

(DRAFT/UNAPPROVED)

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

Tuesday, September 24, 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 9:32 AM.

PRESIDING: **Ling Yuan**, PharmD, Vice Chairman

MEMBERS PRESENT: **Shannon Dowdy**, PharmD
Michelle Hoffer, JD
Kelly Hasty Kale, RPh
Larry Kocot, JD
Wendy Nash, PharmD
Derek Webb, PharmD

MEMBERS ABSENT: **Cheri Garvin**, RPh
Kristopher Ratliff, DPh
Patricia Richards-Spruill, RPh

STAFF PRESENT: **Caroline Juran**, RPh, Executive Director, Virginia Board of Pharmacy
Arne Owens, Director, DHP
Erin Barrett, JD, Director of Legislative and Regulatory Affairs, DHP
James Rutkowski, JD, Senior Assistant Attorney General
Sorayah Haden, Executive Assistant, Virginia Board of Pharmacy
Beth O'Halloran, Deputy Executive Director, Virginia Board of Pharmacy
Ryan Logan, Deputy Executive Director, Virginia Board of Pharmacy
Ellen Shinaberry, PharmD, Deputy Executive Director, Virginia Board of Pharmacy
Tim Reilly, RPh, Pharmacy Compliance and Pilot Program Manager

**PHARMACISTS AWARDED
1-HOUR OF LIVE OR REAL-
TIME INTERACTIVE
CONTINUING EDUCATION
FOR ATTENDING MEETING:**

Michael Elkin

QUORUM: With 7 members present, a quorum was established.

APPROVAL OF AGENDA:

An amended agenda was previously posted online with hard copies available at the meeting. Hearing no additional amendments, Dr. Yuan stated that the amended agenda was approved as presented.

APPROVAL OF PREVIOUS BOARD MEETING MINUTES

The following amendments were offered to the draft minutes for the meetings held between July 11, 2024, and August 29, 2024:

- Spelling corrections of the name “Kelly” Hasty Kale within the final minutes of the Formal Hearing held on August 29, 2024.
- Grammatical correction within the final minutes of the Formal Hearing held on August 29, 2024.

Hearing no other amendments, Dr. Yuan stated that the minutes were approved as presented and amended.

PUBLIC COMMENT:

Dr. Natalie Nguyen, Immediate Past-President, Virginia Society of Health-System Pharmacists (VSHP), thanked the board for its continued efforts with the emergency medical services drug kit transition. She indicated further education on accessible prescription labels will be provided during the VSHP fall seminar.

Jamie Fisher, Executive Director, Virginia Pharmacy Association (VPhA), provided comment regarding VPhA’s continued support and encouragement of the Board to progress with the implementation and expansion of statewide protocols that increases patient access to care. VPhA encourages the Board to review the study and documentation of the “pharmacy deserts” increasing throughout the Commonwealth and the concerns with minimal Medicaid reimbursement rates. A handout of her comments was provided to Ms. Haden.

DHP DIRECTOR’S REPORT:

Arne Owens provided a DHP Director’s Report consisting of the following updates:

- The Perimeter Center is continuing to undergo updated security measures to mirror the safety measures required within downtown state offices. Metal detectors have been installed. The next implementation phase will consist of updated security badges and verification systems for employees.
- The General Assembly will resume in approximately three months.
- The agency will undergo a Salary Study soon.
- The agency held a Wholesale Drug Importation Work Group meeting on behalf of the Secretary of Health and Human Resources. A legislative report will be drafted to detail the work group’s discussion of wholesale drug importation.

LEGISLATIVE/
REGULATORY/GUIDANCE

CHART OF REGULATORY ACTIONS

Erin Barret briefly reviewed the chart in the agenda packet and provided the following regulatory updates:

- 18VAC110-21 *2022 Pharmacists Initiating Treatment* has been approved. It will become effective on November 20, 2024.
- 18VAC110-20 *Requirements for Use of Central Fill Pharmacy and Remote Databases* is currently under review in the Secretary's Office.
- 18VAC110-20 *Crisis Stabilization Services and Use of Automated Dispensing Systems and Remote Dispensing Systems* will be presented for proposed final language before the Board at the December Full Board Meeting.
- 18VAC110-20 *Allowances for Emergency Drugs by EMS Agencies* will be presented for proposed final language before the Board at the December Full Board Meeting.

ADOPTION OF EXEMPT REGULATORY ACTION – ADDITION OF CHEMICALS TO SCHEDULE I

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

MOTION

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

Compounds expected to have depressant properties.

1. **7-Bromo-5-(2-chlorophenyl)-1,3-dihydro-2H-1,4-benzodiazepin-2-one (other name: phenazepam), its alt, isomers, and salts of isomers whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation.**

Compounds classified as a cannabimimetic agent:

1. **Methyl N-[[5-methyl-1H-indazol-3-yl]carbonyl]-3-methyl-valinate (other name: MDMB-5Me-INACA), its alt, isomers, and salts of isomers whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemicals designation. (motion by Hoffer, seconded by Webb)**

ADOPTION OF FINAL REGULATORY ACTION REGARDING EXEMPTIONS OF AUTOMATED DEVICES STOCKED SOLELY WITH EMERGENCY OR STAT-USE MEDICATIONS FROM CERTAIN REQUIREMENTS

The Board reviewed and discussed the public comment received and the draft final version of changes to 18VAC110-20-555 regarding the exemption of automated dispensing devices stocked solely with emergency or stat-use medication from certain requirements.

OF 18VAC110-20-555

MOTION:

The Board voted unanimously to adopt final regulatory amendments of 18VAC110-20-555 as presented and amended by inserting “after the pharmacist has reviewed the prescription order but” into subsection 4c after the word “accessed”. (motion by Kocot, seconded by Dowdy)

ADOPTION OF NOTICE OF INTENDED REGULATORY ACTION REGARDING PROHIBITION OF CONTROLLED SUBSTANCE REGISTRATION ISSUANCE TO A PRIVATE DWELLING OR RESIDENCE

The Board reviewed and discussed the notice of intended regulatory action regarding prohibition of controlled substance registration issuance to a private dwelling or residence. The Board reviewed 18VAC110-50-30 and 18VAC110-20-110 which already contains such prohibition for other licensing types.

MOTION:

The Board voted unanimously to adopt the notice of intended regulatory action to amend 18VAC110-20-690 to prohibit controlled substance registration issuance to a private dwelling or residence. (motion by Dowdy, seconded by Hoffer)

ADOPTION OF FAST-TRACK REGULATORY ACTION TO ALLOW AGENCY SUBORDINATES TO HEAR CREDENTIALS CASES

The Board reviewed and discussed the adoption of the fast-track regulatory action to allow agency subordinates to hear credentials cases, e.g., cases wherein reasons may exist to deny issuance of a license. The review consisted of the draft regulatory amendments to allow agency subordinates to hear credential cases which mirror the statutory amendments passed in HB 1622 of the 2023 General Assembly.

MOTION:

The Board voted unanimously to adopt the fast-track regulatory action to amend 18VAC110-15-10 to allow agency subordinates to hear credentials cases. (motion by Webb, seconded by Kocot)

ADOPTION OF EXEMPT REGULATIONS FOR ACCESSIBLE PRESCRIPTION LABELS

The Board reviewed and discussed the adoption of exempt regulations for accessible prescription labels. The review consisted of HB516 and a draft of 18VAC110-20-351 as recommended by the Visually Impaired Work Group which recently met.

MOTION:

The Board voted unanimously to adopt the exempt regulation 18VAC110-20-351 regarding accessible prescription labels as presented and amended by changing “a person authorized to perform the duties of a pharmacist” to “pharmacy intern” and inserting “pharmacy technician trainee” after “technician” in subsection B. (motion by Hoffer, seconded by Kocot)

ADOPTION OF GUIDANCE DOCUMENT FOR ACCESSIBLE PRESCRIPTION LABELS

The Board reviewed and discussed the adoption of Guidance Document 110-14 regarding accessible prescription labels and recommended by the Visually Impaired Work Group which recently met.

MOTION:

Based on public comment received at the beginning of the meeting to offer additional guidance to pharmacists on options available to assist visually impaired patients, the Board voted unanimously to refer the matter to the Regulation Committee which is scheduled to meet in November. (motion by Nash, seconded by Dowdy)

CONSIDER RECOMMENDATIONS TO AMEND THE FOLLOWING STATEWIDE PROTOCOLS:

HIV PRE-EXPOSURE PROPHYLAXIS (PrEP) STATEWIDE PROTOCOL

The Board reviewed and discussed the draft amendments to the HIV Pre-Exposure Prophylaxis (PrEP) statewide protocol as recommended by the statewide protocol work group, consisting of representatives of the Board of Medicine, Board of Pharmacy, and Department of Health, which recently met.

MOTION:

The Board voted unanimously to amend the HIV Pre-Exposure Prophylaxis (PrEP) Statewide Protocol as presented and recommended by the statewide protocol work group. (motion by Dowdy, seconded by Webb)

PHARMACIST PROTOCOL FOR TESTING AND INITIATING TREATMENT FOR COVID-19 VIRUS INFECTION

The Board reviewed and discussed the recommendations to amend the Pharmacist Protocol for Testing and Initiating Treatment for COVID-19 Virus Infection. There was discussion regarding whether references to the emergency use authorization should be amended. The Board concluded that the EUA remains currently in place for pediatric patients 12 and over.

MOTION:

The Board voted unanimously to amend the Pharmacist Protocol for Testing and Initiating Treatment for COVID-19 Virus Infection as presented and amended by inserting into the first paragraph on the first page of the protocol after “(FDA)” the phrase “approval and”. (motion by Hoffer, seconded Kocot)

ADOPTION OF EXEMPT REGULATORY ACTION – ADDITION OF CHEMICALS TO SCHEDULE I PURSUANT

The Board reviewed and discussed the adoption of exempt regulatory action regarding the addition of chemicals to Schedule I pursuant to Virginia Code

TO VIRGINIA CODE §54.1-3443(E)

§54.1-3443 (E). The Board reviewed excerpts of recent DEA scheduling action from December 2023 through September 12, 2024.

MOTION:

The Board voted unanimously to adopt exempt changes to 18VAC110-20-322 to place the following chemicals into Schedule I in conformity with recent federal scheduling actions and pursuant to Virginia Code §54.1-3443(E):

1. *meta*-fluorofentanyl (other name: *N*-(3-fluorophenyl)-*N*-(1-phenethylpiperidin-4-yl)propionamide);
2. *meta*-fluoroisobutyryl fentanyl (other name: *N*-(3-fluorophenyl)-*N*-(1-phenethylpiperidin-4-yl)isobutyramide);
3. *para*-methoxyfuranyl fentanyl (other name: *N*-(4-methoxyphenyl)-*N*-(1-phenethylpiperidin-4-yl)furan-2-carboxamide);
4. 3-furanyl fentanyl (other name: *N*-(1-phenethylpiperidin-4-yl)-*N*-phenylfuran-3-carboxamide);
5. 2',5'-dimethoxyfentanyl (other name: *N*-(1-(2,5-dimethoxyphenethyl)piperidin-4-yl)-*N*-phenylpropionamide);
6. isovaleryl fentanyl (other name: 3-methyl-*N*-(1-phenethylpiperidin-4-yl)-*N*-phenylbutanamide);
7. *ortho*-fluorofuranyl fentanyl (other name: *N*-(2-fluorophenyl)-*N*-(1-phenethylpiperidin-4-yl)furan-2-carboxamide);
8. *para*-methylcyclopropyl fentanyl (other name: *N*-(4-methylphenyl)-*N*-(1-phenethylpiperidin-4-yl)cyclopropanecarboxamide);
9. Methyl 2-[[1-(4-fluorobutyl)indole-3-carbonyl]amino]-3,3-dimethyl-butanoate (other names: 4F-MDMB-BUTICA; 4F-MDMB-BICA);

(motion by Webb, seconded by Hoffer)

NEW BUSINESS:

REQUEST FROM GATES
HEALTHCARE
ASSOCIATED, INC. TO

Ernest P. Gates Jr., President and Michelle Woosley, Vice President of Gates Healthcare Associates presented a request for Gates Healthcare Associates' pharmacy inspection reports to be recognized as an alternative inspection report if the jurisdiction cannot perform an inspection in a timely manner.

RECOGNIZE ITS
INSPECTION REPORT AS
AN ACCEPTABLE
ALTERNATIVE TO AN
INSPECTION BY THE
LICENSING OR
REGULATORY AGENCY OF
JURISDICTION OR AN
INSPECTION BY THE
BOARD OF PHARMACY'S
OWN AGENT

They provided an over of their inspection report template which was included in Attachment 2 of the amended agenda packet. Mr. Grates and Dr. Woosley verbally walked the board through Gates Healthcare Associates' inspection process and explained the color-coded rubric used for easier comprehension of the inspection's findings. Gates Healthcare Associates expressed their current primary focus are nonresident compounding pharmacies seeking licensure or renewal in Virginia. They indicated that their inspection reports are currently recognized in 12 states. The Board was curious how their inspection report compares to the NABP VPP inspection report which is currently recognized by the Board. Gates indicates they can provide the Board with their USP <795> and <800> inspection reports as well.

MOTION:

The Board voted unanimously to refer the matter to the Regulation Committee for further review and discussion. (motion by Nash, seconded by Kale)

PRESCRIPTION
MONITORING PROGRAM
UPDATES

Ashley Carter, MPH, Director, Prescription Monitoring Program, presented a PowerPoint Presentation explaining the mission and statistics of the Prescription Monitoring Program (PMP). As of September 2024, the PMP consisted of 80,000 registered users. Pharmacists represent 16% of the reported 80,000 users which totals 13,047 registered users. Trending topics for the PMP are the rise in states collecting federally non-controlled substances, regulatory changes to require date sold on all prescription recordkeeping, and emergency dispensing from emergency departments. The program has a compliance reporting of 95%-98%. Reasons for non-compliance consist of changes in DEA numbers, changes in software vendors, and staffing/personnel-related issues. At the current spending rate, the forecasted PMP Trust Account is expected to be depleted in 2032.

REPORTS:

CHAIRMAN'S REPORT

Dr. Yuan thanked the participants on the HB 516 Visually Impaired work group and Statewide Protocol work group for their dedication and hard work. Dr. Yuan informed the Board that Ms. Juran and Mrs. Richards-Spruill will be representing the Virginia Board of Pharmacy at the upcoming NABP/AACP Districts 1 & 2 Meeting in Boston, MA in October.

LICENSURE PROGRAM

Ryan Logan, Deputy Executive Director presented the Licensing Program Report which included data from February 2023 through September 6, 2024. As of September 6, 2024, the Virginia Board of Pharmacy reported a total of 46,113 registered licenses consisting of, but no limited to, the following licenses:

- 16,579 registered pharmacists
- 13,300 registered pharmacy technicians
- 7,951 registered pharmacy technician trainees
- 1,728 registered pharmacies

- 964 registered non-resident pharmacies

INSPECTION PROGRAM

Beth O'Halloran, Deputy Executive Director, presented the Inspections Report including data from April 1, 2024, through June 30, 2024. As of June 30, 2024, the Enforcement Division has conducted 381 inspections during the reported period. A total of 222 deficiencies were documented during routine inspections within the reported period. The Enforcement Division completed a total of 3,636 inspections during the time period of June 30, 2022 through June 30, 2024.

DISCIPLINARY PROGRAM

Dr. Shinaberry presented the Disciplinary Program Report. As of August 21, 2024, the Board of Pharmacy has a current active caseload of 300 cases consisting of 184 patient care cases and 116 non-patient care Cases. The Board is utilizing the Agency Subordinate to perform probable cause review for certain cases. Tim Reilly joined Board staff as the new Pharmacy Compliance and Pilot Program Manager in August 2024.

EXECUTIVE DIRECTOR'S REPORT

Ms. Juran provided the Executive Director's Report consisting of in-person and virtual meetings previously attended and future meetings to attend on behalf of the Board. Updates from the upcoming meetings will be provided upon return. Ms. Juran informed the Board that Virginia's turn to serve as the host state for a future NABP/AACP District 1 & 2 meeting will be approaching sooner than expected. Additional information regarding the date is expected to be received at the upcoming NABP District 1 & 2 meeting in October 2024.

MEETING ADJOURNED:

1:11 PM

Caroline Juran, RPh
Executive Director

DATE: