

(DRAFT/UNAPPROVED)

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

March 30, 2021
Virtual Meeting

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

CALL TO ORDER:

A virtual Webex meeting of the Board of Pharmacy was called to order at 9:12 AM. Due to the COVID-19 declared state of emergency and consistent with Amendment 28 to HB29 (Budget Bill for 2018-2020) and the applicable provisions of § 2.2-3708.2 in the Freedom of Information Act, the Board convened a virtual meeting to consider such regulatory and business matters as was presented on the agenda necessary for the board to discharge its lawful purposes, duties, and responsibilities.

PRESIDING:

Kristopher Ratliff, Chairman

MEMBERS PRESENT:

Cheryl H. Nelson, Vice Chairman
Glen Bolyard
Ryan Logan
Patricia Richards-Spruill
Sarah Melton
Dale St.Clair
William Lee
Bernard Henderson, Jr.

MEMBER ABSENT:

James L. Jenkins, Jr.

STAFF PRESENT:

Caroline D. Juran, Executive Director
Annette Kelley, Deputy Executive Director
Beth O'Halloran, Deputy Executive Director
Ellen B. Shinaberry, Deputy Executive Director
Elaine Yeatts, Senior Policy Analyst, DHP
David E. Brown, D.C., Director, DHP
Barbara Allison-Bryan, M.D., Chief Deputy, DHP
James Rutkowski, Assistant Attorney General
Melody Morton, Inspection Manager, DHP
Kiara Christian, Executive Assistant

**PHARMACISTS AWARDED
1-HOUR OF LIVE OR REAL-
TIME INTERACTIVE**

William Lee
Patricia Richards-Spruill
Farzana Kennedy

CONTINUING EDUCATION
FOR ATTENDING MEETING:

Ademola Are

QUORUM

With nine members participating, a quorum was established.

APPROVAL OF AGENDA:

Mr. Ratliff reported that staff recommended additions to the tentative agenda previously provided.

MOTION:

The agenda was unanimously approved as amended and described below:

- **Insert additional item, Adoption of new guidance document *Proximity for a School or Daycare to a Cannabis Dispensing or Pharmaceutical Processor* (motion by Nelson, seconded by Logan)**

APPROVAL OF PREVIOUS
BOARD MEETING MINUTES

Mr. Ratliff stated that Mr. Henderson had informed staff that Ms. Yeatts name was misspelled on page 5 of the December 10, 2020 draft minutes. Additionally, Mr. Ratliff asked that staff include in the December draft minutes reference to the discussion regarding concerns for l

MOTION:

The board voted unanimously to adopt the minutes for December 9, 2020 through February 23, 2021 as presented and amended to correct Ms. Yeatts name and include reference to the discussion regarding concerns for legislation to authorize adult use marijuana in the December 10, 2020 full board meeting minutes. (motion by Nelson, seconded by Richards-Spruill)

PUBLIC COMMENTS:

Mr. Ratliff stated, as indicated in the meeting notice on Regulatory Townhall and in the agenda package that comments would be received during this public comment period via WebEx from those persons who submitted an email to Caroline Juran no later than 8am on March 30, 2021 indicating that they wish to offer comment.

Farzana Kennedy recommended that the Board perform more due diligence prior to signing the FDA MOU and stated that she is receiving increased requests to ship compounded drugs across states lines. Her pharmacy is located in northern Virginia and she frequently services patients in bordering states and Washington, DC.

Christina Barrille, Executive Director of the Virginia Pharmacists Association (VPhA) stated she was glad to see vaccine allocation to pharmacies increasing, but expressed concern that this may lead to more pharmacist burnout. She also offered thanks to the board and to the Medical Society of Virginia for their assistance throughout the pandemic. Ms. Barrille also asked

the board to delay any action related to the FDA MOU on compounding to the June board meeting. She indicated this would allow counsel more time to determine if signing the MOU would conflict with state law and allow time for national discussions play out.

Cynthia Warriner shared her concerns regarding adult-use of cannabis products. She stated three board members expressed similar concerns at the December 2020 board meeting. She referenced prescription drug interactions with cannabis that were referenced in a presentation during the April 2018 board retreat.

Hunter Jamerson, counsel for Dalitso, offered support of the draft Guidance Document for *Proximity for a School or Daycare to a Cannabis Dispensing or Pharmaceutical Processor Facility*.

DHP DIRECTOR'S REPORT:

Dr. Brown provided the board an update on recent news related to the agency. He discussed environmental protections within Executive Order 77 and that all state agencies are to develop a diversity and equity strategic plan. DHP recently hired a consultant to assist the agency in creating a Diversity, Equity, and Inclusion (DEI) Committee. The last all-staff training event was devoted to DEI issues. Dr. Brown also provided an update on cannabis legislation passed during the 2021 General Assembly session, including language for pharmaceutical processors and adult-use cannabis to be regulated by a new agency by 2024 and authorization for pharmaceutical processors to dispense botanical cannabis.

Barbara Allison-Bryan, M.D., Chief Deputy Director, DHP, shared statistics regarding COVID-19 vaccine administrations in Virginia. Over one-half of the local health departments are in Phase 1C, over 3.6 million doses have been distributed in Virginia, and approximately one-third of Virginians have received one dose with about 15% fully vaccinated. She provided an overview of HB2333 which expanded who may administer a COVID-19 vaccine.

LEGISLATIVE/ REGULATORY/ GUIDANCE

REPORT ON 2021 GENERAL ASSEMBLY

Ms. Yeatts provided an overview of the 2021 General Assembly session on pages 42-50 of the agenda packet.

REPORT ON REGULATORY ACTION:

Ms. Yeatts provided an overview of regulatory actions on pages 51 and 52 of the agenda packet. Mr. Ratliff noted that the prohibition against incentives to transfer prescriptions status remains at the governor's office. Ms. Yeatts also

reviewed a chart, which was shared on the screen for all to see, of future actions that the board will need to take resulting from legislation passed. This includes promulgating emergency regulations, exempt regulations, and convening workgroups to discuss pharmacy technicians and additional protocols for pharmacists to initiate treatment.

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

Ms. Yeatts provided an overview of the draft exempt regulations to temporarily place chemicals into Schedule I as recommended by the Department of Forensic Science and pursuant to 54.1-3443 (D) of the Code of Virginia.

MOTION:

The board voted unanimously to adopt the final regulation amending 18VAC110-20-322 as presented which places the following chemicals into Schedule I:

- 1-{1-[1-(4-bromophenyl)ethyl]-4-piperidinyl}-1,3-dihydro-2H-benzimidazol-2-one (other name: Brorphine)
- N-(4-chlorophenyl)-N-[1-(2-phenylethyl)-4-piperidinyl]-propanamide (other names: parachlorofentanyl, 4-chlorofentanyl)
- 2-[(4-methoxyphenyl)methyl]-N,N-diethyl-5-nitro-1H-benzimidazole-1-ethanamine (other name: Metonitazene)
- N,N-diethyl-2-[[4-ethoxyphenyl)methyl]-1H-benzimidazol-1-yl]ethan-1-amine (other name: Etazene, Desnitroetonitazene)
- 5-(2-chlorophenyl)-1,3-dihydro-3-methyl-7-nitro-2H-1,4-benzodiazepin-2-one (other name: Meclonazepam)
- ethyl-2-[1-(5-fluoropentyl)-1H-indole-3-carboxamido]-3,3-dimethylbutanoate (other name: 5-fluoro EDMB-PICA)

(Motion by St Clair, seconded by Bolyard)

**ADOPTION OF PROPOSED
REGULATIONS FOR
PHARMACISTS TO INITIATE
TREATMENT**

The board reviewed the copy of notice posted on Regulatory Townhall and copy of emergency regulations found on pages 67-72 of the agenda packet. It was noted that emergency regulations remain in place for 18 months, and must be replaced by permanent regulations. The proposed regulations are identical to the emergency regulations in place. No comments were received during the public comment period that ended March 3, 2021.

MOTION:

The board voted unanimously to adopt the proposed regulations as presented. (motion by Nelson, seconded by Lee)

**ADOPTION OF PROPOSED
REGULATIONS FOR
PHARMACY TECHNICIAN
TRAINEE REGISTRATION
AND TRAINING**

The board reviewed the copy of notice posted on Regulatory Townhall and copy of emergency regulations found on pages 73-89 of the agenda packet. It was noted that emergency regulations remain in place for 18 months, and must be replaced by permanent regulations. Ms. Yeatts stated that the board receive one comment during the public comment period that ended March 3, 2021. The board discussed the two recommendations from the Virginia Association of Chain Drug Stores and the National Association of Chain Drug Stores. Because staff is able to issue a pharmacy technician trainee registration within 2-5 days of receiving a complete application and many accredited training programs require didactic training prior to performing duties of a pharmacy technician, the board did not believe an allowance for a person enrolled in a pharmacy technician training program to perform duties of a technician prior to being issued a trainee registration was necessary. The board did agree to the second recommendation to amend 18VAC110-21-140(C) to include reference to “NHA certification” as supported by the statute.

MOTION:

The board voted unanimously to adopt the proposed regulations as presented and amended by inserting “or NHA certification” after “PTCB certification” in 18VAC110-21-140 (C). (motion by Henderson, seconded by Richards-Spruill)

**ADOPTION OF PROPOSED
REGULATIONS FOR
LIMITED LICENSE FOR
DISPENSING SCHEDULE VI
DRUGS FROM A NON-
PROFIT FACILITY**

The board reviewed the copy of notice posted on Regulatory Townhall and copy of emergency regulations found on pages 90-97 of the agenda packet. It was noted that emergency regulations remain in place for 18 months, and must be replaced by permanent regulations. The proposed regulations are identical to the emergency regulations. No comments were received during the recent public comment period that ended March 3, 2021.

MOTION:

The board voted unanimously to adopt the proposed regulations as presented (motion by Nelson, seconded by St Clair)

**GUIDANCE DOCUMENTS
110-27, 110-31, 110- 33**

The board reviewed the draft amendments to guidance documents found on pages 98-110 of the agenda packet. Changes in the pharmacy technician registration process and trainee registration necessitated amendments to Guidance Documents 110-27, 110-33, and repeal of 110-20; the link to the State Veterinarian’s directive for Approved Capture Drugs and Drug Administering Equipment in 110-31 needed updating; and 110-38 needed to be readopted since it was last revised more than four years ago.

**REAFFIRMATION OF
GUIDANCE DOCUMENT
110-38**

**REPEAL OF GUIDANCE
DOCUMENT 110-20**

MOTION:

The board voted unanimously to adopt amendments to Guidance

Documents 110-27, 110-31, and 110-33 as presented, reaffirm Guidance Document 110-38, and repeal Guidance Document 110-20. (motion by Nelson, seconded by Logan)

**NEW GUIDANCE
DOCUMENT PROXIMITY OF
A SCHOOL OR DAYCARE
TO A CANNABIS
DISPENSING FACILITY OR
PHARMACEUTICAL
PROCESSOR**

A draft Guidance Document was shared on the screen for all to see. Because the laws and regulations do not allow for the board to issue conditional approval to cannabis dispensing facilities, Ms. Juran explained that counsel for Dalitso (located in northern Virginia) recently expressed concern about beginning construction and a school or daycare opening within 1,000 feet while construction of the dispensing facility is occurring. They also inquired what action the board would take if a pharmaceutical processor or cannabis dispensing facility is operational and a school or daycare opens within 1,000 feet of the processor or dispensing facility. There was much discussion regarding the attestation wording of the draft language. A motion was offered by Henderson, seconded by Bolyard to table the subject to the June board meeting. The motion was then withdrawn by Henderson and Bolyard.

MOTION:

The board voted unanimously to adopt the guidance document as amended which reads:

Pursuant to 18VAC 110-60-135, a cannabis dispensing facility cannot be located within 1,000 feet of a school or daycare. At the time the dispensing facility application is submitted to the Board, the applicant must ensure that the proposed site at the address recorded on the application complies with this requirement and must attest that no school or daycare has been approved by the locality or licensed, registered, or regulated by the state to operate within 1,000 feet of the proposed site. A pending application is valid for up to 12 months from the date received by the Board.

Prior to issuing the dispensing facility permit, an agent of the Board will inspect the facility for compliance with the laws and regulations. In determining compliance with the requirement that a cannabis dispensing facility cannot be located within 1,000 feet of a school or daycare, the inspector will assess compliance as of the date the application was received by the Board.

Should a school or daycare locate within 1,000 feet of an already permitted cannabis dispensing facility or pharmaceutical processor, the Board will not hold the permit in violation of the 1,000 feet prohibition in 18VAC110-60-135. (motion by Nelson, seconded by St Clair)

NEW BUSINESS:

**DISCUSS SIGNING OF FDA
MOU FOR COMPOUNDING**

Ms. Juran provided an overview of the FDA MOU for compounding.

Related to Section 503A of the Federal Food, Drug, and Cosmetic Act, the FDA published a compounding MOU in October 2020 for the states to potentially enter into with FDA to strengthen state and federal oversight of compounding pharmacies shipping compounded drugs across state lines.

Compounding pharmacies and physicians located in a state that do not enter into the MOU may not distribute compounded drug products out of the State in quantities that exceed 5 percent of the total prescription orders dispensed or distributed by such pharmacy or physician;

Compounding pharmacies and physicians located in states that enter into the MOU may distribute “inordinate amounts” of compounded drug interstate and the State where the compounder is located must provide for appropriate investigation of complaints relating to compounded drug products distributed outside such State;

To assist the states and pharmacies with identifying if a pharmacy or compounding physician is shipping “inordinate amounts” outside of the state, FDA awarded the National Association of Boards of Pharmacy a grant to establish an electronic data sharing network which is now operational. Deadline for signing the MOU is October 2021.

