

(DRAFT/UNAPPROVED)

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

Tuesday, June 25, 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 9:11AM.

PRESIDING: Dale St. Clair, PharmD, Chairman

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

MEMBERS ABSENT: Wendy Nash, PharmD

STAFF PRESENT: Caroline Juran, RPh, Executive Director
Brent Saunders, JD, Senior Assistant Attorney General
Erin Barrett, JD, Director of Legislative and Regulatory Affairs, DHP
James Jenkins, RN, Deputy Director, DHP
Arne Owens, Director, DHP
Sorayah Haden, Executive Assistant
Ellen Shinaberry, PharmD, Deputy Executive Director
Ryan Logan, RPh, 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:**

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

APPROVAL OF AGENDA: The Chairman stated a tentative agenda was previously provided to board

members and the public, and that several handouts were provided that morning at their seat and on the table for the public. The first handout was from Jodi Roth on behalf of the Virginia Association of Chain Drug Stores offering comment on central fill pharmacy regulations. The second was from Jay Gill offering comment on pharmacy technician training requirements. The third was a revised handout related to licensure fees that replaces page 64 of the agenda. The fourth was an illustrative table of changes, current costs, and comparisons related to licensure fees. The sixth was an NABP gap analysis of training requirements for pharmacy technicians, and the seventh was a printout from Regulatory Town Hall regarding a public comment period for the 2022 pharmacists initiating treatment action. Hearing no additional items, the Chairman approved the agenda as presented.

**APPROVAL OF PREVIOUS
BOARD MEETING
MINUTES:**

Hearing no corrections to the minutes, the Chairman stated that the minutes for the meetings held between May 2nd and June 5th were approved as presented.

PUBLIC COMMENT:

- Jeenu Philip, Director of Pharmacy Affairs, Walgreens, provided public comment on behalf of Walgreens Central Fill #21420 regarding the emergency regulations for central fill pharmacies. Walgreens Central Fill #21420 is currently operating as an approved pilot program utilizing a 12:1 pharmacist to pharmacy technician ratio to fill prescriptions. Mr. Philip informed the board the central fill pharmacy in Virginia services 175 Walgreens locations in Virginia and 113 out-of-state locations. It has filled a little under 6 million prescriptions thus far. Mr. Philip requests consistency amongst the emergency regulations and the approved pilot program by removing unlicensed persons to be included in the 12:1 pharmacist to pharmacy Technician ratio.
- Lauren Paul, Executive Director of Pharmacy Affairs, CVS Health provided public comment on behalf of CVS Health regarding the emergency regulations for central fill pharmacies and remote processing by pharmacy technicians. She encouraged the board to keep regulations broad and open to improve workforce conditions.
- Jamie Fisher, Executive Director, VPhA, provided public comment on behalf of the Virginia Pharmacists Association. Ms. Fisher provided updates on active workgroups in place to improve the working conditions of pharmacies throughout the Commonwealth. VPhA requests further analysis of the central fill pharmacy pilot and caution when expanding ratios. It favors enforcing licensing requirements as currently found in 18VAC110-20-276. VPhA requests striking “or possesses credentials similar to Virginia” and stated that “substantially equivalent” is unclear.
- Natalie Nguyen, PharmD, Immediate Past-President, VSHP, provided

public comment on behalf of the Virginia Society of Health-System Pharmacists. VSHP requested clarification regarding if Guidance Document 110-19 *Use of Automated Dispensing Devices in Certain Facilities* excludes facilities currently utilizing automated dispensing devices or if they would now need a CSR. She questioned what information is available across the states regarding ratios and the outcome of the central fill pharmacy pilot. Dr. Nguyen expressed VSHP's concern of increase in possible diversion of highly valuable Schedule VI drugs as the result of allowing unlicensed persons to perform duties within a pharmacy.

- Patrick Baker, PharmD, Senior Vice President and General Manager, Mosaic Pharmacy provided public comment on behalf of Mosaic Pharmacy regarding pharmacy technician educational requirements. Mr. Baker expressed concerns for the decrease in pharmacy technician applicants due to the cost of the ASHP/ACPE-accredited training programs. He shared concerns ASHP/ACPE-accredited training programs appear to favor chain pharmacies over independent pharmacies for serving as clinical sites. Mr. Baker requests the approval of additional training programs such as PTCB-approved programs to provide more affordable educational opportunities. A handout of his public comments was also provided to the Board.

DHP DIRECTOR'S REPORT:

Arne Owens provided general updates on behalf of the Department of Health Professions and indicated that Janet Kelly will soon become Virginia's Secretary of Health and Human Resources.

LEGISLATIVE/
REGULATORY/GUIDANCE

CHART OF REGULATORY
ACTIONS

Erin Barrett briefly reviewed the regulatory actions chart in the agenda packet and provided updated information. The chart provided an update regarding proposed regulations in the Governor's office, Secretary's office, the Attorney General's office, and those recently effective or awaiting publication.

CONSIDERATION OF
PETITION FOR
RULEMAKING TO ADD
KRATOM TO SCHEDULE I

The Board reviewed and discussed the petition for rulemaking received requesting the amendment of 18VAC110-20-322 to add Mitragynine and 7-Hydroxymitragynine (Kratom) to Schedule I. Approximately 3,000 public comments were received on the petition. Approximately 500 comments were in support and over 2,000 were in opposition. Kocot expressed concern for placing it into Schedule I when the elected members of the General Assembly had recently passed legislation regarding the sale of Kratom to persons 21 and older. Ratliff indicated he supported the NOIRA and that it needs to be studied. Garvin stated she was not convinced it should be placed into Schedule I based on the conflicting public comments.

MOTION

The Board voted unanimously to deny the petition for rulemaking to amend 18VAC110-20-322 to place Mitragynine and 7-Hydroxymitragynine (Kratom) into Schedule I as it did not feel it possessed sufficient evidence at the meeting to determine that Kratom has no medicinal value, but that the Board may research and review this matter at a future meeting. (motion by Kocot, seconded by Garvin)

ADOPTION OF EMERGENCY REGULATIONS FOR CENTRAL FILL PHARMACIES AND REMOTE PROCESSING BY PHARMACY TECHNICIANS

The Board reviewed and discussed the emergency regulations for central fill pharmacies and remote processing by pharmacy technicians. The agenda package included HB1068, the draft regulatory changes which comply with legislation, suggested amendments offered by Publix Pharmacy, and relative Boards orders for active pilot programs utilizing central filling and remote pharmacies.

MOTION:

The Board voted unanimously to adopt emergency regulations amending 18VAC110-20-112, 18VAC110-20-276, and adopting 18VAC110-20-277 as presented and amended as indicated below, and to issue a Notice of Intended Regulatory Action for permanent regulations.

- **18VAC110-20-112:** at the end of subsection A, insert “except as provided in 18VAC110-20-276 and 18VAC110-20-277.”
- **18VAC110-20-276:** insert new subsection G to read:

G. A pharmacist may only supervise a maximum of six pharmacy technicians and pharmacy interns performing the duties of pharmacy technicians accessing the employer pharmacy's database from a remote location as provided in subsection F, with a maximum of four of the six on site at the employer pharmacy. The supervising pharmacist shall be readily available to the pharmacy technicians and pharmacy interns and technology shall be available for adequate supervision of pharmacy technicians and pharmacy interns performing the duties of pharmacy technicians.

- **18VAC110-20-277: amend subsection D to read:**

D. A pharmacist practicing at a central fill pharmacy may supervise up to 12 licensed registered persons, to include pharmacy technicians, pharmacy technician trainees, pharmacy interns, and may supervise up to 12 unregistered or unlicensed persons performing non-dispensing functions authorized in this subsection. Each pharmacist shall determine number of persons he can safely and competently supervise at one time.

(motion by Garvin, seconded by Yuan)

ADOPTION OF FINAL ACTION ON ALLOWANCES FOR CENTRALIZED WAREHOUSER/

The Board reviewed and discussed the final regulations regarding allowance for centralized warehouse or wholesale distributor to verify Schedule VI drugs for automated dispensing devices in hospitals.

WHOLESALE DISTRIBUTOR
TO VERIFY SCHEDULE VI
DRUGS FOR ADDs IN
HOSPITALS

MOTION:

The Board voted unanimously to adopt the final regulations regarding allowances for centralized warehouse and wholesale distributor to verify Schedule VI drugs for automated dispensing devices in hospitals as presented and amended to state the following:

- **18VAC110-20-490 (D)(5) – strike “each unit” and replace with “in accordance with the hospital’s policies and procedures”**
- **18VAC110-20-490 (D)(6) – after “automated dispensing device” insert “or associated drug database”.**

(motion by Garvin, seconded by Richards-Spruill)

ADOPTION OF PROPOSED
REGULATORY
AMENDMENTS FOR
LICENSURE FEE INCREASE

The Board reviewed and discussed the proposed regulatory amendments for licensure fee increases. The agenda packet included information regarding factors impacting the needs for fee increases, comparison of neighboring states licensure fees, and proposed fee amendments to Chapter 20, 21, 30, and 50.

MOTION

The Board voted unanimously to adopt the proposed regulatory amendments for licensure fee increases as presented. (motion Dowdy, seconded by Hoffer)

ADOPTION OF EXEMPT
ACTION CONFORMING
SCHEDULING
REGULATION(S) TO
GENERAL ASSEMBLY
ACTIONS

The Board reviewed and discussed the exempt regulatory action pursuant to SB111/HB1333. The agenda packet included draft changes to 18VAC110-20-322 and 18VAC110-20-323 to conform to scheduling changes enacted by the legislature in the 2024 General Assembly Session.

MOTION

The Board voted unanimously to adopt the exempt regulatory amendments of 18VAC110-20-322 and 18VAC110-20-323 as presented. (motion by Kocot, seconded by Garvin)

ADOPTION OF FINAL
REGULATORY ACTION –
IMPLEMENTATION OF 2022
LEGISLATION FOR
PHARMACISTS INITIATING
TREATMENT

The Board reviewed and discussed the adoption of final regulatory action pertaining to the implementation of 2022 legislation for pharmacists initiating treatment.

MOTION

The Board voted unanimously to adopt the final regulatory action of 18VAC110-21-46 as presented and pertaining to the implementation of 2022 legislation for pharmacists initiating treatment. (motion by Yuan,

seconded by Melton)

The Board reviewed and discussed the adoption of exempt regulatory action pertaining to the addition of chemicals to Schedule I. The agenda packet included recommendations from the Department of Forensic Science to place certain chemicals in Schedule I.

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

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

MOTION

F. Pursuant to subsection D of § 54.1-3443 of the Code of Virginia, the Board of Pharmacy places the following in Schedule I of the Drug Control Act:

1. The following compounds expected to have hallucinogenic properties:

a. 1-[(4-fluorophenyl)methyl]-4-methylpiperazine (other names: 4-fluoro-MBZP, 4-fluoro methylbenzylpiperazine), 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.

b. 4-fluoro-alpha-pyrrolidinoisohexiophenone (other name: 4-fluoro-alpha-PiHP), 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.

c. 8-bromo-1-methyl-6-pyridin-2-yl-4H-[1,2,4]triazolo[4,3-a][1,4]benzodiazepine (other name: pyrazolam), 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.

2. The following cannabimimetic agent: Methyl-2-(1-butyl-1H-indazole-3-carboxamido)-3,3-dimethylbutanoate (other name: MDMB-BUTINACA), 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 Richards-Spruill, seconded by Hoffer)

The Board reviewed and discussed the draft amendment of Guidance Document 110-9 to repeal deficiency 125 due to elimination of this language by USP.

**AMENDMENT OF
GUIDANCE DOCUMENT
110-9**

MOTION

The Board voted unanimously to amend Guidance Document 110-9 as presented to repeal deficiency 125. (motion by Garvin, seconded by Dowdy)

DISCUSSION REGARDING
PHARMACY TECHNICIAN
EDUCATIONAL STANDARD
AND WORKFORCE
CHALLENGES

The Board reviewed the background information on this subject in the agenda packet and discussed the difficulties some pharmacies are facing in hiring and training pharmacy technicians, along with the cost associated with completing an ASHP/ACPE-accredited training program.

MOTION

The Board voted unanimously to adopt a legislative proposal that would amend 54.1-3321 (B)(2) by inserting a new section “iii” to allow for successfully completing a pharmacy technician training program that is recognized by PTCB or NHA. (motion by Kocot, seconded by Garvin)

AMEND 2024 PHARMACY
TECHNICIAN WORKFORCE
SURVEY REPORT

Following the adoption of the 2023 Virginia Pharmacy Technician Workforce Survey Report at an earlier meeting, staff identified that the 8,063 pharmacy technician trainees are not included in the report because they do not renew their trainee registration. Thus, the report did not appear to comprehensively represent the total workforce of persons that may be performing the duties of a pharmacy technician. Staff recommended minor amendments to the 2023 report and stated they are working with the Healthcare Workforce Center to capture additional data elements of pharmacy technician trainees in subsequent pharmacy technician workforce reports.

MOTION:

The Board voted unanimously to amend the 2023 Virginia Pharmacy Technician Workforce report as presented. (motion by Kocot, seconded by Garvin)

NEW BUSINESS:

DISCUSSION REGARDING
2024 MAP OF PHARMACY
PERMIT LOCATIONS

The Board reviewed and discussed the 2024 map of pharmacy permit locations. The agenda packet included maps with data from May 2024, maps previously provided to Board using data from June 2023, and an excerpt of current count of licenses as of Q3 2024. Total number of pharmacies as of May 2024 was 1,735 compared to 1,746 in June 2023. There are four counties that do not appear to have a pharmacy.

ELECTION OF CHAIRMAN

Mr. Kocot nominated Ms. Cheri Garvin to serve as the 2024-2025 Chairman of the Virginia Board of Pharmacy.

MOTION

The Board voted unanimously to close nominations for Chairman. (motion by Richards-Spruill, seconded by Dowdy)

The Board voted unanimously to elect Ms. Cheri Garvin to serve as Chairman of the Virginia Board of Pharmacy for the term of July 1, 2024 through June 30, 2025.

ELECTION OF VICE-CHAIRMAN

Mrs. Richards-Spruill nominated Dr. Ling Yuan to serve as the 2024-2025 Vice-Chairman of the Virginia Board of Pharmacy.

Dr. Ratliff nominated Dr. Shannon Dowdy to serve as the 2024-2025 Vice-Chairman of the Virginia Board of Pharmacy.

MOTION

The Board voted (5-4) to elect Dr. Ling Yuan to serve as Vice-Chairman of the Virginia Board of Pharmacy for the term of July 1, 2024 through June 30, 2025.

SCHEDULE 2025 MEETING DATES

The Board chose the following dates for the 2025 Full Board Meetings: March 25th, June 17th, September 30th, and December 10th.

CONSIDERATION OF AGENCY SUBORDINATE RECOMMENDATIONS

The Board reviewed the confidential attachments consisting of the agency subordinate recommendations regarding ten informal conference hearings previously held.

MOTION

The Board voted unanimously to accept the agency subordinate recommendations regarding ten informal conference hearings as presented. (Motion by Ms. Garvin, seconded by Dr. Yuan)

REPORTS:

CHAIRMAN'S REPORT

Dr. Dale St. Clair thanked the board for their service and support of him as the Chairman of the Virginia Board of Virginia. A recap of the year including meetings attended and regulations passed was provided. He emphasized the importance of mental health resources which was the presidential initiative of NABP President Lenora Newsome, and action Virginia has taken to improve questions on licensing applications related to this subject.

BOARD OF HEALTH PROFESSIONS

Dr. Melton reported the Board of Health Professions has not met since the last update provided.

LICENSURE PROGRAM

Mr. Logan presented the Licensing Report of individuals and facilities licenses within Virginia which included data from November 2022 through June 2024. As of June 5, 2024, the Virginia Board of Pharmacy has a total of 44,816 licenses consisting of individual and pharmacy permits currently issued.

INSPECTION PROGRAM

Melody Morton, Inspections Manager with the Enforcement Division, presented the Inspections Report including data from January 2024 through March 2024. A total of 442 pharmacy inspections have been completed from January 2024 through March 2024.

DISCIPLINARY PROGRAM

Dr. Shinaberry presented the Disciplinary Program Report. As of June 5, 2024, the Virginia Board of Pharmacy has a total of 308 open cases consisting of 185 patient care related cases and 123 non-patient care related cases. She also announced that Compliance Case Manager Rose DeMatteo will be retiring on July 24, 2024. The Board expressed sincere appreciation for Ms. DeMatteo's service to the Board and the Commonwealth and wished her all the best in her retirement.

EXECUTIVE DIRECTOR'S REPORT

Ms. Juran provided a report including staff updates such as the addition of Disciplinary Administrative Specialist Nicole Copeland, the transition of Deputy Executive Director Annette Kelley to another health regulatory board at DHP, the upcoming retirement of the Compliance Case Manager Rose DeMatteo, and the ongoing recruitment for this position. The Board is currently working with Impact Makers to review and identify efficiencies in the licensure process. A recap of meetings previously attended and upcoming meetings was also provided.

CONSIDERATION OF CONSENT ORDERS, SUMMARY SUSPENSIONS, OR SUMMARY RESTRICTIONS

SUMMARY SUSPENSION PRESENTATION

Sean Murphy with the OAG presented a possible summary suspension for Board consideration regarding Tyler Coffey (Pharmacist License 0202-219563).

MOTION

Upon a motion by Hoffer, and duly seconded by Ratliff, the Board unanimously voted to summarily suspend the pharmacist license of Tyler Coffey (0202-219563).

CONSENT ORDER

Sean Murphy presented consent orders for Board consideration regarding CVS Pharmacy #7561 (0201-002726) and CVS Pharmacy #1985 (0201-002743)

MOTION

Upon a motion by Garvin, and duly seconded by Richards-Spruill, the Board unanimously voted to accept the consent orders for CVS Pharmacy #7561 (0201-002726) and CVS Pharmacy #1985 (0201-002743).

MEETING ADJOURNED: 3:15 PM

Caroline Juran, RPh
Executive Director

DATE:

DRAFT