in which the prescribing Practitioner determines (1) that immediate Administration of the controlled substance is necessary for proper treatment of the patient, (2) that no appropriate alternative treatment is available, including Administration of a Drug which is not a Schedule II controlled substance, and (3) that it is not reasonably possible for the prescribing Practitioner to provide a written Prescription Drug Order to be presented to the Person Dispensing the substance, prior to the Dispensing.

8.2.16 "Equivalent Drug Product" means a Drug product which has the same established name, active ingredient(s), strength or concentration, dosage form, and route of Administration and which is formulated to contain the same amount of active ingredient(s) in the same dosage form and to meet the same compendial or other applicable standards (i.e., strength, quality, purity, and identity), but which may differ in characteristics, such as shape, scoring, configuration, packaging, excipients (including colors, flavors, preservatives), and expiration time.
(bb) "Fine/Civil Penalty" is a monetary penalty assessed a licensee for violation of the Pharmacy Practice Act or rules and regulations.

8.2.17 "Home Infusion Pharmacy" means a Pharmacy which compounds solutions for direct Administration to a patient in a private residence, Long-Term Care Facility, or hospice setting by means of parenteral, intravenous, intramuscular, subcutaneous, or intraspinal infusion.

8.2.18 "Labeling" means the process of preparing and affixing a label to any Drug container exclusive, however, of the Labeling by a Manufacturer, packer, or Distributor of a Non-Prescription Drug or commercially packaged Legend Drug or Device. Any such label shall include all information required by Federal and State law or rule.

8.2.19 "Long-Term Care Facility" means a nursing home, retirement care, mental care, or other facility or institution that provides extended health care to resident patients.

8.2.20 "Manufacturer" means a Person engaged in the Manufacture of Drugs or Devices.

8.2.21 "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

- substance(s) or Labeling or relabeling of its container, and the promotion and marketing of such Drugs or Devices. Manufacturing also includes the preparation and promotion of commercially available products from bulk compounds for resale by pharmacies, Practitioners, or other Persons.
- 8.2.22** "Medical Order" means a lawful order of a Practitioner that may or may not include a Prescription Drug Order.
- 8.2.23** "Non-Prescription Drug" means a Drug which may be sold without a prescription and which is labeled for use by the consumer in accordance with the requirements of the laws and rules of this State and the Federal government.
- 8.2.24** "Non-Resident Pharmacy" means a Pharmacy located in another State.
- 8.2.25** "Patient Counseling" means the oral communication by the Pharmacist of information, as defined in the rules of the applicable Board, to the patient or care giver, in order to ensure proper use of Drugs and Devices.
- 8.2.26** "Person" means an individual, corporation, subsidiary, partnership, association, organization, affiliate organization, or any other legal entity, including government.
- 8.2.27** "Pharmaceutical Care" is the provision of Drug therapy and other patient care services 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 as defined in the Rules of the Board.
- 8.2.28** "Pharmacist" means an individual currently licensed by this State to engage in the Practice of Pharmacy.
- 8.2.29** "Pharmacist Manager" means a Pharmacist currently licensed in this state who has held an unencumbered license in this or another state for at least one year, who accepts responsibility for the operation of a Pharmacy in conformance with all laws and rules pertinent to the Practice of Pharmacy and the Distribution of Drugs, and who is personally in full and actual charge of such Pharmacy and personnel.
- 8.2.30** "Pharmacy" means any place within this State where Drugs are Dispensed and Pharmaceutical Care is provided and any place outside of this State where Drugs are Dispensed and Pharmaceutical Care is provided to residents of this State.
- 8.2.31** "Practice of Telepharmacy" means the provision of Pharmaceutical Care through the use of telecommunications and information technologies to patients at a distance.
- 8.2.32** "Practice of Telepharmacy Across State Lines" means the provision of Pharmaceutical Care through the use of telecommunications and information technologies that occurs when the patient is physically located within the jurisdiction and the Pharmacist is located outside the jurisdiction.
- 8.2.33** "Practitioner" means an individual currently licensed, registered, or otherwise authorized by the appropriate jurisdiction to prescribe and Administer Drugs in the course of professional practice.
- 8.2.34** "Preceptor" means an individual who is currently licensed as a Pharmacist by the Board of Pharmacy, meets the qualifications as a Preceptor under the Rules of the Board, and participates in the instructional training of Pharmacy Interns.
- 8.2.35** "Prescription Drug" or "Legend Drug" means a Drug which is required under Federal law to be labeled with either of the following statements prior to being Dispensed or Delivered: (I) "Caution: Federal law prohibits Dispensing without prescription"; or (ii) "Caution: Federal law restricts this Drug to use by, or on the order of, a licensed veterinarian"; or (iii) a Drug which is required by any applicable Federal or State law or rule to be Dispensed pursuant only to a Prescription Drug Order or is restricted to use by Practitioners only.

- 8.2.36 "Prescription Drug Order" means a lawful order from a Practitioner for a Drug or Device for a specific patient, including orders derived from Collaborative Pharmacy Practice, that is communicated directly to a Pharmacist in a licensed Pharmacy.
- 8.2.37 "Primary Care" is the first level of contact of individuals, the family, and the community with the health care delivery system, bringing health care as close as possible to where people live and work, and constitutes the first element of a continuing health care process. (Areas of Primary Care where Pharmacists provide Pharmaceutical Care include, but are not limited to, the following: chronic disease management; smoking cessation; maternal and child health; immunizations; family planning; self-care consulting; Drug selection under protocol; treatment of common diseases and injuries; nutrition; and general health education and promotion.)
- 8.2.38 "Significant Adverse Drug Reaction" means any Drug-related incident that may result in serious harm, injury, or death to the patient.
- 8.2.39 "Wholesale Distributor" means any Person engaged in Wholesale Distribution of Drugs, including but not limited to Manufacturers; repackagers; 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 Distributions.

Section 9. Qualifications For Licensure

- 9.1 Applicants must:
 - 9.1.1 Be at least 18 years of age;
 - 9.1.2 Not have committed any acts which affect the ability to practice pharmacy;
 - 9.1.3 Have graduated from an approved pharmacy school. The Board may require a personal interview to demonstrate oral comprehension and facility in the English language;
 - 9.1.4 For foreign-trained applicants, have successfully passed an examination demonstrating that their education was equivalent to the education at a Board-approved school or college;
 - 9.1.5 Have completed an internship or demonstrated experience which is equivalent to an internship;
 - 9.1.6 Have passed the required examinations;
 - 9.1.7 Have completed an application and sent it to the Board;
 - 9.1.8 Have paid the appropriate fee.

Section 10. Acts Which Affect Ability To Practice

- 10.1 The Board may deny licensure if the applicant, sole proprietor, partner, corporate officer, or pharmacist has engaged in acts which directly affect the ability to practice pharmacy. These include acts which lead to the conviction or indictment for a felony or misdemeanor, or disciplinary sanction, for violation of drug or pharmacy related laws, rules or regulations.

Section 11. Examinations

- 11.1 The Board requires an examination consisting of two components. The NAPLEX and the MPJE.
- 11.2 NORTH AMERICAN PHARMACY LICENSURE EXAMINATION
 - 11.2.1 The NAPLEX will be administered at least twice a year, on dates established by the NABP. Contact the Office for the date, time, place, and deadline of the examination.
- 11.3 MULTISTATE PHARMACY JURISPRUDENCE EXAMINATION
 - 11.3.1 The MPJE for Vermont will be administered at least twice a year, on dates established by the NABP. Contact the Office for the date, time, place, and deadline of the examination.

Section 12. Required Examination Scores

- 12.1 A minimum score of 75 must be attained on each component of the exam. An applicant who does not attain the required examination scores may elect to be re-examined. If the required score is not attained within one year, all previous scores shall be forfeited and the applicant must sit for and pass all components of the examination.

Section 13. Score Transfer

- 13.1 Vermont will accept the NAPLEX score attained by an applicant from another state when the following requirements are

met:

- 13.1.1 The score is transferred through the NABP office under the conditions outlined by that Association;
- 13.1.2 An application is submitted;
- 13.1.3 If the applicant did not take the MPJE for Vermont, the required score is attained within one year of the date of the completed NAPLEX.

Section 14. Applications For Examination For Licensure

- 14.1 Applicants shall use the standard form furnished by the Office. A completed application shall consist of:
 - 14.1.1 The Office application form, completed in full and signed by the applicant;
 - 14.1.2 Certification of the applicant's graduation from an accredited college of pharmacy, or, for foreign-trained applicants, certification of successful passage of an examination demonstrating that the applicant's education was equivalent to the education at a Board-approved school or college; and
 - 14.1.3 The prescribed fee.
- 14.2 An applicant who has not graduated may submit an official transcript from his or her pharmacy school and arrange for certification of graduation to be sent to the Board under separate cover. Certification must be received by the Board before the applicant may sit for the examination.

Section 15. Licensure By Endorsement

- 15.1 Applicants for licensure by endorsement shall use the official NABP application form. The Board will license an applicant who is licensed by examination in a state whose current standards are substantially equal to the current standards in Vermont. A completed application consists of:
 - 15.1.1 The NABP form, completed in full and signed by the applicant;
 - 15.1.2 Official verification of original licensure by examination;
 - 15.1.3 Official verification that the original license and any other license(s) granted to the applicant by any other state(s) have not been subject to disciplinary action;
 - 15.1.4 Official verification of good standing of the current license; and
 - 15.1.5 The prescribed fee.

Section 16. Renewal Of License

- 16.1 Applicants for license renewal shall submit:
 - 16.1.1 The completed renewal form;
 - 16.1.2 A statement listing the continuing education programs completed since the licensee's latest license was issued;
 - 16.1.3 The prescribed fee; and
 - 16.1.4 Any late fees or penalties required by law.

Section 17. Inactive Status

- 17.1 Subject to the provisions of 26 V.S.A. § 2045, applicants for license renewal may request inactive status. A person may not practice pharmacy in Vermont without an active pharmacy license from the Board.
- 17.2 A holder of an inactive license must comply with the continuing education requirements set forth in these rules by accumulating a total of 3.0 CEUs (30 hours) for each renewal period during which the license was inactive. A person applying for renewal of an inactive license shall not be assessed the renewal fees for the years during which the license was inactive.

Section 18. Reinstatement Of Lapsed License

- 18.1 Once the expiration date on a license has passed, the license has lapsed, and the license holder must apply for reinstatement according to 26 V.S.A. §2045.
- 18.2 A holder of a lapsed license must comply with the continuing education requirements set forth in these rules by accumulating a total of 3.0 CEUs (30 hours) for each renewal period during which the license was allowed to lapse. A person applying for renewal of a lapsed license shall not be assessed the renewal fees for the years during which the license was lapsed.

Section 19. Scope Of Practice

- 19.1 Pharmacy is that profession which is concerned with the art and science of preparing, from natural and synthetic sources, suitable and convenient materials for distribution and use in the treatment and prevention of disease. It embraces a knowledge of the identification, selection, preparation, preservation, combination, analysis, standardization of

pharmacologic action, and therapeutic use of drugs and medicines. As a health care provider, it also embraces the interpretation, evaluation, and dispensing of prescription drugs or drug orders in the patient's best interest; participation in drug and device selection, drug administration, drug regimen reviews and drug or drug-related research; provision of patient counseling and the provision of those acts or services necessary to provide pharmaceutical care; and the responsibility for compounding and labeling of drugs and devices, proper and safe storage of drugs and devices and maintenance of proper records for them. It includes the management of drug therapy in collaboration with other health care providers responsible for patient care and the research, consultation, selection of drugs under protocol, and recommendation or provision of information necessary for drug therapy.

**PART B. RULES FOR OPERATION OR CLOSURE
OF A DRUG OUTLET**

Section 1. Forms Of Drug Outlet Ownership

1.1 Retail drug outlets may be owned by a sole proprietor, partnership, corporation or professional corporation. Shareholders of a professional corporation shall be considered individual pharmacists for disciplinary purposes.

Section 2. Application And Procedure For Opening A Retail Drug Outlet

2.1 Applicants shall use the standard form furnished by the Office or via the website. Completed applications shall include:

2.1.1 The Office form, completed in full and signed by the applicant;

2.1.2 A scale drawing of the outlet, indicating space utilization and security arrangements in detail, attached to the application;

2.1.3 If a corporation:

2.1.3.1A copy of the corporate charter attached to the application; and

2.1.3.2If non-publicly traded, a list of all stockholders owning five percent or more of the corporation's assets; and

2.1.3.3A list of all stockholders of a parent corporation owning five percent or more of the corporation's assets;

2.1.4 Affirmation by the sole proprietor, or all partners, or corporate officers and directors, and the pharmacist-manager, that they have not been convicted of, and are not under indictment for, any felony or misdemeanor arising from the violation of any drug or pharmacy related law;

2.1.5 The approximate date of completion, if a new drug outlet.

2.2 A Board representative shall make an on-site inspection within 20 days of receiving notice of the completion date. A 30 day temporary license shall then be issued, if security conditions are satisfactory, and the proper equipment and library material, are on hand.

2.3 The applicant shall give at least 10 days' notice to the Board prior to opening for public business.

2.4 If there are no deficiencies that would make the site unsatisfactory, a permanent license shall be issued after the Board receives:

2.4.1 Confirmation of the applicant's DEA license; and

2.4.2 An affidavit showing an adequate supply of drugs.

2.5 If the permanent license is denied:

2.5.1 The representative shall send written notification to the applicant and the Board, noting all deficiencies and opportunity for a hearing;

2.5.2 If the Board does not receive evidence of correction of the deficiencies, or a request for a hearing, within 30 days of the date of notice, all legend drugs shall be transferred upon termination of the temporary license ; or

2.5.3 If the Board receives evidence of correction of the deficiencies, or upon order of the Board, an on-site inspection shall be made by a Board representative within 30 days. A permanent license shall then be issued, or upon finding further deficiencies, the procedures outlined in this subsection shall apply.

Section 3. Changes In Corporation

3.1 A non-publicly traded corporation shall immediately notify the Office, in writing, of any changes in officers or stockholders owning five percent or more of the corporation.

Section 4. Pharmacist-Manager

4.1 The pharmacist-manager shall be responsible for the direct management, supervision, and control of the pharmacy department. A pharmacist-manager shall have been licensed and in good standing as a pharmacist in this state or in another state with substantially similar requirements for licensure for at least one year prior to becoming a pharmacist-

manager.

- 4.2 The current or proposed pharmacist-manager shall be responsible for proper closing of the drug outlet; or if a foreclosure or bankruptcy, the official in charge shall obtain the services of a pharmacist to serve as acting pharmacy-manager.
- 4.3 The pharmacist-manager shall be responsible for required record keeping of drugs and devices that are destroyed, surrendered to the Board, or returned to the wholesaler or manufacturer for disposal.
- 4.4 The pharmacist-manager shall be responsible for enforcing security standards for the prescription area .
- 4.5 The pharmacist shall be manager of only one drug outlet and shall work at least 30 percent of the hours the prescription department is open or at least 40 hours per week, whichever is less.

