OFFICE OF PROFESSIONAL REGULATION
VERMONT SECRETARY OF STATE

Administrative Rules for the Vermont Board of Pharmacy

Effective February 1, 2026

Part 1 Definitions

1-1 **"503B Outsourcer"** means a facility at one geographic location or address that is registered as an outsourcing facility with the FDA under 21 U.S.C. § 353b ("503B").

1-2 **"Administer"** means to directly apply a drug to the body of a patient or research subject by injection, inhalation, ingestion, or any other means.

1-3 **"ACPE"** means the Accreditation Council for Pharmacy Education.

1-4 **"Board"** means the Vermont Board of Pharmacy.

1-5 **"Bona fide representative"** in 18 V.S.A. § 4215b means a patient, an animal's owner, or a person authorized by the patient, by the animal's owner, or by law to receive drugs dispensed for the patient or animal.

1-6 **"Break"** means an uninterrupted period during which a pharmacy professional ceases all activities related to the practice of pharmacy.

1-7 **"Clinical pharmacy"** is defined by 26 V.S.A. § 2022.

1-8 **"Compounding"** means preparing, mixing, assembling, altering, or packaging a drug, drug dosage form, or drug-delivery device for a human or animal patient, as well as adding an ingredient to a commercial product for a patient-specific need. "Compounding" does not include:

(a) adding flavoring agent under 10-4(d); or

(b) reconstituting, as directed by the manufacturer's approved label, a product that is:

(1) conventionally manufactured;

(2) FDA-approved;

(3) prepared for an individual patient; and

(4) not stored for future use.

1-9 "DEA" means the United States Drug Enforcement Administration.

1-10 "**Deliver"** or **"delivery"** means the actual, constructive, or attempted transfer of a drug or device from one person to another, whether or not for compensation.

1-11 "Dispense" or **"dispensing"** is defined at 26 V.S.A. § 2022.

1-12 "Distribute" or **"distribution"** means delivering a drug or device other than by administering or dispensing.

1-13 "Drug" is defined by 26 V.S.A. § 2022.

1-14 "Drug outlet" is defined by 26 V.S.A. § 2022 and includes those entities described in 26 V.S.A. §§ 2021 and 2061(b), including contract manufacturers, brokers, facilitators, and intermediaries.

1-15 "Drug utilization review" includes evaluating prescription drug orders and patient records in order to:

(a) counsel on proper use of the drug;

(b) determine:

(1) known allergies;

(2) rational therapy contraindications; and

(3) reasonable dose, route of administration, and directions for use;

(c) prevent duplication of therapy; and

(d) identify:

(1) drug-drug, drug-food, and drug-disease interactions; and

(2) adverse drug reactions.

1-16 "FDA" means the United States Food and Drug Administration.

1-17 "FDCA" means the federal Food, Drug, and Cosmetic Act, 21 U.S.C. §§ 301-399i.

1-18 "Hazardous drug" or **"HD"** means any hazardous drug as defined by USP <800> or appearing in the National Institute of Occupational Safety and Health's most current "List of Hazardous Drugs in Healthcare Settings."

1-19 "Includes" and **"including"** mean includes and including without limitation.

1-20 "Institutional facility" means a health care facility as defined by 18 V.S.A. § 9432 or a nursing home or residential care facility as defined by 33 V.S.A. § 7102.

1-21 "Institutional pharmacy" means a drug outlet that is located within an institutional facility and serves solely the facility's residents or patients.

1-22 "Legend device" means a device containing a prescription drug, such as an inhaler or epinephrine autoinjector.

1-23 "Licensee" means a person licensed or registered under 26 V.S.A. ch. 36.

1-24 "Manufacturer" and **"Manufacturing"** are defined by 26 V.S.A. § 2022.

1-25 "Nonresident drug outlet" means a drug outlet that is located outside Vermont and dispenses prescription drugs or devices through mail, shipping, or delivery to a person located in Vermont.

1-26 "Office" means the Office of Professional Regulation.

1-27 "Person" is defined by 1 V.S.A. § 128.

1-28 "Pharmacist" means a person licensed under 26 V.S.A. ch. 36 to practice pharmacy or telepharmacy in Vermont.

1-29 "Pharmacist care" means medication therapy management or other clinical services that are:

(a) provided by a pharmacist or pharmacy intern;

(b) within the pharmacy scope of practice, with or without the dispensing of drugs or devices; and

(c) intended to achieve outcomes related to curing or preventing disease, eliminating or reducing symptoms, or arresting or slowing disease process.

1-30 "Pharmacy" means a drug outlet within Vermont where drugs are dispensed and any drug outlet outside of Vermont where drugs are dispensed to a person located in Vermont. "Pharmacy" does not include 503B Outsourcers.

1-31 "Pharmacy intern" means a person registered under 26 V.S.A. ch. 36, engaged in an internship, and working toward licensure as a pharmacist.

1-32 "Pharmacy manager" means a licensed pharmacist designated by a pharmacy to carry out the duties described in 8-7.

1-33 "Pharmacy professional" means a pharmacist, pharmacy technician, pharmacy technician trainee, or pharmacy intern licensed under 26 V.S.A. ch. 36.

1-34 "Pharmacy technician" is defined by 26 V.S.A. § 2022.

1-35 "Practice of pharmacy" is defined by 26 V.S.A. § 2022.

1-36 "Practitioner" is defined by 26 V.S.A. § 2022 and includes a duly licensed or registered telehealth practitioner.

1-37 "Prescription drug" is defined by 26 V.S.A. § 2022.

1-38 "Prescription drug order" or **"prescription"** means a lawful order that is:

(a) for a prescription drug, non-prescription drug, or legend device;

(b) from an authorized prescriber; and

(c) for a specific patient.

1-39 "Regulated drug" is defined by 18 V.S.A. § 4201.

1-40 "Repackaging" means moving a drug product from the manufacturer's container—including combining multiple containers of the same drug—into a different container, without or further manipulating the drug in any way.

1-41 "Repackager" means an entity that repackages and relabels a drug product or package for further sale or distribution.

1-42 "Satellite pharmacy" is referred to as a **"remote pharmacy"** in 26 V.S.A. § 2032 and is defined in 11-1.

1-43 "Theft or significant loss" means any theft or a loss that is significant based on the factors listed in 21 C.F.R. §§ 1301.74, 1301.76.

1-44 "Third-party logistics provider" means a drug outlet that provides or coordinates warehousing or other logistics services on behalf of a drug manufacturer, wholesaler, or dispenser, but that does not take ownership of the drug or have responsibility to direct the sale or disposition of the drug.

1-45 **"USP"** and **"USP-NF"** mean the United States Pharmacopeia National Formulary.

1-46 **"Virtual,"** in reference to a manufacturer or distributor, means a corporate entity that does not have custody of a drug, yet operates as a manufacturer or distributor by contracting with others. 26 V.S.A. § 2022.

1-47 **"Wholesaler"** means **"wholesale distributor"** as defined by 26 V.S.A. § 2022. "Wholesaler" does not include:

(a) an entity distributing only devices that do not contain prescription drugs; or

(b) an institutional pharmacy that distributes to an emergency medical service (EMS) agency under 10-1(b).

Part 2 Pharmacists – Eligibility and Practice Requirements

2-1 **Obligation to be Licensed.** No one may practice in Vermont as a pharmacist or out-of-state telepharmacist unless duly licensed under 26 V.S.A. Ch. 36 and these Rules.

2-2 **Pharmacist Licensure by Examination.** To qualify for pharmacist licensure by examination, an applicant must:

(a) be at least 18 years of age;

(b) either:

(1) if trained within the United States, have graduated from a pharmacy program accredited by the ACPE, its successor organization, or another Board-approved accrediting body; or

(2) if trained outside of the United States:

(A) be certified by the Foreign Pharmacy Graduate Examination Committee, its successor organization, or another Board-approved organization; and

(B) have completed an internship under 26 V.S.A. § 2032 and Part 3 of these rules; and

(c) have passed the North American Pharmacist Licensure Examination, its successor examination, or another Board-approved examination.

2-3 Pharmacist Licensure by Endorsement.

(a) To qualify for pharmacist licensure by endorsement, an applicant must be licensed in good standing in:

(1) a United States jurisdiction with licensure requirements substantially equivalent to Vermont's; or

(2) any United States jurisdiction, regardless of its licensure requirements, for at least 3 years.

(b) The Office may require use of the National Association of Boards of Pharmacy's preliminary application for licensure transfer.

2-4 Out-of-state Telepharmacy. A pharmacist may practice telepharmacy remotely using information technology and telecommunications, subject to the same laws and standards applicable to all pharmacy practice. A pharmacist must be physically present when required by law or by the standard of care.

(a) **Telepharmacy Requirements.** A pharmacist providing telepharmacy services to a patient located in Vermont must be:

(1) a licensed Vermont pharmacist;

(2) a pharmacist licensed in another U.S. jurisdiction who holds a Vermont out-of-state telepharmacist license under 2-4(b); or

(3) the agent of a duly licensed nonresident pharmacy.

(b) **Telepharmacy License.** To be eligible for out-of-state telepharmacist licensure, a pharmacist must:

(1) be licensed in good standing in another U.S. jurisdiction;

(2) specify the name, address, and phone number of the site from which the applicant will practice telepharmacy and, if the site is a pharmacy, its state of licensure and license number;

(3) specify the scope of patient services to be provided;

(4) provide any applicable collaborative practice agreements; and

(5) answer all other application questions.

(c) **Renewal.** To maintain and renew an out-of-state telepharmacy license, a licensee must remain licensed in good standing in another U.S. jurisdiction. An out-of-state telepharmacist must complete continuing education only to the extent required by the home jurisdiction.

Part 3 Pharmacy Interns – Eligibility and Practice Requirements

3-1 Obligation to Register. No one may practice in Vermont as a pharmacy intern unless duly licensed under 26 V.S.A. ch. 36 and these Rules.

3-2 Pharmacy Intern Eligibility. To be eligible to register as a pharmacy intern, an applicant must:

(a) be enrolled in a professional year of an accredited pharmacy program; or

(b) have satisfied 2-2(b)(1) or 2-2(b)(2)(A).

3-3 Supervision required. A pharmacy intern registered under these rules may practice only under the general supervision and direction of a fully licensed Vermont pharmacist in good standing.

3-4 Pharmacy Intern Scope of Practice. A pharmacy intern may engage in any activity within pharmacists' scope of practice, except that a pharmacy intern may not:

(a) serve as a pharmacy manager, interim pharmacy manager, pharmacist on duty, or the coordinating pharmacist of a satellite pharmacy; or

(b) supervise another pharmacy intern toward licensure.

3-5 Requirements for Internship Credit toward Licensure. Internships required under 2-2(b)(2)(B) have the following requirements. Internship hours may include both pre- and post-degree experience.

(a) **Length of Internship.** An internship must be at least 1,500 hours, of which at least 1,000 must take place in the United States or Canada.

(b) **Supervision.** Internship hours must be accrued under supervision as required by the law of the jurisdiction in which the internship takes place.

(c) **Documentation.** The applicant must provide documentation, in a manner specified by the Board, of the clock hours of experience completed.

Part 4 Pharmacy Technicians – Eligibility and Practice Requirements

4-1 Obligation to Register. A person performing the duties of a pharmacy technician must register with the Office as a pharmacy technician or pharmacy technician trainee. A person solely cashiering or delivering drugs is not required to register.

4-2 Designation as Pharmacy Technician. No pharmacy may permit an unregistered person to use the title "Pharmacy Technician" or "Pharmacy Technician Trainee."

4-3 Pharmacy Technician Eligibility. To register or renew registration as a pharmacy technician, an applicant must:

(a) be at least 16 years old; and

(b) be certified by a Board-approved national certifying authority or complete a Board-approved training program provided by:

(1) a college or vocational or technical institution;

(2) a branch of the United States Armed Forces or the Commissioned Corps of the Public Health Service; or

(3) the applicant's employer.

4-4 Standards for employer-provided training programs. An employer-provided training program must ensure competency in:

(a) pharmacology as necessary to perform the duties of a pharmacy technician;

(b) state and federal law and regulations;

(c) skills consistent with the duties of a pharmacy technician;

(d) medication safety;

(e) quality-assurance procedures;

(f) order and fill processes, including dose calculation;

(g) inventory management; and

(h) information systems.

4-5 Pharmacy Technician Trainee Eligibility. To register as a pharmacy technician trainee, an applicant must be at least 16 years old.

4-6 Trainee Registration Renewal; Failure to Train. A trainee registration is valid for 4 years and is not renewable but may be extended for 1 year for good cause.

(a) An employer's failure to provide training is not good cause for extension.

(b) A trainee whose registration expires must cease practicing as a pharmacy technician trainee and may apply for full technician registration upon completion of training.

4-7 Scope of Practice. A pharmacy technician or trainee:

(a) may, under the delegation and supervision of a pharmacist, perform the tasks described in the definition of "pharmacy technician" in 26 V.S.A. § 2022; and

(b) must not:

(1) re-delegate to another technician or trainee any task related to dispensing drugs or administering vaccines; or

(2) perform any act requiring the professional judgment of a pharmacist.

4-8 Technician Product Verification Program (TPVP). A pharmacy may employ a technician product verification program (TPVP) in which fully licensed pharmacy technicians—not trainees—provide technology-assisted final drug product verification during the prescription-filling or medication distribution process. A TPVP must:

(a) ensure that a pharmacist, not a pharmacy technician, performs drug utilization review and prescription and order verification;

(b) provide scanning technology to ensure that each product is accurately filled and verified; and

(c) at least quarterly:

(1) evaluate representative samples of each participating technician's verifications; and

(2) retrain technicians responsible for errors.

Part 5 Clinical Pharmacy

5-1 Collaborative Practice Agreements (CPAs). A CPA is defined in 26 V.S.A. § 2022 and must:

(a) include its initiation date and the names, license numbers, and dated signatures of the pharmacist and the collaborating practitioner or the collaborating facility's designee;

(b) be on file at the pharmacist's place of practice and provided on request to any patient or regulatory authority;

(c) describe the scope of prescribing, administering, or other clinical pharmacy services authorized;

(d) permit prescribing only with a valid practitioner-patient relationship, as defined in 8-10(b), between the collaborating practitioner or facility and the patient receiving care; and

(e) require:

(1) periodic review and renewal of the CPA within a clinically appropriate time frame; and

(2) documented quality assurance evaluation by the collaborating practitioner at least annually.

5-2 Short-term Prescription Extensions by Pharmacists. A pharmacist extending a previous prescription must comply with 26 V.S.A. § 2023(b)(6).

(a) A pharmacist must not extend a prescription for a regulated drug or controlled substance.

(b) When considering an extension of a prescription, a pharmacist must weigh the drug's risk profile, including potential toxicity and misuse, against risks associated with the interruption of the patient's access and use of the drug.

5-3 Immunizations by Pharmacy Professionals.

(a) **Prescribing.** A pharmacist may prescribe vaccines to the extent authorized by 26 V.S.A. § 2023.

(b) **Administration.** Any pharmacy professional may administer a vaccine to the extent authorized by 26 V.S.A. §§ 2023, 2042a.

(c) **Training.** A pharmacy professional administering a vaccine must have taken a vaccine administration course, with proof of training on file at the pharmacy. The course must:

(1) meet U.S. Centers for Disease Control and Prevention guidelines;

(2) be accredited by the ACPE, certified as an American Medical Association Category 1 Credit, or approved by a similar health authority or professional body; and

(3) include instruction on pre-vaccine administration education and screening, vaccine storage and handling, administration of medication, recordkeeping, emergency response, and reporting of adverse reactions.

(d) **Certification.** A pharmacy professional administering vaccines must maintain certification in basic cardiac life support, with the certificate on file at the pharmacy.

(e) **Emergencies.** In an emergency related to an immunization, a pharmacy professional may administer epinephrine, diphenhydramine, or both, without a prescription.

(f) **Recordkeeping.** Unless otherwise exempted by law, a pharmacy must maintain for 3 years the following records for any vaccine administered:

(1) the patient's name, address, date of birth, and known allergies;

(2) the date of administration and site of injection;

(3) the name, dose, manufacturer's lot number, and expiration date of the vaccine and of any emergency epinephrine or diphenhydramine administered;

(4) the name and address of the patient's primary health care provider and, if different, of the prescribing practitioner;

(5) the name of the administering pharmacy professional; and

(6) a record of the pharmacist's consultation with the patient determining that the patient is eligible for immunization.

(g) **Reporting.** The pharmacy professional must report immunization data as required under 18 V.S.A. § 1129.

5-4 Commercial Inducements and Conflicts of Interest.

(a) **Pharmacy commercial inducement ban.** Pharmacy must not require, induce, encourage, or incentivize a pharmacist to alter prescribing practices for commercial purposes, including by:

(1) promoting preferred brands;

(2) establishing prescribing quotas;

(3) steering patients based on commercial relationships; or

(4) initiating automatic prescription renewal except on express written request of a patient.

(b) **Pharmacist conflicts of interest.** A pharmacist must not:

(1) engage in activities that would lead a reasonable person to suspect that the pharmacist's prescribing judgment is influenced by anything other than the best interests of patients;

(2) accept gifts or things of value from drug manufacturers or wholesalers; or

(3) practice clinical pharmacy in a pharmacy that offers commercial inducements.

Part 6 License Renewal and Continuing Education

6-1 Continuing Education. As a condition of license renewal, pharmacists and pharmacy technicians must complete continuing education coursework every biennial period.

(a) **Content Standards.** A continuing education course must be:

(1) designed to maintain or enhance professional competence in the practice of pharmacy; and

(2) approved by ACPE; the American Medical Association as a Category 1 course; the Board; or a Board-designated entity.

(b) **Pharmacists, 30 hours.** A pharmacist must complete at least 30 hours of approved continuing education coursework, including the below as applicable.

(1) A pharmacist with a DEA number or pending application for a DEA number must complete at least 2 hours of continuing education on:

(A) the abuse and diversion, safe use, and appropriate storage and disposal of controlled substances;

(B) the appropriate use of the Vermont Prescription Monitoring System;

(C) risk assessment for abuse or addiction;

(D) pharmacological and nonpharmacological alternatives to opioids for managing pain;

(E) medication tapering and cessation of the use of controlled substances; or

(F) relevant State and federal laws and regulations about the prescription of opioid controlled substances.

(2) A pharmacist who engages in sterile or hazardous drug compounding, or who is a Designated Person under USP chapter <797> or <800>, must complete at least 3 hours of continuing education on sterile or hazardous drug compounding as appropriate to their practice.

(c) **Pharmacy Technicians, 6 hours.** A pharmacy technician must complete at least 6 hours of approved continuing education coursework.

6-2 Inspections of Nonresident Drug Outlets. As a condition of renewal, a nonresident drug outlet must submit the results of an inspection that meets the requirements of 7-4(b).

6-3 Satellite Pharmacy License Renewal. As a condition of renewing a satellite pharmacy license under Part 11, the licensee must demonstrate that:

(a) the remote dispensing site remains necessary to ensure acceptable access to care in the locality;

(b) the satellite pharmacy has complied with operating requirements; and

(c) continued remote operation is in the interest of the public.

Part 7 Eligibility and Practice Requirements for All Drug Outlets

7-1 Applicability. This Part applies to all drug outlets, except that 7-8 and 7-9 apply only to in-state drug outlets.

7-2 Applicable Law. Licensees are responsible for compliance with 26 V.S.A. ch. 36; 3 V.S.A. ch. 5, sub. 3; the Controlled Substances Act, 21 U.S.C. §§ 801 et seq.; the Drug Quality and Security Act, 21 U.S.C. § 351 et seq., which includes the Drug Supply Chain Security Act, 21 U.S.C. § 360eee et seq.; and all other applicable law.

7-3 Obligation to Register; Eligibility. No drug outlet may operate in Vermont, including as a nonresident drug outlet, unless duly licensed under 26 V.S.A. Ch. 36 and these Rules. To be eligible for registration, a drug outlet must provide:

(a) complete answers to all application questions;

(b) proof of registration of its business name with the Vermont Secretary of State;

(c) a chart or description of the drug outlet's ownership or organizational hierarchy;

(d) its DEA registration and unique FDA Establishment Identification Number, if applicable;

(e) proof of a satisfactory inspection under 7-4; and

(f) for a nonresident drug outlet, verification of licensure in good standing in the jurisdiction in which it is physically located.

7-4 Inspection.

(a) **In-state drug outlets.** An in-state drug outlet must pass an Office inspection, which will occur only after the application is otherwise complete.

(b) **Nonresident Drug Outlets.** Except for a 503B outsourcer that has not yet undergone any initial inspection, a nonresident drug outlet must submit a report of an inspection that:

(1) assessed compliance with applicable law and USP standards;

(2) was performed by:

(A) the licensing body in the state where the drug outlet is located;

(B) the National Association of Boards of Pharmacy;

(C) FDA;

(D) another qualified third party recognized by the Office; or

(E) for wholesale drug outlets only, the National Coalition for Drug Quality and Security; and

(3) was completed within:

(A) 2 years before application by an actual manufacturer or a home infusion, compounding, or nuclear radiologic pharmacy; or

(B) 3 years before application by any other nonresident drug outlet.

7-5 Public Interest Findings. The Board may deny a drug outlet registration that would not be in the public interest. 26 V.S.A. § 2069.

(a) **Procedure.** When denying a drug outlet registration as not in the public interest, the Board follows the procedure for a denial for conduct under 3 V.S.A. § 129(e)(1), including any appeal.

(b) **Criteria.** In addition to the factors in 26 V.S.A. § 2069, the Board may consider:

(1) sentinel events, as defined by the Joint Commission or its successor organization, such as recall of compounded products or ignored requests for recall;

(2) adverse event reports related to compounded products (infection, hospitalization, death);

(3) FDA involvement indicating persistent compliance issues, such as: Form 483 with repeat observations; a Warning Letter associated with a Form 483; a Regulatory Meeting request; an Untitled Letter; an injunction; a Health Alert; or seizure of compounded products;

(4) for nonresident drug outlets, inspection concerns leading to a request to cease operations or recall of compounded products; and

(5) the applicant's responses to 7-5(b)(1)–(4).

7-6 Change of Ownership or Physical Location.

(a) **Change of ownership.** When a change occurs in ownership of the licensed entity or at the parent level, a drug outlet:

(1) must submit a new application for licensure; and

(2) may continue operation uninterrupted if the completed application is submitted within 21 days of the change.

(b) **Change of location.** When a change occurs in the physical location of operation, a drug outlet must cease operation:

(1) if nonresident, until a new application is submitted and a new license granted; and

(2) if in-state, until a satisfactory inspection is completed.

(c) **Notice**. A drug outlet must notify the Office within 48 hours of a change in ownership or physical location.

(d) **Violations.** Continued operation in violation of these requirements may be prosecuted as unauthorized practice under 3 V.S.A. § 127.

7-7 Disciplinary Actions or Denials. If an applicant answers "yes" to an application question about disciplinary actions or denials involving the drug outlet, its parent, its subsidiaries, or a person or entity with a controlling interest in the drug outlet, the applicant must submit:

(a) certified copies of the charges, if filed, and of any final disposition order;

(b) a sworn statement from the CEO, COO, president, or equivalent corporate officer, showing how the applicant responded to the charges and sufficient to assure the Board that a similar violation will not occur in Vermont; and

(c) verification of current licensure status in the state in which the disciplinary action was taken.

7-8 Documents, Policies, and Procedures.

(a) **Policies Generally.** A drug outlet must maintain, implement, enforce, and make accessible policies relating:

(1) to the oversight and management of all aspects of safe and efficient acquisition, handling, storage, labeling, repackaging, preparation and distribution, and dispensing of prescription drugs; and

(2) for pharmacies, to pharmacist care and pharmacy operations.

(b) **Inventory.** A drug outlet must maintain records of the disposition of all drugs and devices and must at all times be able to account for its inventory through competent documentation. The records may be electronic.

(c) **Inspection of Medication Areas.** Medication storage areas must be routinely inspected by a qualified pharmacy professional to ensure removal of outdated or adulterated drugs. To prevent inadvertent dispensing or distribution, such drugs must be segregated until properly returned or disposed.

(d) **Recall Procedure.** A drug outlet must have written procedures for recalls of all drugs dispensed by the drug outlet. These procedures must include steps, where appropriate, for identifying and contacting patients to whom such products have been dispensed.

(e) **New practice models and technologies.** A drug outlet may use innovative practice models or technologies as long as the drug outlet complies with these Rules and other applicable law and standards.

(f) **Equipment, supplies, and information systems.** A drug outlet must possess equipment, supplies, and information systems as necessary to operate safely, competently, and lawfully.

7-9 Inspection of In-State Drug Outlets.

(a) **Inspection required.** In-state drug outlets must be open to State inspection with or without notice.

(b) **Trade secrets.** A licensee must not withhold materials relevant to inspection on the basis that they are trade secrets or otherwise proprietary. The Office and Board will keep trade secrets confidential to the extent authorized by law.

(c) **Findings.** An inspection report may include recorded observations, together with citation to applicable laws, rules, or standards. The drug outlet must reply to each finding as directed by the inspector. The Office may share inspection findings with licensees associated with an inspected entity.

7-10 Mandatory Reports. The following events must be reported by both licensees and applicants using the Office's online portal within the timeframes given.

(a) Within 48 hours:

(1) change of ownership, mailing address, or physical location; and

(2) any disaster, accident, or emergency that may affect pharmacy operations or place drugs at risk of adulteration.

(b) Within 21 days, any of the following in connection with compounded or nuclear products:

(1) recall of product;

(2) injunction issued against the licensee;

(3) adverse event reports of any infection, hospitalization, or death;

(4) seizure of product by the FDA or state regulators; and

(5) receipt from the FDA of any Form 483; Warning Letter; Untitled Letter; Regulatory Meeting request; or request for cessation of operations.

(c) Within 30 days:

(1) Claims and Settlements: any legal claim, judgment, or settlement arising from a lawsuit alleging professional negligence, misconduct, or malpractice;

(2) Inaccuracies in Applications: any material inaccuracy or change in circumstance relative to any application question, if the changed circumstance arises before the license issues;

(3) Discipline: in any jurisdiction, adverse action against a professional license or certification relating to an allegation of substandard practice or unprofessional or unethical conduct;

(4) Loss of Privileges: disciplinary action by a drug outlet that limits, suspends, conditions, or terminates a pharmacy professional's privilege to practice or leads to suspension or expulsion from the drug outlet, as well as any discipline of a pharmacy manager;

(5) for wholesalers and manufacturers, any of the reportable events in 7-10(b), other than recalls, in connection with any drug products; and

(6) for nonresident drug outlets, any inspection findings resulting in the cessation of operations or the recall of any drug products.

(d) Contemporaneously with any federal reporting requirements:

(1) any theft or significant loss of any controlled substance;

(2) for wholesalers and third-party logistics providers, all events required to be reported to the FDA; and

(3) for pharmacies, repackagers, and manufacturers, any illegitimate or suspect product required to be reported to the FDA.

Part 8 Pharmacy Practice – In General

8-1 Applicability. 8-2, 8-3, 8-4, 8-10, 8-12(b), and 8-13 apply to all pharmacies, including nonresident pharmacies. The remainder of this Part applies only to in-state pharmacies.

8-2 FDCA and USP Compliance. The FDCA designates the United States Pharmacopeia and National Formulary (USP-NF) as the official compendium of the United States. Failure to comply with applicable chapters may be unprofessional conduct under 3 V.S.A. § 129a(a)(3). FDA enforces FDCA and USP-

NF chapters below <1000>. Chapters <1000> and above are not enforced by the FDA but may be considered by the Board when assessing conformity to essential standards of acceptable and prevailing practice. These standards are regularly updated, and pharmacies are responsible for complying with the standards in place at the time of practice.

8-3 Regulated Drug Laws. Along with all other applicable state and federal law, licensees must comply with Vermont law governing regulated drugs, including 18 V.S.A. §§ 4215, 4215b, and 4289 and related administrative rules.

8-4 Professional Standards Generally. Pharmacists have a duty to use independent professional judgment even when doing so conflicts with the expectations or wishes of employers, prescribers, patients, or others. The Board may consider the American Pharmacists Association *Code of Ethics for Pharmacists* as an authoritative source of professional standards.

8-5 Reference Material. A pharmacy must maintain current, evidence-based reference materials, accessible to pharmacy staff and applicable to the scope of the pharmacy's practice.

8-6 Management. Management, supervision, and control of a pharmacy are the shared responsibility of the drug outlet, the designated pharmacy manager, and all pharmacists on duty.

(a) The pharmacy is responsible for:

(1) data oversight and development of lawful policies and procedures; and

(2) any violation of these rules, regardless of intent or knowledge.

(b) An individual pharmacy professional's responsibility for a violation depends on the professional's autonomy, authority, control, and knowledge of the circumstance.

8-7 Pharmacy Manager (PM).

(a) **PM Required**. A pharmacy may not operate without a designated pharmacy manager (PM) who is responsible for its daily operation, including the implementation of policies and procedures and the performance of all duties relevant to the lawful and professional practice of pharmacy. The PM must be licensed in the jurisdiction where the pharmacy is located.

(b) **PM Presence**. The PM must be physically present in the pharmacy at least 30% of the hours the prescription department is open or up to 40 hours per week, whichever is less.

(c) **PM Experience**. Except as allowed under 8-7(e), the PM must have held an unrestricted pharmacist license in Vermont or another state for the time set forth in 26 V.S.A. § 2061(e).

(d) **Multiple PM Assignments Prohibited**. Except as allowed under 8-7(e), no pharmacist may act as PM for more than one pharmacy at once.

(e) **Experience and multiple assignment waivers.** If consistent with the protection of the public, the Board may waive 8-7(c)'s experience requirement or, for up to 30 days and up to 2 pharmacies, 8-7(d)'s prohibition on multiple assignments. To request a waiver, an applicant must submit in writing:

(1) an explanation of the need for a waiver;

(2) a description of the pharmacy's efforts to comply with the rule;

(3) the pharmacist's familiarity with the systems and procedures at any pharmacy where they would serve as PM;

(4) for experience an experience waiver, a detailed description of the pharmacist's qualifications, including relevant academic credentials and work experience;

(5) for a multiple assignment waiver, the date by which the multiple assignment will end; and

(6) any other information relevant to establishing that a waiver would be consistent with the protection of the public.

(f) **Change Procedure**. A pharmacy must report to the Office the departure of a PM, whether voluntary or involuntary and whether planned or unplanned, within the next business day after that departure. Additionally, within 30 calendar days after a PM change, the pharmacy must:

(1) submit a written change request identifying the incoming and outgoing pharmacy managers; and

(2) complete a physical, written inventory of all controlled drugs, including full explanations of any discrepancies, a certification that the inventory is true and correct, and the signatures of the outgoing and incoming PMs.

If the outgoing PM is unavailable, the inventory must be completed by the incoming PM and another pharmacy professional.

(g) **PM Absence**. If a designated PM is absent or expected to be absent for more than 30 days, the pharmacy must designate an interim PM and notify the Board under 8-7(f).

8-8 Pharmacist Presence. A pharmacist must be present in the pharmacy at all times during hours of operation except as necessary for pharmacist breaks. When the pharmacist is temporarily absent, such as during the pharmacist's break under 8-9(a), pharmacy interns and pharmacy technicians may:

(a) continue performing non-discretionary tasks as authorized by the pharmacist;

(b) provide prescriptions to patients or patient representatives if:

(1) a pharmacist has already performed the final check of the prescription; and

(2) the patient or patient representative declines pharmacist counseling;

(c) receive, process, prepare, and hold prescription drug orders for final check by the pharmacist; and

(d) perform final drug verification within a Technician Product Verification Program under 4-8.

8-9 Workplace Standards.

(a) **Breaks.** A pharmacy must ensure that any pharmacy professional working 8 or more hours take at least one 30-minute break and one 15-minute break during that working period. A pharmacy must not manipulate pharmacy professionals' schedules to avoid providing breaks.

(1) A pharmacy may deviate from this rule if necessary to minimize immediate, significant health risks to patients.

(2) A pharmacy open to the public must:

(A) schedule pharmacists' 30-minute breaks at the same time each day so that patients are familiar with the time of the break; and

(B) when staffed only by a single pharmacist, close for that pharmacist's 30-minute break.

(3) When a pharmacist temporarily leaves the prescription department for 15 minutes or more:

(A) a sign must be conspicuously displayed indicating that no pharmacist is on duty and the time the pharmacist will return;

(B) only pharmacy interns and pharmacy technicians authorized by the pharmacist may remain in the prescription department; and

(C) the pharmacist remains responsible for the direct management, supervision, and control of the prescription department.

(b) **Staffing and Technology.** A pharmacy must:

(1) provide technology and employ staff sufficient to ensure the competent, safe, and lawful practice of pharmacy; and

(2) provide a documentation tool, such as a report form, that may be submitted to the PM by any pharmacy professional concerned that staffing numbers or a technology issue interferes with the competent, safe, and lawful practice of pharmacy.

(A) A submission made under this section must be reviewed at continuous quality improvement meetings held under 8-18.

(B) A licensee must not take disciplinary, retaliatory, or other adverse action in response to submission of a staffing or technology report.

(c) **Hazardous Drugs.** (HDs).

(1) A pharmacy that stocks hazardous drugs (HDs) must:

(A) ensure that any HDs are clearly identifiable to all pharmacy personnel; and

(B) provide appropriate deactivating agents and personal protective equipment to persons handling or manipulating HDs.

(2) Handling of HDs includes unpacking and storing HD containers or unit dose packaging, counting or repackaging HDs, and using or cleaning work surfaces and equipment that come into contact with HD residue.

(3) Manipulating HDs includes crushing or splitting tablets, opening capsules, reconstituting powdered or lyophilized HDs, or pouring oral or topical fluids from one container to another.

8-10 Prescription Drug Orders.

(a) **Filling prescriptions generally.** A pharmacist:

(1) may accept a valid prescription drug order or legend device order from a practitioner licensed in the United States or Canada;

(2) must perform drug utilization review on any prescription filled;

(3) must fill or refill a prescription for a regulated drug or controlled substance only in accordance with 18 V.S.A. § 4215 and DEA requirements; and

(4) must not fill or refill a prescription more than one year after it was written.

(b) **Valid Prescriptions.** A valid prescription is generated by an authorized practitioner for a legitimate medical purpose and arises from a valid patient-practitioner relationship. A valid patient-prescriber relationship means that:

(1) a patient has a medical complaint;

(2) a medical history has been taken;

(3) a patient examination adequate to establish the medical complaint has been performed in person or by telemedicine; and

(4) some logical connection exists between the medical complaint, the medical history, the patient examination, and the drug prescribed.

(c) **Required elements of a prescription drug order.** A prescription drug order must contain:

(1) the full name and date of birth of the patient;

(2) the prescribing practitioner's name, telephone number, and, for controlled substances, the DEA registration number;

(3) the date of the order's issuance;

(4) the name, strength, dosage form, quantity or stop date, and route of administration of the drug prescribed;

(5) directions for use by the patient;

(6) the number of authorized refills; and

(7) except for lawful orally transmitted prescription drug orders, a signature sufficient to show that the prescription is a valid prescription of the prescribing practitioner.

(d) **Labels.** Except where exempted by law, all non-compounded drugs dispensed from retail pharmacies must be dispensed in a container with labeling that complies with 18 V.S.A. § 4064a and includes:

(1) the pharmacy's name, address, and telephone number;

(2) the patient's name or, if the patient is an animal, the owner's first and last name and the animal's name and species;

(3) the prescribing practitioner's name;

(4) the drug's strength, dosage form, and proprietary or generic name;

(5) directions for patient's use, including the prescribed dose and route and frequency of administration;

(6) the date of dispensing;

(7) any cautions required by law;

(8) a unique prescription drug number; and

(9) the drug's expiration date, if less than one year from date of dispensing.

(e) **Refills**.

(1) **No Refills Specified**. A prescription drug order must not be refilled unless it specifies the number of refills or a time limit for refilling.

(2) **Refills and End of Prescriber's Practice**. When a practitioner ceases to practice, a pharmacist may dispense up to a 90-day supply of any remaining refills in a single fill if, in the pharmacist's professional judgment, doing so is in the best interest of the patient.

(3) **Refill Consolidation**. A pharmacist may dispense or refill a prescription drug up to the total remaining amount authorized by the prescriber, including refills, if:

(A) in the pharmacist's professional judgment, refill consolidation is safe and beneficial for medication adherence;

(B) the drug is not a controlled substance;

(C) the prescription does not include "dispense as written" or an equivalent phrase;

(D) the patient consents to the change in dispensing quantity;

(E) the dispensing quantity is within the total quantity prescribed; and

(F) the change in dispensing quantity is documented in the patient's record.

(f) **Security**.

(1) **Paper-based prescriptions.** A paper-based prescription must:

(A) be produced by a tamper-proof method as defined by the Centers for Medicaid and Medicare Services; and

(B) if handwritten, bear the prescriber's manual signature; or

(C) if a hard copy generated from electronic media, bear the prescriber's electronic or manual signature.

(2) **Electronic and faxed prescriptions.** A pharmacist must exercise professional judgment to assess whether a prescription drug order sent by electronic transmission or facsimile meets the security, accuracy, validity, and authenticity requirements of federal or state laws.

(3) **Orally transmitted prescriptions.** Valid prescriptions as defined in 8-10(b) may be orally transmitted to a pharmacy professional by a prescriber or an authenticated prescriber-authorized representative. The prescriber and the pharmacist are ultimately responsible for the prescription's compliance with 8-10(c).

8-11 Prospective Drug Utilization Review (DUR). To ensure effective DUR, a pharmacy must:

(a) at least once annually, determine from every patient or their representative the patient's known allergies, drug reactions, sensitivities, chronic conditions, disease states, and current use of other drugs;

(b) record in the patient's record the information from 8-11(a) and the date of the last update; and

(c) if the annual update is overdue, prompt the patient to update this information each time a prescription is dispensed.

8-12 Patient Counseling. Before dispensing a drug under a new prescription drug order, a non-institutional pharmacy must ensure that the patient is offered pharmacist counseling.

(a) **In-state pharmacies.** An in-state pharmacy open to the public must post a conspicuous notice advising that patients have a right to confidential pharmacist counseling upon request. When practicable, counseling must occur in person or by 2-way communication. A patient's refusal of counseling must be documented in the patient's record.

(b) **Nonresident pharmacies.** A nonresident pharmacy must ensure that patients receive information necessary for them to obtain timely pharmacist counseling.

8-13 Adverse Drug Reactions. Any drug-related incident that could result in serious harm, injury, or death to the patient must be reported by the pharmacist to the practitioner and recorded in the patient's record.

8-14 Display of Information. A pharmacy open to the general public must:

(a) conspicuously post its operating hours, the names of pharmacists on duty, and the license of the pharmacy manager or, for a satellite pharmacy, the coordinating pharmacist;

(b) make available for viewing upon request the printed licenses or registrations of all pharmacy professionals on duty; and

(c) require every pharmacy professional, when in public view, to wear a tag that includes the pharmacy professional's first name, last initial, and license type.

8-15 Size. A pharmacy must be large enough to accommodate:

(a) safe and proper drug storage;

(b) an orderly pharmacist workspace; and

(c) if the pharmacy provides clinical pharmacy services, space appropriate for private clinical consultation about confidential health information.

8-16 Security and Remodeling.

(a) When a pharmacy's prescription area is closed, a pharmacy must:

(1) use an alarm system; and

(2) if the pharmacy is open to the public, lock the prescription area within a partition.

(b) If a pharmacy undergoes remodeling that affects its security, the pharmacy must cease operation until a new inspection is completed.

8-17 Drug Disposal. Non-hazardous drugs requiring disposal, whether or not controlled, must be disposed through a DEA-registered reverse distributor as defined in 21 C.F.R. § 1300.01. Hazardous drugs must be disposed of in accordance with federal and state law regarding hazardous waste.

8-18 Continuous Quality Improvement Programs

(a) **Requirement for CQI program**. A pharmacy must submit all quality-related events to an internal continuous quality improvement (CQI) program or to a patient safety organization certified under 42 U.S.C. § 299b-24.

(b) **"Quality-related event" defined.** "Quality-related event" (QRE) means any departure from the appropriate dispensing or administration of a prescribed drug, whether or not the departure is corrected before the drug reaches the patient. QREs include:

(1) variation from the prescriber's prescription drug order, such as:

(A) incorrect drug, drug strength, dosage form, or patient;

(B) inadequate or incorrect packaging, labeling, or directions;

(2) failure to identify and manage:

(A) drug over-utilization or under-utilization;

(B) therapeutic duplication;

(C) drug-disease, drug-drug, or drug-allergy interactions;

(D) incorrect drug dosage or duration of drug treatment; or

(E) clinical abuse or misuse;

(3) packaging or warnings that fail to meet recognized standards;

(4) delivery of a drug to the wrong patient; and

(5) failure to meet the professional standard of care in the provision of pharmacist care services.

(c) **CQI program requirements**. At least quarterly, a pharmacy that uses an internal CQI program must:

(1) assess QRE and any reports submitted under 8-9(b)(2);

(2) identify any systems, conditions, or processes that increase the likelihood of QREs; and

(3) ensure all necessary steps are taken to prevent the recurrence of QREs.

(d) **Summary required**. A pharmacy must create a CQI summary promptly after each CQI meeting or, if the pharmacy uses a patient safety organization instead of an internal CQI program, at least quarterly. The summary must:

(1) list each CQI meeting's date and participants, if the pharmacy maintains an internal CQI program;

(2) summarize QRE trends and actions taken to address QRE root causes since the last summarization;

(3) omit any information that would identify a patient or a person involved in a QRE;

(4) be available on-site to Office inspectors for at least 4 years after the summary's creation; and

(5) be submitted to the Office upon request within 3 business days.

(e) **Duplication not required**. A pharmacy may incorporate its CQI program into other regularly scheduled meetings as long as 8-18(c) is satisfied. A summary satisfies 8-18(d) if it includes the required information, even if the document was created for other purposes. A pharmacy may redact information not required by 8-18(d) if the result of the redaction is not misleading.

(f) **Patient safety work product protected**. Nothing in this subpart requires a pharmacy to produce patient safety work product as defined in 42 U.S.C. § 299b-22(7) and 42 C.F.R. § 320. The Office may require a pharmacy to produce information that is not patient safety work product, even if that information is also reported to a patient safety organization.

8-19 Recordkeeping.

(a) **Retention of Records.** A pharmacy may store records electronically. Except where exempted by law, all dispensing records and records with a patient's protected health information must be retained:

(1) for at least 3 years; and

(2) in a format that:

(A) complies with health information privacy laws; and

(B) ensures records can be promptly retrieved for authorized persons.

(b) **Content of records.** Dispensing records must include:

(1) the identity of all pharmacists who participated in dispensing;

(2) the quantity of the drug dispensed;

(3) the date the drug was dispensed;

(4) the unique prescription number (or equivalent if an institution) associated with the dispensed drug; and

(5) the number of refills dispensed to date.

8-20 Schedule II Controlled Substance Inventories.

(a) **Perpetual Inventory.** A perpetual inventory is an ongoing system for reviewing and recording the quantity of a drug as it is received, dispensed, administered, or otherwise distributed by the pharmacy. A pharmacy must maintain a 2-year perpetual inventory for all Schedule II controlled substances. An electronic perpetual inventory is permitted if it provides a secure audit trail of entries.

(b) **Physical Schedule II Inventory.** Schedule II controlled substances must be documented and physically inventoried by pharmacy professionals at least:

(1) every 180 days for institutional pharmacies; and

(2) every 90 days for all other pharmacy types.

Part 9 Pharmacy Practice – Changes, Closures, and Specific Situations

9-1 Applicability. 9-2 and 9-6(b) apply to all pharmacies, including nonresident pharmacies. The remainder of this Part applies only to in-state pharmacies and to automated drug cabinets (ADCs) physically located in Vermont.

9-2 Change in Ownership. When one pharmacy acquires another, the acquiring pharmacy and acquired pharmacy are both responsible for ensuring that:

(a) the transition is orderly and compliant with these rules; and

(b) patients of the acquired pharmacy continue to have immediate access to their prescriptions, drugs, and records.

9-3 Change in Regular Operating Hours. At least 48 hours before a change in regular hours or days of operation, a pharmacy must notify the Board of:

(a) the change and the reason for the change; and

(b) whether the change will be temporary, permanent, or indefinite.

9-4 Pharmacy Closure.

(a) **Closures generally**. A closure may be temporary or permanent and planned or unplanned. Closures include both physical closures and changes in pharmacy oversight or staffing that prevent patients from obtaining their prescriptions. **Temporary or permanent**. Upon learning that a temporary

closure will become permanent, a closing pharmacy must follow all requirements for permanent closures.

(2) **Planned or unplanned**. A closure is planned if it foreseeably results from an omission or intentional action of the pharmacy, its agents, or its license holder. A closure is unplanned if it results from emergent circumstances that could not have been reasonably foreseen.

(b) **Continuity of care**. During any closure, a pharmacy must ensure that patients can access their prescriptions, drugs, and records.

(c) **Notice**.

(1) **Contents of notice**. Notice to the Office and public must include:

(A) for any planned closure, the date of the closure;

(B) for any temporary closure, the expected duration of the closure; and

(C) for any permanent closure, the future location of patient files and prescription records.

(2) **Locations of notice**. Notice of closure must be made:

(A) to the Office through the online Office portal;

(B) to the public through conspicuous notices on the pharmacy's physical premises, website, and automated phone systems; and

(C) for permanent closures, by advertisement in a local news publication.

(3) **Timing**. The required notices must be made:

(A) for any unplanned closure, immediately upon closure;

(B) for a planned temporary closure, 30 days before closure or within 48 hours of learning that a temporary closure will occur; and

(C) for a planned permanent closure 30 days before closure.

(4) **Additional notice to Office**. For permanent closures only, notice to the Office must also include the name and address of any person or entity that will obtain the closing pharmacy's:

(A) records of bulk compounding, repackaging, and controlled drug inventory; and

(B) prescription drugs.

(5) **Responsibility**. In a permanent closure, both the closing pharmacy and any pharmacy receiving patient records or prescription files are responsible for ensuring compliance with notice requirements.

(d) **Reporting after permanent closure**. Within 30 days after permanent closure, a pharmacy must provide the Office written confirmation that the closing pharmacy has:

(1) transferred or returned all prescription drugs to another drug outlet, or destroyed them;

(2) destroyed all labels and blank prescription pads;

(3) removed all signs indicating the presence of a pharmacy; and

(4) returned to the DEA the pharmacy's DEA registration and all unused DEA 222 forms.

9-5 Transfer of Prescription Drug Orders. A pharmacy may transfer unfilled prescription orders and original prescription drug prescription drug orders to another pharmacy. A pharmacy making or receiving such a transfer must:

(a) employ a transfer system that does not infringe on a patient's freedom to choose their preferred pharmacy;

(b) communicate prescription drug orders:

(1) directly between lawfully authorized pharmacy professionals; or

(2) through a common electronic file or database for transfers;

(c) adhere to DEA requirements;

(d) document:

(1) the transferring pharmacy's name, address, and telephone number;

(2) the transferring pharmacy professional's full name; and

(3) the original prescription drug order's:

(A) date of issuance;

(B) drug order number;

(C) number of original authorized refills and of valid remaining refills; and

(D) date of original dispensing and of last refill; and

(e) retain the original or transferred prescription drug order for 3 years after the last refill.

9-6 Centralized Prescription Processing (CPP). A pharmacy may perform or outsource centralized prescription processing (CPP) services to other pharmacies or to duly licensed pharmacists practicing telepharmacy.

(a) **CPP defined.** Centralized prescription processing (CPP) means:

(1) the processing by a pharmacy of a request from another pharmacy to fill or refill a prescription drug order; or

(2) the performance of processing functions such as dispensing, drug utilization review, claims adjudication, refill authorizations, and therapeutic interventions.

(b) **Requirements for CPP.** The parties to an agreement for CPP services must:

(1) have the same owner or have a lawful written contract that includes:

(A) the CPP services to be provided; and

(B) the responsibilities of each party;

(2) share a common electronic file or have technology that provides access to information necessary to fill or refill a prescription drug order; and

(3) maintain a system of recordkeeping that:

(A) identifies the pharmacies and responsible pharmacist(s) involved in the dispensing and counseling process;

(B) tracks the prescription drug order during each step in the dispensing process;

(C) protects the confidentiality and integrity of patient information; and

(D) makes patient records readily retrievable;

(c) **Notice to public.** A pharmacy that uses CPP must post a public notice advising that:

(A) the pharmacy uses centralized prescription processing;

(B) the pharmacist who dispenses a prescription to a patient might not be the pharmacist who prepared it; and

(C) the pharmacy will, upon request, provide a further explanation of how centralized prescription processing works.

9-7 Drug Sales to Other Pharmacies. If necessary for an urgent patient care need, a pharmacy may sell or transfer prescription drugs to an entity lawfully entitled to receive prescription drugs. The transferring pharmacy must ensure that:

(a) the transfer adheres to federal regulations for dispensers, if the transferring pharmacy and the receiving entity are not under common ownership; and

(b) each transaction is documented, including:

(1) the name, strength, form, and quantity of the drug;

(2) the date of sale;

(3) the seller and purchaser's names and addresses, and, for controlled drugs, their DEA registration numbers; and

(4) for Schedule II controlled drugs, a copy of the DEA 222 form executed before transfer.

9-8 Automated Drug Cabinets (ADCs) and Overrides. An automated drug cabinet (ADC) is an automated drug storage device that electronically interfaces with pharmacy information systems to dispense drugs prescribed for patients. An override is the removal of a drug from an ADC, for administration to a patient, without an active patient order. A pharmacy maintaining an ADC must:

(a) ensure its safe use, including implementing all safety elements recommended in the American Society of Health System Pharmacists' *Guidelines on the Safe Use of Automated Dispensing Cabinets*;

(b) monitor and regularly assess ADC overrides; and

(c) ensure, by reviewing and addressing the root causes of ADC overrides, that such overrides do not become routine.

Part 10 Registration and Practice Requirements for Specific Drug Outlet Types

10-1 Institutional Pharmacies.

(a) **Applicability**. An institutional facility operating in Vermont must register as an institutional pharmacy.

(b) **Stock Drugs for Emergency Medical Services**. An institutional pharmacy may distribute drugs appropriate to providing emergency medical services to an emergency medical service (EMS) agency licensed under 18 V.S.A. Ch. 17.

(c) **Access to Pharmacy by Non-Pharmacy Professionals**.

(1) A non-pharmacy professional, such as a registered nurse, may access a drug directly from an institutional pharmacy only if:

(A) the non-pharmacy professional is a designated nursing supervisor;

(B) the pharmacy is not staffed at the time of access;

(C) the drug is unavailable from automated drug cabinets; and

(D) an authorized prescriber has ordered the drug to treat the immediate need of a patient whose health would otherwise be jeopardized.

(2) When accessing a drug under this rule, the designated nursing supervisor must leave a copy of the patient order with the drug container and must document for a pharmacist's review:

(A) the patient's name and room number;

(B) the drug's name, strength, and quantity;

(C) the date and time of removal; and

(D) the designated nursing supervisor's signature and printed name.

(d) **Outpatient Dispensing.** An institutional pharmacy may dispense to an outpatient of the institution only:

(1) in association with a legitimate medical evaluation by an institutional clinician and involving a diagnosis for which the medication is clinically indicated;

(2) after a pharmacist or authorized prescriber has completed a prospective drug utilization review and a final check of the labeled drug container; and

(3) in the smallest amount sufficient to last until a retail pharmacy can fill the prescription, unless the patient's welfare clearly requires a larger quantity, such as for post-exposure prophylaxis.

(e) **Investigational Drugs.** Investigational drugs must be stored in and dispensed only from the institutional pharmacy.

(f) **Drugs Brought into the Institution by Patients**. A drug brought into an institutional facility by a patient must not be administered unless it can be identified and the quality of the drug assured.

10-2 Manufacturers.

(a) **Applicability**. Any entity engaged in manufacturing must register as a manufacturer. This applies to all manufacturers doing business in Vermont, including virtual manufacturers and manufacturers contracting with wholesalers that distribute in Vermont.

(b) **Authorized sales**. Before shipping any prescription drug, a manufacturer must verify that the recipient is authorized to receive and possess such drugs. Sales of regulated drugs must conform to 18 V.S.A. § 4213.

10-3 Wholesalers.

(a) **Applicability**. A wholesaler that engages in wholesale distribution in Vermont, including a virtual distributor, must register under these Rules, whether or not the wholesaler is physically located within Vermont.

(b) **Compliance**. A wholesaler must comply with the standards in 21 C.F.R. § 205.50 in addition to all other applicable laws and standards.

(c) **Authorized sales**. Before shipping or distributing any prescription drug, a wholesaler must verify that the recipient is authorized to receive and possess such drugs. Sales of regulated drugs must conform to 18 V.S.A. § 4213.

10-4 Compounding Pharmacies.

(a) **Applicability**. A pharmacy that performs compounding must register as a compounding pharmacy in addition to being licensed as a retail pharmacy. 503B Outsourcers are not required to register as compounding pharmacies.

(b) **Compliance**. A compounding pharmacy must comply with all applicable law and USP chapters, including 21 U.S.C. § 353a, USP <795> for non-sterile compounding, USP <797> for sterile compounding, and USP <800> for compounding of hazardous drugs.

(c) **Requirements**. Compounding must be performed:

(1) pursuant to a practitioner's patient-specific order based on the practitioner-patient-pharmacist-compounder relationship;

(2) in limited quantities and for a specific patient, based on a history of routine, regularly observed prescribing patterns; or

(3) for veterinary use, including resale by veterinary clinics.

(d) **Flavoring**. Adding a flavoring agent to a conventionally manufactured drug product is not compounding if:

(1) the flavoring agent is inert and does not change the product's concentration beyond USP's accepted level of variance;

(2) the product is labeled with an expiration date and storage instructions consistent with any effect of the flavoring agent on stability; and

(3) the flavoring agent's flavor, manufacturer, lot number, and expiration date are documented in the prescription record, reconstitution log, or similar documentation.

10-5 503B Outsourcers.

(a) **Applicability**. A 503B outsourcer doing business in Vermont must register as a 503B outsourcer, whether or not physically located in Vermont.

(b) **Application**. An applicant must submit the name, contact information, and license number of the licensed pharmacist directly supervising compounding.

(c) **Compliance**. A 503B outsourcer must adhere to § 503B of the FDCA (21 U.S.C. § 353b), current Good Manufacturing Practices (cGMPs), and applicable FDA guidance documents. These sources establish the essential standards of acceptable and prevailing practice.

10-6 Home Infusion Pharmacies. A home infusion pharmacy is a pharmacy that compounds sterile preparations for parenteral, intravenous, intramuscular, subcutaneous, or intraspinal infusion to a patient in a private residence, a long-term care facility as defined by 33 V.S.A. § 7102, a hospice setting, or an infusion suite not served by an institutional pharmacy.

(a) **Applicability**. A home infusion pharmacy doing business in Vermont, whether or not physically located in Vermont, must register as a home infusion pharmacy in addition to being licensed as a retail pharmacy.

(b) **Compliance**. A home infusion pharmacy must comply with USP <797> , USP <800>, and 21 U.S.C. § 353a as well as all other applicable laws and standards.

10-7 Third-Party Logistics Providers.

(a) **Applicability**. A third-party logistics provider doing business in Vermont, whether or not physically located in Vermont, must register as a third-party logistics provider.

(b) **Compliance**. A third-party logistics provider must comply with the standards in 19 C.F.R. § 205.50 as well as all other applicable laws and standards.

10-8 Nuclear Pharmacies.

(a) **Applicability**. A pharmacy providing radiopharmaceutical services and doing business in Vermont, whether or not physically located in Vermont, must register as a nuclear pharmacy.

(b) **Personnel**. Pharmacy personnel working in a nuclear pharmacy must be directly supervised by a nuclear pharmacist who is board-certified or has attained:

(1) minimum training required for "authorized user status" of radioactive material, in accordance with the Nuclear Regulatory Commission licensure guidance;

(2) at least 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:

(A) radiation physics, instrumentation, protection, and biology;

(B) mathematics of radioactivity; and

(C) radiopharmaceutical chemistry; and

(3) at least 500 hours of clinical nuclear pharmacy training under the supervision of a qualified nuclear pharmacist.

(c) **Compliance**. A nuclear pharmacy must comply with USP <825> and all applicable Nuclear Regulatory Commission requirements as well as all other applicable laws and standards.

10-9 Nonresident Drug Outlets. A drug outlet physically located outside Vermont, but doing business in Vermont, must register for the applicable license type.

Part 11 Satellite Pharmacies

11-1 Definition. A satellite pharmacy is a licensed pharmacy that is:

(a) staffed by one or more appropriately trained pharmacy technicians; and

(b) maintained by a pharmacy that is:

(1) at a different location;

(2) connected to the satellite pharmacy by secure audiovisual communication and pharmacy information systems; and

(3) staffed by a coordinating pharmacist who supervises and supports the technician for the provision of pharmacy services.

11-2 Approval. A drug outlet may operate as a satellite pharmacy only with the Board's approval. To apply for approval, a drug outlet must:

(a) identify a satellite pharmacy and explain its dispensing process;

(b) show that the community is underserved compared to similar communities because of demand for services, the accessibility of the nearest conventional retail pharmacy, or other compelling circumstances that create barriers to timely pharmacy care;

(c) show that the benefits to the community health, safety, and welfare from improved pharmacy access clearly outweigh the risks inherent to operating without a pharmacist on site;

(d) identify a coordinating pharmacy, which must be a licensed Vermont retail drug outlet with staffing, technology, and prescription volume that allow a pharmacist to safely act as coordinating pharmacist;

(e) submit policies governing the supervision of pharmacy technicians and the training of pharmacy technicians and coordinating pharmacists; and

(f) submit a quality assurance and improvement plan that includes systems for:

(1) maintaining inventories of controlled substances under 8-20; and

(2) identifying, recording, and remediating drug errors.

11-3 Coordinating Pharmacist.

(a) **Responsibilities**. The coordinating pharmacist may not delegate and is responsible for:

(1) continually supervising the satellite pharmacy and its professionals;

(2) interpreting a prescription drug order;

(3) verifying the accuracy of prescription data entry;

(4) interpreting a patient's drug record and conducting drug utilization review;

(5) authorizing an automated medication distribution system to dispense an appropriately labeled prescription drug;

(6) performing the final verification of a dispensed prescription, unless acting within a Technician Product Verification Program under 4-8;

(7) counseling the patient or the patient's caregiver; and

(8) inspecting the satellite pharmacy.

(b) **Location**. The coordinating pharmacist must work from a location that ensures that the responsibilities in 11-3(a) can be performed.

(c) **Qualifications**. Before acting as coordinating pharmacist for a satellite pharmacy, a pharmacist must have been fully licensed for at least one year. The Board may waive this requirement under the same procedure and criteria as for pharmacy managers under 8-7(e).

11-4 Satellite Pharmacy Operation. A satellite pharmacy must post conspicuous signs indicating that it is a licensed satellite pharmacy and including the coordinating pharmacy's name, address, and telephone number.

(a) **Audiovisual Telecommunication Link**. A satellite pharmacy must be connected to its coordinating pharmacist by a reliable, continuously accessible, synchronous audiovisual telecommunications link. Cameras must enable the coordinating pharmacist to discern markings on tablets and capsules. If the link is interrupted, or if the coordinating pharmacist is not present, the remote pharmacy must cease operations.

(b) **Security**. A satellite pharmacy must store drugs in a locked area accessible only to authorized personnel. A satellite pharmacy must have recorded video monitoring viewable in real time by the coordinating pharmacist.

(c) **Drug Orders**. A pharmacy technician at a satellite pharmacy:

(1) must transmit to the coordinating pharmacist any prescription drug order or refill request received;

(2) may input prescription drug orders and refill requests into the pharmacy information system; and

(3) must not receive orally transmitted prescription drug orders, which must be transmitted directly to the coordinating pharmacist by the practitioner or the practitioner's designee.

(d) **Quality Assurance Inspection.** As often as necessary to assure quality and at least once every 30 days, a coordinating pharmacist must inspect the satellite pharmacy consistent with the quality assurance and improvement plan submitted under 11-2(f).

Part 12 Waivers of Rules

12-1 Waiver criteria. The Board or the Director of the Office may waive the application of a rule, with or without limits or conditions, if:

(a) extraordinary circumstances exist;

(b) an interested party makes a written request; and

(c) applying the rule would be clearly unfair, absurd, unjustifiably inefficient, or otherwise contrary to public health, safety, and welfare.

12-2 No right to waiver. This rule does not create any administrative hearing right or cause of action.