Board of Pharmacy

Office of Professional Regulation, Vermont Secretary of State

OPR is holding this meeting in accordance with 1 V.S.A. §§ 310-314. The majority of the Board and OPR staff will be participating remotely. OPR recommends you participate remotely.

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#

If you cannot attend the meeting remotely, connection to the meeting will be available at the Office of Professional Regulation, 89 Main Street, 3rd floor, Montpelier, VT 05602.

Agenda

Wednesday, January 26th, 2022, at 9:00 a.m.

1. **Call to Order**
2. **Changes to the agenda**
3. **Approval minutes of December 15th, 2021**
4. **Discipline:**
   - 9:30am – Timothy M. Davis, Docket # 2021-92: Stipulation and Consent Order.
5. **Executive Officer Update**
   a. Executive Officer Report
   b. Entity License Approvals Since Last Month
   c. Legislative updates
6. **Quarterly Inspection Update** – Derek Everett
   A request for clarification of Board's expectations for satisfaction of Rule 12.3 "Printouts" and Part 14, will also be discussed.
7. **Topics for Discussion**
   a. MPJE - discuss possible alternatives; other States' Board's processes; recap previous public comment; review § 136a. "Uniform Process For Endorsement From Other States" as basis of licensure and MPJE conflict.
   b. State Protocols for Clinical Pharmacy Prescribing:
      - Final Review:
         - Tuberculin Purified Protein Derivative Products (see Appendix A)
         - Dietary Fluoride Supplements (See Appendix B)

   c. Review FDA's recent documents related to 503A hospital compounding and medical office-based compounding
   d. Rule Revisions – Pharmacy Manager; other sections, TBD
   e. Info from Ohio BOP re CVS Virtual Verification
   f. 2022 Board Schedule
8. **Correspondence**
9. **Other Business**
10. **Public Comment**
11. **Discuss items for inclusion on next month's agenda**
12. **Adjournment**

Next Scheduled Meeting – February 23rd, 2022

APPENDIX A

Vermont Pharmacist Prescribing Protocol - Tuberculin purified protein derivative (PPD) products

Background

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), a pharmacist may prescribe and perform tuberculin skin tests (TST), using tuberculin PPD products, to determine if a patient is infected with *Mycobacterium tuberculosis*, the pathogen responsible for causing tuberculosis.

Pharmacists who independently prescribe and perform TSTs with PPD must follow this protocol. When prescribing per this protocol, the pharmacist is the prescriber-of-record.

Definitions

"Tuberculin purified protein derivative products or PPD" means a sterile aqueous solution of a purified protein fraction for intradermal administration as an aid in the diagnosis of tuberculosis.

The "tuberculin skin test" is commonly referred to as the Mantoux tuberculin skin test[1].

"Recipient" means the person to whom a Mantoux tuberculin skin test (TST) will be prescribed and administered.

General Considerations

Prescribing and performance of tuberculin skin testing (TST) with PPD 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 of: testing; failure of patient to return for interpretation of the test; TST results
3. Keep a written copy of the protocol at each location from where diagnostic TSTs are prescribed and performed.
4. Provide a copy of the protocol available upon the request of an inspector.

Procedures

When an individual requests a TST, or when a pharmacist in his or her professional judgement offers to prescribe and perform such tests to individuals, the pharmacist shall complete the following steps:

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. Follow the Vermont Department of Health screening recommendations and Centers for Disease Control and Prevention Clinical Practice Guidelines and recommendations for skin testing.
4. Screen for the following (in the primary spoken language of the recipient):
    a. Patient medical history
    b. Concurrent illness, particularly documented active TB or a clear history of treatment for TB infection or disease
    c. Allergies, hypersensitivities, and adverse reactions, particularly to PPD products
5. Administer via intradermal injection 0.1 mL of tuberculin PPD into the inner surface of the forearm using a tuberculin syringe with the needle bevel facing upward. When placed correctly, the injection should produce a pale elevation of the skin (a wheal) 6 to 10 mm in diameter

[1] Tuberculin purified protein derivative – DrugBank Online https://go.drugbank.com/drugs/DB11601

6. Results must be read 48 to 72 hours post-injection, should a patient not return within 72 hours, they should receive an additional TST.
7. Counseling and written instructions shall be provided to the patient on date of TST. A pharmacist shall not permit the patient to waive the counseling requirement. Counseling and written instructions should include
    a. Necessity to return no later than 72-hours post-placement of PPD for interpretation of TST results
    b. What to expect after PPD placement and injection-site care instructions
8. Interpretation of results shall be reported to the patient and their PCP.
9. Per 18 V.S.A. § 1001 and VDH's Reportable and Communicable Diseases Rule, pharmacist must report positive results to the Vermont Department of Health within 24 hours

Authorized Drugs
Prescribing and administration of PPD products performed pursuant to this protocol is limited to FDA-approved products.

Prescribing Records
The pharmacist must generate a written or electronic prescription for any PPD products administered. 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.

