FIANL/APPROVED

VIRGINIA BOARD OF PHARMACY
MINUTES OF STATEWIDE PROTOCOL WORK GROUP MEETING

August 16, 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 10:07AM.

PRESIDING: Kris Ratliff, DPh, Board of Pharmacy*

MEMBERS PRESENT:
Sarah Melton, PharmD, Board of Pharmacy*
Jacob Miller, D.O., Board of Medicine*
Brenda Stokes, M.D., Board of Medicine*
Laurie Forlano, D.O., MPH, Deputy Director, Office of Epidemiology, Virginia Department of Health (VDH) (arrived 10:15AM)
Will Hockaday, Tobacco Control Program/Outreach Coordinator, VDH
Kristin Collins, MPH, Policy Analyst, Office of Epidemiology, VDH
Kelly Goode, PharmD, BCPS, FAPhA, FCCP, Virginia Commonwealth University (VCU) School of Pharmacy
Iain Pritchard, PharmD, BCACP, Shenandoah University, Bernard J. Dunn School of Pharmacy
Zahra Raza, M.D., VCU School of Medicine
John R. Lucas, D.O., Edward Via College of Osteopathic Medicine
Michelle Thomas, PharmD, CDE, BCACP, Virginia Pharmacists Association (VPhA)
Wendy Klein, M.D., Medical Society of Virginia (MSV)
*voting members

STAFF PRESENT:
Caroline D. Juran, RPh, Executive Director, Board of Pharmacy
William Harp, M.D., Executive Director, Board of Medicine
Ryan Logan, RPh, Deputy Executive Director
Beth O'Halloran, RPh, Deputy Executive Director
Ellen B. Shinaberry, PharmD, 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:

Hearing no suggestions for additional items, Ratliff indicated that the agenda was approved as presented.

PUBLIC COMMENTS:

Kelsey Wilkinson, representing MSV stated VPhA approached them two years ago, that MSV supported HB2079, but that the remaining two agenda items needed further consideration. MSV shares goals of expanding access to care, but that testing is not the same as diagnosis. Full diagnostic tools and physical exam are needed to provide a proper diagnosis. Follow-up care with mental health may be needed for tobacco cessation.

Neely Dahl commented that she is part of the Tobacco Free Alliance of Virginia and is supportive of a tobacco-free life. She supports this protocol initiative. She believes including nicotine replacement therapy (NRT) in a protocol would be good and that use of bupoprion and varenicicline should require additional consultation.

Christina Barrille, Executive Director, VPhA commented that they have been working on this for a while and that patients deserve access to care. She commented that in her experience younger medical and dental students at VCU are very supportive of statewide protocols for pharmacists. Pharmacists have played an important role in administering tests to diagnose patients with COVID-19. She compared the use of a statewide protocol to the common use of telemedicine and highlighted the limitations to physical exams during telemedicine. She stated many patients seek out pharmacists for care and that pharmacists are capable of testing, treating, and referring.

A handout was provided to the work group and the public containing written comments from Mike Ayotte, representing the National Association of Chain Drug Stores. NACDS fully supports the development of protocols for testing and the initiation of treatment guided by CLIA-waived tests and tobacco cessation services, including pharmaceuticals. The comments outlined the number of states that already have such allowances in place for each of these subjects: 41 states allow pharmacy testing services; 19 states allow test and initiation of treatment for influenza, Helicobacter pylori, Group A Streptococcus, and Urinary Tract Infections (UTI); and 13 states allow pharmacists to initiate prescription and over-the-counter products for smoking cessation.

CHARGE OF WORK GROUP

Ratliff provided an overview of the work group's charge pursuant to the fourth enactment clause of HB 2079.

OVERVIEW OF PHARMACIST EDUCATIONAL/TRAINING

Goode provided an overview of the slides included in the agenda packet regarding current pharmacist educational requirements. She stated that 80-90% of the students at VCU School of Pharmacy already have a Bachelor of

STANDARDS:

Science degree upon entry into the PharmD program. Students are taught how to perform a patient assessment, develop a plan, initiate follow-up care, and conduct motivational interviews. She outlined specific courses in the curriculum relevant to the work group's discussion. She commented that students complete 2-4+ credit hour courses of didactic and clinical laboratory skills training on CLIA-waived laboratory testing, infectious diseases such as UTIs, Strep, Influenza, and Tobacco Cessation

VIRGINIA'S DRAFT PHARMACIST WORKFORCE REPORT 2020

Ratliff provided an overview of the 2020 Virginia's Pharmacist Workforce Draft Report included in the agenda packet. He stated 11% of pharmacists work in a non-metro area, 68% have earned a doctorate or other professional degree, 19% have completed a PGY1 residency, 7% have completed a PGY2 residency, and 10% of pharmacists hold a board certification. Among those participating in collaborative practice agreements, common disease management included: anticoagulation, hypertension, hypercholesterolemia, asthma, tobacco cessation, travel medications, and diabetes.

TOBACCO CESSATION

Prior to opening for discussion, Ratliff provided an overview of the agenda materials. He highlighted that as of 2/10/21, 14 states have laws addressing pharmacists prescribing of tobacco cessation aids without a collaborative practice agreement. Klein asked for clarity on the plan for follow-up care in the event of adverse effects. Goode stated that high-risk patients, e.g., former smokers are returning to smoking due to the pandemic. Stokes commented that the protocol included in the agenda packet appears complicated. She questioned if mandatory counseling would be included in the protocol. There was discussion regarding importance of follow-up after 7-21 days. Stokes believes a limit should be placed on the nicotine replacement due to its negative effects. Raza agreed with Stokes on limiting protocol to nicotine replacement. If a patient presents to her after failure of a nicotine replacement, she would like to have alternatives to recommend. Believes follow up visits are very important and should be mentioned in the protocol. Klein opposes smoking. She highlighted that it can be difficult to communicate with patients due to language barriers and literacy, and therefore, the patient may not be able to complete a self-screening tool. Recommends resources to assist with the barriers. Hockaday offered that patients could be referred to the state quit help line. The help line provides qualified representatives with therapy skills which improves the success of quitting. Any additional initiatives would help as more patients are not sticking with replacement therapy or returning to follow-up appointments. Raza commented that COVID-19 may be impairing a patient's ability to use blood pressure monitoring devices at a pharmacy. Goode commented that OTC nicotine replacements do not require blood pressure testing. Comments were made regarding patient harm with continued smoking if access to these medications is not expanded. Lucas questioned the expected outcome of the

work group's meeting and stated that recommendations of what should be included in the protocol should be provided to the appropriate group creating the protocol. Klein stated that recommendations of exclusions should be provided in the protocol. Stokes indicated that access will increase as the world opens back up following the pandemic. Telemedicine appointments will provide additional access to the patients. Thomas recommends increasing access through a protocol and that expanding the health team is a positive action. Hockaday commented that having a larger combination of treatment options improves outcomes, important to have additional points of patient access, and that continued smoking is currently causing harm. Local pharmacies should have access to the Quit Help Line. Allison-Bryan asked about training differences between PharmD graduates and BS Pharmacy graduates. Goode commented that BS graduates of pharmacy may require extra training in motivational interviewing techniques but that they are well-prepared to participate in such a protocol. Follow-up care should be built into the protocol.

MOTION:

The work group voted 2:2 to include a recommendation in the work group's report that pharmacist be authorized to initiate treatment with nicotine replacement therapy (excluding varenicline and bupoprion) via a statewide protocol that requires counseling, appropriate follow-up, and referral. (motion by Stokes, seconded by Miller; opposed by Ratliff and Melton)

MOTION:

The work group voted 2:2 to include a recommendation in the work group's report that pharmacists be authorized to initiate treatment with all relevant medications (nicotine replacement therapy, varenicline and bupoprion) with safeguards similar to the other 5 states where currently allowed, including a requirement to educate patients. (motion by Melton, seconded by Ratliff; opposed by Stokes and Miller)

CONDITIONS WITH CLIA-WAIVED TESTS

INFLUENZA

Stokes inquired regarding the training pharmacists receive in regards to physical exams. Goode indicated pharmacy students complete a 2 credit hour course on physical assessment training with 4 practical sessions. Klein expressed concern for the lack of training of physical exams and commented that it is easy to miss a diagnosis of pneumonia. Lucas recommended that schools of medicine and pharmacy collaborate regarding training for conducting physical exams, focusing on the diseases mentioned in the agenda. Stokes commented that protocols from other states don't include physical exams. It was stated that the FDA is currently reviewing Tamiflu to

determine if it should be available over-the-counter. If available OTC, patients could readily access the drug without any physical exams or testing. Stokes questioned if a statewide protocol would encourage some patients to be seen at a pharmacy when they should be seen at an urgent care center. Raza commented that by the time a lab result is returned, may have missed window for initiating treatment. Goode commented that a statewide protocol for pharmacists would provide patients with access to influenza treatment on weekends and in the evenings when many prescriber offices are closed. Miller expressed concern for simply conducting a CLIA-waived test without performing a physical exam. Stokes stated that it may be difficult to treat everyone by a protocol since everyone is different and that inappropriate prescribing may increase antibiotic resistance. Forlano recommended that a protocol should include antibiotic stewardship and that VDH has a pharmacist who oversees this program who could serve as a resource.

MOTION:

The work group voted 3:1 to not include a recommendation for a statewide protocol for treating Influenza in the work group's report. (motion by Stokes, seconded by Miller; opposed by Melton)

GROUP A STREPTOCOCCUS

Goode indicated that pharmacists in other states are not simply handing out antibiotics, but are referring patients to primary care providers as appropriate. Klein expressed concern for missing something; difficulty in identifying salivary gland verses lymph node. Raza indicated Strep is less prevalent in patients 18 years of age or older, but can be more complicated.

MOTION:

The work group voted 2:2 to not include a recommendation for a statewide protocol for treating Group A Streptococcus in the work group's report. (motion by Miller, seconded by Stokes; opposed by Melton and Ratliff)

URINARY TRACT INFECTIONS

Klein indicated the co-infection rate of sexually transmitted diseases for patients aged 18-45 with UTIs is 20%. She questioned if patients will give a good history. Symptoms of a 20 year old are very different than of a 60 year old with diabetes, prostate issues, or co-infection. She questioned if a protocol could address all of these issues. Goode indicated that pharmacists in Canada have been doing this since 2014 and there is some good data. There is not as much data in the United States. Thomas expressed concern for patients using urgent care centers or emergency departments for UTI symptoms, especially at night or on weekends, which is increasing healthcare costs. Stokes commented that pharmacists may not be able to rule out other infections and questioned if samples would be sent out for microscopy.

MOTION:

The work group voted 2:2 to not include a recommendation for a statewide protocol for treating urinary tract infections in the work group's report. (motion by Stokes, seconded by Miller; opposed by

Melton and Ratliff)

MEETING ADJOURNED: Having completed all business on the agenda, the meeting was adjourned at 11:47AM.

Work Group Chairman

Caroline D. Juran, Executive Director

9-24-21

DATE:

9/24/2021

DATE: