



State of Vermont

Office of the Secretary of State – Board of Pharmacy

*VT Pharmacy Rules, Statutes and Other
Regulations Affecting the Practice of
Pharmacy in VT – A Guided Tour and
Informational Highlights on Recent Changes*

Carrie C. Phillips, Executive Officer, Vermont Board of Pharmacy

November 19 & 20, 2017

Objectives

- Locate VT Pharmacy Rules and Statutes on the Office of Professional Regulation website
- Identify sections/parts of the VT Pharmacy Rules
- List Federal laws and other regulations that must be followed in Vermont with respect to Pharmacy and demonstrate where they can be found
- Outline recent changes to Schedule II controlled substance laws and recent VT statute changes enhancing the practice of pharmacy

Pre-Test Question #1: Regulations regarding pharmacy practice in Vermont?

- A. May be obtained only by contacting the Board and requesting them by mail
- B. Are described in both Administrative Rules created by the Board and Legislative Statutes
- C. Are accessible online via the Secretary of State's Office of Professional Regulation website
- D. Both B and C



Pre-Test Question #2: Vermont has it's own set of Controlled Substance Rules that differ from those of the DEA.

- A. True
- B. False



Pre-Test Question #3: CII prescriptions may be partially filled when

- A. The filling pharmacy has insufficient stock to fill the entire amount prescribed
- B. At the patient's request
- C. At the prescriber's request
- D. All of the Above



*Office of Professional Regulation (OPR)
and
VT Board of Pharmacy (BOP)*



State of Vermont

Office of the Secretary of State – Board of Pharmacy

State of Vermont Regulatory Structure:

*The Office of Professional Regulation is responsible for licensure, certification, registration and disciplinary matters for 45 professions and occupations. **The mission of OPR is public protection.***



Functions of OPR and Vermont BOP

Executive Branch of State Government

- Issue licenses & hold licensees accountable
- Answer questions from licensees
- Hold board meetings
- Draft, adopt, and revise Rules and recommend statutory changes to the General Assembly
- Conduct pharmacy inspections
- Attend conferences and meetings relevant to pharmacy
 - FDA, DEA, NABP

*Where to find VT Pharmacy Rules and
Statutes*

<https://www.sec.state.vt.us/professional-regulation.aspx>



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CONDUCT DECISIONS

DISCIPLINE RESOURCES

CHANGE OF NAME & ADDRESS

VERIFICATION OF LICENSURE FORMS

VERIFICATION OF EDUCATION FORMS

FREQUENTLY ASKED QUESTIONS

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- » How do I update my address and email address?
- » When do I need to renew my license?
- » How do I look up a licensee?

UPCOMING EVENTS

NOV 8 Canceled: General Anesthesia Sub-Committee

NOV 10 Veterans' Day

NOV 13 Nursing, Board of

NOV 14 Funeral Service, Board of

NOV 16 Allied Mental Health, Board of

Full Calendar

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CONTACT INFORMATION

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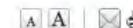
Pharmacy

The Board of Pharmacy is a seven-member board created by the legislature whose members are appointed by the governor to administer the laws for this profession in the state of Vermont. The board's mission is public protection. The board does this by: ensuring that applicants are qualified for licensure; setting standards for the profession by proposing statutes and adopting administrative rules; and, with the assistance of Office of Professional Regulation staff, investigating complaints of unprofessional conduct, taking disciplinary action against licensees when necessary to protect the public. Our website provides links to the laws governing this profession, as well as resources for applicants, licensees, consumers, and employers.

For questions or to contact the board, email or call: [Aprille Morrison](#) | 802-828-2373

To better serve you, we have a list of our most frequently asked questions. *Please click on the button below to find the answer to your question before calling or emailing.*

[Frequently Asked Questions](#)



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Upcoming Meetings

For the schedule of upcoming meetings, please visit the [OPR Calendar](#).

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Current Standing Order for Distribution of Naloxone Prescription for Overdose Prevention

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Opioids for Chronic Pain

Effective August 1, 2015 new Rules governing the prescribing of opioids for chronic pain. [View the Rules.](#)



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- Pharmacy Statutes
- Statutes Governing all Professions
- Administrative Rules**
- Rule Governing the Prescribing of Opioids for Chronic Pain

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**Administrative Rules
of the
Board of Pharmacy**
effective: September 15, 2015
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The Vermont Statutes Online

Title 26: Professions and Occupations

Chapter 36: Pharmacy

Subchapter 1: General Provisions

§ 2021. Statement of purpose

§ 2022. Definitions

§ 2023. Clinical pharmacy

Subchapter 2: Board Of Pharmacy

§ 2031. Creation; appointment; terms; organization

§ 2032. Powers; duties; limitations

Subchapter 3: Licensing

§ 2041. Unlawful practice

§ 2042. Qualifications for licensure

§ 2042a. Pharmacy technicians; qualifications for registration

§ 2042b. Pharmacy technicians; nondiscretionary tasks; supervision

§ 2043. Repealed. 1981, No. 244 (Adj. Sess.), § 17.

<http://legislature.vermont.gov/statutes/chapter/26/036>



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Title 18: Health

Chapter 84: Possession And Control Of Regulated Drugs

Subchapter 1: Regulated Drugs

- [§ 4201. Definitions](#)
- [§ 4202. Powers and duties of the Board of Health](#)
- [§ 4203. Persons exempted](#)
- [§ 4204. Preparations excepted](#)
- [§ 4205. Acts prohibited](#)
- [§ 4206. Licenses](#)
- [§ 4207. Certificates of approval](#)
- [§ 4208. Qualifications for issuance of licenses and certificates](#)
- [§ 4209. Supervision, revocation, and reinstatement of licenses and certificates](#)
- [§ 4210. Authorized sales on written orders, records](#)
- [§ 4211. Records confidential](#)

Controlled Substance (CS) Law

- Vermont follows Federal DEA CS law
 - “Pharmacist’s Manual An Informational Outline of the Controlled Substances Act”
 - https://www.dea diversion.usdoj.gov/pubs/manuals/pharm2/pharm_manual.pdf
 - <https://www.dea diversion.usdoj.gov/21cfr/21usc/829.htm>
- Administrative Rules
 - Part 6 – Pharmacist Manager
 - Part 9 – Standards for Pharmacies
 - Part 10 – Pharmacy Practice
 - Part 11 – Institutional Pharmacy
 - Part 17 – Wholesale Distributors
 - Part 19 – Remote Pharmacies

*Informational Highlights and
Recent Changes*

United States Pharmacopeia (USP) Chapter <800>

(becomes enforceable December 1, 2019)

- October 24, 2017 BOP Meeting: While USP <800> *compliance will be expected*, it will not be required prior to implementation by USP
- USP and the National Association of Boards of Pharmacy (NABP) encourage licensees affected by <800> to begin efforts towards implementation ahead of the enforcement date
 - Applicable to all licensees who “handle” hazardous drugs:
 - “Handling HDs includes, but is not limited to, the receipt, storage, compounding, dispensing, administration, and disposal of sterile and nonsterile products and preparations”
- <http://www.usp.org/frequently-asked-questions/hazardous-drugs-handling-healthcare-settings>
 - Visit this webpage frequently, new FAQ’s get added regularly
 - Can download a free copy of the Chapter!!

Rule 10.3 End of a Prescriber's Practice

- Upon a prescriber's death or withdrawal from practice, a pharmacist may, in extraordinary circumstances, exercise his or her professional judgment to dispense to the prescriber's patient, in one fill, any remaining refills up to a 90-day supply of the drug prescribed.
- The pharmacist of a patient whose prescriber has ceased to practice therefore encounters two choices, to be made based upon his or her professional judgment, including knowledge of the patient and a balancing of risks between unmonitored pharmacotherapy and sudden cessation of existing pharmacotherapy:
 - Whether it is in the patient's interest to dispense a full, 90-day supply of a drug otherwise fillable at shorter intervals
 - Drugs with poor safety profiles, high overdose or dependence risk, or special reasons for monitoring, are less fit for a 90-day fill than relatively safe drugs long used by a known patient.
 - Whether it is in the patient's interest to maintain continuity past ninety days where prescriber oversight is uncertain
 - For example, in a choice between withholding blood pressure medication from a patient who has been on the same therapy for a decade and continuing to fill valid refills for a prescriber who left practice, it often will make good clinical sense to continue the fills, and a pharmacist may

Issuance of Multiple Prescriptions for Schedule II Controlled Substances

- https://www.dea diversion.usdoj.gov/faq/mult_rx_faq.htm#9
 - Q. What is expected of the pharmacist when filling a prescription issued pursuant to this regulation?
 - A. *Where a prescription contains instructions from the prescribing practitioner indicating that the prescription shall not be filled until a certain date, no pharmacist may fill the prescription before that date.* In addition, when filling any prescription for a controlled substance, a pharmacist who fills multiple prescriptions issued in accordance with this regulation has a corresponding responsibility to ensure that each sequential prescription was issued for a legitimate medical purpose by a practitioner acting in the usual course of professional practice. 21 CFR 1306.04(a).

Partial Filling of CII Prescriptions at Patient or Prescriber Request

- July, 2016 “Reducing Unused Medications Act of 2016”
 - Part of Comprehensive Addiction and Recovery Act
 - Amended the Controlled Substance Act
- Allows partial fills of schedule II controlled substances (CII) upon patient or prescriber request
- September, 2017, Senate sought assistance from States’ Governors, professional health organizations to fully implement use of this law
 - OPR and VT Board of Pharmacy contacted by Governor Scott’s office
- OPR is considering
 - options for increasing awareness of this option by patients, prescribers and pharmacists
 - Impediments and potential difficulties

Current Revision Plans

- Licensing and Registration categories
 - 503B/outsourcing facilities
 - Compounding pharmacies – distinguishing type of compounding
- Harmonizing terminology and definitions
 - Administrative Rules, State Statutes, NABP Model Act
- General clarifications to items frequently inquired about
- Part 5 – Pharmacy Technicians
 - Clarification of different tech roles and duties
 - Grandfather Clause for Certified technician
- Part 13 – Sterile Pharmaceuticals

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A. True

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Thank you!

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