

(DRAFT/UNAPPROVED)

**VIRGINIA BOARD OF PHARMACY
MINUTES OF FULL BOARD MEETING**

Thursday, May 2, 2024

Department of Health Professions
Perimeter Center
9960 Mayland Drive
Henrico, Virginia 23233

CALL TO ORDER: A full board meeting was called to order at 9:15AM.

PRESIDING: Dale St. Clair, PharmD, Chairman

MEMBERS PRESENT: Cheri Garvin, RPh, Vice Chair
Shannon Dowdy, PharmD
Michelle Hoffer, JD
Larry Kocot, JD
Wendy Nash, PharmD
Kristopher Ratliff, DPh
Patricia Richards-Spruill, RPh
Ling Yuan, PharmD

MEMBER ABSENT: Sarah Melton, PharmD

STAFF PRESENT: Caroline Juran, RPh, Executive Director
James Rutkowski, JD, Senior Assistant Attorney General
Erin Barrett, JD, Director of Legislative and Regulatory Affairs, DHP
James Jenkins Jr., RN, Agency Deputy Director
Sorayah Haden, Executive Assistant
Ellen Shinaberry, PharmD, Deputy Executive Director
Ryan Logan, RPh, Deputy Executive Director
Annette Kelley, MS, CSAC, Deputy Executive Director
Beth O'Halloran, RPh, Deputy Executive Director

PHARMACISTS AWARDED
1-HOUR OF LIVE OR REAL-
TIME INTERACTIVE
CONTINUING EDUCATION
FOR ATTENDING MEETING: Gill Abernathy
Katrina Trelease

QUORUM: With 9 members present, a quorum was established.

APPROVAL OF AGENDA: The chairman stated that several handouts had been provided at the board

members' seats and on the public table which included: a 2024 updated legislative report; revised draft emergency regulatory amendments related to emergency medical services; revised draft emergency regulatory amendments for crisis stabilization services and use of automated drug dispensing systems and remote dispensing systems; and several written public comments submitted prior to the meeting. No additional amendments were offered. The agenda was approved as presented.

Amendments were offered to the draft minutes included in the agenda packet.

The chairman stated the minutes for the meetings held between March 28, 2024 and April 11, 2024 were approved as presented and amended as follows:

- **Change the respondent's name from "Lewis" to "Turner" in meeting minutes for the Telephone Conference Call held on April 11, 2024.**

In response to Mr. Kocot's inquiry regarding educational standards and workforce challenges of pharmacy technicians, the chairman stated this issue is already tentatively scheduled for the June full board meeting.

Michael Player, Executive Director, Peninsulas EMS Council, Inc. and co-chairman of a regional EMS task force thanked the board and staff for their efforts to accommodate the requests of the EMS stakeholders during the drafting of emergency regulations.

Gill Abernathy, Pharmacy Manager, Inova Health System thanked the board and provided the following public comments:

- Amend 18VAC110-20-500 B to state "Unless prohibited by federal law and regulation, a hospital pharmacy may prepare a kit for an EMS agency provided...",
- Requirements to place only Schedule VI in a drug kit and Schedule II-V in a separate drug kit did not previously exist and may be problematic,
- Insert headings to distinguish the different models,
- Amend 18VAC110-20-721 C1 to remove "emergency" stating.

Josh Crawford provided public comment on behalf of the Virginia Society of Health-System Pharmacists consistent with the written comment previously provided as a handout.

APPROVAL OF PREVIOUS BOARD MEETING MINUTES

MOTION:

ACTION ITEM:

PUBLIC COMMENT:

**LEGISLATIVE/
REGULATORY/GUIDANCE**

**2024 UPDATED
LEGISLATIVE REPORT**

Erin Barrett briefly reviewed the handout of the updated legislative report.

**CHART OF REGULATORY
ACTIONS**

Ms. Barrett briefly reviewed the chart in the agenda packet and provided updated information. Ms. Barrett stated the proposed 18VAC110-20 regulations regarding the Pharmacy Working Conditions is now at the Governor's Office for review.

**ADOPTION OF EMERGENCY
REGULATORY
AMENDMENTS
REGARDING EMERGENCY
MEDICAL SERVICE
AGENCIES**

The Board carefully reviewed and discussed the adoption of the emergency regulatory amendments regarding Emergency Medical Service Agencies. The following documents were taken into consideration: Excerpts of USC §823, DEA Notice of Proposed Rulemaking, written comments received as of 4/18/2024, additional written comments received prior to the board meeting, and the revised draft regulatory amendments provided as a handout.

MOTION:

The Board voted unanimously to adopt emergency regulatory amendments and a Notice of Intended Regulatory Action for replacement regulations regarding emergency medical service agencies as presented in the handout and amended as follows:

- **18VAC110-20-10, amend last sentence of the definition of “other EMS vehicle” by inserting “, regional EMS council” after “...registered to an EMS agency”;**
- **18VAC110-20-10, amend definition of “registered location” by inserting “Schedule II-VI” prior to “controlled substances” and replace “distributors” with “those entities authorized to distribute”;**
- **18VAC110-20-500 A, strike “emergency” after “obtain”;**
- **18VAC110-20-500 B, replace “the US Food and Drug Administration” with “federal law”, strike “hospital” prior to “pharmacy”;**
- **18VAC110-20-500 B1, strike “hospital”, “and Schedule VI controlled devices”, and “The Schedule VI controlled devices may be provided in a kit separate from the prescription drugs.”;**
- **18VAC110-20-500 B2, strike “or Schedule VI controlled devices”;**
- **18VAC110-20-500 B2a, strike “hospital”;**
- **18VAC110-20-500 B3, strike “and devices”;**
- **18VAC110-20-500 B7, strike “and devices”;**
- **18VAC110-20-500 B9, strike “or device”;**
- **18VAC110-20-500 B10, insert “pharmacy technician” before “or prescriber”;**
- **18VAC110-20-500 B11, strike “hospital”;**
- **18VAC110-20-500 C, separate paragraph into the three different scenarios and replace “with written approval from the DEA” with “consistent with federal law”;**
- **18VAC110-20-500 E and E2, strike “hospital”;**
- **18VAC110-20-500 E4, strike “and devices”;**
- **18VAC110-20-500 E5, strike “or devices” in three places;**
- **18VAC110-20-500 E6, strike “or devices”, replace “Schedule II,**

- III, IV, or V” with “such Schedule VI”, and strike “sealed”,
- 18VAC110-20-500 F, strike “and devices”,
 - 18VAC110-20-500 should no longer be included in the hospital section of the regulations now that restrictions to “hospital” have been removed. 18VAC110-20-500 will be repealed, moved to a new section, and incorporate the aforementioned amendments.
 - 18VAC110-20-690 B, after “agencies” insert “and regional EMS councils”,
 - 18VAC110-20-720, insert “unusual” prior to “loss”,
 - 18VAC110-20-720 2, insert at the beginning “Except as provided in subsection 9,”,
 - 18VAC110-20-720 9, restructure wording to accommodate electronic storage allowance in 2,
 - 18VAC110-20-721 B, strike “hospital”, correct lettering of subsection,
 - 18VAC110-20-721 D1, strike “emergency”,
 - 18VAC110-20-721 E, at the beginning insert “To the extent permitted by federal law,”, and
 - 18VAC110-20-505, strike “hospital”. In A1, after “supervising practitioner” insert “or responsible party”, restructure section by creating a new subsection B that applies only to EMS and ensure subsection A applies to pharmacies. (motion by Nash, seconded by Garvin)

REPEAL GUIDANCE DOCUMENT 110-41, “EMERGENCY MEDICAL SERVICES DRUG KITS”

The Board discussed the consideration of repealing Guidance Document 110-41, “Emergency Medical Services Drug Kits”, as it may conflict with the adopted emergency regulatory amendments to EMS-related regulations. Staff indicated it can develop a policy document for educational purposes if needed.

MOTION:

The Board voted unanimously to repeal Guidance Document 110-41. (motion by Richards-Spruill, seconded by Garvin)

ADOPTION OF EMERGENCY REGULATIONS REGARDING CRISIS STABILIZATION SERVICES, USE OF AUTOMATED DRUG DISPENSING SYSTEMS AND REMOTE DISPENSING SYSTEMS

The Board reviewed and discussed the handout of the draft emergency regulatory amendments regarding crisis stabilization services, and use of automated drug dispensing systems, and remote dispensing systems, along with the relevant information in the agenda packet.

MOTION

The Board voted unanimously to adopt the emergency regulatory amendments regarding crisis stabilization services, use of automated drug dispensing systems, and remote dispensing systems as presented

and amended as follows:

- 18VAC110-20-555 3, replace “for the purpose of stocking or reloading” with “as designated by the PIC or pharmacist on duty”,
- 18VAC110-20-555 11, after “envelope” insert “and if not self-administered.”, and
- 18VAC110-20-555 13, replace “cannister” with “placed in bulk bins”. (motion by Yuan, seconded by Hoffer)

GUIDANCE DOCUMENT
110-19:

The board discussed identifying “other facilities” that may use automated dispensing systems and remote dispensing systems pursuant to 54.1-3434.02 in Guidance Document 110-19. The board reviewed the draft version on page 135 of the agenda packet.

MOTION:

The Board voted unanimously to amend Guidance Document 110-19 as presented. (motion by Garvin, seconded by Dowdy)

ADOPTION OF FAST-TRACK
REGULATION OF QUALITY
STANDARDS FOR
LABORATORIES TESTING
SAMPLES FOR
PHARMACEUTICAL
PROCESSORS

Staff indicated there is a requirement for the board to establish quality standards for laboratories pursuant to § 4.1-1602 that was previously in 54.1-3442.6. The standards were previously adopted in 18VAC110-60-300 A but were inadvertently repealed when the medical cannabis program transitioned to the VCCA on January 1, 2024. Staff recommends the board re-adopt the quality standards previously included in 18VAC110-60-300 A to satisfy the statutory requirement for the board to establish quality standards.

MOTION

The Board voted unanimously to adopt a Notice of Intended Regulatory Action for fast-track regulation to establish quality standards for laboratories testing samples of pharmaceutical processors. (motion by Nash, seconded by Garvin)

AMEND GUIDANCE
DOCUMENT 110-33,
“PHARMACY INTERNS AS
PHARMACY TECHNICIANS,
PHARMACY TECHNICIAN
RATIO, DOCUMENTATION
OF PREVIOUS PRACTICE”

Staff sought clarification regarding whether an out-of-state applicant must hold a current active license or registration in another U.S. jurisdiction at the time application is submitted to Virginia for a pharmacy technician registration and if Guidance Document 110-33 needed to be amended. Board counsel advised that the law and regulations do not require an out-of-state applicant to hold a current active license or registration in another U.S. jurisdiction at the time application is submitted to Virginia for a pharmacy technician registration and therefore, such restriction could not be required in guidance. Therefore, no action was taken on Guidance Document 110-33.

**CONSIDERATION OF
CONSENT ORDERS,
SUMMARY SUSPENSIONS,**

**OR SUMMARY
RESTRICTIONS**

CVS Pharmacy #2691
CVS Pharmacy #3794

Sean Murphy, Assistant Attorney General, presented consent orders for Board consideration regarding CVS Pharmacy #2691 (License #0201-003705) and CVS Pharmacy #3794 (License #0201-003379).

DECISION

Upon a motion by Garvin, and duly seconded by Hoffer, the Board unanimously voted to accept the consent orders for CVS Pharmacy #2691 (License #0201-003705) and CVS Pharmacy #3794 (License #0201-003379).

MEETING ADJOURNED:

3:30 PM

Caroline Juran, RPh
Executive Director

DATE:

