



Board of Pharmacy

Office of Professional Regulation, Vermont Secretary of State

89 Main Street, 3rd Floor • Montpelier, VT 05620-3402
<https://sos.vermont.gov/opr/>

Agenda

Wednesday, May 26th, 2021, at 9:00 a.m.

****This will be an online-only meeting ****

[Click here to join the meeting from your computer or mobile app](#)

Or call in for audio only

Phone number: 1(802)828-7667, Phone Conference ID: 70719433#

- 1. Call to Order**
- 2. Changes to the agenda**
- 3. Approval minutes of April 28th, 2021**
- 4. Discipline: None**
- 5. Executive Officer Update**
 - a. Executive Officer Report
 - b. Entity License Approvals Since Last Month
- 6. Topics for Discussion**
 - a. Presentation “Summary of VDH/DHVA Tobacco Cessation Pharmacy Initiative”
 - Rebecca Brookes, Upstream Media, for the Vermont Department of Health (VDH) Tobacco Control Program
 - b. Legislative Updates
 - c. Gates Healthcare Inspection Services
 - Board to make decision
 - d. Request from BCBSVT: Discuss definition and scope of “accessory-type devices” addressed by 26 V.S.A. § 2023(b)(3), particularly in reference to continuous glucose monitors.
 - e. Review & Approve Emergency Rules for Clinical Pharmacy, as required by Act 178 (see Appendix 2)
 - f. Waiver requests for Rule 6.2(a) regarding required 2 years’ experience for pharmacy manager – Walgreens
 - Winooski location, #17485 – Jessica Tardie
 - Morrisville location, #18977 - Mobahil Ahmad
 - Burlington location, #19449 – Brianna Robare
 - g. Administrative Rule Revisions

- MPJE – *the board is seeking input from the public on this topic today*
 - Pharmacy Technician rule revision
 1. Tech-Check-Tech
 - Application of registration requirement to technicians working for a 503B outsourcer
 - Home Infusion Pharmacy
 - Nuclear/Radiologic Pharmacy
- h. UVM White Bagging, follow-up
- Resources from California
 - Re-labeling
- i. Review of proposed Clinical Pharmacy Prescribing State Protocols, pursuant to Act 178
- Tobacco Cessation Products
(see Appendix 1)

7. Other Business

8. Public Comment

9. Discuss items for inclusion on next month's agenda

- a. Rule Revision topics: Nuclear Pharmacy & Home infusion Pharmacy
- b. State Protocol for Clinical Pharmacy Prescribing of Tobacco Cessation products

10. Adjournment

Next Scheduled Meeting – Wednesday, June 23rd, 2021

Vermont Pharmacist Prescribing Protocol – Tobacco Cessation Products

Background

A pharmacist may prescribe and dispense tobacco cessation products, approved by the Food and Drug Administration (FDA), in a manner consistent with a valid State protocol approved by the Commissioner of Health, after consultation with the Director of Professional Regulation and the Board of Pharmacy (BOP). [26 V.S.A. § 2023\(b\)\(2\)\(A\)\(i\)](#).

Pharmacists who independently prescribe FDA-approved tobacco cessation products must follow this protocol. When prescribing per this protocol, the pharmacist is the prescriber-of-record.

General considerations

Prescribing FDA-approved tobacco cessation products under this protocol requires the pharmacist to:

1. Have training and education in that area sufficient to perform the duties involved
2. Document prescribing, including notifying the patient's primary care provider within 5 business days.
3. Keep a written copy of the protocol at each location from where prescriptions are issued for an FDA-approved tobacco cessation product
4. Provide a copy of the protocol available upon the request of an inspector.

