

(FINAL/APPROVED)

VIRGINIA BOARD OF PHARMACY
MINUTES OF STATEWIDE PROTOCOLS WORKGROUP TO INITIATE TREATMENT

Tuesday, August 4, 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 9:13 AM. 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 regulatory and 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*
Jake Miller, *D.O., Member, Board of Medicine*
Brenda Stokes, *M.D., Member, Board of Medicine*
Emily Yeatts, *VDH, Reproductive Health Supervisor*
Stephanie Wheawill, *PharmD, VDH, Director of
Division of Pharmacy Services*

**STAFF PARTICIPATING
VIRTUALLY:**

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

Due to inclement weather and state offices in the metro-Richmond area being closed this day, all workgroup members and staff listed above participated virtually. No other workgroup members or staff participated virtually or from the Perimeter Center building.

**APPROVAL OF AGENDA:
MOTION:**

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

PUBLIC COMMENT:

As noticed in the agenda, Mr. Logan invited those persons who had requested via email to offer comment prior to 8am on August 4, 2020 to offer public comment to the workgroup.

Clark Barrineau, representing Medical Society of Virginia, thanked everyone for a good legislative session and emphasized that it is critical to keep the requirement for referral to primary care providers in mind during the development of the statewide protocols.

Christina Barrille, Executive Director, Virginia Pharmacists Association (VPhA), shared that it introduced HB1506. She thanked Delegate Sickles, Senator Dunnavant and the Medical Society of Virginia for their assistance with the legislation. She said that VPhA members are excited to offer patients another convenient access to point of care and bridging the gap and referring patients back to physicians in order to provide a better relationship between patients and their medical provider. She offered support to the workgroup.

Jill McCormack, Regional Director of Government Affairs for the National Association of Chain Drug Stores, echoed Ms. Barrille's comments about the work that went into the legislative session. She recommended that the workgroup consider protocols that address generally accepted standards of care vs. specific requirements dictating how pharmacist must provide care to patients. She offered that pharmacists should not be required to complete redundant training that could create barriers. She asked that the counseling requirement for naloxone be made broader allowing pharmacist the flexibility to use the best available and most up to date information for education, instead of a specific brochure. She asked that the workgroup allow access to all possible contraceptive options that may be appropriate given unique circumstances and preferences, and that the workgroup not replicate the 15-day waiting period required of Maryland as this appears arbitrary and creates delays. She requested the protocol for prenatal vitamins replace "evidence based

guidelines” and with a reference to ACOG, WHO, or FDA guidelines.

Jodi Roth, representing the Virginia Association of Chain Drug Stores, echoed comments of Christina Barrille and Jill McCormack.

**CHARGE OF WORKGROUP, 2nd
Enactment Clause of HB 1506:**

Mr. Logan reviewed the charge of the workgroup, and Ms. Juran provided background of HB 1506. It was noted that this workgroup will meet twice to develop recommended statewide protocols for board consideration for pharmacists to initiate treatment with, dispense, or administer the following drugs and devices to persons 18 years of age or older:

- Naloxone, or other opioid antagonist, including paraphernalia for administering it;
- Epinephrine;
- Injectable or self-administered hormonal contraception provided the patient completes an assessment consistent with the United States Medical Eligibility Criteria for Contraceptive Use;
- Prenatal vitamins for which a prescription is required;
- Dietary fluoride supplement, in accordance with the American Dental Association for prescribing of such supplements for persons whose drinking water has a fluoride content below recommendation of the US Department of Health and Human Services;
- Medication covered by the patient’s health carrier when the patients out-of-pocket cost is lower than out-of-pocket purchase of the over-the-counter equivalent of the same drug.

It was stated the workgroup must also develop recommended emergency regulations for board consideration to implement the provisions.

**OVERVIEW OF PHARMACIST
EDUCATIONAL/TRAINING
STANDARDS:**

Dave L. Dixon, PharmD, FACC, FCCP, FNLA, BCPS, BCACP, CDCES, CLS, Associate Professor in Ambulatory Care and Vice Chair of Clinical Services in the Department of Pharmacotherapy and Outcome Science at the Virginia Commonwealth University School of Pharmacy, shared a PowerPoint presentation (Attachment

1) and provided a brief overview of Pharmacy Education and Training Standards. He concluded: detailed dosing guidelines in the statewide protocols are likely unnecessary as dosing for epinephrine, naloxone, prenatal vitamins, fluoride, and OTC medications is standardized and does not change; hormonal contraception dosing is based on symptoms and patient preference, and that additional guidance or training on assessing symptoms and patient preferences may be appropriate; and, that pharmacists regularly dispense and make dosing recommendations for the medications being discussed today, therefore, additional guidance or training is not needed.