The board discussed the need for counsel to review the document to determine if signing would conflict with any state laws and staff to identify any challenges with completing investigations based on complaints from individuals residing outside of Virginia. Members expressed general support for allowing compounding pharmacies to ship inordinate amounts of compounded drug interstate, but thought it may be premature to make a decision.

ACTION ITEM:

There was consensus to defer this subject to the June board meeting.

**AMEND PHARMACIST
WORKFORCE SURVEY TO
INCLUDE QUESTION
ABOUT STATEWIDE
PROTOCOLS**

Ms. Juran provided the board an overview of page 134 of the agenda packet. It was noted that a request was received from the VCU School of Pharmacy, Center for Pharmacy Practice Innovation to include a question on the annual pharmacy workforce survey to monitor use of statewide protocols.

MOTION:

The board voted unanimously to amend the Pharmacist Workforce Survey by inserting question #22c as presented which reads:

If you initiate patient treatment in accordance with statewide protocols, which of the statewide protocols below do you utilize? Check all that apply.

Hormonal contraception

Emergency contraception

Prenatal vitamins

Naloxone

Epinephrine

Lowering out-of-pocket expenses (motion by Nelson, seconded by StClair)

RECOGNITION OF FORMER BOARD MEMBERS

The board recognized and expressed appreciation for the leadership and service of former board members Cynthia Warriner, Melvin Boone, and Rebecca Thornbury. Ms. Warriner and Mr. Boone joined the meeting virtually. Ms. Thornbury was unable to participate due to a last-minute conflict.

REPORTS:

CHAIRMAN'S REPORT

Mr. Ratliff thanked all pharmacists and pharmacy technicians for their assistance with COVID-19 vaccine administrations. He also thanked Mr. Johnson for his time with the Board and noted his retirement effective April 1, 2021.

REPORT ON BOARD OF HEALTH PROFESSIONS

Mr. Logan provided an update for the Board of Health Professions meeting held on January 21, 2021. The next meeting is scheduled for May 13, 2021.

REPORT ON LICENSURE AND INSPECTION PROGRAM

Ms. O' Halloran reviewed pages 135-146 of the agenda packet. Melody Morton, Inspection Manager, DHP will provide the board with the Inspection Report going forward and Ms. O'Halloran will continue to provide the Licensure Report. Ms. Morton joined the meeting and requested suggested information that the board would like for her to capture on the Inspection Report in the future. The board agreed that it was not necessary to capture repeat deficiencies in the chart since this required a manual count and was time-consuming for staff to prepare.

REPORT ON PHARMACEUTICAL PROCESSORS

Ms. Kelley reviewed the report provided on page 147 of the agenda packet.

REPORT ON DISCIPLINARY PROGRAM

Ms. Shinaberry reviewed the disciplinary report provided on page 148 of the agenda packet.

**EXECUTIVE DIRECTORS
REPORT**

Ms. Juran reviewed the report provided on page 149 of the agenda packet. She expressed sincere gratitude for former Deputy Executive Director Sammy Johnson who retired on April 1, 2021. Mr. Johnson retired with 25 years of state service, 21 years at DHP. She stated that interviews for this position will be held soon.

**PRESENTATION OF
POSSIBLE SUMMARY
SUSPENSION:
Case #205818**

Assistant Attorney General James Schliessmann, presented information a summary of the evidence in this case. Adjudication Specialist Jess Kelley assisted Mr. Schliessmann.

CLOSED SESSION:

Upon a motion by Ms. Nelson, and duly seconded by Mr. St Clair, the panel voted 9-0, to convene a closed meeting pursuant to § 2.2-3711(A)(27) of the Code of Virginia ("Code"), for the purpose of deliberation to reach a decision regarding a consent order involving Ellen Katherine Daniels. Additionally, it was moved that Caroline Juran, Ellen Shinaberry, Kiara Christian, and Jim Rutkowski attend the closed meeting.

RECONVENE:

Having certified that the matters discussed in the preceding closed meeting met the requirements of § 2.2-3712 of the Code, the panel reconvened an open meeting and announced the decision. (motion by Nelson, seconded by St Clair)

DECISION:

Upon a motion by Melton, and duly seconded by Ms. Richards-Spruill, the panel voted 8-1 (Henderson opposed) to summarily suspend the technician registration of Ellen Katherine Daniels, to notice her for a formal hearing, and to offer a consent order for indefinite suspension for no less than two years, with the suspension stayed upon proof of entry into the Health Practitioners Monitoring Program.

MEETING ADJOURNED:

2:38 PM

Kristopher Ratliff, Chairman

Caroline D. Juran, Executive Director

DATE:

DATE:
