(FINAL/APPROVED)

VIRGINIA BOARD OF PHARMACY MINUTES OF FULL BOARD MEETING

March 26, 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 9:25 am

PRESIDING:

Rafael Saenz, Chairman

MEMBERS PRESENT:

Glenn L. Bolyard, Jr. Melvin L. Boone, Sr. Ryan K. Logan Cheryl H. Nelson Kristopher S. Ratliff Patricia Richards-Spruill Rebecca Thornbury Cynthia Warriner

MEMBER ABSENT:

James L. Jenkins, Jr.

STAFF PRESENT:

Caroline D. Juran, Executive Director

J. Samuel Johnson, Jr., 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 Director, DHP

James Rutkowski, Assistant Attorney General

Kiara Christian, Executive Assistant

QUORUM:

With nine members present, a quorum was established.

APPROVAL OF AGENDA:

The agenda was unanimously approved as presented. (Motion by Warriner,

second by Boone)

APPROVAL OF PREVIOUS

BOARD MEETING

MINUTES

MOTION:

The Board voted unanimously to approve the minutes as presented for the

following meetings:

· December 18, 2018 Full Board Meeting

· December 18, 2018 Public Hearing to Schedule Certain Chemicals

- in Schedule I
- December 18, 2018 Formal Hearing
- · January 9, 2019 Formal Hearing
- January 9, 2019 Public Hearing
- · January 25, 2019 Special Conference Committee
- · February 13, 2019 Special Conference Committee
- February 27, 2019 Formal Hearing
- February 28, 2019 Special Conference Committee (motion by Bolyard, second by Boone)

PUBLIC COMMENTS:

Bill Cropper, President of VACDS, commented that the board should consider eliminating the pharmacist to pharmacy technician ratio in a future regulatory activity as pharmacists should be able to determine how many pharmacy technicians they are able to supervise. He stated the ratio limits quality of care, that there is a national trend to relax or eliminate ratios, that other professional groups do not limit the amount of support they may have, and that it would improve healthcare and costs.

Ken Hutchinson, representing National Healthcareer Association, provided comment on the draft 2020 legislative proposal regarding pharmacy technician educational standards. He expressed support for the idea of revisiting pharmacy technician educational standards, but is concerned that the draft changes would prohibit many individuals from meeting the requirements, have a negative impact on the workforce, and create a financial hindrance for those entering the workforce. Written comment was also provided as a handout.

Janet Sylvester, Vice President of Accreditation Services at the American Society of Health-System Pharmacists, offered comment in support of the draft 2020 legislative proposal on pharmacy technician educational standards, She stated that appropriately educated and accredited pharmacy technicians are needed to improve patient safety, and that public safety depended on uniform educational standards. She added that the Joint Commission of Pharmacy Practitioners voted to adopt national standards, and that currently there are 4 distance learning programs and 2 physical learning programs accredited by ASHP-ACPE in the Commonwealth.

Cindy Williams, Vice President/Chief Pharmacy Officer of Riverside Health System and President of VSHP, commented on the draft 2020 legislation regarding pharmacy technicians. She stated that VSHP supports the draft proposal. She stated she has had difficulty in hiring and retaining well-trained pharmacy technicians. She stated the pharmacy technicians who complete the board-approved pharmacy technician programs, which can be costly to the applicant, do not always have the skills to be successful in their organization.

Jeenu Phillip, member of the Florida Board of Pharmacy and Senior Manager, Pharmacy Affairs, Walgreens offered comment regarding the draft 2020 pharmacy technician legislative proposal. He shared that ASHP/ACPE provides students with a high level of education, but does not focus on the pharmacy technicians' area of practice. He said that shifting to require this

certification would limit the number of training programs available. Mr. Phillip commented that federal programs should be added and that NABP model language should be reviewed as it does not specify the ASHP-ACPE accreditation requirement. He also recommended reviewing the Florida Board of Pharmacy regulations on board-approved pharmacy technician training programs which was recently amended.

Christina Barrille, Executive Director of the Virginia Pharmacists Association commented that she recently attended the American Pharmacists Association convention, which focused on "moving pharmacy forward". She provided information on HB2561 regarding mandatory best practices for pharmacy audits and HJ662 regarding a Joint Commission on Healthcare study which includes a review of the pharmacist's role in prescribing, dispensing, and administering drugs and devices pursuant to collaborative practice agreements, standing orders, and statewide protocols. She also shared that WV has experienced significant savings after undergoing a Medicaid readjustment. Additionally, she asked the board to clarify its position on use of temperature monitoring devices when mailing dispensed drugs. A handout of written comment was also provided to the board.

Angela Cassano, pharmacist, commented in support of the draft 2020 legislative proposal regarding pharmacy technician training programs. She offered that pharmacy technician training programs are not currently in line with other types of programs such as radiology technicians, dental assistants, and cosmetologists. She added that the training programs offered by Walgreens, CVS, and Rite Aid are already ASHP-ACPE accredited.

Michelle Green-Wright, with the Virginia Department of Education (DOE), offered support for the draft legislative proposal for pharmacy technicians. She stated that the DOE currently has 17 high school training programs accommodating 1600 students. The programs prepare the students to take either the ExCPT or PTCB exam. She requested a grace period of two years, if the changes are approved, to accommodate the program's grant funding cycle and to allow time for the instructors to incorporate the new standards into their program. Currently, the DOE's program meets the entry-level ASHP/ACPE requirements and meets many of the advanced-level requirements.

Ms. Juran shared with the board members that a handout of written comment was provided to them at their sit that came from the National Community Pharmacists Association. The comment outlined their concerns for the draft 2020 legislative proposal regarding pharmacy technician educational standards.

Dr. Brown stated that the new DHP website is anticipated to be rolled out soon. He added that the new website design should make it easier to locate information, and will also include functionality for the boards to update their own content to the website. He also shared that there will be a number of legislatively mandated workgroups convened this summer to discuss barriers to licensing foreign trained physicians, telemedicine, licensure of music therapists, and if performing body composition analyses should be regulated. A budget amendment will require the Board of Pharmacy to report to the Joint Commission on Healthcare on proper drug disposal issues. The Secretaries of

DHP DIRECTOR'S REPORT:

Agriculture and Health and Human Resources will report on appropriate standards, if any, for the production of hemp-derived cannabidiol oil. Dr. Brown also expressed concerns for a CDC grant impacting the PMP program as it would require connecting to a new hub for transmitting data.

LEGISLATIVE/ REGULATORY/ GUIDANCE UPDATE

Report of the 2019 General Assembly

Regulatory Update

Adoption of Exempt Regulation to Schedule Certain Chemicals in Schedule I

MOTION:

Ms. Yeatts provided a summary overview of the materials in the agenda packet regarding passed legislation.

Ms. Yeatts reviewed the Chart of Regulatory Actions found in the agenda packet.

There was a public hearing conducted at 9:10AM pursuant to requirements of §54.1-3443 of the Drug Control Act to receive comment on scheduling certain chemicals in Schedule I.

The Board voted unanimously to place the recommended drugs into Schedule I by amending 18VAC110-20-322 to insert a new subsection D as listed below:

"D. Pursuant to subsection D of § 54.1-3443 of the Code of Virginia, the Board of Pharmacy places the following in Schedule I of the Drug Control Act:

1. Synthetic opioid.

a. 3,4-dichloro-N-[2-(dimethylamino)cyclohexyl]-N-isopropyl-benzamide (other name: Isopropyl U-47700), 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. alpha-pyrrolidinoisohexiophenone (other name: alpha-PiHP), 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-hydroxyphenyl)cyclohexyl]piperidine (other name: 3-hydroxy PCP), 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.

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 Warriner, second by Thornbury)

Adoption of proposed regulations on delivery of dispensed prescription devices

MOTION:

Presentation on Telepharmacy

Consideration of comment on periodic review regulations and adoption of final amendments

MOTION:

MOTION:

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

To accommodate travel arrangements, the chairman recommended that the Board move the presentation on telepharmacy up on the agenda schedule. Jessica Adams, PharmD, Manager of Regulatory Affairs with TelePharm provided a presentation to discuss the benefits of the use of telepharmacy in rural areas that may not have a pharmacy within close proximity. The slides were included in the agenda packet. No action was taken by the Board. The subject will be discussed at the Regulation Committee meeting in May.

A 60-day public comment period on the proposed regulations resulting from the periodic regulatory review of chapters 20 and 50 ended February 22, 2019. To aid the board in its deliberations, Ms. Yeatts provided a handout that highlighted sections of regulations for which comment was received. The board discussed each section to determine if the proposed language needed to be amended prior to adopting final regulations.

