

(DRAFT/UNAPPROVED)

VIRGINIA BOARD OF PHARMACY
MINUTES OF STATEWIDE PROTOCOL WORKGROUP MEETING

Monday, September 21, 2020
Virtual Meeting

Department of Health Professions
Perimeter Center
9960 Mayland Drive, Suite 300
Henrico, Virginia 23233-1463

CALL TO ORDER:

A virtual Webex meeting of a Statewide Protocol workgroup convened by the Board of Pharmacy was called to order at 9AM. Due to the COVID-19 declared state of emergency and consistent with Amendment 28 to HB29 (Budget Bill for 2018-2020) and the applicable provisions of § 2.2-3708.2 in the Freedom of Information Act, the workgroup convened a virtual meeting to consider such business matters as was presented on the agenda necessary for the board to discharge its lawful purposes, duties, and responsibilities.

PRESIDING VIRTUALLY:

Ryan Logan, RPh, *Workgroup Chairman*

**WORKGROUP MEMBERS
PARTICIPATING VIRTUALLY:**

Kristopher Ratliff, DPh, *Chairman, Board of Pharmacy (non-voting member)*
Sarah Melton, PharmD, *Member, Board of Pharmacy (departed at 11:03am)*
Dale St.Clair, PharmD, *Member, Board of Pharmacy, (joined at 11:03AM)*
Jake Miller, D.O., *Member, Board of Medicine*
Brenda Stokes, M.D., *Member, Board of Medicine*
Stephanie Wheawill, PharmD, *VDH, Director of Division of Pharmacy Services*
Kristen Collins, MPH, *Policy Analyst, Office of Epidemiology, VDH*
Diana Jordan, *Director, Division of Disease Prevention, VDH*
Joe DiPiro, PharmD, *Dean, VCU School of Pharmacy*
Michael Justice, PharmD, *Assistant Professor, Appalachian College of Pharmacy (joined at 12:05pm)*
Al Arias, M.D., *VCU, School of Medicine*
John R. Lucas, D.O., *Edward Via College of Osteopathic Medicine (joined at 9:30am)*
Donna Francioni-Proffitt, RPh, *Pharmacy Program Manager, DMAS*
Doug Gray, *Executive Director, Virginia Association of Health Plans (joined at 10:05am)*
Kelly Goode, PharmD, *Virginia Pharmacist Association*
Terri Babineau, M.D., *Medical Society of Virginia*
Kerri Musselman, PharmD, *Virginia Society of Health-System Pharmacists*

Summer Williams Kerley, PharmD, *Virginia Association of Chain Drug Stores*
Lincy Abraham, PharmD, *National Association of Chain Drug Stores*

**STAFF PARTICIPATING
VIRTUALLY:**

Caroline Juran, RPh, *Executive Director, Board of Pharmacy*
William Harp, M.D., *Executive Director, Board of Medicine*
Elaine Yeatts, *Senior Policy Analyst, DHP*
Jim Rutkowski, *Assistant Attorney General*
Sammy Johnson, *Pharmacist, Deputy Executive Director, Board of Pharmacy*
Ellen Shinaberry, PharmD, *Deputy Executive Director, Board of Pharmacy*
Kiara Christian, *Executive Assistant, Board of Pharmacy*

**APPROVAL OF AGENDA:
MOTION:**

The workgroup voted unanimously to approve the agenda as presented. (motion by Miller, seconded Stokes)

PUBLIC COMMENT:

As noticed in the agenda, Mr. Logan invited those persons who had requested via email to Ms. Juran or Ms. Christian prior to 8am on September 21, 2020 to offer public comment to the workgroup.

Nathan Emerson, PharmD, Carillion Clinic, asked that the workgroup address the needs of pharmacists related to HIV PrEP management. He stated it is safe with very little risk. Current requirement for patient to see doctor first under collaborative practice agreement requirements is a barrier to care. He referenced allowances in Washington state and California, and requested that PrEP be handled separately from PEP.

Christina Barille, Executive Director, VPhA, thanked staff and the workgroup participants. She stated statewide protocols would not remove current patient access points, but would add to them. Adding point of care testing at community pharmacies will assist rural patients and connect them back to their primary care provider. Need to increase access to care as there are many barriers currently.

Jill McCormack, Director of State Government Affairs NACDS and also representing VACDS, offered support

for expanding access of care for patients. Pharmacists have a vital, safe track record; can provide continuity of care and as a gateway to connect patients with their primary care provider.

Mr. Logan asked if anyone else wished to offer comment even if didn't send email to staff. No other public comments were made.

**REVIEW CHARGE OF THE
WORKGROUP AS DESCRIBED IN
THE 3RD ENACTMENT CLAUSE OF
HB 1506**

Mr. Logan reviewed the charge of the workgroup as outlined in the 3rd enactment clause of HB1506. Recommendations will be included in a legislative report submitted by staff by November 1, 2020 as required in the bill. If the workgroup concludes its work today, the second meeting tentatively scheduled for October 2, 2020 will be cancelled.

**REVIEW REQUEST FROM JOINT
COMMISSION ON HEALTH CARE,
DATES 2/10/2020**

Mr. Logan reviewed a letter received from the Joint Commission on Health Care (JCHC) in February 2020 prior to the passage of HB1506. Because the JCHC is requesting similar information, a copy of the legislative report from this workgroup will be sent to the JCHC as well by November 1, 2020.

**OVERVIEW OF PHARMACIST
EDUCATIONAL/TRAINING
STANDARDS**

Dr. Dean DiPiro provided a brief overview of the current educational and training standards for pharmacists.

**REVIEW WORKFORCE STATISTICS
OF PHARMACISTS**

Ms. Juran highlighted key findings from the 2019 Pharmacist Workforce Survey Report which included: 66% hold a PharmD degree; 19% have completed a one-year residency; 7% have completed a two-year residency; and 10% have obtained a Board certification with 6% of those in Pharmacotherapy.

**COPIES OF RECENTLY ADOPTED
VIRGINIA PROTOCOLS**

Mr. Logan briefly summarized the statewide protocols recently adopted by the Board in response to the 2nd enactment clause of HB 1506.

**PROVIDE RECOMMENDATIONS
REGARDING THE DEVELOPMENT
OF PROTOCOLS FOR THE**

**INITIATING OF TREATMENT WITH
AND DISPENSING AND
ADMINISTERING BY PHARMACISTS
TO PERSONS 18 YEARS OF AGE OR
OLDER OF DRUGS AND DEVICES,
INCLUDING:**

VACCINES

Dr. Stokes supported reporting vaccines to the Virginia Immunization Information System and to the patient's primary care provider (PCP). If no PCP, then counsel on importance of a PCP. Dr. Babineau expressed concern for the financial impact on PCPs.

MOTION:

The workgroup voted 15: 1 with 1 abstention to include in the legislative report a recommendation that pharmacists should be authorized to order and administer vaccines included on the immunization schedule published by the CDC for persons 18 years of age and older, to require reporting to the Virginia Immunization Information System, and to inform the patient's primary care provider (PCP) of the administration or if none, to counsel the patient on the importance of having a relationship with a PCP. (motion by Melton, seconded by Miller; Babineau opposed; Arias abstained)

TOBACCO CESSATION

Dr. Stokes questioned how use bupropion and Chantix would be monitored; stated that behavioral aspects are very important and should require follow-up. Dr. Kerley indicated questionnaires have been used successfully. It was stated that day supply could be limited or require check-ins. Dean DiPiro stated pharmacists are being used increasingly in ambulatory settings and that this subject may be better addressed in that setting. He indicated that pharmacy students are taught to recognize suicidal behavior, perform assessments, and must complete a mental health therapeutic module and a semester-long communication course.

MOTION:

A motion was made by Dr. Melton, seconded by Dr. Abraham to include in the legislative report a recommendation that pharmacists should be authorized to initiate treatment with and dispense and administer drugs approved by the FDA for tobacco cessation therapy, including nicotine replacement therapy.

AMENDED MOTION:

A motion to amend the main motion to exclude Wellbutrin and Chantix was made by Dr. Babineau, seconded by Dr. Miller. The workgroup voted 7:7 with 1 abstention, therefore, the motion to amend the main motion failed due to a tie.

VOTE ON MAIN MOTION:

The workgroup voted 10:5 on the main motion to include in the legislative report a recommendation that pharmacists should be authorized to initiate treatment with and dispense and administer drugs approved by the FDA for tobacco cessation therapy, including nicotine replacement therapy. (supported by St.Clair, Wheawill, DiPiro, Proffitt, Gray, Goode, Musselman, Kerley, Abraham, Logan; opposed by Miller, Stokes, Arias, Lucas, Babineau; Melton departed meeting prior to vote; Collins and Jordan not present for vote).

TUBERCULIN PURIFIED PROTEIN DERIVATIVE FOR TUBERCULOSIS TESTING

Dr. Stokes recommended referral if the TB test was positive. There was little discussion as there appeared to be general support for this particular subject.

MOTION:

The workgroup voted 17:0 to include in the legislative report a recommendation that pharmacists should be authorized to initiate treatment with and dispense and administer tuberculin purified protein derivative for tuberculosis testing. (motion by Lucas, seconded by DiPiro; supported by St.Clair, Wheawill, DiPiro, Proffitt, Gray, Goode, Musselman, Kerley, Abraham, Logan, Miller, Stokes, Arias, Lucas, Babineau, Collins, and Jordan)

CONTROLLED SUBSTANCES OR DEVICES FOR THE TREATMENT OF DISEASES OR CONDITIONS FOR WHICH CLINICAL DECISION MAKING CAN BE GUIDED BY A CLIA-WAIVED TEST, INCLUDING INFLUENZA VIRUS, H. PYLORI BACTERIA, UTI, AND GROUP A STREPTOCOCCUS BACTERIA

It was determined that each condition should be considered separately. Dr. Lucas stated clinical acumen was important to identify the infrequent, serious conditions. Dr. Kerley shared her experience with a very strict protocol which excludes patients that need to be seen by a physician and requires repeat or failed therapy to be referred for immediate care. She recommended a step-wise approach. Dr. Babineau expressed concern for overlooking pneumonia. Dr. Stokes supported influenza due to timeliness of starting medication. Dr. Abraham indicated 17 states allow for CLIA-waived tests and that Tamiflu is slated to move to an over-the-counter status.

INFLUENZA MOTION:

The workgroup voted 15:3 to include in the legislative report a recommendation that pharmacists should be

authorized to initiate treatment with and dispense and administer controlled substances or devices for the treatment of influenza, following use of a CLIA-waived test to guide clinical decisions. (motion by Goode, seconded by DiPiro; supported by St.Clair, Wheawill, DiPiro, Proffitt, Gray, Goode, Musselman, Kerley, Abraham, Logan, Stokes, Lucas, Collins, Justice, and Jordan; opposed by Babineau, Miller, Arias)

HELICOBACTER PYLORI BACTERIA

Dr. Stokes and Dr. Babineau expressed concern for the complexity in diagnosing H. Pylori. Dean DiPiro shared this concern, but stated pharmacists can be very supportive of patient care following diagnosis. Dr. Babineau agreed with DiPiro.

MOTION:

The workgroup voted 13:0 with 4 abstentions to exclude H. Pylori as a recommendation in the legislative report for pharmacists to initiate treatment with and dispense and administer controlled substances or devices. (motion by Miller, seconded by Stokes; supported by St.Clair, DiPiro, Proffitt, Gray, Goode, Musselman, Logan, Stokes, Lucas, Justice, Babineau, Miller, Arias; Wheawill, Collins, Jordan, and Abraham abstained; Kerley not present for vote)

UTI

Dr. Stokes expressed concern for UTI test. Dr. Babineau agreed and stated that a culture test is necessary. Dr. Goode reminded the workgroup that Sen. Dunnavant was supported of the bill.

MOTION:

The workgroup voted 7:8 with 3 abstentions to exclude urinary tract infections as a recommendation in the legislative report for pharmacists to initiate treatment with and dispense and administer controlled substances or devices, therefore, the motion failed. (motion by Miller, seconded by Stokes; supported by Miller, Stokes, Arias, Lucas, Proffitt, Gray, Babineau; opposed by Logan, St.Clair, DiPiro, Goode, Musselman, Kerley, Abraham, Justice; Wheawill, Collins, Jordan abstained)

MOTION:

The workgroup voted 10:5 with 3 abstentions to include in the legislative report a recommendation that pharmacists should be authorized to initiate treatment with and dispense and administer controlled substances or devices for the treatment of urinary tract infections, following use of a CLIA-waived test to guide clinical decisions. (motion by Goode, seconded by

Abraham; supported by Logan, St.Clair, DiPiro, Proffitt, Gray, Goode, Musselman, Kerley, Abraham, Justice; opposed by Miller, Stokes, Arias, Lucas, Babineau; Wheawill, Collins, Jordan abstained)

**GROUP A STREPTOCOCCUS
BACTERIA**

Dr. Babineau expressed concern for CLIA-waived strep tests with false positives or false negatives, and that serious conditions could be missed. She stated diagnostic techniques are needed. Dr. Goode commented that US data suggests tests can be helpful. Dr. Abraham stated 17 states allow pharmacist-use of strep CLIA-waived tests. Dr. Goode stated if symptomatic with negative test pharmacist would refer patient and a confirmatory lab test could be performed. Dr. Babineau shared concern for testing during COVID-19 pandemic.

