FINAL PROPOSED RULE # 25-P001

Final Proposed Filing - Coversheet

Instructions:

In accordance with Title 3 Chapter 25 of the Vermont Statutes Annotated and the "Rule on Rulemaking" adopted by the Office of the Secretary of State, this filing will be considered complete upon filing and acceptance of these forms with the Office of the Secretary of State, and the Legislative Committee on Administrative Rules.

All forms shall be submitted at the Office of the Secretary of State, no later than 3:30 pm on the last scheduled day of the work week.

The data provided in text areas of these forms will be used to generate a notice of rulemaking in the portal of "Proposed Rule Postings" online, and the newspapers of record if the rule is marked for publication. Publication of notices will be charged back to the promulgating agency.

PLEASE REMOVE ANY COVERSHEET OR FORM NOT REQUIRED WITH THE CURRENT FILING BEFORE DELIVERY!

Certification Statement: As the adopting Authority of this rule (see 3 V.S.A. § 801 (b) (11) for a definition), I approve the contents of this filing entitled:

Administrative Rules of the Board of Pharmacy

Sarah Copeland Hanzas , on 10/20/2025
(signature) (date)

Printed Name and Title:
Sarah Copeland-Hanzas

RECEIVED BY: _____

- ☐ Coversheet
- ☐ Adopting Page
- ☐ Economic Impact Analysis
- ☐ Environmental Impact Analysis
- ☐ Strategy for Maximizing Public Input
- ☐ Scientific Information Statement (if applicable)
- ☐ Incorporated by Reference Statement (if applicable)
- ☐ Clean text of the rule (Amended text without annotation)
- ☐ Annotated text (Clearly marking changes from previous rule)
- ☐ ICAR Minutes
- ☐ Copy of Comments
- ☐ Responsiveness Summary

State of Vermont
Office of the Secretary of State
Office of Professional Regulation
89 Main Street, 3rd Floor
Montpelier, VT 05620-3402
sos.vermont.gov

Sarah Copeland Hanzas, Secretary of State
S. Lauren Hibbert, Deputy Secretary
Jennifer B. Colin, Director

Rep. Trevor Squirrell, Chair
Legislative Committee on Administrative Rules
Vermont State House
Montpelier, Vermont
By email to lindsey.schreier@vtleg.gov

October 20, 2025

Re: Final Proposed Administrative Rules for the Board of Pharmacy

Dear Representative Squirrell and Committee Members:

Please find enclosed the final proposed Administrative Rules for the Board of Pharmacy and related documents, which were filed with the Secretary of State today.

I would be happy to answer any questions the Committee may have about the proposed final rules before your next meeting. Please feel free to contact me at emily.b.tredeau@vermont.gov.

Sincerely,

/s/ Emily Tredeau
Emily Tredeau
Staff Attorney

c: Louise F. Corliss, APA Rules, Vermont Secretary of State

Enc: APA filing forms
Final Proposed Rules
Annotated rule
Written comments received
A summary of those comments and agency responses
ICAR minutes approving the proposed Rules with recommendations

1. TITLE OF RULE FILING:
   Administrative Rules of the Board of Pharmacy
2. PROPOSED NUMBER ASSIGNED BY THE SECRETARY OF STATE
   25P 001
3. ADOPTING AGENCY:
   Secretary of State, Office of Professional Regulation
4. PRIMARY CONTACT PERSON:
   (A PERSON WHO IS ABLE TO ANSWER QUESTIONS ABOUT THE CONTENT OF THE RULE).

   Name: Emily Tredeau

   Agency: Office of Professional Regulation

   Mailing Address: 89 Main St., 3rd Fl., Montpelier, VT 05602-3402

   Telephone: 802-828-1505 Fax:

   E-Mail: emily.b.tredeau@vermont.gov

   Web URL *(WHERE THE RULE WILL BE POSTED)*:
   https://sos.vermont.gov/pharmacy/statutes-rules-resources/
5. SECONDARY CONTACT PERSON:
   (A SPECIFIC PERSON FROM WHOM COPIES OF FILINGS MAY BE REQUESTED OR WHO MAY ANSWER QUESTIONS ABOUT FORMS SUBMITTED FOR FILING IF DIFFERENT FROM THE PRIMARY CONTACT PERSON).

   Name: Carrie Phillips

   Agency: Office of Professional Regulation

   Mailing Address: 89 Main St., 3rd Fl., Montpelier, VT 05602-3402

   Telephone: 802-828-1505 Fax:

   E-Mail: carrie.phillips@vermont.gov
6. RECORDS EXEMPTION INCLUDED WITHIN RULE:
   (DOES THE RULE CONTAIN ANY PROVISION DESIGNATING INFORMATION AS CONFIDENTIAL; LIMITING ITS PUBLIC RELEASE; OR OTHERWISE, EXEMPTING IT FROM INSPECTION AND COPYING?) No

   IF YES, CITE THE STATUTORY AUTHORITY FOR THE EXEMPTION:

   PLEASE SUMMARIZE THE REASON FOR THE EXEMPTION:
7. LEGAL AUTHORITY / ENABLING LEGISLATION:

(THE SPECIFIC STATUTORY OR LEGAL CITATION FROM SESSION LAW INDICATING WHO THE ADOPTING ENTITY IS AND THUS WHO THE SIGNATORY SHOULD BE. THIS SHOULD BE A SPECIFIC CITATION NOT A CHAPTER CITATION).
26 V.S.A. § 2032 (Board of Pharmacy mandated to make rules)

3 V.S.A. § 123(a)(11) (Secretary of State as adopting authority for Board rules)

8. EXPLANATION OF HOW THE RULE IS WITHIN THE AUTHORITY OF THE AGENCY:
The agency is authorized to adopt rules "necessary to carry out the purposes of the provisions of" the pharmacy subchapter, 26 V.S.A. ch. 36; determining the scope of the practice of clinical pharmacy, specifying required elements of a collaborative practice agreement, prohibiting conflicts of interest and other ethical concerns, limiting short-term pharmacist prescribing, and establishing privacy standards, id. § 2023; specifying the scope of practice of pharmacy, licensure qualifications, procedural rights, pharmacy technician rules, and inspections, defining internship requirements, and requiring continuing education, id. § 2032; creating standards for creating, licensing, and operating remote pharmacies, id. § 2042; setting criteria for pharmacy professionals' licensure and professional responsibility, id. §§ 2061, 2062; notifications required of pharmacies, id. § 2063; and pharmacy recordkeeping, inspections, monitoring, and background checks, id. § 2068.

9. THE FILING HAS CHANGED SINCE THE FILING OF THE PROPOSED RULE.

10. THE AGENCY HAS INCLUDED WITH THIS FILING A LETTER EXPLAINING IN DETAIL WHAT CHANGES WERE MADE, CITING CHAPTER AND SECTION WHERE APPLICABLE.

11. SUBSTANTIAL ARGUMENTS AND CONSIDERATIONS WERE RAISED FOR OR AGAINST THE ORIGINAL PROPOSAL.

12. THE AGENCY HAS INCLUDED COPIES OF ALL WRITTEN SUBMISSIONS AND SYNOPSES OF ORAL COMMENTS RECEIVED.

13. THE AGENCY HAS INCLUDED A LETTER EXPLAINING IN DETAIL THE REASONS FOR THE AGENCY'S DECISION TO REJECT OR ADOPT THEM.

14. CONCISE SUMMARY (**150 WORDS OR LESS**):

This update reflects changes in pharmacy's legal and practice landscape since 2015 by regulating, among other things:

- new types of pharmacy entity, such as virtual distributors and manufacturers, 503B outsourcers, and third-party logistics providers;

-continuing education requirements related to opioid prescribing;

-devices containing prescription drugs; and

-changes to prescriptions for schedule II controlled substances.

The rule also reflects statutory changes to pharmacy professionals' scopes of practice, including immunizations, and simplifies the licensing of pharmacy technicians into a single credential instead of the current two-tiered system. The rule creates standards for workplace conditions pharmacy staffing necessary to protect the public. The rule streamlines and narrows the legal duties of Pharmacy Managers, clarifying that licensed pharmacies are themselves responsible for compliance with the Rules.

15. EXPLANATION OF WHY THE RULE IS NECESSARY:

Since the rule was last amended in 2015, the General Assembly has made significant changes to the general laws of professional regulation, aimed at streamlining the licensing process, promoting uniformity and consistency among licensing programs, responding to changes in federal antitrust jurisprudence. Federal regulators have also created new types of pharmacy entities, such as 503B outsourcers and third-party logistics providers. The proposed rule addresses Vermont statutes' application to these entities. The proposed rule also eliminates a previous rule that required national certification for pharmacy technicians, which had proven to be a significant hardship for pharmacies. The proposed rule also addresses workplace wellbeing issues. The amended rules are also half the length of the existing rules, reducing the burden of compliance for professionals governed by them.

16. EXPLANATION OF HOW THE RULE IS NOT ARBITRARY:

The rule has been developed carefully in multiple duly-warned public meetings of the Vermont Board of Pharmacy. Board members appointed by the Governor on the strength of their professional qualifications have worked collaboratively with agency legal staff and stakeholders from the public and private sectors to ensure that the rule responds rationally and appropriately to substantial legal and practical developments bearing on pharmacy licensing, regulation, and practice. The Board and Office of Professional Regulation have been guided by clear State licensing policy, set out at 26 V.S.A., Ch. 57, which establishes that the purpose of occupational and professional regulation is to protect the public health, safety, and welfare by the least restrictive means necessary to achieve those ends.

17. LIST OF PEOPLE, ENTERPRISES AND GOVERNMENT ENTITIES AFFECTED BY THIS RULE:

Vermont-licensed pharmacists, pharmacy technicians, pharmacy interns and pharmacy entities both within and outside Vermont(pharmacies, manufacturers, wholesale drug outlets, third-party logistics providers, 503B outsourcers); Vermont Department of Health; Vermont Board of Medical Practice; Green Mountain Care Board; Department of Vermont Health Access; Vermont Association of Hospitals and Health Systems; Vermont Pharmacists Association; Vermont Medical Society; Vermont Society of Health System Pharmacists; hospitals and their patients; pharmacy patients; patients of pharmacies and hospitals, clinical healthcare providers; Department of Financial Regulation.

18. BRIEF SUMMARY OF ECONOMIC IMPACT (150 WORDS OR LESS):

The most significant economic impact will likely be on certain nonresident drug outlets, which will be required to submit an inspection report every 2 years instead of the current requirement of every 3 years.

Other impacts include streamlining and clarifying the rules, which should reduce drug outlets' administrative and legal costs. Removing the requirement of national certification of pharmacy technicians and adding new

training options should make it easier for business to staff their pharmacies.

The rules expand the scope of activities pharmacists may delegate to pharmacy technicians and of activities not requiring technician licensure, such as delivering drugs to a pharmacy or working as a cashier This should ease pharmacy staffing problems by expanding the pool of eligible workers.

The rule revisions are revenue- and cost-neutral to the State.

19. A HEARING WAS HELD.

20. HEARING INFORMATION

(THE FIRST HEARING SHALL BE NO SOONER THAN 30 DAYS FOLLOWING THE POSTING OF NOTICES ONLINE).

IF THIS FORM IS INSUFFICIENT TO LIST THE INFORMATION FOR EACH HEARING, PLEASE ATTACH A SEPARATE SHEET TO COMPLETE THE HEARING INFORMATION.

Date: 2/18/2025

Time: 02:00 PM

Street Address: 89 Main St., Suite 3, Montpelier, VT

Zip Code: 05602

URL for Virtual: MS Teams at https://www.microsoft.com/en-us/microsoft-teams/join-a-meeting
Meeting ID: 293 389 690 612
Passcode: 9Th7n98t
By phone: 1-802-828-7667, conference ID 168 777 875#

Date: 2/19/2025

Time: 10:00 AM

Street Address: 89 Main St., Suite 3, Montpelier, VT

Zip Code: 05602

URL for Virtual: MS Teams at https://www.microsoft.com/en-us/microsoft-teams/join-a-meeting
Meeting ID: 257 060 957 271
Passcode: Hj2ZQ2MN
By phone: 1-802-828-7667, conference ID 207 994 027#

Date: 2/20/2025

Time: 06:00 PM

Street Address: 89 Main St., Suite 3, Montpelier, VT

Zip Code: 05602

URL for Virtual: MS Teams at https://www.microsoft.com/en-us/microsoft-teams/join-a-meeting
Meeting ID: 212 020 234 592
Passcode: RE2J2EA2
By phone: 1-802-828-7667, conference ID 301 656 014#

Date:

Time: AM

Street Address:

Zip Code:

URL for Virtual:

21. DEADLINE FOR COMMENT (NO EARLIER THAN 7 DAYS FOLLOWING LAST HEARING):
3/31/2025

KEYWORDS (PLEASE PROVIDE AT LEAST 3 KEYWORDS OR PHRASES TO AID IN THE SEARCHABILITY OF THE RULE NOTICE ONLINE).

pharmacy
pharmacist
drug
controlled substance
FDA
DEA
prescribe
prescription
compounding
medication
pharmaceutical
medical
immunize
immunization
vaccine

clinical
intern
technician
inspection
USP
regulation

Adopting Page

Instructions:

This form must accompany each filing made during the rulemaking process:

Note: To satisfy the requirement for an annotated text, an agency must submit the entire rule in annotated form with proposed and final proposed filings. Filing an annotated paragraph or page of a larger rule is not sufficient. Annotation must clearly show the changes to the rule.

When possible, the agency shall file the annotated text, using the appropriate page or pages from the Code of Vermont Rules as a basis for the annotated version. New rules need not be accompanied by an annotated text.

1. TITLE OF RULE FILING:
   Administrative Rules of the Board of Pharmacy
2. ADOPTING AGENCY:
   Secretary of State, Office of Professional Regulation
3. TYPE OF FILING (*PLEASE CHOOSE THE TYPE OF FILING FROM THE DROPDOWN MENU BASED ON THE DEFINITIONS PROVIDED BELOW*):
   - **AMENDMENT** - Any change to an already existing rule, even if it is a complete rewrite of the rule, it is considered an amendment if the rule is replaced with other text.
   - **NEW RULE** - A rule that did not previously exist even under a different name.
   - **REPEAL** - The removal of a rule in its entirety, without replacing it with other text.

   This filing is **AN AMENDMENT OF AN EXISTING RULE** .

4. LAST ADOPTED (*PLEASE PROVIDE THE SOS LOG#, TITLE AND EFFECTIVE DATE OF THE LAST ADOPTION FOR THE EXISTING RULE*):
   15-038; effective September 15, 2015

Economic Impact Analysis

Instructions:

In completing the economic impact analysis, an agency analyzes and evaluates the anticipated costs and benefits to be expected from adoption of the rule; estimates the costs and benefits for each category of people enterprises and government entities affected by the rule; compares alternatives to adopting the rule; and explains their analysis concluding that rulemaking is the most appropriate method of achieving the regulatory purpose. If no impacts are anticipated, please specify "No impact anticipated" in the field.

Rules affecting or regulating schools or school districts must include cost implications to local school districts and taxpayers in the impact statement, a clear statement of associated costs, and consideration of alternatives to the rule to reduce or ameliorate costs to local school districts while still achieving the objectives of the rule (see 3 V.S.A. § 832b for details).

Rules affecting small businesses (excluding impacts incidental to the purchase and payment of goods and services by the State or an agency thereof), must include ways that a business can reduce the cost or burden of compliance or an explanation of why the agency determines that such evaluation isn't appropriate, and an evaluation of creative, innovative or flexible methods of compliance that would not significantly impair the effectiveness of the rule or increase the risk to the health, safety, or welfare of the public or those affected by the rule.

1. TITLE OF RULE FILING:

   Administrative Rules of the Board of Pharmacy

2. ADOPTING AGENCY:

   Secretary of State, Office of Professional Regulation

3. CATEGORY OF AFFECTED PARTIES:

   LIST CATEGORIES OF PEOPLE, ENTERPRISES, AND GOVERNMENTAL ENTITIES POTENTIALLY AFFECTED BY THE ADOPTION OF THIS RULE AND THE ESTIMATED COSTS AND BENEFITS ANTICIPATED:

   Vermont-licensed pharmacists, pharmacy technicians, pharmacy interns and pharmacy entities both in VT and nonresident (pharmacies, manufacturers, wholesale drug outlets, third-party logistics providers, 503B outsourcers); Vermont Association of Pharmacists; Vermont Department of Health; Vermont Board of Medical Practice; Green Mountain Care Board; Department of

Vermont Health Access; Vermont Association of Hospitals and Health Systems; Vermont Medical Society; Vermont Society of Health System Pharmacists; hospitals and their patients; pharmacy patients; patients of pharmacies and hospitals, clinical healthcare providers.

Costs: The most significant economic impact will likely be on certain nonresident drug outlets, which will be required to submit an inspection report every 2 years instead of the current requirement of every 3 years. Drug outlets located in jurisdictions that do not inspect at least every 3 years will, for some renewal cycles, have to pay for inspections to comply. The National Association of Boards of Pharmacy, a major provider of inspections, currently charges between $4,750 and $10,500 per inspection, depending on the type of pharmacy.

In addition, pharmacies currently staffed below levels acceptable under these rules will need to increase staffing. Pharmacies that do not already have rule-compliant Continuous Quality Improvement programs will have to establish them. Pharmacies that currently employ untrained pharmacy technicans will have to provide training as needed.

Benefits: The rules could decrease staffing costs by allowing pharmacy managers, preceptors, and satellite pharmacy coordinating pharmacists with fewer years of experience than currently required; increased opportunity for pharmacists to work remotely; increased opportunity for satellite pharmacies; and increased opportunity for centralized prescription processing. In addition, removing the requirement of national certification of pharmacy technicians and adding new training options should make it easier for business to staff their pharmacies.

The rules expand the scope of activities pharmacists may delegate to pharmacy technicians and of activities not requiring technician licensure, such as delivering drugs to a pharmacy or working as a cashier. This

should ease pharmacy staffing pressure by expanding the pool of eligible workers.

The rule revisions are revenue- and cost-neutral to the State.

4. IMPACT ON SCHOOLS:
INDICATE ANY IMPACT THAT THE RULE WILL HAVE ON PUBLIC EDUCATION, PUBLIC SCHOOLS, LOCAL SCHOOL DISTRICTS AND/OR TAXPAYERS CLEARLY STATING ANY ASSOCIATED COSTS:

The nature of this rule is such that it will have no impact on public education, public schools, local school districts, or taxpayers.

5. ALTERNATIVES: *CONSIDERATION OF ALTERNATIVES TO THE RULE TO REDUCE OR AMELIORATE COSTS TO LOCAL SCHOOL DISTRICTS WHILE STILL ACHIEVING THE OBJECTIVE OF THE RULE.*

No alternatives were considered because there are no costs to ameliorate.

6. IMPACT ON SMALL BUSINESSES:
INDICATE ANY IMPACT THAT THE RULE WILL HAVE ON SMALL BUSINESSES (EXCLUDING IMPACTS INCIDENTAL TO THE PURCHASE AND PAYMENT OF GOODS AND SERVICES BY THE STATE OR AN AGENCY THEREOF):

The proposed rule would ease small business practice by streamlining and clarifying the rules with which independent pharmacies must comply. In addition, removing the requirement of national certification for pharmacy technicians would add new training options and relieve small pharmacies from having to terminate appropriately trained technicians who chose not to become nationally certified. This change will make it easier for small businesses to staff their pharmacies. Removing the national certification requirement would also ease staffing pressures in smaller critical access hospitals.

Workplace wellbeing regulations would require small businesses to plan for adequate breaks and required staffing. Long-term, it is hoped that these regulations will improve all pharmacies' ability to retain talent and will put businesses that already prioritize employee wellbeing on a level playing field.

For small nonresident entities, the change from an inspection no older than 3 years to no older than 2 years as a requirement for a complete renewal application could possibly result in additional costs-of-doing-business here if they are in a state that will not do inspections upon request, leading them to pay for an inspection by an approved organization.

7. SMALL BUSINESS COMPLIANCE: *EXPLAIN WAYS A BUSINESS CAN REDUCE THE COST/BURDEN OF COMPLIANCE OR AN EXPLANATION OF WHY THE AGENCY DETERMINES THAT SUCH EVALUATION ISN'T APPROPRIATE.*

It is not appropriate for small businesses to reduce the cost/burden of compliance with these Rules apart from the adoption of efficient practices across all aspects of their business. The purpose of the Rules is to protect the public from conduct that could be lethal if performed unprofessionally. The need for this protection applies equally to small independent pharmacies as to large institutional or chain pharmacies. The rules already eliminate avoidable costs associated with compliance by using an all-electronic licensing system and by permitting electronic recordkeeping and management of reference tools.

8. COMPARISON:

COMPARE THE IMPACT OF THE RULE WITH THE ECONOMIC IMPACT OF OTHER ALTERNATIVES TO THE RULE, INCLUDING NO RULE ON THE SUBJECT OR A RULE HAVING SEPARATE REQUIREMENTS FOR SMALL BUSINESS:

Having no rule on the practice of pharmacy would, in the long run, be very costly to all pharmacies, including small and independent pharmacies. The drug supply is regulated by federal agencies (FDA, DEA) setting standards that are enforced by state boards of pharmacy via licensing. If the Board of Pharmacy abdicated that role by failing to promulgate and maintain administrative rules, in the long run independent pharmacies would suffer massive liability to consumers and federal enforcement authorities.

Separate requirements for small business would be inappropriate because the risk to the public posed by the unsafe practice of pharmacy is just as serious in independent pharmacies as in larger pharmacies. Many of

the costs of compliance, such as licensing fees for pharmacies and pharmacy professionals, automatically scale to the size of the business because fewer staff and locations means fewer licenses.

9. SUFFICIENCY: *DESCRIBE HOW THE ANALYSIS WAS CONDUCTED, IDENTIFYING RELEVANT INTERNAL AND/OR EXTERNAL SOURCES OF INFORMATION USED.*
This analysis was conducted by consideration of the nature of the rules.

Environmental Impact Analysis

Instructions:

In completing the environmental impact analysis, an agency analyzes and evaluates the anticipated environmental impacts (positive or negative) to be expected from adoption of the rule; compares alternatives to adopting the rule; explains the sufficiency of the environmental impact analysis. If no impacts are anticipated, please specify "No impact anticipated" in the field.

Examples of Environmental Impacts include but are not limited to:

- Impacts on the emission of greenhouse gases
- Impacts on the discharge of pollutants to water
- Impacts on the arability of land
- Impacts on the climate
- Impacts on the flow of water
- Impacts on recreation
- Or other environmental impacts

1. TITLE OF RULE FILING:

   Administrative Rules of the Board of Pharmacy

2. ADOPTING AGENCY:

   Secretary of State, Office of Professional Regulation

3. GREENHOUSE GAS: *EXPLAIN HOW THE RULE IMPACTS THE EMISSION OF GREENHOUSE GASES (E.G. TRANSPORTATION OF PEOPLE OR GOODS; BUILDING INFRASTRUCTURE; LAND USE AND DEVELOPMENT, WASTE GENERATION, ETC.):*

   The proposed updated rules make explicit that patient records may be maintained in solely electronic form. This practice is already permissible under the existing rules, but based on inquires OPR receives from licensees, some licensees still believe that paper records are required. The proposed updated rules will reduce the emission of greenhouse gases by eliminating printing resulting from confusion about the current rule.

   The proposed updated rules also expand opportunities

for the practice of telepharmacy, for centralized prescription processing, and for satellite pharmacy. If licensees take advantage of these opportunities, the amount of driving needed for pharmacy professionals and patients to access physical pharmacies may be reduced, resulting in decreased emission of greenhouse gases.

4. WATER: *EXPLAIN HOW THE RULE IMPACTS WATER (E.G. DISCHARGE / ELIMINATION OF POLLUTION INTO VERMONT WATERS, THE FLOW OF WATER IN THE STATE, WATER QUALITY ETC.):*
   The rule has no impact on water. Disposal of drugs could affect water quality, but requirements for disposal of unsalable drugs are set by federal regulation and not affected by this rule.
5. LAND: *EXPLAIN HOW THE RULE IMPACTS LAND (E.G. IMPACTS ON FORESTRY, AGRICULTURE ETC.):*
   This rule has no direct impact on land. Indirectly, the rule could marginally reduce the use of land for waste processing or for paper forestry by reducing the use of paper as discussed in the response to question 3.
6. RECREATION: *EXPLAIN HOW THE RULE IMPACTS RECREATION IN THE STATE:*
   This rule has no impact on recreation.
7. CLIMATE: *EXPLAIN HOW THE RULE IMPACTS THE CLIMATE IN THE STATE:*
   The impact on climate is identical to the impact on greenhouse gas, discussed in the response to question 3.
8. OTHER: *EXPLAIN HOW THE RULE IMPACT OTHER ASPECTS OF VERMONT'S ENVIRONMENT:*
   The rule has no other impact on Vermont's environment.
9. SUFFICIENCY: *DESCRIBE HOW THE ANALYSIS WAS CONDUCTED, IDENTIFYING RELEVANT INTERNAL AND/OR EXTERNAL SOURCES OF INFORMATION USED.*
   This analysis was conducted by considering the subject matter of the rules and their extremely limited impact on the environment.

Public Input Maximization Plan

Instructions:

Agencies are encouraged to hold hearings as part of their strategy to maximize the involvement of the public in the development of rules. Please complete the form below by describing the agency's strategy for maximizing public input (what it did do, or will do to maximize the involvement of the public).

This form must accompany each filing made during the rulemaking process:

1. TITLE OF RULE FILING:

   Administrative Rules of the Board of Pharmacy

2. ADOPTING AGENCY:

   Secretary of State, Office of Professional Regulation

3. PLEASE DESCRIBE THE AGENCY'S STRATEGY TO MAXIMIZE PUBLIC INVOLVEMENT IN THE DEVELOPMENT OF THE PROPOSED RULE, LISTING THE STEPS THAT HAVE BEEN OR WILL BE TAKEN TO COMPLY WITH THAT STRATEGY:

   The proposed rule was discussed at length at public warned meetings of the Board of Pharmacy and developed in collaboration with the Board. The public had the opportunity to comment at those meetings. In addition, stakeholders discussed below in paragraph 4 will be contacted and informed of the times of public hearings and invited to participate and/or submit written comment.

4. BEYOND GENERAL ADVERTISEMENTS, PLEASE LIST THE PEOPLE AND ORGANIZATIONS THAT HAVE BEEN OR WILL BE INVOLVED IN THE DEVELOPMENT OF THE PROPOSED RULE:

   In addition, following stakeholders are/have been aware of and/or have participated in the drafting process (to varying levels): Vermont Pharmacists Association, Vermont Medical Society, Board of Medical Practice, lobbyists/members of the National Association of Chain Drug Stores, Vermont Retail Druggists, representatives from various pharmacy industry sectors (Cardinal Health telepharmacy and others), Vermont Association of

Hospitals and Health Systems, Vermont Medical Society, Board of Medical Practice, Vermont Society of Health System Pharmacists, the Department of Financial Regulation, and the National Association of Boards of Pharmacy. These entities will also be informed of public hearings on the Rule and invited to submit written comments.

Incorporation by Reference

THIS FORM IS ONLY REQUIRED WHEN INCORPORATING MATERIALS BY REFERENCE. PLEASE REMOVE PRIOR TO DELIVERY IF IT DOES NOT APPLY TO THIS RULE FILING:

Instructions:

In completing the incorporation by reference statement, an agency describes any materials that are incorporated into the rule by reference and how to obtain copies.

This form is only required when a rule incorporates materials by referencing another source without reproducing the text within the rule itself (e.g., federal or national standards, or regulations).

Incorporated materials will be maintained and available for inspection by the Agency.

1. TITLE OF RULE FILING:

   Administrative Rules of the Board of Pharmacy

2. ADOPTING AGENCY:

   Secretary of State, Office of Professional Regulation

3. DESCRIPTION (*DESCRIBE THE MATERIALS INCORPORATED BY REFERENCE*):

   Code of Federal Regulations (C.F.R.)

   United States Code (U.S.C.)

   Vermont Statutes (V.S.A.)

   United States Pharmacopeia National Formulary (USP-NF)

   The American Society of Health System Pharmacists' "ASHP Guidelines on the Safe Use of Automated Dispensing Cabinets"

   The American Pharmacists Association's "Code of Ethics for Pharmacists"

   The National Institute of Occupational Health's "Procedures for Developing the NIOSH List of Hazardous Drugs in Healthcare Settings"

4. FORMAL CITATION OF MATERIALS INCORPORATED BY REFERENCE:

United States Pharmacopeial Convention, United States Pharmacopeia and National Formulary, 2023 and subsequent revisions.

American Pharmacists Association, "Code of Ethics for Pharmacists," https://www.pharmacist.com/Code-of-Ethics

American Society of Health System Pharmacists, "ASHP Guidelines on the Safe Use of Automated Dispensing Cabinets," available at https://www.ashp.org/-/media/assets/policy-guidelines/docs/guidelines/safe-use-of-automated-dispensing-devices.ashx

National Institute of Occupational Health, "Procedures for Developing the NIOSH List of Hazardous Drugs in Healthcare Settings," available at https://www.cdc.gov/niosh/docs/2023-129/default.html.

1 V.S.A. § 128
3 V.S.A. § 127
3 V.S.A. § 129
3 V.S.A. § 129a
18 V.S.A. § 4215b
18 V.S.A. § 4289
18 V.S.A. § 1129
18 V.S.A. § 4064a
18 V.S.A. § 4201
18 V.S.A. § 4213
18 V.S.A. § 4215
18 V.S.A. § 9432
18 V.S.A. Ch. 17
26 V.S.A. § 2042a
26 V.S.A. § 2021
26 V.S.A. § 2022
26 V.S.A. § 2023
26 V.S.A. § 2032
26 V.S.A. § 2061
26 V.S.A. § 2069
26 V.S.A. ch. 36

33 V.S.A. § 7102

19 C.F.R. § 205.50
21 C.F.R. § 1300.01
21 C.F.R. § 1301.74
21 C.F.R. § 1301.76
42 C.F.R. § 320

21 U.S.C. § 353a
21 U.S.C. § 353b
42 U.S.C. § 299b-22
42 U.S.C. § 299b-24
42 C.F.R. § 320

5. OBTAINING COPIES: *(EXPLAIN WHERE THE PUBLIC MAY OBTAIN THE MATERIAL(S) IN WRITTEN OR ELECTRONIC FORM, AND AT WHAT COST)*:

The entire Code of Federal Regulations (C.F.R.) is available free online at ecfr.gov and also at the Cornell Library of Vermont Law and Graduate School.

The entire United States Code (U.S.C.) is available free online at uscode.house.gov and also at the Cornell Library of Vermont Law and Graduate School.

All Vermont Statutes (V.S.A.) are available free online at legislature.vermont.gov/statutes and also at the Cornell Library of Vermont Law and Graduate School.

The United States Pharmacopeia National Formulary is available online at store.uspnf.org. An annual single-user subscription currently costs $700.

The American Society of Health System Pharmacists' "ASHP Guidelines on the Safe Use of Automated Dispensing Cabinets" is available free online at https://www.ashp.org/-/media/assets/policy-guidelines/docs/guidelines/safe-use-of-automated-dispensing-devices.ashx

The American Pharmacists Association's "Code of Ethics for Pharmacists" is available free online at https://www.pharmacist.com/Code-of-Ethics

The National Institute of Occupational Health's "Procedures for Developing the NIOSH List of Hazardous Drugs in Healthcare Settings" is available free online

at https://www.cdc.gov/niosh/docs/2023-129/default.html.

6. MODIFICATIONS (*PLEASE EXPLAIN ANY MODIFICATION TO THE INCORPORATED MATERIALS E.G., WHETHER ONLY PART OF THE MATERIAL IS ADOPTED AND IF SO, WHICH PART(S)ARE MODIFIED)*:

None.

Run Spell Check

From: Robert Elkins
To: SOS - OPR Comments
Subject: Comment regarding the proposed Administrative Rules
Date: Monday, March 31, 2025 8:52:26 PM
Attachments: image.png

Hello,

I am a retail floater pharmacist with Walgreens in Vermont and find that it can be a nuisance requiring a **street address** (not a PO Box) on prescriptions. I continuously fax prescribers asking for them to resend scripts in with a street address. Prescribers will typically ignore my requests to help us to adhere to VT rules & regulations, occasionally they tell me that they are unable to resend a script with a street address for the patient because they do not have one for the patient or due to software limitations, and *very* rarely prescribers will resend the script with a patient's address.

My request is that the word ***street*** be removed from the highlighted portion pictured below within the document found at https://outside.vermont.gov/dept/sos/office_professional_regulation/professions/pharmacy/pharmacy_proposed_administrative_rules_draft.pdf

Thank you for your consideration.

Sincerely,

Rob Elkins, PharmD
(352)871-8971
Robert.Elkins@alumni.acphs.edu

From: Johnny Alexander
To: SOS - OPR Comments
Subject: Comments on Pharmacy Administrative Rules Proposal
Date: Monday, March 17, 2025 9:02:18 AM

Good morning!

Please see below my comments on the Pharmacy Administrative Rules proposal. I am making these comments on behalf of myself, my fellow pharmacists, and Northern Tier Center for Health, where I serve as the Director of Pharmacy.

1-12 "Compounding" means the preparation, mixing, assembling, altering, packaging, or labeling of a drug, drug dosage form, or drug-delivery device for human or animal patients, as well as manipulation of commercial products that may require the addition of one or more ingredients for patient-specific needs. For purposes of these Rules, "compounding" does not include: (a) reconstituting a conventionally manufactured, FDA-approved product in accordance with the directions contained in the approved labeling provided by the product's manufacturer, provided that the product is prepared for an individual patient and not stored for future use; or (b) addition of flavoring agent consistent with the requirements of Part 9-4(d).
COMMENT: This description is too broad due to syntax. The use of the word "or" can be construed as meaning that labeling a drug would be defined as compounding. This should be changed to "and".

1-15 "Deliver" or "Delivery" means the actual, constructive, or attempted transfer of a drug or device from one person to another, whether or not for consideration.
COMMENT: The last phrase of this definition is ambiguous. Recommend removing "whether or not for consideration" or rephrasing to clarify intent.

1-44 "Pharmacist Care" means the provision by a pharmacist or pharmacy intern of medication therapy management services, with or without the dispensing of drugs or devices, intended to achieve outcomes related to the cure or prevention of a disease, elimination or reduction of a patient's symptoms, or arresting or slowing of a disease process.
COMMENT: This should be expanded to include all potential non-dispensing and clinical services that may be provided by a pharmacist. Recommend that "and any other clinical services that may fall under the pharmacist scope of practice" be added after "medication therapy management services" and before "with or without the dispensing

of drugs or devices".

1-40 "Patient counseling" means the oral communication by the pharmacist or pharmacy intern of information to the patient or caregiver to ensure proper use of drugs and devices.
COMMENT: This does not include accessible forms of communication such as written and sign language. Recommend changing "oral" to "multimodal" to promote inclusivity and accessibility.

1-45 "Pharmacy" means a drug outlet within this state where drugs are dispensed, and any drug outlet outside of this state where drugs are dispensed to a person located in Vermont. "Pharmacy" does not include 503B Outsourcers.
COMMENT: This means pharmacies in other states that don't dispense drugs to VT residents are not pharmacies. The distinction that appears to be attempted here is already provided in the description of a "Non-resident Pharmacy". Recommend removing "to a person located in Vermont" and replacing it with "in accordance with relevant State and Federal laws, rules, and regulations".

1-50 "Pharmacy, Scope of Practice" means the performing the following activities in the best interest of the patient: (a) the identification, selection, preparation, preservation, combination, analysis, standardization with clinical guidelines, and evaluation of the therapeutic use of drugs for use in the treatment of disease; (b) the interpretation and evaluation of Medical Orders and the dispensing of prescription drugs; (c) immunization; (d) the performance of drug utilization reviews and the participation in drug and device selection, drug regimen reviews, drug or drug-related research, and, where permitted, drug administration; (e) provision of patient counseling and those acts or services necessary to provide pharmacist care; (f) the compounding, labeling, proper and safe storage, and maintenance of proper records of drugs and devices; and (g) the management of drug therapy, in collaboration with other health care providers responsible for patient care, through research, consultation, selection of drugs under protocol, and recommending actions or providing information necessary for drug therapy.
COMMENT: Recommend fixing typo: "...the performing **of** the following..."

4-8 Technician Product Verification Program. A pharmacy may develop and implement a technician product verification program (TPVP) in which technicians provide technology-assisted final drug product verification during the prescription-filling or medication distribution process. A TPVP shall include: (a) scanning technology to ensure each product is accurately filled and verified; and (b) competent policies and procedures governing: (1) quarterly quality-assurance evaluations reviewing a representative sample

of prescriptions verified by each participating technician; (2) review and evaluation of any errors in the pharmacy's CQI program; and (3) re-training of technicians responsible for errors.
COMMENT: This policy may create an unsafe environment in understaffed pharmacies if implemented without limitations. Language should be added to clarify that a pharmacist must still perform DUR & prescription/order verification on all dispensed medications.

5-3 (b) Commercial Inducement Ban. A pharmacy shall not require, induce, encourage, incentivize, or otherwise attempt to influence a pharmacist to alter prescribing practices for commercial purposes, including without limitation by promoting preferred brands, establishing prescribing quotas, steering patients based on commercial relationships, **or initiating automatic prescription renewal without an express written request from a patient**. A pharmacist who works in a pharmacy that offers such inducements shall not practice clinical pharmacy.
COMMENT: This creates an undue burden and can interrupt patient care. Pharmacies often submit proactive renewal requests in order to ensure continuity of care. If this is intended to prevent automatically processing and dispensing refills, the language should be more clear about this. Recommend removing "or initiating automatic prescription renewal without an express written request from a patient" and replacing it with "or initiating the processing, adjudication, and dispensing of a refill on an automatically and regularly recurring basis without an express written request or authorization from a patient."

8-20 (e)
(1) Paper-based prescriptions. Handwritten prescriptions shall be written on a tamper-resistant prescription form and shall bear the original signature of the prescriber. The signature shall be handwritten and not stamped or otherwise artificially reproduced. Computer-generated printed prescriptions shall be printed on tamper-resistant prescription paper or other tamper-proof methods, as defined by the Centers for Medicaid and Medicare Services.
(2) Electronic prescriptions. The pharmacist shall exercise professional judgment to assess whether a prescription drug order communicated by way of electronic transmission meets the security, accuracy, validity, and authenticity requirements of federal or state laws.
COMMENT: This does not provide clear guidance for faxed prescriptions. Recommend adding "either through an electronic prescribing platform or via facsimile" after "electronic transmission" and before "meets the security"

CONCISE SUMMARY This update reflects changes in pharmacy's legal and practice landscape since 2015 by regulating, among other things:

...

-the prescribing of opioids;

...

-naloxone dispensing; and

-changes to prescriptions for schedule II controlled substances

COMMENT:

- Summary mentions the regulating of the dispensing of naloxone, however there are no relevant mentions of naloxone in the draft.
- Summary mentions changing prescriptions for schedule II controlled substances, however all specific rules for CII prescriptions have been removed from the original rules, and there is no replacement guidance in the draft.
- Summary mentions changing the prescribing of opioids however there are no subsequent changes in the draft.

Johnny Alexander, PharmD
Pharmacy Director
Northern Tier Center for Health
He / Him / His

From: McMillian, Wes D.
To: SOS - OPR Comments
Cc: McMillian, Wes D.
Subject: Comments to proposed Administrative Rules for Pharmacy / Public Hearing
Date: Tuesday, February 11, 2025 2:53:10 PM

Dear OPR staff,

Please, accept the below comments to the proposed administrative rules for pharmacy for version 2025-01-0808.

- 1-21(b)(3) uncapitalize administration
- Add DSCSA to the definition section
- Add NCDQS to the definition section
- 1-50 should be the "pharmacist" scope of practice. "Pharmacy" is defined in 1-45 as a drug outlet and not a profession.
- 3-2(c) "North American Pharmacist Licensure Examination"
- 3-4(b) this does not specifically call for separate registration to become a preceptor, yet website has a requirement to register. Need to add in this section or eliminate the requirement to register on the website (preferred).
- 4-2(a) it would be great to allow high school students the opportunity to work in a pharmacy (trainee) to gain experience. Can a waiver be created to support, or flexibility added to this section?
- 4-7 pharmacist delegate to technicians (technicians do not delegate). This section should be titled "Out of scope for Pharmacy Technicians" or this section should be moved to section 3 as a pharmacist non-delegable function.
- 4-8(b)(1) quarterly is very frequent. This would be a significant administrative burden to pharmacy staff.
- 5-1 and 5-2 should be combined. *Rationale: most of 5-2 does not add clarity to what now exists in 5-1. 5-2 b, and c are now covered in 5-1, and we support that content over the 5-2 language. 5-2d is duplicative with 5-1c. 5-2e is now incorporated into 5-1.*
    - 5-1 Collaborative Practice Agreements (CPAs) - Generally. A CPA is a written agreement between a pharmacist and a health care facility or practitioner that permits the pharmacist to engage in the practice of clinical pharmacy, as defined in 26 V.S.A. § 2022(15)(B), for the benefit of solely the facility or practitioner's patients.
    - (a) CPAs shall be maintained on file at the place of the collaborating pharmacist's practice and be readily available to any patient or regulatory authority that may request to review the CPA.
    - (b) Each CPA shall include the date of initiation, signatures of the pharmacist and the

collaborating practitioner or facility's designee, and a plan for periodic review and renewal of the CPA within a time frame that is clinically appropriate.
    - (c) Subject to the pharmacy scope of practice, as defined in Part 1-50 and in 26 V.S.A. §§ 2022(15) and 2023, CPAs shall identify the types of patient care activities the pharmacist(s) may perform and, if any, the clinical decisions they may make;
    - (d) CPAs shall include provisions requiring no less than an annual quality assurance evaluation by the collaborating practitioner.
- 6-6(a)(3) please, define "oversee".
- 6-6(b) 10 hours of CE for technicians may lead to financial hardship to techs and employers and may be a barrier to hiring and retaining staff. Recommend to remove.
- 6-6 we would like to see provisional CE waiver for new pharmacists for their first cycle of licensure. Do not want pharmacists having to get 30 hours of CE in 2 months if they become licensed in VT right before renewal cycle.
- 7-8(d) this section is confusing. Is this for any compounded medication (patient specific), for 503a batch compounds, or 503b compounds? Is this for manufacturer recalls or something different?
- 7-11(d)(2) please, define what is significant.
- 8-1 "All pharmacies where the practice of pharmacy is conducted"..."pharmacies required to be registered"...."are required to be registered under these rules"..
- 8-8 the scope of pharmacist practice within the pharmacy.

Thanks,
Wes

Wesley D. McMillian, PharmD, MS, BCPS, FCCM (he/him/his)
Chief Pharmacy Officer | Vice President of Pharmacy
The University of Vermont Health Network
356 Mountain View Drive
Colchester, VT 05446
802-847-3546

From: Nathan, Darren M
To: Tredeau, Emily B; SOS - OPR Comments
Subject: Feedback on Proposed Pharmacy Administrative Rules
Date: Tuesday, March 4, 2025 1:56:46 PM

Ms. Tredeau,

Thank you for reaching out for input on Vermont's proposed Pharmacy Administrative Rules.
https://sos.vermont.gov/pharmacy/statutes-rules-resources/

As Pfizer's manager responsible for all facility State Licensure, I have reviewed the proposed rules and have the following questions, concerns, and recommendations.

Your feedback on these items will be appreciated.

1. Parts 6.4 (which references 7-3) now requires that for all renewal applications, an inspection report be submitted that is less than two years old. While we understand that an National Association of Boards of Pharmacy (NABP) Supply Chain Inspection is accepted, Pfizer's concern is because these NABP Inspections are only conducted every three years. Pfizer Inc. maintains two facilities in Wisconsin whose board does not conduct inspections, leaving Pfizer no choice but to submit its NABP Inspection results for licensure requirements. **Recommendation**: Pfizer recommends language be added to this section allowing a three-year timeframe when utilizing NABP. This would then be consistent with that Board's practices.

2. Part 7.5 addresses the requirement to submit a new application when there is a change of ownership but doesn't give a time frame. **Question**: Is there another section that clarifies the time frame requirement for submitting this application?

3. Part 7-11 says a change of ownership must be reported via the online portal within "the next business day" after discovery. **Recommendation**: Pfizer recommends this be extended to five days to allow the necessary time to confirm the details of the change of ownership.

4. Pfizer would like to clarify the scope of 9-2 that pertains to Manufacturers. Section c within Part 9-2 specifies "shipping any **prescription** drug". **Question**: Can we get confirmation from Vermont's OPR that the intent of all of part 9-2 is for Manufacturers of Prescription Drugs only and not those facilities that only produce Active Pharmaceutical Ingredients and ship them to other facilities for further processing? Note the facilities in question are all outside of Vermont and only ship into Vermont via a licensed wholesale distributor.

Thank you for your consideration. If you have any questions, please reach out to me at your convenience.

Regards,
Darren

Darren Nathan
Compliance Manager
Pfizer Global Supply Chain
1855 Shelby Oaks Drive North
Memphis, TN 38134
T: 901-380-6368

NOTE: I am emailing at a time convenient for me; please read and respond at a time that works for you."

Outlook

FW: Comments on Pharmacy Administrative Rules Proposal

From SOS - OPR Comments <sos.opr.comments@vermont.gov>
Date Mon 3/17/2025 10:15 AM
To Phillips, Carrie <Carrie.Phillips@vermont.gov>

From: Johnny Alexander <jalexander@notchvt.org>
Sent: Monday, March 17, 2025 9:02 AM
To: SOS - OPR Comments <sos.opr.comments@vermont.gov>
Subject: Comments on Pharmacy Administrative Rules Proposal

Good morning!

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Johnny Alexander, PharmD
Pharmacy Director
Northern Tier Center for Health
He / Him / His

Outlook

FW: Comments to proposed Administrative Rules for Pharmacy / Public Hearing

From SOS - OPR Comments <sos.opr.comments@vermont.gov>
Date Fri 2/21/2025 4:16 PM
To Phillips, Carrie <Carrie.Phillips@vermont.gov>

From: McMillian, Wes D. <Wes.McMillian@uvmhealth.org>
Sent: Tuesday, February 11, 2025 2:53 PM
To: SOS - OPR Comments <sos.opr.comments@vermont.gov>
Cc: McMillian, Wes D. <Wes.McMillian@uvmhealth.org>
Subject: Comments to proposed Administrative Rules for Pharmacy / Public Hearing

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Wes

Wesley D. McMillian, PharmD, MS, BCPS, FCCM (he/him/his)
Chief Pharmacy Officer | Vice President of Pharmacy
The University of Vermont Health Network
356 Mountain View Drive
Colchester, VT 05446
802-847-3546

Outlook

FW: Feedback on Proposed Pharmacy Administrative Rules

From SOS - OPR Comments <sos.opr.comments@vermont.gov>
Date Wed 3/5/2025 6:07 AM
To Phillips, Carrie <Carrie.Phillips@vermont.gov>

More pharmacy comments to add to the chart. Thank you!

From: Nathan, Darren M <Darren.Nathan@pfizer.com>
Sent: Tuesday, March 4, 2025 1:57 PM
To: SOS - OPR Comments <sos.opr.comments@vermont.gov>
Subject: FW: Feedback on Proposed Pharmacy Administrative Rules

From: Nathan, Darren M
Sent: Tuesday, March 4, 2025 12:57 PM
To: Emily.B.Tredeau@vermont.gov; :sos.opr.comments@vermont.gov
Subject: Feedback on Proposed Pharmacy Administrative Rules

Ms. Tredeau,

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Thank you for your consideration. If you have any questions, please reach out to me at your convenience.

Regards,
Darren

Darren Nathan
Compliance Manager
Pfizer Global Supply Chain
1855 Shelby Oaks Drive North
Memphis, TN 38134
T: 901-380-6368

NOTE: I am emailing at a time convenient for me; please read and respond at a time that works for you."

Outlook

FW: Public Hearing: Pharmacy

From SOS - OPR Comments <sos.opr.comments@vermont.gov>
Date Fri 2/21/2025 4:16 PM
To Phillips, Carrie <Carrie.Phillips@vermont.gov>

Comment for response

From: Nick Dumont <nick.r.dumont@gmail.com>
Sent: Wednesday, January 22, 2025 12:26 PM
To: SOS - OPR Comments <sos.opr.comments@vermont.gov>
Subject: Public Hearing: Pharmacy

To whom it may concern,
Thank you for the time and diligence put into the proposed Pharmacy Administrative Rules. I think the proposed updates are timely and supportive of current Pharmacy practice. While I don't have any major objections to the proposed rules I would ask the Board to consider limiting the scope of section *8-26 Continuous Quality Improvement Programs* to non-institutional pharmacies. I'm concerned this requirement would complicate the existing CMS framework for certain tools and committees such as Medication Safety Committee, Quality Committee, Compliance Committee, and electronic occurrence reporting systems that we should all already have in place at our institutions. My concern is that implementation of the Continuous Quality Improvement Program in the institutional setting will add another meeting to our calendars but will be less productive and is more limited in scope than mechanisms we already have in place to enhance quality and improve safety in our settings. I believe this CQI requirement would force a rehashing of agendas from all these other groups just for the purpose of being able to provide inspectors with a consolidated summary document. I don't believe this is value-added in the institutional setting.

Thank you for all your work and consideration of these comments.
-Nick

State of Vermont
Agency of Administration
109 State Street
Montpelier, VT 05609-0201
www.aoa.vermont.gov

[phone] 802-828-3322

Sarah Clark, Interim Secretary

INTERAGENCY COMMITTEE ON ADMINISTRATIVE RULES (ICAR) MINUTES

Meeting Date/Location: November 15, 2024, virtually via Microsoft Teams
Members Present: Chair Sean Brown, Jared Adler, Jennifer Mojo, John Kessler, Michael Obuchowski, Natalie Weill, Diane Sherman and Nicole Dubuque
Members Absent: None
Minutes By: Anna Reinold

- 1:00 p.m. meeting called to order, welcome and introductions.
- Review and approval of minutes from the October 14, 2024 meeting.
- No additions/deletions to agenda. Agenda approved as drafted.
- No public comments made.
- Presentation of Proposed Rules on pages 2-5 to follow.
  1. Guidelines for Distinguishing between Primary and Specialty Mental Health and Substance Abuse Services, Department Financial Regulation, page 2
  2. Vermont Water Supply Rule, Agency of Natural Resources, page 3
  3. Administrative Rules of the Board of Pharmacy, Secretary of State, Office of Professional Regulation, page 4
  4. Rules of the Vermont Employment Security Board, Department of Labor, page 5
- Next scheduled meeting is Monday, December 9, 2024 at 2:00 p.m.
- 2:12 p.m. meeting adjourned.

3) **Proposed Rule:** Administrative Rules of the Board of Pharmacy, Secretary of State, Office of Professional Regulation

Presented By: Emily Tredeau and Carrie Phillips

Motion made to accept the rule by Sean Brown, seconded by Nicole Dubuque, and passed unanimously with the following recommendations:

1. Proposed Filing - Coversheet:
    a. #8: Need to clarify the major changes of the proposed filing and describe the areas generally being regulated.
    b. #8: Change 'dated or unnecessary' to 'outdated', 'obsolete' or similar phrasing.
2. Economic Impact Analysis: Add more detailed information and clarify any additional costs.

From: Sandy Rosa
To: SOS - OPR Comments
Subject: Fwd: administrative rules-comments
Date: Friday, March 28, 2025 2:22:54 PM
Attachments: VPA rules suggestions.docx

---------- Forwarded message ---------
From: **Sandy Rosa** <swrosa@gmail.com>
Date: Fri, Mar 28, 2025 at 2:19 PM
Subject: administrative rules-comments
To: Phillips, Carrie <Carrie.Phillips@vermont.gov>, <carrie.phillips@sec.state.vt.us>, Tredeau, Emily B <Emily.B.Tredeau@vermont.gov>, <sos.opr.comments@vermont.go>

Good afternoon,
Please find attached our suggestions (in red) for inclusion into the administrative rules for Pharmacy.
Please let me know if you have any questions.
Thank you and have a great day,
Sandy Rosa
Executive Director, Vermont Pharmacists' Assn.

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Sandy Rosa

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Sandy Rosa

From: Nick Dumont
To: SOS - OPR Comments
Subject: Public Hearing: Pharmacy
Date: Wednesday, January 22, 2025 12:25:54 PM

To whom it may concern,

Thank you for the time and diligence put into the proposed Pharmacy Administrative Rules. I think the proposed updates are timely and supportive of current Pharmacy practice. While I don't have any major objections to the proposed rules I would ask the Board to consider limiting the scope of section *8-26 Continuous Quality Improvement Programs* to non-institutional pharmacies. I'm concerned this requirement would complicate the existing CMS framework for certain tools and committees such as Medication Safety Committee, Quality Committee, Compliance Committee, and electronic occurrence reporting systems that we should all already have in place at our institutions. My concern is that implementation of the Continuous Quality Improvement Program in the institutional setting will add another meeting to our calendars but will be less productive and is more limited in scope than mechanisms we already have in place to enhance quality and improve safety in our settings. I believe this CQI requirement would force a rehashing of agendas from all these other groups just for the purpose of being able to provide inspectors with a consolidated summary document. I don't believe this is value-added in the institutional setting.

Thank you for all your work and consideration of these comments.
-Nick

From:	Sandy Rosa
To:	Phillips, Carrie; Phillips, Carrie; Tredeau, Emily B; SOS - OPR Comments
Subject:	Revised VPA Rules comments/suggestions
Date:	Monday, March 31, 2025 3:19:05 PM
Attachments:	VPA Response to Administrative Rules.docx

Good afternoon,

Getting pharmacists together is like herding cats (which is just one step above being a Brownie Troop leader!)
Here, at the last minute, is the VPA response.

Thank you for your patience

--
Rosa

From:	Emma C. Shouldice
To:	SOS - OPR Comments
Cc:	Tredeau, Emily B
Subject:	VACDS Rule Revision Comments
Date:	Monday, March 17, 2025 11:33:15 AM
Attachments:	image001.png VACDS Rule Revision Comments.pdf

EXTERNAL SENDER: Do not open attachments or click on links unless you recognize and trust the sender.

Thank you for the opportunity to submit comments for the draft rule revisions. Please see attached comments and let me know if you have any questions.

Best,
Emma

Emma Shouldice
William Shouldice & Associates LLC
802.503.2523

Vermont Association of Chain Drug Stores

To: Vermont Board of Pharmacy
From: Emma Shouldice
Date: March 17, 2025
Re: Pharmacy Rule Revision

Our Association appreciates the work the Board has done to update the pharmacy rules. VACDS represents community pharmacies, from regional chains with three stores to national companies. We have included comments below for your consideration.

Part 1: Definitions

- **1-40** "Patient counseling" means the oral communication by the pharmacist or pharmacy intern of information to the patient or caregiver to ensure proper use of drugs and devices.
    - *What is the reasoning behind oral being the only communication method? We would advocate that there be two-way communication.*
- **1-59 & 1-61 -** Satellite pharmacy and telepharmacy practice
    - *Respectively, the language is generally permissive. We would like to highlight with the remote/satellite pharmacy provisions, the rule permits these types of operations with one technician – which would seem to limit capacity. It would be better if the language allowed multiple pharmacy technicians to be working in remote/satellite pharmacies.*

Part 2: Administration and Procedures

- **2-2 Applications** "… An application expires if not completed within six months of initial submission, after which a new application and fee will be required. The Board may refuse to accept any application found to be redundant with a denied or in-process application."
    - *To be in line with other states, we would ask that the Board allow for expiration after 1 year to allow for any mix-ups to be cleared or if items need to be obtained by the licensee, such as inspections or hard to obtain documents or if the Board wishes for a prospective licensee to obtain an evaluation.*
- **2-3 New Application Required** Drug outlets must file a new application for new licensure whenever there is a change of ownership of the licensed entity, of ownership at the "parent" level, or in the physical location of operation.
    - *If a pharmacy moves to a new location and there is no change in ownership, this should not be considered a new license. Most states permit a change in location application. This appears to state, they would need a new license - which would result in having to apply for new 3rd party contracts and could potentially put an existing pharmacy out of business. We are comfortable with a change in location application, but it shouldn't be considered a new license.*

- **2-7 Waivers** -The Board will not grant routine waivers or variances from any provisions of these rules without amending the rules. 3 V.S.A. § 845. Where, in extraordinary circumstances, application of a rule would result in manifest unfairness, an absurd result, unjustifiable inefficiency, or an outcome otherwise contrary to the public health, safety, and welfare, the Board or Director may, upon written request of an interested party, find grant a waiver with or without conditions and limitations, and record the action and justification in a written memorandum. This rule shall not be construed as creating any administrative hearing right or cause of *action.*
    - *Consider addition of "innovative practice models or technologies" as an additional reason. This allows the Board to permit new innovation under a controlled environment and then consider rulemaking while this is occurring.*

Part 3: Pharmacists and Pharmacy Interns: Eligibility and Practice Requirements

- **3-5 Telepharmacy-** Requires pharmacists providing telepharmacy services to patients in Vermont to be a Vermont licensed pharmacist, or for out of state pharmacists, to be licensed within another jurisdiction and hold a Vermont out-of-state telepharmacist license
    - *For out of state pharmacists, it should be adequate to be licensed by another jurisdiction.*

Part 5: Clinical Pharmacy

- **5-5 Privacy-** A pharmacy that offers clinical services shall provide patients with space appropriate for a private clinical consultation about confidential health information. At a minimum, the consultation space shall: (a) shield a patient from the view of others if the patient may be required to partially disrobe (e.g., to receive a vaccine); (b) be suitably acoustically isolated; and (c) not be monitored by audio or video surveillance, including by store security equipment.
    - *Overly prescriptive language. Recommend using a modified version of the previous language: "Each pharmacy providing outpatient prescriptions directly to the public or employees, shall maintain an area designated for the provision of patient counseling* ***or clinical services.*** *This area shall be designed to provide reasonable privacy."*

- **5-6 Immunizations**
    - Statute allows pharmacy vaccinators to basically give all the ACIP recommended vaccines to adults, but limits pharmacists'/technicians' ability to vaccinate kids. The rule tracks with the existing statutory limitations for the adults vs. kids, but on a positive note, the rule language is crafted in a way that if the statutory limitations around vaccines to kids change, the rules wouldn't necessarily have to be updated to accommodate that.
    - Regarding technician vaccinations, the rule language expressly requires that a pharmacist be "present" for tech-administered vaccines

- *This language limits tech vaccines to pharmacies where the pharmacist is physically present. Ideally, this language should be revised so that techs working in remote / satellite pharmacies who are under the remote supervision of a pharmacist can perform the technical act of giving a vaccine that has been ordered by the supervising pharmacist.*

Part 6: License Renewal and Continuing Education

- **6-6 (a) (1)-** at least 10 hours of continuing education coursework shall be live (i.e. synchronous and in-person or online)
  - *We are seeing some states moving away from the "live" requirement. Consider striking this as a requirement. The goal of CE is to ensure that the subjects being educated on relate to the type of practice the pharmacist engages in. We recommend allowing the pharmacist to best decide what those educational options*

Part 7: Eligibility and Practice Requirements for Drug Outlets

- **7-5 Change of Ownership or Location.** Application for new licensure is required whenever there is a change of ownership of the outlet or at the "parent" level or a change in physical location of operation.
  - *Same concern as 2-3; If a pharmacy moves to a new location and there is no change in ownership, this should not be considered a new license. Most states permit a change in location application. This appears to state, they would need a new license - which would result in having to apply for new 3rd party contracts and could potentially put an existing pharmacy out of business. We are comfortable with a change in location application, but it shouldn't be considered a new license. It is not clear if a new license # is issued when a pharmacy changes location. We aim to ensure that when a pharmacy relocates, the pharmacy can retain its original license number.*
- **7-11 Mandatory Reports** The following events shall be reported by both licensees and applicants using the Office's online portal within the timeframes given. (a) Within the next business day after discovery of the reportable event
  - *How does the Board reconcile the "next business day" language with the 48 Hour requirement elsewhere in the rules for these same items? Also, does this supersede requirements in Statute 26-2063 which mentions 48 Hours?*
- **(d) (2) -Drug Loss reporting -** (2) Drug Loss: any significant theft or significant loss of Prescription Drugs;
  - *Recommend changing to "confirmed" significant... Clarifies that reporting is done after investigation is completed and loss is confirmed.*

Part 8: Practice Requirements for All Pharmacies

- **8-9 Information to be Displayed.** A pharmacy open to the general public shall post in a conspicuous location its operating hours, the names of pharmacists on duty, and the printed licenses or registrations of all pharmacy professionals on duty. When in view of the public, Pharmacists, Pharmacy Interns, and Pharmacy Technicians shall wear tags identifying them by name, license type, and title.