Section 5. Transfer Of Ownership

- 5.1 Business may continue uninterrupted when ownership of the retail drug outlet is transferred if the new owner:
 - 5.1.1 Notifies the Board within 48 hours after the transfer;
 - 5.1.2 Submits a completed application within 5 business after the transfer;
 - 5.1.3 Submits plans for correction of deficiencies in the drug outlet allowed under grandfather clauses, if any, with the application; and
 - 5.1.4 States the date of transfer on the application.
- 5.2 The Board may then issue a temporary license, pending correction of any deficiencies by a specified date. Upon written request, establishing necessity, the Board may continue the temporary license to allow more time for correcting deficiencies. If an extension is not requested, or the request denied, the temporary license shall expire and the drug outlet shall close.
- 5.3 After receiving written notification of correction of all deficiencies, the Board shall proceed following Sections 3.400 and 3.500 above.

Section 6. Change Of Address Or Location

- 6.1 The licensee shall submit immediate written notification of any change in mailing address of a drug outlet.
- 6.2 A licensee shall notify the Board within 48 hours after changing the location of a drug outlet, and shall not open for business in the new location until after completion of a satisfactory inspection.
- 6.3 In order to continue business without interruption, the licensee shall, at least 60 days prior to a change in location of a drug outlet, submit an application for a new license. All equipment and library materials approved for use in the new location must be transferred prior to opening for public business.

Section 7. Renovations

- 7.1 Before reopening for business after remodeling or relocation which effects the security of a pharmacy, the drug outlet must complete a satisfactory inspection. In order to continue business, the licensee shall notify the Board 60 days prior to the changes, submitting a scale drawing of the outlet, indicating space utilization and security arrangements in detail.

Section 8. Natural Disaster; Fire

- 8.1 Upon written request, the Board may issue an immediate 60 day emergency license for operation of the drug outlet at a new location after natural disaster or fire.
- 8.2 A Board representative shall conduct an on-site inspection at the proposed location. The Board shall issue the emergency license if security conditions are satisfactory.
 - 8.2.1 No equipment, supplies, or drug inventory from the old location shall be used in the new location without Board approval.
- 8.3 Upon application, prior to the expiration of the emergency license, the Board may continue the emergency license up to a period of two years from the original date of the emergency license.

Section 9. Death Of Owner

- 9.1 Following death of a sole proprietor or partner, the Board may issue a temporary license only if the legally appointed representative of the decedent's estate has named a licensed pharmacist-manager to operate the drug outlet.
- 9.2 The temporary license shall be effective until:
 - 9.2.1 The drug outlet has been properly reorganized; or
 - 9.2.2 Ownership has been transferred; or
 - 9.2.3 The drug outlet has been closed; or
 - 9.2.4 One year has elapsed since death of the owner.

Section 10. Termination Of License To Operate A Drug Outlet

- 10.1 Unless a temporary license has been obtained, a license to operate a drug outlet is immediately terminated under the

following conditions:

- 10.1.1 If a sole proprietorship: death of owner, change of location, change in ownership, or change in business name.
- 10.1.2 If a partnership: death of a partner, change of location, change in partners or other change in ownership, change in business name, or other factors as provided in statutes governing partnerships.
- 10.1.3 If a corporation: Change in location, or change in corporate name or charter.
- 10.1.4 Failure to register a change in pharmacist-manager.

Section 11. Drug Outlet Closing

- 11.1 If the closing of a drug outlet is not planned, the licensee shall notify the Board of the closing within 48 hours. The licensee shall notify the general public of the intent of the licensee and the future location of prescription files by advertising in a newspaper with a general circulation in the area served.
- 11.2 The licensee shall arrange for a responsible agent to maintain all prescription drug outlet records for three years from the date the outlet is closed.
- 11.3 If the closing of a drug outlet is planned, the licensee shall, at least 15 days prior to the closing, send the Board written notification of the following:
 - 11.3.1 The date the outlet will close for public business;
 - 11.3.2 The name(s) and address(es) of the person(s) with custody of prescription, bulk compounding, repackaging, and controlled drug inventory records;
 - 11.3.3 The names and addresses of all persons who will acquire legend drugs when the drug outlet closes.
- 11.4 The licensee shall, within 30 days of closing the drug outlet, send the Board a written report, indicating:
 - 11.4.1 The licensee voluntarily surrendered the license to operate a drug outlet;
 - 11.4.2 All legend drugs were transferred to another authorized drug outlet, or returned to wholesalers or manufacturers, or destroyed, and the name(s) and address(es) of the drug outlet(s) receiving the legend drugs;
 - 11.4.3 All labels and blank prescription pads were destroyed;
 - 11.4.4 All signs indicating the presence of a drug outlet were removed.
- 11.5 The licensee shall, at least 30 business days in advance, notify the general public of the date of closing and the future location of prescription files, in the following manner:
 - 11.5.1 Advertise in a newspaper with a general circulation in the area served; and
 - 11.5.2 Post signs in a conspicuous place in the drug outlet.

PART C. RULES FOR PHARMACEUTICAL CARE

Section 1. Facility

- 1.1 Minimum requirements for a pharmacy:
 - 1.1.1 The pharmacist-manager, or the pharmacist delegated by him or her, shall have 24 hours access to the pharmacy department. Each pharmacy shall be of sufficient size (minimum of 200 square feet) to allow for the safe and proper storage of prescription drugs and for the safe and proper compounding and preparation of prescription drug orders.
 - 1.1.2 If the store is open at times when the prescription department is closed, the prescription area must be permanently enclosed by a partition or Board-approved barrier device at least nine feet six inches in height, except where the ceiling is less than nine feet six inches, in which case the partition or Board-approved barrier device shall be from floor to ceiling.
 - 1.1.3 The prescription department must contain a counter twelve feet in length and two feet in width. If two or more pharmacists are on duty at the same time, the counter shall be four feet longer for each additional pharmacist. The prescription counter shall be kept free of any items not being used in the practice of pharmacy. No television monitors shall be located in the prescription department, and no such equipment shall be placed to as to distract the pharmacist from the practice of pharmacy. The aisle space behind the prescription counter shall be wide enough to allow free movement and shall be kept free of obstructions. The prescription department shall have a sink of appropriate size, exclusive of drainboard area, necessary to fulfill the needs of the pharmacy. The sink shall be connected to hot and cold running water, shall have a working drain, and shall be convenient to the compounding area for the purpose of hand scrubs prior to compounding.
- 1.2 By January 1, 2004, each pharmacy providing outpatient prescriptions directly to the public or employees, shall maintain an area designated for the provision of patient counseling services. This area shall be designed to provide a reasonable

expectation of privacy.

Section 2. Signs and Names

- 2.1 The only name(s) used to identify the drug outlet at the site or in advertisements shall be the name(s) registered with the Board.
- 2.2 The drug outlet shall display only current licenses of current employees.
- 2.3 The drug outlet shall display pharmacy business hours and the name of the pharmacist on duty in a conspicuous manner visible to the public.
- 2.4 Use of words “drugs,” “medicines,” “drugstore,” “pharmacy,” or similar term or combination of terms shall be restricted to the area registered by the Board. Nothing in this restriction shall prevent the placement of signs on the outside of the establishment, indicating the presence of a drug outlet inside.

Section 3. Display of Licenses

- 3.1 All pharmacists shall display their current licenses in a conspicuous manner visible to the public.
- 3.2 Pharmacists employed in more than one drug outlet may elect to have their current license displayed at either drug outlet. The wallet portion of the license must be available for examination by any consumer, Board inspector, or law officer upon demand.

Section 4. Display of Drug Outlet License

- 4.1 The drug outlet’s current license shall be displayed in a conspicuous manner visible to the public.

Section 5. Security

- 5.1 Each pharmacist, while on duty, shall be responsible for the security of the pharmacy, including provisions for effective control against theft or diversion of drugs or devices.
- 5.2 The pharmacy shall be secured by either a physical barrier with suitable locks or an electronic barrier to detect entry at a time when the pharmacy is not open and secure from access by the public at all times. Only support personnel directly involved in the prescription dispensing process, non-pharmacist management, maintenance personnel, law enforcement personnel, or emergency services personnel shall be allowed entry into the prescription department and then only when a pharmacist is present in the drug outlet.
- 5.3 Prescription and other patient health care information shall be secure from access by the public, and the information shall be kept confidential. Prescriptions, orders, records, and stocks of regulated drugs shall be open for inspection to authorized agents of the Board (18 V.S.A. § 4211). A person who gives information to specifically authorized agents of the Board concerning the use of regulated drugs, or the misuse by other persons or regulated drugs, shall not be subject to any civil, criminal or administrative liability or penalty for giving such information (18 V.S.A. § 4218©)).

Section 6. Hygiene Standards

- 6.1 The drug outlet shall:
 - 6.1.1 Comply with all federal, state, and local health laws;
 - 6.1.2 Have walls, ceilings, windows, and floors kept clean and in good repair;
 - 6.1.3 Have waste receptacles located in convenient areas;
 - 6.1.4 Have equipment kept clean and stored in an orderly manner;
 - 6.1.5 Be well lighted;
 - 6.1.6 Be dry and well ventilated;
 - 6.1.7 Have adequate restroom facilities for employees.

Section 7. Drugs and Devices

- 7.1 Definitions:

- 7.1.1 Adulterated: consists in whole or in part of any filthy, putrid, decomposed substance; or does not meet FDA standards.
- 7.1.2 Misbranded: outdated, or label is false or misleading, or does not meet FDA standards.
- 7.2 Any drug or device that is misbranded, adulterated, or expired shall not be sold or given away and shall be removed from inventory and stored in a separate location within the prescription drug area until processed for return or destruction.
- 7.3 There shall be a system to monitor drug recalls and, where appropriate, notify patients to whom the recalled drug products have been dispensed.
- 7.4 All areas where drugs and devices are stored shall be dry, well-lighted, well-ventilated, and maintained in a clean and orderly condition. Storage areas shall be maintained at temperatures which will ensure the integrity of the drugs prior to their dispensing as stipulated by the USP or the manufacturer's or distributor's labeling unless otherwise indicated by the Board.

Section 8. Equipment

- 8.1 The pharmacy shall carry and utilize the equipment and supplies necessary to conduct a pharmacy in a manner that is in the best interest of the patients served and to comply with all state and federal laws.
 - 8.1.1 One class A prescription balance with metric weights from 10 milligrams to 50 grams or automatic sensitivity requirement of six mg. with no load, or an electronic balance;
 - 8.1.2 A refrigerator with a temperature control and thermometer;
 - 8.1.3 Distilled or sterile water;
 - 8.1.4 An automated data processing system;
 - 8.1.5 At least one telephone in the prescription area, with the same number as the telephone number printed on the drug outlet prescription labels;
 - 8.1.6 A tablet and capsule counting tray;
 - 8.1.7 Containers which meet official compendia standards, available with closures that meet Federal Poison Prevention Packaging Act of 1970 requirements, as well as regular closures;
 - 8.1.8 Prescription labels imprinted or computer-generated with the name, address, and telephone number of the drug outlet that do not contain any symbol or background logo that interferes with the reading and interpretation of any information written by the pharmacist on the label;
 - 8.1.9 Auxiliary labels;
 - 8.1.10 Prescription filing devices for record keeping;
 - 8.1.11 Sufficient equipment, graduates, mortars, funnels, etc., to maintain the scope of practice;
 - 8.1.12 Any drug outlet involved in the preparation of sterile pharmaceutical products must meet the requirements of the Sterile Pharmaceuticals rules.

Section 9. Reference Library

- 9.1 Each pharmacy shall maintain on file at least one reference in each of the following categories. Computerized, on-line versions are acceptable instead of a hard copy of the current manual. Whether in hard copy or computerized, this reference work must be complete and must include an explanation of drug interactions, either in the form of a manual or otherwise:
 - 9.1.1 State and federal drug laws relating to the practice of pharmacy, including a current copy of these statutes and rules, and the legal distribution of drugs and any rules or regulations adopted pursuant thereto;
 - 9.1.2 Current manual of drug interactions equivalent to Hansten's or Drug Facts, with quarterly updates, which has been pre-approved by the Board.
 - 9.1.3 Current Facts and Comparisons, with monthly updates;
 - 9.1.4 Current reference on pediatric dosages;
 - 9.1.5 Pharmacies offering for sale herbal or alternative medicines, must possess a current reference for such; computerized version or hard copy.

Section 10. Inspection of Drug Outlets

- 10.1 Biennially, a Board member, a representative appointed by the Board, or an employee of or contractor with the Office

of Professional Regulation, shall inspect a drug outlet during regular business hours, for compliance with these rules.

- 10.2** The Board shall not authorize any inspection that extends to financial data, sales data other than shipping data or pricing data of the drug outlet.

Section 11. Persons Authorized to Prescribe

- 11.1** Pharmacists may accept prescription legend drug orders from authorized practitioners within the United States and Canada, including:
- 11.1.1** Dentist;
 - 11.1.2** Naturopathic physician, as authorized by naturopathic physician formulary rules;
 - 11.1.3** Nurse practitioner, as authorized by protocol;
 - 11.1.4** Optometrist;
 - 11.1.5** Osteopath;
 - 11.1.6** Physician;
 - 11.1.7** Physician’s assistant, as authorized by protocol;
 - 11.1.8** Podiatrist;
 - 11.1.9** Scientific investigator;
 - 11.1.10** Veterinarian.

Section 12. Prescription Pick-up and Delivery

- 12.1** A licensee may, upon request by the patient, accept or deliver a drug or device to the patient or licensed facility in which patient resides. The licensee may delegate the pick-up and delivery of prescription drugs and devices to an employee of the drug outlet, or the U.S. mail, or a common carrier. The drug or device shall be properly labeled as a finished dispensed prescription product.

Section 13. Advertising Prescription Drugs

- 13.1** Prescription legend drug and device advertising shall be truthful, reasonable, informative, and understandable to the consumer. Advertisements for drugs at special prices for a limited time must state the termination date of the special price, and that prices may change after that date.

Section 14. Advertising Controlled Substances

- 14.1** Controlled substances named in Schedules II, III, IV, V, or any drug regulated by the Vermont Board of Health, shall not be promoted to the public in any manner.

Section 15. Sale of Prescription Legend Drugs

- 15.1** Legend drugs may be sold or transferred to a licensed pharmacist, or practitioner qualified to prescribe, or drug outlet, or drug outlet owner, or manufacturer, wholesaler, or distributor of such drugs. The transaction shall be recorded on a written invoice or appropriate form and kept in the drug outlet. See 26 V.S.A. §§ 2067-2076 (wholesale drug distributors) for requirements relating to wholesalers and 26 V.S.A. § 2022(16) for the definition of “wholesale distribution.”

Section 16. Sale of Prescription Legend Drugs at Auction

- 16.1** Prescription legend drugs may be sold at auction, under the direct supervision of a licensed pharmacist, if:
- 16.1.1** The auctioneer submits the name of the supervising pharmacist to the Board, in writing, prior to the auction;
 - 16.1.2** All legend drugs are transferred only to licensees;
 - 16.1.3** The supervising pharmacist submits, in writing, the names of all licensees who purchased drugs at the auction.

Section 17. Voluntary Surrender of Drug Outlet License

- 17.1** The Board may accept a license to operate a drug outlet that has been surrendered voluntarily, if:
 - 17.1.1** The licensee submits, in writing, a signed statement setting forth the reasons the license is being surrendered; and
 - 17.1.2** All prescription legend drugs are properly disposed of under these rules; and
 - 17.1.3** The Board does not have cause for disciplinary action under statutes and rules governing the Board.

Section 18. Personnel

- 18.1** Duties and responsibilities of the pharmacist-manager:
 - 18.1.1** No person shall operate a pharmacy without a pharmacist-manager. The pharmacist-manager of a pharmacy shall be designated in the application of the pharmacy for license, and in each renewal thereof. A pharmacist may not serve as pharmacist-manager unless he or she is physically present in the pharmacy a sufficient amount of time (30% of the hours the prescription department is open or at least 40 hours per week, whichever is less), to provide supervision and control. A pharmacist may not serve as pharmacist-manager for more than one pharmacy at any one time.
 - 18.1.2** The pharmacist-manager has the following responsibilities. (All policies and procedures shall be in computerized form or if written shall be collected in a format such as a three-ring binder that can be easily accessed, updated and revised as necessary.)
 - 18.1.2.1** The pharmacist-manager shall develop or adopt, implement, and maintain a pharmacy technician training manual for the specific practice setting of which the pharmacist-manager is in charge. The training manual shall be similar to that of the National Community Pharmacists' Association (NCPA) and National Association of Chain Drug Stores (NACDS), or as approved by the Board.
 - 18.1.2.2** Assuring that the automated pharmacy dispensing system is in good working order and accurately dispenses the correct strength, dosage form, and quantity of the drug prescribed while maintaining appropriate record keeping and security safeguards.
 - 18.1.2.3** Implementing an ongoing quality assurance program that monitors performance of the automated pharmacy dispensing system, which is evidenced by written policies and procedures developed by the pharmacy.
 - 18.1.2.4** Assuring that all pharmacists employed at the pharmacy are currently licensed and that all pharmacy interns employed at the pharmacy are currently registered with the Board of Pharmacy.
 - 18.1.2.5** Notifying the Board of Pharmacy immediately of any of the following changes on forms provided by the Board:
 - (A)** Change of employment or responsibility as the pharmacist-manager;
 - (1)** Within 48 hours, the outgoing and incoming pharmacist-managers shall notify the Board, in writing, regarding his or her change in employment.
 - (2)** The outgoing pharmacist-manager shall conduct a physical written inventory of all controlled drugs, explain any discrepancies in full, certify as true and correct and retain a copy for his or her records.
 - (3)** The inventory shall be certified as true and correct, by the incoming pharmacist-manager, and filed with the permanent records of the drug outlet.
 - (4)** The inventory shall be signed by both the incoming and outgoing pharmacist-managers, and a copy submitted to the Board as an attachment to the forms provided.
 - (5)** A new license, indicating the name of the new pharmacist-manager will be

issued upon approval.

- (B) Change of ownership of the pharmacy;
- (C) Change of address of the pharmacy;
- (D) In the event of bankruptcy or foreclosure, the official in charge shall obtain the services of a pharmacist to serve as acting pharmacist manager.
- (E) Permanent closing of the pharmacy.

18.1.2.6 Making or filing any reports required by state or federal laws and rules.

18.1.2.7 Responding to the Board of Pharmacy regarding any ~~minor~~ violations brought to his or her attention.

18.1.2.8 Establishing policies and procedures for maintaining the integrity and confidentiality of prescription information and patient health care information, or verifying the existence thereof and ensuring that all employees of the pharmacy read, sign, and comply with the established policies and procedures.

18.1.2.9 Providing the Board with prior written notice of the installation or removal of automated pharmacy systems. Such notice must include, but is not limited to:

- (A) The name and address of the pharmacy;
- (B) The name and location of the automated equipment; and
- (C) The identification of the responsible pharmacist.

18.1.3 The pharmacist-manager shall be assisted by a sufficient number of pharmacists and pharmacy technicians as may be required to competently and safely provide pharmacy services.

18.1.4 The pharmacist-manager shall develop and implement a written procedure for proper management of drug recalls which may include, where appropriate, contacting patients to whom the recalled drug product(s) have been dispensed.

18.2 Pharmacist meal/rest breaks:

18.2.1 Whenever the prescription department is staffed by a single pharmacist, the pharmacist may take a meal/rest break for a period of up to 30 minutes without closing the pharmacy and removing support personnel from the pharmacy, provided that the pharmacist reasonably believes that the security of the prescription drugs will be maintained in the pharmacist's absence.

18.2.2 The time of the meal/rest break shall be at the discretion of the owner of the drug outlet. However, breaks should be scheduled as close as possible to the same time each day, so that patients may become familiar with the approximate time of the breaks.

18.2.3 Meal/rest breaks are encouraged but are not mandatory and are a part of the total hours worked by the pharmacist each week.

18.2.4 The pharmacist shall remain on the premises of the drug outlet during the meal/rest break and shall be available for emergencies, as defined by the patient.

18.2.5 If two or more pharmacists are on duty in the prescription department, the pharmacists shall stagger their meal/rest breaks so that the prescription department is not left without a pharmacist on duty.

18.2.6 Whenever the pharmacist temporarily leaves the prescription department for a meal/rest break, a sign indicating that there is no pharmacist on duty shall be conspicuously displayed in full view of patients approaching the prescription department service area. The sign shall also indicate the time when the pharmacist will return.

18.2.7 Only support personnel directly involved in the prescription dispensing process and authorized by the pharmacist on duty and non-pharmacist management may remain in the prescription department while

the pharmacist is on a meal/rest break.

- 18.2.8** When the pharmacist is temporarily absent from the prescription department, support personnel authorized by the pharmacist on duty may continue to perform non-discretionary duties as delineated by the pharmacist. All such duties performed by support personnel shall be reviewed by the pharmacist upon return from the meal/rest break.
- 18.2.9** When a pharmacist is not in the prescription department, there shall be **no** dispensing of **new** prescriptions that the pharmacist has checked and that are waiting to be picked up, nor shall counseling be provided by support personnel.
- 18.2.10** New, written prescriptions presented by the patient or the patient's agent may be accepted by support personnel. The processing of such prescriptions, up to the final check, may occur in the absence of the pharmacist. However, no new prescriptions may be dispensed until the final check is completed by the pharmacist after return to the prescription department.
- 18.2.11** New prescriptions conveyed by telephone shall not be accepted. The caller should be instructed to call back, or a telephone number should be obtained for the pharmacist to call upon return to the prescription department.
- 18.2.12** During the pharmacist's absence, prescription refills which have been previously prepared and checked by a pharmacist may be picked up by the patient or the patient's agent. Support personnel must offer the patient counseling by the pharmacist. If the patient has no questions, dispensing may proceed as usual, with the patient signing for the counseling refusal. If the patient desires counseling, the patient should be asked to wait for the pharmacist to return from the meal/rest break. Alternatively, the patient may be asked to leave a telephone number for the pharmacist to call later the same day.
- 18.2.13** Telephone refill orders and refill requests presented in person by the patient or the patient's agent may be accepted by support personnel. Such refill orders may be processed by support personnel up to the final check. However, no such refill orders shall be dispensed until the final check is completed by the pharmacist after return from the meal/rest break.
- 18.2.14** Under this rule, the pharmacist-manager remains responsible for the direct management, supervision, and control of the prescription department.
- 18.2.15** If, for security reasons or otherwise, the pharmacist determines that the prescription department should close during the pharmacist's absence, the pharmacist shall close the prescription department and remove all support personnel from the prescription department during the pharmacist's absence. A sign informing the public of the pharmacist's temporary absence and time of return shall be conspicuously posted.
- 18.2.16** Using this rule as a guide, the pharmacist-manager, in conjunction with the pharmacy license holder, should develop written policies and procedures regarding operation of the prescription department while the pharmacist is temporarily absent on a meal/rest break. The policies and procedures should include authorized duties of support personnel and should define the pharmacist's responsibilities for checking all work performed by support personnel and for maintaining security of the prescription department. The pharmacist-manager should review the policies and procedures with support personnel. After review, each support person should be requested to initial the policies and procedures to indicate that the policies and procedures are understood.

Section 19. Pharmacy Practice

19.1 Prescription drug order:

19.1.1 A Prescription drug order shall contain the following information at a minimum:

19.1.1.1 Full name and street address of the patient (which may appear on the back of the prescription drug order);

- (D) In the case of an emergency situation, a prescription drug order for a Schedule II controlled substance may be communicated by the practitioner orally or by way of electronic transmission, provided that:
- (1) The quantity prescribed and dispensed is limited to the amount adequate to treat the patient during the emergency period (dispensing beyond the emergency period must be pursuant to a written prescription drug order signed by the prescribing practitioner);
 - (2) The orally communicated prescription drug order shall be immediately reduced to writing by the pharmacist, or, if necessary, the prescription drug order communicated by way of electronic transmission shall be immediately reduced to a hard copy, and either shall contain the information required above in the sub-section above on prescription drug orders;
 - (3) If the prescribing practitioner is not known to the pharmacist, he or she must make a reasonable effort to determine that the oral authorization came from a registered practitioner, which may include a callback to the practitioner using the practitioner's phone number as listed in the telephone directory or other good faith efforts to insure his identity; and
 - (4) Within 72 hours after authorizing an emergency oral prescription drug order, the practitioner shall cause a written prescription drug order for the emergency quantity prescribed to be delivered to the dispensing pharmacist. In addition to conforming to the requirements of the sub-section above on prescription drug orders, the prescription drug order shall have written on its face "Authorization for Emergency Dispensing," and the date of the orally or electronically transmitted prescription drug order. The written prescription drug order may be delivered to the pharmacist in person or by mail, but if delivered by mail, it must be postmarked within the 72-hour period. Upon receipt, the dispensing pharmacist shall attach this written prescription drug order to the emergency oral prescription drug order which had earlier been reduced to writing or to the hard copy of the electronically transmitted prescription drug order. The pharmacist shall notify the nearest office of the U.S. Drug Enforcement Administration if the prescribing practitioner fails to deliver a written prescription drug order.

- 19.3.1.5** All prescription drug orders communicated by way of electronic transmission shall:
- (A) Be transmitted directly to a pharmacist in a licensed pharmacy of the patient's choice with no intervening person having access to the prescription drug order. This does not apply to the computer transition systems and persons necessary for the electronic transmission of prescriptions;
 - (B) Identify the transmitter's phone number for verbal confirmation, the time and date of transmission, and the identity of the pharmacy intended to receive the transmission, as well as any other information required by federal or state law;
 - (C) Be transmitted by an authorized practitioner or his or her designated agent; and
 - (D) Be deemed the original prescription drug order, provided it meets the requirements of this sub-section.
- 19.3.1.6** The prescribing practitioner may authorize his agent to communicate a prescription drug order orally or by way of electronic transmission to a pharmacist in a licensed pharmacy, provided that the identity of the transmitting agent is included in the order.
- 19.3.1.7** The pharmacist shall exercise professional judgment regarding the accuracy, validity, and authenticity of the prescription drug order communicated by way of electronic transmission

consistent with existing federal or state laws and rules.

19.3.1.8 All electronic equipment for receipt of prescription drug orders communicated by way of electronic transmission shall be maintained so as to ensure against unauthorized access.

19.3.1.9 Persons other than those bound by a confidentiality agreement pursuant to Section 5.300 above shall not have access to pharmacy records containing confidential information or personally identifiable information concerning the pharmacy's patients.

19.3.2 No prescription for a Schedule II controlled drug shall be filled more than 10 days after issuance of the prescription.

19.3.3 No prescription for a non-controlled drug may be filled or refilled more than one year after the prescription was written.

19.3.4 Carbon or duplicate written prescriptions are not valid prescriptions.

19.4 Transfer of a prescription drug order:

19.4.1 Pharmacies utilizing automated data processing systems shall satisfy all information requirements of a manual mode for prescription drug order transferral, except as noted in subsection (D) below. The transfer of original prescription drug order information for the purpose of refill dispensing is permissible between pharmacies subject to the following requirements:

19.4.1.1 The information is communicated directly between two pharmacists and the transferring pharmacist records the following information:

- (A) Write the word "VOID" on the face of the invalidated prescription drug order;
- (C) Record on the reverse side of the invalidated prescription drug order the name and address of the pharmacy to which it was transferred and the name of the pharmacist receiving the prescription drug order;
- (D) Record the date of the transfer and the name of the pharmacist transferring the information; and
- (E) A computerized prescription record which contains all of the elements of (A), (B), and (C) above is acceptable.

19.4.2 The pharmacist receiving the transferred prescription drug order information shall reduce to writing the following:

19.4.2.1 Write the word "TRANSFER" on the face of the transferred prescription drug order;

19.4.2.2 Provide all information required to be on a prescription drug order pursuant to state and federal laws and rules, and include:

- (A) Date of issuance of original prescription drug order;
- (B) Original number of refills authorized on original prescription drug order;
- (C) Date of original dispensing;
- (D) Number of valid refills remaining and date of last refill;
- (E) Pharmacy's name, address, and original prescription number from which the prescription drug order information was transferred; and
- (F) Name of transferring pharmacist.
- (G) A computerized prescription record which contains all of the elements of (A) through (F) above is acceptable

19.4.2.3 Systems providing for the electronic transfer of information shall not infringe on a patient's freedom of choice as to the provider of pharmaceutical care.

19.4.3 Both the original and transferred prescription drug order shall be maintained for a period of three (3) years from the date of last refill.

19.4.4 Pharmacies accessing a common electronic file or database used to maintain required dispensing information are not required to transfer prescription drug orders or information for dispensing purposes between or among pharmacies participating in the same common prescription file, provided, however,

that any such common file shall contain complete records of each prescription drug order and refill dispensed, and, further, that a hard copy record of each prescription drug order transferred or accessed for purposes of refilling shall be generated and maintained at the pharmacy refilling the prescription drug order or to which the prescription drug order is transferred. A hard copy need not be generated and transfer information may be kept electronically as long as the electronic information is readily available and hard copies are able to be generated immediately upon request.

19.4.5 Pharmacies with automated systems that are unable to meet the transfer requirements of this section may transfer prescriptions and document such transfers using a manual method.

19.5 Drug product selection by the pharmacist

19.5.1 When a pharmacist receives a prescription for a drug which is listed either by generic name or brand name in the U.S. Department of Health and Human Services publication Approved Drug Products With Therapeutic Equivalence Evaluations (the "Orange Book"), he or she shall select the lowest priced drug from the formulary which in his or her professional judgment is chemically and therapeutically equivalent and which he or she has in stock, unless otherwise instructed by the purchaser or prescriber.

19.5.2 The purchaser shall be informed by the pharmacist or his or her representative that an alternative selection as provided under subsection 19.510 of this section will be made unless the purchaser chooses to refuse the substitution.

19.5.3 Any pharmacist substituting a generically equivalent drug shall charge no more than the usual and customary retail price for that selected drug. This charge shall not exceed the usual and customary retail price for the prescribed brand.

19.5.4 If the prescriber does not wish substitution to take place, he or she shall write "brand necessary" or "no substitution" in his or her own handwriting on the prescription blank. In the case of an unwritten prescription, there shall be no substitution if the prescriber expressly indicates to the pharmacist that the brand name drug is necessary and substitution is not allowed.

19.6 Labeling

19.6.1 All drugs dispensed for use by inpatients of a hospital or other health care facility, whereby the drug is not in the possession of the ultimate user prior to administration, shall meet the following requirements:

19.6.1.1 The label of a single-unit package of an individual-dose or unit-dose system of packaging of drugs shall include:

- (A) The non-proprietary or proprietary name of the drug;
- (B) The route of administration, if other than oral;
- (C) The strength and volume, where appropriate, expressed in the metric system whenever possible;
- (D) The control number and expiration date;
- (E) Identification of the re-packer by name or by license number shall be clearly distinguishable from the rest of the label; and
- (F) Special storage conditions, if required.

19.6.1.2 When a multiple-dose drug distribution system exceeding a 24 hour supply is utilized, including dispensing of single unit packages, the drugs shall be dispensed in a container to which is affixed a label containing the following information:

- (A) Identification of the dispensing pharmacy;
- (C) The patient's name;
- (D) The date of dispensing;
- (E) The non-proprietary or proprietary name of the drug dispensed; and
- (F) The strength, expressed in the metric system whenever possible.

19.6.2 All drugs dispensed to inpatients for self-administration shall be labeled in accordance with Subparagraph 19.610 of this Section.

- 19.6.3** Whenever any drugs are added to parenteral solutions, such admixtures shall bear a distinctive label indicating:
- 19.6.3.1** Name of solution, lot number, and volume of solution;
 - 19.6.3.2** Patient's name;
 - 19.6.3.3** Infusion rate;
 - 19.6.3.4** Bottle sequence number or other system control number;
 - 19.6.3.5** Name and quantity of each additive;
 - 19.6.3.6** Date of preparation;
 - 19.6.3.7** Beyond-use date and time of parenteral admixture; and
 - 19.6.3.8** Ancillary precaution labels.
- 19.6.4** All drugs dispensed to ambulatory or outpatients shall contain a label affixed to the container in which such drug is dispensed including:
- 19.6.4.1** The name and address and telephone number of the pharmacy dispensing the drug;
 - 19.6.4.2** The name of the patient for whom the drug is prescribed, or, if the patient is an animal, the last name, name of animal, and type of animal;
 - 19.6.4.3** The name of the prescribing practitioner;
 - 19.6.4.4** Such directions as may be stated on the prescription drug order;
 - 19.6.4.5** The date of dispensing;
 - 19.6.4.6** Any cautions which may be required by federal or state law;
 - 19.6.4.7** The serial number of the prescription drug order;
 - 19.6.4.8** The name or initials of the dispensing pharmacist;
 - 19.6.4.9** The proprietary or generic name of the drug dispensed and its strength.
 - 19.6.4.10** The name of the manufacturer or distributor of the drug.
- 19.6.5** Centralized prescription processing
- 19.6.5.1** "Centralized prescription processing" means the processing by a pharmacy of a request from another pharmacy to fill or refill a prescription drug order or to perform processing functions such as dispensing, drug utilization review, claims adjudication, refill authorizations, and therapeutic interventions.
 - 19.6.5.2** A pharmacy may perform or out source centralized prescription processing services provided the parties:
 - (A) have the same owner; or
 - (B) have a written contract outlining the services to be provided and the responsibilities and accountabilities of each party in fulfilling the terms of the contract in compliance with federal and state laws and regulations; and
 - (C) share a common electronic file or have appropriate technology to allow access to sufficient information necessary or required to fill or refill a prescription drug order.
 - 19.6.5.3** The parties performing or contracting for centralized prescription processing services shall maintain a policy and procedures manual and documentation that implementation is occurring in a manner that shall be made available to the Board for review upon request and that includes, but is not limited to, the following:
 - (A) a description of how the parties will comply with federal and state laws and regulations;
 - (B) the maintenance of appropriate records to identify the responsible pharmacist(s) in the dispensing and counseling process;
 - (C) the maintenance of a mechanism for tracking the prescription drug order during each step in the dispensing process;
 - (D) the maintenance of a mechanism to identify on the prescription label all pharmacies involved in dispensing the prescription drug order;
 - (E) the provision of adequate security to protect the confidentiality and integrity of patient information;
 - (F) the maintenance of a quality assurance program for pharmacy services designed to objectively and systematically monitor and evaluate the quality and appropriateness of patient care, pursue opportunities to improve patient care, and resolve identified problems.

19.6.6 No radiopharmaceutical may be dispensed unless a label is affixed to the immediate container bearing the following information:

- 19.6.6.1** The standard radiation symbol;
- 19.6.6.2** The words “Caution – Radioactive Material”; and
- 19.6.6.3** The prescription number.

19.6.7 No radiopharmaceutical may be dispensed unless a label is affixed to the outer or delivery container bearing the following information:

- 19.6.7.1** The standard radiation symbol;
- 19.6.7.2** The words “Caution – Radioactive Material”;
- 19.6.7.3** The radionuclide and chemical form;
- 19.6.7.4** The activity and date and time of assay;
- 19.6.7.5** The volume, if in liquid form;
- 19.6.7.6** The requested activity and the calibrated activity;
- 19.6.7.7** The prescription number;
- 19.6.7.8** Patient name or space for patient name. Where the patient’s name is not available at the time of dispensing, a 72-hour exemption is allowed to obtain the name of the patient. No later than 72 hours after dispensing the radiopharmaceutical, the patient’s name shall become a part of the prescription drug order to be retained for a period of three years;
- 19.6.7.9** The name and address of the nuclear pharmacy;
- 19.6.7.10** The name of the practitioner; and
- 19.6.7.11** The lot number of the prescription.

19.8 Patient records:

19.8.1 A patient record system shall be maintained by all pharmacies for patients for whom prescription drug orders 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 drug order is presented for dispensing. The pharmacist shall make a reasonable effort to obtain, record, and maintain the following information:

- 19.8.1.1** Full name of the patient for whom the drug is intended;
- 19.8.1.2** Street address and telephone number of the patient;
- 19.8.1.3** Patient’s age or date of birth;
- 19.8.1.4** Patient’s gender;
- 19.8.1.5** A list of all prescription drug orders obtained by the patient at the pharmacy maintaining the patient record during the three years immediately preceding the most recent entry showing the name of the drug, prescription number, name and strength of the drug, the quantity and date received, and the name of the practitioner; and
- 19.8.1.6** Pharmacist comments relevant to the individual’s drug therapy, including any other information peculiar to the specific patient or drug.

19.8.2 The Pharmacist shall make a reasonable effort to obtain from the patient or the patient’s agent and shall record any known allergies, drug reactions, idiosyncrasies, and chronic conditions or disease states of the patient and the identity of any other prescription drugs, currently being used by the patient which may relate to prospective drug review.

19.8.3 A patient record shall be maintained for a period of not less than three years from the date of the last entry in the profile record. This record may be maintained either on paper or on electronic media.

19.8.4 Confidential information is to be handled in conformance with HIPAA federal regulations. Confidential information or personally identifiable information may be released to the patient or the patient’s authorized representative, the prescriber or other licensed practitioner then caring for the patient, another licensed pharmacist, the Board or its representative, or any other person duly authorized by law to receive such information. Confidential information or personally identifiable information in the patient medication record may be released to others only on written release of the

patient.

19.9 Prospective drug review:

19.9.1 A pharmacist shall review the patient record and each prescription drug order presented for dispensing for purposes of promoting therapeutic appropriateness by identifying:

19.9.1.1 Over-utilization or under-utilization;

19.9.1.2 Therapeutic duplication;

19.9.1.3 Drug-disease contraindications;

19.9.1.4 Drug-drug interactions (including serious interactions with non-prescriptive or over-the-counter drugs);

19.9.1.5 Incorrect drug dosage or duration of drug treatment;

19.9.1.6 Drug-allergy interactions;

19.9.1.7 Clinical abuse or misuse.

19.9.2 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.

19.10 Patient counseling:

19.10.1 Patient counseling is the effective oral consultation by the pharmacist, in the exercise of his or her professional judgment and consistent with state statutes and Board rules regarding confidential information, with the patient or care giver, in order to improve therapy by ensuring the proper use of drugs and devices.

19.10.2 Upon receipt of a prescription drug order and following a review of the patient's record, a pharmacist may personally initiate discussion of matters which will enhance or optimize drug therapy with each patient or care giver of such patient. Such discussion shall be in person, whenever practicable, or by telephone and shall include appropriate elements of patient counseling. Such elements may include the following:

19.10.2.1 The name and description of the drug;

19.10.2.2 The dosage form, dose, route of administration, and duration of drug therapy;

19.10.2.3 Intended use of the drug and expected action;

19.10.2.4 Special directions and precautions for preparation, administration, and use by the patient;

19.10.2.5 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;

19.10.2.6 Techniques for self-monitoring drug therapy;

19.10.2.7 Proper storage;

19.10.2.8 Prescription refill information;

19.10.2.9 Action to be taken in the event of a missed dose; and

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

19.10.3 Alternative forms of patient information may be used to replace patient counseling in an emergency situation when verbal face-to-face counseling is not possible. Alternative forms of patient information may be used to supplement patient counseling when appropriate. Examples include written information leaflets, pictogram labels, video programs, etc.

19.10.4 A pharmacist providing telepharmacy services across state lines shall:

19.10.4.1 Identify himself or herself to patients as a "licensed pharmacist;"
and

19.10.4.2 Notify patients of the jurisdiction in which he or she is currently licensed to practice pharmacy.

19.10.4.3 The pharmacist shall provide patients with that jurisdiction's board of pharmacy address and phone number upon request.

19.10.5 Patient counseling, as described above and defined in these rules, shall not be required for inpatients of

a hospital or institution where other licensed health care professionals are authorized to administer the drug(s).

19.10.6 A pharmacist shall not be required to counsel a patient or care giver when the patient or care giver refuses such consultation and such refusal is documented.

19.11 Adverse drug reactions:

19.11.1 Unless already reported by the patient to the practitioner, significant adverse drug reactions shall be reported by the pharmacist to the practitioner and, in either case, an appropriate entry on the patient's record shall also be made.

19.12 Records of dispensing:

19.12.1 Records of dispensing for original and prescriptions for all drugs or devices are to be made and kept by pharmacies for three years in hard copy. Records of dispensing for refill prescriptions may be kept in either hard copy or electronic format. Records of dispensing for new and/or refill prescriptions shall include, but not be limited to:

- (A) Quantity dispensed for original and refills, if different from original;
- (B) Date of dispensing;
- (C) Serial number of prescription (or equivalent if an institution);
- (D) Identification of the pharmacist dispensing;
- (E) Name and manufacturer of drug dispensed if drug product selection occurs and more than a 24-hour supply is dispensed; and
- (F) records of refills to date.

19.12.2 A written perpetual inventory shall be maintained in hard copy for at least two years for all Schedule II drugs.

Section 20. Computer Systems For Data Processing

20.1 Computer systems for data processing may be used for record keeping in licensed pharmacies, if:

20.1.1 Patient records may be viewed at any time on the computer screen;

20.1.2 Patient records are available as printed documents;

20.1.3 Information in the computer is backed up at least once each business day;

20.1.4 An auxiliary record keeping system is established for use when the computer system is temporarily inoperable, and such records are entered into the system when operations are restored;

20.1.5 A backup copy must be kept off-site or in fire-proof storage;

20.1.6 A software provision must be implemented that will flag or otherwise warn of allergies or medication interactions.

20.1.7 Pharmacies accessing a common electronic file or database used to maintain required dispensing information are not required to transfer prescription drug orders or information for dispensing purposes between or among pharmacies participating in the same common prescription file. Provided, however, that any such common file shall contain complete records of each prescription drug order and refill dispensed and further, that a hard copy record of each prescription drug order accessed for purposes of refilling shall be generated and maintained at the pharmacy refilling the prescription drug order.

20.1.8 The computerized system shall have the capability of producing a printout of any prescription drug order data. The system shall provide a refill-by-refill audit trail for any specified strength and dosage form of any drug. Such an audit trail shall be by printout, and include the name of the prescribing practitioner, name and location of the patient, quantity dispensed on each refill, date of dispensing of each refill, name or identification code of the dispensing pharmacist, and unique identifier of the prescription drug order.

20.1.9 Any facility maintaining centralized prescription records shall be capable of sending a requested printout to the pharmacy within 72 hours.

20.1.10 The system shall have the capability of producing sight-readable information on all original and refill prescription drug orders. The term "sight-readable" means that an authorized individual shall be able to

examine the record and read the information from the cathode ray tube (CRT), microfiche, microfilm, printout, or other method acceptable to the Board.

- 20.1.11** The system shall provide on-line retrieval (via CRT or hard-copy printout) of original prescription drug order information. Such information shall include, but not be limited to, the prescription drug order requirements and records of dispensing as indicated in these rules.
- 20.2** The pharmacist responsible for dispensing shall:
 - 20.3.1** Provide a printout of each day's prescription drug order information. The printout shall be verified, dated, and signed in the same manner as signing a check or legal document (e.g., J.H. Smith or John H. Smith) by the individual pharmacist verifying that the information indicated is correct. Such printout shall be maintained three years from the date of last dispensing.
- 20.4** If an automated pharmacy system is used (for example, PYXIS) the pharmacist-manager shall have the sole responsibility to:
 - 20.4.1** Assign, discontinue, or change access to the system;
 - 20.4.2** Ensure that access to the medications comply with state and federal regulations;
 - 20.4.3** Ensure that the automated pharmacy system is filled and stocked accurately and in accordance with established, written policies and procedures.
- 20.5** The filling and stocking of all medications in the automated pharmacy system shall be accomplished by qualified personnel under the supervision of a licensed pharmacist.
- 20.6** A record of medications filled or stocked into an automated pharmacy system shall be maintained and shall include identification of the persons filling or stocking and checking for accuracy.
- 20.7** All containers of medications stored in the automated pharmacy system shall be packaged and labeled in accordance with federal and state laws and regulations.
- 20.8** All aspects of handling controlled substances shall meet the requirements of all state and federal laws and regulations.
- 20.9** The automated pharmacy system shall provide a mechanism for securing and accounting for all medications removed from and subsequently returned to the automated pharmacy system, all in accordance with existing state and federal law.
- 20.10** The automated pharmacy system shall provide a mechanism for securing and accounting for wasted medications or discarded medications in accordance with existing state and federal law.
- 20.11** To maintain the confidentiality of patient records, the system shall have adequate security and systems safeguards designed to prevent and detect unauthorized access, modification, or manipulation of patient records. Once the drug has been dispensed, any alterations in prescription drug order data shall be documented, including the identification of the pharmacist responsible for the alteration.
- 20.12** Automated pharmacy systems shall have adequate security systems and procedures, evidenced by written policies and procedures to:
 - 20.12.1** Prevent unauthorized access;
 - 20.12.2** Comply with federal and state regulations; and
 - 20.12.3** Maintain patient confidentiality.
- 20.13** Records and electronic data kept by the automated pharmacy system shall meet the following requirements:
 - 20.13.1** All events involving the contents of the automated pharmacy system must be recorded electronically.
 - 20.13.2** Records must be maintained by the pharmacy and must be readily available to the Board or its agent. Such records shall include:
 - (A) Identity of system accessed;
 - (B) Identification of the individual accessing the system;
 - (C) Type of transaction;
 - (D) Name, strength, dosage form, and quantity of the drug accessed;
 - (E) Name of the patient for whom the drug was ordered.

