

(FINAL/APPROVED)

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

December 10, 2020
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 9:20 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
James L. Jenkins, Jr.
Glen Bolyard
Ryan Logan
Patricia Richards-Spruill
Sarah Melton
Dale St.Clair
William Lee
Bernard Henderson, Jr.

STAFF PRESENT:

Caroline D. Juran, Executive Director (On-Site)
Ellen B. Shinaberry, Deputy Executive Director
J. Samuel Johnson, Jr., Deputy Executive Director
Annette Kelley, Deputy Executive Director
Beth O'Halloran, Deputy Executive Director
Elaine Yeatts, Senior Policy Analyst, DHP (On-Site)
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**

Cheryl Nelson
David Ombengi
Katrina C Trelease

CONTINUING EDUCATION
FOR ATTENDING MEETING:

Caroline Juran

QUORUM

With ten 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 as described below:

- **Insert topic Authorization for the Ad-hoc committee to direct staff to collect additional information necessary before the review of pharmaceutical processor applications. (motion by Nelson, seconded by Jenkins)**

APPROVAL OF PREVIOUS
BOARD MEETING MINUTES

Ms. Nelson offered that the September 8 Informal Conference minutes should be amended to correctly identify Aviance S. Lewis as a Pharmacist.

MOTION:

The Board voted unanimously to adopt the minutes for the September 8, 2020 Informal Conference as amended by removing pharmacy technician and replacing with Pharmacist, and adopted the minutes for the other meetings held between September 9, 2020 and November 16, 2020 as presented. (motion by Nelson, seconded by Richards-Spruill)

PUBLIC COMMENTS:

Mr. Ratliff offered a reminder that the public comment period related to Regulatory action on medication carousel or RFID was closed. 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 December 10, 2020 indicating that they wish to offer comment.

Christina Barrille, Executive Director of the Virginia Pharmacists Association (VPhA), thanked the board for their work thorough the pandemic and for the board prioritizing the state protocol workgroup meetings. She said that VPhA is planning a conference to help educate pharmacist interested in implementing the new services into their practice. VPhA anticipates that HHS will implement authority for Pharmacist to prescribe therapies to patients with a positive COVID test. She encouraged the board to take a proactive position for the board to keep medical cannabis oversite under control of medical providers. Ms. Barrille asked the board to take due diligence when reviewing pharmaceutical processor applications. She asked that the guidance for

collaborative practice agreement found on page 79 of the agenda packet be amended to remove number 2 to conform to the code. She offered support of the recommendation for a periodic review of the collaborative practice agreements. She thanked the committee for accepting VPhA's bullet point 2 located on page 96 of the agenda packet. Ms. Barille shared an invitation to a VPhA workshop to be held with The Medical Society of Virginia regarding the storage and administration of Pfizer's vaccine.

DHP DIRECTOR'S REPORT:

Dr. Brown welcomed Bernard Henderson to the board. Dr. Brown stated the Legislative Session would be held virtually this year in response to the COVID pandemic. He said there are no bills from the Department of Health Professions being presented. Dr. Brown offered that he anticipated bills being introduced to allow pharmaceutical processors to distribute marijuana flower.

Dr. Allison Bryan thanked pharmacist for their services provided for administration of the COVID vaccine. She offered her anticipation of the medical use authorization from the FDA for the Pfizer COVID vaccine.

LEGISLATIVE/
REGULATORY/ GUIDANCE

REPORT ON REGULATORY
ACTION:

Ms. Yeatts provided an overview of regulatory actions on pages 51 and 52 of the agenda packet. Many of the actions are in the Governor's office.

Mr. Ratliff asked about the prohibition against incentives to transfer prescriptions. Ms. Yeatts stated she would follow up with the Governor's office for an update.

ADOPTION OF PROPOSED
REGULATION TO PROHIBIT
OIL PRODUCTS INTENDED
TO BE VAPED THAT
CONTAIN VITAMIN E
ACETATE

Ms. Yeatts provided the board with a review of the emergency action leading up to the proposed regulation language as presented on page 56 of the agenda packet.

MOTION:

The board voted unanimously to adopt the language in 18VAC110-60-280 as presented. (motion by Nelson, seconded by St. Clair)

ADOPTION OF EXEMPT
REGULATION TO PLACE
CHEMICALS INTO
SCHEDULE I

Ms. Yeatts provided an overview of the exempt regulations to place chemicals into schedule one. She reviewed page 57-62 of the agenda packet.

