

(FINAL/APPROVED)

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

September 25, 2019  
Commonwealth Conference  
Center  
Second Floor  
Board Room 2

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

**CALL TO ORDER:** The meeting of the Board of Pharmacy was called to order at 9:20 am.

**PRESIDING:** Cynthia Warriner, Chairman

**MEMBERS PRESENT:** Kristopher S. Ratliff, Vice Chairman  
Glen Bolyard  
Melvin L. Boone, Sr.  
James L. Jenkins, Jr.  
William Lee  
Ryan Logan  
Cheryl H. Nelson (Arrived at 9:34)  
Patricia Richards-Spruill  
Rebecca Thornbury

**STAFF PRESENT:** Caroline D. Juran, Executive Director  
Ellen B. Shinaberry, Deputy Executive Director  
Annette Kelley, Deputy Executive Director  
Elaine Yeatts, Senior Policy Analyst, DHP  
David E. Brown, D.C., Director, DHP (Departed 12:28pm)  
James Rutkowski, Assistant Attorney General  
Mykl Egan, Disciplinary Case Manager (Arrived 12:32pm)  
Kiara Christian, Executive Assistant

**QUORUM:** With ten members present, a quorum was established.

**APPROVAL OF AGENDA:** Ms. Warriner advised that an amended agenda had been provided as a handout that included the following new agenda items: Amend Guidance Document 110-36, *Compliance with USP Standards*; Adopt Guidance Document for *Pharmacies Within Opioid Treatment Programs*; and, an oral report from board counsel. She also requested that the board move the "New Business" section to after the "Possible Summary Suspension/Consent Orders" section of the agenda.

**MOTION:** **The amended agenda was adopted unanimously as presented and amended. (motion by Ratliff, seconded by Rebecca)**

**APPROVAL OF PREVIOUS  
BOARD MEETING  
MINUTES**

**The Board voted unanimously to adopt the minutes as presented for the**

**MOTION:**

**following meetings:**

- **June 5, 2019, Full Board Meeting**
- **June 5, 2019, Public Hearing for Increase in Fees**
- **June 27, 2019, Special Conference Committee**
- **July 18, 2019, Special Conference Committee**
- **July 25, 2019, Special Conference Committee**
- **July 31, 2019, Formal Hearing**
- **August 14, 2019, Special Conference Committee- Innovative Pilot Program**
- **August 22, 2019, Formal Hearing**  
(motion by Ratliff, seconded by Richards-Spruill )

**PUBLIC COMMENTS:**

Aaron Lopez, representing Political Capital, offered public comment on implementation of new USP requirements. Mr. Lopez acknowledged that the board appears to be addressing the implementation of USP 795, 797, and 800, and that Political capital is interested in a possible 6-month delay.

Christina Barrille, Executive Director, Virginia Pharmacists Association, began her comment by congratulating Ms. Warriner for her appointment as Chairman, Mr. Ratliff as Vice Chairman and welcoming Mr. Lee. She referred the board to the public comment offered by VPhA and VSHP in a joint letter dated September 24, 2019 that was given as a handout and urged the board to review the action items suggested. She also asked the board to consider implementing a requirement in 2020 for pharmacists to obtain one hour of CE related to the dispensing of naloxone.

Mark Hickman, representing Commonwealth Strategy Group, asked the board to consider the public comments offered in the joint letter submitted by VPhA and VSHP concerning the enforcement of new USP 797 and 800 requirements. Mr. Hickman also expressed concerns specifically on USP 797 requirements and the possible impact of patient access to care.

Cynthia Williams, Vice President, Riverside Health Systems, asked the board to review the two letters submitted by Riverside Health Systems. Ms. Williams shared concerns of challenges regarding the USP implementation date. She provided an estimated cost of \$5 million for Riverside to comply with new requirements. Ms. Williams also shared challenges related to remodeling, such as finding contractors and budget resources, and how this may impact patient access.

