Board of Pharmacy

Office of Professional Regulation, Vermont Secretary of State

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Agenda

Wednesday, March 24th, 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 of minutes from 2/24/21 meeting**
4. **Discipline** – none at this time
5. **Quarterly Inspection Update** – Derek Everett Q1 2021 Inspection Numbers
6. **Executive Officer Update**
   a. Executive Officer Report
   b. Entity License Approvals Since Last Month
7. **Topics for Discussion**
   a. Legislative Updates
      - H.289 An act relating to professions and occupations regulated by the Office of Professional Regulation (The OPR Bill)
        1. Passed in the House, is now under review in the Senate Government Operations committee
      - H.225 An act relating to possession of a therapeutic dosage of buprenorphine
        1. No movement since initial reading
      - H.212 An act relating to expanding the distribution and availability of opioid antagonists
        1. No movement since initial reading
      - H.85 An act relating to requiring employment breaks
        1. No movement since initial reading
      - H.50 An act relating to pharmacists providing information on the proper disposal of unused regulated drugs
        1. No movement since initial reading (other than a committee shift)

   b. Administrative Rules Revision
      - Pharmacy technician rules
      - MPJE discussion

   c. Task Force Update – meeting to be held 3/24/21 from 11:30 to 1:30

   d. Review of proposed Clinical Pharmacy Prescribing State Protocols, pursuant to Act 178
      - Appendix 1, for second review (introduced at Feb. Board meeting
        1. Self-Administered Hormonal Contraceptives
      - Appendix 2, 3, 4, for final review
        1. Influenza Vaccines
        2. COVID-19 Vaccines
        3. Opioid Antagonists
8. **Other Business**
9. **Public Comment**
10. **Discuss items for inclusion on next month's agenda**
11. **Adjournment**

Appendix 1

Vermont Pharmacist Prescribing Protocol – Self-Administered Hormonal Contraceptives

Background

A pharmacist may prescribe, order, or administer self-administered hormonal contraceptives 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 self-administered hormonal contraceptives must follow this protocol. When prescribing per this protocol, the pharmacist is the prescriber-of-record.

Definitions

Per 26 V.S.A. § 2022 (21) "Self-administered hormonal contraceptives" means a contraceptive medication or device approved by the U.S. Food and Drug Administration that prevents pregnancy by using hormones to regulate or prevent ovulation and that uses an oral, transdermal, or vaginal route of administration.

"Recipient" means a person capable of becoming pregnant and who wished to use hormonal contraception

General considerations

Prescribing self-administered hormonal contraceptives 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 a self-administered hormonal contraceptive
4. Provide a copy of the protocol available upon the request of an inspector.

Procedures

When an individual requests a prescription for self-administered hormonal contraceptives, or when a pharmacist in his or her professional judgement offers to prescribe self-administered hormonal contraceptives to an individual, the pharmacist shall:

1. Prescribe a contraceptive only if the intended use is contraception
2. Have the patient complete the *Vermont Hormonal Contraceptive Self-Screening Questionnaire*, in the primary language spoken by the patient
    a. A prescription cannot be issued if a patient does not compete the questionnaire
    b. A patient must complete the questionnaire at least once every 12 months
    c. Questionnaires should be kept on file for a minimum of 2 years
3. Review of the completed questionnaire with the patient and clarify responses, if necessary.
4. Measure and record the patient's, seated, blood pressure
5. The *Vermont Board of Pharmacy Standard Procedures Algorithm for Prescribing of Contraceptives*, on page 4, is available as a guide for this process. Evaluation of the patient's health and history should be in accordance with the most current United States Medical Eligibility Criteria (US MEC) for Contraceptive Use, as adopted by the US Centers of Disease Control and Prevention (CDC). The summary chart of the US MEC for Contraceptive Use, from the CDC's website may be used, or, the Summary Chart of the US MEC for Contraceptive Use in this protocol that has been color-coded to correspond to the *Vermont Hormonal Contraceptive Self-Screening Questionnaire*
    a. Only if the evaluation indicates no contraindications to hormonal contraceptives exist, may a prescription be issued to the patient

b. If the evaluation indicates the patient should be referred to their primary care provider (PCP), or clinic/hospital if the patient doesn't have a PCP, the pharmacist shall not issue a prescription, and shall make the referral and provide a written visit summary (the *Pharmacist Referral and Visit Summary* template below may be used for this purpose).

