COMMONWEALTH of VIRGINIA

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MEMORANDUM

TO: Jeff Lunardi
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FROM: Caroline D. Juran, RPh
Executive Director, Virginia Board of Pharmacy
Department of Health Professions

DATE: October 28, 2020

RE: **Report on Expansion of Statewide Standing Orders/Development of Protocols for Pharmacist-Initiation of Treatment**

This report is provided to you pursuant to a written request from the Joint Commission on Health Care dated February 10, 2020. Please feel free to contact me at (804) 367-4578 or caroline.juran@dhp.virginia.gov should you have any questions.

Report on Expansion of Statewide Standing Orders/Development of Protocols for Pharmacist-Initiation of Treatment

Virginia Department of Health Professions

Pursuant to Request from Joint Commission on Health Care and HB 1506

October, 2020

Expansion of Statewide Standing Orders/Development of Protocols for Pharmacist-Initiation of Treatment

Virginia Board of Pharmacy

Pursuant to Request from Joint Commission on Health Care and HB 1506

The request from Joint Commission on Health Care (JCHC), dated February 10, 2020 specifies:

"...that the Board of Pharmacy and the Board of Medicine convene a work group of expert stakeholders to develop recommendations regarding the expansion of statewide standing orders to include additional conditions for which CLIA Waiver tests exist and drugs, (e.g., antiviral drugs, hormonal birth control and smoking cessation drugs) that may be dispensed by a licensed pharmacist without a practitioner prescription. Recommendations should include whether, and if so what, additional training is required in order for a licensed pharmacist to dispense any new drug added to a statewide standing order and whether, and if so what, other requirements may be needed to ensure that new dispensing authorities will pose no risk to individual or public health.

The work group should include members from the Virginia Boards of Pharmacy and Medicine and may include other expert stakeholders, such as representatives from the Virginia Department of Health, the Virginia Department of Medical Assistance Services and the Office of the Secretary of Health and Human Resources. The work group shall provide recommendations to the Joint Commission on Health Care by October 1, 2020 and may reconvene periodically thereafter to address any additions and/or changes to statewide standing orders. Recommendations from additional meetings shall be provided to the Commission as they are determined."

The third enactment clause of HB 1506 specifies:

3. That the Board of Pharmacy (the Board) shall establish a work group consisting of representatives of the Board of Medicine, the Department of Health, schools of medicine and pharmacy located in the Commonwealth, and such other stakeholders as the Board may deem appropriate to 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 (i) vaccines included on the Immunization Schedule published by the Centers for Disease Control and Prevention; (ii) drugs approved by the U.S. Food and Drug Administration for tobacco cessation therapy, including nicotine replacement therapy; (iii) tuberculin purified protein derivative for tuberculosis testing; (iv) controlled substances or devices for the treatment of diseases or conditions for which clinical decision making can be guided by a clinical test that is classified as waived under the federal Clinical Laboratory Improvement Amendments (CLIA) of 1988, including influenza virus, Helicobacter pylori bacteria, urinary tract infection, and group A Streptococcus bacteria; (v) 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; and (vi) drugs other than

controlled substances, including drugs sold over the counter, for which the patient's health insurance provider requires a prescription. The work group shall report its findings and recommendations to the Governor and the Chairmen of the House Committee on Health, Welfare and Institutions and the Senate Committee on Education and Health by November 1, 2020.

In accordance with the request from the JCHC and the legislative provision, the Board of Pharmacy reports the following information:

WORK GROUPS:

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 Board of Pharmacy convened two virtual work group meetings on August 4, 2020 and August 17, 2020.

The work group was comprised of the following voting individuals:

Ryan Logan, RPh, *Work group Chairman, Member, Board of Pharmacy*
Kris Ratliff, DPh, *Chairman, Board of Pharmacy*
Jake Miller, D.O., *Member, Board of Medicine*
Brenda Stokes, M.D., *Member, Board of Medicine*
Emily Yeatts, *Reproductive Health Supervisor, VDH*
Stephanie Wheawill, PharmD, *VDH, Director of Division of Pharmacy Services*

A second work group convened a virtual meeting on September 21, 2020 to 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 for other conditions as specified in the third enactment clause of HB 1506.

The work group was comprised of the following voting individuals:

Ryan Logan, RPh, *Work group Chairman, Member, Board of Pharmacy*
Sarah Melton, PharmD, *Member, Board of Pharmacy (departed early)*
Dale St.Clair, PharmD, *Member, Board of Pharmacy (replaced Dr. Melton)*
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*
Al Arias, M.D., *VCU, School of Medicine*
John R. Lucas, D.O., *Edward Via College of Osteopathic Medicine*
Donna Francioni-Proffitt, RPh, *Pharmacy Program Manager, DMAS*
Doug Gray, *Executive Director, Virginia Association of Health Plans*
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*

The following individuals staffed the work group meetings:
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*

RECOMMENDATIONS:

The work group that met in August developed recommended statewide protocols for the following subjects as required by HB 1506 which were adopted by the Board of Pharmacy on September 9, 2020: naloxone, other opioid antagonist, including paraphernalia; epinephrine; prenatal vitamins; fluoride supplements; over-the-counter medications; and, hormonal contraceptives. Pharmacists may begin initiating drug treatment consistent with the protocols once the regulations become effective.

The following recommendations were offered by the work group that met September pursuant to the third enactment clause of HB 1506:

Vaccines

The work group was generally supportive and 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 Centers for Disease Control and Prevention 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

There was some concern expressed by physician members for how a pharmacist would monitor certain prescription-only drug therapies requiring the monitoring of patient behavioral aspects. Pharmacist members generally believed that monitoring is currently being performed successfully through questionnaires in other states, could be addressed through a limitation of day supply or required follow-up appointments, and stated that pharmacy students are taught to recognize suicidal behavior, how to perform patient assessments, and must complete a mental health therapeutic module, along with a semester-long communication course.

After a failed motion to exclude these prescription-only drugs from an allowance for pharmacists to initiate treatment, the work group voted 10:5 that pharmacists should be authorized to initiate treatment with and dispense and administer drugs approved by the United States Food and Drug Administration for tobacco cessation therapy, including nicotine replacement therapy. (motion by Melton, seconded by Abraham; 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

The work group appeared to be in agreement on this subject and 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:

Influenza

There was some disagreement regarding the use of a CLIA-waived test to guide clinical decisions regarding influenza. A physician member expressed concern for possibly overlooking pneumonia. Another physician member expressed support based on ability to increase timeliness in patients starting medication treatment. Pharmacist members generally supported the ability, indicated seventeen states allow use of CLIA-waived tests, and stated that the prescription-only drug, Tamiflu, is slated to move to an over-the-counter status.

The work group 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

There appeared to be general agreement among physician and pharmacist members that diagnosing medical conditions involving Helicobacter Pylori bacteria was complex. The work group voted 13:0 with 4 abstentions to exclude Helicobacter Pylori as a condition for pharmacists to initiate treatment with and dispense and administer controlled substances or devices.

Urinary Tract Infection

Two physician members expressed concern for using a CLIA-waived test to guide clinical decisions regarding urinary tract infections and stated that a more complex culture test is necessary. Pharmacist members appeared to disagree. After a failed motion with a vote of 7:8 with 3 abstentions to exclude urinary tract infections as a recommendation in the legislative report, the work group 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

There was some disagreement regarding the use of CLIA-waived tests for group A streptococcus bacteria. Some physician members expressed concern for the possibility of false negative or false positive tests, that a serious condition could be missed, and that diagnostic techniques are needed. Pharmacist members indicated U.S. data suggests these CLIA-waived tests can be helpful, reiterated that seventeen states allow pharmacist-use of CLIA-waived tests, and stated that the protocol should require a pharmacist to refer a symptomatic patient with a negative CLIA-waived test to a primary care provider for a confirmatory lab test.

After a failed motion with a vote of 7:8 with 3 abstentions to exclude Group A Streptococcus bacteria as a recommendation, the work group 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 Pursuant to Guidelines and Recommendations of the Centers for Disease Control and Prevention

VDH members indicated a well-constructed statewide protocol with a thorough assessment could meet public need, VDH has experience working with pharmacists performing HIV testing, and that Pre-Exposure Prophylaxis (PrEP) and Post-Exposure Prophylaxis (PEP) could be built into a protocol. The work group 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

The work group acknowledged that this subject appears to have already been addressed by a statewide protocol recently adopted by the Board. It was noted that the term "drugs" as defined in law does not include "devices". The workgroup supported a pharmacist's ability to prescribe devices such as glucometers, controlled paraphernalia such as insulin pen needles and syringes, and possibly other durable medical equipment.

The work group 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, controlled paraphernalia such as insulin pen needles and hypodermic syringes, and possibly other durable medical equipment 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.)