

(DRAFT/UNAPPROVED)

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

Thursday, March 28, 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 9:08 AM.

PRESIDING: Dale St. Clair, PharmD, Chairman

MEMBERS PRESENT: Cheri Garvin, RPh
Larry Kocot, JD
Ling Yuan, PharmD
Wendy Nash, PharmD
Patricia Richards-Spruill, RPh
Shannon Dowdy, PharmD
Michelle Hoffer, JD
Sarah Melton, PharmD

MEMBERS ABSENT: Kristopher Ratliff, DPh

STAFF PRESENT: Caroline Juran, RPh, Executive Director
James Rutkowski, JD, Senior Assistant Attorney General
Erin Barrett, JD, Director of Legislative and Regulatory Affairs, DHP
Arne Owens, Director, DHP
Sorayah Haden, Executive Assistant
Beth O'Halloran, RPh, Deputy Executive Director
Ellen Shinaberry, PharmD, Deputy Executive Director
Ryan Logan, RPh, Deputy Executive Director

**PHARMACISTS AWARDED
1-HOUR OF LIVE OR REAL-
TIME INTERACTIVE
CONTINUING EDUCATION
FOR ATTENDING MEETING:** Jen Brandt
Bobby Ison
Tim Robertson

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

APPROVAL OF AGENDA: An amended agenda was provided which included two additional items. At the

end of the *Legislative/Regulatory/Guidance* section of the agenda, the item entitled “Consideration of Enforcement Deadline for Revised USP Chapters <795> and <797>” was added. Additionally, under the *New Business* section, a new third bullet was added to hear a brief update on the accreditation status of Hampton University School of Pharmacy from Dr. Iyer, Dean and Professor at Hampton University School of Pharmacy. Hearing no additional amendments, the Chairman announced that the amended agenda was approved as presented.

**APPROVAL OF PREVIOUS
BOARD MEETING MINUTES**

Hearing no additions or corrections, the Chairman announced that the minutes for the meetings held on December 6 through February 14th were approved as presented.

ACTION ITEMS:

Ms. Nash requested an update on the action item from the December 2023 meeting regarding suggested topics. The Chairman indicated the Board could consider the issue at the June meeting.

Mr. Kocot requested an update on the action item from the December 2023 meeting regarding pharmacy technician educational standards. The Chairman indicated the Regulation Committee could consider the issue in May, if necessary.

PUBLIC COMMENT:

Jeremiah McCloud provided public comment on behalf of Akina Pharmacy. Mr. McCloud expressed concerns with the April 30, 2024 enforcement of revised USP chapters as indicated in Guidance Document 110-36. Supply chain concerns resulting in backlogs of up to 12-14 months with reference labs still exist. Mr. McCloud requested the Board’s consideration of extending the enforcement date of revised USP Chapters <795> and <797> to November 1, 2024.

Natalie Nguyen, PharmD, provided public comment on behalf of VCU Health Pharmacy. She supported a pathway for a delayed enforcement date for revised USP Chapters <795> and <797>. Dr. Nguyen also provided written comment, provided to the Board as a handout, on behalf of the Virginia Society of Health-System Pharmacists.

Jamie Fisher, Executive Director, Virginia Pharmacists Association (VPhA) highlighted that two of the three healthcare members of the General Assembly are pharmacists. She supported written comments offered by the Virginia Society of Health Systems Pharmacists regarding EMS drug kits and expressed appreciation for board staff’s attendance at the recent VPhA annual meeting.

In addition to the written comment provided to the Board as a handout, Cindy Williams, BS Pharm, Vice President/Chief Pharmacy Officer at Riverside Health System verbally commented that she currently serves as co-chair of the EMS Medication Kit Transition Workgroup. She supports the written

comments offered by the Virginia Society of Health Systems Pharmacists regarding EMS drug kits and expressed appreciation for the board's engagement in this issue.

