

FINAL/APPROVED

**VIRGINIA BOARD OF PHARMACY
MINUTES OF STATEWIDE PROTOCOL WORK GROUP MEETING**

August 9, 2021

Department of Health Professions
Perimeter Center
9960 Mayland Drive
Henrico, Virginia 23233

- CALL TO ORDER:** A meeting of a Statewide Protocol Work Group was called to order at approximately 9:10 AM.
- PRESIDING:** Dale St. Clair, PharmD, Board of Pharmacy*
- MEMBERS PRESENT:** Patricia Richards-Spruill, RPh, Board of Pharmacy*
Jacob Miller, D.O., Board of Medicine*
Brenda Stokes, M.D., Board of Medicine*
Diana Jordan, Virginia Department of Health (VDH), Office of Epidemiology (arrived approx. 10:00am)
Stephanie Wheawill, PharmD, VDH (arrived approx. 10:30am)
*voting members
- STAFF PRESENT:** Caroline D. Juran, RPh, Executive Director, Board of Pharmacy
William Harp, M.D., Executive Director, Board of Medicine
Ryan Logan, Deputy Executive Director
Beth O'Halloran, Deputy Executive Director
Ellen B. Shinaberry, Deputy Executive Director
Elaine Yeatts, Senior Policy Analyst, DHP
Barbara Allison-Bryan, M.D., Chief Deputy Director, DHP
James Rutkowski, Assistant Attorney General
- QUORUM** With all four voting members present, a quorum was established.
- APPROVAL OF AGENDA:** St.Clair stated that an amended agenda had been posted on Regulatory Town Hall on August 6, 2021 and that a hard copy was provided at their seats. The amended agenda included a draft Tuberculosis (TB) one-step and two-step protocol provided by VDH, draft HIV pre-exposure prophylaxis (PrEP) and post-exposure prophylaxis (PEP) protocols as of 8/5/2021 provided by VDH, and public comment submitted by the Medical Society of Virginia (MSV).
- MOTION:** **The work group voted to unanimously approve the amended agenda as presented. (motion by Miller, seconded by Stokes)**

PUBLIC COMMENTS:

Clark Barrineau, Executive Director, Medical Society of Virginia (MSV) offered comments consistent with the written comments submitted by MSV and included in the agenda packet.

Mike Ayotte offered comments on behalf of the National Association of Chain Drug Stores. He applauded the expansion in access to care, stating that pharmacists are sometimes the only healthcare access point in rural areas. He commented that high-risk patients go to a pharmacy approximately 35 times per year. Pharmacists have dispensed HIV drugs and counseled patients in a confidential manner for years. Excessive regulations will limit access. North Carolina is also advancing statewide protocols on TB, HIV PEP and PrEP.

Christina Barrille, Executive Director, Virginia Pharmacists Association (VPhA) offered comments and aligned her comments with Ayotte's. She stated VPhA has no problem with connecting patients with primary care providers for follow-up care. She encouraged the work group members to direct staff to gather additional information if needed and stated that Juran will be providing a law update at the 140th VPhA annual meeting on August 13, 2021.

St.Clair read comments from Nathan Everson, PharmD who is a clinical pharmacy specialist in infectious disease with nine years of experience in inpatient and ambulatory infectious diseases including HIV. Juran received his comments via email and the comments were provided as a handout to the members and public. Everson offered supportive comments for the HIV PEP and PrEP statewide protocols. He commented that the draft protocol appears to be written primarily for community pharmacy and to consider large population of ambulatory pharmacists in primary and specialty care clinics who have access to providers. He offered suggested testing requirements and encouraged the work group to use the draft CDC 2021 guidance. He stated that the PrEP protocol should include both Truvada and Descovy, because insurances can often prefer one over the other, and to account for the robust PrEP pipeline.

CHARGE OF WORK GROUP

St.Clair provided an overview of the work group's charge pursuant to the second and third enactment clauses of HB 2079.

LOWER OUT-OF-POCKET
EXPENSES:

The work group reviewed the draft amendments to the statewide protocol to lower out-of-pocket expenses included in the agenda packet. Juran provided the example that the amendments would allow a pharmacist to initiate the dispensing of paraphernalia such as hypodermic needles that would be covered by a patient's health insurance which may be less expensive than buying them without a prescription.

MOTION:

The work group voted unanimously to recommend to the Board of Pharmacy that it amend the statewide protocol to lower out-of-pocket expenses as presented. (motion by Stokes, seconded by Miller)

VACCINES:

The work group discussed the draft vaccine statewide protocol included in the agenda packet which corresponds to the Centers for Disease Control and Prevention (CDC) Immunization Schedule for persons 18 years of age and older. Juran commented that the CDC indicates on its website in the context of shared-clinical decision making that the CDC defines a healthcare provider as anyone who provides or administers vaccines: primary care physicians, specialists, physician assistants, nurse practitioners, registered nurses, and pharmacists. A couple of amendments were offered.

MOTION:

The work group voted unanimously to recommend to the Board of Pharmacy that it adopt the vaccine statewide protocol as presented and amended as follows: under Patient Inclusion Criteria, insert a clarification that the pharmacist shall screen the patient's medical history to ensure vaccine administration is appropriate for the patient's medical conditions such as pregnancy and an immunocompromised state; and under Patient Exclusion Criteria, insert a clarification that certain patients may be ineligible based on medical conditions as indicated in the CDC Immunization Schedule. (motion by Richards-Spruill, seconded by Stokes)

HIV PREP:

The work group discussed this topic next. Jordan indicated it is anticipated that the CDC will release revised guidelines in the next six months that liberalize requirements in an effort to increase access to these medications. There was consensus that Oregon's checklist model may be easier to use.

MOTION:

The work group voted unanimously to recommend to the Board of Pharmacy that it adopt an HIV PrEP statewide protocol consistent with the Oregon statewide protocols included in the agenda packet and amended as follows: insert additional laboratory tests for Hepatitis C, pregnancy, and ALT/AST; insert VDH's recommendations for counseling, safe needle practices, documentation, and notification/referral to prescriber. (motion by Stokes, seconded by Miller)

HIV PEP:

Jordan commented that VDH is very interested in this pharmacy-based model. Again, there was consensus for use of the Oregon checklist model.

MOTION:

The work group voted unanimously to recommend to the Board of Pharmacy that it adopt an HIV PEP statewide protocol consistent with the Oregon statewide protocol included in the agenda packet and amended as follows: clarify age restriction of 18 years and older; modify drug regimens to be consistent with VDH's draft language found on page

11 of the handout (8/5/21 draft version) but retain Oregon's "Notes" listed on page 101 of the agenda packet; use active ingredient names and not brand names; insert a requirement to attempt to obtain HIV baseline, but to not require prior to initiation of treatment; and insert VDH's draft "Counseling" found on page 12 of the handout. (motion by Miller, seconded by Richards-Spruill)

TUBERCULOSIS:

Juran provided a handout of a draft TB Risk Assessment Form that intends to consolidate the draft information provided by VDH into a single checklist.

MOTION:

The work group voted unanimously to recommend to the Board of Pharmacy that it adopt a TB testing statewide protocol as follows:

- Incorporate staff's handout of the draft TB Risk Assessment Form but amend by inserting LTBI into question #8; move question #10 regarding the screening of BCG to after the screening of high burden countries; correct the numbering of the questions in the assessing other risks for acquiring LTBI section; add a question regarding employer requirement of test even if no risk; replace the last page of the draft risk assessment form handout with information from VDH's Appendix E as found in the draft handout provided by VDH (pages 14 and 31 but remove reference to IGRA, chest x-ray, include referral to PCP for positive test and under TB Screening/Testing Conclusion replace "free from communicable TB" language with language that simply indicates a negative test; move the patient authorization section up on the form; clarify record retention requirements to be consistent with regulation 18VAC110-21-46; insert a checkbox for the patient to indicate who to notify of a positive test when the patient does not have a PCP; clarify that patients who have received a BCG vaccination should be referred to a PCP;
- Incorporate VDH's draft one-step and two-step protocols as presented but amend by removing requirement to indicate name of person who provided training and date of training but insert a requirement to maintain training records; remove duplicative information included on the draft risk assessment form; under the Procedures for Monitoring and Follow Up section, strike "Consistent with Virginia professional practice acts, only a physician, physician's assistant, nurse practitioner, registered nurse, or pharmacist may interpret the results of the reading of the TST." and insert a requirement that only a trained pharmacist at the same pharmacy location where the test was administered, or a different location if the trained pharmacist has access to the patient's records, may interpret the results of the reading of the TST; under the Documentation section, clarify #4, if possible; under the Notification and Referral section, change two business days to three business days and strike the last

paragraph in this section, along with striking the Terms and Signatures sections;

- Incorporate the draft Appendices B and C included in VDH's handout (pages 10-13) into both protocols;
- Incorporate the draft Appendix D in VDH's handout (pages 29-30) into the Two-Step protocol;
- Require referral upfront if patient does not consent to notifying someone of a positive test; and,
- Insert requirements to notify PCP and counsel on importance of relationship as required in Code. (Motion by Miller, seconded by Richards-Spruill)

ADOPTION OF EMERGENCY REGULATIONS:

The work group reviewed the draft regulations included in the agenda packet for implementing the provisions of HB 2079. No amendments were offered.

MOTION:

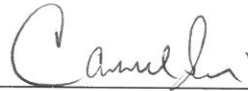
The work group voted unanimously to recommend to the Board of Pharmacy that it adopt the emergency regulations as presented. (motion by Stokes, seconded by Miller)

MEETING ADJOURNED:

Having completed all business on the agenda, the meeting was adjourned at approximately 1:00pm.



Chairman



Caroline D. Juran, Executive Director

9/23/21

DATE:

9/24/2021

DATE: