

(DRAFT/UNAPPROVED)

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

Monday, September 6, 2022
Commonwealth Conference Center
Second Floor
Board Room 2

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

CALL TO ORDER: A full board meeting was called to order at 9:10AM.

PRESIDING: Dale St.Clair, PharmD, Chairman

MEMBERS PRESENT: Larry Kocot, J.D.
Bill Lee, DPh
Wendy Nash, PharmD
Kristopher Ratliff, DPh
Patricia Richards-Spruill, RPh
Ling Yuan, PharmD

MEMBERS ABSENT: Jim Jenkins, RN
Cheri Garvin, RPh
Sarah Melton, PharmD

STAFF PRESENT: Caroline D. Juran, RPh, Executive Director
Erin Barrett, J.D., DHP Senior Policy Analyst
David Brown, D.C., DHP Director
Mykl Egan, J.D., Disciplinary Case Manager
Annette Kelley, MS, CSAC, Deputy Executive Director
Ryan Logan, RPh, Deputy Executive Director
Beth O'Halloran, RPh, Deputy Executive Director
Ileita Redd, Disciplinary Specialist
James Rutkowski, J.D., Assistant Attorney General
Ellen Shinaberry, PharmD, Deputy Executive Director

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

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

APPROVAL OF AGENDA: The agenda was adopted as presented.

**APPROVAL OF PREVIOUS
BOARD MEETING MINUTES**

MOTION: **The Board voted unanimously to adopt the minutes for the meetings held between May 23, 2022 and August 17, 2022 as presented. (Motion by Richards-Spruill , seconded by Ratliff; Kocot abstained)**

The Board voted unanimously to adopt the minutes for the meetings held on August 18, 2022 and August 23, 2022 as presented. (Motion by Kocot, seconded by Yuan)

PUBLIC COMMENT: Lauren Paul, Executive Director, Pharmacy Regulatory Affairs, CVS Health offered public comment. She applauded efforts made in Virginia to expand pharmacy clinical services. She requested the Board amend Guidance Document 110-33 to authorize a pharmacist to delegate to a Board-registered pharmacy technician trainee who has completed the practical immunization training approved by ACPE and has obtained a certificate in basic CPR to administer vaccines. She stated the pharmaceutical processor advertising language regarding an “image” was confusing and questioned why advertising allowances needed to be broadened since safeguards should be in place. She offered supportive comments for the draft language in Guidance Document 110-6.

Becky Hobden, Lab Director, Green Analytics Virginia offered verbal comment, in addition to the written comment provided to the Board as a handout. Green Analytics is a cannabis testing lab. She stated that testing residual solvents as proposed may be cost prohibitive, that some of the solvents on the list are not used in cannabis extraction, and that labs may not have an ability to test for all of the solvents on the proposed list. She offered to provide staff with a list of chemicals for which a lab test may not exist if the Board wanted to carve out certain solvents for which there is no ability to test for their presence.

The Board paused for a few minutes to read the written comment provided by gLeaf that was provided to the Board as a handout.

DHP DIRECTOR’S REPORT: Dr. David Brown welcomed the newly appointed board members and congratulated those who were reappointed. He provided an update on the HPMP and suggested the Board invite representatives of the HPMP to offer an overview presentation at a future meeting. He stated that the agency is still experiencing supply chain delays regarding the AV equipment upgrade in the conference center.

LEGISLATIVE/
REGULATORY/GUIDANCE

CHART OF REGULATORY
ACTIONS

Ms. Barrett briefly reviewed the chart in the agenda packet and provided updated information regarding the length of time of each proposed regulation in the various stages of administrative review.

ADOPTION OF EXEMPT
FINAL REGULATIONS TO
PLACE CERTAIN
CHEMICALS INTO
SCHEDULE I

MOTION:

The Board voted unanimously to adopt the exempt final regulations for 18VAC110-20-322 to place the following chemicals in Schedule I as presented:

The following compound is classified as a synthetic opioid. Compounds of this type have been placed in Schedule I (§ 54.1-3446(1)) in previous legislative sessions.

- 1. N,N-diethyl-2-[5-nitro-2-(4-propoxybenzyl)-1H-benzimidazol-1-yl]ethanamine (other name: Protonitazene), its isomers, esters, ethers, salts, and salts of isomers, esters, and ethers, unless specifically excepted, whenever the existence of these isomers, esters, ethers and salts is possible within the specific chemical designation.**

Based on their chemical structures, the following compounds are expected to have hallucinogenic properties. Compounds of this type have been placed in Schedule I (§ 54.1-3446(3)) in previous legislative sessions.

- 2. 1-(1,3-benzodioxol-5-yl)-2-(cyclohexylamino)butan-1-one (other names: Cybutylone, N-cyclohexyl Butylone), 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.**

Based on its chemical structure, the following compound is expected to have depressant properties. Compounds of this type have been placed in Schedule I (§ 54.1-3446(4)) in previous legislative sessions.

- 3. 8-bromo-6-(2-chlorophenyl)-1-methyl-4H-[1,2,4]triazolo[4,3-a][1,4]benzodiazepine (other names: Clobromazolam, Phenazolam), 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.

The following compounds are classified as cannabimimetic agents. Compounds of this type have been placed in Schedule I (§ 54.1-3446(6)) in previous legislative sessions.

- 4. 5-bromo-N-(1-amino-3,3-dimethyl-1-oxobutan-2-yl)-1H-indazole-3-carboxamide (other name: ADB-5Br-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.**
- 5. N-(1-amino-3,3-dimethyl-1-oxobutan-2-yl)-5-bromo-1-butyldiazole-3-carboxamide (other name: ADB-5'Br-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 Kocot, seconded by Lee)**

ADOPTION OF EXEMPT
FINAL REGULATIONS TO
CONFORM DRUG
SCHEDULES TO FEDERAL
SCHEDULING ACTION

MOTION:

The Board voted unanimously to adopt the exempt final regulations for 18VAC110-20-323 to conform drug schedules to federal scheduling action as presented and listed below:

Needs to be Placed into Schedule I to conform to federal scheduling:

- 1. 4-methyl-5-(4-methylphenyl)-4,5-dihydro-1,3-oxazol-2-amine (4,4'-Dimethylaminorex, 4,4'-DMAR);**
- 2. 1-(5-fluoropentyl)-N-(2-phenylpropan-2-yl)pyrrolo[2,3-b]pyridine-3-carboxamide (5F-CUMYL-P7AICA);**
- 3. ethyl N-phenyl-N-[1-(2-phenylethyl)piperidin-4-yl]carbamate (fentanyl carbamate);**
- 4. N-(2-fluorophenyl)-N-[1-(2-phenylethyl)piperidin-4-yl]prop-2-enamide (ortho-fluoroacryl fentanyl);**
- 5. N-(2-fluorophenyl)-2-methyl-N-[1-(2-phenylethyl)piperidin-4-yl]propanamide (ortho-fluoroisobutyryl fentanyl);**
- 6. N-(4-fluorophenyl)-N-[1-(2-phenylethyl)piperidin-4-yl]furan-2-carboxamide (para-fluoro furanyl fentanyl);**
- 7. N-(2-fluorophenyl)-N-[1-[2-(2-fluorophenyl)ethyl]piperidin-4-yl]propanamide (2'-fluoro ortho-fluorofentanyl; 2'-fluoro 2-**

- fluorofentanyl);
8. N-[1-[2-(4-methylphenyl)ethyl]piperidin-4-yl]-N-phenylacetamide (4'-methyl acetyl fentanyl);
 9. N,3-diphenyl-N-[1-(2-phenylethyl)piperidin-4-yl]propanamide (β' -phenyl fentanyl; beta'-phenyl fentanyl; 3-phenylpropanoyl fentanyl);
 10. N-phenyl-N-[1-(2-phenylpropyl)piperidin-4-yl]propanamide (β -methyl fentanyl);
 11. N-(2-fluorophenyl)-N-[1-(2-phenylethyl)piperidin-4-yl]butanamide (ortho-fluorobutyryl fentanyl; 2-fluorobutyryl fentanyl);
 12. N-(2-methylphenyl)-N-[1-(2-phenylethyl)piperidin-4-yl]acetamide (ortho-methyl acetylfentanyl; 2-methyl acetylfentanyl);
 13. 2-methoxy-N-(2-methylphenyl)-N-[1-(2-phenylethyl)piperidin-4-yl]acetamide (ortho-methyl methoxyacetylfentanyl; 2-methyl methoxyacetyl fentanyl);
 14. N-(4-methylphenyl)-N-[1-(2-phenylethyl)piperidin-4-yl]propanamide (para-methylfentanyl; 4-methylfentanyl);
 15. N-phenyl-N-[1-(2-phenylethyl)piperidin-4-yl]thiophene-2-carboxamide (thiophene fentanyl);
 16. N-(4-chlorophenyl)-2-methyl-N-[1-(2-phenylethyl)piperidin-4-yl]propanamide (para-chloroisobutyryl fentanyl);
 17. 24. 2-[2-[(4-butoxyphenyl)methyl]-5-nitrobenzimidazol-1-yl]-N,N-diethylethanamine (Butonitazene);
 18. 25. N,N-diethyl-2-[2-[(4-fluorophenyl)methyl]-5-nitrobenzimidazol-1-yl] ethanamine (Flunitazene)

Needs to be Placed into Schedule II to conform to federal scheduling:

1. Oliceridine

Needs to be Exempted from Schedule II to conform to federal scheduling:

1. Removal of Samidorphan

Needs to be Placed into Schedule IV to conform to federal scheduling:

1. Remimazolam
2. Serdexmethylphenidate
3. Lemborexant
4. Daridorexant

Needs to be Placed into Schedule V to conform to federal Scheduling:

1. Ganaxolone

(Motion by Kocot, seconded by Lee)

ADOPTION OF EXEMPT
FINAL REGULATIONS TO
REMOVE CHEMICALS
RECENTLY SCHEDULED IN
CODE

MOTION:

The Board voted unanimously to adopt exempt final regulations for 18VAC110-20-322 and 18VAC110-20-323 as presented to remove Scheduled substances which are now in the Code. (motion by Kocot, seconded by Lee)

ADOPTION OF EMERGENCY
REGULATIONS/NOIRA FOR
PHARMACISTS INITIATING
TREATMENT

During the discussion, Dr. Lee commented that perhaps the Board should consider in a future periodic regulatory review an amendment to 18VAC110-20-150 (G) to require medical-grade refrigeration.

MOTION:

Pursuant to HB 1323, the Board voted unanimously to adopt emergency regulations to amend 18VAC110-21-46 as presented for pharmacist initiating treatment and a NOIRA for replacement regulations. (motion by Yuan, seconded by Kocot)

AMEND CURRENT
STATEWIDE PROTOCOLS:

To conform with statutory changes resulting from HB 1323 and recommendations from a recent statewide protocol workgroup hosted by the Board of Medicine regarding vaccine protocols, the Board voted unanimously to amend the following current statewide protocols as presented:

- **Pharmacist Emergency Contraception Statewide Protocol;**
- **Pharmacist Statewide Protocol to Lower Out-of-Pocket Expenses;**
- **Tuberculin Skin Testing One-Step Protocol;**
- **Tuberculin Skin Testing Two-Step Protocol;**
- **Pharmacist Epinephrine Statewide Protocol;**
- **Pharmacist Naloxone Statewide Protocol;**
- **Pharmacist Prenatal Vitamin Statewide Protocol;**
- **Pharmacist Hormonal Contraceptive Statewide Protocol;**
- **Pharmacist Vaccine Statewide Protocol**

(motion by Richards-Spruill, seconded by Lee)

ADOPTION OF EXEMPT

**REGULATIONS FOR
PHARMACEUTICAL
PROCESSORS:**

MOTION:

In response to HB933/SB671 and public comments received during the 60-day public comment period, the Board voted unanimously to adopt the exempt regulations for pharmaceutical processors as presented and amended as outlined below:

- **Strike “a” after “Virginia” in 18VAC110-60-170 (D);**
- **Strike 18VAC110-60-170 (D) (6);**
- **Insert “Virginia” after “any” in 18VAC110-60-280(B)(2)(b) and replace “state” with “Virginia” in 18VAC110-60-280 (B)(2)(c) and 18VAC110-60-281(B)(5);**
- **Insert new subsection “H” in 18VAC110-60-281 to reference use of an approved list of hydrocarbon-based solvents for cannabis oil products;**
- **Amend 18VAC110-60-300 (G)(6) to acknowledge approved list of hydrocarbon-based solvents in 18VAC110-60-281(H). (motion by Ratliff, seconded by Richards-Spruill)**

ACTION ITEM:

Board to develop guidance document to reference approved list of hydrocarbon-based solvents for which there is a lab test to assess residual solvent.

**ADOPTION OF EMERGENCY
REGULATIONS/NOIRA FOR
PHARMACY WORKING
CONDITIONS:**

A revised draft of regulatory amendments was provided to the Board for its consideration.

In response to HB1324, the Board voted unanimously to adopt the emergency regulations to amend 18VAC110-20-110 and 18VAC110-20-113 as presented in the handout and amended as outlined below:

- **18VAC110-20-113(B)(1), end sentence after “safety”; strike “recognizing that”; and, replace last sentence with language akin to “Staffing levels cannot solely be determined based on total prescription volume, but shall consider any other requirements of pharmacy staff during working hours.”;**
- **18VAC110-20-113(B)(4), replace “and” with “as” after “experience”;**
- **18VAC110-20-113(E), insert requirements for permit holder to acknowledge receipt of the staffing report, document steps toward addressing the issue, report action or inaction back to the PIC or reporting pharmacist, and maintain the documentation on-site at the pharmacy or produce the documentation for inspection by the**

Board within 48 hours of request. (motion by Nash, seconded by Yuan)

**Consider Ability for
Pharmacy Technician
Trainees to Administer
Vaccines**

MOTION:

The Board voted unanimously to amend Guidance Document 110-33 as presented to not allow pharmacy technician trainees to administer vaccines, consistent with the Board’s interpretation of the current allowances in the PREP Act. (motion by Ratliff, Richards-Spruill)

AMEND GUIDANCE
DOCUMENT 110-25 TO
ADDRESS LIFE OF
WRITTEN CERTIFICATION
WHEN PRESCRIBER NO
LONGER IN PRACTICE

MOTION:

The Board voted unanimously to amend Guidance Document 110-25 as presented to address the life of a written certification when the prescriber is no longer in practice. (motion by Lee, seconded by Nash)

ACTION ITEM:

At the Board’s request, Ms. Juran will research if there is evidence correlating the number of hours worked by pharmacists to patient harm. She will also discuss with the Workforce Data Center whether a question could be reasonably added to the pharmacist workforce survey to identify the number of pharmacists working longer than 12 consecutive hours.

AMEND GUIDANCE
DOCUMENT 110-6
REGARDING OPIOID
TREATMENT PROGRAMS

Ms. Barrett stated that staff recommends that the last two sentences stricken in the second bullet point on the first page of the draft included in the agenda packet that begins “The nurse must ensure....” should remain in the guidance document and not be stricken.

