(FINAL/APPROVED)

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

Tuesday, August 17, 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 9:03 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*
William Lee, *Member, 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* (departed meeting during discussion of contraceptive protocols due to availability conflict and rejoined prior to conclusion of this topic discussion)
Christy Gray, MPH, CHES, CHTS-CP, VDH, *Director, Division of Immunization* (departed meeting at 10:38am)

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*

All workgroup members and staff listed above participated virtually.

APPROVAL OF AGENDA:
MOTION:

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

Ms. Emily Yeatts was unable to participate in the vote due to connectivity issues, but rejoined the meeting following the vote.

PUBLIC COMMENT:

As noticed in the agenda, Mr. Logan invited those persons who had requested via email to Ms. Juran to offer comment prior to 8am on August 17, 2020 to offer public comment to the workgroup.

Christina Barrille, Executive Director, Virginia Pharmacists Association (VPhA), and Kelly Goode, PharmD reviewed VPhA's written public comment which was screen-shared for viewing at this time. Key comments included: clarification for the Board that devices are intended to be included in the statewide protocol for lowering costs to the patient; recommendation to consider Kentucky's protocol regarding naltrexone; suggestion to provide clarity regarding patient inclusion in the epinephrine protocol, but to not be too prescriptive; recommendation to not require an appointment in the contraception protocol; refer to the most recent 2020 version of the US Medical Eligibility Criteria for Contraception; clarify language regarding breastfeeding; recommendation to include question regarding vaping; consider requirement for pharmacist to follow-up with patient who has never used hormonal contraception before; clarify use of ulipristal on emergency contraception protocol; recommendation to contact OB/GYN on prenatal vitamin protocol; suggestion for board to communicate legislative need to amend age in fluoride protocol; and recommendation to offer best practice in notifying practitioner, but not to be too prescriptive.

Ms. Juran shared that she had received an email from Sharon Gatewood, PharmD that echoed the comments provided by VPhA.

Natalie Nguyen, PharmD, representing Virginia Society of Health-System Pharmacists, offered support of the comments provided by VPhA. She recommended that the board standardize the minimum information that must be communicated with healthcare providers. She also asked the workgroup to consider adding to patient exclusion criteria that an individual with a documented allergic reaction to Naloxone be excluded from the Naloxone Protocol. She recommended additions to inclusion information for epinephrine to include a definition of reporting a diagnosis of allergies that may result in anaphylaxis, and to add medication with high reaction probability. She asked that a definition for the therapeutic category be provided in the protocol related to out of pocket cost. She questioned if the required CE would be an annual requirement. It was also recommended that the date of last physical exam or pap be required in the protocol for hormonal contraception.

Jill McCormack, Regional Director of Government Affairs, National Association of Chain Drug Stores (NACDS), suggested that language be included to support new products coming into the market into the epinephrine protocol. She said that they agree with VPhA that the law includes medical supplies and devices into the protocol related to out-of-pocket cost. She recommended that the protocol mirror the requirements in the health commissioner's standing order. She shared that NACDS appreciates the inclusion of emergency contraceptive into the Emergency and Hormonal contraceptive protocol. She recommended that all methods of training be allowed. Ms. McCormack stated pharmacists have found it challenging in other states to use the state paper forms on this subject and requested an allowance for a pharmacy to convert the state form into an electronic form to facilitate electronic use in the future. She recommended pharmacists have the ability to schedule patient appointments for prescribing contraception.

APPROVAL OF MINUTES:

The workgroup voted unanimously to approve the August 4, 2020 Workgroup meeting minutes as presented. (motion by Miller, second by Stokes)

Adopt recommended statewide protocols for board consideration for pharmacists to initiate treatment with, dispense, or

administer the following drugs and devices to persons 18 years or age or older:

NALOXONE OR OTHER OPIOID ANTAGONIST, INCLUDING SUCH CONTROLLED PARAPHENALIA, AS DEFINED IN §54.1-3466, AS MAY BE NECESSARY TO ADMINISTER SUCH NALOXONE OR OTHER OPIOID ANTAGONIST

The workgroup briefly discussed adding naltrexone to the protocol and concluded that it would review Kentucky's protocol at a later time for possible inclusion in the protocol in the future. The workgroup also had some discussion about which providers should receive notification and if the exclusion criteria should be modified to outline certain medical conditions that should be excluded from receiving naloxone under this protocol. Ms. Juran shared that the Department of Behavioral Health and Developmental Services recommends pharmacists provide patients with the REVIVE! naloxone brochure when dispensing naloxone, consistent with the Board's current naloxone protocol under the Health Commissioner's standing order.

MOTION:

The workgroup voted unanimously to amend the naloxone protocol as follows:

- **Under Patient Exclusion Criteria – regarding pain patients, insert sentence at the end of the bullet to refer patient to primary care provider to determine if naloxone is appropriate**

and to recommend to the full board that it adopt the protocol as amended. (motion by Miller, seconded by Stokes)

EPINEPHRINE

The workgroup discussed whether the patient inclusion criteria should include patients who are taking drugs with a black box warning that use of the drug may result in anaphylaxis. The workgroup concluded that the current language was written broadly and should remain in place.

MOTION:

The workgroup voted unanimously to recommend to the full board that it adopt the epinephrine protocol as presented. (motion by Miller, seconded by Stokes)

PRENATAL VITAMINS FOR WHICH A PRESCRIPTION IS REQUIRED

There was some discussion by the workgroup regarding how a pharmacist should notify the primary care provider when initiating therapy under the statewide protocols. There appeared to be a general consensus that it should be left to the pharmacist's discretion and that a fax may be sufficient.

The workgroup considered a recommendation to notify the patient's primary care provider and OB/GYN.

MOTION:

The workgroup voted unanimously to amend the prenatal vitamin statewide protocol as follows:

- **Under Notification of Primary Care Provider, insert in the first sentence "and obstetrician/gynecologist (OB/GYN)" after "provider";**

And to recommend to the full board that it adopt the protocol as amended. (motion by Miller, seconded by Stokes)

DIETARY FLUORIDE SUPPLEMENTS, IN ACCORDANCE WITH RECOMMENDATIONS OF THE AMARICAN DENTAL ASSOCIATION FOR PRESCRIBING OF SUCH SUPPLEMENTS FOR PERSONS WHOSE DRINKING WATER HAS FLUORIDE CONTENT BELOW THE CONCENTRATION RECOMMENDED BY THE U.S DEPARTMENT OF HEALTH AND HUMAN SERVICES

The workgroup acknowledged that the law restricts statewide protocols to patients 18 years of age and older and that the American Dental Association does not recommend use of fluoride supplements to persons of this age category.

MOTION:

The workgroup voted unanimously to recommend to the full board that it adopt the fluoride supplement protocol as presented. (motion by Miller, seconded by Stokes)

MEDICATIONS COVERED BY THE PATIENTS HEALTH CARRIER WHEN THE PATIENTS OUT-OF-POCKET COST IS LOWER THAN THE OUT-OF-POCKET COST TO PURCHASE AN OVER-THE-COUNTER EQUIVALENT OF THE SAME DRUG

Dr. Miller objected to the draft language allowing for the prescribing of a medication in the same "therapeutic category" and recommended that the drug be identical to the originally prescribed drug. The workgroup discussed the statutory definition of "therapeutically equivalent drug products". There was discussion regarding whether the law supports this protocol including an allowance for pharmacists to prescribe and dispense ancillary devices required for drug administration. The workgroup proceeded in a manner that the law may not support inclusion of devices. Several members, including Dr. Ratliff and Dr. Miller, supported inclusion of devices and recommended a legislative proposal in 2021 for such an allowance, if necessary.

MOTION:

The workgroup voted unanimously to amend the protocol to lower out-of-pocket expense as follows:

- **Under Pharmacist Education and Training – strike "over-the-counter";**
- **Under Patient Inclusion Criteria – second bullet, replace "in the same therapeutic category" with "a therapeutically equivalent drug product, as defined in §54.1-3401," and include a footnote referencing the statutory definition at the bottom of the page**

and to recommend to the full Board that it adopt the protocol as amended. (motion by Miller, seconded by Stokes)

INJECTABLE OR SELF-ADMINISTERED HORMONAL CONTRACEPTIVES, PROVIDED THE PATIENT COMPLETES AN ASSESMENT CONSISTENT WITH THE UNITED STATES MEDICAL ELIGIBILITY CRITERIA FOR CONTRACEPTIVE USE

The workgroup discussed if there was a need for ongoing pharmacist training on this topic to be outlined in the protocol. They concluded that a one-time continuing education (CE) requirement was sufficient. It was suggested that the Board could post a list of applicable CE on its website. Staff raised some concerns with using a color-coded self-screening questionnaire that correlates with a color-coded US Summary of Eligibility Criteria as it may disadvantage persons who are color-blind and may increase opportunity for errors if the CDC updates its chart before board staff is aware or able to update the color-coded version. The workgroup concluded it should not use a color-coded system and to facilitate ease of use the self-screening questionnaire could simply reference the categories as indicated on the US Summary of Eligibility Criteria for Contraceptive Use.

There was discussion about patient eligibility criteria for this protocol and the process to handle ineligible patients with referrals to healthcare providers. The workgroup also discussed possible tracking of patients who may transfer to different pharmacies. The workgroup acknowledged that if the patient did not want to obtain the drug from the pharmacy that initiated the therapy, the prescribing pharmacist should issue a prescription to the patient to take to another pharmacy for dispensing.

There was some discussion about the record keeping requirements for this protocol and consideration for the recommendation to allow for a pharmacist to instruct the patient to take a pregnancy test, when necessary to rule out pregnancy. The workgroup recommended referring such patient to a primary care provider and not including such an allowance in the protocol.

The workgroup discussed the draft algorithms. It was recommended that box number three be removed from the two draft algorithms since the medication screening could be accomplished in the first box when screening for contraindications. It was recommended to conform the references to blood pressure on the two documents to 140/90. The workgroup agreed that it would be acceptable for an electronic version of the self-screening questionnaire to be created by a pharmacy if the collection of patient information and assessment process is identical to the Virginia Routine Hormonal Contraceptive Self-Screening Questionnaire.

MOTION:

The workgroup voted unanimously to amend the Pharmacist Hormonal Contraceptive Statewide Protocol as follows:

- **Under Patient Inclusion Criteria – insert "most current version of the" before "Centers" and insert "i.e., the prescribed drug is assessed at a "1" or "2" for all conditions applicable to the patient" after "use";**
- **Under Process for Handling Ineligible Patients – add at the end of section "If the patient does not have a primary care provider, the pharmacist shall 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."**
- **Under Further Conditions – strike 1b regarding referral of abuse; strike 2 regarding dispensing as soon as practicable; strike 3a regarding prohibition for requiring an appointment; and insert in 3b, a sentence confirming that the "evidence of a clinical visit" may be obtained by the response on the self-screening questionnaire regarding the date of the patient's last women's health clinical visit.;**
- **Under Notification of Primary Care Provider – insert requirement to also notify the patient's OB/GYN;**

Amend the *Virginia Hormonal Contraceptive Self-Screening Questionnaire* as follows:

- **In the title, insert "Routine" after "Virginia";**
- **Insert the pregnancy screening questions from the draft algorithms to this document;**

- **Insert question regarding number of cigarettes per day;**

Amend the *Standard Procedures Algorithm for Virginia Pharmacists Prescribing of Contraceptives* as follows:

- **Delete box three and insert "/Medications" after "Contraindicating Conditions" in box 1;**
- **In box 6, insert "Regular" prior to "Quick";**
- **In box 7, amend to conform to notification requirement in law.**

Amend the *Standard Procedures Algorithm for Pharmacists Prescribing and Administering Depot Medroxyprogesterone Acetate* as follows:

- **Delete box three and insert "/Medications" after "Contraindicating Conditions" in box 1;**
- **In box 4, change "160/100" to "140/90";**
- **In box 6, Ongoing Administration, change "15" to "13" and strike "Do not administer if <11 weeks ago."**
- **In box 7, amend to conform to notification requirement in law.**

Amend *Pharmacist Emergency Contraception Statewide Protocol* as follows:

- **Under Patient Inclusion Criteria – insert "most current version of the" before "Centers";**
- **Under Process for Handling Ineligible Patients – add at the end of section "If the patient does not have a primary care provider, the pharmacist shall 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."**
- **Under Additional Prescribing and Dispensing Considerations – insert "Ella may be more effective if it has been more than 72 hours since the last day of unprotected intercourse." and "Pharmacist must counsel the patient on the proper use of the EC and side effects, to include providing written educational materials.";**
- **Under Notification of Primary Care Provider – insert requirement to also notify the patient's OB/GYN.**

and to recommend to the full Board that it adopt the Pharmacist Hormonal Contraceptive Statewide Protocol, the Algorithm for Virginia Pharmacists Prescribing of Contraceptives, the Algorithm for Pharmacists Prescribing and Administering Depot

Medroxyprogesterone Acetate, the Virginia Routine Hormonal Contraceptive Self-Screening Questionnaire, and the Pharmacist Emergency Contraception Statewide Protocol as amended and the Virginia Emergency Contraception Self-*Screening Questionnaire* as presented. (motion by Miller, seconded by Stokes; Wheawill abstained)

It was suggested that the Board could contact schools of pharmacy to request that it develop written educational materials for pharmacists to provide to patients regarding "key facts" surrounding the use of EC, which could include the statements from the Additional Prescribing and Dispensing Considerations section of the protocol. Links to educational materials could be posted on the Board's website.

ADOPT RECOMMENDED EMERGENCY REGULATIONS FOR BOARD CONSIDERATION TO IMPLEMENT PROVISIONS

The workgroup reviewed the draft emergency regulations for implementing these provisions.

MOTION:

The workgroup voted unanimously to amend 18VAC110-21-46 by inserting in (B)(2) "If the drug being initiated is an injectable or self-administered hormonal contraceptive or a prenatal vitamin, the pharmacist shall also notify the patient's obstetrician or gynecologist" after "notification", and to recommend to the full Board that it adopt 18VAC110-20-150 as presented and 18VAC110-21-46 as amended. (motion by Miller, seconded by Stokes; Wheawill abstained)

ADJOURNED:

With all business concluded, the workgroup adjourned the meeting at 4:53 pm.

~~Ryan Logan,~~ Chairman
KRISTOPHER S. RAFF
9-9-2020
Date

Caroline Juran, Executive Director
9/9/2020
Date