The Board received a significant amount of comment regarding whether live or real-time interactive continuing education (CE) should be required. It was clarified that live webinars that offered the ability to interact with the presenter would satisfy the requirement for "live or real-time interactive" CE, but that recorded webinars that did not offer the opportunity to interact with the presenter would not satisfy the requirement. There was much discussion regarding this issue and the required number of hours.

The Board voted unanimously to amend the proposed language in 18VAC110-21-120 subsection C by decreasing "five" hours to "three" hours of live or real-time interactive continuing education. (motion by Warriner, second by Richards-Spruill)

The Board voted unanimously to amend the proposed language in 18VAC110-20-425 by removing reference to a "root cause analysis" and have subsection (4)(h) read, "Appropriately performing analysis to investigate, identify, and correct sources of discrepancies or errors associated with the robotic pharmacy system" and subsection (6) read, "If it is identified that the robot selected an incorrect medication, the pharmacy shall identify and correct the source of discrepancy or error in

compliance with the pharmacy's policies and procedures prior to resuming full operations of the robot. An investigation of the cause of the event shall be completed and the outcome of the corrective action plan shall be summarized and documented in a readily retrievable format." (motion by Warriner, second by Logan)

MOTION:

The Board voted 3:6 to amend the proposed language in 18VAC110-20-110 regarding a minimum number of years of experience required for eligibility to serve as a pharmacist-in-charge by decreasing the proposed "two" years to "one" year. Motion failed due to a lack of votes. (motion by Bolyard, second by Thornbury; opposed by Warriner, Logan, Boone, Nelson, Ratliff, Richards-Spruill)

MOTION:

The Board voted 7:2 to adopt as presented the proposed language in 18VAC110-20-110 requiring "a minimum of two years of experience practicing in Virginia or another US jurisdiction" and allowing for the granting of exceptions "for good cause shown". (motion by Nelson, second by Boone; opposed by Thornbury and Bolyard)

MOTION:

The Board voted unanimously to amend the proposed language in 18VAC110-20-270 by inserting at the end of subsection A, "In cases of failed electronic prescriptions, Schedule VI prescriptions transmitted electronically may be routed to the pharmacy's facsimile machine and may bear an electronic signature". (motion by Warriner, second by Thornbury)

MOTION:

The Board voted unanimously to amend the first sentence of proposed subsection E in 18VAC110-20-270 by deleting "on-duty" and changing "the pharmacist" to "a pharmacist" and having it read, "An on-hold prescription shall be entered into the automated date procession system if such system is employed by the pharmacy, and a pharmacist shall verify the accuracy of the date entry at that time." (motion by Saenz, second by Nelson)

MOTION:

The Board voted unanimously to amend the proposed subsection B of 18VAC110-20-530 to read: "A pharmacist employed by or contracted with a pharmacy providing services to a long-term care facility may share a copy of a Schedule VI prescription or order with a pharmacist at another pharmacy for the purpose of dispensing an immediate supply of drugs, not to exceed a seven-day supply, without transferring the prescription pursuant to 18VAC110-20-360". (motion by Warriner, second by Thornbury)

MOTION:

The Board voted unanimously to adopt the final regulations for periodic review of chapters 20 and 50, and to adopt new chapters 21 and 15, as presented and amended. (motion by Warriner, second by Logan)

Preliminary Discussion of 2020 Legislative Proposals:

Pharmacy Technician Training Requirements

Compounding of Essentially Copies

Ms. Juran highlighted the draft legislative proposals in the agenda packet. The board did not engage in discussion, but referred the matter to the Regulation Committee for consideration.

OLD BUSINESS

Request from Gates Healthcare Associates, Inc. regarding cGMP Inspections

Ms. Juran stated she has communicated with Gates Healthcare Associates (GHA) and was informed that Gates does not have additional information to provide at this time. Because the Board's needs for recognizing an outside entity to perform cGMP inspections is very limited and is currently being met, GHA will withdraw its request for consideration. However, GHA would like to remain as a consideration in the future should the need arise.

NEW BUSINESS

Overview of Pharmacist and Pharmacy Technicians Workforce Survey Reports

Elizabeth Carter, PhD, Director of DHP Healthcare Workforce Date Center (HWDC) and Yetty Shobo, PhD, Deputy Director of DHP HWDC provided an overview of the 2018 Virginia Pharmacist and Pharmacy Technician Workforce Survey Reports provided as attachments to the meeting agenda. A handout of their slides regarding the key findings of the workforce surveys was provided to the Board. Key findings for pharmacists included: 26% increase in licensees, 11% increase in state workforce numbers, but full time equivalency declined; percent female increasing, median age is 44; percent with educational debt increasing overall; and, income stable for past two years. Key findings for pharmacy technicians included: 7% increase in licensees, 7% increase in state workforce numbers, but full time equivalency units declined; percent female stable with percent younger than 40 years old increasing; percent with educational debt increased slightly; income increasing although stable recently. Overall, there is a declining proportion of pharmacists in the state workforce, increasing median education debt, and over 20% of pharmacists and 14% of pharmacy technicians plan to retire in a decade. Three other handouts were provided to the Board. One handout from the US Bureau of Labor Projections Statistics Estimates (www.projectionscentral.come/projections/longterm) displayed the percent of employment growth 2016-2026 in the US vs. Virginia and nearby states, base vs. projected jobs, and annual average job openings for pharmacists and pharmacy technicians. Projected jobs for pharmacy technicians are higher than base with 870 projected annual average job openings. Projected jobs for pharmacists are higher than base with 360 projected annual average job openings. The second handout was from VirginiaLMI.com and demonstrated supply and demand. As of 3/14/19, there were 0.29 pharmacy technician

candidates available per job opening, or 544 jobs for 159 candidates. While the potential number of candidates is spread throughout the Commonwealth, the density of job openings is found in select areas of the Commonwealth. For pharmacists, there were 0.37 candidates available per job opening as of 3/14/19, or 160 jobs available for 59 candidates. While potential candidates are located in certain areas of the Commonwealth, the density of job openings also exist in select areas of the Commonwealth. The third handout listed the 2018 Data Products produced by the Healthcare Workforce Data Center.

Presentation on HPMP

Because the Board has five new board members as of last year, Ms. Peggy Wood, Program Manager of the Virginia Health Practitioners Monitoring Program (HPMP), provided a training overview of the HPMP program. A one-page flyer regarding referrals to the program was provided as a handout.

Training on disciplinary process and conduct during informal conferences and formal hearings

To expand on information provided during the new board member orientation, Ms. Shinaberry provided an overview of the disciplinary process, from the time the Enforcement Division receives a complaint through the appeals process. A one-page flowchart outlining the steps was provided to the Board. A video outlining the process for performing probable cause review was shown to the Board. However, due to technical difficulties with the sound, staff stopped the video and Ms. Juran completed the training with a verbal overview. A handout regarding sample motions for disciplinary proceedings was also provided. Mr. Rutkowski then discussed appropriate conduct for Board members when participating in informal conferences and formal hearings. A handout of his slides was also provided to the board.

REPORTS

Chairman's Report

Report on Board of Health Professions

Report on Inspection and Licensure Program

Report on Disciplinary Program

Executive Director's Report

Mr. Saenz provided a brief oral report which included information on a recent Leadership Forum that focused on pharmacy technicians.

Mr. Logan shared that he attended a Board of Health Professions meeting February 25, 2019. He added that policies and procedures were adopted for reviewing emerging health professions and that the agency disciplinary case disposition time is under review.

Ms. O'Halloran reported the Board currently licenses 35,414 individuals and facilities. The Board issued 900 licenses and registrations for the period of December 1, 2018 through February 28, 2019. Inspectors conducted 455 facility inspections including 159 routine inspections of pharmacies: 57 (36%) resulted in no deficiency, 55 (34%) with deficiencies and 47 (30%) with deficiencies and a consent order.

Ms. Shinaberry provided a statistical update regarding the disciplinary program by reviewing the information provided in the agenda packet.

Ms. Juran provided a verbal overview of recent meetings and presentations attended, as well as upcoming meetings that staff will be attending. She stated she attended a Congressional Briefing on February 27, 2019 on cannabinoid research. She shared some highlights of the briefing with the Board.

Regarding the Board Retreat on April 16, 2019, she stated that Carmen Catizone, Executive Director/Secretary of NABP will present on standard of care regulations, Peter Vlasses, Executive Director of ACPE will present on pharmacy technician educational standards, and Al Domeika, pharmacist-in-charge of Prime Wellness of CT will present on treating patients with medical marijuana. Lastly, she encouraged board members to attend the NABP annual meeting in May in MN.

ADJOURN:

With all business concluded, the meeting adjourned at 4:10pm.

Rafael Sagnz, Chairman

DATE:

Caroline D. Juran, Executive Director

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