Procedures

When an individual requests a prescription for FDA-approved tobacco cessation products, or when a pharmacist in his or her professional judgement offers to prescribe FDA-approved tobacco cessation products to an individual, the pharmacist shall perform the procedures outlined below:

1. Direct the patient to the counseling area, as required in [Administrative Rule 9.2](#), to provide reasonable privacy
2. Determine if the patient has a primary care clinician and encourage them to seek routine primary care. If the patient does not have a primary care clinician, provide referral to patient for finding primary care services, such as [VT-211](#) or, for Medicaid beneficiaries, the [Vermont Medicaid Provider lookup](#).
3. Patient assessment of readiness to quit
 - a. Ask about tobacco use at every encounter and assess a patient's readiness to quit.
 - b. For those interested and/or ready to quit, per current guidelines, common approaches for clinicians to assess patients' tobacco use include the following:
 - i. The 5 As: (1) **A**sk about tobacco use; (2) **A**dvice to quit through clear, personalized messages; (3) **A**ssess willingness to quit; (4) **A**ssist in quitting; and (5) **A**rrange follow-up and support
 - ii. "Ask, Advise, Refer," which encourages clinicians to ask patients about tobacco use, advise them to quit, and refer them to telephone quit lines, other evidence-based cessation interventions, or both.
 - iii. Vital Sign: Treating smoking status as a vital sign and recording smoking status at every health visit are also frequently used to assess smoking status.
 - c. The pharmacist may offer to prescribe tobacco cessation medication to tobacco users and provide behavioral counseling and/or a referral to counseling.
4. Patient health screening for eligibility
 - i. Utilize and document a health screening procedure to identify appropriate candidates for

treatment by the pharmacist, an example screening tool appears on page 4. Screening shall include:

1. Current and past medical conditions
2. Allergies and hypersensitivities
3. Medication history
4. Determination of high-risk patients

ii. The health screen may also include:

1. social history
2. family history
3. current living environment

5. Determination and referral of high-risk patients

- i. The pharmacist shall assess for certain risk factors that may cause adverse events related to medication use and consult with or refer high-risk patients to a primary care provider, psychiatrist, or other provider, as appropriate.
- ii. For purposes of this protocol, the following patients are considered high-risk:
 1. Patient is pregnant or planning to become pregnant in the next six months
 2. Patient has cardiovascular disease and:
 - a. Has had a heart attack in the past 2 weeks
 - b. Has a history of arrhythmias or irregular heartbeat
 - c. Has unstable angina or experience chest pain with strenuous activity
 3. Patient has history of mental health disorder(s) and is not perceived to be stable.

6. Prescribing and dispensing to eligible patients

- a. Prescribing shall be performed in adherence to recommendations in appropriate, current clinical guidelines (see "Pharmacist Resources" on page 3)
- b. The pharmacist, in consultation with the patient, may prescribe and dispense any tobacco cessation product (alone or in combination) approved by the FDA.
- c. When a tobacco cessation product is dispensed under the protocol, the pharmacist shall provide necessary information about the product including but not limited to:
 - i. The name and description of the medicine
 - ii. The route, dosage form, dosage, route of administration, and recommended duration of drug therapy
 - iii. Special directions and precautions, as applicable
 - iv. Common adverse effects or interactions and therapeutic contraindications that may be encountered, including their avoidance and the action required if they occur

- v. Techniques for self-monitoring drug therapy
- vi. Proper storage
- vii. Prescription refill information
- viii. Action to be taken in the event of a missed dose

7. Counseling

- a. Once the appropriate tobacco cessation product(s) has been determined, the pharmacist shall provide the patient with counseling on the administration, possible side effects, contraindications, and warnings associated with the therapy.
- b. The patient should be encouraged to ask questions and will be supplied with educational material on any therapies dispensed.
- c. Pharmacists shall provide appropriate behavioral counseling and/or refer the patient to other resources for assistance, including but not limited to the Vermont Tobacco Quitline (802Quits) at 1-800-QUITNOW.

8. Follow-up

- a. To reassess the appropriateness and/or continuation of therapy, pharmacists shall follow up with patients:
 - i. Within two weeks of initiating therapy
 - ii. After completion of a course of therapy

Authorized Drugs

Prescribing and dispensing done pursuant to this protocol is limited to FDA-approved tobacco cessation products.

