

FINAL/APPROVED

**VIRGINIA BOARD OF PHARMACY
MINUTES OF VIRTUAL REGULATION COMMITTEE MEETING**

November 12, 2020
Second Floor
Board Room 2

Perimeter Center
9960 Mayland Drive
Henrico, Virginia 23233-1463

- CALL TO ORDER:** A virtual Webex meeting of the Regulation Committee was called to order at 9:08AM. 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 committee convened a virtual meeting to consider such business matters as was presented on the agenda necessary for the board to discharge its lawful purposes, duties, and responsibilities.
- PRESIDING:** Cheryl Nelson, Committee Chairman
- MEMBERS PRESENT:** Glen Bolyard, Jr.
Dale St.Clair
William Lee
Patricia Richards-Spruill
- STAFF PRESENT:** Caroline D. Juran, Executive Director
Ellen B. Shinaberry, Deputy Executive Director
J. Samuel Johnson, Jr., Deputy Executive Director
Beth O'Halloran, Deputy Executive Director
Elaine J. Yeatts, Senior Policy Analyst, DHP
James Rutkowski, Assistant Attorney General
Matt Treacy, Media Production Specialist
- QUORUM:** With four members of the Committee present, a quorum was established.
- APPROVAL OF AGENDA:** Agenda was approved as provided.
- PUBLIC COMMENT:** Natalie Nguyen, PharmD, representing VSHP stated they support the intent of remote order processing by a pharmacy technician. She recommended the Board consider recent COVID experience. She recommended a hard upper limit for a pharmacist to pharmacy technician ratio. She reminded the board that space in a pharmacy is limited.
- Cindy Warriner, RPh, representing Appalachian College of Pharmacy reacted to several items in the agenda packet. She recommended amending #2 in Guidance Document 110-13, expressed concern for removing personal supervision of a pharmacy technician, opposed a store

manager having the ability to determine the number of pharmacy technicians, and recommended keeping the square footage for a pharmacy.

Monet Stanford, PharmD representing Kaiser Permanente stated that pharmacy technicians can complete remote processing tasks under secure technology and can increase capacity of healthcare workforce.

Christina Barrille, Executive Director, VPhA encouraged the Board to strike B3 of 18VAC110-40-20. She recommended allowing a pharmacist to use professional discretion regarding the closing of the pharmacy during a required break. Regarding page 29 of the agenda packet, she recommended waiting until the pharmacy technician workgroup meets. She stated they oppose removing pharmacist supervision and ridding of pharmacist to pharmacy technician ratio. She commented that a pharmacy square footage can be waived, if necessary.

Update on Regulatory Actions

A more current version of the Chart of Regulatory Actions was shared on the screen via WebEx. Ms. Yeatts provided an overview of the chart.

Amendments to Guidance Documents

Ms. Yeatts indicated several guidance documents need to be amended based on recent statutory changes.

MOTION:

The committee voted unanimously to recommend to the full board that it amend Guidance Documents 110-1 (Categories of Facility Licensure), 110-29 (Guidance on Physician Dispensing Licenses), and 110-44 (Naloxone Protocol) as presented. (motion by Richards-Spruill, second by Bolyard)

The committee considered public comment received to amend #2 of Guidance Document 110-13, but concluded that such an amendment would require a regulatory change.

MOTION:

The committee voted unanimously to recommend to the full board that it amend Guidance Document 110-13 (Guidance Regarding Collaborative Practice Agreements) as presented. (motion by St.Clair, second by Richards-Spruill)

Staff indicated that Guidance Document 110-41 was recently incorporated into regulation during the last periodic regulatory review.

MOTION:

The committee voted unanimously to recommend to the full board that it repeal Guidance Document 110-41 (Changes a Pharmacist May Make to a Prescription Written for a Schedule II Controlled Substance) as presented. (motion by Bolyard, second by St.Clair)

There was much discussion regarding Guidance Document 110-39

(Guidance for Continuous Hours Worked by Pharmacists and Breaks). There was general support for a pharmacist exercising discretion regarding whether he or she would close the pharmacy during a required pharmacist break, however, the Committee believed it was important to post in advance for the public the time period that the pharmacy may be closed.

MOTION:

The committee voted in favor 4:1 to recommend to the full board that it amend Guidance Document 110-39 to allow the pharmacist on-duty to determine if the pharmacy will close during a required pharmacist break, but to require the pharmacy to post in advance the time period that the pharmacy may be closed. (motion by Bolyard, second by Richards-Spruill; St.Clair opposed)

The Board discussed the draft guidance document regarding contract employees accessing the premises of a pharmaceutical processor.

MOTION:

The committee voted unanimously to recommend to the full board that it adopt the guidance document (Contracted Employee Access to Pharmaceutical Processor) as presented. (motion by St.Clair, second by Bolyard)

Consideration of Remote Order Processing by a Pharmacy Technician Outside of a Pharmacy

Staff reminded the Board that this issue resulted from a petition from rulemaking from Bioscript. In June 2020, the Board voted to not initiate rulemaking but to refer the issue to the Regulation Committee for further consideration. An excerpt of minutes from a 10/5/2020 special conference committee denying a request for a pilot was included in the agenda packet. There was discussion regarding the appropriate level of pharmacist supervision and use of technology to monitor pharmacy technician activities.

MOTION:

The committee voted in favor 3:2 to defer consideration of remote order processing by a pharmacy technician outside of a pharmacy to the workgroup to be convened in 2021 pursuant to HB 1304 to consider additional duties that a pharmacy technician may perform. (motion by Lee, second by Richards-Spruill; opposed by Bolyard and St.Clair)

Consideration of Amendments – Medication Carousels and RFID Technology

There was discussion regarding whether the preliminary text language requiring scanning of each drug unit, blister card, and unopened container was appropriate. Some commenters stated that it may not be efficient to scan each unit, particularly in a large hospital. Other commenters stated it was necessary for patient protection. The committee did not believe any changes were necessary to the preliminary text on RFID technology.

MOTION:

The committee voted unanimously to recommend to the full board that it adopt the proposed language as amended by: requiring the same safety processes for “spoke and wheel”, i.e., allowing drugs to be pulled from the med carousel for wholesale distribution to an offsite entity; in 18VAC110-20-425(C), changing the second “3” to

“4” and replacing “the robotic pharmacy system to guide” with “barcode scanning technology to verify the accuracy of”; and inserting a requirement for a pharmacist 5% verification as is currently required in the innovative pilots for using med carousels. (motion by Lee, second by St.Clair)

Adoption of NOIRA/Notice of Periodic Review

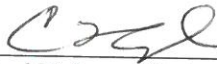
The committee did not review each item previously submitted following the last periodic review, but rather decided to recommend to the full board that it notice the public of a periodic review and request comments on changes it would like to have considered. If published, a 30-day public comment period would open.

MOTION:

The committee voted unanimously to recommend to the full board that it issue a Notice of Periodic Regulatory Review for Chapters 20, 21, 30, 40, and 50 and that it request comments on changes that the public would like to have considered. (motion by St.Clair, second by Richards-Spruill)

ADJOURN:

With all business concluded, the meeting adjourned at approximately 12:10 PM.



Cheryl Nelson, Chairman



Caroline D. Juran, Executive Director

12-17-20

DATE

12/10/2020

DATE