Resources
Vermont Department of Health Tuberculosis Resources and Regulations
- TB Testing and Diagnosis https://www.healthvermont.gov/immunizations-infectious-disease/tuberculosis/tb-testing-and-diagnosis
- Resources for Health Care Professionals and Partners https://www.healthvermont.gov/immunizations-infectious-disease/tuberculosis/resources-health-care-professionals-and-partners
- Infectious Disease Reporting and Data https://www.healthvermont.gov/disease-control/disease-reporting
- Reportable Disease List https://www.healthvermont.gov/sites/default/files/documents/pdf/hs_id_reportable_disease_list.pdf
- Chapter 4 – Health Surveillance and Infectious Disease, Subchapter 1: Reportable and Communicable Diseases Rule https://www.healthvermont.gov/sites/default/files/documents/pdf/hs_id_reportable_communicable_diseases_rule.pdf
- Title 18: Health, Chapter 021: Communicable Diseases, § 1001. Reports to Commissioner of Health https://legislature.vermont.gov/statutes/section/18/021/01001

Centers for Disease Control and Prevention (CDC)
- TB Guidelines – Testing and Diagnosis https://www.cdc.gov/tb/publications/guidelines/testing.htm
- Latent Tuberculosis Infection Resources https://www.cdc.gov/tb/publications/ltbi/ltbiresources.htm
- Latent Tuberculosis Infection: A Guide for Primary Health Care Providers https://www.cdc.gov/tb/publications/ltbi/default.htm
- Targeted Tuberculosis Testing and Interpreting Tuberculin Skin Test Results – Fact Sheet https://www.cdc.gov/tb/publications/factsheets/testing/skintestresults.htm
- Tuberculin Skin Testing – Fact Sheets https://www.cdc.gov/tb/publications/factsheets/testing/skintesting.htm
- Patient and General Public Materials https://www.cdc.gov/tb/education/patient_edmaterials.htm

Education and Training

- CDC's Core Curriculum on Tuberculosis: What the Clinician Should Know, Seventh Edition, 20221 https://www.cdc.gov/tb/education/corecurr/index.htm#Anchor_Interactive (see Chapter on Testing for Tuberculosis Infection in either the PDF or the interactive slides)
- Washington State Pharmacy Association ACPE Tuberculin Skin Testing Training https://www.wsparx.org/page/tuberculincert

References

This protocol was prepared using The KY and NM Boards of Pharmacy protocols as templates

APPENDIX B

Vermont Pharmacist Prescribing Protocol – Dietary Fluoride Supplements

Background

A pharmacist may prescribe dietary fluoride supplements 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 prescribes dietary fluoride supplements must follow this protocol. When prescribing per this protocol, the pharmacist is the prescriber-of-record.

General Considerations

Prescribing dietary fluoride supplements 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 dietary fluoride supplements.
4. Provide a copy of the protocol available upon the request of an inspector.

Procedures

When an individual requests a prescription for dietary fluoride supplements, or when a pharmacist in his or her professional judgement offers to prescribe them, the pharmacist shall complete the following steps:

1. Determine if the patient has a dental practitioner and encourage them to seek routine dental care. If the patient does not have a dental practitioner, provide referral to patient for finding primary care services, such as VT-211 or, for Medicaid beneficiaries, the Vermont Medicaid Provider lookup .
2. To accurately prescribe fluoride supplementation, the pharmacist shall ascertain the patient's drinking water source for determination of fluoride content and shall follow the guidelines in Vermont Department of Health's Dental Periodicity Schedule
3. Provide oral or written counsel to the recipient, or their representative, on the product dispensed to include:
    a. administration
    b. effectiveness
    c. adverse effects
    d. storage conditions and shelf-life
    e. any other information deemed necessary in the professional judgment of the pharmacist

Authorized Drugs

1. Prescribing and dispensing done pursuant to this protocol is limited to FDA-approved dietary fluoride supplements. A pharmacist may not prescribe a compounded version of a dietary fluoride supplement.
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

d. insurance coverage and other cost factors
e. any other pertinent factor

Prescribing Records

The pharmacist must generate a written or electronic prescription for dietary fluoride supplements 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.

Resources

Vermont's Guide to Fluoride Levels in the Public Water Systems
https://www.healthvermont.gov/sites/default/files/documents/pdf/guide_to_fluoride_levels_in_public_water_systems.pdf

VDH Health Care and Screening Guidelines https://www.healthvermont.gov/children-youth-families/health-care-children-youth/health-care-and-screening-guidelines

VDH Fluoride in Vermont, includes information on well water testing
https://www.healthvermont.gov/wellness/oral-health/fluoride#:~:text=Testing%20is%20available%20through%20the,to%20get%20your%20test%20kit.

Vermont Preventive Pediatric Oral Health Care Recommendations for Pediatric and General Dental Health Care Providers
https://www.healthvermont.gov/sites/default/files/documents/pdf/Vermont%20Dental%20Periodicity%20Schedule.pdf

Centers for Disease Control and Prevention (CDC) Recommendations for Using Fluoride to Prevent and Control Dental Caries in the United States https://www.cdc.gov/mmwr/preview/mmwrhtml/rr5014a1.htm

American Dental Association (ADA) Fluoride: Topical and Systemic Supplements
https://www.ada.org/resources/research/science-and-research-institute/oral-health-topics/fluoride-topical-and-systemic-supplements