- 20.14** Access to and limits on access (e.g., security levels) to the automated pharmacy system must be defined by policy and procedures and must comply with state and federal regulations.
- 20.15** System backup (auxiliary records maintenance):
- 20.15.1** The auxiliary system shall be in place to provide for the maintenance of all necessary patient drug information (as outlined in this rule) until the automated system becomes operational. However, nothing in this section shall preclude the pharmacist from using professional judgment for the benefit of a patient's health and safety.
 - 20.15.2** When the automated system is restored to operation, the information regarding prescription drug orders dispensed and refilled during the inoperative period shall be entered into the automated system within 96 hours.
 - 20.15.3** Routine backup systems and procedures (hard copy, copy, disk, etc.) shall be in place and operational to ensure against loss of patient data.
 - 20.15.4** In the event that permanent dispensing information is lost due to unscheduled system interruption, the Board of Pharmacy shall be notified within 72 hours.

Section 21. Oral Communication of Prescriptions

- 21.1** Designated employees of practitioners qualified to prescribe drugs may transmit an order for a prescription via telephone. The practitioner shall be responsible for record keeping and the accuracy of the prescription information. Any new prescription drug order being transmitted by a practitioner or his or her agent by telephone must be received and noted by a pharmacist.

Section 22. Disposal of Controlled and Non-Controlled Substances

- 22.1** The Board accepts Drug Enforcement Administration (DEA) approved reverse distribution organizations. A list may be obtained by contacting Diversion at the regional DEA office in Boston, Massachusetts. Telephone 888-272-5174; fax 617-5572126. The DEA list is compiled from applications for registration and is amended periodically.

PART D. CONTINUING EDUCATION

Section 1. Definitions

- 1.1** ACPE: American Council on Pharmaceutical Education
- 1.2** AMA: American Medical Association
- 1.3** CEU: Continuing education unit; equivalent to 10 contact hours of participation in post-licensure education courses.
- 1.4** Live Programs (Didactic Sessions) : Covers all programs that provide for direct interaction between faculty and participants and may include lectures, symposia, live teleconferences, and workshops.

Section 2. Continuing Education Requirements

- 2.1** The licensee must complete at least 1.5 CEUs (15 hours), of which 0.5 CEUs (5 hours) shall be obtained during participation in a live program (didactic session), for each full year since the date the applicant's latest license was issued for a total of 3.0 CEUs (30 hours) per renewal period. Continuing education participation must be reported every two-year renewal period. For newly-licensed pharmacists, see Rule 5.1 below.
- 2.2** CEUs may not be transferred or carried over from one renewal period to another.
- 2.3** A licensee who fails to fulfill the continuing education requirements of these rules may be required by the Board to develop and complete a specific corrective action plan within 90 days, prior to license renewal.
- 2.4** Upon a showing a hardship, the Board may waive the continuing education requirement. To apply for a waiver, the licensee must submit a written statement setting forth the conditions of hardship with specificity. After review, the Board shall send written notification of its decision, and the reasons therefore, to the licensee.
- 2.5** A licensee residing in another jurisdiction who has met the continuing education requirements for the current biennial renewal period in that jurisdiction will be deemed by the Board to have met the continuing education requirements for

license renewal in Vermont.

Section 3. Topics and Formats of Study

- 3.1 Topics and formats of study shall include subject matter designed to maintain the professional competence of pharmacists licensed to practice and to improve their professional skills in order to protect the public health and safety.
- 3.2 Documentation of continuing education in Board-approved programs is required for license renewal. All ACPE and AMA Category I approved programs and programs approved by pharmacy boards in other states are approved by this Board and do not require advance approval. Organizations or licensees may have a program approved by submitting, in advance, the program outline, including learning objectives, and the names and qualifications of the presenters. After review, the Board shall send written notification of its decision to the organization or licensee.

Section 4. Verification of Continuing Education

- 4.1 Pharmacists shall provide the Board with verification of completion of the required continuing education programs by such means as designated by the Board. The Board may conduct random audits to verify completion of continuing education up to four years after a license is renewed. Upon request by the Board, the licensee shall submit certificates of completion for all programs listed in the licensee's renewal application.
- 4.2 All renewals of inactive or lapsed licenses shall be audited and shall be accompanied by documentation of continuing education. During each biennial renewal period, the Board may audit the continuing education activities of a random sample of pharmacists. Pharmacists shall submit for inspection the documents necessary to verify the reported continuing education.

Section 5. Newly Licensed Pharmacists

- 5.1 For applicants granted an initial license to practice by the Board, accumulation of CEUs shall commence on the opening date of the first biennial renewal period following grant of initial licensure.

PART E. PHARMACY INTERNS

Section 1. Definitions

- 1.1 **Internship:** 1500 hours practical experience. This may be fulfilled by postgraduate experience, supervised practice, and experience gained during participation in college-coordinated externship and clerkship programs.
- 1.2 **Supervised practice:** experience obtained during participation in Board-approved programs, as the sole intern under the direct supervision of a Board-approved preceptor. The programs shall be designed to give the participant experience in the type of setting in which the preceptor practices.
- 1.3 **Externship:** experience obtained during participation in college-supervised programs, under the supervision of a Board-approved preceptor. The programs must be conducted outside the classroom, in licensed pharmacies.
- 1.4 **Clinical clerkship or clerkship:** experience gained during participation in college-supervised programs which involve patient contact in either community or institutional settings. The programs must be designed with an emphasis on monitoring and evaluation of drug therapy. The clinical clerkship or clerkship must:
 - 1.4.1 Be conducted in patient care settings where the student is provided with actual experiences in patient care;
 - 1.4.2 Emphasize all phases of drug therapy relative to the disease states of individual patients;
 - 1.4.3 Involve provision of clinical services on either an outpatient or inpatient basis as a primary activity;
 - 1.4.4 Involve a minimal amount of drug distribution;
 - 1.4.5 Be approved by the state board of pharmacy where the pharmacy school is located; and
 - 1.4.6 Be a component of the college curriculum for which academic credit is given.
- 1.5 **Post-graduate internship:** experience obtained after graduation, under the supervision of a preceptor, to earn the required hours of internship for examination for licensure.
- 1.6 **Preceptor:** a licensed pharmacist, in good standing, with at least one year of experience in the actual practice of pharmacy, approved by the board of pharmacy in his or her state of licensure to supervise and direct the training of a pharmacy intern.

Section 2. Registration of Pharmacy Interns

- 2.1 Every individual shall be registered by the Board before beginning his or her internship in this State. Registration to practice pharmacy as an intern shall be granted only to individuals who have achieved at least third-year standing by completing the second year of the five-year or six-year pharmacy curriculum, or who have obtained Foreign Pharmacy Graduate Examination Committee (FPGEC) certification. The Board will approve all pharmacy schools or colleges accredited by the Canadian Council for Accreditation of Pharmacy Programs (CCAPP).
- 2.2 Forms required for proper registration of interns, along with instructions for their use, are available from the Board. Prior to beginning any period of internship in Vermont, a prospective intern shall submit, on official forms, the following information:
 - 2.2.1 The intern's name and address;
 - 2.2.2 The name and address of the pharmacy where the internship is being served;
 - 2.2.3 The name, address, and license number of each preceptor at the internship site; and
 - 2.2.4 A complete statement of the intern's qualifications, to be provided directly to the Board by the pharmacy school or college.

Section 3. Externship and Internship Program Requirements

- 3.1 Experience gained in externships and clinical clerkships may not exceed 1,000 hours.
- 3.2 At least 500 hours of internship experience must be outside the classroom in a setting in which the intern provides direct patient care services, as the sole intern under the direct supervision of a pharmacist.
- 3.3 Experience obtained in hospital or retail settings should include compounding, dispensing, inventorying prescription drugs, and maintaining prescription records.
- 3.4 With approval of the Board, the internship may also include experience obtained in one of the following:
 - 3.4.1 A demonstration project related to pharmacy;
 - 3.4.2 The pharmaceutical industry; or
 - 3.4.3 A program which will expose the intern to any area of health care where pharmacists have an impact.

Section 4. Internship Training and Practice Site Requirements

- 4.1 The pharmacy at which an intern is being trained shall provide an environment that is conducive to the learning of the practice of pharmacy by an intern. The pharmacy must:
 - 4.1.1 Conform to all standards set by governmental agencies;
 - 4.1.2 Provide a broad scope of pharmaceutical services;
 - 4.1.3 Provide for systematic rotation of interns through all general practice activities;
 - 4.1.4 Use a patient medication record system;
 - 4.1.5 Provide the opportunity for chart review in a practice setting in which charts are used;
 - 4.1.6 Maintain contact with other health professionals and, when possible, provide pharmaceutical services to institutionalized patients;
 - 4.1.7 Provide patient counseling services;
- 4.2 It is expected that the intern will be exposed to all facets of the practice of pharmacy, including but not limited to, the following:
 - 4.2.1 Evaluation of prescription drug orders;
 - 4.2.2 Preparation and labeling of drugs;
 - 4.2.3 Dispensing of drugs;
 - 4.2.4 Patient profile update and review;
 - 4.2.5 Drug use review;
 - 4.2.6 Patient counseling; and
 - 4.2.7 Proper and safe storage of drugs.

Section 5. Other Conditions Governing Internship

- 5.1 Interns enrolled in an approved pharmacy school may participate in cooperative plans or other suitable arrangements developed by the pharmacy school and approved by the Board. Internship programs in non-traditional practice sites

(e.g., industry-sponsored programs) must be approved by the Board prior to granting of internship credit.

- 5.2 Members of the armed forces who served under conditions fulfilling internship requirements may submit documentation for approval by the Board. Participation in activities equaling or exceeding Vermont internship requirements shall be recognized on an hour-for-hour basis.
- 5.3 The Board will give credit for out-of-state or Canadian internship experience upon presentation of an affidavit or certificate of approval indicating the internship was approved in the state or province where the experience was obtained. The intern shall abide by all the provisions of the internship rules in that state or province and shall provide evidence from that state's or province's board of pharmacy of the number of clock-hours of experience actually participated in by the intern.
- 5.4 All hours worked during participation in an approved internship shall be credited by the Board towards the 1500 required hours.
- 5.5 Students enrolled part-time in an approved pharmacy school shall be considered full-time for the purposes of these rules.

Section 6. Responsibilities of Intern

- 6.1 The intern shall be required to perform only those duties which are normally performed by the pharmacist.
- 6.2 The intern shall not be in charge of the pharmacy department at any time.
- 6.3 The intern shall notify the Board within two weeks of beginning practice as an intern, on a form provided by the Board, of the identity of the internship site and of the preceptor.
- 6.4 The intern shall be so designated in his or her professional relationships and shall in no manner falsely assume, directly or by inference, to be a pharmacist. The Board shall issue a confirmation letter to the intern for purposes of identification and verification of his or her role as an intern. An individual who is not properly registered with the Board as an intern shall not take, use, or exhibit the title of intern, or any other similar term.
- 6.5 All interns shall notify the Board immediately upon change of location, employment, preceptor, or residence address.
- 6.6 Applicants for licensure as pharmacists shall submit evidence on Board-approved forms that they have satisfactorily completed not less than 1500 hours of internship credit under the instruction and supervision of a preceptor.

Section 7. Responsibilities of Preceptor

- 7.1 The preceptor shall have been engaged in the practice of pharmacy for at least one year on a full-time basis immediately prior to serving as a preceptor and shall be licensed in good standing with the Board or with the board of pharmacy in the state where the internship site is located.
- 7.2 The preceptor shall have the primary responsibility for the training of the intern.
- 7.3 The preceptor may allow others under his or her direct supervision to aid in the training process. An intern shall be allowed to engage in the practice of pharmacy provided that such activities are under the direct supervision of a pharmacist. A pharmacist shall be in continuous personal contact with and actually giving instructions to the intern during all professional activities throughout the entire internship period. The pharmacist shall physically review the prescription drug order and the dispensed product before the product is delivered to the patient or the patient's agent. The pharmacist is responsible for the work of the intern.
- 7.4 The preceptor shall submit, on approved forms, such information as the Board requires.
- 7.5 A preceptor shall not manage the training of more than two interns.

PART F. INSTITUTIONAL PHARMACY

Section 1. Applicability

- 1.1 The following rules are applicable to all institutions and institutional pharmacies as defined below. In addition, all relevant sections of the rules for PHARMACEUTICAL CARE apply to institutional pharmacies that are engaged in filling prescriptions for employees or outpatients.

Section 2. Definitions

- 2.1** “Institutional facility” means any organization whose primary purpose is to provide a physical environment for patients to obtain health care services, including but not limited to a(n):
- 2.1.1** Hospital;
 - 2.1.2** Convalescent home;
 - 2.1.3** Nursing home;
 - 2.1.4** Extended or long-term care facility;
 - 2.1.5** Mental health facility;
 - 2.1.6** Rehabilitation center;
 - 2.1.7** Psychiatric center;
 - 2.1.8** Developmental disability center;
 - 2.1.9** Drug abuse treatment center;
 - 2.1.10** Family planning clinic;
 - 2.1.11** Penal institution or correctional facility;
 - 2.1.12** Hospice;
 - 2.1.13** Public health facility;
 - 2.1.14** Athletic facility;
 - 2.1.15** Residential care home;
 - 2.1.16** Physician’s office.
- 2.2** “Institutional pharmacy” means that physical portion of an institutional facility where drugs, devices, and other materials used in the diagnosis and treatment of injury, illness, and disease (hereinafter referred to as “drugs”) are dispensed, compounded, and distributed and pharmaceutical care is provided, and which is licensed by the Board.

Section 3. Personnel

- 3.1** Each institutional pharmacy shall be directed by a pharmacist, hereinafter referred to as the pharmacist-manager, who is licensed to engage in the practice of pharmacy in Vermont.
- 3.2** The institutional pharmacy shall;
- 3.2.1** Be under the direct supervision of a full-time pharmacist-manager;
 - 3.2.2** Employ support personnel to perform technical and secretarial duties appropriate to their training and skill level;
 - 3.2.3** Employ licensed pharmacists as needed to adequately direct and supervise the work of support personnel.

Section 4. Responsibilities of the Pharmacist-Manager

- 4.1** The pharmacist-manager shall be responsible for:
- 4.1.1** The safe and efficient distribution and control of all pharmaceutical products;
 - 4.1.2** Preparation, sterilization, and admixture of parenteral medications;
 - 4.1.3** Inservice education of nursing personnel about incompatibility of parenteral admixtures;
 - 4.1.4** Compounding within the institutional pharmacy;
 - 4.1.5** Participation in developing a formulary for the institution;
 - 4.1.6** Correct filling and labeling of containers;
 - 4.1.7** Supply and inventory of emergency antidote drugs, if not kept in the emergency room;
 - 4.1.8** Record keeping;
 - 4.1.9** Participation in the institution’s patient care evaluation program;
 - 4.1.10** Cooperation with teaching and research programs in the institution;
 - 4.1.11** Implementation of the institution’s policies and procedures;
 - 4.1.12** Efficient and effective messenger and delivery service within the institution;
 - 4.1.13** Setting quality assurance standards;
 - 4.1.14** Development and implementation of written policies and procedures;
 - 4.1.15** Inspections of medication storage areas.
- 4.2** The pharmacist-manager shall develop and implement written policies and procedures for the safe and efficient distribution of drugs and for the provision of pharmaceutical care. An annual updated copy of such procedures shall be on hand for inspection by the Board. Written policies and procedures shall include:
- 4.2.1** Duties of support personnel;
 - 4.2.2** Night cabinets;

- 4.2.3 Emergency drug kits;
- 4.2.4 Distribution of pharmaceutical products;
- 4.2.5 Disposition of adulterated, misbranded or discontinued drugs;
- 4.2.6 Recall of drugs;
- 4.2.7 Storing and returning drugs brought into the institution by patients.

Section 5. Absence of Pharmacist

- 5.1 During such times as an institutional pharmacy may be unattended by a pharmacist, arrangements shall be made in advance by the pharmacist-manager for provision of drugs to the medical staff and other authorized personnel of the institutional facility by use of night cabinets and, in emergency circumstances, by access to the pharmacy. A pharmacist must be “on call” during all absences.

- 5.2 In the absence of a pharmacist, drugs for distribution to patients shall be stored in a locked cabinet (“night cabinet”) or other enclosure constructed and located outside of the pharmacy area, to which only specifically authorized personnel may obtain access by key or combination, and which is sufficiently secure to deny access to unauthorized persons. The pharmacist-manager shall, in conjunction with the appropriate committee of the institutional facility, develop inventory listings of those drugs to be included in the night cabinet(s) and determine who may have access, and shall insure that:
 - 5.2.1 Drugs are properly labeled;
 - 5.2.2 Only prepackaged drugs are available, in amounts sufficient for immediate therapeutic requirements;
 - 5.2.3 Whenever access to the cabinet occurs, date and time of access, written practitioner’s orders and proofs-of-use are provided;
 - 5.2.4 All drugs in the night cabinet are inventoried by a pharmacist or designee no less than once per week;
 - 5.2.5 A pharmacist reviews all medication orders for drugs removed from the night cabinet within 24 hours of their removal;
 - 5.2.6 A complete audit of all activity concerning the night cabinet is conducted no less than once per month; and
 - 5.2.7 Written policies and procedures are established to implement the requirements of this section.

Section 6. Access to Pharmacy During Emergency

- 6.1 The institutional pharmacy shall be secure from access by unauthorized persons at all times. Whenever any drug is not available from floor supplies or night cabinets, and the drug is required to treat the immediate needs of a patient whose health would otherwise be jeopardized, the drug may be obtained from the pharmacy in accordance with the requirements of this section.

- 6.2 One supervisory nurse in any given eight-hour shift is responsible for obtaining drugs from the pharmacy. The responsible nurse shall be designated in writing by the appropriate committee of the institutional facility. Removal of any drug from the pharmacy by an authorized nurse must be recorded on a suitable form showing patient name, room number, name of drug, strength, amount, date and time of removal, and signature of nurse. Doses should be in unit-of-use (unit-dose) packaging whenever possible. The form shall be left in the institutional pharmacy with the container from which the drug was removed, as notice to the next pharmacist on duty.

Section 7. Emergency Kits

- 7.1 For an institutional facility that does not have an institutional pharmacy, drugs may be provided for use by authorized personnel by means of emergency kits located at the institutional facility, provided that such kits meet the following requirements:
 - 7.1.1 Emergency kit drugs are those drugs which may be required to meet the immediate therapeutic needs of patients and which are not available from any other authorized source in sufficient time to prevent risk of harm to patients by delay resulting from obtaining such drugs from other authorized sources;
 - 7.1.2 All drugs are properly labeled;
 - 7.1.3 All emergency kit drugs are equipped with a breakable seal, are sealed by a pharmacist, and are secure from access by unauthorized personnel;
 - 7.1.4 The supplying pharmacist, nursing staff, and the medical staff of the institutional facility shall jointly determine the drugs, by identity and quantity, to be included in emergency kits;
 - 7.1.5 Emergency kits shall be stored in secured areas to prevent unauthorized access and to ensure a proper

environment for preservation of drugs in the kits;

7.1.6 The exterior of each emergency kit shall be labeled so as to clearly indicate that it is an emergency drug kit and that it is for use in emergencies only. The label shall contain a listing of the drugs contained in the kit, including name, strength, quantity, expiration date and lot number of the contents, and the name, address(es) and telephone number(s) of the supplying pharmacist;

7.1.7 Drugs shall be removed from emergency kits pursuant to a valid prescription drug order only;

7.1.8 Whenever an emergency kit is opened, the supplying pharmacist shall be notified within 24 hours and the pharmacist shall restock and reseal the kit within a reasonable time so as to prevent risk of harm to patients;

7.1.9 The expiration date of an emergency kit shall be the earliest date of expiration of any drug supplied in the kit. Upon the occurrence of the expiration date, the supplying pharmacist shall replace the expired drug;

7.1.10 The pharmacist and medical staff shall develop and implement written policies and procedures for using emergency drug kits.

7.2 Emergency kits in non-federal registered long-term care facilities (LTCF):

7.2.1 An LTCF may obtain controlled substances for emergency kits from a DEA-registered hospital, clinic, pharmacy, or practitioner.

7.2.2 An LTCF must have security safeguards for each emergency kit stored in the LTCF which include the designation of individuals who may have access to the emergency kits and a specific limitation of the type and quantity of controlled substances permitted to be placed in each emergency kit.

7.2.3 The LTCF and the providing registered DEA hospital, clinic, pharmacy, or practitioner must maintain complete and accurate records of the controlled substances placed in the emergency kits and the disposition of these controlled substances, and must take periodic physical inventories.

7.2.4 Controlled substances in emergency kits may be administered to patients in an LCTF only by personnel expressly authorized by an individual practitioner and in compliance with federal regulations on controlled substances.

7.2.5 Violation of these rules may result in disciplinary action by the Board or any other appropriate federal or state licensing authority.

Section 8. Physical Requirements

8.1 The institutional pharmacy shall meet the same standards as a retail drug outlet.

8.2 Prescription area:

8.2.1 The pharmacist-manager, or the pharmacist delegated by him or her, shall have 24 hour access to the institutional pharmacy. The prescription area shall be large enough to properly store and prepare a prescription. The Board recommends 200 square feet.

8.2.2 If the institutional facility is open at times when the institutional pharmacy is closed, the prescription area must be permanently enclosed by a partition or Board-approved barrier device at least nine feet six inches in height, except where the ceiling is less than nine feet six inches, in which case the partition or Board-approved barrier device shall be from floor to ceiling.

8.2.3 The institutional pharmacy must be secure from access when the institutional facility is closed and secure from access by the public at all times. Only support personnel directly involved in the prescription dispensing process and non-pharmacist management shall be allowed entry into the institutional pharmacy and then only when a pharmacist is present in the institution.

8.2.4 The institutional pharmacy must contain a counter 12 feet in length and two feet in width. If two or more pharmacists are on duty at the same time, the counter shall be four feet longer for each additional pharmacist. The prescription counter shall be kept free of any items not being used in the practice of pharmacy. No television monitors shall be located in the institutional pharmacy, and no such equipment shall be placed so as

to distract the pharmacist from the practice of pharmacy. The aisle space behind the prescription counter shall be wide enough to allow free movement and shall be kept free of obstructions. The institutional pharmacy shall have a sink of appropriate size, exclusive of drainboard area, necessary to fulfill the needs of the pharmacy. The sink shall be connected to hot and cold running water and shall have a working drain.

8.3 Hygiene standards:

8.3.1 The institutional pharmacy shall:

- 8.3.1.1** Comply with all federal, state, and local health laws;
- 8.3.1.2** Have walls, ceilings, windows, and floors kept clean and in good repair;
- 8.3.1.3** Have waste receptacles located in convenient areas;
- 8.3.1.4** Have equipment kept clean and stored in an orderly manner;
- 8.3.1.5** Be well lighted;
- 8.3.1.6** Be dry and well ventilated;
- 8.3.1.7** Have adequate restroom facilities for employees.

Section 9. Equipment

9.1 The following equipment and miscellaneous supplies shall be provided:

- 9.1.1** One class A prescription balance with weights or automatic sensitivity requirement of six mg. with no load;
- 9.1.2** One set of metric weights from 10 milligrams to 50 grams;
- 9.1.3** A refrigerator with a temperature control and thermometer;
- 9.1.4** Distilled and/or sterile water;
- 9.1.5** An automated data processing system;
- 9.1.6** At least one telephone in the prescription area, with the same number as the telephone number printed on the drug outlet prescription labels;
- 9.1.7** A tablet and capsule counting tray;
- 9.1.8** Containers which meet official compendia standards, available with closures that meet Federal Poison Prevention Packaging Act of 1970 requirements, as well as regular closures;
- 9.1.9** Prescription labels imprinted or computer-generated with the name, address, and telephone number of the institutional pharmacy that do not contain any symbol or background logo that interferes with the reading and interpretation of any information written by the pharmacist on the label;
- 9.1.10** Auxiliary labels;
- 9.1.11** Prescription filing devices for record keeping;
- 9.1.12** Sufficient equipment, graduates, mortars, funnels, etc., to maintain the scope of practice;
- 9.1.13** A current copy of the Vermont Pharmacy Laws and Rules and Regulations;
- 9.1.14** Any institutional pharmacy involved in the preparation of sterile pharmaceutical must meet the requirements of the STERILE PHARMACEUTICALS provisions of these rules.
- 9.1.15** Each pharmacy shall maintain on file at least one reference in each of the following categories. Computerized, on-line versions are acceptable instead of a hard copy of the current manual. Whether in hard copy or computerized, this reference work must be complete and must include an explanation of drug interactions, either in the form of a manual or otherwise:
 - 9.1.15.1** State and federal drug laws relating to the practice of pharmacy, including a current copy of these statutes and rules, and the legal distribution of drugs and any rules or regulations adopted pursuant thereto;
 - 9.1.15.2** Current manual of drug interactions equivalent to Hansten's or Drug Facts, with quarterly updates, which has been pre-approved by the Board.
 - 9.1.15.3** Current Facts and Comparisons, with monthly updates;
 - 9.1.15.4** Current reference on pediatric dosages;
 - 9.1.15.5** IV admixture compatibility reference (such as King's Guide to Parenteral Admixtures);
 - 9.1.15.6** Injectable Drug Handbook (ASHP);
 - 9.1.15.7** American Hospital Formulary Service Drug Information text.

Section 10. Storage

10.1 All drugs shall be stored in designated areas within the institutional pharmacy, at temperatures recommended by the U.S. Pharmacopoeia.

Section 11. Security

11.1 The institutional pharmacy shall be locked by key or combination when unattended.

Section 12. Labeling

12.1 All drugs dispensed for use within the institution shall:

12.1.1 Be in appropriate containers;

12.1.2 Be labeled with the patient's name, patient's location, brand or generic name, strength, quantity of drug, and expiration date.

12.2 All drugs dispensed for use outside the institution shall comply with standards set for a retail drug outlet.

12.3 All drugs shall be in unit dose packaging specifying drug name, strength, and expiration date. Either the drug manufacturer and lot number must be labeled on the package, or there must be a system that allows for retrieval of such information.

Section 13. Discontinued Drugs

13.1 All discontinued, outdated, or misbranded drugs shall be returned to the institutional pharmacy and properly disposed of by the pharmacist manager or his or her authorized designee.

Section 14. Physician's Orders

14.1 Drugs may be dispensed from the institutional pharmacy if:

14.1.1 Ordered by an authorized practitioner;

14.1.2 The drug order includes the name and location of the patient, name and dosage of the drug, directions for use, date of order, and signature of the physician or his or her authorized designee;

14.1.3 Telephone or verbal orders are transcribed into the patient record and noted as a telephone or verbal order. Telephone or verbal orders shall be countersigned by the prescribing physician within 30 days. The authority to receive telephone or verbal orders must be officially granted in the institutions's rules and regulations or medical staff bylaws.

14.1.4 All abbreviations and symbols used in written orders are approved for use by the institution.

14.1.5 Pharmacists may adjust medication doses if the order is part of a medication or dosing protocol that has been approved by the medical staff of the institution. This section should not be construed as giving prescribing privileges to pharmacists.

14.2 Prescription orders issued by an authorized practitioner may be telephoned to a retail drug outlet by a nurse licensed by the Vermont Board of Nursing.

Section 15. Controlled Drug Accountability

15.1 The following information must be recorded each time a controlled drug is administered;

15.1.1 Name of drug;

15.1.2 Dosage;

15.1.3 Name of patient;

15.1.4 Date and time the drug was administered;

15.1.5 Name of person administering the drug;

15.1.6 Name of prescriber.

Section 16. Recall

16.1 All drugs and pharmaceutical devices shall be retrieved from within the institution for safe and proper disposal in the institutional pharmacy.

Section 17. Adverse Drug Reactions

17.1 All adverse drug reactions shall be reported to the patient's physician and documented in the patient chart and may

also be entered into the patient profile.

Section 18. Medications Brought Into the Institution By Patients

18.1 Drugs brought into an institutional facility by a patient shall not be administered unless they can be identified and the quality of the drug assured. If such drugs are not to be administered, then the pharmacist manager shall, according to procedures specified in writing, have them turned in to the pharmacy, which shall package and seal them and return them to an adult member of the patient's immediate family, or store and return them to the patient upon discharge.

Section 19. Investigational Drugs

- 19.1** Investigational drugs shall be stored in and dispensed from the pharmacy only. Investigational drugs may be administered if:
- 19.1.1** Prior approval of the protocol has been granted by the institution's investigational drug review board or committee;
 - 19.1.2** Informed consent to treatment with these drugs has been given in writing by the patient or authorized representative;
 - 19.1.3** Administered under the direct and personal supervision of the principal physician-investigator, or his or her authorized clinician, or a nurse educated and trained in administration of investigational drugs;
 - 19.1.4** All essential information pertaining to the investigational drug is maintained, stored, updated, and dispensed by the institutional pharmacy;
 - 19.1.5** The institution participating in investigational studies assures that such studies contain adequate safeguards for the patient, the institution, and the scientific integrity of the study;
 - 19.1.6** The institution participating in investigational studies has written policies and procedures for the approval, management, and control of these studies;
 - 19.1.7** The pharmacist is responsible to the institution and to the principal investigator for seeing that procedures for the control of investigational drug use are developed and maintained.

Section 20. Records and Reports

- 20.1** The following records and reports shall be kept on file for three years and submitted to the Board upon request:
- 20.1.1** The practitioner's orders, or direct copies. The ability to retrieve these orders from a patient's medical record is acceptable;
 - 20.1.2** Records of medications dispensed;
 - 20.1.3** Reports of suspected adverse drug reactions;
 - 20.1.4** Inventories of night cabinets, emergency kits, the institutional pharmacy, and controlled substances;
 - 20.1.5** Alcohol and flammables reports;
 - 20.1.6** Authorized removal of drugs from the institutional pharmacy by a nurse.

Section 21. Inspection of Medication Areas

- 21.1** Every month, the pharmacist manager or his or her qualified designee shall inspect all matters for which he or she is responsible, to verify compliance with these rules, and document the following:
- 21.1.1** Drugs are dispensed only under the direct supervision of a licensed pharmacist;
 - 21.1.2** Support personnel are properly directed and supervised;
 - 21.1.3** Disinfectants and drugs for external use are stored separately from drugs for internal or injectable use;
 - 21.1.4** Compliance with all special storage conditions for each drug;
 - 21.1.5** Outdated drugs are not stocked in the institution or the institutional pharmacy;
 - 21.1.6** Distribution and administration of controlled substances are adequately documented by pharmacy, medical, and nursing personnel;
 - 21.1.7** There is an adequate supply of emergency drugs;
 - 21.1.8** All security and storage standards are met;
 - 21.1.9** Metric-apothecary weight and measure conversion tables and charts are reasonably available to all medical and nursing personnel;
 - 21.1.10** Compliance with policies and procedures pertaining to the pharmacy.

PART G. STERILE PHARMACEUTICALS

Section 1. Purpose and Scope

- 1.1 The purpose of this section is to assure positive patient outcomes through the provision of standards for (1) pharmaceutical care, (2) the preparation, labeling, and distribution of sterile pharmaceuticals by pharmacies, pursuant to or in anticipation of a prescription drug order, and (3) product quality and characteristics, such as sterility and potency, that would be associated with environmental quality, preparation activities, and checks and tests carried out in the pharmacy.
- 1.2 These standards are intended to apply to all sterile pharmaceuticals, notwithstanding the location of the patient (e.g., home, hospital, nursing home, hospice, doctor's office). All requirements of this rule shall apply to any pharmacy engaged in the preparation of sterile pharmaceutical products.

Section 2. Definitions

- 2.1 "Biological safety cabinet" means a containment unit suitable for the preparation of low to moderate risk agents where there is a need for protection of the product, personnel, and environment, according to National Sanitation Foundation (NSF) Standard 49.
- 2.2 "Class 100 environment" means an atmospheric environment which contains less than 100 particles 0.5 microns in diameter per cubic foot of air, according to Federal Standard 209E.
- 2.3 "Cytotoxic" means a pharmaceutical that has the capability of killing living cells.
- 2.4 "Enteral" means within or by way of the intestine.
- 2.5 "Parenteral" means a sterile preparation of drugs for injection through one or more layers of the skin.
- 2.6 "Positive patient outcomes" include the cure or prevention of disease, elimination or reduction of a patient's symptoms, or arresting or slowing of a disease process so as to improve the patient's quality of life.
- 2.7 "Product quality and characteristics" include: sterility, potency associated with environmental quality, preparation activities, and checks and tests.
- 2.8 "Sterile pharmaceutical" means any dosage form devoid of viable microorganisms, including, but not limited to, parenterals, injectables, and ophthalmics.

Section 3. Policy and Procedure Manual

- 3.1 A policy and procedure manual shall be prepared and maintained for the compounding, dispensing, delivery, administration, storage, and use of sterile pharmaceutical prescription drug orders.
- 3.2 The policy and procedure manual shall include a quality assurance program for the purpose of monitoring patient care and pharmaceutical care outcomes, adverse drug reactions, personnel qualifications, training and performance, product integrity, equipment, facilities, infection control, and guidelines regarding patient education.
- 3.3 The policy and procedure manual shall be current and available for inspection by a Board-designated agent.

Section 4. Physical Requirements

- 4.1 The pharmacy shall have a designated area with entry restricted to designated personnel for preparing parenteral products. This area shall be structurally isolated from other areas with restricted entry or access and must be designed to avoid unnecessary traffic and airflow disturbances from activity within the controlled facility. It shall be used only for the preparation of these specialty products. It shall be of sufficient size to accommodate a laminar airflow hood and to provide for the proper storage of drugs and supplies under appropriate conditions of temperature, light, moisture, sanitation, ventilation, and security.
- 4.2 The pharmacy preparing parental products shall have:
- 4.2.1 Appropriate environmental control devices capable of maintaining at least Class 100 conditions in the workplace where critical objects are exposed and critical activities are performed; furthermore, these devices are capable of maintaining Class 100 conditions during normal activity. Examples of appropriate devices include laminar airflow hoods and zonal laminar flow of high efficiency particulate air (HEPA) filtered air;
- 4.2.2 Appropriate disposal containers for used needles, syringes, etc., and if applicable, for cytotoxic waste from the preparation of chemotherapy agents and infectious wastes from patients' homes;

- 4.2.3 When cytotoxic drug products are prepared, appropriate environmental control also includes appropriate biohazard cabinetry;
- 4.2.4 Temperature-controlled delivery container if products are to be stored unrefrigerated for more than two hours;
- 4.2.5 Infusion devices, if appropriate.
- 4.3 The pharmacy shall maintain supplies adequate to maintain an environment suitable for the aseptic preparation of sterile products.
- 4.4 The pharmacy shall maintain on file at least one current reference related to preparation of sterile products, equivalent to Trissel's or King's.

Section 5. Records and Reports

- 5.1 In addition to standard record and reporting requirements, the following additional records and reports must be maintained for sterile pharmaceuticals:
 - 5.1.1 A policy and procedure manual, including policies and procedures for cytotoxic or infectious waste, or both, if applicable, and
 - 5.1.2 Lot numbers of the components used in compounding sterile prescriptions, except for preparations made for a specific patient and which will be used within 30 days.

Section 6. Delivery Service

- 6.1 The pharmacist manager shall assure the environmental control of all products shipped. Any compounded, sterile pharmaceutical must be shipped or delivered to a patient in appropriate temperature-controlled (as defined by USP Standards) delivery containers and stored appropriately in the patient's home.

Section 7. Disposal of Cytotoxic or Hazardous Wastes

- 7.1 The pharmacist manager is responsible for assuring that there is a system for the disposal of cytotoxic or infectious waste in a manner so as not to endanger the public health.

Section 8. Emergency Kit

- 8.1 When sterile pharmaceuticals are provided to home care patients, the dispensing pharmacy may supply the nurse or patient with emergency drugs, if the physician has authorized the use of these drugs by a protocol, in an emergency situation (e.g., anaphylactic shock).

Section 9. Cytotoxic Drugs

- 9.1 In addition to the minimum requirements for a pharmacy established by rules of the Board, the following requirements are necessary for those pharmacies that prepare cytotoxic drugs to insure the protection of the personnel involved:
 - 9.1.1 All cytotoxic drugs should be compounded in a vertical flow, Class II, biological safety cabinet. Other products should not be compounded in this cabinet.
 - 9.1.2 Protective apparel shall be worn by personnel compounding cytotoxic drugs. This shall include disposable masks, gloves, and gowns with tight cuffs.
 - 9.1.3 Appropriate safety and containment techniques for compounding cytotoxic drugs shall be used in conjunction with the aseptic techniques required for preparing sterile products.
 - 9.1.4 Disposal of cytotoxic waste shall comply with all applicable local, state, and federal requirements.
 - 9.1.5 Written procedures for handling both major and minor spills of cytotoxic agents must be developed and must be included in the policy and procedure manual.
 - 9.1.6 Prepared doses of cytotoxic drugs must be dispensed, labeled with proper precautions inside and outside, and shipped in a manner to minimize the risk of accidental rupture of the primary container.

Section 10. Patient Education and Training

- 10.1 If appropriate, the pharmacist must document the patient's training and competency in managing this type of therapy provided by the pharmacist to the patient in the home environment. A pharmacist must be involved in the patient training process in any area that relates to drug compounding, labeling, administration, storage, stability, compatibility, or disposal. The pharmacist must be responsible for seeing that the patient's competency in the above

area is reassessed on an ongoing basis.

Section 11. Quality Assurance for Compounding and Preparation of Sterile Pharmaceuticals

- 11.1 There shall be a documented, ongoing quality assurance control program that monitors personnel performance, equipment, and facilities. Appropriate samples of finished products shall be examined to assure that the pharmacy is capable of consistently preparing sterile pharmaceuticals meeting specifications.
- 11.2 All clean rooms and laminar flow hoods shall be certified by an independent contractor according to Federal Standard 209E, or National Sanitation Foundation Standard 49 for operational efficiency at least every six months. Appropriate records shall be maintained.
- 11.3 There shall be written procedures developed requiring sampling if microbial contamination is suspected.
- 11.4 If bulk compounding of parenteral solutions is performed using non-sterile chemicals, extensive end-product testing must be documented prior to the release of the product from quarantine. This process must include appropriate tests for particulate matter and testing for pyrogens.
- 11.5 There shall be written justification of the chosen beyond-use dates for compounded products.
- 11.6 There shall be documentation of quality assurance audits at regular, planned intervals, including infection control and sterile technique audits.

Section 12. Pharmaceutical Care Outcomes

- 12.1 There shall be a documented, ongoing quality assurance control program that monitors patient care and pharmaceutical care outcomes, including but not limited to the following:
 - 12.1.1 Routine performance of prospective drug use review and patient monitoring functions by a pharmacist;
 - 12.1.2 Patient monitoring plans that include written outcome measures and systems for routing patient assessment (examples include infection rates, rehospitalization rates, and the incidence of adverse drug reactions);
 - 12.1.3 Documentation of patient training as specified in Section 10 above; and
 - 12.1.4 Appropriate collaboration with other health care professionals.

PART H. NUCLEAR/RADIOLOGIC PHARMACY

Section 1. Purpose and Scope

- 1.1 The practice of nuclear/radiologic pharmacy is a specialty of pharmacy practice regulated by the Board. 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.

Section 2. Definitions

- 2.1 “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.
- 2.2 “Internal test assessment” means, but is not limited to, conducting those tests of quality assurance necessary to ensure the integrity of the test.
- 2.3 “Nuclear pharmacy” means a pharmacy providing radiopharmaceutical services or, as provided in Section 3 below, the appropriate area of any institutional facility.
- 2.4 “Qualified licensed professional” means a non-pharmacist individual (such as a physician, nurse, or technologist) who possesses a current state license, if applicable, and who has sufficient training and experience to safely handle and dispense radiopharmaceuticals as defined by the Board.
- 2.5 “Qualified nuclear pharmacist” means a currently licensed pharmacist in Vermont who is certified as a nuclear pharmacist by a certification board recognized by the Board, or who meets the following standards:
 - 2.5.1 Minimum standards of training for “authorized user status” of radioactive material, as defined by the Vermont Department of Health (VDH).
 - 2.5.2 Completed a minimum of 200 contact hours of instruction in nuclear pharmacy and the safe handling and use of radioactive materials from a program approved by the Board, with emphasis on the following areas:

- 2.5.2.1 Radiation physics and instrumentation;
- 2.5.2.2 Radiation protection;
- 2.5.2.3 Mathematics of radioactivity;
- 2.5.2.4 Radiation biology; and
- 2.5.2.5 Radiopharmaceutical chemistry.

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

- 2.6 “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.
- 2.7 “Radiopharmaceutical service” means, but shall not be limited to, the procurement, storage, handling, preparation, labeling, quality assurance testing, dispensing, delivery, record keeping, and disposal of radiopharmaceuticals and other drugs.
- 2.8 “Radiopharmaceuticals” are radioactive drugs as defined by the FDA.

Section 3. General Requirements for Pharmacies Providing Radiopharmaceutical Services

- 3.1 A license to operate a pharmacy providing radiopharmaceutical services shall be issued only 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. In emergency situations when a qualified nuclear pharmacist is not present, designated qualified licensed professionals may have access to the licensed area. These individuals may prepare single doses of radiopharmaceuticals for the immediate emergency, and must document such activities.
- 3.2 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 Vermont or as otherwise defined by the Board.
- 3.3 The nuclear pharmacy area shall be secured from unauthorized personnel.
- 3.4 Nuclear pharmacies shall maintain records of acquisition, inventory, and disposition of all radioactive drugs and other radioactive materials in accordance with the requirements of the Vermont Department of Health.
- 3.5 All pharmacies handling radiopharmaceuticals shall provide a radioactive storage and product decay area. Detailed floor plans shall be submitted to the Board and the Vermont Department of Health before approval of the certification to practice nuclear pharmacy.
- 3.6 Radiopharmaceuticals are to be dispensed only upon a prescription drug order from a practitioner authorized to possess, use, and administer radiopharmaceuticals.
- 3.7 The permit to operate a nuclear pharmacy is conditioned upon an approved Vermont Department of Health (VDH) or Nuclear Regulatory Commission (NRC) license. Copies of the VDH or NRC inspection reports shall be made available upon request for Board inspection.

Section 4. Other Requirements

- 4.1 All nuclear/radiologic pharmacies shall also adhere to the rules for pharmaceutical care as they pertain to the practice of nuclear pharmacy.

PART I. UNPROFESSIONAL CONDUCT

Section 1. Definitions

- 1.1 The Board may take disciplinary action against a licensee or applicant for any of the grounds of unprofessional conduct set forth in 26 V.S.A. § 2051 or in 3 V.S.A. § 129a. As used in § 2051(1), “unprofessional conduct” means:

- 1.1.1 Giving or receiving improper assistance in connection with any part of the examinations for licensure.
- 1.1.2 Failing to provide, or false documentation of, continuing education.
- 1.1.3 False affirmation of any information provided to the Board.
- 1.1.4 Participating in, or agreeing to, activities whereby prescription orders, or prescription drugs and devices may be regularly delivered, or received, or solicited, or accepted by or to any non-licensed person.
- 1.1.5 Providing prescription pads or blanks inscribed with the pharmacist's name, or the name and address of the drug outlet, for office use by a practitioner.