MOTION:

Resulting from SB511 and to address the allowance for a nurse to perform the duties of a pharmacy technician in an opioid treatment program, the Board voted unanimously to amend Guidance Document 110-6 as presented and amended by retaining the last two sentences of the second bullet point on the first page that begins “The nurse must ensure...” (motion by Lee, seconded by Nash)

AMEND GUIDANCE
DOCUMENT 110-35

REGARDING
PRESCRIPTION
REQUIREMENTS

MOTION:

To further educate licensees, the Board voted unanimously to amend Guidance Document 110-35 as presented to acknowledge the legal provisions for prescriptions for expedited partner therapy. (motion by Yuan, seconded by Richards-Spruill)

AMEND GUIDANCE
DOCUMENT 110-45
REGARDING MINORS
WORKING AS PHARMACY
TECHNICIAN TRAINEES

In response to concerns raised to staff by the Department of Labor and Industry, a draft guidance document recommending that pharmacy technician trainees under the age of 18 only handle Schedule VI drugs was presented for consideration by the Board.

MOTION/ACTION ITEM:

The Board voted unanimously to table the adoption of a guidance document recommending that pharmacy technician trainees under the age of 18 only handle Schedule VI drugs and to invite a representative from the Department of Labor and Industry to a future meeting to discuss the matter. (motion by Nash, seconded by Lee)

AMEND GUIDANCE
DOCUMENT 110-20

MOTION:

To clarify which material owners of a pharmaceutical processor or cannabis dispensing facility must perform a criminal background check when no owner has 5% or greater ownership, the Board voted unanimously to amend Guidance Document 110-20 as presented and amended as outlined below:

- **Strike “such as the chief executive officer and chief financial officer”. (motion by Kocot, seconded by Ratliff)**

NEW BUSINESS:

ELECTION OF VICE-
CHAIRMAN:

Dr. Ratliff recommended Bill Lee for Vice-Chairman of the Virginia Board of Pharmacy. Term is for September 6, 2022 through June 30, 2023. No other nominations were recommended.

MOTION:

The Board voted unanimously to close nominations for election of the 2022-2023 Vice-Chairman of the Virginia Board of Pharmacy. (motion by Richards-Spruill, seconded by Kocot)

VOTE:

The Board voted unanimously to elect Bill Lee as the 2022-2023 Vice-

Chairman of the Virginia Board of Pharmacy.

REPORTS:

CHAIRMAN’S REPORT

Dr. St.Clair thanked the former board members and welcomed the newly appointed board members. He encouraged attendance at the NABP/AACP Districts 1 and 2 meeting in October and the NABP annual meeting in May.

BOARD OF HEALTH PROFESSIONS

On behalf of Dr. Melton, Dr. St.Clair stated that the last meeting of the Board of Health Professions was cancelled and there was nothing to report.

LICENSURE OF INDIVIDUALS AND IN-STATE FACILITIES

Mr. Logan reviewed the Licensing Report of Individuals and In-State Facilities included in the agenda packet.

LICENSURE OF NONRESIDENT FACILITIES

Ms. O’Halloran reviewed the Licensing Report of Nonresident Facilities included in the agenda packet.

INSPECTION PROGRAM

Melody Morton, Inspections Manager with the Enforcement Division presented the Inspections Report which was included in the agenda packet.

PHARMACEUTICAL PROCESSORS

Annette Kelley reviewed the Pharmaceutical Processors Report included in the agenda packet. .

DISCIPLINARY PROGRAM

Dr. Shinaberry reviewed the disciplinary report included in the agenda packet.

EXECUTIVE DIRECTOR’S REPORT

Ms. Juran reviewed her report which was included in the agenda packet. Additionally, she expressed appreciation to staff members Ileita Redd and Mykl Egan who were attendance at the meeting.

MEETING ADJOURNED:

With all business concluded, the meeting adjourned at 3PM.

Dale St.Clair, Chairman

Caroline Juran, Executive Director

DATE:

DATE: