

FINAL/APPROVED

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

May 18, 2020  
Virtual Meeting

Department of Health Professions  
Perimeter Center  
9960 Mayland Drive  
3<sup>rd</sup> Floor  
Henrico, Virginia 23233

CALL TO ORDER:

A virtual WebEx meeting of the Board of Pharmacy was called to order at 9:15 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:

Cynthia Warriner, Chairman (On-Site)

MEMBERS  
PARTICIPATING  
VIRTUALLY:

Kristopher S. Ratliff, Vice Chairman  
Glen Bolyard  
Melvin L. Boone, Sr.  
James L. Jenkins, Jr.  
Ryan Logan  
Cheryl H. Nelson  
Patricia Richards-Spruill  
Rebecca Thornbury  
William Lee

STAFF PRESENT:

Caroline D. Juran, Executive Director (On-Site)  
James Rutkowski, Assistant Attorney General (On-Site)  
Kiara Christian, Executive Assistant (On-Site)

STAFF PARTICIPATING  
VIRTUALLY

Ellen B. Shinaberry, Deputy Executive Director  
James Johnson, Deputy Executive Director  
Annette Kelley, Deputy Executive Director  
Beth O' Halloran, Deputy Executive Director  
Elaine Yeatts, Senior Policy Analyst, DHP  
David E. Brown, D.C., Director, DHP

QUORUM:

With ten members present, a quorum was established.

APPROVAL OF AGENDA:

**MOTION:**

**The agenda was unanimously approved as presented. (motion by Jenkins, second by Ratliff)**

APPROVAL OF PREVIOUS  
BOARD MEETING  
MINUTES

**MOTION:**

**The Board voted unanimously to adopt the minutes as presented and amended for the following meetings:**

- **December 4, 2019, Special Conference Committee**
- **December 9, 2019, Full Board Meeting**
- **December 9, 2019, Public Hearing for Delivery of Schedule VI Devices and White Bagging/Brown Bagging**
- **December 9, 2019, Formal Hearing**
- **December 9, 2019, Formal Hearing**
- **December 10, 2019, Formal Hearing**
- **February 14, 2020, Telephone Conference Call**
- **February 18, 2020, Special Conference Committee**
- **March 10, 2020, Special Conference Committee (motion by Nelson, second by Richards-Spruill)**

**PUBLIC COMMENTS:**

Ms. Warriner 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 from only those persons who submitted an email to Caroline Juran no later than 8am on May 18, 2020 indicating that they wish to offer comment. Ms. Juran received an email from the following individuals and the chairman invited them to offer comment.

Christina Barrille, Executive Director of the Virginia Pharmacists Association thanked the Board for acting quickly and being proactive during pandemic. She also thanked the State Health Commissioner and VDH. Ms. Barrille commented that members are prepared to offer COVID-19 testing and vaccinations. She referenced HB1506 and SB1026 as means to increase access to patient care, clinical preventative services, and development of statewide protocols. Ms. Barrille congratulated Ms. Juran on her election as NABP President-Elect.

Phil Abraham, Director & General Counsel for Vectre Corp, offered comment on behalf of Covetrus Maine, an online nonresident pharmacy servicing animals. Mr. Abraham commented that Atlas Pharmaceuticals, an affiliated entity of Covetrus Maine, received an FDA warning letter which precluded Covetrus Maine from obtaining a required NABP certification, but that FDA has not had an opportunity to close out the issues with Atlas due to the pandemic. He noted that Virginia had recently renewed the Atlas nonresident outsourcing facility registration. Mr. Abraham asked the board to adopt one of the following: 1) find as the state of Indiana that certification from LegitScript is substantially similar to the NABP certification required in Code; 2) acknowledge that Covetrus Maine only does

business within the Commonwealth in limited transactions and waive the requirement to obtain certification from NABP or a substantially similar program pursuant to 54.1-3434.1(A)(4).

Jennifer O'Grady, Vice President of Pharmacy Operations Global Tech Solutions for Covetrus, requested the board recognize certification from LegitScripts. She shared her experience working with LegitScript and found it to provide a thorough review. She stated it is nationally recognized.

Charlton McGinley emailed Ms. Juran indicating a desire to offer public comment. It was unclear if she would be participating in the meeting virtually. Ms. Juran asked during the meeting if she was present. After no response, Ms. Juran read the email to the board which requested information regarding expedited licenses issued to military spouses. Ms. Juran informed the board that staff would respond to her email.

Greg O'Grady, PIC with Covetrus Maine thanked the board for the opportunity to provide comment and offered support of the comments offered by Mr. Abraham and Ms. O'Grady.