REVIEW OF WORKFORCE STATISTICS:

Ms. Juran shared the following statistics from the Draft 2019 Pharmacist Workforce Survey:

- 15,875 pharmacist licensees, 97% of renewing pharmacists responded to the survey;
- 8,734 in Virginia's workforce with 7,137 FTEs;
- Large community pharmacies (>10 locations) most common working establishment, followed by hospital pharmacies and smaller pharmacies;
- Educational attainment continues to increase; 66% in 2019 held pharmacy doctorate with 34% holding baccalaureate;
- 19% completed 1-year residency program; 7% completed 2-year residency program; 10% hold board certification;
- 66% female, median age of 44;
- 528 participate in collaborative practice management agreements involving anticoagulation, diabetes, hypertension, hypercholesterolemia, asthma, tobacco cessation, or travel medications;
- 32% provide immunization services, 29% provide medication management services, and 25% provide compounding services.

RECOMMENDED COMPONENTS OF STATEWIDE PROTOCOL:

The workgroup reviewed the excerpt included in the agenda packet from *PHARMACIST STATEWIDE PROTOCOLS: KEY ELEMENTS FOR LEGISLATIVE AND REGULATORY AUTHORITY*, March 2017.

**DEVELOPMENT OF
RECOMMENDED STATEWIDE
PROTOCOLS:**

The workgroup discussed the material included in the agenda packet for each drug category.

**Naloxone, other opioid antagonist,
including paraphernalia**

Dr. Stokes questioned if there could be some inclusion criteria put into the guidance similar to Board of Medicine (BOM) co-prescribing requirements. It was noted that certain populations should be excluded from receiving naloxone such as hospice or end of life patients. Staff noted they would refer to the BOM regulations for possible language.

Ms. Juran confirmed that the dispensing of naloxone would be reported to the PMP. Dr. Wheawill commented about the counseling requirement. Ms. Yeatts suggested that the Department of Behavioral Health and Developmental Services be consulted regarding use of the REVIVE! Brochure. Ms. Juran confirmed for Dr. Miller that the pharmacist cannot require the patient to obtain the naloxone.

Epinephrine

Dr. Miller recommended the protocol should allow for prescribing/dispensing epinephrine to children. However, the current statute restricts protocols to 18 years of age and older. Under Patient Inclusion Criteria, it was recommended to insert "or demonstrating signs and symptoms of anaphylaxis" after "at risk for experiencing anaphylaxis". It was suggested to include language on how to identify persons "at risk" such as someone with a dispensing history of obtaining epinephrine or who informs the pharmacist of a history of allergies that could result in anaphylaxis.

Prenatal Vitamins

The workgroup identified that sometimes patients use their OB/GYN as their primary care provider, and offered that the notification should be to the patient's primary care provider and/or OB/GYN. Under Pharmacist Education and Training, Ms. Juran noted that NACDS provided comment suggesting that "evidence based guidelines" be replaced with "guidelines from ACOG, FDA, or WHO". Dr. Stokes recommended leaving as written since the broader language would include these specific guidelines. Staff reported that the referenced statute under Notification of Primary Care Provider in all of the draft protocols should read 54.1-3303.1.

Fluoride Supplements

Ms. Juran shared that the American Dental Association (ADA) does not recommend the use of fluoride supplements to persons over the age of 16. Ms. Yeatts recommended that the protocol should simply read that the ADA does not recommend the use of fluoride supplements in persons 18 years of age and older.

Over-the-Counter Medications

The workgroup had some discussion about the term “equivalent” and if the protocol was intended to capture both OTC drugs and prescription drugs. Suggested examples provided for the protocol included the prescribing of an OTC if the health carrier would cover the expense which may be cheaper than paying out-of-pocket for the OTC drug, and the prescribing of a prescription drug in the same therapeutic class as an OTC drug, e.g., nasal corticosteroid sprays or antacids, that may be covered by the health carrier and cheaper than paying out-of-pocket for the similar or “equivalent” OTC drug. Mr. Ratliff recommended the protocol also include needles, syringes, and diabetic test strips, because often the prescriber fails to issue a prescription for these accompanying items. There was some discussion regarding whether “medication” included paraphernalia and medical devices.

Hormonal Contraceptives

Ms. Emily Yeatts and Dr. Stokes indicated they liked Colorado’s protocol, algorithm, and color-coded questionnaire the best of the options provided in the agenda packet. Both recommended that the protocol should include emergency contraception. Ms. Emily Yeatts recommended inserting “vaping” in the questionnaire and including a question about use of emergency contraception in the last five days. For depot medroxyprogesterone acetate, it was recommended to look at Oregon or California’s algorithm. There was discussion that pharmacists should be required to obtain ACPE-accredited training through continuing education as was recommended by Dr. Dixon from VCU. It was noted that several states appear to recognize a 4-hour online ACPE-accredited program. Staff indicated they would work on preparing a draft protocol for the next meeting.

Regulations

There was discussion that the regulations should include a recordkeeping requirement. Ms. Elaine Yeatts recommended looking at the Board of Medicine’s requirements of six years. There was consensus that six years would not be overly burdensome.

ADJOURNED:

With all business concluded, the workgroup adjourned the meeting at 12:33 pm.

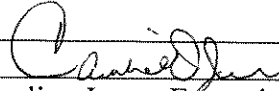


Ryan Logan, Chair

KRISTOPHER S. RATLFF

9-9-2020

Date



Caroline Juran, Executive Director

9/9/2020

Date