Prescribing Records

The pharmacist must generate a written or electronic prescription for any FDA-approved tobacco cessation product pursuant to protocol-based prescribing. The prescription must include all the information required by [Administrative Rule 10.1](#). The prescription must be processed in the same manner that any other prescription is processed, pursuant to the applicable statutes and rules for the dispensing of prescription drugs. The prescription shall be kept on file and maintained for a minimum of three years, as required by the rules of the Vermont BOP. Pharmacists are reminded to adhere to record-keeping requirements for prescriptions paid for by Medicare and Medicaid, which may differ from those required by BOP.

Pharmacist Resources – Clinical Practice Guidelines, Education and Training:

US Department of Health and Human Services, Public Health Services Task Force (USPSTF), [Interventions for Tobacco Smoking Cessation in Adults, Including Pregnant Persons](#) (updated January 2021)

[Surgeon General's Report on Smoking Cessation 2020](#)

[Clinical Practice Guideline for Treating Tobacco Use and Dependence. \(see attached examples\)https://www.ahrq.gov/prevention/guidelines/tobacco/clinicians/update/index.html](#)

Rx for Change (<http://rxforchange.ucsf.edu>).

<http://quitworks.makesmokinghistory.org/uploads/Intake%20Assess%20Guide%209.6.10.pdf>

<https://802quits.org/providers/>

https://www.cdc.gov/tobacco/campaign/tips/partners/health/index.html?CDC_AA_refVal=https%3A%2F%2Fwww.cdc.gov%2Ftobacco%2Fcampaign%2Ftips%2Fpartners%2Fhealth%2Fpharmacist%2Findex.html (Includes resources such as Quit Line information, posters, videos, and 800-quit-now notepads, etc.)

Example Assessment Resources – kindly supplied by, and adapted from, the Indiana Pharmacists Association

1. Patient Intake Form (for health screening), page 4
2. Patient Treatment Plan Summary, page 7
3. Fourteen-Day Follow-up Form, page 9
4. Final Contact Form, page 11

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Date: Time: Pharmacist's name:

Section 1: Patient information

Name (Last, First): Date of birth: Gender:

Primary phone number: Home address:

Insurance provider:

BIN	PCN	Cardholder ID	Group number

PCP name: PCP phone number:

Section 2: Medical conditions

Current medical conditions:

- 1
- 2
- 3
- 4
- 5

Past medical conditions:

- 1
- 2
- 3
- 4
- 5

Section 3: High-risk screening

- | | | | |
|---|--|----|-----|
| 1 | Pregnant or planning to become pregnant in the next 6 months? | No | Yes |
| 2 | Heart attack in past 2 weeks? | No | Yes |
| 3 | History of arrhythmias or irregular heartbeat? | No | Yes |
| 4 | Unstable angina or chest pain with strenuous activity? | No | Yes |
| 5 | History of mental health disorder and is perceived to not be stable? | No | Yes |

IF YES, consult with or refer patient to PCP.

Section 4: Other history

- 1 Family history of tobacco use or tobacco-related disease
- 2 Other medical conditions
- 3 Current living environment
- 4 Social history

Section 5: Medications and allergies/hypersensitivities

Current medications:

Allergies/hypersensitivities:

Section 6: Assess Tobacco Use History

ASK: Are you ready to set a quit date? **N Y** (if yes, record quit date below under “Documentation”)

ASK: What types of tobacco / nicotine do you use?

Type	How much and how often (per day)?	How long used?
Cigarettes		
E-cigarettes/JUUL/vaping		
Smokeless tobacco (dip, chew)		
Cigars or cigarillos		
Other:		

ASK: How many minutes after you wake up do you have your first cigarette/tobacco/nicotine?

ASK: Any recent changes in your tobacco/nicotine use?

ASK: Have you tried to quit before? **Y N**

— **If YES:** How many times? When was last quit attempt? Longest quit attempt?

ASK: Did you call the tobacco quitline or participate in any other form of counseling? **Y N**

— **If YES:** What did you like, or not like, about it?

ASK: What quitting medicines have you tried in the past? Discuss effectiveness, withdrawal symptoms, how med was taken (daily and duration), overall experience (does it make sense to try it again?).

ASK: Main reasons for returning smoking/tobacco use? Anticipated challenges this time?

IF READY TO SET QUIT DATE, complete the following and initial to the left of each requirement.

- Discuss medication options and select treatment
- Ask patient to choose a quit date (if using bupropion SR or varenicline, consider medication start date)

Patient's planned quit date is:

- Refer patient to Indiana Tobacco Quitline (1-800-QUIT NOW) or another program:
- Document treatment plan
- Schedule follow-up appointment within 2 weeks of quit date:

Date and time:

Circle one: In-person or **Telephone** **ASK:** Confirm preferred contact #

- Advise patient to follow-up with PCP
- Contact patient's PCP within 3 business days

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PCP name:

Telephone #:

Fax #:

Dear Clinician: We have provided tobacco cessation treatment to your patient, as referenced below in Section 1.

Please document this in his or her chart. We will meet with your patient again within the next two weeks (in person or via telephone, based on their preference), and again at the end of treatment and have advised him or her to follow-up with you. If you have questions, please contact us:

Pharmacy name and address:

Dispensing pharmacist's name:

Telephone #:

Section 1: Patient information

Name (Last, First):

Date of birth:

Primary phone number:

Section 2: Treatment plan

■ **Medication 1 dispensed (name, strength):**

Dosing:

The following were discussed with the patient:

- Proper use, duration of drug therapy, drug storage
- Techniques for self-monitoring of drug therapy
- What to do if a dose is missed
- Common adverse effects; how to avoid, and what to do if encountered
- Refill information

■ **Medication 2 dispensed (name, strength)** *[X-out Med 2 if not applicable]*

Dosing:

The following were discussed with the patient:

- Proper use, duration of drug therapy, drug storage
- Techniques for self-monitoring of drug therapy
- What to do if a dose is missed
- Common adverse effects; how to avoid, and what to do if encountered
- Refill information

■ **Behavioral counseling plan:**

___ Patient was advised to reduce caffeine intake (due to drug interaction with smoking)

Select one or more of the following:

- ___ A fax referral was sent to the Indiana Tobacco Quitline (1-800-QUIT NOW)
- ___ Patient was advised to call and enroll in the Indiana Tobacco Quitline program
- ___ Patient was referred to a group or web-based program
- ___ Patient will be receiving behavioral counseling at the pharmacy

■ **Date contacted patient's PCP:**

Date/time called or faxed:

If called, spoke with:

Initials:

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Date:

Time:

Pharmacist's name:

Section 1: Patient information

Name (Last, First):

Date of birth:

Quit date:

Section 2: Behavioral assistance

- Patient is enrolled with the Indiana Tobacco Quitline (1-800-QUIT NOW)
- Patient is participating in a group or web-based program
- Patient is receiving behavioral counseling at the pharmacy
- Other:

Does the patient feel he/she is getting sufficient help/support?

What coping challenges have they had since the quit date? Cravings?

Section 3: Medication use

- Cessation medication(s) (name, strength) currently being used:
- Date medication(s) were initiated:
- Are the medication(s) being taken correctly? Yes No [describe below]
- Is the patient experiencing any adverse effects due to the medication(s)? Yes No [describe below]
- Are the patient's withdrawal symptoms being managed? Yes No [describe below]
- Plans for terminating the medication(s):

Section 4: Interventions

Describe what is working as well as any changes that are recommended.

1 Medication regimen:

2 Behavioral assistance recommendations:

Section 5: Patient questions and concerns

Documentation

Complete the following and initial to the left of each requirement.

- Discussed current medication use and modified regimen, if appropriate
- Discussed behavioral assistance and modified recommendations, if appropriate
- Documented ongoing treatment plan
- Discussed plans for termination of medications
- Notified patient that you will contact them at the *end* of their medication regimen

Date:

ASK: Confirm preferred contact #

- Remind patient to follow-up with PCP at their next visit

Final Contact Form

This document should be completed by the pharmacist at the anticipated end of each patient's medication regimen.
The contact can be made in person or via telephone.

Date: _____ **Time:** _____ **Pharmacist's name:** _____

Section 1: Patient information

Name (Last, First): _____

Date of birth: _____

Quit date: _____

Section 2: Cessation outcomes

Patient has successfully quit

Patient quit but relapsed

Duration of quit attempt: _____

Reason(s) for relapse: _____

Patient did not attempt to quit (did not stay off of tobacco for more than 24 hours)

Patient is unable to be reached

Date of contact attempt #1: _____

Date of contact attempt #2: _____

Section 3: Quitting strategies used

Behavioral: [Check all that apply]

Indiana Tobacco Quitline (1-800-QUIT NOW)

Group or web-based program

Behavioral counseling at the pharmacy

Other: _____

None

Does the patient feel he/she received sufficient help/support? (describe) _____

Medication: [Check one]

No medication was provided

Patient completed full duration of therapy

Patient completed partial course of therapy

Duration: _____

Challenges: _____

– **Did the patient experience any adverse effects due to the medication(s)?** **No** **Yes [If Yes, describe below]**

– Were the patient’s withdrawal symptoms adequately managed? No Yes *[If No, describe below]*

– Plans for terminating the medication(s):

Section 4: Future plans

___ For tobacco-free patients: Prevent relapse

___ For relapsed patients willing to try again: Initiate a new quit attempt

___ For relapsed patients not willing to try again: Establish future resources for when they are ready

Notes:

Section 5: Patient questions and concerns

___ None noted

___ Questions/concerns discussed: *[Describe below]*

APPENDIX 2

Emergency Rules for Clinical Pharmacy

1. Collaborative Practice Agreements: Required Elements

Collaborative Practice Agreements involving clinical pharmacy prescribing shall conform to 26 V.S.A. § 2023 and the requirements of the Administrative Rules of the Board of Pharmacy, § 1.10(a)(8). In addition, a collaborative practice agreement involving clinical pharmacy prescribing must:

- a. permit prescribing only in the presence of a bona fide, established prescriber-patient relationship between a collaborating practitioner and patients receiving clinical care pursuant to the agreement;
- b. contain the name(s), license number(s), and dated signature(s) of each covered practitioner;
- c. specify start and end dates separated by not more than one year;
- d. describe the scope of clinical pharmacy services and/or prescribing to be provided, including any limitations on the scope of those services; and
- e. be readily available to any patient or regulatory authority that may request it.

2. Conflicts of Interest & Commercial Incentives

a. **Gift Ban.** Pharmacists shall comply with 18 V.S.A. § 4631a and shall not accept gifts or things of value from drug manufacturer or wholesalers.

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 subject to such inducements shall not practice clinical pharmacy.

A pharmacist practicing clinical pharmacy shall avoid circumstances that would lead a reasonable and informed observer to suspect the pharmacist's prescribing judgment is influenced other than by the best interests of patients. In addition:

3. Short-term Prescribing by Pharmacists

A pharmacist extending a previous prescription shall do so in a manner consistent with 26 V.S.A. § 2023(b)(6) and only after taking steps reasonable under the circumstances to verify a patient's claim to hold an established prescription. Short-term prescribing of controlled drugs is prohibited. When determining whether short-term prescribing is clinically appropriate, a pharmacist shall consider the risk profile of a drug, including potential toxicity and misuse, and shall weigh potential risks against risks associated with interruption of access.

4. Privacy

- a. shield a patient who may be required to partially disrobe, for example, to receive a vaccine, from the view of others;
- b. be suitably isolated to offer confidence that health consultations, carried out at ordinary conversational volume, cannot be overheard;
- c. not be subject to audio or video surveillance of which a patient may be unaware, for example, by store security equipment.

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

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