COMMONWEALTH of VIRGINIA

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TO: The Honorable Ralph S. Northam
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The Honorable Mark D. Sickles
Chair, House Committee on Health, Welfare and Institutions

The Honorable L. Louise Lucas
Chair, Senate Committee on Education and Health

The Honorable Patrick A. Hope
Chair, Joint Commission on Health Care

FROM: Caroline D. Juran
Executive Director, Board of Pharmacy

DATE: October 29, 2021

RE: **Report on Additional Protocols for Pharmacist Initiation of Treatment**

Attached is the report of the Board of Pharmacy on recommendations regarding the protocols for initiation of treatment with and dispensing and administration of drugs by pharmacists for certain diseases or conditions pursuant to HB2079 of the 2021 Special Session I of the General Assembly.

The report comes from a workgroup composed of an equal number of representatives of the Boards of Pharmacy and Medicine along with other stakeholders that convened to discuss and make recommendations regarding the developing of protocols for the initiation of treatment with and dispensing and administering of certain drugs and devices by pharmacists to persons 18 years of age or older.

Should you have questions about this report, please feel free to contact me at caroline.juran@dhp.virginia.gov or at (804) 367-4578.

Virginia Department of Health Professions

Report on the Development of Recommendations for Possible Statewide Protocols for Pharmacists to Initiate Treatment for Tobacco Cessation and other Specific Conditions: HB2079

OCTOBER 15, 2021

VIRGINIA BOARD OF PHARMACY

VIRGINIA DEPARTMENT OF HEALTH PROFESSIONS

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I. EXECUTIVE SUMMARY

Pursuant to the fourth enactment clause of House Bill 2079 passed during the 2021 General Assembly Session, the Board of Pharmacy convened a work group on August 16, 2021 to develop recommendations for possible statewide protocols for pharmacists to initiate treatment for tobacco cessation and conditions for which CLIA-waived tests may be used to guide clinical diagnosis and treatment, including influenza, Group A Streptococcus, and urinary tract infections. Motions regarding recommendations for statewide protocols for tobacco cessation, Group A Streptococcus, and urinary tract infections failed and therefore, no recommendations resulted. A motion to not recommend a statewide protocol for treating influenza passed 3:1.

Work Group Members

Kris Ratliff, DPh
Work Group Chairman
Board of Pharmacy member*

Sarah Melton, PharmD
Board of Pharmacy member*

Jacob Miller, D.O.
Board of Medicine member*

Brenda Stokes, M.D.
Board of Medicine member*

Laurie Forlano, D.O., MPH
Deputy Director, Office of Epidemiology
Virginia Department of Health

Will Hockaday, Tobacco Control Program/Outreach Coordinator
Virginia Department of Health

Kristin Collins, MPH
Policy Analyst Office of Epidemiology
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Kelly Goode, PharmD, BCPS, FAPhA, FCCP
Virginia Commonwealth University School of Pharmacy

Iain Pritchard, PharmD, BCACP
Shenandoah University, Bernard J. Dunn School of Pharmacy

Zahra Raza, M.D.
Virginia Commonwealth University School of Pharmacy

John R. Lucas, D.O.
Edward Via College of Osteopathic Medicine

Michelle Thomas, PharmD, CDE, BCACP
Virginia Pharmacists Association

Wendy Klein, M.D.
Medical Society of Virginia

*Voting members

II. PHARMACIST EDUCATION AND TRAINING STANDARDS

A brief overview of pharmacist educational and training standards was provided by Dr. Goode. She indicated that 80-90% of students at VCU School of Pharmacy already have a Bachelor of Science degree upon entry into the Doctor of Pharmacy (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 course 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 regarding infectious diseases such as urinary tract infections, Strep, Influenza, and Tobacco Cessation. Dr. Goode indicated that older pharmacists who graduated with a Bachelor's of Science degree in pharmacy are well-prepared to participate in protocols, but may need some additional training in motivational interviewing techniques relative to those pharmacists who graduated with a PharmD degree.

III. PHARMACIST HEALTHCARE WORKFORCE SURVEY RESULTS

Dr. Ratliff provided a summary of the 2020 draft Pharmacist Healthcare Workforce Suvey results. He reported that 11% of pharmacists work in a non-metro area, 68% have earned a doctorate or ther professional degree, 19% have completed a PGY1 residency, 7% have completed a PGY2 residency, and 10% hold a board certification. Among those participating in collaborative practice agreements, common disease management included: anticoagulation, hypterention, hypercholesterolemia, asthma, tobacco cessation, travel medications, and diabetes.

IV. TOBACCO CESSATION

Fourteen states have laws addressing pharmacist prescribing of tobacco cessation aids without a collaborative practice agreement. The work group discussed the merits and challenges to allowing a statewide protocol for pharmacists to initiate drug therapy for tobacco cessation. Pharmacist members, along with the VDH Tobacco Control Program/Outreach Coordinator appeared to believe that additional access points could assist with the increased number of patients that are returning to smoking during the pandemic, that the state quit help line could be included in a protocol to provide support via qualified representatives with therapy skills to improve the success of quitting, and that patient harm with continued smoking would continue if access to these medications is not expanded. Physician members generally expressed the following considerations: the protocol included in the agenda packet used by another state seemed complicated; importance of follow-up within 7-21 days; a protocol should be limited to over-the-counter nicotine replacement therapy due to negative effects of the prescription-only drugs used for this purpose; desire to retain treatment option of prescribing prescription-

only drugs when patient who has failed on over-the-counter nicotine replacement therapy presents to physician; difficulty for some patients to complete a self-screening tool based on language barriers; and access to care will open up following the pandemic and telemedicine is currently increasing access.

Recommendation - No recommendation was offered by the work group.

A motion to recommend that pharmacists be authorized to initiate treatment with only over-the-counter nicotine replacement therapy failed 2:2 (motion by Dr. Stokes, seconded by Dr. Miller; opposed by Dr. Ratliff and Dr. Melton). A second motion to recommend that pharmacists be authorized to initiate treatment with both over-the-counter nicotine replacement therapy and the prescription-only drugs varenicline and bupoprion also failed 2:2 (motion by Dr. Melton, seconded by Dr. Ratliff; opposed by Dr. Stokes and Dr. Miller.

V. CONDITIONS WITH CLIA-WAIVED TESTS

A. Influenza

During discussion physician work group members generally offered the following considerations: concern for lack of training regarding physical exams and risk of misdiagnosing pneumonia; concern that protocols from other states don't include a requirement for a physical exam; risk that a protocol may encourage some patients to be seen at a pharmacy when they should be seen at an urgent care center; delays in receiving lab results may exceed window of opportunity for initiating treatment; difficulty in developing a protocol that could address all patients; and, the possibility of inappropriate prescribing of antibiotics increasing antibiotic resistance. The following considerations were generally offered by pharmacist work group members: pharmacy students minimally complete a 2-credit hour course on physical assessment training with 4 practical sessions; FDA is currently evaluating if Tamiflu should be made available over-the-counter based on its safety profile; and, a statewide protocol for pharmacists would allow patients to receive care at night and on the weekends when physician offices are often closed. Dr. Lucas offered that schools of medicine and pharmacy could collaborate regarding training for conducting physical exams, focusing on the diseases mentioned in the agenda. Dr. Forlano commented that a protocol should include antibiotic stewardship and that the pharmacist at VDH that oversees this program could serve as a resource.

Recommendation: 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 Dr. Stokes, seconded by Dr. Miller; opposed by Dr. Melton).

B. Group A Streptococcus

Dr. Goode stated that pharmacists in other states are referring patients to primary care providers as appropriate and not inappropriately prescribing antibiotics. Dr. Klein expressed concern that something could be missed and that it can be difficult to identify salivary glands compared to lymph nodes. Dr. Raza stated that Group A Streptococcus is less prevalent in patients 18 years of age and older and can be more complicated.

Recommendation: No recommendation was offered by the work group. A motion to not include a recommendation for a statewide protocol for treating Group A Streptococcus in the work group's report failed 2:2 (motion by Dr. Miller, seconded by Dr. Stokes; opposed by Dr. Melton and Dr. Ratliff).

C. Urinary Tract Infections

The following comments were generally offered by physician work group members: the co-infection rate of sexually transmitted diseases for patients aged 18-45 with urinary tract infections is 20%; concern that patients may not provide a good history; symptoms for a younger patient may vary from an older patient with diabetes, prostate issues, or co-infection; concern if a protocol could appropriately address all of the variabilities; concern that pharmacists may not be able to rule out other infections; and question if urine samples would also be sent to laboratories for further analysis. The pharmacist work group members generally expressed the following: pharmacists in Canada have been doing this since 2014 and that there is good data on their program; concern for patients unnecessarily driving up healthcare costs by presenting at emergency departments or urgent care centers at night or on weekends with urinary tract symptoms that could be addressed or triaged at a pharmacy.

Recommendation: No recommendation was offered by the work group. A motion to not include in the work group's report a recommendation for a statewide protocol for treating urinary tract infections failed 2:2 (motion by Dr. Stokes, seconded by Dr. Miller; opposed by Dr. Ratliff and Dr. Melton).