David Creecy, pharmacist with Poquoson Compounding, shared concerns related specifically to retail pharmacies, and decrease in patient access pending the implementation of USP 795, 797, and 800. He also said that he had concerns about the significant cost for the required renovations and how this may impact patient cost and services. Mr. Creecy said that a delay in USP 800 would be helpful.

Katie Hellabush, Virginia Cannabis Association, shared support of the passing of SB 1719.

DHP DIRECTOR'S  
REPORT:

Dr. Brown welcomed Mr. Lee to the Board and provided information related to the security at the Perimeter Center. He shared that DHP will host an agency-wide board member training on October 7<sup>th</sup> and encouraged attendance.

UPDATE FROM VCU'S  
SCHOOL OF PHARMACY

Joseph DiPiro, Dean of the VCU School of Pharmacy shared a handout with informational updates from the VCU School of Pharmacy.

LEGISLATIVE/  
REGULATORY/  
GUIDANCE UPDATE

Update on Regulatory/Policy  
Actions

Ms. Yeatts reviewed the Chart of Regulatory Actions found in the agenda packet. She also stated that DHP has learned that the board's legislative proposals will not be included in the Governors legislative packet for the 2020 General Assembly session.

Adoption of exempt  
regulation to schedule  
certain chemicals in  
Schedule I

**MOTION:**

**The board voted unanimously to place the drugs identified by the Department of Forensic Science into Schedule I by amending 18VAC110-20-322 as follows: 1) delete subsections A through D as the chemicals have been now scheduled in the Drug Control Act and 2) insert a new subsection C to read "C. Pursuant to subsection D of §54.1-3443 of the Code of Virginia, the Board of Pharmacy placed the following chemicals into Schedule I of the Drug Control Act:**

**1. Synthetic opioids:**

- a. N-[2-(dimethylamino)cyclohexyl]-N-phenylfuran-2-carboxamide (other name: Furanyl UF17), 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.**
- b. N-[2-(dimethylamino)cyclohexyl]-N-phenylpropionamide (other name: UF-17), 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.**

## 2. Research Chemicals

- a. **5-methoxy-N,N-dibutyltryptamine (other name: 5-methoxy-DBT), its optical, position, and geometric isomers, salts and salts of isomers, whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation.**
- b. **1-(1,3-benzodioxol-5-yl)-2-(ethylamino)-1-butanone (other name: Eutylone, bk-EBDB), its optical, position, and geometric isomers, salts and salts of isomers, whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation.**
- c. **1-(1,3-benzodioxol-5-yl)-2-(butylamino)-1-pentanone (other name: N-butylpentylone), its optical, position, and geometric isomers, salts and salts of isomers, whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation**
- d. **N-benzyl-3,4-dimethoxyamphetamine (other name: N-benzyl-3,4-DMA), its optical, position, and geometric isomers, salts and salts of isomers, whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation**
- e. **3,4-methylenedioxy-N-benzylcathinone (other name: BMDP), its optical, position, and geometric isomers, salts and salts of isomers, whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation.**

## 3. Cannabimimetic agents:

- a. **Ethyl 2-({1-[(4-fluorophenyl)methyl]-1H-indazole-3-carbonyl}amino)-3-methylbutanoate (other name: EMB-FUBINACA), 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. **Methyl 2-[1-(4-fluorobutyl)-1H-indazole-3-carboxamido]-3,3-dimethylbutanoate (other name: 4-fluoro-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.**

**The placement of drugs listed in this subsection shall remain in effect until (18 months from the effective date of the regulation), unless enacted into law in the Drug Control Act.” (motion by Logan, seconded by Bolyard)**

Adoption of emergency regulations for Pharmaceutical Processors

The board reviewed SB1719 passed during the 2019 General Assembly session and draft amendments relating to registered agents and wholesale distribution of CBD and THC-A oil. It was noted that SB1719 required the adoption of emergency regulations regarding the registration of registered agents for patients certified to receive cannabidiol or THC-A oil and for the wholesale distribution of oils between processors. During discussion, it was noted by the board that a Power of Attorney could obtain registration as a registered agent, but not as a parent/guardian.

**MOTION:**

**The board voted unanimously to adopt the emergency regulations and Notice of Intended Regulatory Action to replace the emergency regulations for Pharmaceutical Processors as presented. (motion by Logan, seconded by Boone)**

Adoption of exempt regulations for Pharmaceutical Processors

The board reviewed SB1719 and draft amendments to 18VAC110-60-130 and 18VAC110-60-170. SB1719 allows a processor to employ individuals with less than two years of experience to perform certain tasks under supervision and allows a processor to begin cultivation as soon as a permit is issued. These statutory amendments require an exempt regulatory action to conform the requirements in regulation to the new statutory allowances.

**MOTION:**

**The board voted unanimously to adopt the exempt regulations for Pharmaceutical Processors as presented. (motion by Ratliff, seconded Nelson)**

During discussion, several board members expressed concern for vaped products based on recent warnings from the CDC and FDA involving patient harm.

**ACTION ITEM:**

**The board requested staff to research with counsel whether it had legal discretion in registering CBD and THC-A oil products that are intended to be vaped or it could prohibit pharmaceutical processors from producing vaped products.**

Adoption of Proposed Regulations for Labeling Dispensed Prescriptions

At the June 5, 2019 board meeting, the board requested that staff send a letter regarding the proposed regulations for Labeling Dispensed Prescriptions to consumer groups such as Senior Connections and AARP to obtain feedback on this topic. The board was provided copies of the letters sent to Senior Connections, Virginia Citizen Consumer Council, Virginia Association of Area Agencies on Aging, Virginia Navigators, and Virginia AARP. The board did not receive any feedback from these organizations. The board reviewed the proposed amendments to 18VAC110-20-275 as recommended by the Regulation Committee and included in the agenda packet.

**MOTION:**

**The board voted 7:3 to adopt the proposed amendments as recommended by the Regulation Committee. (motion by Nelson, seconded Boone; opposed by Warriner, Ratliff, and Jenkins)**

Adoption of Final

The board was provided a handout containing projected revenue and expenditures over the next few years and reviewed the proposed regulations for

Regulations for Fee  
Increase

an increase in fees as found in the agenda packet. A public hearing was conducted on June 5, 2019. Public comments were accepted from May 27, 2019 to July 27, 2019. No comment was received.

**MOTION:**

**The board voted 9:1 to adopt the final regulations as presented regarding an increase in licensure fees. (motion by Logan, seconded by Richards-Spruill; opposed by Jenkins)**

Amend Guidance  
Document 110-7,  
*Practitioner/Patient  
Relationship and the  
Prescribing of Drugs for  
Family or Self*, and  
Guidance Document 110-8,  
*Information on Prescriptive  
Authority in Virginia*

The board reviewed the amended draft of Guidance Documents 110-07 *Practitioner/Patient Relationship and the Prescribing of Drugs for Family or Self*, and 110-08 *Prescriptive Authority in Virginia* for readoption. It was shared that there were no substantial changes to the documents and that the text was revised for clarity, and the text of the statutes were revised to be current.

**MOTION:**

**The board voted unanimously to adopt the amendments to Guidance Document 110-07 *Practitioner/Patient Relationship and the Prescribing of Drugs for Family or Self* as presented.(motion by Jenkins, Seconded by Bolyard)**

**MOTION:**

**The board voted unanimously to adopt the amendments to Guidance Document 110-08 *Information on Prescriptive Authority in Virginia* as presented. (motion by Nelson, seconded by Boone)**

Amend Guidance  
Document 110-36,  
Compliance with USP  
Standards for  
Compounding