- *This is not practical for pharmacies that may have pharmacists covering a shift for a day or temporarily. For patient safety considerations, ensuring that pharmacists, interns, and technicians are properly identified should be sufficient. Consider revising to allow for "available upon request" or amend to something similar to below:*
- *Each licensee shall: (1) Display the license or registration readily available and visible in which the licensee is working; or if this is not the individual's normal working location, (2) Have the license or registration on the person available for viewing.*

- **8-18 Prospective Drug Utilization Review (DUR)** To ensure effective DURs, at least once annually a pharmacy shall determine from the patient or the patient's representative, the patient's known allergies, drug reactions, sensitivities, chronic conditions, disease states, and the current use of other drugs which may relate to a prospective DUR. The information obtained shall be recorded in the patient's record, as well as the date and outcomes of each annual update. A patient who has not provided an update within the year shall be prompted to do so each time a prescription is dispensed.
    - *Vermont would be the only state in the nation that we are aware of that has this requirement to document the date of the annual update. We would recommend striking to align with national standards.*
- **8-19 Significant adverse Drug Reactions.** Any drug-related incident that may result in serious harm, injury, or death to the patient shall be reported by the pharmacist to the practitioner and recorded in the patient's record.
    - *This appears to be written in the future tense vs. past tense. Should this be "did" or "has resulted"?*
- **8-20 (b)-Required elements of a prescription drug order**. Except where exempted by State or federal law, a prescription drug order shall contain the following information, at a minimum:
    - Full name, date of birth, and street address of the patient;

      (2) The prescribing practitioner's name, address, telephone number, and, where applicable, facility or practice name;

      (3) If the prescription drug order is for a controlled substance, the DEA registration number of the prescribing practitioner;

      (4) Date of issuance;

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

      (6) Directions for use by patient;

      (7) Number of authorized refills, if any, or a specified time limit after which refills, if allowed, are not permitted; and

      (8) Except for authorized oral Prescription Drug Orders, a signature sufficient to show the prescription is a valid prescription of the prescribing practitioner;
        - Option 1: 3rd party auditors look to claw-back otherwise valid prescriptions due to a minor missing element that is maintained within the pharmacies database. We recommend adding in 3rd party audit protection language. NC rule 46.2301 uses the below language when the information is

maintained electronically. The references below have been updated to match VT rule:

- **"Information in Subparagraphs (b)(1), (b)(2), (b)(3), (b)(5) and (b)(7) may be stored in a readily retrievable data file specifically compiled for use in the pharmacy, which is not a commercial publication, in lieu of the requirements of the named Subparagraphs."**

- Option 2: Strike all items within this subsection that are not ABSOLUTELY necessary or can be obtained from the patient or are already in the pharmacies database. This updates the rule to recognize that a pharmacist cannot fill a prescription unless the absolute necessary elements are on the prescription. Section **(a)** of this rule already addresses the validation requirements of a prescription. We would highly recommend having overly prescriptive requirements to avoid unnecessary 3rd party chargebacks for prescriptions that would be considered valid otherwise.

- Full name~~, date of birth, and street address of the~~ patient; if for an animal, the species.

(2) The prescribing practitioner's name~~, address, telephone number, and, where applicable, facility or practice name;~~

(3) If the prescription drug order is for a controlled substance, the address and DEA registration number of the prescribing practitioner;

(4) Date of issuance;

(5) Name, strength, ~~dosage form,~~ quantity or stop date of the drug prescribed, ~~and route of administration of the drug prescribed~~;

(6) Directions for use by patient;

~~(7) Number of authorized refills, if any, or a specified time limit after which refills, if allowed, are not permitted; and~~

(8) Except for authorized oral Prescription Drug Orders, a signature sufficient to show the prescription is a valid prescription of the prescribing practitioner;

- **8-20 (e) Security – Regarding prescriptions**
  - *Do we need to clarify if faxes are still permitted?*
- **8-25 – Pharmacy Closing:**
  - (a)(1) **Temporary unplanned closures** & (b)(1) **Temporary planned closures.**
    - *Recommend changing to "business hours" due to the portal upload limitations. Otherwise, they should be willing to accept email notification as sufficient.*
  - **(b) 6-** A summarization document containing the information listed below shall be created after each CQI meeting and shall be retained on-site within the pharmacy. The summarization document shall be available for review at inspections and submitted to the Office or the Board within 3 business days of a request for the summarization

document. The summarization document shall be subject to the Vermont Public Records Act once submitted to the Office or the Board. The summarization document shall:

- *Concern around pharmacies with PSO's needing to produce documents that should be protected under the PSO.*

Part 10: Satellite Pharmacies

- This rule language tracks with the existing rule language for "remote pharmacies" (under current BOP rules Part 19). The existing rules that are essentially being maintained in these draft rules are arguably too restrictive. For example, in order to open up a satellite pharmacy in a community, the applicant has to show that the community is underserved relative to comparable communities.
    - *That's a vague and questionable standard – especially given the current market pressures that pharmacies throughout the state are facing.*
- **10-3-** the rule specifies activities that only the "coordinating pharmacist" can perform – including TPV. It also requires the coordinating pharmacist to receive any oral drug orders from prescribers.
    - *Given that pharmacy technicians are authorized to perform TPV under Part 4-8 of the draft rules and are not otherwise prohibited from accepting oral drug orders from prescribers in traditional community pharmacies, technicians working on satellite pharmacies should also be allowed to do these tasks.*
- **10-2** also requires the coordinating pharmacist to perform documented weekly inspections of a satellite pharmacy.
    - *This is overkill relative to other states that allow remote / satellite pharmacies. Instead, the rule language should be revised to permit "regular inspections"*
- **10-5 Conversion** --The Board may, without beginning disciplinary proceedings, direct a satellite pharmacy to convert its operation to that of a conventional retail pharmacy with a pharmacist on site, if the Board finds that:
    - *The board should consider the prohibitive nature of this language. It's highly unlikely for a business to leverage the tremendous amount of capital necessary to introduce any business if the state can decide, without due process, to force potential closure of its business. It would make sense to introduce this language if there were instances of abuse...but providing this extensive protection language is poor consideration of the use of the standard of care model.*

Grace Sesi, PharmD
Executive Director, CVS Health
One CVS Drive
Woonsocket, RI 02895

c 313-516-6915
f 401-652-2213
Grace.Sesi@cvshealth.com

Via electronic mail: sos.opr.comments@vermont.gov
Public Hearing: Pharmacy
Vermont Office of the Secretary of State, Office of Professional Regulation
89 Main Street, 3rd Floor Montpelier
Vermont 05602

March 5th, 2025

Dear Executive Director Phillips,

I am writing to you in my capacity as Executive Director of Regulatory Affairs for CVS Health and its family of pharmacies located across the United States. Our purpose at CVS Health is bringing our heart to every moment of our patients' health. We are committed to patient safety, technological and process advances, and expanded pharmacy services that will assist in achieving our stated purpose. CVS Health would like to thank the Board for their dedication to continuous improvement through the rules and regulations that guide pharmacists, pharmacy interns and pharmacy technicians serving Vermont patients. We appreciate the opportunity to comment on amended proposed administrative rules.

Part 5-5 Privacy

CVS Health supports and is committed to providing an environment that protects the health, safety, and welfare of patients while they are in our buildings. The newly proposed privacy language is concerning because it does not allow for a pharmacy to maximize security camera coverage of the entire pharmacy department, inclusive of a consultation space. CVS Health requests that the Board amend the proposed language in Part 5-5 Privacy as depicted below. Given that existing HIPAA laws and pharmacy best practices already require appropriate privacy measures, these additional restrictions appear unnecessary.

Suggested Language for Proposed Amended Part 5-5 Privacy

Privacy. A pharmacy that offers clinical services shall provide patients with space appropriate for a private clinical consultation about confidential health information. At a minimum, the consultation space shall:

a. shield a patient from the view of others if the patient may be required to partially disrobe (e.g., to receive a vaccine);

b. be suitably acoustically isolated; and
c. not be monitored by audio or video surveillance, including by store security equipment, unless a patient is notified.

Part 7-11: Mandatory Reporting

CVS Health appreciates the Boards intent around streamlining these regulations to ensure reporting duties are clear. However, several items within this part are addressed elsewhere which may cause confusion. We outline the duplicative and, sometimes conflicting, language in bullets below and suggest revisions.

- Part 7-11 Mandatory Reporting (a)(3), which requires notification within the next business day, is in conflict with Part 8-25 Pharmacy Closing (a)(1) and (b)(1), which requires notification of a temporary closure within 48 hours. Therefore, we suggest striking 7-11(a)(3), as depicted below, allowing 8-25 to regulate closure notifications without conflict and confusion.
- Similarly, 7-11(a)(6) may cause confusion as PM departure reporting is described in detail in 8-15(e)-(f) as a two-step process, but 7-11 suggests only one step via an online portal that is not described in 8-15. Therefore, we suggest striking 7-11(a)(5), as depicted below.
- Relatedly, 7-11(a)(5) is in conflict with 8-4, which requires notice of changes in regular hours of operation 48 hours prior to the change. We propose striking section 8-4.
- Additionally, Part 7-11 is crafted to pertain to both pharmacy licensees and individual licensees, often with specification as to exactly who is responsible for reporting, but it is unclear who is responsible to report within 7-11(a)(6). Therefore, we suggest clarifying the requirement as depicted below.

Suggested Language for Proposed Amended Part 7-11 Mandatory Reports

7-11 Mandatory Reports. The following events shall be reported by ~~both~~ licensee~~s~~ or applicant~~s~~ as applicable using the Office's online portal within the timeframes given.

(a) Within the next business day after discovery of the reportable event:

(1) Change of ownership;

(2) Change of mailing address or physical location;

~~(3) Planned and unplanned closures as defined in Part 8-25;~~

(4~~3~~) Calamity: any disaster, accident, and emergency which may affect pharmacy operations or place drugs at risk of adulteration; and

(5~~4~~) Changes in regular hours of operation; ~~and~~

(6~~5~~) ~~The departure of a pharmacist from the role of Pharmacy Manager, whether voluntary or involuntary and planned or unplanned. This shall include temporary absences of a Pharmacy Manager expected to last thirty (30) or more calendar days.~~

Part 8-6: FDCA and USP Compliance

CVS Health opposes the proposed requirement to incorporate **all** Federal Food, Drug, and Cosmetic Act (FDCA) and United States Pharmacopeia (USP) standards by reference, as it is overly broad, imposes burdensome standards on pharmacies when those standards are not relevant to the practice conducted by those pharmacies and violates the Vermont Administrative Procedures Act. Tens of thousands of pages of standards would be incorporated into Vermont regulations by reference, which is equivalent to adding those page counts into the administrative regulations themselves. In order to comply with all USP standards, pharmacists would need to be positioned to read understand and incorporate all aspects of those standards. This is an unreasonable requirement.

3 V.S.A. § 838(d)(1)(B) allows for a rule to incorporate by reference all or any part of a code, standard, or rule that has been adopted by an agency of the United States, this State, or another state or by a nationally recognized organization or association, if the reference in the rule fully identifies the incorporated code, standard, or rule by citation, date, and place where copies are available. The proposed regulation does not identify the standard by citation, date, and place where copies are available. Therefore, when the USP changes, the regulations change without giving the public notice or the opportunity to provide comment, which is required by the Vermont Administrative Procedures Act.

Furthermore, 3 V.S.A. § 838(2) requires materials incorporated by reference to be readily available to the public, which means:

> (A) Each filing states where copies of the incorporated code, standard, or rule are available in written or electronic form from the agency adopting the rule or the agency of the United States, this State, another state, or the organization or association originally issuing the code, standard, or rule.
>
> (B) A copy of the code, standard, or rule is made available for public inspection at the principal office of the agency, and is available at that office for copying in the manner set forth in 1 V.S.A. § 316 and subject to the exceptions set forth in 1 V.S.A. § 317(c).
>
> (C) The incorporated code, standard, or rule is made available for free public access online unless the agency is prevented from providing such access by law or legally enforceable contract.

The USP is protected under Copyright and would require each user to subscribe, at a cost, in order to access the material based on USP's "Terms of Use". Therefore, it is not possible for the Vermont Board of Pharmacy to comply with the requirement to make the contents readily available to the public without violating USP's copyright.

We recommend the Board to only enforce specific USP chapters, as required under the Federal Food, Drug and Cosmetics Act such as Chapter 795, 797 and 800, and ensure the incorporation by reference complies with the Vermont Administrative Procedures Act.

Part 8-26: Continuous Quality Improvement (CQI) Programs

While we appreciate the Board's recognition of the value of continuous quality improvement (CQI) programs, we have concerns that, as currently drafted, the proposed requirements introduce vague mandates that could be interpreted inconsistently across pharmacies, causing confusion, over-burdening pharmacists, and ultimately undermining the goal of improving patient safety and quality.

We strongly urge the Board to consider streamlining Part 8-26: Continuous Quality Improvement (CQI) Programs and relevant definitions to not only reduce regulatory complexity but also enable pharmacies to focus on continuous improvement efforts that directly enhance patient care, and drive patient safety and quality.

We ask the Board to consider revisions to the proposed rules as set forth below:

1-55 "Quality-related event" or "QRE" means ~~a potential or~~ an ~~actual~~ error~~, actual adverse incident, or actual unsafe condition~~ that occurs in the review, preparation, dispensing, or administration of drugs by pharmacy staff. Examples of QREs include giving a drug to an incorrect patient; providing an incorrect drug, incorrect directions for use, or incorrect quantity, strength, or dosage form of a drug; and listing the incorrect prescriber.

The term "potential…error" is vague and open to many interpretations, including those that are vast in scope, which would impose significant burden on pharmacists in documenting, causing unnecessary and unwarranted disruptions to pharmacy workflow and patient care, thus with the potential for the relevant provision to be counterproductive. Additionally, adverse incidents, or adverse events, as the term is commonly used, include a multitude of adverse reactions or side effects entirely outside of pharmacies' and pharmacists' control, meaning that there would be no opportunity for addressing through pharmacy CQI; as such, the inclusion of "adverse incidents" in the scope of "quality-related events" raises concerns similar to those raised by the inclusion of "potential…errors." Accordingly, we strongly urge the Board to remove "potential…error[s]" and "adverse incidents" from the scope of "quality-related events" and, in turn, the CQI documentation requirements. (We additionally propose below a revision to the proposed rules to leave adverse events subject to any applicable requirements for reporting such as MedWatch or VAERS).

8-26 Continuous Quality Improvement Programs

a. **Purpose**. Each pharmacy shall establish and manage a continuous quality improvement (CQI) program. The CQI shall assess errors that occur during the review, preparation, dispensing, or administration of medications by pharmacy professionals, and shall ensure appropriate action is taken to reduce the probability of a recurrence of an error. Programs established pursuant to this section shall be non-punitive and seek to identify improvements to processes, systems, technology, or training that may improve patient safety.

b. Program Requirements.

1. Quality-related and/or adverse events shall be reported to the FDA's MedWatch, FDA's adverse events reporting system and FDA's vaccine adverse events reporting system, and other appropriate reporting systems, when required.

We propose the above revision to account for the proposed change to the definition of "Quality-related event."

*****

6. A summarization document containing the information listed below shall be created after each CQI meeting and shall be retained on-site within the pharmacy. The summarization document shall be available for review at inspections and submitted to the Office or the Board within 3 business days of a request for the summarization document. The summarization document shall be ~~subject to~~ confidential under the Vermont Public Records Act, upon creation and ~~once~~ after submission~~tted~~ to the Office or the Board and shall not be subject to public inspection or copying, or be otherwise discoverable except by the Office or the Board. The summarization document shall:

A. Not contain identifiable patient information or information that would identify individuals involved in a quality-related event;

B. List ~~all~~ any identified trends in QREs since the previous meeting;

C. List all individuals in attendance at the CQI meeting; and

D. Contain a summary of steps or actions taken since the previous meeting intended to improve processes, systems, technology, training, or staffing inadequacies related to QRE root cause(s).

Consistent with the Board's recognition of the importance of the non-punitive nature of CQI programs as set forth in the "Purpose" section of the proposed rule, we urge the Board to clarify that the records that must be maintained under the proposed rule shall be confidential and not subject to public inspection or discoverable other than by the Board upon request, in accordance with 1 V.S.A. § 317(c).

Part 10-5 Conversions

CVS Health appreciates the efforts the Board has undertaken to build-out a satellite pharmacy platform in the state. However, section 10-5, which grants the Board the authority to close a satellite pharmacy at any point, raises significant concerns for the potential disruption of pharmacy services. Such broad discretionary authority, if exercised, can jeopardize the continuity of care for patients who rely on these satellite facilities, particularly in underserved areas where access to essential medications is critical. Without clearly defined criteria or sufficient procedural safeguards, the provision risks undermining both the economic stability of the pharmacy and the confidence of the communities they serve.

We respectfully urge the Board to reconsider the language in Section 10-5 and to incorporate robust procedural protections before exercising such sweeping authority. Establishing clear,

transparent criteria for closure along with an opportunity for affected pharmacies to appeal or remediate identified issues would strike a more appropriate balance between ensuring public safety and maintaining reliable access to pharmacy services. This revision would help ensure that any decision to close a satellite pharmacy is both fair and justified, thereby preserving the essential role these facilities play in patient care.

Suggested Language for Proposed Amended Part 5-5 Privacy

10-5 **Conversion.** The Board may close a satellite pharmacy only after it issues written notice explaining the specific health or safety concerns and giving the pharmacy 30 calendar days to correct them. If the pharmacy does not resolve the issues within that period, the Board may move forward with closure. However, the pharmacy must have the right to appeal the decision before any closure is finalized. ~~without beginning disciplinary proceedings, direct a satellite pharmacy to convert its operation to that of a conventional retail pharmacy with a pharmacist on site, if the Board finds that:~~

~~a. a remote dispensing site is no longer necessary to ensure acceptable access to care in the locality;~~
~~b. a remote dispensing pharmacy has been unable to comply with operating requirements; or~~
~~c. continued remote operation is no longer in the interest of the public.~~

The Boards efforts to modernize pharmacy regulations and decrease regulations from over 100 pages to close to 50 are commendable. However, the sections outlined above introduce excessive regulatory costs, administrative burdens, and compliance uncertainties that could ultimately harm pharmacy operations and patient access to care.

CVS Health thanks the Board for welcoming comments which will increase access to the citizens of Vermont and is aligned with CVS' mutual mission that pharmacists can leverage their full clinical ability to provide patient access to care. Please feel free to reach out to me directly at (313) 516-6915, and I will be happy to address any questions you may have.

Regards,

Grace Sesi, PharmD
Executive Director, Pharmacy Regulatory Affairs
CVS Health

Regarding the subjects required biennially for pharmacist license renewal:

The requirements set forth in **Continuing Education 6-6(a) (2)** regarding controlled substances could be left as the broad language in **(2)** rather than the specific examples outlined in **Subsections (A) thru (F)** which may not be inclusive of every potential controlled substance topic.

The requirements set forth in **Section 3** of five hours of CE for pharmacists who oversee or engage in sterile compounding or hazardous-drug compounding are excessive. The section leaves out pharmacists who may not do the compounding but approve the final product. ***Two hours of CE would be appropriate for each licensure period***. Managing pharmacists could be required to take four hours of CE prior to assuming the role of pharmacy manager in a sterile compounding or hazardous-drug compounding pharmacy.

If any of these are hours are related to federal or state laws regarding compounding, the courses should also count as a **"Law"** requirement. (see below).

In addition:

Law- Because Vermont no longer requires the MPJE, it is important for pharmacists to stay abreast of new federal and state rules/laws. A law requirement of 1 CEU per biennium would ensure that all pharmacists are up to date of new legal requirements.

Immunization- Most adult vaccinations in Vermont are provided by professional pharmacy staff. Since the APhA and other immunization programs do not require CEUs, it is in the best interest of Vermonters for the state to ensure that all ACIP (as referred to in the immunization section) schedules are reviewed and put into practice for pharmacist/technician/Intern immunizers. ACIP meets several times a year and issues new schedules, vaccines, etc. yearly. ***We recommend that the 2 CEU requirement be re-instated.***

In conclusion: While these recommendations increase the requirements for renewal, not all pharmacists compound sterile and hazardous drugs, and not all pharmacists immunize. Therefore, they should not be subject to those requirements.

6-6 Continuing Education. As a condition of biennial license renewal, beginning with the first biennial licensing period following initial license issuance, pharmacists and pharmacy technicians licensed in Vermont shall complete continuing education coursework in accordance with the requirements in this subpart. A

Continuing Education course shall only be accepted as fulfilling the requirements of this Rule if approved by ACPE; by the American Medical Association as a Category 1 course; by the Board; or by entities designated by the Board.

(a) Pharmacists, 30 hours. A pharmacist shall complete at least 30 hours of approved continuing education coursework every biennial period. The continuing education shall meet the following requirements:

(1) at least 10 hours of continuing education coursework shall be live (i.e., synchronous and in-person or online);

(2) at least two total hours of continuing education coursework shall be on one or more of the following topics:

(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; and

(F) relevant State and federal laws and regulations about the prescription

of opioid controlled substances; and

(3) for pharmacists who oversee or engage in sterile compounding or hazardous-drug compounding, at least five hours of the continuing education coursework shall relate to those specialties.

Regarding the subjects required biennially for pharmacist license renewal:

The requirements in **Section 2** regarding opioids seem a little "in the weeds" and perhaps should be just left in broader language. There are plenty of CEs out there which deal with opioids in those circumstances outlined in sections A-F that qualify for a 2 CE "opioid" presentation.

The requirements in **Section 3** regarding compounding seem to be a heavy lift (5 CEs in 2 years) and to date there are few states (MA excepted) that require so many credits. Also, the Event that precipitated the requirement was in 2012 and guidelines have been strengthened for sterile and hazardous drug compounding, rendering such heavy requirements moot. Perhaps a 2CEU requirement would be more appropriate. One of these credits could double as a **"Law"** requirement. (see below).

This also presumes that non-sterile, non-hazardous drug compounding, which has historically been the purview and training of pharmacists, would not be subject to this requirement (creams, ointments, capsules, suspensions, sprays, etc.)

In addition:

Law- since VT no longer requires the MPJE, it is important for pharmacists to stay abreast of new rules. A law requirement of 1CEU per biennium would ensure that all pharmacists are up to date on any new developments (both state and federal). We realize that all pharmacists need to be conversant in the rules, a law requirement would be a reminder to review them periodically as there may be changes to state and federal law in between renewal periods.

Immunization- Since the APhA and other Immunization programs do not require CEUs, it behooves the state to ensure that all ACIP (as referred to in the immunization section) schedules are reviewed and in practice for pharmacist/technician/Intern immunizers. ACIP meets several times a year and issues new schedules, vaccines, etc. yearly and that the 2CEU should be re-instated.

In conclusion: While these recommendations increase the requirements for renewal, not all pharmacists compound sterile and hazardous drugs, and not all pharmacists immunize, and would, therefore, not be subject to those requirements.

Administrative Rules for the Board of Pharmacy:
Summary of Substantial Arguments, Agency Responses, and Amendments

Note: There have been some reorganization and renaming of the Parts of the rule. This summary is organized to correspond with the proposed rule filed with the Secretary of State.

Part 1: Definitions

Comment: Multiple commenters suggested changing the definition of patient counseling to allow for the use of adaptive technologies.

Response: This change has been made. In addition, discussion of patient counseling has been moved from Definitions to Part 8, Pharmacy Practice – In General.

Comment: One commenter suggested broadening the definition of "Pharmacist Care" to include all clinical services within the pharmacy scope of practice.

Response: This change has been made.

Comment: One commenter suggested changing the definition of out-of-state pharmacies to remove the limitation to pharmacies dispensing drugs to persons located in Vermont. "This means," the commenter argued, that "means pharmacies in other states that don't dispense drugs to VT residents are not pharmacies" within the meaning of the rules.

Response: That is the intended meaning. Vermont has no jurisdiction over out-of-state pharmacies that do not dispense into Vermont. No change has been made.

Comment: One commenter pointed out that "DSCSA" and "NCDQS" are undefined.

Response: We have spelled out the acronyms where used.

Comment: One commenter pointed out that the definition of "Compounding," as currently worded, could be interpreted to include any labeling of a drug and is therefore overbroad.

Response: The definition has been revised to remove "labeling."

Comment: One commenter recommended removing "whether or not for consideration" from the definition of "deliver" or "delivery," arguing it is ambiguous.

Response: "Consideration" has been replaced with "compensation."

Part 2: Administration and Procedures

Comment: When a pharmacy changes location, both the proposed and current rules require a new pharmacy application, resulting in a new pharmacy license. Commenters informed OPR that some third-party contracts require re-negotiation if a pharmacy's license number changes. The commenters asked that OPR build a system that allows a pharmacies to change locations and undergo re-inspection without obtaining a new license.

Response: The rules have been revised to allow in-state drug outlets to retain their license numbers when changing location, provided that ownership does not also change. Upon such a change, operations must cease pending re-inspection, and operation prior to re-inspection would be considered unauthoraized practice under 3 V.S.A. § 127. No change has been made for nonresident drug outlets, for two reasons. One, it would be much harder for OPR to enforce the requirement to cease operation pending re-inspection, as we would be much less likely to learn of the illicit operation than with an in-state drug outlet. Two, nonresident drug outlets contract with suppliers primarily through their home-state license numbers, and moreover do business across multiple states, and so a change in their Vermont license number would disrupt the business as a whole far less than an in-state drug outlet. It should be noted that OPR's data systems do not allow us issue duplicate license numbers or manually change license numbers.

Comment: Two commenters asked for a provision allowing the Board to waive the rules to allow experimentation with new practice models or technology.

Response: The proposed rules as a whole are much less prescriptive of day-to-day pharmacy practice than the existing rules; the proposed rules focus on outcomes (compliance with fixed third-party or statutory standards) rather than how licensees achieve those outcomes. Notably, neither commenter pointed to anything in the rules that would prohibit innovation. Language has been added make clear that no presumption against innovation should be inferred, but no additional waiver authority has been added.

Part 3: Pharmacists and Pharmacy Interns: Eligibility and Practice Requirements

Comment: One commenter suggested that OPR either codify the existing requirement for internship preceptors, or to eliminate the requirement.

Response: This is an excellent point. Virtually all internships now take place within the pharmacy degree program, and it is not necessary to enforce eligibility criteria for preceptors of Vermont-based internships when we do not do so for out-of-state internships. The registration requirement will be discontinued.

Comment: One commenter asked that OPR allow pharmacists licensed out of state to practice telepharmacy on Vermont patients without obtaining a Vermont telepharmacy credential.

Response: Under this proposal, OPR would have no jurisdiction over the practice of out-of-state telepharmacy, because there would be no license to prosecute nor any unauthorized practice occurring. No change has been made.

Part 4: Pharmacy Technicians: Eligibility and Practice Requirements

Comment: One commenter asked about a waiver of the high-school diploma / GED requirement for pharmacy technicician trainnes.

Response: The GED / high-school diploma requirement for trainees has been removed entirely and replaced with a 16-year age minimum.

Comment: The proposed rules require pharmacies using TPVPs to have a pharmacist review the accuracy of a sample of technician verifications at least quarterly. One commenter said that quarterly is "very frequent" and "would be a significant administrative burden."

Response: The proposed rules around TPVPs are based on those of the Iowa Board of Pharmacy, which piloted the concept for years before promulgating final TPVP rules in 2019. The results of that pilot were published in a peer-reviewed journal. *See* "The Iowa new practice model: Advancing technician roles to increase pharmacists' time to provide patient care services," 58 J. Am. Pharm. Ass'n 268 (2018). Based on that study, Iowa's Board concluded that quarterly review was appropriate. We have no basis to second-guess this conclusion. No change has been made.

Comment: One commenter asked for clarification that pharmacy technicians may not perform drug utilization review or prescription/order verificataion.

Response: Language to this effect has been added.

Part 5: Clinical Pharmacy

Comment: Multiple commenters pointed out that the two rules about collaborative practice agreements were redundant and inconsistent.

Response: We thank the commenters catching this. The rules have been combined.

Comment: A commenter expressed concern that the commercial inducement would prevent proactive renewal requests and automatic refills.

Response: This section has no impact on prescription drug orders made by non-pharmacist prescribers. The purpose of this section is to bar pharmacies' commercial interests from influencing pharmacists' clinical judgment *as prescribers*, not as fillers of other prescriber's prescriptions. No change has been made.

Comment: Multiple commenters criticized the rules as overly prescriptive regarding the physical spaces needed for the practice of clinical pharmacy. They recommended taking a more general approach.

Response: We agree. The has been revised and simplified.

Comment: One commenter opined that pharmacy technicians should be authorized to administer vaccines without a pharmacist present, because that requirement prevents vaccination administration in satellite pharmacies.

Response: This point is well taken. The proposed rules already require any pharmacy technician administering vaccines to take an accredited course that meets CDC guidelines. The explicit requirement for pharmacist presence for vaccinations has been removed. The general requirement for pharmacist presence during pharmacy operations remains, with the only exception being satellite pharmacy operations.

Part 6: License Renewal and Continuing Education

Comment: One commenter asked that out-of-state entities be allowed to use 3-year-old inspections instead of 2-year-old inspections if using an NABP supply chain inspection.

Response: All in-state entities are inspected at least every 2 years. The problem with allowing 3-year-old inspections is that OPR is on a 2-year renewal cycle, so a licensed entity could potentially use the same inspection for 2 renewals and thereby undergo inspection only every 4 years. Much can change in 4 years.

The risk of patient harm from unsanitary or otherwise dangerous practices is greatest for actual manufacturers, compounding pharmacies, home infusion pharmacies, 503B outsourcers, and nuclear/radiologic pharmacies. We have maintained the 2-year inspection requirement for those entities. For other entities, the rule has been revised back to the current requirement for an inspection within the past 3 years.

Comment: Two commenters suggested removing the requirement that 10 of the 30 required hours of pharmacist continuing education be live rather than asynchronous. The commenter opined that licensees should be allowed to decide for themselves which CE format best suits their educational needs.

Response: We agree. The requirement has been removed.

Comment: One commenter opined that it would be overly burdensome to require pharmacy technicians to obtain 10 hours of continuing education each year.

Response: On the Board's recommendation, we have revised the rule to require 6 hours of pharmacy technician CE.

Comment: One commenter suggested that the Office mandate continuing pharmacist education on changes in the legal landscape as well as immunization recommendtions and standards.

Response: The commenter did not provide any examples of harm to the public occuring because of pharmacists falling behind in these areas. The Board trusts pharmacists to use their own judgment in choosing CE courses appropriate to their practice and knowledge.

Comment: One commenter opined that the rules are too granular regarding the topics required for pharmacists' continuing education related to opiate prescribing and related subjects.

Response: Broader language would conflict with Act 173 (2016), which the rule tracks word for word. No change has been made.

Comment: One commenter opined that pharmacists who engage in sterile compounding or hazardous-drug compounding should not have to complete 5 hours of CE on those topics, and recommended a lower requirement to align with other states.

Response: The requirement has been reduced to 3 hours.

Comment: One commenter asked that the rules define "oversee[ing]" sterile compounding or hazardous-drug compounding.

Response: The rule has been amended to reference the USP definition of "Designated Person" as related to these specialties.

Comment: One commenter asked for a continuing education waiver for pharmacists in their first licensure cycle so that they don't need to scramble if they are licensed shortly before the next renewal cycle.

Response: 3 V.S.A. § 123(a)(12)(B) controls this situation and already exempts licensees from fulfilling renewal requirements (including CE) if they become licensed within 90 days of the next renewal cycle. No change has been made.

Part 7: Eligibility and Practice Requirements for Drug Outlets

Comment: One commenter wondered what time frame was associated with the requirement that a pharmacy submit a new application when ownership changes.

Response: We intended to carry over the time frame from the existing rules, which allow, after a change in drug outlet ownership, 48 hours to notify the Board and 15 business days to file a new application. We have worded "15 business days" to "21 days" in keeping with more recent "a day is a day" drafting convention.

Comment: One commenter asked for clarification about the scope of the requirement for recall procedures for compounded drugs.

Response: The rule has been revised to make clear that the recall procedure requirement applies to all drugs.

Comment: One commenter pointed out a conflict between provisions on the timelines for pharmacies to report pharmacy closures and changes in regular operating hours.

Response: We agree. The sections on closures and changes of hours have been substantially revised.

Comment: One commenter pointed out potential confusion springing from two different provisions about reporting requirements for departures and absences of pharmacy managers. The commenter recommended deleting one provision.

Response: One of these sections has been deleted and the other revised for clarity.

Comment: Pharmacies are required to report any theft or significant loss of prescription drugs. One commenter suggested that we require these reports only if the thefts or loss is "confirmed."

Response: The rule requires that these reports be made within 30 days. If the pharmacy determines within those 30 days that no theft or significant loss has occurred, no report is required. Conversely, if a pharmacy can't confirm within 30 days whether a drug theft or significant loss has occurred, OPR may need to investigate the pharmacy's security and recordkeeping. No change has been made.

Comment: One commenter asked us to define "significant" in "significant loss" of prescription drugs.

Response: This langauge comes from the code of federal regulations, which contains a list of factors to consider. A reference to that regulation has been added.

Comment: One drug manufacturer asked that OPR extend the deadlne to report drug outlet changes of ownership from 1 business day to 5 days. Another commenter pointed out that the "next business day" language conflicts with a statutory requirement of 48 hours.

Response: The deadline has been changed to 48 hours, as required by statute.

Part 8: Practice Requirements for All Pharmacies

Comment: A commenter opined that it is unduly burdensome to require licensees to comply with USP chapters below <1000> because those standards are constantly changing. The commenter also complained that OPR has failed to comply with 3 V.S.A. § 838(2)'s requirement to provide information about materials incorporated by refrence.

Response: Federal law has incorporated the USP--the United States Pharmacopoeia—since the 1906 passage of the original Food, Drug, and Cosmetics Act. Part 8-6 merely references this existing requirement and imposes no new burdens on licensees. As for 3 V.S.A. § 838(2), OPR properly included the USP in its "Incorporation by Reference" cover sheet. No change has been made.

Comment: The proposed and existing rules require retail pharmacies to conspicuously display the licenses or registrations of all pharmacy professionals on duty. Two commenters said that this requirement was impractical for pharmacists working temoprarily and recommended a requirement to make licenses available upon request.

Response: The reasoning behind this requirement is that few consumers will feel comfortable asking to see a license that is not on display. The confrontational nature of the request would chill complaints that could lead to necessary enforcement. At the same time, we understand that wall space can be at a premium and that chain pharmacies especially may have many staff moving between locations. We have compromised by allowing pharmacies to display pharmacy professional licenses only at the professional's "principal place of business," as required by 26 V.S.A. § 2042(d). Copies of the licenses of other pharmacy professionals can be on-site and available for viewing upon request. At the same time, since we know many consumers would never make this request, we have added a requirement that name tags include last initials. This is to help the public and OPR investigators identify pharmacy professionals about whom a complaint is made.

Comment: The proposed and existing rules require that retail pharmacies reverify patients' known allergies, drug sensitivities, and other information at least annually, to enable prospective drug utilization review. The proposed and existing rules require pharmacies to document that this annual verification has been performed. Representatives of two drugstore chains said that it is operationally impractical to document this verification.

Response: Annual reverification saves patient lives by preventing severe allergic reactions and drug interactions. OPR is currently prosecuting a licensee for failure to perform this annual reverification. During rule review, Board counsel asked how the Office could enforce annual verification without a documentation requirement. The Board had no answer; one of the commenters suggested, essentially, the honor system. Moreover, a representative of a third drugstore chain said that their company has been able to build this documentation ability into its computer system. No change has been made.

Comment: The proposed rule requires pharmacists to inform prescribers of "Any drug-related incident that may result in serious harm, injury, or death to the patient shall be reported by the pharmacist to the practitioner and recorded in the patient's record." One commenter asked if this was supposed to be in the past tense and cover only incidents that have resulted in serious harm, injury, or death, rather than potential serious harm, injury or death.

Response: The rule is drafted as intended. No change has been made.

Comment: Regarding required elements of a prescription drug order, one commenter noted that 3rd-party auditors "look to claw-back otherwise valid prescriptions due to a minor missing element" required under state law. The commenter asked that we strike all elements not absolutely necessary to fillng a prescription. Another commenter noted that patients' street addresses, in particular, are often omitted by prescribers, preventing the prescription from being filled.

Response: We have revised the rule to remove nonessential elements, including the patient's street address. Prescribers and pharmacists should note that DEA regulations may require patient addresses on prescriptions for controlled substances.

Comment: Two commenters asked for clarification about whether the rules permit pharmacists to fill faxed prescriptions.

Response: Language has been added explicitly permitting faxed prescriptions.

Comment: The proposed rule requires pharmacies to notify the Board within 48 hours of an unplanned closure or within 48 hours of becoming aware a planned closure will occur. One commenter asked that the rule specify "during business hours," "due to the portal upload limitations."

Response: There are no such portal limitations. OPR's licensee portal is avilable 24 hours a day, every day. No change has been made with respect to unplanned closures. The deadline for planned closures has been changed to 30 days before the closure or within 48 hours of becoming aware that the planned closure will occur. This is to allow pharmacies to plan closures (such as for renovations) long in advance without requiring notice to the public impractically long in advance.

Comment: Commenters asked that the Board streamlne or eliminate the section on Continuous Quality Improvement Programs. Concerns included the scope of "potential errors," documentation burdens, and redundancy with existing systems. Another commenter expressed concern about being required to produce information protected by federal law.

Response: The CQI section as a whole has been streamlined. The definition of QRE has been revised to eliminate the term "potential error," instead adapting language from the model rules of the National Association of Boards of Pharmacy. Language has been added making explicit that OPR will respect federal protections of patient safety work product. Language has also been added clarifying that licensees may combine CQI

analysis and documentation with existing processes so long as the programs' core requirements are met.

Part 9: Registration and Practice Requirements for Specific Drug Outlet Types

Comment: Part 9-1(f) concerns drugs brought into institutions by patients. One commenter noted that FDA guidance around controlled substances brought into institutions by patients is unclear, that institutions are not generally equipped to store drugs brought by patients, and that either way this is not a pharmacy issue outside of assuring the safety of any drugs administered. The commenter asked that the second two sentences of Part 9-1(f) be deleted.

Response: This change has been made.

Comment: A Pfizer representative asked for confirmation that manufacturing licenses are not required for "facilities that only produce Active Pharmaceutical Ingredients and ship them to other facilities for further processing."

Response: Those facilities require a manufacturing license. 26 V.S.A. §§ 2022(6)(D), 2022(11)(A). No change has been made.

Part 10: Satellite Pharmacies

Comment: One commenter said that requring weekly inspections of satellite pharmacies is "overkill."

Response: The proposed rules require monthly inspections, not weekly.

Comment: One commenter pointed out that the proposed rule implied that no more than one pharmacy technician at a time may staff a satellite pharmacy.

Response: The rule has been revised to remove that implication.

Comment: One commenter said that pharmacy technicians in satellite pharmacies should be able to receive oral prescription drug orders and perform final verifications within TPVPs, as they can in regular retail pharmacies.

Response: We agree. These changes have been made.

Comment: One commenter opined that the Board's authority to convert a satellite pharmacy license to a regular retail pharmacy license denies license holders due process and discourages businesses from investing in the creation of satellite pharmacies.

Response: We appreciate these concerns. At the same time, allowing satellite pharmacies to persist in operating without an on-site pharmacist, despite changing conditions, could over time make satellite operation the norm. The rule has been revised to remove the Board's authority to convert satellite pharmacy licenses without warning. Instead, satellite pharmacy licensees must demonstrate the ongoing need for and safety of their satellite operation as a condition of license renewal. This allows license holders to be prepared to make this showing on a predictable biennial schedule.

Comment: One commenter complained that the proposed rules for satellite pharmacies "track[] with the existing rule language for 'remote pharmacies'" and are "arguably too restrictive." The commenter complained that the requirement that the satellite pharmacy's community be underserved relative to comparable commmunities is "vague and questionable."

Response: The proposed rules differ widely from the existing rules from remote pharmacies, which are three times longer than those proposed. The commenter has proposed no alternative to the standard they call "vague and questionable." It is not the Board's intention to permit pharmacies to operate without on-site pharmacists routinely or without a showing that such operation is in the public interest. No change has been made.

Annotated Text

Administrative Rules of the Board of Pharmacy

effective: September 15, 2015

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Administrative Rules
Vermont Board of Pharmacy
Effective: September 15, 2015

(cite as B.O.P. Rule x.x.)

Part 1 General Information

1.1 The Board's Purpose 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, among other authority set forth in Chapter 36 and in Chapter 5 of Title 3, setting standards for examining and licensing qualified applicants, and regulating the practice of pharmacy.

1.2 Board Restrictions The Board may not make any rule that is designed or implemented to limit 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.

1.3 Business Address The Board is located at the Office of the Secretary of State, Office of Professional Regulation, 89 Main St., Fl. 3, Montpelier, VT 05620-3402 ("the Office"). The Board's mailing address is the same. The Office telephone number is 1-802-828-1505. Applications, copies of these rules, and additional information about the Board may be obtained by contacting the Office or by accessing the Board's website, http://vtprofessionals.org/.

1.4 Board Members And Officers 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. § 2031 other than as consumers or possible consumers. Members of the Board are appointed by the governor as provided in 3 V.S.A. sections 129b and 2004. The Board elects a chair, a vice chair and 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 or the website.

1.5 Hearings The Board conducts hearings in accordance with the Administrative Rules for the Office of Professional Regulation, 3 V.S.A. § 129, and the provisions of the Vermont Administrative Procedure Act for contested cases, 3 V.S.A. §§ 801-816.

1.6 Regular, Special, And Emergency Meetings 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.

1.7 Laws That Govern The Board

(a) 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. The Board is also governed by and exercises authority granted in Chapter 5 of Title 3 of the Vermont statutes. In addition, the Board must comply with several other statutes, such as the "Law of Professional Regulation," (3 V.S.A. §§121- 132), 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. Please note that 3 V.S.A. § 129a also defines unprofessional conduct which can be the basis of disciplinary action.

(b) 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 .

(c) The profession of pharmacy is governed by other state and federal laws among which are 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. §§ 4201-42, and postal regulations to be followed when shipping legend drugs.

1.8 Rules Of The Board

(a) 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. These rules may be cited as "BOP Rule x.x"

(b) Violation of these rules may result in disciplinary action by the Board or other federal or state authorities.

1.9 Abbreviations Used in These Rules As used in these rules:

(a) ACPE: Accreditation Council for Pharmacy Education.

(b) DEA: Drug Enforcement Administration.

(c) FDA: Food and Drug Administration.

(e) FPGEC: Foreign Pharmacy Graduate Examination Committee.

(f) FPGEE: Foreign Pharmacy Graduate Equivalence Examination.

(g) MPJE: Multistate Pharmacy Jurisprudence Examination.

(h) NABP: National Association of Boards of Pharmacy.

(i) NAPLEX: North American Pharmacy Licensure Examination.

(j) OPR: Office of Professional Regulation, or "office."

(k) TOEFL: Test of English as a Foreign Language.

(i) TSE: Test of Spoken English.

(m) VAWD: Verified Accredited Wholesale Distributor.

1.10 Definitions (a) As used in these rules:

(1) "Administer" or "Administration" means the direct application of a drug to the body of a patient or research subject by injection, inhalation, ingestion, or any other means.

(2) "AMDS" means automated medication distribution system. An AMDS is an automated device or series of devices operated by an electronic interface with one or more computers that is used to

prepare, package, or dispense specified dosage units of drugs for administration or dispensing to a patient or the ultimate user. "AMDS" includes a device that prepares and packages a drug for unit dose dispensing, that prepares and packages a drug into outpatient prescription vials, and that dispenses pre-packaged drugs.

(3) "Alternative evidence of the individual's identity" as referred to in 18 V.S.A. § 4215b means documents which reasonably permit a pharmacist to conclude that the individual is who he or she purports to be.

(4) "Bona fide representative of a patient" as referred to in 18 V.S.A. § 4215b means an individual who is authorized by law, or known to the patient and authorized by the patient to receive drugs dispensed by prescription for the patient.

(5) "Bona fide representative of an animal owner" as referred to in 18 V.S.A. § 4215b means the owner of an animal or a person authorized by the owner to receive drugs dispensed by prescription for the animal.

(6) "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 caregiver a time beyond which the contents of the prescription are not recommended to be used.

(7) "Board of Pharmacy" or "Board" means the Vermont Board of Pharmacy, or its designee.

(8) "Collaborative Pharmacy Practice" means that portion of pharmacy practice where a pharmacist may perform certain patient care functions under a protocol of specified conditions or limitations in collaboration with a practitioner. Collaborative practice agreements must be in writing and are valid for up to one year. After one year, a new written agreement is necessary for the collaboration to continue. Each collaborative practice agreement shall include provisions for no less than an annual quality assurance review by the collaborating practitioner. A pharmacist may have collaborative practice agreements with more than one practitioner.

(9) "Compounding" means the preparation of any active ingredients or added substances into a drug product

(A) 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;

(B) 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. Compounding does not include mixing, reconstituting, or other such acts that are performed in accordance with directions contained in approved labeling provided by the product's manufacturer.

(10) "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.

(11) "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.

(12) "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."

(13) "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.

(14) "Distribute" or "Distribution" means the delivery of a drug or device other than by administering or dispensing.

(15) "Drug" means:

(A) 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;

(B) articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in humans or other animals;

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

(D) articles intended for use as a component of any articles specified in clause (A) (B) or (C) of this definition.

(16) "Drug regimen review and/or "drug utilization review" includes but is not limited to the following activities:

(A) Evaluation of the prescription drug order(s) and patient record(s) for:

(1) known allergies;
(2) rational therapy-contraindications;
(3) reasonable dose and route of Administration; and
(4) reasonable directions for use:

(B) Evaluation of the prescription drug order(s) and patient record(s) for duplication of therapy;

(C) Evaluation of the prescription drug order(s) and patient record(s) for interactions:

(1) drug-drug;
(2) drug-food;
(3) drug-disease; and
(4) adverse drug reactions.

(D) Evaluation of the Prescription Drug Order(s) and patient record(s) for proper utilization

(including over or under-utilization), and optimum therapeutic outcomes.

(17) "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.

(18) "Electronic transmission intermediary" means an entity that provides the infrastructure that connects the computer systems or other electronic devices used by health care providers, prescribers, pharmacies, health care facilities, pharmacy benefit managers, health insurers, third party administrators, and agents and contractors of those persons in order to facilitate the secure transmission of an individual's prescription drug order, refill, authorization request, claim, payment, or other prescription drug information.

(19) "Electronic digital signature" means an electronic signature based upon cryptographic methods of originator authentication, and computed so that the identity of the signer and the integrity of the data can be verified.

(20) "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.

(21) "Equivalent Drug Product" means a drug product which has the same 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.

(22) "Fine/Civil/Administrative Penalty" is a monetary penalty permitted by law assessed against a licensee for violation of federal or state statutes or rules governing the practice of the profession.

(23) "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.

(24) "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.

(25) "Legend drug" see definition of prescription drug below.

(26) "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.

(27) "Manufacturer" means a person engaged in the manufacture of drugs or devices.

(28) "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.

(29) "Medical Order" means a lawful order of a practitioner that may or may not include a prescription drug order.

(30) "Medication Therapy Management" means a distinct service or group of services that optimize therapeutic outcomes for individual patients. Medication Therapy Management services are independent of, but can occur in conjunction with, the provision of a medication or a medical device.

(31) "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.

(32) "Office" means Office of Professional Regulation.

(33) "Patient Counseling" means the oral communication by the pharmacist of information, as defined in the rules of the applicable Board, to the patient or caregiver, in order to ensure proper use of drugs and devices.

(34) "Person" means an individual, corporation, subsidiary, partnership, association, organization, affiliate organization, or any other legal entity, including government.

(35) "Pharmacist Care" is the provision by a pharmacist of medication therapy management services, with or without the dispensing of drugs or devices, intended to achieve outcomes related to the cure or prevention of a disease, elimination or reduction of a patient's symptoms, or arresting or slowing of a disease process, as defined in the Rules of the Board.

(36) "Pharmacist" means an individual currently licensed by this state to engage in the practice of pharmacy.

(37) "Pharmacist-Manager" (also referred to as "Pharmacist in Charge") means a pharmacist currently licensed in this state who has held an unencumbered license in this or another state for at least two years, 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.

(38) "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.

(39) "Pharmacy Intern" is a person working toward licensure as a pharmacist as set forth in Part 4 of these rules.

(40) "Pharmacy, Scope of Practice." See, 26 V.S.A. § 2032(a)(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 profession, it also embraces the interpretation, evaluation, and dispensing of prescription drugs or drug orders in the patient's best interest; immunization; 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.

(41) "Practice of Telepharmacy" means the provision of pharmaceutical care through the use of telecommunications and information technologies to patients at a distance.

(A) "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.

(B) Those providing telepharmacy services must register with the Board and meet the requirements set forth in Rules 2.9 and 2.10.

(42) "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.

(43) "Preceptor" means an individual who is currently licensed as a pharmacist by the Board of Pharmacy, who meets the qualifications as a preceptor under the rules of the Board, and participates in the instructional training of pharmacy interns.

(44) "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:

(A) "Caution: Federal law prohibits dispensing without prescription;" or

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

(C) a drug which is required by any applicable federal or state law or rule to be dispensed pursuant only to a prescription drug order or is restricted to use by practitioners only.

(45) "Prescription Drug Order" means a lawful order from an authorized prescriber 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. Non-verbal non-electronic prescriptions must bear the signature of the prescriber.

(46) "Tamper resistant prescription form" means a form meeting the requirements of Rule 9.5.

(47) "These Rules" mean the Administrative Rules of the Board of Pharmacy;

(48) "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.)

(49) "Repackage" means changing the container, wrapper, quantity, and labeling of a product or device to further the distribution of the drug or device.

(50) "Repackager" means one who repackages drugs or devices.

(51) "Signature" for purposes of a prescription, means an authorized prescriber's name handwritten by that person on a "hard" prescription, or that person's "electronic digital signature" as part of an electronic prescription sent directly to a pharmacy.

(52) "Significant Adverse Drug Reaction" means any drug-related incident that may result in serious harm, injury, or death to the patient.

(53) "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.

1.11 Acts Which May Affect Licensure, Registration, or Renewal The Board may discipline or deny licensure, registration, or renewal under these rules if any applicant, sole proprietor, partner, corporate officer, or owner has engaged in unprofessional conduct violating these rules, 3 V.S.A. § 129a, and 26 V.S.A. § 2051, or acts which directly affect the ability to practice pharmacy.

1.12 Licenses, Registrations, and First Renewal An applicant issued an initial license or registration within 90 days of the renewal date will not be required to renew or pay the renewal fee. The license will be issued through the next full license period. An applicant issued an initial license more than 90 days prior to the renewal expiration date will be required to renew and pay the renewal fee.

1.13 Renewals All licenses and registrations are renewed biennially on a schedule as determined by the office.

Part 2 Requirements for Pharmacist Licensure

2.1 Routes to Licensure There are two routes to licensure as a pharmacist, licensure by examination and licensure by endorsement.

2.2 Licensure by Examination, Qualifications For Licensure To be eligible for licensure as a pharmacist, an applicant must:

(a) Be at least 18 years of age;

(b) Submit an official transcript showing graduation from a pharmacy school approved by ACPE or other accrediting body approved by the Board;

(c) For foreign-trained applicants, have successfully passed the FPGEE, TOEFL, and TSE examinations or their successor examinations and hold an FPGEC certificate or its successor certificate demonstrating that their education was equivalent to the education at a school or college specified in subsection (b) above;

(d) Have completed an internship or demonstrated experience which is equivalent to an internship as set forth in Part 4 of these rules;

(e) Have passed the required examinations as set forth in Rule 2.3 below; and

(f) Have submitted an application form with photograph, and paid the appropriate fee.

2.3 Examinations Licensure requires successful completion of the "NAPLEX" and the "MPJE." Contact NABP through its web site http://www.nabp.net/ for the date, time, and place of the examination.

2.4 Required Examination Scores 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.

2.5 Score Transfer Vermont will accept the NAPLEX score attained by an applicant from another state when the following requirements are met:

(a) The score is transferred through the NABP office under the conditions outlined by that Association;

(b) An application is submitted;

(c) The NAPLEX was taken no more than one year prior to submitting the application.

2.6 Pre-Graduation Applications An applicant who has not yet 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.

2.7 Licensure By Endorsement The Board may license an applicant who possesses an active license in a state whose current standards are substantially equivalent to the current standards in Vermont. The applicant shall submit:

(a) The Vermont application form and official NABP form, completed in full and signed by the applicant;

(b) Official verification of original licensure by examination;

(c) Official verification of current active license and report of disciplinary history;

(d) The prescribed application fee; and

(e) shall successfully complete the MPJE for Vermont.

2.8 License Renewals Applicants for license renewal shall submit:

(a) The completed renewal form;

(b) A statement listing the continuing pharmacy education programs completed since the licensee's latest license was issued showing compliance with continuing education requirements;

(c) The prescribed fee; and

(d) Any late fees or penalties required by law.

2.9 Registration for Telepharmacy Across State Lines Pharmacy services may be provided via telepharmacy. A pharmacist providing telepharmacy services into the State of Vermont from another state is required to be registered as an "out of state registered pharmacist" with the Board. This registration requirement does not apply to pharmacists practicing in a non-resident licensed pharmacy.

(a) An applicant applying for registration to engage in the practice of telepharmacy across state lines shall:

(1) Present to the Board proof of licensure in another state and proof that such license is in good standing;
(2) Submit an application in the form prescribed by the Board;
(3) Pay the fee(s) specified by the Board for the issuance of the Registration; and
(4) Comply with all other requirements of the Board.

(b) The application required shall request of the applicant, at a minimum, the following information:

(1) Name, address, and current pharmacist licensure information in all other states, including state(s) of licensure and license number(s);
(2) Name, address, phone number, and, if applicable, state of licensure and license number of the site where the practice of telepharmacy will originate;
(3) A statement of the scope of patient services that will be provided;
(4) A description of the protocol or framework by which patient care will be provided;
(5) If applicable, any collaborative practice agreements with other health care practitioners; and
(6) A statement attesting that the applicant understands and will abide by the pharmacy laws and regulations of the State of Vermont.

(c) Registrations under this section shall be for the time period and follow the time schedule used for license and registration renewals.

2.10 Telepharmacy Disclosure Requirements A pharmacist whose application for providing telepharmacy services across state lines has been approved shall:

(a) Identify himself or herself to patients as an "out of state registered pharmacist;"

(b) Notify patients of the jurisdiction in which he or she is currently licensed to practice pharmacy; and

(c) Provide patients with that jurisdiction's Board of Pharmacy address and phone number upon request.

2.11 Inactive Status Subject to the reinstatement provisions of 26 V.S.A. § 2045, applicants for

license renewal may request inactive status as permitted by law. A person who does not possess an active Vermont license may not practice pharmacy in Vermont.

2.12 Reinstatement of an Inactive or Expired License
(a) Once the expiration date on a license has passed, the license expires, and the license holder may not practice until reinstated. 26 V.S.A. § 2045.

(b) To reinstate a license a holder of an inactive or expired license must comply with the continuing pharmacy education requirements set forth in these rules by accumulating a total of 30 hours for each renewal period during which the license was inactive. A person applying for renewal of an inactive or expired license shall not be assessed the renewal fees for the years during which the license was inactive or expired.

2.13 Five Years Expired or Inactive Status
(a) A pharmacist whose Vermont license has expired for 5 years or more, who is currently licensed in good standing in another US jurisdiction must, before practicing independently,

(1) complete 60 hours of continuing education within four years preceding the application; and
(2) successfully complete the MPJE.

(b) A pharmacist whose Vermont license has expired for five years or more, and who has not been licensed in more than three years in another United States jurisdiction, must, before practicing independently,

(1) practice as an intern for no less than 200 hours under the direct supervision of a licensed pharmacist preceptor approved by the Board;
(2) complete 60 hours of continuing education within four years preceding the application; and
(3) successfully complete the MPJE.

Part 3 Continuing Pharmacy Education

3.1 Definitions
(a) ACPE: Accreditation Council for Pharmacy Education

(b) AMA: American Medical Association

(c) 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.

3.2 Continuing Pharmacy Education (CPE) Requirements The licensee must complete a total of 30 CPE hours per renewal period. A minimum of ten hours shall be obtained during participation in live programs (didactic sessions). Continuing pharmacy education participation must be reported every two-year renewal period. For newly-licensed pharmacists, see Rule 3.11 below.

3.3 Limits CPE hours may not be transferred or carried over from one renewal period to another.

3.4 Corrective Plan A licensee who fails to fulfill the continuing pharmacy education

requirements of these rules may be required by the Board to develop and complete a specific corrective action plan within 90 days.

3.5 Hardship Waiver Upon a showing a hardship, the Board may in its sole discretion waive the continuing pharmacy 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.

3.6 Out of State Licensees A licensee residing and licensed in another jurisdiction is required to meet the continuing pharmacy education requirements for license renewal in Vermont.

3.7 Topics and Formats of Study 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.

3.8 Documentation and Approval Providing documentation of continuing pharmacy education in Board-approved programs may be required to maintain licensure.

(a) All ACPE and AMA Category I approved programs and programs approved by pharmacy boards in other states may be approved by this Board.

(b) Organizations or licensees may have a program approved in advance by submitting the program outline, including learning objectives, and the names and qualifications of the presenters to the Board. After review, the Board shall send written notification of its decision to the organization or licensee.

3.9 Verification of Continuing Pharmacy Education Pharmacists shall provide the Board with verification of completion of the required continuing pharmacy education programs by such means as designated by the Board. The Board may conduct random audits to verify completion of continuing pharmacy education up to four years after a license is renewed. Licensees must retain continuing education records to cover this period. Upon request by the Board, the licensee shall submit certificates of completion for all programs listed in the licensee's renewal application.

3.10 Audits All reinstatements of inactive or expired licenses shall be audited and shall be accompanied by documentation of continuing pharmacy education. During each biennial renewal period, the Board may audit the continuing pharmacy education activities of a random sample of pharmacists. The Board may also audit currently conditioned licensees and licensees who in any of the preceding 3 renewal cycles were initially found to have not met continuing education renewal requirements. Pharmacists shall submit for inspection the documents necessary to verify the reported continuing pharmacy education.

3.11 Newly Licensed Pharmacists

(a) For applicants granted an initial license to practice by the Board, accumulation of CPE's shall commence on the opening date of the first biennial renewal period following receiving initial Vermont licensure.

(b) For those licensees granted an initial license within 90 days of the end of the licensing period/renewal date and who are not then required to renew their licenses, the continuing education requirement begins with the first day of the biennial licensing period so that all people licensed for two years at the time of their first renewal must show compliance with the continuing education requirements.

Part 4 Pharmacy Interns

4.1 Definitions

(a) **Internship**: means the practical pre-licensure experience where the intern is provided the knowledge and practical experience needed for licensure. The internship requirement may be fulfilled by postgraduate experience, supervised practice, and experience gained during participation in college-coordinated externship and clerkship programs.

(b) **Supervised practice**: means experience obtained during participation in Board-approved programs, as an intern under the direct supervision of a qualified preceptor as defined by these rules. The programs shall be designed to give the participant experience in the type of setting in which the preceptor practices.

(c) **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.

(d) **Clinical Clerkship or Clerkship**: means 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) Be conducted in patient care settings where the student is provided with actual experiences in patient care;
(2) Emphasize all phases of drug therapy relative to the disease states of individual patients;
(3) Involve provision of clinical services on either an outpatient or inpatient basis as a primary activity;
(4) Involve a minimal amount of drug distribution;
(5) Be approved by the state board of pharmacy where the pharmacy school is located; and
(6) Be a component of the college curriculum for which academic credit is given.

(e) **Preceptor**: means a pharmacist with an active license, who has at least 2,000 hours 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. To be a preceptor in Vermont the licensee must possess an unencumbered license. The Board at its discretion upon good cause may permit a licensee with a conditioned license to act as a preceptor.

4.2 Registration of Pharmacy Interns

(a) Every individual shall be registered with the Board before beginning an internship in this State.

(b) Prior to beginning any period of internship in Vermont, a prospective intern shall submit, on official forms, the following information:

(1) The intern's name and address;
(2) The name and address of the pharmacy where the internship is being served;
(3) The name, address, and license number of each preceptor at the internship site; and
(4) A complete statement of the intern's qualifications, to be provided directly to the Board by the pharmacy school or college.

(c) Forms required for proper registration of interns, along with instructions for their use, are available from the Board.

4.3 Pharmacy Intern Qualifications Registration to practice pharmacy as an intern shall be granted only to:

(a) an individual who is currently enrolled the first professional year in an accredited pharmacy program; or

(b) a graduate of an ACPE accredited pharmacy program; or

(c) a graduate of a pharmacy program located outside the United States who has successfully completed the FPGEE, TOEFL, and TSE examinations or their successor examinations, and obtained Foreign Pharmacy Graduate Examination Committee (FPGEC) certification.

4.4 Internship Non-Classroom Hours 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 an intern under the direct supervision of a pharmacist. Documentation shall be provided on a form available from the Board.

4.5 Internship Expected Experience Experience obtained in hospital or retail settings should include compounding, dispensing, inventorying prescription drugs, and maintaining prescription records.