- 1.1.6 Any disciplinary action in any jurisdiction by a licensing authority regulating the practice of a health-related profession.
- 1.1.7 Dealing with drugs or devices that the licensee knows or should know are stolen drugs or devices or that the licensee knows or should know were obtained through distribution channels that do not comply with licensing requirements.
- 1.1.8 Attempting to circumvent the patient counseling requirements, or discouraging the patient from receiving patient counseling concerning his or her prescription drug order.

- 1.1.9 Divulging or revealing to unauthorized persons patient or practitioner information or the nature of professional pharmacy services rendered without the patient's express consent, or without order or direction of a court. The following are considered authorized persons:
 - 1.1.9.1 Patient or patient's agent, or another pharmacist acting on behalf of a patient;
 - 1.1.9.2 Practitioner who issued the prescription drug order;
 - 1.1.9.3 Certified or licensed health care personnel who are responsible for the care of the patient;
 - 1.1.9.4 A member, inspector, agent, or investigator of the Board or any federal, state, county, or municipal officer whose duty is to enforce the laws of this State or the United States relating to drugs or devices or both and who is engaged in a specific investigation involving a designated person or drug; and
 - 1.1.9.5 An agency of government charged with the responsibility of providing medical care for the patient, upon a written request by an authorized representative of the agency requesting such information.

- 1.1.10 Selling, giving away, or otherwise disposing of accessories, chemicals, or drugs or devices found in illegal drug traffic when the pharmacist knows or should have known of their intended use in illegal activities.

- 1.1.11 Selling a drug for which a prescription drug order from a practitioner is required, without having received a prescription drug order for the drug.

- 1.1.12 Willfully and knowingly failing to maintain complete and accurate records of all drugs received, dispensed, or disposed or in compliance with the federal laws and regulations and state laws and rules.

- 1.1.13 Obtaining any remuneration by fraud, misrepresentation, or deception, including but not limited to, receiving remuneration for amending or modifying, or attempting to amend or modify, a patient's pharmaceutical care, absent a clear benefit to the patient, solely in response to promotion or marketing activities.

Section 2. Initiating a Complaint

- 2.1 Anyone wishing to make a complaint of unprofessional conduct against a licensed professional should file a written complaint with the Office of the Secretary of State, Office of Professional Regulation, 26 Terrace Street, Montpelier, Vermont, or mail it to the Office at Drawer 09, Montpelier, Vermont 05609-1106. The telephone number is (802) 828-2363. A complaint form may also be accessed via the Office Web site at <http://www.vtprofessionals.org>.

- 2.2 The Board may decide on its own to open an investigation without receiving a complaint. Possible sources of information include articles or advertisements in newspapers, periodicals, or directories, or written information from staff investigators or Board members.

- 2.3 The Board follows the current complaint procedure recommended by the Office of Professional Regulation. A copy of the procedure and more information about the complaint process can be obtained from the Office.

Section 3. Confidentiality and Appeals

- 3.1** All complaints and investigations shall remain confidential until disciplinary action is commenced. Only the date and nature of the complaint, a summary of the investigation, and the date the matter was closed is public information. The identity of a licensee accused of unprofessional conduct is confidential. Once the Board commences disciplinary proceedings by serving a Notice of Charges, the name and business address of the licensee becomes public. Similarly, the Notice of Charges, any evidence presented at a formal hearing, the Board's findings and order, any stipulations entered into, and the hearing itself are public. The licensee is entitled to any information in the Board's possession relating to that licensee, with the exception of investigatory files which have not resulted in charges of unprofessional conduct and attorney work product.
- 3.2** Appeal from a final decision of the Board may be taken within 30 days of the effective date of the Board's decision to the Director of the Office of Professional Regulation, who will assign the case to an appellate officer. Information about the appeal process can be obtained from the Office of Professional Regulation. Further appeals to the Superior and Supreme Courts are authorized by statute.

Section 4. Reinstatement

- 4.1** A licensee whose license has been revoked may apply for reinstatement at any time after one year has elapsed from the effective date of the revocation, or the date of the last application for reinstatement, if more than one application has been made, unless an order of the Board provides otherwise. An application for reinstatement must show, among other requirements, that the licensee is fully rehabilitated from the conduct which produced the revocation, and should include supporting recommendations from pharmacists who have personal knowledge of the applicant's activities since the revocation. Information about other requirements and necessary documentation may be obtained from the Director of the Office of Professional Regulation.
- 4.2** A licensee whose license has been suspended, restricted, or placed under supervision may apply for modification of the Board's order at anytime after six months have elapsed from the effective date of the order, or the date of the last application, if more than one application has been made, unless an order of the Board provides otherwise. An application for reinstatement of unrestricted license must show, among other requirements, that the licensee is fully rehabilitated from the conduct which produced the disciplinary action, and should include supporting recommendations from pharmacists who have personal knowledge of the applicant's activities since the action. Information about other requirements and necessary documentation may be obtained from the Director of the Office of Professional Regulation.

PART J. NON-RESIDENT PHARMACY

Section 1. Definitions

- 1.1** "Non-resident pharmacy" means a drug outlet located outside of this state which has as its principal business the dispensing of prescription drugs or devices for Vermont residents or residents of other states and which mails, ships, or delivers such prescription drugs or devices into this state. Non-resident pharmacies include pharmacies operating by means of the Internet.

Section 2. Licensure

- 2.1** An applicant must provide to the Board:
- 2.1.1** evidence that the applicant holds a pharmacy license, registration, or permit issued by the state in which the pharmacy is located that is valid and in good standing;
 - 2.1.2** the location, names, and titles of all principal corporate officers and all pharmacists who are dispensing drugs to residents of this state, including the pharmacist-manager in charge of the non-resident pharmacy license;
 - 2.1.3** evidence of the applicant's ability to provide to the Board a record of a prescription drug order dispensed by the applicant to a resident of this state not later than 72 hours after a request for the record by the Board;
 - 2.1.4** an affidavit by the pharmacist-manager which states that he or she has read and understands the Vermont laws and rules relating to a non-resident pharmacy;
 - 2.1.5** evidence that during its regular hours of operation, but not less than six days per week, for a minimum of 40 hours per week, a toll-free telephone service is provided to facilitate communication between patients in this state and a pharmacist at the pharmacy who has access to the patients' records. The toll-free number must be disclosed on the label affixed to each container of drugs dispensed to residents of this state; and evidence that during its regular hours of operation, but not less than six days per week, for a minimum of 40 hours per week, a toll-free telephone service is provided to facilitate communication between patients in this state and a

pharmacist at the pharmacy who has access to the patients' records. The toll-free number must be disclosed on the label affixed to each container of drugs dispensed to residents of this state; and **2.1.6a** copy of the most recent inspection report from the state in which the pharmacy is located.

Section 3. Personnel

3.1 A non-resident pharmacy shall be under the continuous on-site supervision of a pharmacist and shall designate one pharmacist licensed to practice pharmacy by the regulatory or licensing agency of the state in which the non-resident pharmacy is located to serve as the pharmacist-manager in charge of the non-resident pharmacy license.

Section 4. Prescription Records

4.1 A non-resident pharmacy shall maintain prescription records available for review if required by the Board. Such records shall provide the following information concerning each prescription for a drug or device that is shipped, mailed, or delivered to a resident of Vermont:

- 4.1.1** the name of the patient;
- 4.1.2** the name of the prescriber;
- 4.1.3** the number of the prescription;
- 4.1.4** the date of the prescription;
- 4.1.5** the name of the drug;
- 4.1.6** the strength and quantity of the dose; and
- 4.1.7** name or other identification of the dispensing pharmacist.

Section 5. Substitution of Drug

5.1 A non-resident pharmacy that is located outside this state and which provides mail order service to a resident of Vermont may substitute a drug if the substitution is made in accordance with the provisions of the laws and regulations of the state in which the non-resident pharmacy is located.

Section 6. Toll-free Telephone Service

6.1 A non-resident pharmacy that is located outside this state and which provides mail order service to Vermont residents shall provide during its regular hours of operation, but not less than six days per week, for a minimum of 40 hours per week, a toll-free telephone service to facilitate communication between patients in this state and a pharmacist at the pharmacy who has access to the patients' records. The toll-free number must be disclosed on the label affixed to each container of drugs dispensed to residents of this state.

Section 7. Disciplinary Action

7.1 In addition to any other provisions of law, the Board may initiate disciplinary action when:

- 7.1.1** a violation of these rules pertaining to non-resident pharmacies has occurred;
- 7.1.2** a violation affecting a resident of this state has occurred and the state where the non-resident pharmacy is located has taken no action within 45 days from the date the violation was reported;
- 7.1.3** an emergency arises that would constitute an immediate threat to the health and safety of the residents of this state.

PART K. LICENSURE OF WHOLESALE DISTRIBUTORS

Section 1. Minimum Required Information for Licensure

1.1 The Board of Pharmacy requires the following from each wholesale distributor as part of the initial licensing procedure and as part of any renewal of such license:

- 1.0.1** Name, full business address, and telephone number of the licensee;
- 1.1.2** All trade or business names used by the licensee;
- 1.1.3** Addresses, telephone numbers, and the names of contact persons for the facility used by the licensee for storage, handling, and distribution of drugs;
- 1.1.4** Type of ownership or operation (i.e., partnership, corporation, or sole proprietorship); and
- 1.1.5** Name(s) of the owner and the operator of the licensee, including:
 - 1.1.5.1** If a person: the name, address, and social security number and/or date of birth;
 - 1.1.5.2** If a partnership: the name, address, and social security number and/or date of birth of each partner, and the name of the partnership;

1.1.5.3 If a corporation: the federal identification number of the corporation, the name, address, social security number and date of birth, and title of each corporate officer and director, the corporate names, the name of the State of incorporation, and the name of the parent company, if any; the name, address, and social security number of each shareholder owning ten percent (10%) or more of the voting stock of the corporation, including over-the-counter stock, unless the stock is traded on a major stock exchange and not over-the-counter;

1.1.5.4 If a sole proprietorship: the full name, address, and social security number and date of birth of the sole proprietor and the name of the business entity.

1.2 Changes in any information in this section shall be submitted to the Board.

1.3 The information required for initial licensure or renewal of a license of a wholesale distributor shall be submitted on forms prepared by the Board, and shall be submitted to the Board accompanied by the applicable fee as directed on such form.

Section 2. Minimum Qualifications

2.1 The Board of Pharmacy will consider the following factors in determining the eligibility for licensure of wholesale distributors:

2.1.1 Any conviction of the applicant under any federal, state or local laws relating to drug samples, wholesale or retail drug distribution or distribution of controlled substances;

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

2.1.3 The applicant's past experience in the manufacture or distribution of prescription drugs, including controlled substances;

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

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

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

2.1.7 Compliance with the requirements to maintain or make available to the Board or to federal, state, or local law enforcement officials those records required to be maintained or made available by wholesale drug distributors;

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

Section 3. Personnel

3.1 The licensed wholesale distributor shall employ adequate personnel with the education and experience necessary to safely and lawfully engage in the wholesale distribution of drugs.

Section 4. Minimum Requirements for the Storage and Handling of Drugs and for Establishment and Maintenance of Drug Records

4.1 The following are required for the storage and handling of drugs, and for the establishment and maintenance of drug distribution records by wholesale distributors and their officers, agents, representatives, and employees:

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

4.1.1.1 be of suitable size and construction to facilitate cleaning, maintenance, and proper operations;

4.1.1.2 have storage areas big enough to provide adequate lighting, ventilation, temperature, sanitation, humidity, space, equipment, and security conditions;

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

4.1.1.4 be maintained in a clean and orderly condition.

Section 5. Security

5.1 All facilities used for wholesale drug distribution shall be secure from unauthorized entry.

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

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

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

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

5.3 All facilities shall be equipped with a security system that will provide suitable protection against theft and diversion. When appropriate, the security system shall provide protection against theft or diversion that is facilitated or hidden

by tampering with computers or electronic records.

Section 6. Storage

6.1 All 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 requirements in the current edition of an official compendium.

6.1.1 If no storage requirements are established for a 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.

6.1.2 Appropriate manual, electromechanical, or electronic temperature and humidity recording equipment, devices, and/or logs shall be utilized to document proper storage of drugs.

6.1.3 The record keeping requirements in Section 9, below, be followed for all stored drugs.

Section 7. Examination of Materials

7.1 Upon receipt, each outside shipping container shall be visually examined for identity and to prevent the acceptance of contaminated drugs, or 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.

7.2 Each outgoing shipment shall be carefully inspected for identity of the drug products and to ensure that there is no delivery of drugs that have been damaged in storage or held under improper conditions.

7.3 The record keeping requirements in Section 9, below, shall be followed for all incoming and outgoing drugs.

Section 8. Returned, Damaged, and Outdated Drugs

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

8.2 Any drug 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 drugs until they are either destroyed or returned to the supplier.

8.3 If the conditions under which a 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.

8.4 The record keeping requirements in Section 9, below, of this rule shall be followed for all outdated, damaged, deteriorated, misbranded, or adulterated drugs.

Section 9. Record Keeping

9.1 Wholesale distributors shall establish and maintain inventories and records of all transactions regarding the receipt and distribution or other disposition of drugs. These records shall include the following information:

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

9.1.2 The identity and quantity of the drugs received and distributed or disposed of; and

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

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

9.3 Records described in this section that are kept at the inspection site or that can be immediately retrieved by computer

or other electronic means shall be readily available for authorized inspection during the retention period. Records kept at a central location apart from the inspection site and not electronically retrievable shall be made available for inspection within two working days of a request by an authorized official of any governmental agency charged with enforcement of these rules.

Section 10. Written Policies and Procedures

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

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

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

10.1.2.1 any action initiated at the request of the Food and Drug Administration or other federal, state, or local law enforcement or other government agency, including the Board of Pharmacy;

10.1.2.2 any volunteer action by the Manufacturer to remove defective or potentially defective drugs from the market; or

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

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

10.1.4 A procedure to ensure that any outdated 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 drugs. This documentation shall be maintained for two years after disposition of the outdated drugs.

Section 11. Responsible Individuals

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

Section 12. Compliance with Federal, State, and Local Laws

12.1 Wholesale distributors shall operate in compliance with applicable federal, state, and local laws and rules.

12.2 Wholesale distributors shall permit the Board of Pharmacy 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.

12.3 Wholesale distributors that deal in controlled substances shall register with the Drug Enforcement Administration (DEA), and shall comply with all applicable state, local, and DEA requirements.

Section 13. Salvaging and Reprocessing

13.1 Wholesale distributors shall be subject to the provisions of any applicable federal, state, or local laws or rules that relate to drug product salvaging or reprocessing, including Chapter 21, parts 207, 210, and 211k of the Code of Federal Regulations.

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