MOTION:

The workgroup voted 7:8 with 3 abstentions to exclude Group A Streptococcus bacteria as a recommendation in the legislative report for pharmacists to initiate treatment with and dispense and administer controlled substances or devices, therefore, the motion failed. (motion by Miller, seconded by Stokes; supported by Miller, Stokes, Arias, Lucas, Proffitt, Gray, Babineau; opposed by Logan, St.Clair, DiPiro, Goode, Musselman, Kerley, Abraham, Justice; Wheawill, Collins, Jordan abstained)

MOTION:

The workgroup voted 8:6 with 4 abstentions to include in the legislative report a recommendation that pharmacists should be authorized to initiate treatment with and dispense and administer controlled substances or devices for the treatment of Group A Streptococcus bacteria, following use of a CLIA-waived test to guide clinical decisions. (motion by Goode, seconded by Abraham; supported by Logan, St.Clair, DiPiro, Goode, Musselman, Kerley, Abraham, Justice; opposed by Miller, Stokes, Arias, Lucas, Proffitt, Babineau; Wheawill, Collins, Jordan, Gray abstained)

**CONTROLLED SUBSTANCES FOR
THE PREVENTION OF HUMAN
IMMUNODEFICIENCY VIRUS,
INCLUDING CONTROLLED
SUBSTANCES PRESCRIBED FOR
PRE-EXPOSURE AND POST-
EXPOSURE PROPHYLAXIS**

Ms. Jordan stated VDH believes a well-constructed protocol with a thorough assessment could meet public need. VDH has experience working with pharmacists performing HIV testing and that PEP and PrEP could be built into a protocol. Dr. Abraham echoed Ms. Jordan's comments. Dr. Babineau expressed concern for assessing creatinine clearance. It was stated that retail/community

**PURSUANT TO GUIDELINES AND
RECOMMENDATIONS OF THE CDC**

pharmacies have been very positive environments for HIV testing. Dr. Stokes commented that a protocol on this subject would provide a good service to a community and agreed that documentation of creatinine clearance would be important.

MOTION:

The workgroup voted unanimously 18:0 to include in the legislative report a recommendation that pharmacists should be authorized to initiate treatment with and dispense and administer controlled substances for the prevention of human immunodeficiency virus, including controlled substances prescribed for pre-exposure and post-exposure prophylaxis pursuant to guidelines and recommendations of the Centers for Disease Control and Prevention. (motion by Abraham, seconded by DiPiro; supported by Logan, St.Clair, DiPiro, Goode, Musselman, Kerley, Abraham, Justice, Miller, Stokes, Arias, Lucas, Proffitt, Babineau, Wheawill, Collins, Jordan, and Gray)

**DRUGS OTHER THAN
CONTROLLED SUBSTANCES,
INCLUDING DRUGS SOLD OVER
THE COUNTER, FOR WHICH THE
PATIENT’S HEALTH INSURANCE
PROVIDER REQUIRES A
PRESCRIPTION**

It was stated that this subject appears to have already been addressed by a statewide protocol recently adopted by the Board. It was acknowledged that the term “drugs” does not include “devices”. There were comments supportive of a pharmacist’s ability to prescribe devices such as glucometers, pen needles, syringes, and possibly other durable medical equipment. Dr. St.Clair recommended that a recommendation should not reference health insurance or limit the provision to times when the health plan is paying for it. Dr. Babineau expressed support and recommended that the provision be very specific. Dr. Stokes recommended looking at the Oregon protocol found on page 81 of the agenda packet. Mr. Gray and Dr. Babineau also supported Oregon’s approach.

MOTION:

The workgroup voted 17:0 with 1 abstention to include in the legislative report a recommendation that pharmacists should be authorized to initiate treatment with and dispense and administer devices to lower out-of-pocket expenses, not covered by a health plan. (motion by Goode, seconded by St.Clair; supported by Logan, St.Clair, DiPiro, Goode, Musselman, Kerley, Abraham, Justice, Miller, Stokes, Arias, Lucas, Proffitt, Babineau, Wheawill, Collins, and Gray; Jordan abstained.)

ADJOURNED:

With all business concluded, the workgroup adjourned the meeting at 2:14 pm.

Ryan Logan, Chairman

Caroline Juran, Executive Director

Date

Date