6. When a prescription for a hormonal contraceptive is issued, counsel the patient in accordance with Vermont's Administrative Rules and provide written patient education materials about the drug prescribed. Counseling should include providing any necessary training for self-administration of the hormonal contraceptive prescribed, if needed.
7. When a prescription for a hormonal contraceptive is issued, provide to the patient a written record of the medication prescribed (the *Pharmacist Referral and Visit Summary* template below may be used for this purpose).

Authorized Drugs

Prescribing and dispensing done pursuant to this protocol is limited to FDA-approved, self-administered hormonal contraceptives.

Prescribing Records

The pharmacist must generate a written or electronic prescription for any self-administered hormonal contraceptive pursuant to protocol-base 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 Referral and Visit Summary

Patient Name:_____ Date of birth:_____ Date: _____

Self-administered hormonal contraceptive prescribed today: _____
Quantity prescribed: _____ Refills authorized: _____

If you have a question, my name is _____

Please review the information above with your primary care or women's health provider.

OR

____I am not able to prescribe hormonal contraception to you today, because:

☐ Pregnancy cannot be ruled out. *(Notes:_____)*

☐ You have a health condition than requires further evaluation. *(Notes:_____)*

☐ You take medication(s) or supplements that may interfere with contraceptives. *(Notes:_____)*

☐ Your blood pressure reading is higher than 140/90. *(_____/_____)*

Each requires additional evaluation by another healthcare provider. Please share this information with your provider.

Pharmacist Name _____
Pharmacy Name _____
Pharmacy Address _____
Pharmacy Phone Number _____

***Attention Pharmacy**: This is a template document. Please feel free to customize it to your particular company, however you **must retain all elements** set forth by this template.*

VERMONT BOARD OF PHARMACY STANDARD PROCEDURES ALGORITHM FOR PRESCRIBING OF CONTRACEPTIVES*

1) Health and History Screen
Review Hormonal Contraceptive Self-Screening Questionnaire.
To evaluate health and history, refer to the CDC USMEC, 2016.
1 or 2 (green boxes) - Hormonal contraception is indicated, proceed to next step.
3 or 4 (red boxes) - Hormonal contraception is contraindicated --> Refer

Contraindicating Condition(s) → Refer

No Contraindicating Conditions

2) Pregnancy Screen
a. Did you have a baby less than 6 months ago, are you fully or nearly-fully breast feeding, *AND* have you had no menstrual period since the delivery?
b. Have you had a baby in the last 4 weeks?
c. Did you have a miscarriage or abortion in the last 7 days?
d. Did your last menstrual period start within the past 7 days?
e. Have you abstained from sexual intercourse since your last menstrual period or delivery?
f. Have you been using a reliable contraceptive method consistently and correctly?

If YES to AT LEAST ONE and is free of pregnancy symptoms, proceed to next step.
If NO to ALL of these questions, pregnancy can NOT be ruled out --> Refer

Possible Pregnancy → Refer

Patient is not pregnant

3) Medication Screen (Questionnaire #24 + med list)
Caution: anticonvulsants, antiretrovirals, antimicrobials, barbiturates, herbs & supplements, including:

carbamazepine	lumacaftor/ivacaftor	primidone	*(*PLEASE ALWAYS REFER TO CURRENT USMEC*)*
felbamate	oxcarbazepine	rifampin / rifabutin	
griseofulvin	phenobarbital	topiramate	
lamotrigine	phenytoin	fosamprenavir (when not combined with ritonavir)	

Contraindicating Medications → Refer

No Contraindicating Medications

4) Blood Pressure Screen:
Take and document patient's current blood pressure. Is BP <140/90?
Note: RPH may choose to take a second reading, if initial is high.

BP ≥ 140/90 → Refer or consider POP

BP < 140/90

5) Evaluate patient history, preference, and current therapy for selection of treatment.

Not currently on birth control

5a) Choose Contraception
Initiate contraception based on **patient preferences,** adherence, and history for new therapy.

Prescribe up to 12 months of desired contraception and dispense product. Quantity based on professional judgment and patient preference, but the pharmacist must not prescribe refills to the patient unless the patient has evidence of a clinical visit with a physician, physician assistant, or advanced practice registered nurse within the preceding three years.

Patient is currently on birth control

5b) Choose Contraception
Continue current form of contraception, if no change is necessary
-or-
Alter therapy based on patient concerns, such as side effects patient may be experiencing; or refer, if appropriate.

Prescribe up to 12 months of desired contraception and dispense product. Quantity based on professional judgment and patient preference, but the pharmacist must not prescribe refills to the patient unless the patient has evidence of a clinical visit with a physician, physician assistant, or advanced practice registered nurse within the preceding three years.

6) Discuss Initiation Strategy for Initial Treatment/Change in Treatment (asapplicable)
a) Counseling - Quick start - Instruct patient she can begin contraceptive today; use backup method for 7 days.
b) Counseling - Discuss the management and expectations of side effects (bleeding irregularities, etc.)
c) Counseling - Discuss adherence and expectations for follow-up visits
d) Counseling - Provide any other relevant information.

7) Discuss and Provide Referral / Visit Summary to patient
Encourage: Routine health screenings, STD prevention, and notification to care provider

Adapted from Minnesota Board of Pharmacy Algorithm

Vermont Hormonal Contraceptive Self-Screening Questionnaire

Patient Name_____Health Care Provider's Name_____ Date_____
Date of Birth_____Age_____Weight _____Do you have health insurance? Yes / No
What was the date of your last women's health clinical visit? _____
Any allergies to Medications? *Yes / No* If yes, list them here _____

Do you have a preferred method of birth control that you would like to use?

□ a daily pill □ a weekly patch □ a vaginal ring

Background Information:

1	Do you think you might be pregnant now?	Yes □ No□
2	What was the first day of your last menstrual period?	___/___/___
3	Have you ever taken birth control pills, or used a birth control patch, ring, or injection?	Yes □ No □
	Have you previously had contraceptives prescribed to you by a pharmacist?	Yes □ No □
	Did you ever experience a bad reaction to using hormonal birth control?	Yes □ No □
	- If yes, what kind of reaction occurred?	_____
	Are you currently using any method of birth control including pills, or a birth control patch, ring or shot/injection?	Yes □ No □
	- If yes, which one do you use?	_____
4	Have you ever been told by a medical professional not to take hormones?	Yes □ No □
5	Do you smoke cigarettes?	Yes □ No □

Medical History:

6	Have you had a recent change in vaginal bleeding that worries you?	Yes □ No □
7	Have you given birth within the past 21 days? If yes, how long ago?	Yes □ No □
8	Are you currently breastfeeding?	Yes □ No □
9	Do you have diabetes?	Yes □ No □
10	Do you get migraine headaches?	Yes □ No □
10a	If so, have you ever had the kind of headaches that start with warning signs or symptoms, such as flashes of light, blind spots, or tingling in your hand or face that comes and goes completely away before the headache starts?	Yes □ No □
11	Are you being treated for inflammatory bowel disease?	Yes □ No □
12	Do you have high blood pressure, hypertension, or high cholesterol? (Please indicate yes, even if it is controlled by medication)	Yes □ No □
13	Have you ever had a heart attack or stroke, or been told you had any heart disease?	Yes □ No □
14	Have you ever had a blood clot?	Yes □ No □
15	Have you ever been told by a medical professional you are at risk of developing a blood clot?	Yes □ No □
16	Have you had recent major surgery or are you planning to have surgery in the next 4 weeks?	Yes □ No □
17	Will you be immobile for a long period? (e.g. flying on a long airplane trip, etc.)	Yes □ No □
18	Have you had bariatric surgery or stomach reduction surgery?	Yes □ No □
19	Do you have or have you ever had breast cancer?	Yes □ No □
20	Have you had a solid organ transplant?	Yes □ No □
21	Do you have or have you ever had hepatitis, liver disease, liver cancer, or gall bladder disease, or do you have jaundice (yellow skin or eyes)?	Yes □ No □
22	Do you have lupus, rheumatoid arthritis, or any blood disorders?	Yes □ No □
23	Do you take medication for seizures, tuberculosis (TB), fungal infections, or human immunodeficiency virus (HIV)?	Yes □ No □
	- If yes, list them here:	
24	Do you have any other medical problems or take any medications, including herbs or supplements?	Yes □ No □
	- If yes, list them here:	

*Signature*_____*Date*_____

Adapted, with kind permission, from Minnesota Board of Pharmacy Self-Screening Questionnaire

Vermont Hormonal Contraceptive Self-Screening Questionnaire: Optional Side *– May be used by the prescribing pharmacist. This side of form may be customized by prescribing pharmacist – Do not make edits to the Questionnaire (front side)*

Pregnancy Screen	
a. Did you have a baby less than 6 months ago, are you fully or nearly-fully breast feeding, AND have you had no menstrual period since the delivery?	Yes □ No □
b. Have you had a baby in the last 4 weeks?	Yes □ No □
c. Did you have a miscarriage or abortion in the last 7 days?	Yes □ No □
d. Did your last menstrual period start within the past 7 days?	Yes □ No □
e. Have you abstained from sexual intercourse since your last menstrual period or delivery?	Yes □ No □
f. Have you been using a reliable contraceptive method consistently and correctly?	Yes □ No □

☐ verified DOB with valid photo ID ☐ BP Reading_____/_____**Must be taken by RPH*

Note: RPH must refer patient if either systolic or diastolic reading is out of range, per algorithm

℞

Drug Prescribed_____Rx_____
Directions for Use _____
Pharmacist Name_____RPH Signature _____
Pharmacy Address_____Pharmacy Phone _____

☐

_____
_____
_____

Adapted, with kind permission, from Minnesota Board of Pharmacy Self-Screening Questionnaire

Summary Chart of U.S. Medical Eligibility Criteria for Contraceptive Use

*Updated July 2017.** This summary sheet only contains a subset of the recommendations from the USMEC. It is color coded in the left column to match the corresponding question of the Vermont Board of Pharmacy Self-Screening Risk Assessment Questionnaire.

For complete guidance, see: http://www.cdc.gov/reproductivehealth/unintendedpregnancy/USMEC.htm

Key:		
1	No restriction (method can be used)	
2	Advantages generally outweigh theoretical or proven risks	
3	Theoretical or proven risks usually outweigh the advantages	
4	Unacceptable health risk (method not to be used)	

Note: Most contraceptive methods do not protect against sexually transmitted diseases (STDs). Consistent and correct use of the male latex condom reduces the risk of STDs and HIV.

Corresponding to the Vermont* Self-Screening Risk Assessment Questionnaire:

Condition	Sub-condition	Combined pill, patch (CHC)		Progestin-only Pill (POP)		DMPA (Inj)		Other Contraception Options Indicated for Patient
		Initiating	Continuing	Initiating	Continuing	Initiating	Continuing	
a. Age		Menarche to <40=1		Menarche to <18=1		Menarche to <18=2		Yes
		>40=2		18-45=1		18-45=1		Yes
				>45=1		>45=2		Yes
b. Smoking	a) Age < 35	2		1		1		Yes
	b) Age > 35, < 15 cigarettes/day	3		1		1		Yes
	c) Age > 35, >15 cigarettes/day	4		1		1		Yes
c. Pregnancy	(Not Eligible for contraception)	NA*		NA*		NA		NA*
d. Vaginal Bleeding	Unexplained or worrisome vaginal bleeding	2		2		3		Yes
e. Postpartum (see also Breastfeeding)	a) < 21 days	4		1		1		Yes
	b) 21 days to 42 days:							
	(i) with other risk factors for VTE	3*		1		1		Yes
	(ii) without other risk factors for VTE	2		1		1		Yes
	c) > 42 days	1		1		1		Yes
f. Breastfeeding (see also Postpartum)	a) < 1 month postpartum	3/4*		2*		2*		Yes
	b) 30 days to 42 days							
	(i) with other risk factors for VTE	3*		2*		2*		Yes
	(ii) without other risk factors for VTE	2*		1*		1*		Yes
	c)> 42 days postpartum	2*		1*		1*		Yes
g. Diabetes mellitus (DM)	a) History of gestational DM only	1		1		1		Yes
	b) Non-vascular disease							
	(i) non-insulin dependent	2		2		2		Yes
	(ii) insulin dependent‡	2		2		2		Yes
	c) Nephropathy/ retinopathy/ neuropathy‡	3/4*		2		3		Yes
	d) Other vascular disease or diabetes of >20 years' duration‡	3/4*		2		3		Yes
h. Headaches	a) Non-migrainous	1*		1		1		Yes
	b) Migraine:							
	i) without aura (includes menstrual migraines)	2*		1		1		Yes
	iii) with aura	4*		1		1		Yes
i. Inflammatory Bowel Disease	a) Mild; no risk factors	2		2		2		
	b) IBD with increased risk for VTE	3						
j. Hypertension	a) Adequately controlled hypertension	3*		1*		2*		Yes
	b) Elevated blood pressure levels (properly taken measurements):							
	(i) systolic 140-159 or diastolic 90-99	3*		1*		2*		Yes
	(ii) systolic ≥160 or diastolic ≥100‡	4*		2*		3*		Yes
	c) Vascular disease	4*		2*		3*		Yes
k. History of high blood pressure during pregnancy		2		1		1		Yes
l. Peripartum cardiomyopathy‡	a) Normal or mildly impaired cardiac function:							
	(i) < 6 months	4		1		1		Yes
	(ii) > 6 months	3		1		1		Yes
	b) Moderately or severely impaired cardiac function	4		2		2		Yes
m. Multiple risk factors for arterial CVD	(such as older age, smoking, diabetes, hypertension, low HDL, high LDL, or high triglyceride levels)	3/4*		2*		3*		Yes
n. Ischemic heart disease‡	Current and history of	4		2	3	3		Yes
o. Valvular heart disease	a) Uncomplicated	2		1		1		Yes
	b) Complicated‡	4		1		1		Yes
p. Stroke‡	History of cerebrovascular accident	4		2	3	3		Yes
q. Known Thrombogenic mutations‡		4*		2*		2*		Yes

I = initiation of contraceptive method; C = continuation of contraceptive method; NA = Not applicable
* Please see the complete guidance for a clarification to this classification: www.cdc.gov/reproductivehealth/unintendedpregnancy/USMEC.htm
‡ Condition that exposes a woman to increased risk as a result of unintended pregnancy.

**Adapted, with kind permission, from document prepared by the Minnesota Board of Pharmacy*

Appendix 2

Vermont Pharmacist Prescribing Protocol – Influenza Vaccinations

Background

A pharmacist may prescribe, order, or administer influenza vaccines 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 influenza vaccines must follow this protocol. When prescribing per this protocol, the pharmacist is the prescriber-of-record.

Definitions

"Influenza vaccine" means a vaccine for the prevention and control of seasonal influenza, approved by the US Food and Drug Administration's Center for Biologics Evaluation and Research, and listed in the Centers for Disease Control's Advisory Committee for Immunization Practices (ACIP) recommendations, for the current influenza season.

"Recipient" means the person, 18 years of age and older, to whom an influenza vaccine is being supplied.

General considerations

Prescribing an influenza vaccine under this protocol requires the pharmacist to:

1. Have training and education in that area sufficient to perform the duties involved
2. Comply with immunization registry and adverse reaction reporting requirements described in 18 V.S.A. § 1129 and 18 V.S.A. § 1132
3. Document prescribing and administration of the vaccine
4. Keep a written copy of the protocol at each location from where prescriptions are issued for, or administration of, an influenza vaccine occurs
5. Provide a copy of the protocol available upon the request of an inspector.

Procedures

When an individual requests an influenza vaccine, or when a pharmacist in his or her professional judgement offers to prescribe an influenza vaccine to an individual, the pharmacist shall:

1. Screen for contraindications to receiving an influenza vaccination, as described in the current season's ACIP recommendations (if contraindication exists, no influenza vaccine should be prescribed or administered).
2. Provide the recipient with the most updated Vaccine Information Statement (VIS) for the vaccine administered

Authorized Drugs

Prescribing and dispensing done pursuant to this protocol is limited to FDA-approved influenza vaccines.

Prescribing Records

The pharmacist must generate a written or electronic prescription for any influenza vaccine administered pursuant to protocol-base 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.

Appendix 3

Vermont Pharmacist Prescribing Protocol – Influenza Vaccinations

Background

A pharmacist may prescribe, order, or administer influenza vaccines 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 influenza vaccines must follow this protocol. When prescribing per this protocol, the pharmacist is the prescriber-of-record.

Definitions

"Influenza vaccine" means a vaccine for the prevention and control of seasonal influenza, approved by the US Food and Drug Administration's Center for Biologics Evaluation and Research, and listed in the Centers for Disease Control's Advisory Committee for Immunization Practices (ACIP) recommendations, for the current influenza season.

"Recipient" means the person, 18 years of age and older, to whom an influenza vaccine is being supplied.

General considerations

Prescribing an influenza vaccine under this protocol requires the pharmacist to:

1. Have training and education in that area sufficient to perform the duties involved
2. Comply with immunization registry and adverse reaction reporting requirements described in 18 V.S.A. § 1129 and 18 V.S.A. § 1132
3. Document prescribing and administration of the vaccine
4. Keep a written copy of the protocol at each location from where prescriptions are issued for, or administration of, an influenza vaccine occurs
5. Provide a copy of the protocol available upon the request of an inspector.

Procedures

When an individual requests an influenza vaccine, or when a pharmacist in his or her professional judgement offers to prescribe an influenza vaccine to an individual, the pharmacist shall:

1. Screen for contraindications to receiving an influenza vaccination, as described in the current season's ACIP recommendations (if contraindication exists, no influenza vaccine should be prescribed or administered).
2. Provide the recipient with the most updated Vaccine Information Statement (VIS) for the vaccine administered

Authorized Drugs

Prescribing and dispensing done pursuant to this protocol is limited to FDA-approved influenza vaccines.

Prescribing Records

The pharmacist must generate a written or electronic prescription for any influenza vaccine administered pursuant to protocol-base 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.

Appendix 4
Vermont Pharmacist Prescribing Protocol - Opioid Antagonists

Background
A pharmacist may prescribe, order, or administer opioid antagonists 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 opioid antagonists must follow this protocol. When prescribing per this protocol, the pharmacist is the prescriber-of-record.

Definitions
"Opioid antagonist" means naloxone or other product approved by the U.S. Food and Drug Administration for emergency treatment of known or suspected opioid overdose, as manifested by respiratory and/or central nervous system depression.

"Recipient" means the person to whom an opioid antagonist is being supplied. The recipient might be someone other than the person for whom the use of the opioid antagonist is intended.

General Considerations
Prescribing an opioid antagonist 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, or dispensing of, an opioid antagonist occurs.
4. Provide a copy of the protocol available upon the request of an inspector.

Pharmacists and pharmacies are encouraged to post a notice or to otherwise alert customers that pharmacists may prescribe and dispense opioid antagonists.

Procedures
When an individual requests an opioid antagonist, or when a pharmacist in his or her professional judgement offers to prescribe an opioid antagonist to an individual, the pharmacist shall complete the following steps:
1. Screen for the following (in the primary spoken language of the recipient, upon request and when possible):
    a. Does the recipient understand that opioid antagonists can only be used for opioid overdoses and cannot be used for other drug overdoses?
    b. Does the person to whom the opioid antagonist would be administered have a known hypersensitivity to the drug? (an answer of yes precludes prescribing and dispensing)
    c. Provide training in opioid overdose prevention and recognition, the administration of the opioid antagonist, and the appropriate response to an opioid overdose, including the need to pursue immediate, follow-up treatment (e.g., calling 911)
2. When an opioid antagonist is dispensed, the prescribing pharmacist shall counsel the recipient on the product dispensed and provide appropriate written information, to include:

d. administration
    i. an opioid antagonist may be administered in cases of unknown or mixed substance overdoses
    ii. an opioid antagonist should be administered if the patient's sensitivity to the drug is unknown
e. effectiveness
f. adverse effects
g. storage conditions and shelf-life
h. a recommendation that 911 be called if the opioid antagonist is administered
i. any other information deemed necessary in the professional judgment of the pharmacist

A prescribing pharmacist, dispensing an opioid antagonist pursuant to this protocol, shall not permit the recipient to waive the provision of the written information or the counseling required by this protocol.

The pharmacist should provide information, whether written or oral, to the recipient in the primary language of the recipient.

Authorized Drugs

1. Prescribing and dispensing done pursuant to this protocol is limited to FDA-approved opioid antagonist products. A pharmacist may not prescribe or dispense a compounded version of an opioid antagonist
    a. A pharmacist may also recommend optional items when appropriate, such as alcohol pads, rescue breathing masks, and protective gloves
2. Selection of a product for which a prescription will be issued shall involve collection of information from the recipient regarding:
    a. products available
    b. recipient or patient preference
    c. limitations in ability to administer a particular dosage form (i.e. injection vs. nasal spray)
    d. insurance coverage and other cost factors
    e. Any other pertinent factor

Prescribing Records

The pharmacist must generate a written or electronic prescription for any opioid antagonist dispensed. 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.