Wayne Bowen, Chesterfield County Fire and EMS Battalion Chief commented in support of the Board adopting emergency EMS regulations that mirror the draft regulations included in the agenda packet. He urged the regulations be approved as soon as possible since an abrupt halt of medications would have a negative impact. He recommended there be an effective communication strategy to provide guidance to the EMS agencies. The agencies are supportive of the proposed single Controlled Substance Registration (CSR) allowance with the ability for designated locations. Mr. Bowen requested consideration to the alarm requirement when staff is present, except for emergency runs.

Allen Yee, MD, provided verbal comment on behalf of the Virginia Chapter of the National Association of EMS Physicians, in addition to the written comment provided to the Board as a handout. He thanked Ms. Juran for her engagement on this subject. He expressed support of a single CSR with designated locations. A communication plan of action is requested from the Board and Office of Emergency Services to be distributed to EMS agencies before the implementation. The following specific amendments were proposed:

- Amend the definition of definition of "EMS vehicles" to reflect "EMS agency vehicle". An EMS agency vehicle allows for more flexibility of transferring drugs and equipment such as using an ambulance or a sufficient pickup truck or SUV that may not be a licensed EMS vehicle.
- Amend the alarm system verbiage of the "24-hour staffing" requirement as the agencies are not staffed while they are out servicing an emergency call but doors are locked, bays are closed, and no one can enter.
- Consider allowance for a Basic Life Support kit containing over-the-counter drugs and limited Schedule VI drugs without requiring a CSR.

John Morgan, MD, Operational Medical Director for Loudoun County provided comment in support of the Board adopting regulations similar to those proposed by the DEA. He supports a single CSR with designated locations. He recommended the Board keep the allowance for 1:1 exchange of Schedule VI drugs. He requested an allowance for kits containing drugs in Schedules II-V to be stored in the stationhouse when trucks are out of service. He commented that many will not have the ability to prepare boxes and will need to adjust funding priorities. Small agencies will lack group purchasing power. He recommended separating requirements for Schedule VI from those for Schedules II-V. He referenced additional written comments that he submitted to the Board on behalf of the 15 Northern Virginia Fire Department

Chiefs, Northern Virginia EMS Council, and the 10 Northern Virginia Operational Medical Directors, which was provided to the Board as a handout.

In addition to the written comment provided to the Board as a handout, James Larrick commented verbally on behalf of the Central Shenandoah EMS Council. He requested clarification on who may serve as responsible party on the CSR verses having access to the drug stock. He supports emergency action for implementation.

Amir Louka, MD, Operational Medical Director for James City County Fire Department commented in support of emergency regulations if federal requirements will preclude EMS agencies from obtaining emergency drug kits from hospitals. He expressed concern for the EMS agencies' ability to provide immediate care for patients in rural areas.

Eddie Ferguson, Jr., Fire-Rescue Chief for Goochland County commented in support of those comments offered by Chief Bowen and Dr. Yee. Ferguson request a "blanket Controlled Substance Registration". He stated this transition will be very impactful, particularly for rural counties providing advance life support with few EMTs and maybe one paramedic. They may require mutual aid assistance from other rural counties. He recommended consideration for a medication kit suitable for those areas as recommended by Dr. Yee. He supports a single CSR and exemptions from an alarm system.

Wayne Perry provided comment on behalf of the Rappahannock EMS Council. He requested clarification on who may serve as the responsible party of a CSR and clear communication between licensees and board inspectors to ensure issuance of CSRs.

DHP DIRECTOR'S REPORT:

Mr. Owens provided the agency Director's Report including the following updates:

- The General Assembly will resume on April 17th. The agency expects to soon hear the determination of multiple bills submitted by boards throughout the agency.
- DHP is currently partnering with a third-party contractor, Impact Makers, to update and improve the licensing process of the regulatory boards.
- Due to recent retirements, the agency has ongoing recruitments for a new Chief of Staff and Director of Communication.
- A new Director of Enforcement recently started.

**LEGISLATIVE/
REGULATORY/GUIDANCE**

CHART OF REGULATORY

ACTIONS

Ms. Barrett briefly reviewed the chart in the agenda packet and provided updated information.

2024 LEGISLATIVE REPORT

Ms. Barrett referenced the legislative report included in the agenda packet regarding relevant bills considered or passed by the 2024 General Assembly.

ACTION ITEM:

The Board requested a status update on pending bills at a future meeting.

CONSIDERATION TO AMEND EMS-RELATED REGULATIONS

The Board identified a need for further regulatory discussion to determine the consideration of amending EMS-related regulations. At the Board's request, the upcoming Regulation Committee meeting previously scheduled to be held on May 2, 2024, will be replaced with a Full Board Meeting. This will expedite the adoption of regulations by allowing the full board to adopt the emergency regulatory amendments on May 2nd, in lieu of the Regulation Committee offering recommendation to the full board for adoption at the June 25th full board meeting. Ms. Barrett commented that it may take approximately 2 ½ months for the completion of the administrative review process, following the board's adoption, before the emergency regulations become effective.

MOTION:

The Board voted unanimously to change the Regulation Committee meeting scheduled for May 2, 2024, to a Full Board Meeting. (motion by Nash, seconded by Garvin)

Based on scheduling conflicts of presenters, the chairman requested the Board take the next agenda items out of order.

ADOPTION OF 2023 PHARMACISTS AND PHARMACY TECHNICIAN WORKFORCE SURVEY REPORTS:

Barbara Hodgdon, PhD, Deputy Director, DHP Healthcare Workforce Data Center and Data Analytics Division provided a PowerPoint presentation of highlights of the 2023 Pharmacists and Pharmacy Technician Healthcare Workforce Survey Reports. A handout of the presentation was also provided to the Board and public.

MOTION

The Board voted unanimously to accept the Pharmacist and Pharmacy Technicians Workgroup Survey Reports as presented. (motion by Yuan, seconded by Richards-Spruill)

HAMPTON UNIVERSITY SOP ACCREDITATION STATUS UPDATE

Anand Iyer, PhD, MBA, Dean and Professor at Hampton University School of Pharmacy informed the board that Hampton University School of Pharmacy has been approved by ACPE to re-establish a PharmD program. The program will begin Fall 2024 semester with pre-candidate accreditation status through 2025. The program will participate in routine visits and inspections during candidate status review during the 2024/2025 year. Hampton University School of Pharmacy has produced the largest number of

black pharmacists within Virginia due to its innovative curriculum. Dr. Iyer highlighted that black pharmacists assist with addressing healthcare disparities and cultural sensitivities. The school has developed a 10-year strategic plan and has established an advisory board.

The Board reviewed and discussed the proposed amendments to 18VAC110-20-322 and recommendations from the Department of Forensic Science to place certain chemicals in Schedule I.

**ADOPTION OF EXEMPT
FINAL REGULATION TO
PLACE CERTAIN
CHEMICALS INTO
SCHEDULE I**

MOTION:

The Board voted unanimously to adopt the exempt changes to 18VAC110-20-322 to add the following chemicals to Schedule I as presented:

Chemicals with hallucinogen properties

- 1. 1-(1,3-benzodioxol-5-yl)-2-(isobutylamino)-1-pentanone (other name: N-isobutylpentylone), its salts, isomers, and salts of isomers whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation.**
- 2. 1-(1,3-benzodioxyl-5-yl)-2-(tert-butylamino)-1-pentanone (other name: N-tert-butyl pentylone), its salts, isomers (optical, position, and geometric), and salts of isomers, whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation.**
- 3. 1-Phenyl-N-propylcyclohexanamine (other names: N-(1-phenylcyclohexyl)propanamine, PCPr), its salts, isomers (optical, position, and geometric), and salts of isomers, whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation.**

Cannabimimetic agent

- 4. Methyl N-(1H-indazol-3-ylcarbonyl)-3-methyl-valinate (other name: MDMB-INACA), its salts, isomers, and salts of isomers whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation. (motion by Dowdy seconded by Melton)**

**ADOPTION OF PROPOSED
REGULATIONS FOR 2023
PHARMACISTS INITIATING
TREATMENT:**

The Board reviewed and discussed the proposed regulations to replace emergency regulations pursuant to 2023 pharmacists initiating treatment legislation.

MOTION

The Board voted unanimously to adopt the proposed regulatory changes to 18VAC110-21-46 for pharmacists initiating treatment as presented.

(motion by Yuan, seconded by Garvin)

AMEND GUIDANCE
DOCUMENT 110-9:
PHARMACY INSPECTION
DEFICIENCY MONETARY
PENALTY GUIDE

The following amendments to Guidance Document 110-9: Pharmacy Inspection Deficiency Monetary Penalty Guide were presented as follows:

- Amend Deficiency #24 to read “Sterile compounding of hazardous drugs performed in a non-compliant, clean room.”
- Amend Deficiency #33 to read “Immediate use, Category 1, or Category 2 to CSPs assigned inappropriate beyond use date (BUD).

MOTION

The Board voted unanimously to adopt the proposed amendments to Guidance Document 110-9 as presented. (motion by Richards-Spruill, seconded by Garvin)

AMEND GUIDANCE
DOCUMENT 110-33:
PHARMACY INTERNS AS
PHARMACY TECHNICIANS,
PHARMACY TECHNICIAN
RATIO

The Board reviewed and discussed the draft amendments to Guidance Document 110-33: Pharmacy Interns as Pharmacy Technicians; Pharmacy Ratio to clarify acceptable documentation of previous practice for pharmacy technician applicants who have previous experience in another U.S. jurisdiction.

MOTION

The Board voted unanimously to amend Guidance Document 110-33 as presented to provide guidance on acceptable documentation of previous practice performing the duties of a pharmacy technician in another U.S. jurisdiction as required in 18VAC110-21-141. (motion by Nash, seconded by Hoffer)

AMEND GUIDANCE
DOCUMENT 110-35:
GUIDANCE ON VIRGINIA
PRESCRIPTION
REQUIREMENTS

Staff indicated a physician requested that the Board include requirements for opioid prescriptions to be electronically transmitted in Guidance Document 110-35 to assist licensees’ awareness. The Board reviewed and discussed the proposed amendments to Guidance Document 110-35.

MOTION

The Board voted unanimously to adopt the amendments to Guidance Document 110-35 as presented which reference the requirement in §54.1-3408.2 to electronically transmit an opioid prescription and the acknowledgement in §54.1-3410 that a dispenser receiving a non-electronic opioid prescription is not required to verify that an exception applies. (motion by Garvin, seconded by Dowdy)

REPEAL GUIDANCE
DOCUMENT 110-39:
GUIDANCE FOR
CONTINUOUS HOURS
WORKED BY
PHARMACISTS AND

The Board reviewed and discussed Guidance Document 110-39: Guidance for Continuous Hours Worked by Pharmacists and Breaks. Staff indicated it is no longer needed since the language is now included in the recently adopted working conditions emergency regulations (18VAC110-20-110 and 18VAC110-20-113).

BREAKS

MOTION

The Board voted unanimously to repeal Guidance Document 110-39 (motion by Garvin, seconded by Richards-Spruill)

CONSIDERATION OF ENFORCEMENT DEADLINE FOR REVISED USP CHAPTERS <795> AND <797>

The Board reviewed a handout related to the consideration of amending the enforcement deadline listed in question #11 of Guidance Document 110-36 as “When will the Board begin enforcing USP’s revised chapters <795> and <797> that become effective November 1, 2023? There was robust discussion regarding industry backlogs and its impact on compounding and patient care.

MOTION

The Board voted (8-1) to amend the enforcement date of revised USP Chapters <795> and <797> within question #11 in Guidance Document 110-36 to October 31, 2024. (Motion by Nash, seconded by Garvin; opposed by St.Clair)

NEW BUSINESS:

AMEND TB ONE-STEP AND TWO-STEP STATEWIDE PROTOCOLS

As noted in the agenda packet, staff received an inquiry regarding whether a pharmacist must complete Appendix C and have a trainer observe the placement of a TST as part of the pharmacist’s education and training. Staff researched and confirmed with VDH who originally recommended the placement of Appendix C within the protocol simply as a helpful listing, but agreed that it was not intended to be part of the pharmacist’s education and training.

MOTION

The Board voted unanimously to amend the TB Skin Testing One-Step Protocol and the TB Skin Testing Two-Step Protocol to include the following statement at the end of the “Pharmacist Education and Training” section: “Note: Appendix C is provided as a resource listing detailed procedures for placing the TST, but a trainer is not required to observe or complete this form as part of the pharmacist’s education and training.” (motion by Melton, seconded by Hoffer)

AMEND HIV PrEP STATEWIDE PROTOCOL

Ms. Juran stated that she is still working with VDH on draft amendments for consideration. VDH is interested in the Board adding the injectable formulation to the HIV PrEP protocol. Ms. Juran recommended this subject be tabled to a future meeting.

ACTION ITEM:

Consider possible amendments to the HIV PrEP protocol at a future meeting to add the injectable formulation as requested by VDH.

REPORTS

CHAIRMAN’S REPORT

Dr. St. Clair informed the Board he will be attending the upcoming NABP Annual Meeting scheduled to be held in Texas in May 2024.

BOARD OF HEALTH PROFESSIONS

Dr. Melton stated the Board of Health Professions has not met since the last Virginia Board of Pharmacy full board meeting. No report was provided.

LICENSURE OF INDIVIDUALS AND FACILITIES

Mr. Logan provided an overview of the Licensing Report of Individuals and In-State Facilities included in the agenda packet referencing data from August 2022 through January 2024. As of March 10, 2024, the Virginia Board of Pharmacy has a total of 43,915 licensees consisting of individuals and facilities.

INSPECTION PROGRAM

Melody Morton, Inspections Manager with the Enforcement Division provided an overview of the Inspections Report included in the agenda packet referencing data from October 1, 2023 through December 31, 2023. 336 pharmacy inspections were completed within the last quarter.

TRANSITION OF PHARMACEUTICAL PROCESSOR PROGRAM

In Ms. Kelley’s absence, Ms. Juran provided an overview of the Pharmaceutical Processor Report included in the agenda packet. The medical cannabis program successfully transitioned to the Virginia Cannabis Control Authority on January 1, 2024. Board staff continues to share the VCCA contact information in response to occasional inquiries from patients and practitioners. Ms. Kelley and DHP Finance unit are continuing to work with a few 2020 RFA applicants to facilitate their ability to accept the application fee refund.

DISCIPLINARY PROGRAM

Dr. Ellen Shinaberry provided an overview of the Disciplinary Program Report included in the agenda packet. As of February 14, 2024, the Board has 383 open disciplinary cases consisting of 194 patient care cases and 189 non-patient care cases. The Discipline Program has hired an Agency Subordinate to assist the Board with their case load.

EXECUTIVE DIRECTOR’S REPORT

Ms. Juran provided an overview of her report included in the agenda packet which focused on staffing updates and meetings recently attended.

CONSIDERATION OF CONSENT ORDERS, SUMMARY SUSPENSIONS, OR SUMMARY RESTRICTIONS

MELISSA WARE STUTTS

Sean Murphy, Assistant Attorney General, and Chris Andreolli, DHP Adjudication Specialist, presented a case to the Board for consideration of a possible summary suspension regarding Melissa Ware Stutts (#0202206180).

CLOSED MEETING

Upon a motion by Garvin, and duly seconded by Dowdy, the Board voted unanimously to convene a closed meeting pursuant to §2.2-3711(A)(27) of the Code of Virginia (“Code”) to reach a decision regarding the matter of Melissa Ware Stutts (#0202206180). Additionally, she moved that Caroline Juran, James Rutkowski, Ellen Shinaberry, Mykl Egan, and Sorayah Haden attend the closed meeting because their presence is deemed necessary and will aid the Board in its deliberations.

RECONVENE

Upon the motion by Garvin, and duly seconded by Yuan, having certified that the matters discussed in the closed meeting met the requirements of §2.2-3712 of the Code, the Board reconvened an open meeting and announced the decision.

DECISION

Upon a motion by Garvin, and duly seconded by Melton, the Board unanimously voted to summarily suspend the pharmacist license of Melissa Stutts (#0202206180), notice her for a formal hearing, offer her a consent order in lieu of the formal hearing for indefinite suspension for no less than two years stayed upon the entry and compliance of the HPMP.

EVERY GUPTON
#0230-039018

Dr. Ellen Shinaberry presented a consent order for Board consideration regarding Avery Gupton (#0230039018).

CLOSED MEETING

Upon a motion by Garvin, and duly seconded by Kocot, the Board voted unanimously to convene a closed meeting pursuant to §2.2-3711(A)(27) of the Code of Virginia (“Code”) to reach a decision regarding the matter of Avery Gupton (#0230039018). Additionally, she moved that Caroline Juran, James Rutkowski, Ellen Shinaberry, Mykl Egan, and Sorayah Haden attend the closed meeting because their presence is deemed necessary and will aid the Board in its deliberations.

RECONVENE

Upon the motion by Garvin, and duly seconded by Kocot, having certified that the matters discussed in the closed meeting met the requirements of §2.2-3712 of the Code, the Board reconvened an open meeting and announced the decision.

DECISION

Upon a motion by Kocot, and duly seconded by Hoffer, the Board voted unanimously to accept the consent order for pharmacy technician Avery Gupton (#0230039018).

DILLON BREEDING
#0202-217989

Dr. Shinaberry presented case no. 234885 for Board consideration of a possible offering of a consent order for revocation of the right to renew the pharmacist license of Dillon Breeding (#0202217989).

CLOSED MEETING

Upon a motion by Kocot, and duly seconded by Hoffer, the Board voted unanimously to convene a closed meeting pursuant to §2.2-3711(A)(27) of the Code of Virginia (“Code”) to reach a decision regarding the matter of

Dillon Breeding (#0202217989). Additionally, he moved that Caroline Juran, James Rutkowski, Ellen Shinaberry, Mykl Egan, and Sorayah Haden attend the closed meeting because their presence is deemed necessary and will aid the Board in its deliberations.

RECONVENE

Upon the motion by Kocot, and duly seconded by Dowdy, having certified that the matters discussed in the closed meeting met the requirements of §2.2-3712 of the Code, the Board reconvened an open meeting and announced the decision.

DECISION

Upon a motion by Dowdy, and duly seconded by Richards-Spruill, the Board unanimously voted to offer a prehearing consent order for the revocation of the right to renew pharmacist license for Dillon Breeding (#0202-217989).

CVS CAREMARK
#0214-000732

Dr. St. Clair recused himself from hearing this matter and left the room. Dr. Garvin began serving as the presiding officer. Dr. Shinaberry presented a possible settlement for Board consideration regarding CVS Caremark (#0214000732).

CLOSED SESSION

Upon a motion by Kocot, and duly seconded by Hoffer, the Board voted unanimously to convene a closed meeting pursuant to §2.2-3711(A)(27) of the Code of Virginia (“Code”) to reach a decision regarding the matter of CVS Caremark (#0214000732). Additionally, he moved that Caroline Juran, James Rutkowski, Ellen Shinaberry, Mykl Egan, and Sorayah Haden attend the closed meeting because their presence is deemed necessary and will aid the Board in its deliberations.

RECONVENE

Upon the motion by Kocot, and duly seconded by Dowdy, having certified that the matters discussed in the closed meeting met the requirements of §2.2-3712 of the Code, the Board reconvened an open meeting and announced the decision.

DECISION

Ms. Garvin stated there is consensus that no action be taken regarding the matter for CVS Caremark (#0214000732).

MEETING ADJOURNED:

2:14 PM

Caroline Juran, RPh
Executive Director

Date

DRAFT