4.6 Internship Other Possible Experiences With approval of the Board, the internship may also include experience obtained in one of the following:

(a) A demonstration project related to pharmacy;

(b) The pharmaceutical industry; or

(c) A program which will expose the intern to any area of health care where pharmacists have an impact.

4.7 Internship Training and Practice Site Requirements 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:

(a) Conform to all standards set by governmental agencies;

(b) Provide a broad scope of pharmaceutical services;

(c) Provide for systematic rotation of interns through all general practice activities;

(d) Use a patient medication record system;

(e) Provide the opportunity for chart review in a practice setting in which charts are used;

(f) Maintain contact with other health professionals and, when possible, provide pharmaceutical services to institutionalized patients; and

(g) Provide patient counseling services.

4.8 Exposure to Practice Areas It is expected that the intern will be exposed to all facets of the practice of pharmacy, including but not limited to, the following:

(a) Evaluation of prescription drug orders;

(b) Preparation and labeling of drugs;

(c) Dispensing of drugs;

(d) Patient profile update and review;

(e) Drug use review;

(f) Patient counseling; and

(g) Proper and safe storage of drugs.

4.9 Other Conditions Governing Internships Interns enrolled in a pharmacy school approved by ACPE 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.

4.10 Armed Forces Members 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.

4.11 Out of State Credit 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. Documentation may be provided on a form available from the Board.

4.12 Responsibilities of Intern The intern may perform only those duties assigned by the pharmacist.

4.13 Internship: No Supervisory Duties The intern shall not be in charge of the pharmacy department at any time.

4.14 Pharmacy Interns Identified

(a) The Board shall issue a confirmation letter or registration certificate to the intern for purposes of identification and verification of his or her role as an intern.

(b) A pharmacy intern shall wear a name tag bearing in a clearly legible font the individual's name and title "Pharmacy Intern."

(c) 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.

4.15 Change of Information All interns shall notify the Board immediately upon change of name or address.

4.16 1,740 Internship Hours Required Applicants for licensure as pharmacists shall submit evidence on Board-approved forms that they have satisfactorily completed no fewer than 1,740 hours of internship credit under the instruction and supervision of a preceptor.

4.17 End of Registration Without Board approval on a showing of extenuating circumstances Registration ends upon:

a) dismissal from pharmacy school, or

b) one year after graduation or until licensed, whichever occurs first.

4.18 Board Jurisdiction Over Interns Interns are subject to the disciplinary authority of the Board. Interns must report a conviction of any felony or any offense related to the practice of the profession in a Vermont district court, a Vermont superior court, a federal court, or a court outside Vermont within 30 days.

4.19 Preceptor, Primary Responsibility The preceptor shall have the primary responsibility for the training of the intern. This includes ensuring that the pharmacy intern is registered with the Board.

4.20 Preceptor Duties

(a) The preceptor may allow other pharmacists to aid in the training process.

(b) The preceptor may permit an intern to provide services normally provided by a pharmacist provided that the services performed are under the direct supervision of a pharmacist.

(c) A pharmacist shall be in continuous personal contact with and actually give 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.

4.21 Preceptor Intern Information Required The preceptor shall submit, on approved forms, such information as the Board requires.

4.22 Preceptor Limitation A pharmacist may not act as a preceptor of more than two interns working at a pharmacy at any one time.

Part 5 Pharmacy Technicians

5.1 Definition of Pharmacy Technician A pharmacy technician is "an individual who performs tasks relative to dispensing and only while assisting and under the supervision and control of a licensed pharmacist." 26 V.S.A. § 2022(13).

(a) Effective July 1, 2017: These rules create two categories of pharmacy technicians,

"certified pharmacy technicians" and pharmacy technicians who are not certified. The latter group are referred to as "pharmacy technicians."

(b) Cashiers, and delivery people who enter or have access to the prescription department must register as pharmacy technicians.

5.2 "Certified Pharmacy Technician" Certified pharmacy technician means a person registered with the Board who has completed a pharmacy technician certification program approved by the Board and is certified by that Board and who practices in Vermont.

(a) Effective July 1, 2017 each individual preforming the acts in subsection (b) below must be registered with the Board as a "certified pharmacy technician."

(b) A certified pharmacy technician may, under the supervision of a Pharmacist, perform certain activities involved in the Practice of Pharmacy, such as:

(1) receiving new written or electronic Prescription Drug Orders, prescription data entry;
(2) compounding;
(3) assisting in the dispensing process; and
(4) performing all functions allowed to be performed by pharmacy technicians.

(c) A certified pharmacy technician may not perform:

(1) drug utilization review (DUR);
(2) clinical conflict resolution;
(3) receipt of new oral prescription drug orders
(4) prescriber contact concerning prescription drug order clarification or therapy modification;
(5) patient counseling;
(6) prescription transfer;
(7) dispensing process validation; or
(8) any act requiring the exercise of professional judgment by a pharmacist.

5.3 Certified Pharmacy Technician Registration

(a) To be registered as a certified pharmacy technician, an applicant shall:

(1) submit a completed application showing that the applicant is certified by a national pharmacy technician certification authority approved by the Board;
(2) pay the fee specified in statute;
(3) not have engaged in acts which affect the ability of the applicant to practice as a pharmacy technician;
4) have attained the age of 18 years and be a high school graduate or equivalent.

(b) An individual who has held a pharmacist license that has been revoked or suspended for unprofessional conduct, or whose application for licensure as a pharmacist has been denied for unprofessional conduct, shall not be eligible to be registered as a certified pharmacy technician unless the Board, in its sole discretion, determines that good cause exists to register than individual.

(c) A certified pharmacy technician while working in the prescription department shall wear a name tag bearing in a clearly legible font, at a minimum, the individual's first name and title "Certified Pharmacy Technician."

(d) A person whose application for registration has not been approved may not act as a certified

pharmacy technician.

5.4 Maintaining Certification An individual registered with the Board as a certified pharmacy technician must maintain national certification. A person whose national certification has lapsed or has in any other way not met the requirements for continued national certification shall not practice as a registered certified pharmacy technician.

5.5 "Pharmacy Technician" Pharmacy Technician means an individual registered with the Board as a pharmacy technician.

(a) A pharmacy technician may, under the supervision of the pharmacist, assist in the pharmacy and perform such functions as:
(1) receiving requests for refills of current prescriptions;
(2) processing of medical coverage claims;
(3) inventory responsibilities; and
(4) cashiering.

(b) A pharmacy technician may not perform such functions as:
(1) assisting in the dispensing process;
(2) drug utilization review (DUR);
(3) clinical conflict resolution;
(4) prescriber contact concerning prescription drug order clarification or therapy modification;
(5) patient counseling;
(6) prescription transfer;
(7) receipt of new prescription drug orders; or
(8) any act requiring the exercise of professional judgment by a pharmacist.

(c) A pharmacy technician in training to become a certified pharmacy technician may, after registering with the Board, under the direct supervision of a pharmacist, engage in certified pharmacy technician acts for up to 18 months. A pharmacy technician who has not successfully completed the requirements to become a registered certified pharmacy technician in 18 months may apply to the Board for an extension. The Board shall, in its sole discretion, determine whether such an extension is appropriate.

5.6 Pharmacy Technician Registration
(a) To be registered as a pharmacy technician, an applicant shall:
(1) submit a completed application;
(2) not have engaged in acts which affect the ability of the applicant to practice as a pharmacy technician.

(b) An individual who has held a pharmacist license that has been revoked or suspended for unprofessional conduct, or whose application for licensure as a pharmacist has been denied for unprofessional conduct, shall not be eligible to be registered as a certified pharmacy technician unless the Board, in its sole discretion, determines that good cause exists to register than individual.

(c) A pharmacy technician while working in the prescription department shall wear a name tag bearing in a clearly legible font, at a minimum, the individual's first name and title "Pharmacy Technician."

(d) A person whose application for registration has not been approved may not act as a pharmacy technician.

5.7 Renewals Certified pharmacy technician registrations and pharmacy technician registrations shall be renewed biennially on a schedule as determined by the Office.

5.8 Jurisdiction Certified pharmacy technicians and pharmacy technicians are subject to the disciplinary authority of the Board.

5.9 Transitional Provision Grandfather Clause: effective July 1, 2017. A person who has not completed a national pharmacy technician program approved by the Board may be registered as a Vermont certified pharmacy technician if:

a) As of July 1, 2017 the person has been a Vermont registered pharmacy technician in good standing with an unencumbered registration continuously since July 1, 2014;

b) The person currently engages in the tasks reserved for certified pharmacy technicians under Rule 5.2(b);

c) The person pays the applicable fee and submits an application for transition from a Vermont Registered Pharmacy Technician to a Vermont Certified Pharmacy Technician which application shall include a verification by oath or affirmation containing:

1. a detailed description of the certified pharmacy technician tasks set forth in these rules and that the applicant has engaged in, signed by both the applicant and the pharmacist-manager or supervising pharmacist; and

2. verification by the pharmacist manager or supervising pharmacist that the applicant/pharmacy technician currently performs those certified pharmacy technician tasks competently to the satisfaction of the pharmacy manager or supervising pharmacist, and a statement by the pharmacist-manager or supervising pharmacist that the applicant/pharmacy technician is qualified to serve as a certified pharmacy technician in that pharmacy practice location.

d) A person registered as a Vermont certified pharmacy technician under this Rule is not as a condition of renewal required to obtain or maintain certification from a national certification program approved by the Board.

e) An individual who becomes a Vermont certified pharmacy technician under this Rule may continue to practice as a certified pharmacy technician only in that person's current practice pharmacy location and employer. Registration with the Board as a Vermont certified pharmacy technician under this rule will terminate with the cessation of practice at the registrant's current practice location. To be hired to practice at any other pharmacy location will require that the individual obtain and maintain certification from a national certification program approved by the Board.

f) A person registered as a Vermont Certified Pharmacy technician under this rule must notify the Board within 10 days of terminating employment at his or her current location.

g) **Registration as a certified pharmacy technician under this rule is available between July 1, 2017 and July 1, 2018.** The Board will permit applications to be submitted in March of 2017 in hopes that successful candidates will be able to receive their certified pharmacy technician registrations and be ready to practice under them on July 1, 2017. Unsuccessful applicants will be advised of the appeal process.

h) The intent of this grandfather clause is to ensure that after July 1, 2017 all *newly hired* certified pharmacy technicians in Vermont are certified by a national certification program approved by the Board.

Part 6 Pharmacist-Manager

6.1 Pharmacist-Manager Required No pharmacy may operate unless its designated pharmacist-manager has been approved by the Board.

6.2 General Duties and Limitations The pharmacist-manager shall be responsible for the direct management, supervision, and control of the pharmacy department.

(a) After the effective date of these rules, to serve as a pharmacist manager a pharmacist 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 two years. Unless granted written permission by the Board, a licensee is required to possess an unencumbered license while serving as a pharmacist-manager.

(b) 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.

(c) A pharmacist may not serve as pharmacist-manager for more than one pharmacy at any one time except as specifically allowed by written permission from the Board.

6.3 Duties Included The pharmacist-manager shall:

(a) 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.

(b) 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.

(c) be responsible for enforcing security standards for the prescription area.

(d) ensure that all policies and procedures are 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.

(e) assure 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.

(f) implement an ongoing quality assurance program that monitors performance of the automated pharmacy dispensing system, which is evidenced by written policies and procedures adopted by the pharmacy.

(g) assure that all pharmacists employed at the pharmacy are properly licensed, all pharmacy technicians are properly registered and Health Insurance Portability and Accountability Act (HIPAA) trained, and that all pharmacy interns employed at the pharmacy are properly registered with the Board of Pharmacy.

(h) report to the Board within 10 days, along with supporting information and evidence, any disciplinary action taken by it or its staff, after an initial investigation, or hearing in which a pharmacist, pharmacist intern, or pharmacy technician has been afforded the opportunity to participate, which limits or suspends, conditions, or terminates that person's employment for drug diversion or violations of the rules and statutes governing pharmacy practice. If the pharmacy manager is disciplined, the pharmacy owner shall report the action to the board. See, 3 V.S.A. § 128.

(i) Notify the Board of Pharmacy immediately of any of the following changes on forms provided by the Board:

(1) Any theft or significant loss of prescription drugs shall be reported to the Board immediately by telephone, email or fax. Within three days, a written report shall be made on forms available from the Board and on line for this purpose;
(2) Change of ownership of the pharmacy, including the filing of a new application for licensure by the owner, corporate officer of partner;
(3) Change of address of the pharmacy, or if change of location, including the filing of a new application;
(4) In the event of bankruptcy or foreclosure, the official in charge shall obtain the services of a pharmacist to serve as acting pharmacist-manager;
(5) Permanent closing of the pharmacy; and
(6) Disasters, accidents and emergencies which may affect the strength, purity or labeling of drugs, medications, devices or other materials used in the diagnosis or the treatment of injury, illness and disease shall be immediately reported to the Board;

(j) Make or file any reports required by state or federal laws and rules;

(k) Respond to the Board of Pharmacy regarding any violations brought to his or her attention;

(l) Establish 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;

(m) Provide the Board with prior written notice of the installation or removal of automated pharmacy systems. The notice must include, but is not limited to:

(1) The name and address of the pharmacy;
(2) The name and location of the automated equipment; and
(3) The identification of the responsible pharmacist.

6.4 Pharmacy Technicians, When Required 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.

6.5 Pharmacy Technician Training Manual The pharmacist-manager shall develop or adopt, implement, and maintain a pharmacy technician training manual for that pharmacy. The training manuals of the National Community Pharmacists' Association (NCPA) and National Association of Chain Drug Stores (NACDS), or others as approved by the Board may be used as guides.

6.6 Implementing a Procedure for Drug Recalls 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.

6.7 Change of Pharmacist-Manager When a pharmacist-manager changes employment or responsibilities, he or she shall do the following:

(a) Within 5 days, the outgoing and incoming pharmacist-managers shall notify the Board, in writing, regarding his or her change in employment.

(b) The outgoing pharmacist-manager shall conduct a physical written inventory of all controlled drugs, explain any discrepancies in full, certify the inventory as true and correct, and retain a copy for his or her records.

(c) The inventory shall be certified as true and correct, by the incoming pharmacist-manager, and filed with the permanent records of the drug outlet.

(d) 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.

(e) A new license, indicating the name of the new pharmacist-manager will be issued upon approval.

Part 7 Rules for Operation of Drug Outlets

7.1 Forms of Ownership 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.

7.2 Application and Procedure for Opening a Retail Drug Outlet Applicants shall use the standard form available from the Office or via the website. Completed applications shall include:

(a) The Office application form, completed in full and signed by an owner, corporate officer or partner;

(b) A scale drawing of the outlet, indicating space utilization and security arrangements in detail, and showing in detail the patient counseling area, attached to the application;

(c) Verification of current business registration; and

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

(e) 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; and,

(f) If the applicant is a corporation:
(1) A copy of the corporate charter; and
(2) If non-publicly traded, a list of all stockholders owning five percent or more of the corporation's assets.

(g) The approximate date of completion, if a new drug outlet.

7.3 Inspection Before Licensure

(a) A Board representative shall make an on-site inspection within 20 days of a request for inspection. The pharmacist-manager must be present for this inspection.

(b) If deficiencies are found:
(1) The Board representative shall send written notification to the applicant and the Board, noting all unremedied deficiencies.
(2) 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. If an unremedied deficiency remains after a re-inspection, the procedures outlined in this rule shall apply. A denial of licensure based on an unsatisfactory inspection may be appealed as provided by 3 V.S.A. § 129(e).

7.4 Successful Inspection, License Issued, Time of Opening

(a) If there are no deficiencies, or deficiencies noted above have been corrected, a license shall be issued.

(b) The pharmacy may not open until it has provided the Board:
(1) confirmation of the its DEA license; and

(2) confirmation of an adequate supply of drugs.

7.5 Pharmacist-Manager Required No pharmacy shall be operated without a designated pharmacist-manager approved by the Board. The pharmacist-manager of a pharmacy shall be designated in the application of the pharmacy for license, and in each renewal thereof. Requirements for pharmacist-managers and their responsibilities are set forth in Part 6 of these rules. Additional pharmacist-manager duties are specified elsewhere in these rules.

7.6 Opening Date Notice Required The applicant shall give at least 10 days' notice to the Board prior to opening for public business.

7.7 Changes in Corporation 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.

7.8 Change or Transfer of Ownership Business may continue uninterrupted when ownership of the retail drug outlet is changed or transferred to an individual or entity required to be listed as an owner in an application for initial licensure if the new owner:

(a) Notifies the Board within 48 hours after the transfer;

(b) Submits a completed application within 15 business days after the transfer;

(c) Submits plans for correction of deficiencies with the application; and

(d) States the date of transfer on the application.

7.9 Change of Mailing Address Or Location

(a) The licensee shall submit immediate written notification of any change in mailing address of a drug outlet.

(b) 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 successful completion of an inspection.

(c) 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.

7.10 Renovations Before reopening for business after remodeling or relocation which affects the security of a pharmacy, the drug outlet must successfully complete an 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. The pharmacist-manager shall notify the Board in writing when renovations are completed.

7.11 Natural Disaster, Fire, or Other Catastrophe

(a) Upon written request after a natural disaster or fire, the Board may issue an immediate 60 day emergency license for operation of the drug outlet at a new location.

(b) 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.

(c) No equipment, supplies, or drug inventory from the old location shall be used in the new location without Board approval.

(d) 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.

7.12 Death Of Owner

(a) 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.

(b) The temporary license shall be effective until:

(1) The drug outlet has been properly reorganized; or

(2) Ownership has been transferred; or

(3) The drug outlet has been closed; or

(4) One year has elapsed since death of the owner.

Part 8 Drug Outlet Closure

8.1 Voluntary Surrender of Drug Outlet License The Board may accept a license to operate a drug outlet that has been surrendered voluntarily, if:

(a) The licensee submits, in writing, a signed statement setting forth the reasons the license is being surrendered; and

(b) All prescription legend drugs are properly disposed of under these rules; and

(c) The Board does not have cause for disciplinary action under statutes and rules governing the Board.

8.2 Termination of License to Operate A Drug Outlet Unless a temporary license has been applied for within 5 business days of the following, a license to operate a drug outlet is immediately terminated:

(a) If a sole proprietorship: death of owner, change of location, change in ownership, or change in business name.

(b) 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.

(c) If a corporation: change in location, or change in corporate name or charter.

(d) Failure to register a change in pharmacist-manager.

8.3 Drug Outlet Closing 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, and by posting signs in a conspicuous place at or near the drug outlet.

(a) 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.

(b) 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:

(1) The date the outlet will close for public business;

(2) The name(s) and address(es) of the person(s) with custody of prescription, bulk compounding, repackaging, and controlled drug inventory records;

(3) The names and addresses of all persons who will acquire legend drugs when the drug outlet closes.

(c) The licensee shall, within 30 days of closing the drug outlet, send the Board a written report, indicating:

(1) The licensee voluntarily surrendered the license to operate a drug outlet;

(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;

(3) All labels and blank prescription pads were destroyed;

(4) All signs indicating the presence of a drug outlet were removed; and

(5) Confirmation that the DEA registration and all unused DEA 222 forms were returned to the DEA.

(d) 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:

(1) Advertise in a newspaper with a general circulation in the area served; and

(2) Post signs in a conspicuous place in the drug outlet.

Part 9 Standards for Pharmacies

9.1 Facility Minimum requirements for a pharmacy:

(a) No pharmacy may operate without a designated pharmacist-manager.

(b) Each dispensing 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.

(c) 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.

(d) The prescription department must contain no less than 12 feet of counter space 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 drain board 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.

(e) Each pharmacy shall provide internet access as needed for compliance with the prescription monitoring system.

9.2 Counseling Area Required 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 reasonable privacy.

9.3 24 Hour Access The pharmacist-manager, or a pharmacist designated by him or her, shall have 24 hours access to the pharmacy department.

9.4 Signs and Names

(a) 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.

(b) The drug outlet shall display pharmacy business hours and the name of the pharmacist on duty in a conspicuous manner visible to the public.

(c) 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.

9.5 Display of Licenses

(a) The drug outlet's current license shall be displayed in a conspicuous manner visible to the public.

(b) All pharmacists, pharmacy interns, and pharmacy technicians shall display their current licenses or registrations in a conspicuous manner visible to the public.

(c) 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 enforcement officer upon demand.

9.6 Name Tags and Identification

(a) A pharmacist shall wear a name tag bearing in a clearly legible font the individual's name and title "Pharmacist."

(b) No pharmacist may verbally or by other means, identify his or her self as a "doctor" unless he or she possesses a doctoral level degree in pharmacy from an accredited school of pharmacy and clarifies that he or she is not a medical doctor.

9.7 Security

(a) 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.

(b) The pharmacy shall be secured by a physical barrier with suitable locks and an electronic barrier to detect entry and report the entry to appropriate persons at a time when the pharmacy is not open. The prescription department shall be secure from access by unauthorized personnel 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 only with the consent of the pharmacist who is present in the pharmacy.

(c) 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(c)).

9.8 Hygiene Standards The drug outlet shall:

(a) comply with all federal, state, and local health laws;

(b) have walls, ceilings, windows, and floors kept clean and in good repair;

(c) have waste receptacles located in convenient areas;

(d) have equipment kept clean and stored in an orderly manner;

(e) be well lighted;

(f) be dry and well ventilated;

(g) have adequate restroom facilities for employees.

9.9 Drugs and Devices, Definitions

(a) Adulterated: means consisting, in whole or in part, of any filthy, putrid, decomposed substance; or does not meet FDA standards.

(b) Misbranded: means outdated, or label is false or misleading, or does not meet FDA standards.

9.10 Drugs Removed from Inventory 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 for no more than one year from the date of expiration in a separate location within the prescription drug area until processed for return or destruction.

9.11 Recalled Drugs There shall be a system to monitor drug recalls and, where appropriate, to notify patients to whom the recalled drug products have been dispensed.

9.12 Disposal of Controlled and Non-Controlled Substances The Board accepts Drug Enforcement Administration (DEA) approved reverse distribution organizations. A list may be obtained by contacting the Diversion Unit at the regional DEA office in Boston, Massachusetts. Telephone 888-272-5174; fax 617-557-2126. The DEA list is compiled from applications for registration and is amended periodically.

9.13 Drug Storage Areas 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.

9.14 Equipment 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 comply with all state and federal laws. The pharmacy must have at a minimum the following equipment:

(a) A refrigerator with a temperature control and thermometer;

(1) The refrigerator shall have a thermometer and maintain temperature between 36

degrees F and 46 degrees F (+2 to + 8 Celsius). Unless electronically monitored on a continual basis, a logged compliance check at least monthly is required.

(2) Non- pharmacy related items may not be stored in the pharmacy refrigerator intended for medications.

(b) If the facility carries drugs which require storage in a freezer: the freezer temperature must be maintained at or below minus 15 degrees Celsius;

(c) Distilled or sterile water;

(d) An automated data processing system;

(e) At least one telephone in the prescription area, with the same number as the telephone number printed on the drug outlet prescription labels;

(f) A tablet and capsule counting tray;

(g) Containers which meet official compendia standards, available with closures that meet Federal Poison Prevention Packaging Act of 1970 requirements, as well as regular closures;

(h) 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;

(i) Auxiliary labels;

(j) equipment and supplies sufficient for the scope of practice; If needed for compounding: 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.

(k) Any drug outlet involved in the preparation of sterile pharmaceutical products must meet the requirements of the Sterile Pharmaceuticals rules.

9.15 Reference Library Each pharmacy shall maintain on file at least one reference in each of the categories listed below. Computerized, on-line versions are acceptable instead of a hard copy of the current manual only if made known and accessible to every pharmacist at the pharmacy. 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:

(a) 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;

(b) Current manual of drug interactions equivalent to *Hansten's* or *Drug Facts*, with quarterly updates, which has been pre-approved by the Board.

(c) *Current Facts and Comparisons*, with monthly updates or its equivalent which has been approved by the Board.

(d) Current reference on pediatric dosages;

(e) Pharmacies offering for sale herbal or alternative medicines, must possess a current reference for such; computerized version or hard copy.

9.16 Inspection of Drug Outlets

(a) 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 in Vermont during regular business hours, for compliance with these rules. Deficiencies shall be handled in the manner set forth in Rule 7.2(i).

(b) 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.

9.17 Persons Authorized to Prescribe Pharmacists may accept prescription legend drug orders from authorized practitioners within the United States and Canada. At the time these rules are adopted, authorized prescribers include:

(a) Dentist;

(b) Naturopathic physician, as authorized by law;

(c) Nurse practitioner, as authorized by law;

(d) Optometrist;

(e) Osteopath;

(f) Physician;

(g) Physician's assistant, as authorized by law;

(h) Podiatrist;

(i) Scientific investigator;

(j) Veterinarian;

(k) Certified Nurse Midwife as permitted by law; and

(l) Others as permitted by Vermont and federal law.

9.18 Prescription Pick-Up and Delivery

(a) 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. Upon a showing of special circumstances, the Board may approve delivery to and pick up from a secure site in a medical facility under conditions set by the Board.

(b) 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.

9.19 Advertising Prescription Drugs 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.

9.20 Sale of Prescription Legend Drugs

(a) 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.

(b) 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."

(c) The invoice shall contain the name, strength, form, and quantity of the drug, the date of sale, and the name and address of the seller and purchaser.

(d) If the product is a controlled substance, the invoice shall also include the DEA registration number of both the purchaser and seller. If the product is a Schedule II controlled substance and is sold or transferred, the purchaser or transferee must give a DEA 222 or its successor form to the supplier before the transfer/sale can proceed.

(e) Receipt, dispensing, and distribution records. Except as provided in this sub-rule, a coordinating pharmacy shall maintain a record of all drugs received, dispensed, and distributed from the coordinating pharmacy and from each remote dispensing site.

9.21 Pharmacist Meal/Rest Breaks

(a) 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.

(b) No pharmacist shall work more than 8 hours without a meal/rest break. 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

(c) The pharmacist shall remain on the premises of the drug outlet during the meal/rest break and shall be available for emergencies.

(d) 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.

(e) 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. . The sign shall also indicate the time when the pharmacist will return.

(f) Only support personnel directly involved in the prescription dispensing process and authorized by

the pharmacist on duty may remain in the prescription department while the pharmacist is on a meal/rest break.

(g) 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.

(h) 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.

(i) 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 prescription may be dispensed until the final check is completed by the pharmacist after return to the prescription department.

(j) New prescriptions conveyed by telephone shall not be accepted by support personnel. 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.

(k) 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.

(l) 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.

(m) Under this rule, the pharmacist-manager remains responsible for the direct management, supervision, and control of the prescription department.

(n) 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.

(o) 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.

(1) 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.

(2) After review, each support person should be requested to initial the policies and procedures to indicate that the policies and procedures are understood.

Part 10 Pharmacy Practice

10.1 Prescription Drug Orders A Prescription drug order shall contain the following information at a minimum:

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

(b) Name, address, facility or practice name where applicable, and telephone number, and, if a controlled substance, address and DEA registration number of the prescribing practitioner;

(c) Date of issuance;

(d) Name, strength, dosage form, quantity or stop date, and route of administration of drug prescribed;

(e) Directions for use by patient;

(f) Number of authorized refills or specified time limit; if number of refills or time limit is not specified, prescription is non-refillable; and

(g) If a manually written prescription drug order, the prescribing practitioner's handwritten signature.

10.2 Legitimate Prescriptions A prescription or drug order for a legend drug is not valid unless it is issued for a legitimate medical purpose arising from a prescriber-patient relationship which includes a documented patient evaluation adequate to establish diagnoses and identify underlying conditions and/or contraindications to the treatment. Treatment, including issuing a prescription or drug order, based solely on an online questionnaire or consultation outside of an ongoing clinical relationship does not constitute a legitimate medical purpose.

10.3 End of Prescriber's Practice If a practitioner as defined in 26 V.S.A. § 2022(15) ceases to practice for any reason, a pharmacist may, pursuant to a prescription written by that practitioner, dispense all remaining refills up to a 90-day supply of the drug prescribed, to enable the patient to obtain the services of another practitioner.

10.4 Allowed Forms of Prescription Drug Orders Prescription drug orders must be communicated directly to a pharmacist. This may be accomplished in one of the following ways.

(a) A prescription drug order, including that for a controlled substance listed in Schedules II through V, may be communicated in written, oral, or electronic form.

(b) A prescription drug order, including that for a controlled substance listed in Schedules III through V, and, in certain situations, that for a controlled substance listed in Schedule II, may be communicated orally (including telephone voice communication) or by way of electronic transmission as permitted by federal law provided the vendor of the software meets the requirements set forth by the DEA for authentication.

(c) A pharmacist may transfer an unfilled prescription order to another pharmacy.

10.5 Tamper Resistant Prescription Forms

(a) Prescriptions shall be written so as to:

(1) prevent unauthorized copying of a completed or blank prescription form,

(2) prevent erasure or modification of information written on the prescription by the prescriber; and

(3) prevent the use of counterfeit prescription forms.

(b) Handwritten prescriptions must be written on a tamper resistant pad.

(c) Computer generated printed prescriptions must be printed on tamper resistant paper or other tamper proof methods as defined by the Centers for Medicaid and Medicare Services, including micro-printing and/or printing a "void" pantograph accompanied by a reverse "Rx," which causes a word such as "Void," "Illegal," or "Copy" to appear when the prescription is photocopied.

(d) Prescriptions written which comply with Medicaid rules will satisfy this rule.

(e) Prescription form features which will satisfy this rule could, for example, include the following properties:

(1) a colored background with a watermark;

(2) when photocopied read "void" in the background;

(3) have printed on the form the name of the prescriber or hospital identification and batch numbering with serially numbered pages for prescriptions;

10.6 Loss of Prescription Pads or Forms Loss of any prescription pads or forms should be immediately reported to local law enforcement officials and the Board of Pharmacy.

10.7 Prescriptions Not Hand Written If communicated orally or by way of electronic transmission, the prescription drug order shall be immediately reduced to a form by the pharmacist that shall be maintained for the time required by laws or rules.

10.8 Schedule II Prescriptions

(a) Except as provided below, a prescription drug order for a Schedule II controlled substance may be communicated in written form or electronically prescribed, provided the prescriber has proper software as certified by the DEA for this purpose. The electronic prescription order shall be maintained in accordance with the section below on patient records.

(b) A prescription drug order for a Schedule II controlled substance may be communicated by the practitioner by facsimile, provided the original written, signed prescription drug order is presented to the pharmacist for review prior to the actual dispensing of the controlled substance, except as noted in sub-sections or (c), (d) or (e) below in this section. The original, written prescription drug order shall be maintained in accordance with the section below on patient records.

(c) A prescription drug order for a Schedule II narcotic substance to be compounded for the direct administration to a patient by parenteral, intravenous, intramuscular, subcutaneous, or intraspinal infusion may be communicated by the practitioner or the practitioner's agent to a home infusion pharmacy by way of electronic transmission if permitted by federal law.

(d) A prescription drug order for a Schedule II controlled substance for a resident of a long term care

facility may be communicated by the practitioner or the practitioner's agent by way of electronic transmission if permitted by federal law.

(e) A prescription drug order for a Schedule II narcotic substance for a resident under hospice care, no matter where provided, may be communicated by the practitioner or the practitioner's agent by way of electronic transmission as provided by federal law. The practitioner or the practitioner's agent must note on the prescription that the patient is a hospice patient.

(f) In an emergency situation, a prescription drug order for a Schedule II controlled substance may be communicated by the practitioner orally, 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, and shall contain the information required in Rule 9.1 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 legal 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 the practitioner's identity; and

(4) Within 7 days after authorizing an emergency oral prescription drug order, the prescribing 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 7 day 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.

10.9 Electronic Transmission 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 electronic transmission intermediary.

(b) Provide 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 Rule 10.1 herein.

10.10 Authorized Agents for Oral Transmission 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 and the identity of the person calling in the prescription must be received and documented by a pharmacist or sufficiently trained pharmacy intern.

10.11 Electronic Signatures Required An electronic prescription transmission to a pharmacist in a licensed pharmacy requires the electronic signature of the prescriber.

10.12 No Carbon or Duplicate Prescriptions Carbon or duplicate written prescriptions are not valid prescriptions. A written prescription must bear the original signature of the prescriber, not a copy or photo copy or stamp of the signature of the prescriber.

10.13 Use of Independent Professional Judgment 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.

10.14 Security of Electronic Equipment All electronic equipment for receipt of prescription drug orders communicated by way of electronic transmission shall be maintained in the pharmacy area so as to ensure against unauthorized access or observation.

10.15 Unauthorized Access Persons other than pharmacists, pharmacy technicians, pharmacy interns and others specifically authorized by law shall have no access to pharmacy records containing confidential information or personally identifiable information concerning the pharmacy's patients.

10.16 Filling Time Limits, Future Fill Dates

(a) No prescription for a Schedule II controlled substance written without a future fill date may be filled more than 30 days after the date the prescription was issued.

(b) An individual practitioner may issue multiple prescriptions authorizing the patient to receive a total of up to a 90-day supply of a Schedule II controlled substance. Each prescription must contain both the original date of issue and the future fill date. For guidance, refer to regulations implementing the federal Controlled Substances Act.

(c) No prescription for a Schedule II controlled substance written to be filled at a future date may be filled more than 90 days after the date the prescription was issued.

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

10.18 Transfer of a Prescription Drug Order

(a) Pharmacies utilizing automated data processing systems shall satisfy all information requirements of a manual mode for prescription drug order transferal, 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:

(1) The information is communicated directly between two pharmacists and the transferring pharmacist records the following information:

(A) Write the word "Transferred" on the face of the invalidated prescription drug order;

(B) 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;

(C) Record the date of the transfer and the name of the pharmacist transferring the information; and

(D) A computerized prescription record which contains all of the elements of (A), (B), and (C) above is acceptable.

(b) The pharmacist receiving the transferred prescription drug order information shall reduce to writing the following:

(1) Write the word "TRANSFER" on the face of the transferred prescription drug order;

(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, telephone number, and original prescription number from which the prescription drug order information was transferred; and

(F) First and last name of transferring pharmacist.

(G) A computerized prescription record which contains all of the elements of (A) through (F) above is acceptable.

(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.

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

(d) 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 is not necessary as long as the electronic information is readily available and hard copies can be generated immediately upon request.

(e) 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.

(f) A pharmacist may transfer an unfilled prescription order to another pharmacy.

10.19 Drug Product Selection by the Pharmacist

(a) 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"), the pharmacist shall select the lowest priced drug from the list which in his or her professional judgment is an generically equivalent drug product and which he or she has in stock, unless otherwise instructed by the purchaser or prescriber.

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

(c) 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.

(d) If the prescriber does not wish substitution to take place, he or she shall clearly indicate "brand necessary" or "no substitution" on the prescription. 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. Pharmacists are advised to monitor changes to 18 V.S.A. §§ 4605 and 4606.

10.20 Hospital/Health Care Facility Labeling Requirements All drugs dispensed for use by inpatients of a hospital or other health care or institutional facility, where the drug is not in the possession of the ultimate user prior to administration, shall meet the following requirements:

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

(1) The non-proprietary or proprietary name of the drug;
(2) The route of administration, if other than oral;
(3) The strength and volume, where appropriate, expressed in the metric system whenever possible;
(4) The control number and expiration date;
(5) Identification of the re-packager by name or by license number shall be clearly distinguishable from the rest of the label; and
(6) Special storage conditions, if required.

(b) 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:

(1) Identification of the dispensing pharmacy;
(2) The patient's name;
(3) The date of dispensing;
(4) The non-proprietary or proprietary name of the drug dispensed; and
(5) The strength, expressed in the metric system whenever possible.

(c) All drugs dispensed to inpatients for self-administration shall be labeled in accordance with Rule 10.21 below.

(d) Whenever any drugs are added to parenteral solutions, such admixtures shall bear a distinctive label indicating:

(1) Name of solution, lot number, and volume of solution;
(2) Patient's name;
(3) Infusion rate;
(4) Bottle sequence number or other system control number;
(5) Name and quantity of each additive;
(6) Date of preparation;
(7) Beyond-use date and time of parenteral admixture; and
(8) Ancillary precaution labels.

10.21 Pharmacy Dispensed Drugs: Labels All drugs, except those dispensed under Rule 10.20 above shall be dispensed in a container whose label shall include:

(a) The name and address and telephone number of the pharmacy;

(b) The name of the patient, or, if the patient is an animal, the first and last name of the owner, name of animal, and species of animal;

(c) The name of the prescribing practitioner;

(d) directions for use;

(e) The date of dispensing;

(f) Any cautions which may be required by federal or state law;

(g) The serial number of the prescription drug order;

(h) The name or initials of the dispensing pharmacist;

(i) The proprietary or generic name of the drug dispensed and its strength;

(j) The name of the manufacturer or distributor of the drug and;

(k) The expiration date of the drug, if it is less than one year from the date of dispensing. See, 18 V.S.A. § 4064(a)(2)(B).

10.22 Centralized Prescription Processing

(a) "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.

(b) A pharmacy may perform or outsource centralized prescription processing services provided the parties:

(1) have the same owner; or

(2) 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

(3) 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.

(c) 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:

(1) a description of how the parties will comply with federal and state laws and regulations;

(2) the maintenance of appropriate records to identify the responsible pharmacist(s) in the dispensing and counseling process;

(3) the maintenance of a mechanism for tracking the prescription drug order during each step in the dispensing process;

(4) the maintenance of a mechanism to identify on the prescription label all pharmacies involved in dispensing the prescription drug order;

(5) the provision of adequate security to protect the confidentiality and integrity of patient information;

(6) 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.

(d) Pharmacies using centralized processing shall post a notice to the public advising that:

(1) the pharmacy employs centralized processing;

(2) the pharmacist who dispenses a prescription to a patient may not be the pharmacist who prepared it, and;

(3) that upon request, the pharmacy shall provide a further explanation of how centralized processing works.

10.23 Drugs Compounded in a Pharmacy Except for sections (c) and (e) below which do not apply to compounded drugs for veterinary clinic use, parenteral and sterile product prescriptions shall be compounded as follows: (See, Part 13 for requirements for Sterile Pharmaceuticals.)

(a) For all compounded prescriptions, the pharmacist shall be responsible for all compounding records and the proper maintenance, cleanliness and use of all equipment used in compounding.

(b) Every pharmacist who engages in non-sterile drug compounding shall be proficient, in the art of compounding and shall maintain that proficiency through participation in seminars, studying appropriate literature and/or becoming certified by a compounding certification program. Also, every pharmacist who engages in drug compounding must practice in accordance with NABP's ***Good Compounding Practices***.

(c) A prescription shall be compounded and dispensed only pursuant to a specific order for an individual patient issued by a prescriber. A limited quantity may be compounded in anticipation of prescription drug orders based on routine, regularly observed prescribing patterns.

(d) A Pharmacist may not compound a drug that appears on the FDA ***List of Drugs Withdrawn or Removed from the Market for Safety Reasons*** **or on the FDA** ***List of Drug Products that Present Demonstrable Difficulties in Compounding.***

(e) Pharmacists shall not offer compounded drug products to other State-licensed persons or commercial entities for subsequent resale, except in the course of professional practice for a practitioner to administer to an individual patient, in limited quantities.

(f) In addition to the requirements in Rules 10.20 and 10.21, the label of compounded prescriptions shall also contain an expiration or beyond-use date.

(g) Pharmacists shall maintain a compounding record that contains at least the following information:

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

(2) the formula to compound, including mixing instructions, all ingredients and their quantities, and any additional information needed to prepare the compound;

(3) the prescription number or assigned internal identification number;

(4) the date of preparation;

(5) the manufacturer and lot number of each ingredient;

(6) beyond-use date;
(7) the name of the person who prepared the compound; and
(8) the name of the pharmacist who approved the compound;

(h) These records must be kept for 3 years and shall be readily available for Board inspection.

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

(a) The standard radiation symbol;

(b) The words "Caution – Radioactive Material"; and

(c) The prescription number.

(d) The radionuclide and chemical form;

(e) The activity and date and time of assay;

(f) The volume, if in liquid form;

(g) The requested activity and the calibrated activity;

(h) Patient name or space for patient name.
(1) 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.
(2) 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;

(i) The name and address of the nuclear pharmacy;

(j) The name of the practitioner; and

(k) The lot number of the prescription.

10.25 Patient Records 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:

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

(b) Street address and telephone number of the patient;

(c) Patient's age or date of birth;

(d) Patient's gender;

(e) 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:

(1) the name of the drug;
(2) prescription number;
(3) name and strength of the drug;
(4) the quantity and date received; and
(5) the name of the prescriber.

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

10.26 Allergy and Health Information The Pharmacist or certified pharmacy technician or intern shall make a reasonable effort to ascertain from the patient or the patient's representative the patient's known allergies, drug reactions, idiosyncrasies, chronic conditions, or disease states and current use of other drugs which may relate to prospective drug review. The information shall be recorded in the patient profile. It shall be updated periodically, but not less than once per year.

10.27 Patient Records Retention 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.

10.28 Records of Dispensing Records of dispensing for original and prescriptions for all drugs or devices are to be made and kept by pharmacies for three years. 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.

10.29 Confidential Information 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.

10.30 Prospective Drug Review

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

(1) Over-utilization or under-utilization;
(2) Therapeutic duplication;

(3) Drug-disease contraindications;
(4) Drug-drug interactions (including serious interactions with non-prescriptive or over-the-counter drugs);
(5) Incorrect drug dosage or duration of drug treatment;
(6) Drug-allergy interactions; and
(7) Clinical abuse or misuse.

(b) 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.

10.31 Patient Counseling
(a) 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 caregiver, in order to improve therapy by ensuring the proper use of drugs and devices.

(b) Upon receipt of a new prescription drug order and following a review of the patient's record, a pharmacist, pharmacy technician, or pharmacy intern shall offer counseling with the pharmacist or pharmacy intern of matters which will enhance or optimize the patient's drug therapy. The discussion with the pharmacist or intern shall be in person, whenever practicable, or by telephone and shall include appropriate elements of patient counseling which may include the following:
(1) The name and description of the drug;
(2) The dosage form, dose, route of administration, and duration of drug therapy;
(3) Intended use of the drug and expected action;
(4) Special directions and precautions for preparation, administration, and use by the patient;
(5) Common severe side or adverse effects or interactions and therapeutic contraindications that may be encountered, including their avoidance, and the action required if they occur;
(6) Techniques for self-monitoring drug therapy;
(7) Proper storage;
(8) Prescription refill information;
(9) Action to be taken in the event of a missed dose; and
(10) Pharmacist comments relevant to the individual's drug therapy. .

(c) Alternative forms of patient information may be used to replace patient counseling 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.

(d) Each pharmacy shall post a notice advising, "You have the right to confidential consultation with a pharmacist about your prescription. If you wish, a confidential consultation will be provided."

(e) 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).

(f) A pharmacist shall not be required to counsel a patient or caregiver when the patient or caregiver refuses such consultation and such refusal is documented.

10.32 Adverse Drug Reactions 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.

10.33 Perpetual Inventory A perpetual inventory shall be maintained for at least two years for all Schedule II controlled substances. Electronic versions may be permitted if they provide a secure audit trail of entries.

10.34 Schedule II Inventory All Schedule II controlled substances must be physically inventoried and documented at least once every thirty (30) days.

10.35 Immunizations For patients 18 or older: A pharmacist or intern may administer a vaccine pursuant to a written protocol including emergency measures e.g., epinephrine and/or diphenhydramine based on a collaborative practice agreement or a patient-specific prescription from a licensed prescriber.

(a) A properly trained pharmacist or intern may administer vaccines to a patient 18 years of age or older.

(1) A pharmacist or intern must take an accredited training course on immunizations and keep proof of training on file in the pharmacy. The immunization course must, at a minimum, meet U.S. Center for Disease Control and Prevention (CDC) Guidelines and be accredited by the Accreditation Council for Pharmacist Education (ACPE) or AMA (American Medical Association) Category I approval or a similar health authority or professional body, and include pre-administration education and screening, vaccine storage and handling, administration of medication, record-keeping, emergency response and reporting of adverse reactions.

(2) A pharmacist or intern must maintain current training in **Basic Cardiac Life Support**.

(b) In an emergency related to an immunization a pharmacist or intern **may administer** epinephrine and/or diphenhydramine without a practitioner's prescription.

(c) A pharmacist administering immunizations shall complete a minimum of two (2) hours of continuing education related to immunizations in each licensing period.

(d) Recording keeping and reporting requirements: Unless specifically required by federal or state law. a pharmacist shall maintain for ten (10) years the following documentation regarding each immunization administered:

(1) The name, address, and date of birth of the patient;
(2) Any known allergies;
(3) The date of administration and site of injection;
(4) The name, dose, manufacturer's lot number, and expiration date of the vaccine or, in an emergency, epinephrine or diphenhydramine;
(5) The name and address of the patient's primary health care provider;
(6) The name and address of the prescriber, if different from the patient's primary provider;
(7) The name of the pharmacist administering the immunization;
(8) A record of the pharmacist's consultation with the patient determining that the patient is eligible for immunization.

(e) The pharmacist shall provide:

(1) a notification to the patient's primary health care provider of the immunization administered; and,

(2) to comply with the 18 V.S.A. § 1129's immunization registry, notice as required to the Vermont Department of Health.

10.36 Independent Practice of Pharmacists A pharmacist may provide pharmacist care services outside of a licensed pharmacy if all the following conditions are met:

(a) the pharmacist has access to prescription records, patient profiles, or other relevant medical information for purposes of pharmacist care services and appropriately reviews such information before performing any such functions;

(b) access to the information described in paragraph (a) of this rule is secure from unauthorized access and use, and all access by pharmacists is documented; and

(c) a pharmacist providing pharmacist care services outside the premises of a licensed pharmacy shall maintain the records or other patient-specific information used in such activities in a readily retrievable form in a system that is secured and managed by the pharmacy with whom the pharmacist is providing such services or, if acting independent of a pharmacy, a secure system maintained by the pharmacist. Such records or information shall:

(1) provide accountability and an audit trail;
(2) be provided to the Board upon request; and
(3) be preserved for a period of at least three years from the date relied upon or consulted for the purposes of performing any such function.

Part 11 Institutional Pharmacy

11.1 Introduction In addition to requirements set forth in other parts of these rules, the rules in this Part are specifically applicable to all institutions and institutional pharmacies as defined below.

11.2 Definitions

(a) "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):

(1) Hospital;
(2) Convalescent home;
(3) Nursing home;
(4) Extended or long-term care facility;
(5) Mental health facility;
(6) Rehabilitation center;
(7) Psychiatric center;
(8) Developmental disability center;
(9) Drug abuse treatment center;
(10) Family planning clinic;
(11) Penal institution or correctional facility;
(12) Hospice;
(13) Public health facility;
(14) Athletic facility; and
(15) Residential care home.

(b) "Institutional pharmacy" means any drug outlet licensed by the Board which provides pharmaceutical care to current residents or patients in 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. A pharmacy that provides services to patients who do not reside in institutional settings (with the exception of a one-time dispensing upon discharge from an institution) cannot be classified as an "institutional pharmacy."

11.3 Personnel The institutional pharmacy shall:

(a) Be under the direct supervision of a full-time Vermont licensed pharmacist-manager;

(b) Employ support personnel to perform technical and secretarial duties appropriate to their training and skill level;

(c) Employ licensed pharmacists as needed to adequately direct and supervise the work of support personnel; and

(d) Employ registered pharmacy technicians as needed to perform appropriate tasks.

11.4 Responsibilities of the Pharmacist-Manager The pharmacist-manager shall be responsible for:

(a) The safe and efficient distribution and control of all pharmaceutical products;

(b) Preparation, sterilization, and admixture of parenteral medications;

(c) In-service education of nursing personnel about incompatibility of parenteral admixtures;

(d) Compounding within the institutional pharmacy;

(e) Participation in developing a formulary for the institution;

(f) Correct filling and labeling of containers;

(g) Supply and inventory of emergency antidote drugs, if not kept in the emergency room;

(h) Record keeping;

(i) Participation in the institution's patient care evaluation program;

(j) Cooperation with teaching and research programs in the institution;

(k) Implementation of the institution's policies and procedures;

(l) Efficient and effective messenger and delivery service within the institution regarding medication use;

(m) Setting quality assurance standards;

(n) Development and implementation of written policies and procedures; and

(o) Inspections of medication storage areas.

11.5 Written Policies 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:

(a) Duties of support personnel;

(b) Night cabinets;

(c) Emergency drug kits;

(d) Distribution of pharmaceutical products;

(e) Disposition of adulterated, misbranded or discontinued drugs;

(f) Recall of drugs; and

(g) Storing and returning drugs brought into the institution by patients.

11.6 Absence of Pharmacist 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.

11.7 Night Cabinets/Temporary Storage 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:

(a) Drugs are properly labeled;

(b) Only prepackaged drugs are available, in amounts sufficient for immediate therapeutic requirements until a pharmacist is available;

(c) Whenever access to the cabinet occurs, date and time of access, written practitioner's orders and proofs-of-use are provided;

(d) All drugs in the night cabinet are inventoried by a pharmacist or designee no less than once per week;

(e) A pharmacist reviews all medication orders for drugs removed from the night cabinet within 24 hours of their removal;

(f) A complete audit of all activity concerning the night cabinet is conducted no less than once per month; and

(g) Written policies and procedures are established to implement the requirements of this section.

11.8 Access to Pharmacy During Emergency 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.

11.9 Designated Nurse Access

(a) One supervisory nurse in any given eight-hour shift is responsible for obtaining drugs from the pharmacy.

(b) The responsible nurse shall be designated in writing by the appropriate committee of the institutional facility.

11.10 Nurse Removal of Drugs Removal of any drug from the pharmacy by an authorized nurse must be recorded on a suitable form showing:

(a) patient name;

(b) room number;

(c) name of drug;

(d) strength, amount,

(e) date and time of removal, and

(f) signature of nurse.

11.11 Doses Doses should be in unit-of-use (unit-dose) packaging whenever possible. The physician order shall be left in the institutional pharmacy with the container from which the drug was removed, as notice to the next pharmacist on duty. The amount should be sufficient only for the patient's emergency needs.

11.12 Emergency Kits An institutional facility lacking an institutional pharmacy may provide drugs from emergency kits. The drugs may be administered by authorized personnel, provided that such kits meet the following requirements:

(a) Emergency kits contain those drugs which may be required to meet the immediate therapeutic needs of patients;

(b) The drugs are not available from any other authorized source in sufficient time to prevent risk of harm to patients;

(c) All drugs are properly labeled;

(d) All emergency kit drugs are equipped with a breakable seal, are sealed by a pharmacist, and are secure from access by unauthorized personnel;

(e) 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;

(f) The 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;

(g) 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.

(h) The label on the emergency kit shall contain a listing of the drugs contained in the kit, including name, strength, quantity, earliest expiration date and the name, address(es) and telephone number(s) of the supplying pharmacist;

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

(j) Whenever an emergency kit is opened, the supplying pharmacist shall be notified within 24 hours, and the pharmacist shall ensure that the kit is restocked and resealed within a reasonable time so as to prevent risk of harm to patients;

(k) 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; and

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

11.13 Emergency Kits in Non-Federal Registered Long-term Care Facilities (LTCF)
(a) An LTCF may obtain controlled substances for emergency kits from a DEA-registered hospital, clinic, pharmacy, or practitioner.

(b) 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.

11.14 Emergency Kit Records 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.

11.15 Authorized Emergency Kit Users 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.

(a) It is the Board's intent that the last person to inspect and seal an emergency drug kit must be a **pharmacist**. This task may **not be delegated to a technician or a nurse**. To further clarify this point, if the emergency drug kit is to be exchanged in its entirety and leaves the pharmacy after being sealed by a pharmacist, the intent of the rules has been met.

(b) If the drugs in the emergency drug kit are individually sealed in tamper proof containers, such as plastic cubes which are sealed either by plastic locks or tamper evident tape, then individual drugs may be "swapped" out of kits as long as they are properly labeled and it is done by authorized personnel.

(c) A nurse or technician at the long term care facility may replenish emergency drug kits with a drug item, provided the drug item is pre-sealed in an individual container and placed in a pre-designated part of the kit. This requirement is to prevent loose unit-dosed medications from being placed in the wrong locations in an emergency drug kit.

11.16 Physical Requirements The institutional pharmacy shall meet the same standards as a retail drug outlet.

(a) Prescription area: The pharmacist-manager, or the pharmacist designated 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.

(b) If the institutional facility is open at times when the institutional pharmacy is closed, the pharmacy must be permanently enclosed by a partition or Board-approved barrier device from floor to ceiling, or at least nine feet six inches in height, whichever is less.

(c) The institutional pharmacy must be secure from access when the institutional facility is closed. It must be secure from access by unauthorized personnel 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.

(d) 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 drain board 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.

11.17 Hygiene Standards The institutional pharmacy shall:

(a) comply with all federal, state, and local health laws;

(b) have walls, ceilings, windows, and floors kept clean and in good repair;

(c) have waste receptacles located in convenient areas;

(d) have equipment kept clean and stored in an orderly manner;

(e) be well lighted;

(f) be dry and well ventilated; and

(g) have adequate restroom facilities for employees.

11.18 Equipment The following equipment and miscellaneous supplies shall be present:

(a) One class A prescription balance with weights or automatic sensitivity requirement of six mg. with no load;

(b) One set of metric weights from 10 milligrams to 50 grams;

(c) A refrigerator with a temperature control and thermometer;

(d) Distilled and/or sterile water;

(e) An automated data processing system;

(f) At least one telephone in the prescription area, with the same number as the telephone number printed on the drug outlet prescription labels;

(g) A tablet and capsule counting tray;

(h) Containers which meet official compendia standards, available with closures that meet Federal Poison Prevention Packaging Act of 1970 requirements, as well as regular closures;

(i) 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;

(j) Auxiliary labels;

(k) Prescription filing devices for record keeping;

(l) Sufficient equipment, graduates, mortars, funnels, etc., to maintain the scope of practice;

(m) A current copy of the Vermont Pharmacy Laws and Rules and Regulations;

(n) Any institutional pharmacy involved in the preparation of sterile pharmaceutical must meet the requirements of the "Sterile Pharmaceuticals" provisions of these rules; and

(o) Telephone number of a poison control center.

11.19 Reference Materials 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:

(a) 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;

(b) Current manual of drug interactions equivalent to "Hansten's" or "Drug Facts," with quarterly updates, which has been pre-approved by the Board.

(c) Current Facts and Comparisons, with monthly updates;

(d) Current reference on pediatric dosages;

(e) IV admixture compatibility reference (such as "King's Guide to Parenteral Admixtures");

(f) Injectable Drug Handbook ("Trissel's"); and

(g) American Hospital Formulary Service Drug Information text.

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

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

11.22 Labeling All drugs dispensed for use within the institution shall:

(a) Be in appropriate containers; and

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

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

11.24 Unit Dose Packaging 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.

11.25 Discontinued Drugs 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.

11.26 Physician's Orders Drugs may be dispensed from the institutional pharmacy if:

(a) Ordered by an authorized practitioner;

(b) 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;

(c) 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' rules and regulations or medical staff bylaws.

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

(e) 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.

11.27 Telephone Orders Prescription orders issued by an authorized practitioner may be telephoned to a retail drug outlet by a licensed registered or practical nurse.

11.28 Controlled Drug Accountability The following information must be recorded each time

a controlled drug is administered;

(a) Name of drug;

(b) Dosage;

(c) Name of patient;

(d) Date and time the drug was administered;

(e) Name of person administering the drug; and

(f) Name of prescriber.

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

11.30 Adverse Drug Reactions All adverse drug reactions shall be reported to the patient's physician and documented in the patient chart and shall also be entered into the patient profile.

11.31 Medications Brought Into the Institution By Patients 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.

11.32 Investigational Drugs Investigational drugs shall be stored in and dispensed from the pharmacy only. Investigational drugs may be administered if:

(a) Prior approval of the protocol has been granted by the institution's investigational drug review board or committee;

(b) Informed consent to treatment with these drugs has been given in writing by the patient or authorized representative;

(c) 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;

(d) All essential information pertaining to the investigational drug is maintained, stored, updated, and dispensed by the institutional pharmacy;

(e) 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;

(f) The institution participating in investigational studies has written policies and procedures for the approval, management, and control of these studies; and

(g) 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.

11.33 Records and Reports The following records and reports shall be kept on file for three years and submitted to the Board upon request:

(a) The practitioner's orders, or direct copies. The ability to retrieve these orders from a patient's medical record is acceptable;

(b) Records of medications dispensed;

(c) Reports of suspected adverse drug reactions;

(d) Inventories of night cabinets, emergency kits, the institutional pharmacy, and controlled substances;

(e) Alcohol and flammables reports;

(f) Authorized removal of drugs from the institutional pharmacy by a nurse.

11.34 Inspection of Medication Areas 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:

(a) Drugs are dispensed only under the direct supervision of a licensed pharmacist;

(b) Support personnel are properly directed and supervised;

(c) Disinfectants and drugs for external use are stored separately from drugs for internal or injectable use;

(d) Compliance with all special storage conditions for each drug;

(e) Outdated drugs are not stocked in the institution or the institutional pharmacy;

(f) Distribution and administration of controlled substances are adequately documented by pharmacy, medical, and nursing personnel;

(g) There is an adequate supply of emergency drugs;

(h) All security and storage standards are met;

(i) Metric-apothecary weight and measure conversion tables and charts are reasonably available to all medical and nursing personnel; and

(j) Compliance with policies and procedures pertaining to the pharmacy.

Part 12 Computer Systems and AMDS Usage

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

(a) Patient records may be viewed at any time on the computer screen;

(b) Patient records are available as printed documents;

(c) Information in the computer is backed up at least once each business day;

(d) 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;

(e) A backup copy must be kept off-site or in fire-proof storage;

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

12.2 Common files or Data bases 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.

12.3 Printouts 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.

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

12.5 Sight Readable Information 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 computer monitor, microfiche, microfilm, printout, or other method acceptable to the Board.

12.6 On-Line Retrieval The system shall provide on-line retrieval (via computer monitor or hard-copy printout) of original prescription drug order information. The information shall include, but not be limited to, the prescription drug order requirements and records of dispensing as indicated in these rules.

12.7 Daily Records Each pharmacist responsible for dispensing shall create a retrievable record of each day's prescription drug order information. The pharmacist shall in a log book sign a daily verification that prescription information in the record is correct. The verification shall be 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. Daily records shall be retained for three years.

12.8 Automated Systems If an automated pharmacy system is used the pharmacist-manager shall have the ultimate responsibility to:

(a) Assign, discontinue, or change access to the system;

(b) Ensure that access to the medications comply with state and federal regulations;

(c) Ensure that the automated pharmacy system is filled and stocked accurately and in accordance with established, written policies and procedures.

(d) If an automated dispensing system is utilized in the LTCF, only those systems that are designed to prevent improper placement of medications may be utilized.

12.9 Personnel 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.

12.10 Records 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. These records shall be maintained for three (3) years.

12.11 Dispensing and Distributing

(a) All drugs stored in an AMDS shall be packaged and labeled as required by federal and state statutes and regulations.

(b) All aspects of handling controlled substances dispensed via an AMDS shall comply with applicable state and federal statutes and regulations.

12.12 Confidentiality 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.

12.13 Automated Pharmacy System Records in Institutions Records and electronic data kept by the automated pharmacy system shall meet the following requirements:

(a) All events involving the contents of the automated pharmacy system must be recorded electronically.

(b) Records must be maintained by the pharmacy and must be readily available to the Board or its agent. Such records shall include:

(1) Identity of system accessed;
(2) Identification of the individual accessing the system;
(3) Type of transaction;
(4) Name, strength, dosage form, and quantity of the drug accessed; and
(5) Name of the patient for whom the drug was ordered.

12.14 AMDS Records

(a) Records and/or electronic data kept by Automated Pharmacy Systems shall be maintained at the AMDS site and must be readily available to the Board. Such records shall include:

(1) identification of the individual accessing the system;
(2) the date the AMDS was accessed,
(3) the name, strength, dosage form, and quantity of the Drug accessed;
(4) the name of the patient for whom the Drug was ordered; and
(5) A record of medications filled/stocked into an AMDS and identification of the persons filling/stocking and checking for accuracy;

(6) such additional information as the coordinating pharmacist may deem necessary.

(b) Records must be maintained and retrievable a minimum of three years.

12.15 System Backup

(a) Routine backup systems and procedures (hard copy, copy, disk, etc.) shall be in place and operational to ensure against loss of patient data.

(b) In the event that permanent dispensing information is lost due to unscheduled system interruption, the Board of Pharmacy shall be notified within 72 hours.

12.16 Policies and Procedures

(a) A remote pharmacy must be operated pursuant to policies and procedures adopted by the coordinating pharmacy.

(b) The policies and procedures shall require on-going documentation by the coordinating pharmacist manager to assure:

(1) that access to the AMDS is available to registered or licensed pharmacy personnel or AMDS maintenance personnel only;

(2) 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

(3) appropriate record keeping and security safeguards, and

(4) a mechanism for securing and accounting for medications removed from and subsequently returned to the AMDS; and

(5) a mechanism for securing and accounting for wasted medications or discarded medications; and

(6) patient confidentiality.

12.17 Oral Communication of Prescriptions Designated employees of practitioners qualified to prescribe drugs may transmit an order for a prescription via telephone.

Part 13 Sterile Pharmaceuticals

13.1 Purpose and Scope 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.

13.2 Applicability 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.

13.3 Definitions

(a) "Compounding Aseptic Containment Isolator" also known as "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.

(b) "ISO 5" (International Organization for Standards) 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.

(c) "Cytotoxic" means a pharmaceutical that has the capability of killing living cells.

(d) "Enteral" means within or by way of the intestine.

(e) "Parenteral" means a sterile preparation of drugs for injection through one or more layers of the skin.

(f) "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.

(g) "Product quality and characteristics" include: sterility, potency associated with environmental quality, preparation activities, and checks and tests.

(h) "Sterile pharmaceutical" means any dosage form devoid of viable microorganisms, including, but not limited to, parenterals, injectables, and ophthalmics.

(i) "USP 797" means the current version of USP-NF General Chapter 797 Pharmaceutical Compounding - Sterile Preparations published annually by the U.S. Pharmacopeial Convention.

13.4 Policy and Procedure Manual 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.

(a) 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.

(b) The policy and procedure manual shall be current and available for inspection by a Board-designated agent.

13.5 Physical Requirements The pharmacy shall have a designated area with entry restricted to designated personnel for preparing parenteral products. This area shall be:

(a) structurally isolated from other areas with restricted entry or access;

(b) be designed to avoid unnecessary traffic and airflow disturbances from activity within the controlled facility;

(c) used only for the preparation of these specialty products;

(d) 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.

13.6 ISO 5 Compliance The pharmacy preparing parenteral products shall have:

(a) appropriate environmental control devices capable of maintaining at least ISO 5 conditions in the workplace where critical objects are exposed and critical activities are performed; furthermore, these devices are capable of maintaining ISO 5 conditions during normal activity. Examples of appropriate devices include laminar airflow hoods and zonal laminar flow of high efficiency particulate air (HEPA) filtered air;

(b) 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;

(c) When cytotoxic drug products are prepared, appropriate environmental control also includes appropriate biohazard cabinetry;

(d) Temperature-controlled delivery container if products are to be stored unrefrigerated for more than two hours; and

(d) Infusion devices, if appropriate.

13.7 Supplies The pharmacy shall maintain supplies adequate to maintain an environment suitable for the aseptic preparation of sterile products.

13.8 Reference Materials The pharmacy shall maintain on file at least one current reference related to preparation of sterile products, equivalent to "Trissel's" or "King's."

13.9 Records and Reports In addition to standard record and reporting requirements, the following additional records and reports must be maintained for sterile pharmaceuticals:

(a) A policy and procedure manual, including policies and procedures for cytotoxic or infectious waste, or both, if applicable, and

(b) 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.

13.10 Delivery Service 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.

13.11 Emergency Kit 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).

13.12 Cytotoxic Drugs 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:

(a) All cytotoxic drugs should be compounded in a vertical flow, Class II, Compounding Aseptic Containment Isolator. Other products should not be compounded in this cabinet.

(b) Protective apparel shall be worn by personnel compounding cytotoxic drugs. This shall include disposable masks, gloves, and gowns with tight cuffs.

(c) Appropriate safety and containment techniques for compounding cytotoxic drugs shall be used in conjunction with the aseptic techniques required for preparing sterile products.

(d) Disposal of cytotoxic waste shall comply with all applicable local, state, and federal requirements.

(e) 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.

(f) Prepared doses of cytotoxic drugs shall 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.

13.13 Disposal of Cytotoxic or Hazardous Wastes 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.

13.14 Patient Education and Training 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.

13.15 Quality Assurance for Compounding and Preparation of Sterile Pharmaceuticals 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.

13.16 Sanitation Standards - Certification of Compliance All clean rooms and laminar flow hoods shall be certified by an independent contractor according to ISO Standard 14644 for operational efficiency at least every six months. Appropriate records shall be maintained.

13.17 Written Protocol There shall be written procedures developed requiring sampling if microbial contamination is suspected.

13.18 End Product Testing 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.

13.19 Beyond Use Dates There shall be written justification of the chosen beyond-use dates for compounded products.

13.20 Quality Assurance Audits There shall be documentation of quality assurance audits at regular, planned intervals, including infection control and sterile technique audits.

13.21 Pharmaceutical Care Outcomes 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:

(a) Routine performance of prospective drug use review and patient monitoring functions by a pharmacist;

(b) 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);

(c) Documentation of patient training as required by Section 13.14 above; and

(d) Appropriate collaboration with other health care professionals.

13.22 USP 797 Compliance for Compounded Sterile Products

(a) All pharmacies, either in state or out of state, dispensing or distributing compounded sterile products as defined by USP 797 to Vermont patients, institutions or providers shall meet all requirements of USP 797.

(b) Such pharmacies shall file with the Board proof of USP 797 compliance or an affidavit describing their procedures for quality assurance, sterilization methods, environmental controls, sterility and pyrogen testing, and maintenance of the quality of sterile products throughout packaging, handling, and distribution. The Board may conduct audits of any licensee.

Part 14 Licensing of Investigative and Research Projects

14.1 Licenses Required Licensing of Investigative and Research Projects is required by 26 V.S.A. § 2061(5). A legitimate institution or entity which possess prescription drugs in the course of conducting research or investigation shall apply to the Board for a license. The Board may issue a license when it determines that:

(a) The entity requesting the license is a legitimate research entity, recognized by state or national licensing or accreditation organizations approved by the Board;

(b) The entity explains with its application;

(1) where and how regulated drugs used for research or investigation will be stored, secured, and accounted for,

(2) who will be responsible for ensuring compliance with the requirements of this rule and;

(c) The Board can conclude that the regulated drugs can be handled in a manner consistent with these rules.

14.2 Conditions The Board may set reasonable conditions on licenses granted under this section.
The license holder will notify the Board within 5 working days if there is a change in the person responsible for compliance.

14.3 Exemptions Medical facilities such as clinics and physicians' offices which are

otherwise legally entitled to possess prescription drugs or are otherwise licensed by this Board are not required to be licensed under this Part 13 of the rules.

Part 15 Nuclear/Radiologic Pharmacy

15.1 Purpose and Scope 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.

15.2 Definitions

(a) "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.

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

(c) "Nuclear pharmacy" means a pharmacy providing radiopharmaceutical services or, as provided in Rule 14.3 below, the appropriate area of any institutional facility.

(d) "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.

(e) "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:

(1) Minimum standards of training for "authorized user status" of radioactive material, as defined by the Vermont Department of Health (VDH).

(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:

(A) Radiation physics and instrumentation;
(B) Radiation protection;
(C) Mathematics of radioactivity;
(D) Radiation biology; and
(E) Radiopharmaceutical chemistry.

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

(f) "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.

(g) "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.

(h) "Radiopharmaceuticals" are radioactive drugs as defined by the FDA.

15.3 General Requirements for Pharmacies Providing Radio-Pharmaceutical Services
(a) A license to operate a pharmacy providing radio-pharmaceutical services shall be issued only to a qualified nuclear pharmacist.

(b) All personnel performing tasks in the preparation and distribution of radioactive drugs shall be under the direct supervision of a qualified nuclear pharmacist.

(c) 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.

(d) 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 radio-pharmaceuticals for the immediate emergency, and must document such activities.

15.4 Physical Requirements 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.

15.5 Security The nuclear pharmacy area shall be secured from unauthorized personnel.

15.6 Records 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.

15.7 Radioactive Storage 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.

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

15.9 Permit Prerequisites 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.

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

Part 16 Non-Resident Pharmacy

16.1 Definitions
(a) "Non-resident pharmacy" means a drug outlet or business located outside of Vermont which dispenses 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, or which provides any type

of pharmacy services.

(b) "Pharmacy services" as defined in this section includes consulting or medication therapy management. Non-resident pharmacies include pharmacies operating by means of the Internet.

(c) "Medication Therapy Management" as used in this section means a distinct service or group of services that optimize therapeutic outcomes for individual patients. Medication Therapy Management services are independent of, but can occur in conjunction with, the provision of a medication or a medical device.

16.2 Licensure An applicant for initial licensure must provide to the Board:

(a) 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;

(b) 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;

(c) name(s) of the owner(s) of the licensee, including:

(1) If a person: the name, business address, and date of birth;

(2) If a partnership: the name, business address, and date of birth of each partner, and the name of the partnership;

(3) If a sole proprietorship: the full name, business address, social security number, and date of birth of the sole proprietor and the name of the business entity; and

(4) If a corporation: the federal identification number of the corporation, the name, business address, 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, business address of each shareholder owning five percent 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;

(d) 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;

(e) 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;

(f) 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;

(g) evidence that during its regular hours of operation, but not fewer than five 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 fewer 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;

(h) a copy of the most recent inspection report from the state in which the pharmacy is located; and

(i) For internet non-resident pharmacies, a copy of an inspection report not more than three years old by either:

(1) the state in which the pharmacy is located; or

(2) Verified Internet Pharmacy Practice Sites (VIPPS) certification.

16.3 Change of Information Changes of information required in Rule 16.2 above shall be submitted to the Board within 30 days.

16.4 Personnel 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.

16.5 Prescription Records A non-resident pharmacy shall maintain for three years 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:

(a) the name of the patient;

(b) the name of the prescriber;

(c) the number of the prescription;

(d) the date of the prescription;

(e) the name of the drug;

(f) the strength and quantity of the dose; and

(g) name or other identification of the dispensing pharmacist.

16.6 Substitution of Drug A non-resident pharmacy which provides mail order service to a resident of Vermont may substitute a drug as required by the substitution provisions of Title 18 Chapter 91 and as set forth in Rule 10.19 herein.

16.7 Toll-Free Telephone Service 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 fewer 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.

16.8 Disciplinary Action In addition to any other provisions of law, the Board may initiate

disciplinary action when:

(a) a violation of these rules pertaining to non-resident pharmacies is alleged;

(b) a violation affecting a resident of this state is alleged and the state where the non-resident pharmacy is located has taken no action within 45 days from the date the violation was reported;

(c) an emergency arises that would constitute an immediate threat to the health and safety of the residents of this state.

Part 17 Wholesale Distributors

17.1 Minimum Required Information for Licensure 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:

(a) Name, full business address, and telephone number of the licensee;

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

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

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

(e) Name(s) of the owner and the operator of the licensee, including:

(1) If a person: the name, address, and social security number and date of birth;

(2) If a partnership: the name, address, and social security number and date of birth of each partner, and the name of the partnership;

(3) If a corporation: the federal identification number of the corporation, the name, address, 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, and address of each shareholder owning five percent 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;

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

(5) 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 or under investigation for, any felony or misdemeanor arising from the violation of any drug or pharmacy related law.

17.2 Required Forms 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.

17.3 Change of Information Changes of information required in Rule 17.1 above shall be submitted to the Board within 30 days.

17.4 Acts Which May Affect Licensure Among the factors the Board of Pharmacy will

consider when deciding whether to grant a license to a wholesale distributor are:

(a) 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;

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

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

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

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

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

(g) 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;

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

17.5 Personnel 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.

17.6 Minimum Requirements for the Storage and Handling of Drugs All facilities at which drugs are stored, warehoused, handled, held, offered, marketed, or displayed shall:

(a) be of suitable size and construction to facilitate cleaning, maintenance, and proper operations;

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

(c) 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; and

(d) be maintained in a clean and orderly condition.

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

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

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

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

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

17.8 Diversion Prevention 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.

17.9 Storage 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.

(a) 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.

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

17.10 Inspections All wholesalers must submit proof with initial and renewal applications that they have successfully passed and have maintained a current inspection (not more than three years old) certification by the Pharmacy Board in the state in which they reside, or have successfully obtained and maintained VAWD certification, or from inspection certification from another similar body approved by the Board.

17.11 Examination of Materials 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.

17.12 Examination of Outgoing Shipments 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.

17.13 Returned, Damaged, and Outdated Drugs 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.

17.14 Compromised Packaging 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.

17.15 Drug Safety/Quality Questions

(a) 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.

(b) 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.

17.16 Record Keeping

(a) Wholesale distributors shall establish and maintain inventories and records of all transactions regarding the receipt and distribution or other disposition of drugs. This includes:

(1) stored drugs;
(2) all incoming and outgoing drugs; and
(3) all outdated, damaged, deteriorated, misbranded, or adulterated drugs.

(b) These records shall include the following information:

(1) The source of the drugs, including the name and principal address of the seller or transferor, and the address of the location from which the drugs were shipped;
(2) The identity and quantity of the drugs received and distributed or disposed of; and
(3) The dates of receipt and distribution or other disposition of the drugs.

17.17 Availability of Records 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.

17.18 Record Retention

(a) 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.

(b) 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.

17.19 Reporting Thefts Any theft or significant loss of prescription drugs shall be reported to the Board within 5 days. The report should be made on forms available from the Board for this purpose.

17.20 Written Policies and Procedures

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.

17.21 Written Policies, Contents

Wholesale distributors shall include in their written policies and procedures the following:

(a) 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.

(b) 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:

(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;
(2) any volunteer action by the Manufacturer to remove defective or potentially

defective drugs from the market; or

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

(4) 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.

(5) A procedure to ensure that any outdated drugs shall be segregated from other drugs and either returned to the manufacturer or destroyed.

(A) This procedure shall provide for written documentation of the disposition of outdated drugs.

(B) This documentation shall be maintained for two years after disposition of the outdated drugs.

17.22 Responsible Individuals 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.

17.23 Compliance with Federal, State, and Local Laws Wholesale distributors shall operate in compliance with applicable federal, state, and local laws and rules.

17.24 Inspections Authorized 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.

17.25 Controlled Substances Compliance Requirements 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.

17.26 Salvaging and Reprocessing 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 Title 21, parts 207, 210, and 211 subpart K of the Code of Federal Regulations.

Part 18 Community Based Long Term Care Pharmacies

18.1 Community Based Long Term Care Pharmacies Community based long term care pharmacies are those pharmacies that are closed to retail trade and only provide services to patients who may or may not reside in institutional settings, but who require a higher level of service than that typically provided by retail pharmacies. These would include unit dose or multi dose packaging promoting compliance with drug treatment regimens, and higher levels of medication therapy management.

18.2 Applicable Rules Community Based Long Term Care Pharmacies shall comply with Part 9 herein, Pharmacy Practice Rules.

18.3 Community Based Long Term Care Pharmacies Versus Institutional Long Term Care pharmacies Community based long term care pharmacies are distinguished from Institutional Long

Term Care Pharmacies which are addressed in 10.2(b) of these Rules.

Part 19 Remote Pharmacies

19.1 General Purpose:

(a) This Part is enacted pursuant to 26 V.S.A. § 2032 which in 2006 initially authorized the Board of Pharmacy to conduct pilot remote pharmacy experiments and to then propose rules governing remote pharmacy and remote pharmacy practice.

(b) The Board's experiment shows that residents of identified under-served areas of Vermont can benefit from having access to remote pharmacies. Vermonters in under-served areas are significantly restricted in their ability to obtain needed prescription drugs. Remote pharmacies enable Vermonters to obtain prescription drugs in their own communities while still being able to consult with a pharmacist in a manner where public health, safety and welfare can be assured.

(c) Remote pharmacies should be located only in those areas where residents require basic pharmacy services and do not have a reasonably accessible retail pharmacy nearby. Remote pharmacies are designed to allow patients to, as closely as possible, receive the basic care, attention, and services that they would expect from a traditional retail pharmacy. Because a pharmacist is not required to be on the premises at all times however, the remote pharmacy cannot provide the full range of services normally provided by a retail pharmacy.

(d) Remote pharmacies are not intended to be a substitute for retail pharmacies where a pharmacist is present whenever prescription drugs are dispensed.

19.2 Definitions

(a) "Certified pharmacy technician" means an individual who is:

(1) registered with the Board as a pharmacy technician;
(2) whose registration is unencumbered;
(3) who has obtained and maintains current certification from a national technician certification authority approved by the Board; and
(4) who has a minimum of 2,000 hours experience as a registered pharmacy technician.

(b) "Coordinating pharmacist" means a Vermont licensed pharmacist with an unencumbered license who provides remote pharmacy services and who has no less than three years licensed practice experience.

(c) "Coordinating pharmacist manager" means a Vermont licensed pharmacist who has full responsibility for all aspects of one or more remote pharmacies.

(d) "Coordinating pharmacy" as used in this Part means a licensed pharmacy located within the State of Vermont or a Vermont licensed pharmacist not affiliated with a pharmacy. The "coordinating pharmacy," as permitted by the Board, provides remote pharmacy services at one or more licensed remote dispensing/pharmacy sites.

(e) "Remote pharmacy" means a licensed pharmacy facility where pharmacy services are provided by a coordinating pharmacist. The remote pharmacy is designed so that a pharmacist at a different location provides pharmacy services electronically via a computer system and via video and audio

communication system approved by the Board.

(f) "Remote pharmacy practice" means the provision of pharmaceutical care services, including the storage and dispensing of prescription drugs, drug regimen review, and patient counseling, at a staffed remote dispensing site.

19.3 Coordinating Pharmacist Manager

(a) The Coordinating pharmacist manager is a Vermont licensed pharmacist who:

1) has no less than three years licensed practice experience;
2) possesses an unencumbered license; and
3) has been specifically designated and registered with the Board to serve as a coordinating pharmacist manager.

(b) When the remote pharmacy is affiliated with a Vermont retail pharmacy, the retail pharmacy's pharmacist manager shall be the coordinating pharmacist manager.

19.4 Coordinating Pharmacist Manager Responsibilities The coordinating pharmacist manager shall be responsible for, at a minimum, the following:

(a) Submitting for Board approval the operational plan for the remote pharmacy service, including:

(1) justification of the need for the remote pharmacy service as provided in this Part.
(2) identification of the coordinating site;
(3) identification of the remote dispensing site;
(4) the names and titles of key personnel at both locations;
(5) the quality assurance and improvement plan;
(6) a policies and procedure manual; and
(7) explanation of the remote dispensing process to be utilized at the remote dispensing site;

(b) Ensuring that the practice of pharmacy performed at the remote pharmacy and the supervision of pharmacy technicians complies with applicable federal and state statutes and regulations and these rules;

(c) Ensuring that:

(1) any automated pharmacy system is in good working order;
(2) the AMDS accurately dispenses the correct strength, dosage form, and quantity of the prescribed drug and accurately prints the prescription label while maintaining appropriate record-keeping, security, and quality assurance safeguards;

(d) Ensuring that all pharmacists and pharmacy technicians authorized to provide remote pharmacy services at the managing pharmacy or the remote site:

(1) maintain current licensure or registration with the Board;
(2) are trained in the operation of any automated pharmacy system; and
(3) are familiar with policies and procedures relating to the remote pharmacy practice.

19.5 Change of Coordinating Pharmacist Manager A change in the coordinating pharmacist manager shall be reported in the manner a change of a pharmacist manager is reported under Part 6 of these Rules.

19.6 Coordinating Pharmacist Duties Only the coordinating pharmacist may perform the

activities listed in this rule. These activities may not be delegated to a pharmacy technician at a remote site.

(a) Receiving an oral prescription drug order from a prescriber or the prescriber's agent for dispensing to a patient at the remote site;

(b) Interpreting a prescription drug order;

(c) Verifying the accuracy of prescription data entry;

(d) Interpreting the patient's drug record and conducting a drug utilization review;

(e) Authorizing any AMDS to dispense a prescription drug and print a prescription label at the remote site;

(f) Performing the final verification of a dispensed prescription;

(g) Counseling the patient or the patient's care-giver; and

(h) Completing and documenting the weekly inspection of the remote site.

19.7 License Required for Remote Pharmacy Services - General Requirements

(a) To be eligible for a remote pharmacy license, the applicant shall comply with the application process set forth in Rules 7.2 and Rule 7.3 herein and demonstrate to the Board that there is limited access to pharmacy services in the community where the remote site is proposed.

(b) In determining whether a community has limited access to pharmacy services, the Board may consider, but is not limited to the following factors:

(1) the proximity of a licensed retail or remote pharmacy;
(2) the geographical location of the community and proximity or ease of access to a retail pharmacy; and
(3) the nature of the community and its demographics.

(c) In no event will the Board approve a remote pharmacy if a retail pharmacy is located within a ten (10) mile drive by motor vehicle.

(d) Notwithstanding subsection (c) above, a remote pharmacy approved by the Board as part of the pilot project before adoption of these rules may, so long as it remains in compliance with these rules, continue to operate at its present locations.

19.8 Laws Applying to Remote Pharmacies

(a) Each remote pharmacy shall, in addition to meeting the requirements of these rules, comply with all applicable federal and state laws.

(b) If controlled substances are dispensed from the remote pharmacy, the remote pharmacy must obtain its own DEA registration.

(c) Where remote pharmacy rules conflict with the other rules governing retail pharmacies, the requirements of this Part shall apply. Space requirements for retail pharmacies do not apply to remote pharmacies.

19.9 Policy and Procedure Manual The coordinating pharmacy and remote pharmacy shall operate pursuant to a written policy and procedure manual that is established by the coordinating pharmacy. The policy and procedure manual shall include, but is not limited to the following:

(a) a current list containing the name and business address of the coordinating pharmacist and personnel designated by the coordinating pharmacist manager to have access to the area where drugs are stored at the remote pharmacy;

(b) duties that may only be performed by a pharmacist; and

(c) policies and procedures for:
- (1) operation of the video/auditory communication system;
- (2) security;
- (3) sanitation;
- (4) storage of drugs;
- (5) dispensing;
- (6) supervision; and
- (7) drug procurement, receipt of drugs, and delivery of drugs.

19.10 Record Keeping The coordinating pharmacist manager shall, at least annually, review and revise as necessary the written policies and procedures, and document such review.

19.11 Remote Pharmacy Staffing

(a) A pharmacist, pharmacy technician, or pharmacy intern performing services in support of a remote pharmacy, whether those services are performed at the coordinating pharmacy or the remote pharmacy, must be licensed by or registered with the Board.

(b) Remote pharmacies shall be staffed by certified pharmacy technicians under the continuous supervision of a Pharmacist. A remote pharmacy where the sole operation is limited to an AMDS dispensing pre-packaged medications in a secure dispensing unit may be staffed by a certified pharmacy technician, licensed practical nurse, registered nurse, or authorized prescriber any of whom shall register as a pharmacy technician with the Board and shall be under the continuous supervision of a Pharmacist.

(c) Pharmacy interns may not work at a remote pharmacy unless a pharmacist is physically present at the remote pharmacy.

(d) A pharmacist who is engaged in the operation of a retail, institutional, or mail order pharmacy shall not simultaneously operate more than one remote pharmacy.

(e) A coordinating pharmacist who is also engaged in retail or institutional pharmacy may supervise the interpretation, evaluation, and implementation of a prescription drug order, including the preparation of a drug or device to a patient or patient's agent, to an average of 125 prescriptions at the remote pharmacy per work day in any one week or a peak of 150 prescriptions on any one day. This supervision limit does not apply to central filled or refill prescriptions dispensed at the remote pharmacy.

(f) A pharmacist who is not engaged in the operation of a retail, institutional or mail order pharmacy may operate no more than three simultaneously open Remote Pharmacies. A coordinating pharmacist providing only remote pharmacy services may supervise the interpretation, evaluation, and implementation of a prescription drug order, including the preparation of a drug or device to a

patient or patient's bona fide representatives to an average of 250 prescriptions per work day in any one week or a peak of 300 prescriptions per day.

(g) A coordinating pharmacy providing remote pharmacy services shall provide sufficient staffing to meet the prescription work load. In an emergency, a temporary exception to this limit may, in the Board's discretion, be granted where the Coordinating Pharmacy has documented a need to supervise additional remote pharmacies and has demonstrated that appropriate safeguards are in place to ensure proper supervision of each.

19.12 Notices and Displays

(a) Each remote pharmacy shall have a notice clearly visible to the public stating: "This is a licensed remote pharmacy. A pharmacist may not be physically present. A pharmacist from the [name of coordinating pharmacy] pharmacy in [location] reviews every prescription dispensed here. Whether physically present here or at the [name of coordinating pharmacy] pharmacy, the pharmacist is required to speak with you before your prescription will be dispensed."

(b) The license, or a copy thereof, of any pharmacist providing remote pharmacy services must be prominently displayed at the remote pharmacy.

(c) The registration and national certification, or copy thereof, of any pharmacy technician at a remote pharmacy shall be prominently displayed.

(d) Remote pharmacies must display all signs required by state or federal law for any retail pharmacy.

19.13 Storage Security Drugs stored at Remote pharmacy shall be stored in an area that is:

(a) separate from any other drugs at a health care facility; and

(b) locked by key or combination, so as to prevent access by unauthorized personnel.

(c) Access to the area where drugs are stored at the remote pharmacy must be limited to registered or licensed pharmacy personnel.

19.14 Audiovisual link

(a) There must be a continuously accessible, two-way audiovisual link between the coordinating pharmacist and the remote pharmacy. The transmission of information through the computer link must make information available to the coordinating pharmacist and the remote pharmacy simultaneously. The video camera used for the certification of prescriptions must be of sufficient quality and resolution so that the coordinating pharmacist can visually identify the markings on tablets and capsules. No prescription may be dispensed if the audio/visual link is not fully operational.

(b) Audio/video and IT communications disruptions shall be documented and retained for three years.

(c) The audio/visual link shall be recorded while the remote pharmacy is in operation. The recording shall be retained for 30 days.

(d) Each remote pharmacy shall have security cameras which shall capture movement within the remote pharmacy at all times. The coordinating pharmacist shall be able to monitor the security cameras at all times.

19.15 AMDS Requirements An AMDS used in a remote pharmacy must comply with AMDS provisions contained in Part 11 of these rules.

19.16 Remote Pharmacy Operation

(a) A remote pharmacy may utilize an AMDS located in an area accessible only to registered or licensed pharmacy personnel.

(b) The coordinating pharmacist shall have access to the remote pharmacy's automated data processing system to perform a prospective drug utilization review (DUR) prior to dispensing. The pharmacist shall ensure, through the use of the video/auditory communication system, that the certified pharmacy technician has accurately and correctly prepared the drug for dispensing according to the prescription drug order.

(c) The remote pharmacy may be open only if the computer link, video link, and audio link with the coordinating pharmacy are functioning properly. If any link is not functioning properly, the remote pharmacy must be closed unless a pharmacist is working at the remote pharmacy.

(d) Any prescription filled at the remote pharmacy must be reviewed and interpreted by a pharmacist before the prescription is dispensed.

(e) A remotely dispensed prescription must have a properly prepared label attached to the final drug container before the pharmacist approves the prescription for dispensing.

(f) The computer must be capable of carrying the initials of the technician preparing the prescription and the pharmacist verifying the prescription.

(g) No compounding may occur at a remote pharmacy unless a pharmacist is physically present.

19.17 Written or Electronic Prescription Drug Orders

(a) A remote dispensing site may receive only written, faxed, or electronic prescription drug orders. The pharmacy technician at the remote site shall either transmit the prescription drug order or refill request to the coordinating pharmacy. The pharmacy technician may input the prescription drug order or refill request so that coordinating pharmacist may perform a prospective drug utilization review and verify the prescription information prior to authorizing dispensing from the remote site.

(b) A pharmacy technician at a remote pharmacy shall not receive oral prescription drug orders from a practitioner or practitioner's agent. Oral prescription drug orders shall be communicated directly to a coordinating pharmacist.

19.18 Schedule II Prescriptions Schedule II prescriptions shall be dispensed as follows:

(a) patient presents original hard copy of Schedule II prescription to the remote pharmacy; (faxed prescriptions are not permitted)

(b) after verifying that the prescribed drug is in stock, technician dates, cancels, and signs the original hard copy;

(c) the technician scans the prescription into patient file;

(d) the coordinating pharmacist prints and reviews scanned prescription;

(e) the coordinating pharmacist dates, cancels, and signs the printed scanned prescription;

(f) the coordinating pharmacist re-scans the prescription to the patient file;

(g) the technician at the remote site prints the pharmacist's cancelled prescription and attaches it to the original prescription.

(h) No less than once per week, the original prescription must be reviewed in person by a pharmacist who then cancels, signs, and dates the original prescription.

19.19 Counseling Unless the patient affirmatively refuses counseling, which refusal shall be documented, counseling is required for all new prescriptions.

19.20 No Returned Drugs A remote pharmacy may not receive "take backs" except drugs returned due to a prescription dispensing error made at that site.

19.21 Inspections and Board of Pharmacy Access to Records
(a) All policies and procedures for any remote pharmacy must be maintained both in the coordinating pharmacy and the remote pharmacy and be available for inspection by the Board. The Board may physically inspect a remote pharmacy as it deems appropriate.

19.22 Quality Assurance The coordinating pharmacist manager must:

(a) conduct an inspection of the remote pharmacy at weekly intervals or more frequently if necessary. Inspection must be documented and kept on file at the remote pharmacy and available upon request by the Board;

(b) implement and conduct a quality assurance plan that provides for on-going review of dispensing errors, with appropriate action taken, if necessary, to assure patient safety;

(c) verify the accuracy and legitimacy of controlled substance prescriptions during weekly inspections;

(d) Maintain records of all controlled substances stocked by the remote pharmacy through a daily perpetual inventory. Controlled substance perpetual inventory records must be available for Board inspection;

(e) conduct an inventory of all controlled substances at least monthly to verify accuracy; and

(f) maintain a record of medication errors.

19.23 Reports to the Board
(a) **Initial Report** After 180 days of operation the coordinating pharmacist manager for each remote pharmacy shall submit a report to the Board. The report shall:

(1) summarize identified errors by category and shall include the total number of errors identified, the reasons for the errors, the corrective actions taken to prevent the recurrence of those errors.

(2) state the number of prescriptions dispensed each month.

(b) **Subsequent reports, annually**. Within 15 days of the anniversary of the opening date, the

coordinating pharmacist manager for each remote pharmacy shall submit a report to the Board. The report shall contain all the information required in subsection (a) of this rule.

19.24 Renewal Requirements
(a) Before a remote pharmacy license will be renewed, the licensee must demonstrate a continuing need for the remote pharmacy addressing the criteria upon which the initial license was granted. The Board's renewal form may contain questions to assist the renewal evaluation process so that the Board can determine whether there is a continuing need for the remote pharmacy.

(b) Remote renewals applications must be submitted using forms approved by the board.

(c) The Board will not renew a remote pharmacy license if a retail pharmacy is granted a license to operate within ten (10) miles by motor vehicle of the remote pharmacy's location. The remote pharmacy may apply to the Board for a pharmacy license for that location.

19.25 Remote Pharmacy Closing A remote pharmacy which is to close shall comply with the drug outlet closing provisions of these Rules.

Part 20 Unprofessional Conduct and Disciplinary Information

20.1 Definitions The Board may take disciplinary action against a licensee, former 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. 3 V.S.A. § 129a(a)(3) includes within the definition of unprofessional conduct, "(3) [f]ailing to comply with provisions of federal or state statutes or rules governing the practice of the profession." Unprofessional conduct includes:

(a) Giving or receiving improper assistance in connection with any part of the examinations for licensure.

(b) Failing to provide, or false documentation of, continuing pharmacy education.

(c) False affirmation of any information provided to the Board.

(d) 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.

(e) 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 prescriber.

(f) Any disciplinary action in any jurisdiction by a licensing authority regulating the practice of a health-related profession.

(g) 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.

(h) Attempting to circumvent the patient counseling requirements, or discouraging the patient from receiving patient counseling concerning his or her prescription drug order.

(i) 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) Patient or patient's agent, or another pharmacist acting on behalf of a patient;

(2) Practitioner who issued the prescription drug order;

(3) Certified or licensed health care personnel who are responsible for the care of the patient;

(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

(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.

(j) Except for the sale of syringes, 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.

(k) Selling a drug for which a prescription drug order from a practitioner is required, without having received a prescription drug order for the drug.

(l) 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.

(m) 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.

20.2 Independent Judgment 3 V.S.A. § 129a(b) requires practitioners to practice competently. This includes conforming to essential standards of acceptable and prevailing practice. Part of a pharmacist's responsibilities is the duty to use independent professional judgment.

(a) A licensed pharmacist must comply with federal and state statutes and rules including the rules of the Vermont Board of Pharmacy. The nature of contemporary pharmacy practice may from time to time place a pharmacist in a position where adherence to legal requirements may conflict with the expectation of prescribers, employers or others.

(b) When such conflicts arise, the pharmacist's obligation is to exercise independent professional judgment. This may require a pharmacist to tell patients, prescribers, employers or others that his or her legal obligations prevent him or her from taking a certain course of action or complying with the wishes of others.

20.3 Initiating a Complaint 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, 89 Main St., Fl. 3, Montpelier, VT 05620-3402. The telephone number is (802) 828-1505. A complaint form may also be accessed from the Office Web site http://www.vtprofessionals.org.

20.4 Investigations The Board may receive complaints from any source. 3 V.S.A. § 129(b).

20.5 Disciplinary Process 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.

20.6 Confidentiality Confidentiality of disciplinary matters is governed by 3 V.S.A. § 131.

20.7 Appeals Appeals from Board decisions are governed by 3 V.S.A. § 130.

20.8 Reinstatement After Revocation

(a) Unless the Board orders otherwise in a disciplinary decision, 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.

(b) 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.

20.9 Modification of Orders

(a) A licensee whose license has been suspended, restricted, or placed under supervision may apply for modification of the Board's order at any time 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.

(b) An application for reinstatement of an 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 or other relevant persons 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.

Effective Date: September 15, 2015

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OFFICE OF PROFESSIONAL REGULATION
VERMONT SECRETARY OF STATE

Administrative Rules for the Vermont Board of Pharmacy

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.

The Vermont Statutes Online

The Statutes below include the actions of the 2024 session of the General Assembly.

The Vermont Statutes Online will be down for maintenance on Wednesday, October 22 while we load the actions of the 2025 General Assembly.

NOTE: The Vermont Statutes Online is an unofficial copy of the Vermont Statutes Annotated that is provided as a convenience.

Title 26 : Professions and Occupations

Chapter 036 : Pharmacy

Subchapter 002 : BOARD OF PHARMACY

(Cite as: 26 V.S.A. § 2032)

§ 2032. Powers; duties; limitations

(a) The Board shall adopt rules necessary for the performance of its duties, including:

(1) scope of the practice of pharmacy;

(2) qualifications for obtaining licensure;

(3) explanations of appeal and other rights given to licensees, applicants, and the public;

(4) rules regulating pharmacy technicians; and

(5) provisions for the inspection of any regulated entity or commercial location where legend drugs are manufactured or kept.

(b) The Board of Pharmacy shall supervise the practice of pharmacy in this State, including the following:

(1) the determination and issuance of standards for recognition and approval of schools and colleges of pharmacy whose graduates shall be eligible for licensure in this State, and the specification and enforcement of requirements for practical training;

(2) the enforcement of those provisions of this chapter relating to the conduct or competence of pharmacists practicing in this State, and the suspension, revocation, or restriction of licenses to engage in the practice of pharmacy; and

(3) an internship program that shall have the following elements:

(A) a curriculum governing the internship that requires an intern to spend at least 50 percent of the internship on compounding, dispensing, or inventorying prescription

drugs under the direct supervision of a licensed pharmacist, and maintaining required records;

(B) the establishment of a referral function administered by the Office of Professional Regulation whereby the Board collects information on available internships and disseminates this information to prospective interns; and

(C) allowance of up to 1,240 hours of the program to be "concurrent time" or internship time served under the supervision of, concurrent with, or part of an educational course requirement leading to a pharmacy degree, as defined by Board rule, or by equivalent service in any branch of the U.S. Armed Forces, as defined by Board rule.

(c) The Board of Pharmacy shall also have the following responsibilities in regard to medications, drugs, legend devices, and other materials used in this State in the diagnosis, mitigation, and treatment or prevention of injury, illness, and disease:

(1) the regulation of the sale, compounding, administration, and dispensing of medications, drugs, legend devices, and other materials, including the right to seize any such drugs, legend devices, and other materials found to be detrimental to the public health and welfare by the Board pursuant to an appropriate hearing as required under the Administrative Procedure Act;

(2) the specifications of minimum professional and technical equipment, environment, supplies, and procedures for the compounding or dispensing of such medications, drugs, legend devices, and other materials within the practice of pharmacy;

(3) the control of the purity and quality of such medications, drugs, legend devices, and other materials within the practice of pharmacy; and

(4) the issuance of certificates of registration and licenses of drug outlets.

(d) The Board:

(1) shall make examinations available at least twice each year and pass upon the qualifications of applicants for licensing; and

(2) may enact rules for continuing education requirements and approve continuing education programs.

(e) With the approval of the Board, the Director of the Office of Professional Regulation may employ or contract with persons as may be necessary to carry out the duties of the Board.

(f) The Board or its authorized representatives shall also have power to investigate and gather evidence concerning alleged violations of the provisions of this chapter or of the rules and regulations of the Board. The Board may take testimony under oath and may compel the attendance of witnesses and the production of tangible evidence by serving a subpoena.

(g) The Board may by rule adopt standards for creating, licensing, and operating remote pharmacies and automatic dispensing units in Vermont.

(h) It shall be lawful for a drug outlet licensed under this chapter to sell and distribute nonprescription drugs. Drug outlets engaging in the sale and distribution of such items shall not be deemed to be improperly engaged in the practice of pharmacy. A rule or regulation shall not be adopted by the Board under this chapter that shall require the sale of nonprescription drugs by a licensed pharmacist or under the supervision of a licensed pharmacist or otherwise apply to or interfere with the sale and distribution of such medicines. (Added 1977, No. 266 (Adj. Sess.), § 1; amended 1979, No. 158 (Adj. Sess.), § 4, eff. April 28, 1980; 1981, No. 244 (Adj. Sess.), § 4; 1983, No. 230 (Adj. Sess.), § 8; 1989, No. 250 (Adj. Sess.), § 4(d); 1997, No. 40, § 24; 2001, No. 127 (Adj. Sess.), § 2b, eff. June 13, 2002; 2003, No. 60, § 8; 2005, No. 148 (Adj. Sess.), § 17; 2007, No. 163 (Adj. Sess.), § 13; 2009, No. 4, § 104a, eff. April 29, 2009; 2009, No. 35, § 33; 2011, No. 66, § 6, eff. June 1, 2011; 2013, No. 27, § 23; 2019, No. 30, § 14.)

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Title 3 : Executive

Chapter 005 : Secretary of State

Subchapter 003 : PROFESSIONAL REGULATION

(Cite as: 3 V.S.A. § 123)

§ 123. Duties of Office

(a) The Office shall provide administrative, secretarial, financial, investigatory, inspection, and legal services to the boards. The services provided by the Office shall include:

(1) Sending, receiving, and processing applications for licenses.

(2) Issuing, recording, renewing, and reinstating all licenses as ordered by the boards, an appellate officer, the Director, an administrative law officer, or a court.

(3) Revoking or suspending licenses as ordered by the boards, the Director, an administrative law officer, or a court.

(4) Keeping all files and records of the boards, including minutes of meetings.

(5) Compiling and maintaining a current register of all licensees.

(6) Compiling and maintaining statistical information for each board, including the number of applications received; the number of licenses, certificates, registrations, and permits issued, renewed, and reinstated; examination results; the number and disposition of inspections and complaints; and the number of board meetings.

(7) Collecting and depositing all fees into the Professional Regulatory Fee Fund.

(8) Arranging payment of all expenses incurred by the boards within the limits of the funds appropriated to them.

(9) Standardizing, to the extent feasible and with the advice of the boards, all applications, licenses, and other related forms and procedures, and adopting uniform

procedural rules governing the investigatory and disciplinary process for all boards set forth in section 122 of this chapter.

(10) Notifying the public and board members of all meetings and examinations to be held by the boards and arranging for places for those meetings and examinations.

(11) Assisting the boards in developing rules consistent with the principles set forth in 26 V.S.A. chapter 57. Notwithstanding any provision of law to the contrary, the Secretary of State shall serve as the adopting authority for those rules.

(12) With the assistance of the boards, establishing a schedule of license renewal and termination dates so as to distribute the renewal work in the Office as effectively as possible.

(A) Licenses may be issued and renewed according to that schedule for periods of up to two years.

(B) A person whose initial license is issued within 90 days prior to the set renewal date shall not be required to renew the license until the end of the first full biennial licensing period following initial licensure.

(13) To the extent that resources permit, providing other administrative services that are necessary or desirable for the efficient operation of the boards.

(b) The Director shall consult with each board and prepare a consolidated budget for the Office. The consolidated budget shall also contain funds deemed to be required by the Director for the administration of this chapter. The Director shall submit the consolidated budget to the Secretary of State.

(c) The Director may purchase examination materials and contract with examination providers to administer examinations.

(d) The Director may adopt procedures for the effective administration of this section.

(e) The Secretary of State shall contract with and appoint one or more attorneys licensed to practice in this State to serve as administrative law officers under subsection 129(j) of this title or appellate officers under section 130a of this title.

(f) Classified State employees who are employed as investigators by the Secretary of State who have successfully met the standards of training for a Level III law enforcement officer under 20 V.S.A. chapter 151 shall have the same powers as sheriffs in criminal matters and the enforcement of the law and in serving criminal process and shall have all the immunities and matters of defense now available or hereafter made available to sheriffs in a suit brought against them in consequence for acts done in the course of their employment.

(g)(1) The Office shall establish uniform procedures applicable to all of the professions and boards set forth in section 122 of this chapter, providing for:

(A) appropriate recognition of education, training, or service completed by a member of the U.S. Armed Forces toward the requirements of professional licensure; and

(B) expedited issuance of a professional license to a person who is licensed in good standing in another regulatory jurisdiction; and

(i) whose spouse is a member of the U.S. Armed Forces and who has been subject to a military transfer to Vermont; and

(ii) who left employment to accompany his or her spouse to Vermont.

(2) The Director may evaluate specific military credentials to determine equivalency to credentials required for professions attached to the Office. The determinations shall be adopted through written policy that shall be posted on the Office's website.

(3) The Director may evaluate apprenticeship programs recognized or administered by the Vermont Department of Labor, Agency of Education, or U.S. Department of Labor to determine equivalency to credentials required for professions attached to the Office. The determinations shall be adopted through written policy that shall be posted on the Office's website.

(h) Notwithstanding any provision of Title 26 of the Vermont Statutes Annotated to the contrary, the Office, on behalf of the Director or a board, may use electronic mail to send notices and reminders that would otherwise be sent by mail, except certified mail, and may use online services to elicit information and sworn attestations that would otherwise be obtained on a paper form.

(i)(1) The Director shall actively monitor the actions of boards attached to the Office and shall ensure that all board actions pursued or decided are lawful, consistent with State policy, reasonably calculated to protect the public, and not an undue restraint of trade.

(2) If the Director finds an exercise of board authority or discretion does not meet those standards, the Director may, except in the case of disciplinary actions:

(A) provide written notice to the board explaining the perceived inconsistency, which notice shall have the effect of staying that action and implementing any alternative prescribed by the Director;

(B) schedule a public meeting with the board to resolve questions about the action and explore alternatives; and

(C) within 60 days following that meeting, issue a written directive finding that:

(i) the exercise of board authority or discretion is consistent with State policy, in which case the action shall be reinstated;

(ii) the exercise of board authority or discretion is inconsistent with State

policy in form, but may be modified to achieve consistency, in which case the board may issue a modified action consistent with the Director's recommendation; or

(iii) the exercise of board authority or discretion is inconsistent with State policy in purpose, in which case any alternative prescribed by the Director shall stand as the regulatory policy of the State.

(j)(1) The Office may inquire into the criminal background histories of applicants for initial licensure and for license renewal of any Office-issued credential, including a license, certification, registration, or specialty designation for the following professions:

(A) licensed nursing assistants, licensed practical nurses, registered nurses, and advanced practice registered nurses licensed under 26 V.S.A. chapter 28;

(B) private investigators, security guards, and other persons licensed under 26 V.S.A. chapter 59;

(C) real estate appraisers and other persons or business entities licensed under 26 V.S.A. chapter 69;

(D) osteopathic physicians licensed under 26 V.S.A. chapter 33;

(E) physical therapists and physical therapist assistants licensed under 26 V.S.A. chapter 38;

(F) licensed clinical mental health counselors licensed under 26 V.S.A. chapter 65;

(G) audiologists licensed under 26 V.S.A. chapter 67;

(H) licensed marriage and family therapists licensed under 26 V.S.A. chapter 76;

(I) speech-language pathologists licensed under 26 V.S.A. chapter 87;

(J) social workers licensed under 26 V.S.A. chapter 61;

(K) individuals registered on the roster of psychotherapists who are nonlicensed and noncertified;

(L) psychologists licensed under 26 V.S.A. chapter 55;

(M) occupational therapists licensed under 26 V.S.A. chapter 71;

(N) peer support providers and peer recovery support specialists certified under 26 V.S.A. chapter 60; and

[Subdivision (j)(1)(O) effective July 1, 2026.]

(O) community-based perinatal doulas certified under 26 V.S.A. chapter 84.

(2) Prior to acting on an initial or renewal application, the Office may obtain with respect to the applicant a Vermont criminal history record, an out-of-state criminal history record, and a criminal history record from the Federal Bureau of Investigation. Federal

Bureau of Investigation background checks shall be fingerprint-supported, and fingerprints so obtained may be retained on file and used to notify the Office of future triggering events. Each applicant shall consent to the release of criminal history records to the Office on forms developed by the Vermont Crime Information Center.

(3) Applicants subject to background checks shall be notified that a check is required, if fingerprints will be retained on file, and that criminal convictions are not an absolute bar to licensure, and shall be provided such other information as may be required by federal law or regulation.

(k) For any profession attached to it, the Office shall provide a pre-application determination of an individual's criminal background. This determination shall not be binding on the Office in a future application if the individual violates probation or parole or is convicted of another crime following the determination.

(1) The Office shall initiate this determination upon an individual's "second chance" determination request. This request shall provide documentation related to the individual's conviction or convictions, evidence of rehabilitation, and identification of the profession or professions for which the individual seeks licensure.

(2) The individual shall submit this request online, accompanied by the fee for preapplication determinations set forth in section 125 of this subchapter.

(3) The Office shall:

(A) process a request within 30 days of receiving a complete request;

(B) assess the nature of the underlying conviction or convictions, the nexus to the profession or professions for which the individual seeks licensure, and the provided evidence of rehabilitation; and

(C) respond to the individual's request in writing.

(l) When, by reason of disqualification, resignation, vacancy, or necessary absence, a board is unable to form a quorum or assign one or more members to assist in the investigation and prosecution of complaints or license applications, or to adjudicate a contested case, the Secretary of State may appoint ad hoc members, either as voting members to establish a quorum at a specific meeting or as nonvoting members to assist Office investigators and prosecutors.

(m) The provisions of subsection 116a(b) of this title shall not apply to the Office. The Office shall utilize the procedures within 26 V.S.A. chapter 57 to review whether regulation of a profession is still necessary. (Added 1989, No. 250 (Adj. Sess.), § 1; amended 1997, No. 40, § 2; 1999, No. 133 (Adj. Sess.), § 51; 2003, No. 122 (Adj. Sess.), § 78g; 2005, No. 27, § 1; 2007, No. 163 (Adj. Sess.), § 1; 2009, No. 33, § 4; 2009, No. 103 (Adj. Sess.), § 1; 2011, No. 116 (Adj. Sess.), § 2; 2013, No. 27, § 1; 2013, No. 138 (Adj. Sess.), § 2; 2013, No. 141 (Adj. Sess.), § 11, eff. July 1, 2015; 2017, No. 48, § 1; 2017, No. 115 (Adj.

Sess.), § 2, eff. Jan. 1, 2020; 2017, No. 144 (Adj. Sess.), § 1; 2019, No. 152 (Adj. Sess.), § 1, eff. April 1, 2021; 2019, No. 178 (Adj. Sess.), § 2, eff. Oct. 1, 2020; 2021, No. 69, § 2; 2023, No. 34, § 2, eff. July 1, 2023; 2023, No. 35, § 2, eff. July 1, 2023; 2023, No. 36, § 4, eff. July 1, 2023; 2023, No. 91 (Adj. Sess.), § 2, eff. April 23, 2024; 2023, No. 112 (Adj. Sess.), § 3, eff. July 1, 2025; 2023, No. 158 (Adj. Sess.), § 1a, eff. June 6, 2024; 2023, No. 170 (Adj. Sess.), § 2, eff. July 1, 2025; 2025, No. 50, § 3, eff. July 1, 2026; 2025, No. 58, § 4, eff. July 1, 2025.)

VERMONT

Proposed Rules Postings
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Search Rules

Deadline For Public Comment

Deadline: Mar 31, 2025

The deadline for public comment has expired. Contact the agency or primary contact person listed below for assistance.

Rule Details

Rule Number:	25P001
Title:	Administrative Rules of the Board of Pharmacy
Type:	Standard
Status:	Proposed
Agency:	Board of Pharmacy, Office of Professional Regulation
Legal Authority:	26 V.S.A. § 2032, and 3 V.S.A. § 123(a)(11).
Summary:	This update reflects changes in pharmacy's legal and practice landscape since 2015 by regulating, among other things: - new types of pharmacy entity, such as virtual distributors and manufacturers, 503B outsourcers, and third-party logistics providers; - the

	prescribing of opioids; - devices containing prescription drugs; - naloxone dispensing; and - changes to prescriptions for schedule II controlled substances. The rule also reflects statutory changes to pharmacy professionals' scopes of practice, including immunizations, and simplifies the licensing of pharmacy technicians into a single credential instead of the current two-tiered system. The rule creates standards for workplace conditions pharmacy staffing necessary to protect the public. The rule streamlines and narrows the legal duties of Pharmacy Managers, clarifying that licensed pharmacies are themselves responsible for compliance with the Rules.
Persons Affected:	Vermont-licensed pharmacists, pharmacy technicians, pharmacy interns and pharmacy entities both within and outside Vermont(pharmacies, manufacturers, wholesale drug outlets, third-party logistics providers, 503B outsourcers); Vermont Department of Health; Vermont Board of Medical Practice; Green Mountain Care Board; Department of Vermont Health Access; Vermont Association of Hospitals and Health Systems; Vermont Pharmacists Association; Vermont Medical Society; Vermont Society of Health System Pharmacists; hospitals and their patients; pharmacy patients; patients of pharmacies and hospitals, clinical healthcare providers; Department of Financial Regulation.
Economic Impact:	The most significant economic impact will likely be on nonresident drug outlets, which will be required to submit an inspection report every 2 years instead of the current requirement of every 3 years. Drug outlets located in jurisdictions that do not inspect at least every 3 years will have to pay for inspections to comply. Other impacts include streamlining and clarifying the rules, which should reduce drug outlets' administrative and legal costs. Removing the requirement of national certification of pharmacy technicians and adding new training options should make it easier for business to staff their pharmacies. The rules expand the scope of activities pharmacists may delegate to pharmacy technicians and of activities not requiring technician licensure, such as delivering drugs to a pharmacy or working as a cashier This should ease pharmacy staffing problems by expanding the pool of eligible workers. The rule revisions are revenue- and cost-neutral to the State.
Posting date:	Jan 15,2025

Hearing Information

Information for Hearing # 1

Hearing date:	02-18-2025 2:00 PM ADD TO YOUR CALENDAR
Location:	Office of Professional Regulation Board Room
Address:	89 Main Street, 3rd Floor
City:	Montpelier
State:	VT
Zip:	05602
Hearing Notes:	

Information for Hearing # 2

Hearing date:	02-18-2025 2:00 PM ADD TO YOUR CALENDAR
Location:	Virtually via MS Teams
Address:	https://www.microsoft.com/en-us/microsoft-teams/join-a-meeting
City:	Meeting ID: 293 389 690 612 Passcode: 9Th7n98t By phone: 1-802-828-7667, conference ID 168 777 875#
State:	VT
Zip:	n/a
Hearing Notes:	Virtual Hearing: MS Teams at https://www.microsoft.com/en-us/microsoft-teams/join-a-meeting Meeting ID: 293 389 690 612 Passcode: 9Th7n98t By phone: 1-802-828-7667, conference ID 168 777 875#;

Information for Hearing # 3

Hearing date:	02-19-2025 10:00 AM ADD TO YOUR CALENDAR
Location:	Office of Professional Regulation Board Room
Address:	89 Main Street, 3rd Floor
City:	Montpelier
State:	VT
Zip:	05602
Hearing Notes:	

Information for Hearing # 4

Hearing date:	02-19-2025 10:00 AM ADD TO YOUR CALENDAR
Location:	Virtually via MS Teams
Address:	https://www.microsoft.com/en-us/microsoft-teams/join-a-meeting
City:	Meeting ID: 257 060 957 271 Passcode: Hj2ZQ2MN By phone: 1-802-828-7667, conference ID 207 994

	027#;
State:	VT
Zip:	n/a
Hearing Notes:	Virtual Hearing: MS Teams at https://www.microsoft.com/en-us/microsoft-teams/join-a-meeting Meeting ID: 257 060 957 271 Passcode: Hj2ZQ2MN By phone: 1-802-828-7667, conference ID 207 994 027#;

Information for Hearing # 5

Hearing date:	02-20-2025 6:00 PM ADD TO YOUR CALENDAR
Location:	Office of Professional Regulation Board Room
Address:	89 Main Street, 3rd Floor
City:	Montpelier
State:	VT
Zip:	05602
Hearing Notes:	

Information for Hearing # 6

Hearing date:	02-20-2025 6:00 PM ADD TO YOUR CALENDAR
Location:	Virtually via MS Teams
Address:	https://www.microsoft.com/en-us/microsoft-teams/join-a-meeting
City:	Meeting ID: 212 020 234 592 Passcode: RE2J2EA2 By phone: 1-802-828-7667, conference ID 301 656 014#.
State:	VT
Zip:	n/a
Hearing Notes:	Virtual Hearing: MS Teams at https://www.microsoft.com/en-us/microsoft-teams/join-a-meeting Meeting ID: 212 020 234 592 Passcode: RE2J2EA2 By phone: 1-802-828-7667, conference ID 301 656 014#.

Contact Information

Information for Primary Contact

PRIMARY CONTACT PERSON - A PERSON WHO IS ABLE TO ANSWER QUESTIONS ABOUT THE CONTENT OF THE RULE.

Level:	Primary
Name:	Emily Tredeau
Agency:	Office of Professional Regulation, Office of the Secretary of State
Address:	89 Main Street, 3rd Floor
City:	Montpelier

State: VT
Zip: 05602
Telephone: 802-828-1505
Fax:
Email: emily.b.tredeau@vermont.gov
SEND A COMMENT

Website Address: https://sos.vermont.gov/pharmacy/statutes-rules-resources/
VIEW WEBSITE

Information for Secondary Contact

SECONDARY CONTACT PERSON - A SPECIFIC PERSON FROM WHOM COPIES OF FILINGS MAY BE REQUESTED OR WHO MAY ANSWER QUESTIONS ABOUT FORMS SUBMITTED FOR FILING IF DIFFERENT FROM THE PRIMARY CONTACT PERSON.

Level: Secondary
Name: Carrie Phillips
Agency: Office of Professional Regulation, Office of the Secretary of State
Address: 89 Main Street, 3rd Floor
City: Montpelier
State: VT
Zip: 05602
Telephone: 802-828-1505
Fax:
Email: carrie.phillips@vermont.gov
SEND A COMMENT

Keyword Information

Keywords:

Pharmacy
Pharmacist
Drug
Controlled Substance
FDA
DEA
Prescribe
Prescription
Compounding
Medication
Pharmaceutical

Medical
Immunize
Immunization
Vaccine
Clinical
Intern
Technician
Inspection
USP
Regulation

Back

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	Times Argus / Rutland Herald Classified Ads (classified.ads@rutlandherald.com)	Tel: 802-747-6121 ext 2238 FAX: 802-776-5600
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	Newport Daily Express (jlafoe@newportvermontdailyexpress.com)	Tel: 334-6568 FAX: 334-6891 Attn: Jon Lafoe
	News & Citizen (mike@stowereporter.com)	Tel: 888-2212 FAX: 888-2173
	St. Albans Messenger Legals (legals@samessenger.com; cfoley@orourkemediagroup.com)	Tel: 524-9771 ext. 117 FAX: 527-1948 Attn: Legals
	The Islander (islander@vermontislander.com)	Tel: 802-372-5600 FAX: 802-372-3025
	Vermont Lawyer (hunter.press.vermont@gmail.com)	Attn: Will Hunter

FROM: APA Coordinator, VSARA **Date of Fax:** October 27, 2025

RE: The "Proposed State Rules " ad copy to run on **January 23, 2025**

PAGES INCLUDING THIS COVER MEMO: **3**

NOTE **8-pt font in body. 12-pt font max. for headings - single space body. Please include dashed lines where they appear in ad copy. Otherwise minimize the use of white space. Exceptions require written approval.**

If you have questions, or if the printing schedule of your paper is disrupted by holiday etc. please contact VSARA at 802-828-3700, or E-Mail sos.statutoryfilings@vermont.gov, Thanks.

PROPOSED STATE RULES

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By law, public notice of proposed rules must be given by publication in newspapers of record. The purpose of these notices is to give the public a chance to respond to the proposals. The public notices for administrative rules are now also available online at https://secure.vermont.gov/SOS/rules/ . The law requires an agency to hold a public hearing on a proposed rule, if requested to do so in writing by 25 persons or an association having at least 25 members.

To make special arrangements for individuals with disabilities or special needs please call or write the contact person listed below as soon as possible.

To obtain further information concerning any scheduled hearing(s), obtain copies of proposed rule(s) or submit comments regarding proposed rule(s), please call or write the contact person listed below. You may also submit comments in writing to the Legislative Committee on Administrative Rules, State House, Montpelier, Vermont 05602 (802-828-2231).

Administrative Rules of the Board of Pharmacy.

Vermont Proposed Rule: 25P001

AGENCY: Board of Pharmacy, Office of Professional Regulation

CONCISE SUMMARY: This update reflects changes in pharmacy's legal and practice landscape since 2015 by regulating, among other things: - new types of pharmacy entity, such as virtual distributors and manufacturers, 503B outsourcers, and third-party logistics providers; - the prescribing of opioids; - devices containing prescription drugs; - naloxone dispensing; and - changes to prescriptions for schedule II controlled substances. The rule also reflects statutory changes to pharmacy professionals' scopes of practice, including immunizations, and simplifies the licensing of pharmacy technicians into a single credential instead of the current two-tiered system. The rule creates standards for workplace conditions pharmacy staffing necessary to protect the public. The rule streamlines and narrows the legal duties of Pharmacy Managers, clarifying that licensed pharmacies are themselves responsible for compliance with the Rules.

FOR FURTHER INFORMATION, CONTACT: Emily Tredeau, Office of Professional Regulation 89 Main Street, 3rd Floor, Montpelier, VT 05602-3402 Tel: 802-828-1505 Email: emily.b.tredeau@vermont.gov URL: https://sos.vermont.gov/pharmacy/statutes-rules-resources/.

FOR COPIES: Carrie Phillips, Office of Professional Regulation 89 Main Street, 3rd Floor, Montpelier, VT 05602-3402 Tel: 802-828-1505 Email: carrie.phillips@vermont.gov.

Note: The four rules below are being promulgated by the Cannabis Control Board who has requested the notices be combined to facilitate a savings for the board. Please note the title and number of the rule(s) you are interested in when contacting the board.

- Rule 1: Licensing of Cannabis Establishments.
  Vermont Proposed Rule: **25P002**
- Rule 2: Regulation of Cannabis Establishments.
  Vermont Proposed Rule: **25P003**

- Rule 3: Medical Cannabis.
  Vermont Proposed Rule: **25P004**
- Rule 4: Compliance and Enforcement
  Vermont Proposed Rule: **25P005**

AGENCY: Cannabis Control Board.

CONCISE SUMMARY: This is a comprehensive update to rules governing adult-use cannabis establishments and the medical cannabis system. Amendments to Rule 1 streamline renewal; establish siting requirements for retailers; simplify license changes; provide for tier changes based on performance; require deposit accounts; increase flexibility to address past misconduct by applicants; and retire a cumbersome system of prequalification. Amendments to Rule 2 clarify safety standards and allowable use of the Inventory Tracking System; prohibit consignment; standardize transport manifests; disallow illusory brands; standardize warning symbols; provide for product remediation; provide for curbside transactions; implement propagation cultivator licensing; integrate hemp-derived additives; and prohibit cannabinoids in beverage alcohol. Amendments to Rule 3 provide for retailer medical endorsements and raise standards for medical products. Amendments to Rule 4 create a process for orders concerning adulterated products.

FOR FURTHER INFORMATION, CONTACT: Gabriel M. Gilman, Cannabis Control Board 89 Main Street, 3rd Floor, Montpelier, VT 05602-2948 Tel: 802-261-1510 E-Mail: gabriel.gilman@vermont.gov URL: https://ccb.vermont.gov/laws-rules-and-regulations.

FOR COPIES: Patrick Crowley, Cannabis Control Board 89 Main Street, 3rd Floor, Montpelier, VT 05602-2948 Tel: 802-636-7548 E-mail: patrick.crowley@vermont.gov. ----------
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