MOTION:

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

- N,N-diethyl-2-[(4-methoxyphenyl)methyl]-1H-benzimidazole-1-ethanamine (other name: Metodesnitazene)
- 4-fluoro-3-methyl-alpha-pyrrolidinovalerophenone (other name: 4-fluoro-3-methyl-alphaPVP)
- 4-fluoro-alpha-methylamino-valerophenone (other name: 4-fluoropentedrone)
- N-(1,4-dimethylpentyl)-3,4-dimethoxyamphetamine (other name: N-(1,4-dimethylpentyl)-3,4- DMA)
- 4,5-methylenedioxy-N,N-diisopropyltryptamine (other name: 4,5-MDO-DIPT)
- alpha-pyrrolidinocyclohexanophenone (other name: alpha-PCYP)
- 3,4-methylenedioxy-alpha-pyrrolidinoheptiophenone (other name: MDPV8)
- Bromazolam
- Deschloroetizolam
- 7-chloro-5-(2-fluorophenyl)-1,3-dihydro-1,4-benzodiazepin-2-one (other name: Norfludiazepam)
- Methyl-2-[1-(4-fluorobutyl)-1H-indole-3-carboxamido]-3,3-dimethylbutanoate (other name: 4-fluoro-MDMB-BUTICA)
- Ethyl-2-[1-(5-fluoropentyl)-1H-indole-3-carboxamido]-3-methylbutanoate (other name: 5- fluoro-EMB-PICA)

ADOPTION OF EXEMPT REGULATIONS – SCHEDULING CHANGE FOR CONSISTENCY WITH DEA

Ms. Yeatts reviewed page 67 of the agenda. Ms. Juran clarified that the language mirrors the action that was taken by DEA, and offered that DEA only schedules products I-V, and does not govern schedule VI,

MOTION:

The board voted unanimously to amend 18VAC110-20-323 as presented by deleting number 4 which removes cannabidiol from Schedule V to conform with DEA's action. (motion by Nelson, seconded by Lee)

CONSIDERATION OF AMENDMENTS TO INCORPORATE CHANGES CURRENTLY IN APPROVED PILOTS- MEDICATION CAROUSELS AND RFID TECHNOLOGY

Ms. Yeatts provided a review on the background of the action. Ms. Yeatts pointed out the highlighted language that was not included in the notice of intent. Ms. Yeatts reminded the board that the action is now to propose language to go into the regulation, and that there would be a 60 day public comment period and public hearing

Ms. Juran provided an overview of the changes made. There was discussion by the board concerning the verification rate. Ms. Juran gave a review of the background of robotic technology and medication carousel and offered that no errors had been reported with use of the technology.

MOTION:

The board voted unanimously to adopt amendments recommended by the Regulation Committee to 18VAC110-20-425 and new section 18VAC110-20-505, as posted with the Notice of Intended Regulatory Action (NOIRA), to incorporate allowances for medication carousels with robotic systems and for use of RFID technology in provision of floor stock. (motion by Lee, seconded by Nelson)

AMENDMENTS TO
GUIDANCE DOCUMENTS

Ms. Yeatts recommended that Guidance 110-13 be reviewed as a separate topic so that the board may consider public comment received.

Ms. Yeatts reviewed Guidance Documents on pages 75-98 of the agenda packet stating many changes were to conform to legislative changes made by the General Assembly and recommendations made by the regulation committee.

Guidance Document 110-39

The board discussed the Guidance Document 110-39 “Continuous Hours Worked by Pharmacist and Breaks”, allowing a pharmacist to use professional judgement when closing the pharmacy, and whether public notice is required.

MOTION:

The board voted 9-0 (Logan abstained), to amend the recommendation of the Regulation Committee and adopt Guidance Document 110-39 with the addition of “14 days” before “in advance of the closure”. (motion by Richards-Spruill, seconded by St. Clair).

Guidance Document 110-1,
110-29, 110, 44, 110-40, repeal
Guidance Document 110-41

MOTION:

The board voted unanimously to accept the recommendations from the Regulation Committee to adopt Guidance Document 110-1, 110-29, 110, 44, and 110-40 as presented, and to repeal Guidance Document 110-41.

Guidance Document 110-13

Ms. Yeatts provided a review of Guidance Document 110-13 on page number 79 of the agenda packet.

Ms. Juran reminded the board that this chapter will be considered for periodic review later on the agenda. There was discussion about removing number 2 from the document. Ms. Juran stated that removing number 2 from the document does not remove the requirement of the regulation. In order to change the requirement, the regulation must be amended. Ms. Yeatts stated that removing number 2 is not going to change the requirement which is word for word in the regulation.

A motion was made to strike number 2 from guidance document 110-13. (motion by Lee, seconded by Jenkins). Second retracted by Jenkins. There was no second and the motion died.

MOTION:

The board voted 7-3 (opposed Henderson, Lee, Ratliff) to adopt Guidance Document 110-13 as presented. (motion by St. Clair, seconded by Nelson)

ADOPTION OF A NOTICE OF PERIODIC REVIEW

Ms. Yeatts reviewed the recommendation by the regulation committee to initiate a periodic review of the following chapters:

- 18 VAC 110-20 Regulations Governing the Practice of Pharmacy
- 18 VAC 110-21 Regulations Governing the Licensure of Pharmacist and Registration of Pharmacy Technicians
- 18 VAC 110-30 Regulations for the Practitioners of the Healing Arts to Sell Controlled Substances
- 18 VAC 110-40 Regulations Governing Collaborative Practice Agreements
- 18 VAC 110-50 Regulations Governing Wholesale Distributors, Manufacturers and Warehousemen

MOTION:

The board voted unanimously to accept the recommendation of the Regulation Committee to initiate a periodic review for the recommended chapters.

AUTHORIZATION FOR THE AD-HOC COMMITTEE TO ASK STAFF TO COLLECT ADDITIONAL INFORMATION NECESSARY FOR REVIEW OF PHARMACEUTICAL PROCESSORS

Mr. Ratliff asked the board to consider authorization for the Ad-hoc committee to direct staff to collect additional information necessary for review of pharmaceutical processor applications.

MOTION:

The board voted unanimously to delegate authority to the ad hoc committee to direct staff to collect additional information from the pharmaceutical processors applications if necessary. (motion by Nelson, seconded by Bolyard)

Mr. Ratliff expressed concern for upcoming legislation that may authorize adult-use marijuana and asked what action the board could take on this subject. There was a brief discussion regarding possible harmful effects and drug-drug interactions. Ms. Yeatts explained that the board could not take an official position on a bill and that DHP's position must be aligned with the Governor's position. No action was taken on this subject.

REPORTS:

CHAIRMAN'S REPORT

Mr. Ratliff thanked pharmacist and technicians for their services during

COVID. He offered that he looks forward to attending the NABP Interactive Forum. Mr. Ratliff thanked board staff, Cheryl Nelson, and Jim Jenkins, and welcomed Mr. Bernard Henderson to the board.

**REPORT ON BOARD OF
HEALTH PROFESSIONS**

Mr. Logan offered that the Board of Health Professions meeting for November was rescheduled for January.

**REPORT ON LICENSURE
REPORT**

Ms. O' Halloran reviewed page 100 of the agenda packet

**REPORT ON INSPECTION
PROGRAM**

Mr. Johnson reviewed the report provided on pages 101-111 of the agenda packet. Melody Morton, Inspection Manager, was available for questions about current inspections. She provided an overview of the inspection process during the COVID-19 declared emergency.

**REPORT ON
PHARMACEUTICAL
PROCESSORS**

Ms. Kelley reviewed the report provided on page 112 of the agenda packet.

**REPORT ON DISCIPLINARY
PROGRAM**

Ms. Shinaberry reviewed the disciplinary report provided on page 113 of the agenda packet.

**EXECUTIVE DIRECTORS
REPORT**

Ms. Juran reviewed the report provided on page 114 of the agenda packet. She reviewed the legislation reports on paged that were recently required of the Board.

CLOSED SESSION:

Upon a motion by Ms. Nelson, and duly seconded by Mr. Richards-Spruill, the panel voted 10-0, 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 Andrew E. Norris. 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 re-convened an open meeting and announced the decision. (motion by Nelson, seconded by Henderson)

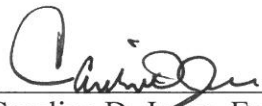
DECISION:
Andrew E. Norris

Upon a motion by Nelson, and duly seconded by Mr. Richards-Spruill, the panel voted 10-0 to accept the consent order proposed by Ms. Shinaberry regarding Andrew E. Norris.

MEETING ADJOURNED:

1:13 PM


Kristopher Ratliff, Chairman


Caroline D. Juran, Executive Director

DATE:

3/30/21

DATE:

3/30/2021