Board of Pharmacy

Office of Professional Regulation, Vermont Secretary of State

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Agenda

Wednesday, 27th January 2021 at 9:00 a.m.

1. **Call to Order**
2. **Changes to the agenda**
3. **Approval of minutes from 12/2/20 meeting**
4. **Discipline** – *Thomas P. French, Docket No. 2017-421 - Request to remove conditions hearing and proposed order.*
5. **Executive Officer Update**
   a. Executive Officer Report
   b. Entity License Approvals Since Last Month
6. **Topics for Discussion**
   a. Presentation from National Coalition for Drug Quality & Security (NCDQS) for Board consideration of their services as acceptable from applicants

   b. Legislative Updates

   c. Administrative Rules Revision
      - Draft Rule 6.8 Workplace Conditions

   d. 12:00 noon UVMHN Letter to Board, *Interpretation & Guidance - BOP Rule 9.18*, Nate Arwich and Christina DeGraff-Murphy

   e. Review of proposed Clinical Pharmacy Prescribing State Protocols, pursuant to Act 178 – ***appended to this agenda***
      - Appendix 1 - Opioid Antagonists
      - Appendix 2 - Influenza Vaccination
      - Appendix 3 - COVID-19 Vaccination (updated since December's review)

   f. Correspondence

   g. Discussion about USP <800> and <825>

   h. Inspections Report, Quarterly update – Derek Everett
7. **Other Business**
8. **Public Comment**
9. **Discuss items for inclusion on next month's agenda**
10. **Adjournment**

Next Scheduled Meeting – Wednesday, February 24th, 2020

Please check the office website for updates

APPENDIX 1

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:

a. 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
b. effectiveness
c. adverse effects
d. storage conditions and shelf-life
e. a recommendation that 911 be called if the opioid antagonist is administered
f. 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.

Whenever possible, 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

Records

The pharmacist must generate a written or electronic prescription for any opioid antagonist dispensed. The prescription must include all of 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 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:

5. Have training and education in that area sufficient to perform the duties involved, including those contained in Administrative Rule 10.35
6. Comply with immunization registry and adverse reaction reporting requirements described in 18 V.S.A. § 1129 and 18 V.S.A. § 1132
7. Document prescribing and administration of the vaccine
8. Keep a written copy of the protocol at each location from where prescriptions are issued for, or administration of, an influenza vaccine occurs
9. 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:

3. 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);
4. Provide the recipient with the most updated Vaccine Information Statement (VIS) for the vaccine administered; and
5. Comply with all requirements in Administrative Rule 10.35.

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 State Protocol: Pharmacist Ordering and Administration of COVID-19 Vaccines

The Commissioner of the Vermont Department of Health hereby finds and declares that the SARS-CoV-2 (COVID-19) pandemic presents a significant public health risk to Vermonters, for which existing channels for vaccine administration are insufficient to meet public health needs. Following consultation with the Director of Professional Regulation and a period for comment, the Commissioner approves the following protocol, pursuant to 26 V.S.A. § 2023(b)(2)(A)(viiii).

Requirements

A pharmacist may prescribe, order, and administer FDA-authorized or FDA-licensed COVID-19 vaccines in conformity with the Advisory Committee on Immunization Practices' (ACIP's) COVID-19 vaccine recommendations.

Currently, two COVID-19 vaccines received FDA Emergency Use Authorizations (EUA), the Pfizer-BioNTech COVID-19 vaccine and the Moderna vaccine.

The US Health and Human Services (HHS) amendments of, and guidance's about the PREP Act, grants pharmacists immunity under the PREP Act with respect to ordering and administering vaccines issued EUAs. The training, record-keeping and reporting required by HHS under these amendments, follows.

Training

Pharmacists wishing to provide COVID-19 vaccines must:

- Complete a practical training program of at least 20 hours approved by the Accreditation Council for Pharmacy Education (ACPE). This training program must include hands-on injection technique, clinical evaluation of indications and contraindications of vaccines, and the recognition and treatment of emergency reactions to vaccines;
- Have a current certificate in basic cardiopulmonary resuscitation; and
- Complete a minimum of two hours of ACPE-approved, immunization-related continuing pharmacy education during each State licensing period.

Recordkeeping and Reporting

- Before administering any vaccine, review each patient's current IMR "forecaster" in Vermont's Immunization Registry (IMR).
- Record vaccine administration in the IMR within CDC's required reporting timeline.
- Inform pediatric patients and their adult caregivers of the importance of a well-child visit with a pediatrician.
- Give direct notice to the patient's primary-care provider when possible.

Guidelines

Please access and utilize the December 24th Health Alert "General Information about the Pfizer-BioNTech and Moderna COVID-19 Vaccines." It can be found here.

Ordering

A pharmacist needs a National Provider Identification (NPI) number place patient vaccines order. A pharmacist without an NPI number may order through a collaborative practice agreement with a prescriber.

Adverse Events
Vaccine safety monitoring is required under the Emergency Use Authorization (EUA) for the COVID-19 vaccine.

Certain adverse events are required to be reported to the Vaccine Adverse Event Reporting System, or VAERS, (i.e., vaccine administration errors, serious adverse events, multisystem inflammatory syndrome (MIS) in children or adults, and cases of COVID-19 that result in hospitalization or death).

Any revised safety reporting requirements should also be adhered to. FDA's EUA website containing letter(s) of authorization and fact sheets should be checked for any updates that may occur.

Any additional clinically significant adverse events following vaccination should be reported to the VAERS.

Mandatory Patient Information and Notification
Pharmacists shall provide an EUA fact sheet for recipients or vaccine information statement (VIS), as applicable, to each vaccine recipient/parent/legal representative prior to vaccination.

Helpful Resources

- CMS
    - The National Provider Identifier (NPI) is a Health Insurance Portability and Accountability Act (HIPAA) Administrative Simplification Standard.

      https://www.cms.gov/Regulations-and-Guidance/Administrative-Simplification/NationalProvIdentStand
    - Reimbursement Guidance

      https://www.cms.gov/covidvax-provider

- Vermont Department of Health Immunization Registry (to apply for IMR account, find help line, general information about IMR):

  https://www.healthvermont.gov/health-statistics-vital-records/registries/immunization

  Form to submit for access:
  https://www.healthvermont.gov/sites/default/files/documents/pdf/IMR_Confidentiality_agreement_practices.pdf
  Tutorials. "Using Registry in Emergency":
    - How to manually enter an immunization quickly https://youtu.be/PqkGfWRktB4
    - How and why to add vaccine to library https://youtu.be/8SBauz0Ixoc
    - How to manually add a patient https://youtu.be/NxKQj288y80
    - How to Use Vaccine Forecaster https://youtu.be/lM45xc1WDW8

  For questions about how to submit a batch file, call IMR Manager 802-951-4094

- Centers of Disease Control (CDC) and Advisory Committee on Immunization Practices (ACIP)
    - The Advisory Committee on Immunization Practices' Interim Recommendation for Use of Pfizer-BioNTech COVID-19 Vaccine

http://dx.doi.org/10.15585/mmwr.mm6950e2

- Interim Clinical Considerations for Use of Pfizer-BioNTech COVID-19 Vaccine

  https://www.cdc.gov/vaccines/covid-19/info-by-product/pfizer/clinical-considerations.html?CDC_AA_refVal=https%3A%2F%2Fwww.cdc.gov%2Fvaccines%2Fcovid-19%2Finfo-by-manufacturer%2Fpfizer%2Fclinical-considerations.html
- Healthcare Professionals: Preparing for COVID-19 Vaccination

  https://www.cdc.gov/vaccines/covid-19/hcp/index.html

- Vaccine Adverse Event Reporting System

  https://vaers.hhs.gov/

- Accreditation Council for Pharmacy Education (ACPE)

  Application of ACPE CPE Standards for Continuing Pharmacy Education, Policies, and Procedures based on HHS Guidance under PREP Act for Administration of COVID-19 and Childhood Vaccines
  https://www.acpe-accredit.org/continuing-education-provider-accreditation/

- Vaccine Information Statements

  https://www.immunize.org/vis/

- 18 V.S.A. § 1129 Immunization Registry

  https://legislature.vermont.gov/statutes/section/18/021/01129

- 18 V.S.A. § 1132 Vaccine Adverse Event Reporting System

  https://legislature.vermont.gov/statutes/section/18/021/01132