DHP DIRECTOR'S  
REPORT:

Dr. Brown thanked the Board for coordinating the use of Webex for this meeting. He offered that the Board of Pharmacy has issued many waivers to assist in the COVID-19 pandemic. Dr. Brown shared that DHP closed the building, and has had no meetings or hearings to date. DHP is currently in the process of developing a policy for meetings after the state of emergency expires to follow a method for high risk individuals to participate remotely, but will require an in-person quorum. He said that >75% of staff is teleworking with some physical presence in building, and that he anticipates long-term use of some of these accommodations will continue in order to increase efficiencies. Dr. Brown congratulated Ms. Juran for being elected NABP President-Elect.

LEGISLATIVE/  
REGULATORY/  
GUIDANCE UPDATE

Update on Legislative/Policy  
Actions

Information relevant to the 2020 General Assembly Session was included in the agenda package and Ms. Yeatts offered to answer any questions. Ms. Juran reported on the Governor's amendments to SB 976 that were not captured in the agenda package. Mr. Lee asked if USP defines "cannabis oil". Ms. Juran indicated that she was not familiar with USP having such a definition. Mr. Ratliff suggested that a front line pharmacist currently practicing be included on the workgroup required by HB 1506 and with any discussions regarding costs of drugs. Ms. Nelson noted the deadlines for reports are rapidly approaching and commented about the impact of the pandemic. Ms. Yeatts stated it's possible the deadlines may be extended. Ms. Juran also stated that it's possible that discussions

regarding the Joint Commission on Health Care request for consideration of statewide orders may overlap with board discussions regarding HB 1506.

**ACTION ITEM:**

**The Board requested staff to share with them at the September meeting the naloxone language required to appear on the upcoming pharmacist license renewal per the request from the Joint Commission on Health Care.**

Update on Regulatory Actions

Ms. Yeatts reviewed the Chart of Regulatory Actions found in the agenda packet, and noted a change in that the proposed regulations for an increase in fees has been approved by the Secretary's office and is now in the Governor's office. Mr. Ratliff expressed concern for the *Prohibition against incentives to transfer prescriptions* regulatory packet that has been in the Governor's Office for over 700 days. Staff indicated they routinely check on the status of this regulatory packet and others.

Adoption of Exempt  
Regulation to Schedule  
Certain Chemicals into  
Schedule I

Ms. Yeatts commented that the proposed final regulations included in the agenda packet do not show the deletion of chemicals that were scheduled by the 2020 General Assembly and placed into Code.

**MOTION:**

**The board voted unanimously to adopt the exempt regulation of 18VAC110-20-322 as presented and amended to remove the drugs scheduled into Code by the 2020 General Assembly and to place the following drugs identified by the Department of Forensic Science into a new subsection D:**

**1. Synthetic opioids**

- a. N-phenyl-N-[1-(2-phenylmethyl)-4-piperidinyl]-2-furancarboxamide (other name: N-benzyl Furanyl norfentanyl), 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. 1-[2-methyl-4-(3-phenyl-2-propen-1-yl)-1-piperazinyl]-1-butanone (other name: 2-methyl AP-237), 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. N-hexyl-3,4-dimethoxyamphetamine (other names: N-hexyl-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.
- b. N-heptyl-3,4-dimethoxyamphetamine (other names: N-heptyl-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.
- c. 2-(isobutylamino)-1-phenylhexan-1-one (other names N-Isobutyl Hexedrone, a-isobutylaminohexanphenone), 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. 1-(benzo[ d] 1, 3Dioxol-5-yl)-2-( sec-butylamino )pentan-1-one ( other name: N-sec-butyl Pentylone), 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. 2-fluoro-Deschloroketamine (other name: 2-(2-fluorophenyl)-2-(methylamino)-cyclohexanone), 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. Methyl 2-[1-(5-fluoropentyl)-1 H-indole-3-carboxamido]-3-methylbutanoate ( other name: MMB 2201 ), 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-penten-1-yl)-1 H-indole-3-carboxamido]-3-methylbutanoate (other names: MMB022, MMB-4en-PICA), 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.
- c. Methyl 2-[1-(5-fluoropentyl)-1 H-indole-3-carboxamido]-3-phenylpropanoate (other name: 5-fluoro-MPP-PICA), 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.
- d. 1-( 5-fluoropentyl)-N-( 1-methyl-1-phenylethyl)-1 H-indole-3-carboxamide (other name: 5-fluoro CUMYL-PICA), 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 after the effective date of the regulation), unless enacted into law in the Drug Control Act. (motion by Jenkins, second by Richards-Spruill)

Adoption of Exempt  
Regulation to Conform Drug  
Schedules to Actions Taken  
by DEA

### MOTION:

The board voted unanimously to adopt the exempt regulation as presented to amend 18VAC110-20-323 by adding the following drugs to conform drug schedules to actions taken by DEA:

- 5. Adds methyl 2-(1-(cyclohexylmethyl)-1H-indole-3-carboxamido)-3,3-

dimethylbutanoate (other name: MDMB-CHMICA, MMB-CHMINACA), including its salts, isomers, and salts of isomers whenever the existence of such salts, isomers, and salts of isomers is possible, in Schedule I.

6. Adds solriamfetol (2-amino-3-phenylpropyl carbamate), including its salts, isomers, and salts of isomers whenever the existence of such salts, isomers, and salts of isomers is possible, to Schedule IV.

7. Adds noroxymorphone, including its salts, isomers, and salts of isomers whenever the existence of such salts, isomers, and salts of isomers is possible, to Schedule II.

8. Adds lasmiditan [2,4,6-trifluoro-N-(6-(1-methylpiperidine-4-carbonyl)pyridine-2-yl)-benzamide], including its salts, isomers, and salts of isomers whenever the existence of such salts, isomers, and salts of isomers is possible, to Schedule V.

9. Adds brexanolone (3 $\alpha$ -hydroxy-5 $\alpha$ -pregnan-20-one), including its salts, isomers, and salts of isomers whenever the existence of such salts, isomers, and salts of isomers is possible, in schedule IV.

10. Deletes naloxegol and 6 $\beta$ -naltrexol from Schedule II.

11. Replaces 4-anilino-N-phenethyl-4-piperidine (CASRN 21409-26-7) in Schedule II with 4-anilino-N-phenethylpiperidine (ANPP).

12. Adds ethyl 2-(1-(5-fluoropentyl)-1H-indazole-3-carboxamido)-3,3-dimethylbutanoate (other name: 5F-EDMB-PINACA), methyl 2-(1-(5-fluoropentyl)-1H-indole-3-carboxamido)-3,3-dimethylbutanoate (other name: 5F-MDMB-PICA), and 1-5-fluoropentyl-N-(2-phenylpropan-2-yl)-1H-indazole-3-carboxamide (other name: 5F-CUMYL-PINACA), and their optical, positional, and geometric isomers, salts, and salts of isomers to Schedule I.

13. Adds other name 5F-APINACA to N-(adamantan-1-yl)-1-(4-fluorobenzyl)-1H-indazole-3-carboxamide (other name: FUB-AKB48) which is currently placed in Schedule I. (motion by Thornbury, second by Nelson)

Adoption of Final Regulations  
for Delivery of Prescription  
Devices

**MOTION:**

The board voted 9-0 to adopt the final regulation of 18VAC110-50-55 as presented regarding delivery of prescription devices. (motion by Ratliff, second by Nelson; Mr. Bolyard temporarily lost connection and did not vote)

Adoption of Final Regulations  
for Delivery of Dispensed  
Prescriptions, Labeling

Ms. Warriner expressed concerns for the regulatory amendment and requested the recent comment period be extended since the pandemic may have precluded persons from offering comment. Ms. Juran stated that she received an email on 5-17-20 asking if the public comment period could be extended due to the COVID health crisis. Counsel noted that a public hearing on the subject was noticed for the March board meeting which was subsequently cancelled due to the pandemic.

**MOTION:**

The board voted unanimously to extend the public comment period to the June 16<sup>th</sup> board meeting and conduct a public hearing on this topic at that meeting. (motion by Ratliff, second by Nelson)

Adoption of Proposed  
Regulations for

Pharmaceutical Processors

**MOTION:**

**The board voted unanimously to adopt proposed amendments to 18VAC110-60 et. seq. as presented to replace emergency regulations for registered agents and wholesale distribution by pharmaceutical processors. (motion by Nelson, second by Boone)**

Adoption of Final Regulations  
for White Bagging and Brown  
Bagging

**MOTION:**

**The board voted unanimously to adopt the final regulation of 18VAC110-20-275 as presented regarding white bagging and brown bagging. (motion by Thornbury, second by Jenkins)**

Adoption of Regulatory  
Amendments for Handling  
Fee for Returned Check

Ms. Yeatts commented that the Office of the Comptroller advised DHP that it should be charging \$50 for a return check, rather than the current \$35.

**MOTION:**

**The board voted unanimously to amend 18VAC110-20-20, 18VAC110-50-20, and 18VAC110-60-20 as presented to increase the handling fee for returned check or dishonored credit card or debit card from \$35 to \$50. (motion by Nelson, second by Bolyard)**

NEW BUSINESS:

Consideration of  
certification from a  
substantially similar program  
approved by the Board for  
nonresident pharmacies (§  
54.1-3434.1(A)(4))

Ms. Juran provided background information indicating that § 54.1-3434.1(A)(4) was amended in 2008 to require a nonresident pharmacy that dispenses more than 50 percent of its total prescription volume pursuant to an original prescription order received as a result of solicitation on the Internet, including the solicitation by electronic mail, to hold certification from the National Association of Boards of Pharmacy that it is a Verified Internet Pharmacy Practice Site (VIPSS), or certification from a substantially similar program approved by the Board. Shortly after the law passed, NABP created Vet-VIPPS for veterinary online pharmacies, but this certification was discontinued in 2016. Additionally, the VIPPS certification is no longer available as it was incorporated into the Digital Pharmacy accreditation. Ms. Juran indicated that board has been accepting the Digital Pharmacy accreditation from nonresident pharmacies as satisfying compliance with § 54.1-3434.1(A)(4) since VIPPS was incorporated into it. However, Digital Pharmacy accreditation does not extend to prescription drugs/devices, human or veterinary, that are dispensed to animals. Digital Pharmacy accreditation requires the pharmacy to obtain .Pharmacy and .Pharmacy is available for veterinary pharmacies. .Pharmacy is a secure and trustworthy Top-Level Domain indicating to users that it is a legitimate online pharmacy.

There was discussion that Covetrus Maine is ineligible, per NABP's policy, for the Digital Pharmacy accreditation because an affiliated outsourcing facility was

issued an FDA warning letter. The nonresident outsourcing facility registration is current active in Virginia.

**MOTION:**

**The Board voted unanimously that online pharmacies dispensing only to animals are doing business within the Commonwealth in limited transactions and therefore, the Board waives pursuant to § 54.1-3434.1(A)(4) the requirement to obtain Verified Internet Pharmacy Practice Site (VIPSS) certification or certification from a substantially similar program approved by the Board, if the pharmacy is credentialed with .Pharmacy from NABP or certification from LegitScript. (motion by Thornbury, second by Richards-Spruill)**

**ACTION ITEM:**

**The Board requested staff to prepare guidance for adoption at the June board meeting related to credentialing requirements from .Pharmacy or LegitScript for nonresident online pharmacies dispensing only to animals.**

Ms. Warriner asked if there was any other business to consider. Mr. Jenkins commented that he remains concerned for the Board's proposed increased in licensure fees particularly in light of the pandemic's impact on the economy.

**REPORTS**

**Chairman's Report**

Ms. Warriner reminded the Board that the regulatory requirement for a PIC to have a minimum of two years of experience as a licensed pharmacist became effective 12/11/19, and that there is an allowance to grant an exception. She stated staff will seek guidance from the board at the June board meeting. Thus far, she has worked with Ms. Juran in reviewing exemption requests. If the PIC does not have 2 years of experience but assumed the role prior to the regulation becoming effective, he or she may continue to serve in this capacity. However, if the person relocates to another pharmacy, the two year minimum requirement must be taken into account at the time that application is submitted and the person may be denied eligibility to serve as the PIC. Ms. Warriner discussed her participation with the Virtual NABP meeting. Ms. Warriner congratulated Ms. Juran on behalf of the Board for being elected President-Elect of NABP. There were five resolutions that were passed. One included a task force and she encouraged board members interested in participating to contact staff. Information for volunteering is also noted on the NABP webpage. Ms. Warriner served as the Resolution Committee member for District 2.



Report on Board of Health Professions

Mr. Logan provided updates from the most recent Board of Health Professions meeting.

Report on Inspection and Licensure Program

Report was included in the agenda packet. No questions were asked of staff.

Report on Pharmaceutical Processors

Report can be found on page 169 of the agenda packet. No questions were asked of staff.

Report on Disciplinary Program

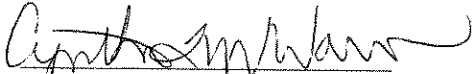
Report can be found on page 170-175 of the agenda packet. No questions were asked of staff.

Executive Director's Report

Report can be found on page 176 of the agenda packet. No questions were asked of staff.

**ADJOURNMENT:**

With all business concluded, the meeting adjourned at 11:48 AM.

  
Cynthia Warriner, Chairman

  
Caroline D. Juran, Executive Director

6/16/2020  
DATE:

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