

---FINAL APPROVED---

Statewide Pharmacy Protocols
Work Group

Monday, August 8, 2022

Department of Health Professions

Henrico, VA

CALL TO ORDER: Dr. Miller called the meeting to order at 9:08 a.m.

ROLL CALL Ms. Opher called the roll; a quorum was declared.

MEMBERS PRESENT: Jacob Miller, DO, Chair – Board of Medicine
Laura Forlano, MD – Department of Health
William Hutchens, MD – Board of Medicine
William Lee, DPh, MPA, FASCP – Board of Pharmacy
Patricia Richards-Spruill, RPh – Board of Pharmacy
Joel Silverman, MD – Board of Medicine
Stephanie Wheawill, PharmD – Department of Health
Ling Yuan, PharmD – Board of Pharmacy

MEMBERS ABSENT: None

STAFF PRESENT: William L. Harp, MD, Executive Director – Board of Medicine
Caroline Juran, RPh – Executive Director - Board of Pharmacy
Colanthia Morton Opher, Deputy Executive Director for Administration
Erin Barrett, DHP Senior Policy Analyst
Danielle Sangiuliano, Administrative Assistant

OTHERS PRESENT: Jennifer Deschenes, JD
Michael Sobowale, LLM

EMERGENCY EGRESS INSTRUCTIONS

Dr. Harp welcomed the members and provided the emergency egress instructions.

INTRODUCTION OF WORK GROUP MEMBERS

Dr. Miller asked everyone around the table to introduce themselves and provide a brief overview of their background, after which he identified the eight members designated to vote on agenda items.

ADOPTION OF AGENDA

Dr. Silverman moved to adopt the agenda as presented. The motion was seconded and carried unanimously.

PUBLIC COMMENT ON AGENDA ITEMS

Dr. Miller opened the floor for public comment. There being none, the floor was closed.

CHARGE OF THE WORK GROUP

Dr. Harp reminded the members that the work group was formed to address HB1323 from the 2022 Session which seeks to amend and reenact §§32.1-325, 54.1-3303.1, and 54.1-3321 of the Code relating to pharmacists; initiation of treatment with and dispensing and administration of vaccines. Dr. Harp noted that the Board of Pharmacy had led the Statewide Pharmacy Protocols work group for the last 2 years and produced 7 protocols that became effective in 2021. The 2022 law has 3 new protocol requirements.

54.1-3303.1 – Initiating of treatment with and dispensing and administering of controlled substances by pharmacists

54.1-3303.1(A)

Notwithstanding the provisions of 54.1-3303, a pharmacist may initiate treatment with, dispense, or administer the following drugs, devices, controlled paraphernalia, and other supplies and equipment to persons 18 years of age or older with whom the pharmacist has a bona fide pharmacist-patient relationship and in accordance with a statewide protocol developed by the Board in collaboration with the Board of Medicine and the Department of Health and set forth in regulations of the Board:

7. Vaccines included on the Immunization Schedule published by the Centers for Disease Control and Prevention and vaccines for COVID-19

10. Nicotine replacement and other tobacco cessation therapies, including controlled substances as defined in the Drug Control Act (§ [54.1-3400](#) et seq.), together with providing appropriate patient counseling; and

11. Tests for COVID-19 and other coronaviruses.

54.1-3303.1(B)

Notwithstanding the provisions of § [54.1-3303](#), a pharmacist may initiate treatment with, dispense, or administer the following drugs and devices to persons three years of age or older in accordance with a statewide protocol as set forth in regulations of the Board:

1. Vaccines included on the Immunization Schedule published by the Centers for Disease Control and Prevention and vaccines for COVID-19; and

2. Tests for COVID-19 and other coronaviruses.

The italicized language in the sections below may or may not need to be incorporated into new and existing protocols.

54.1-3303.1(C)

A pharmacist who initiates treatment with or dispenses or administers a drug or device pursuant to this section shall notify the patient's primary health care provider that the pharmacist has initiated treatment with such drug or device or that such drug or device has been dispensed or administered to the patient, provided that the patient consents to such notification. *No pharmacist shall limit the ability of notification to be sent to the patient's primary care provider by requiring use of electronic mail that is secure or compliant with the federal Health Insurance Portability and Accountability Act (42 U.S.C. § 1320d et seq.).* If the patient does not have a primary health care provider, the pharmacist shall counsel the patient regarding the benefits of establishing a relationship with a primary health care provider and provide information regarding primary health care providers, including federally qualified health centers, free clinics, or local health departments serving the area in which the patient is located. If the pharmacist is initiating treatment with, dispensing, or administering injectable or self-administered hormonal contraceptives, the pharmacist shall counsel the patient regarding seeking preventative care, including (i) routine well-woman visits, (ii) testing for sexually transmitted infections, and (iii) pap smears.

54.1-3303.1(D)

A pharmacist who administers a vaccination pursuant to *subdivisions A 7 and B 1* shall report such administration to the Virginia Immunization Information System in accordance with the requirements of § [32.1-46.01](#).

54.1-3303.1(E)

A pharmacist who initiates treatment with, dispenses, or administers drugs, devices, controlled paraphernalia, and other supplies and equipment pursuant to this section shall obtain a history from the patient, including questioning the patient for any known allergies, adverse reactions, contraindications, or health diagnoses or conditions that would be adverse to the initiation of treatment, dispensing, or administration.

54.1-3303.1(F)

A pharmacist may initiate treatment with, dispense, or administer drugs, devices, controlled paraphernalia, and other supplies and equipment pursuant to this section through telemedicine services, as defined in § [38.2-3418.16](#), in compliance with all requirements of § [54.1-3303](#) and consistent with the applicable standard of care.

54.1-3303.1(G)

A pharmacist who administers a vaccination to a minor pursuant to subdivision B 1 shall provide written notice to the minor's parent or guardian that the minor should visit a pediatrician annually.

And,

54.1-3321 Registration of pharmacy technicians

8. *Under the supervision of a pharmacist, meaning the supervising pharmacist is at the same physical location of the technician or pharmacy intern, and consistent with the requirements of § 54.1-3303.1, administration of the following drugs and devices to persons three years of age or older as set forth in regulations of the Board: vaccines included on the Immunization Schedule published by the Centers for Disease Control and Prevention and vaccines for COVID-19;*

For clarification, Dr. Miller advised that the Work Group would review and make recommendations to the draft protocols, after which development of regulations and updates will fall under the purview of the Board of Pharmacy.

Vaccines

Dr. Miller led the members in a discussion of vaccines while referring to the existing Pharmacist Vaccine State Protocol that became effective December 22, 2021, the CDC Recommended Child and Adolescent Immunization Schedule, the CDC information on COVID-19 vaccines, the HHS renewal of the public health emergency on April 12, 2022, and the draft Vaccine Statewide Protocol.

After a robust discussion, the Work Group members unanimously agreed to the following modification of the draft document identified as the “Vaccine Statewide Protocol” which addresses the administration of vaccines to persons 3 years of age or older to become effective upon the expiration of the provisions of the federal Declaration Under the PREP Act. Ms. Juran indicated she would recommend to the Board of Pharmacy that it amend the current “Pharmacist Vaccine Statewide Protocol”, which addresses administration of vaccines to persons 18 years of age and older, in a similar manner.

PATIENT INCLUSION CRITERIA

Amend the first bullet to reflect the following:

An individual 3 years of age or older whose immunization history is incomplete or unknown and for whom a vaccine is recommended at his or her age in accordance with the most current Child and Adolescent Immunization Schedule or the Adult Immunization Schedule published by the CDC inclusive of additional information for COVID-19 vaccination.

Amend the third bullet to reflect the following:

PATIENT EXCLUSION CRITERIA

The following patients are NOT eligible for vaccines under this protocol:

- An individual who ~~is fully vaccinated~~ has received all CDC recommended doses for their age, medical condition or other indicators.

Break

The Work Group took a 15-minute break and reconvened at 10:37 a.m.

Nicotine Replacement and other Tobacco Cessation Therapies

The Work Group reviewed two articles created by the American Cancer Society on nicotine replacement and prescription medicines for tobacco cessation, existing protocols from Oregon, North Carolina, Indiana, and Utah, as well as a draft “Virginia Board of Pharmacy Pharmacist Statewide Protocol for Tobacco Cessation.”

After discussion, the Work Group unanimously agreed to:

1. Adopt the proposed “Virginia Board of Pharmacy Pharmacist Statewide Protocol for Tobacco Cessation” to be derived by staff from the Oregon Protocol with the presentation of information similar to that used in the North Carolina Protocol. This will standardize the process and systematically identify at-risk patients.
2. Include guidance on patient counseling; and,
3. Include the requirement for the pharmacist to notify the patient’s primary care provider.

COVID-19 Testing

Dr. Miller acknowledged the pharmacist’s ability to currently conduct COVID-19 testing, and pointed out that the purpose of this protocol was to address the addition of individuals 3 years and older.

It was noted that this protocol does not become effective until the federal emergency ends.

After discussion, the Work Group unanimously agreed to adopt the draft Virginia Board of Pharmacy Pharmacist Statewide Protocol for Coronavirus Testing with the following amendments:

FIRST PARAGRAPH

Consistent with Virginia Code Section 54.1-3303.1 and CLIA requirements administered by the U.S. Food and Drug Administration, a pharmacist may initiate ~~treatment with, dispense, or and~~ administer tests for COVID-19 and other coronaviruses to persons ~~18~~ 3 years of age or older.

RECORDKEEPING

The pharmacist shall maintain records in accordance with 18VAC110-21-46 and shall report all positives to the local or state health department in accordance with 32.1-36 and 12VAC5-90.

EXCLUSIONS

Nothing shall preclude a pharmacist, pharmacy technician, or pharmacy intern under the supervision of a pharmacist, meaning that the pharmacist is at the same physical location as the pharmacy technician or pharmacy intern, from performing CLIA-waived tests in accordance with the Food and Drug Administration's CLIA requirements.

Adjournment

Dr. Miller provided the travel reimbursement instructions to the Work Group. With no other business to conduct the meeting adjourned at 11:29 a.m.

William L. Harp, MD
Executive Director