The board was provided a handout containing draft amendments of Guidance Document 110-36 *Compliance with USP Standards for Compounding* in response to certain USP chapters being under appeal which will delay the effective date of the chapters. Staff explained that on September 23, 2019, USP published a Notice of Intent to Revise which stated Chapters 795, 797, and 825 were under appeal and that "USP's Bylaws provide that the official date of a standard under appeal must be postponed while an appeal is pending. Therefore, USP is postponing the official dates of the revised <795> and <797>, and the new general chapter <825> until further notice. In the interim, the currently official chapters of <795> (last revised in 2014) and <797> (last revised in 2008) including the section Radiopharmaceuticals as CSPs will remain official. General Chapter <800> is not subject to any pending appeals and will become official on December 1, 2019. During the postponement and pending resolution of the appeals of <795> and <797>, <800> is informational and not compendially applicable." While USP and the Board encourages utilization of <800> in the interest of advancing public health, the Board cannot legally require compliance with requirements in 800 related to compounding until the appeals of 795 and 797 are resolved and the revised

chapters become effective.

During discussion, the board suggested the following amendment:

“51.) If the pharmacy does not compound with hazardous drugs, but ~~does split~~ performs splitting of tablets of hazardous drugs, must the pharmacy comply with the requirements of Chapter <800>?”

Ms. Yeatts indicated that if the board adopts the amendments, the guidance document will be published in the Registrar after permission to publish is received and a public comment period of 30 days must conclude prior to the guidance document being effective.

**MOTION:**

**The board voted unanimously to adopt amendments to Guidance Document 110-36 *Compliance with USP Standards for Compounding* as presented and amended by changing “does split” to “performs splitting of” in question number 51. (motion by Jenkins, seconded Richards-Spruill)**

Amend Guidance Document 110-44, *Naloxone Protocols* and Guidance Document 110-1, *List of Categories of Facility Licenses*, and Repeal Guidance Document 110-45

The board reviewed an amended draft of Guidance Documents 110-44 *Naloxone Protocols* and 110-1 *List of Categories of Facility Licensure*. It was shared that because of substantial changes in the Code relating to the dispensing and distribution of naloxone the protocols adopted by the Board for such activities need to be amended. The draft combines both 110-44 and 110-45 into one document in effort to streamline the information to reduce any possible confusion with having two separate protocols. Additionally, minor edits were necessary in Guidance Document 110-1 as a result of the statutory requirement for obtaining a controlled substances registration when certain entities dispense naloxone.

**MOTION:**

**The board voted unanimously to adopt amendments to Guidance Documents 110-44 and 110-1 as presented, and to repeal Guidance Document 110-45. (motion Logan, seconded Thornbury)**

Consider allowances for hot and cold running water; Amend Guidance Document 110-28, *Guidance for Free Clinic Pharmacy Applicants*

The board reviewed the amended draft of Guidance Documents 110-28 *Guidance for Free Clinic Pharmacy Applications*. Ms. Juran shared that a physician selling controlled substances applicant requested a waiver of regulation to allow for use of a bathroom sink as the source of hot and cold running water. The chairman and executive director denied the request and the physician requested further consideration. If the matter was to be considered by the board, the chairman and staff requested that the board consider a similar allowance for free clinic pharmacies. Counsel advised that it would be better for an informal conference committee of the board to further consider the physician selling controlled substances waiver request. The board directed staff to inform the physician of this information and the board took no action on Guidance Document 110-28.

New Guidance Document

The board was provided with a draft handout of new Guidance Document 110-6 *Guidance for Pharmacies within Opioid Treatment Programs*. Ms. Juran

110-6 Guidance for  
Pharmacies within Opioid  
Treatment Programs

explained that DEA expressed concern for practices within opioid treatment programs that may pose a risk for diversion. It was requested that the board educate licensees practicing in this environment.

**MOTION:**

**The board voted unanimously to adopt the new Guidance Document 110-6 *Guidance for Pharmacies within Opioid Treatment Programs* as presented. (motion by Thornbury, seconded Boone)**

REPORTS

Chairman's Report

Ms. Warriner shared her experience of attending the NABP/AACP Districts 1 & 2 meeting, and encouraged the board to participate in NABP meetings moving forward. She was elected to serve as the District 2 representative on the NABP Resolution Committee. Ms. Warriner also shared her concerns with the number of recent pharmacy closings and patient access to pharmaceutical needs. She asked that staff provide a report reflecting the number of pharmacy closures to include the pharmacy name, address, and license number.

**ACTION ITEM:**

**Board staff will provide the board at a subsequent meeting with a list of pharmacies that have closed each year for the last several years. The list will contain the pharmacy names, addresses, and license numbers, at a minimum.**

Report on Board of Health  
Professions

Mr. Logan shared that he could not attend the last Board of Health Professions meeting and that he would provide an update at the next Full Board Meeting

Report on Inspection and  
Licensure Program

Ms. Juran provided an update of the licensing/inspection report included in the agenda packet.

Report on Pharmaceutical  
Processors

Ms. Kelley reviewed the Pharmaceutical Processor report included in the agenda packet. She shared that the report to be prepared by the Secretaries of Health and Human Resources and Agriculture regarding the appropriate structure for oversight of industrial hemp products is due to the legislators by November 1, 2019, and may be available as a public document by the next board meeting.

Report on Disciplinary  
Program

Ms. Shinaberry provided an overview of the update included in the agenda packet. She introduced Mr. Mykl Egan, J.D. as the new Disciplinary Case Manager.



Executive Director's Report

Ms. Juran provided an overview of the update included in the agenda packet. She shared information regarding the NABP/AACP Districts 1 & 2 Meeting in Vermont and encouraged attendance at the next District 1&2 meeting.

Board Counsel's Report

Mr. Rutkowski provided the board with an update on the New Age case. He shared that New Age has appealed the Board of Pharmacy's decision to deny its pharmaceutical processor application to the Virginia Court of Appeals.

New Business

The board confirmed 2020 meeting dates as follows:

Full Board Meeting: March 24, 2020, June 16, 2020, September 9, 2020, December 10, 2020

Formal Hearing: January 14, 2020, February 5, 2020, April 22, 2020, May 13, 2020, July 21, 2020, August 5, 2020, October 7, 2020, November 12, 2020

Special Conference Committee: January 7, 2020, February 18, 2020, March 10, 2020, April 1, 2020, May 5, 2020, June 23, 2020, July 7, 2020, August 18, 2020

Regulation Committee: May 13, 2020 and November 12, 2020

Consideration of Consent  
Orders

**MOTION:**

**The board voted unanimously to enter into closed session pursuant to §2.2-3711(A)(11) to consult with counsel regarding actual or probable litigation. Additionally, it was moved that Caroline Juran, Ellen Shinaberry, and Kiara Christian attend the closed meeting because their presence was deemed necessary and would aid the Board. (motion by Ratliff, seconded by Jenkins)**

**MOTION:**

**The Board voted unanimously that only public business matters lawfully exempted from open meeting requirements and only such public business matters as were identified in the motion for a closed meeting were heard, discussed, or considered during the closed session just concluded. (motion by Ratliff, seconded by Logan)**

Innocent Akani

License No. 0202-205580

**DECISION:**

**Upon a motion by Ms. Thornbury, and duly seconded by Ms. Richards-Spruill, the panel voted 8 in favor, 1 opposed (Jenkins), and 1 abstained (Nelson) to accept the consent order for revocation of the pharmacist license for Innocent Akani.**

Nayan Patel

License No. 0202-209826

**DECISION:**

**Upon a motion by Mr. Lee, and duly seconded by Mr. Boone, the panel voted unanimously to accept the consent order to reinstate the pharmacist license for Nayan Patel.**

Central Drugs

Permit No. 0214-001254

**DECISION:**

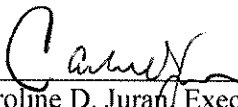
**Upon a motion by Mr. Ratliff, and duly seconded by Mr. Bolyard, the panel voted unanimously to accept the consent order to reinstate the non-resident pharmacy registration for Central Drugs.**

**ADJOURN:**

With all business concluded, the meeting adjourned at 2:50 pm.

  
\_\_\_\_\_  
Cynthia Warriner, Chairman

12-9-19  
DATE:

  
\_\_\_\_\_  
Caroline D. Juran, Executive Director

12/9/19  
DATE: