

(FINAL/APPROVED)

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

September 24, 2021

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

CALL TO ORDER: A full board meeting was called to order at 9:18 AM.

PRESIDING: Cheryl H. Nelson, Chairman

MEMBERS PRESENT: R. Dale St. Clair Jr, Vice Chairman
Bernard Henderson, Jr.
James L. Jenkins, Jr.
William Lee
Sarah Melton
Patricia Richards-Spruill
Glenn Bolyard
Cheryl Garvin
Kristopher Ratliff

STAFF PRESENT: Caroline D. Juran, Executive Director
Annette Kelley, Deputy Executive Director
Ryan Logan, Deputy Executive Director
Beth O'Halloran, Deputy Executive Director
Ellen B. Shinaberry, Deputy Executive Director
Elaine Yeatts, Senior Policy Analyst, DHP
Barbara Allison-Bryan, M.D., Chief Deputy, DHP
James Rutkowski, Assistant Attorney General
Sorayah Haden, Executive Assistant, DHP

**PHARMACISTS AWARDED
1-HOUR OF LIVE OR REAL-
TIME INTERACTIVE
CONTINUING EDUCATION
FOR ATTENDING MEETING:** Ademola Are

QUORUM With ten members participating, a quorum was established.

APPROVAL OF AGENDA: An amended agenda, along with several documents, were provided as handouts. Changes included on the amended agenda were: reference to

handouts for amended minutes from June 28, 2021 and July 13, 2021; two handouts regarding Guidance Documents 110-9 and 110-34; a handout regarding the Adoption of Policy Regarding Meetings with Electronic Participation; and a handout regarding a Request from the Virginia Hospital and Healthcare Association (VHHA) for stakeholder meetings on white bagging. The amended agenda was accepted as presented.

**APPROVAL OF PREVIOUS
BOARD MEETING MINUTES**

Several amendments were offered to the draft minutes included in the agenda packet.

MOTION:

The Board voted unanimously to adopt the minutes for June 3, 2021 through August 24, 2021 as presented and amended as follows:

- **On page 2 of June 4, 2021 full board minutes, under “Approval of Previous Board Meeting Minutes”, correct to read “insert legislation to authorize adult use marijuana...” after “discussions regarding concerns for I”;**
- **On page 3 of the July 26, 2021 Special Conference Committee, change “he” to “she” regarding Tina Dodson. (motion by Jenkins, seconded by Richards-Spruill)**

PUBLIC COMMENTS:

Christina Barrille, Executive Director, Virginia Pharmacists Association, welcomed newly-appointed board member, Cheri Garvin, and thanked staff, all pharmacists and pharmacy technicians for their hard work. She referenced National Pharmacists Month during the month of October. She provided a one-page handout of technical comments on agenda pages 160-214 regarding statewide protocols. She expressed concern for employee burnout and reported that October 5, 2021 is VPhA’s Buddy Check Day.

The chairman highlighted to the Board that a handout of written public comment was provided at their seat. Staff received the written comment via email prior to the meeting from Ryan M. Martin, Esq. regarding “Board of Pharmacy Policy Regarding Department of Behavioral Health Licensed Facilities”.

DHP DIRECTOR’S REPORT:

Barbara Allison-Bryan, M.D., Chief Deputy Director, Department of Health Professions presented the Director’s Report on behalf of Dr. Brown. Dr. Allison-Bryan commented that 70% of the agency is currently teleworking and expected to return to the office in January 2022. She presented the vaccination status of the state. Virginia is ranked as the 12th state within the U.S. of vaccinated people. 71% of the people 18 years and older have received both doses of the vaccine. 80% of people 18 years and older have received at least one of the doses. DHP has implemented the mandate to be vaccinated or participate in weekly testing. 80% of DHP is currently fully vaccinated. IT has created a tracking portal for COVID testing and vaccination status on the Intranet for agency staff. She stated that a substance

abuse-related workgroup will meet next week regarding HB 2300.

CHART OF REGULATORY
ACTIONS

Mrs. Yeatts briefly reviewed the information on pages 148-151 of the agenda.

REGULATORY/POLICY
ACTIONS RESULTING
FROM 2021 GENERAL
ASSEMBLY SESSION

Required legislative reports are currently being prepared.

AMEND EMERGENCY
REGULATIONS
REGARDING
PHARMACISTS INITIATING
TREATMENT

Ms. Yeatts commented that the red language reflects draft proposed language based on 2021 legislative changes.

MOTION:

The Board voted unanimously to adopt the emergency regulations as presented. (motion by St. Clair Jr, seconded by Melton)

ADOPTION OF STATEWIDE
PROTOCOLS FOR
INITITATING TREATMENT

PHARMACIST VACCINE
PROTOCOL

MOTION:

The Board unanimously adopted the vaccine statewide protocol for pharmacists to initiate treatment as presented. (motion by St. Clair, seconded by Melton)

PHARMACIST PROTOCOL
TO LOWER OUT-OF-
POCKET EXPENSES

MOTION:

The Board voted unanimously to amend the current protocol to lower out-of-pocket expenses as presented. (motion by Jenkins, seconded by Henderson)

HIV PrEP PROTOCOL

There was discussion regarding whether a pharmacist may order the labs referenced in the protocol. Ms. Juran commented that the law regarding collaborative practice agreements authorizes pharmacists to order labs. Counsel confirmed that the law regarding a pharmacist's ability to initiate

treatment appears to authorize pharmacists to order labs that would be necessary to determine if a particular drug should be initiated and at what dose.

MOTION:

The Board voted unanimously to adopt the PrEP protocol as presented and amended by: including a footnote that a pharmacy may convert the protocol documents to an electronic format if the questions and process are identical to the adopted protocol; changing drug brand names to generic names; and inserting a statement on page 171 of the agenda packet that the pharmacist may order necessary labs if not complete. (motion by Lee, seconded by Richards-Spruill)

HIV PEP

MOTION:

The Board voted unanimously to adopt the PEP protocol as presented and amended by: including a footnote that a pharmacy may convert the protocol documents to an electronic format if the questions and process are identical to the adopted protocol. (motion by St.Clair, seconded by Melton)

TUBERCULIN SKIN TEST
ONE-STEP PROTOCOL

MOTION

The Board voted unanimously to adopt the Tuberculin Skin Test One-Step protocol as presented and amended by: including a footnote that a pharmacy may convert the protocol documents to an electronic format if the questions and process are identical to the adopted protocol. (motion by Richards-Spruill, seconded by Jenkins)

TUBERCULIN SKIN
TESTING TWO-STEP
PROTOCOL

There was discussion that Appendix C is simply to show how to place the TST.

MOTION:

The Board voted unanimously to adopt the Tuberculin Skin Test Two-Step protocol as presented and amended by: including a footnote that a pharmacy may convert the protocol documents to an electronic format if the questions and process are identical to the adopted protocol. (motion by Richards-Spruill, seconded by Bolyard)

REGULATIONS
GOVERNING
PHARMACEUTICAL
PROCESSORS

The Board previously adopted a NOIRA based on a petition for rulemaking. Actions identified on page 219. St.Clair acknowledged that educational presentations may be offered at offsite locations.

ACTION ITEM:

Staff will research more information regarding request #4 on page 226 to

amend 18VAC110-60-290 to remove duplicative information between the product label and patient label.

ACTION ITEM:

Regarding request #7 on page 226, staff will research if there is a better regulation to amend since really verifying patient registration prior to accessing facility and not prior to dispensing product.

MOTION:

The Board voted unanimously to adopt the proposed regulations as presented. (motion by Jenkins, seconded by St.Clair)

The Board voted unanimously to withdraw the three following pharmaceutical processor regulatory actions previously adopted by the Board since they have now been incorporated into the regulations that become effective September 1, 2021: 1)Action relating to changes in to law in 2020 General Assembly Session; 2) Action related to wholesale distribution and registered agents; and 3) Action related to vaping. (motion by Bolyard, seconded by Richards-Spruill)

**HEALTHCARE
WORKFORCE DATA
CENTER DIRECTOR'S
REPORT**

Elizabeth Carter, PhD reported that pharmacist job satisfaction is up, even during a pandemic. 68% of the pharmacists responding to the survey obtained a PharmD degree. The workforce data center is starting to look at unemployment. Pharmacy technicians are making more money, but there are fewer in the workforce.

MOTION:

The Board voted unanimously to change any reference to “license” or “licensee” to “registration” or “registrant” in the Pharmacy Technician Workforce Survey Report. (motion by Richards-Spruill, seconded by Henderson)

MOTION:

The Board voted unanimously to adopt the 2020 Pharmacist and Pharmacy Technician Healthcare Workforce Survey Reports as presented and amended. (motion by Henderson, seconded by Richards-Spruill)

**PETITION FOR
RULEMAKING REGARDING
AUTOMATED DISPENSING
DEVICES**

MOTION:

The Board voted unanimously to accept the petition and initiate rulemaking regarding 18VAC110-20-460 and 18VAC110-20-490.

**REPEALING PARTS OF
18VAC110-20-322
SCHEDULE I CHEMICALS**

All of the board actions in 18VAC110-20-322 A through C have now been scheduled in the Drug Control Act so they need to be removed from the regulations.

MOTION: The Board voted unanimously to adopt the final regulation of 18VAC110-20-322 as presented. (motion by Ratliff, seconded by Richards-Spruill)

GUIDANCE DOCUMENTS

MOTION: The Board voted unanimously to amend the draft language in Guidance Document 110-34 regarding background checks for certain facilities by changing six months to 90 days. (motion by Henderson, seconded by Jenkins)

MOTION: The Board voted unanimously to amend the following guidance documents as presented and amended:

- 110-1 (Facility Categories)
- 110-5 (Theft/Loss Reports)
- 110-9 (Monetary Penalties)
- 110-30 (Animal Shelters), amend further by removing reference to “Pound” as this term has been removed from the Code;
- 110-31 (Approved Capture Drugs), amend further by changing Code section to 3.2-6500
- 110-44 (Naloxone)
- 110-34 (Certain Facility Background Checks) as previously amended. (motion by Richards-Spruill, seconded by Henderson)

MOTION: The Board voted unanimously to repeal Guidance Document 110-50 (Telemedicine by Registered Practitioners of Cannabis Oil) as this is outdated based on recent legislative changes. (motion by St.Clair, seconded by Bolyard)

MOTION: The Board voted unanimously to adopt as presented a new Guidance Document 110-20 regarding background checks for cannabis dispensing facilities. (motion by Henderson, seconded by Jenkins)

MOTION: The Board voted unanimously to adopt as presented a new Guidance Document 110-19 regarding use of automated dispensing devices in certain DBHDS-licensed facilities. (motion by Ratliff, seconded by Lee)

MOTION/ACTION ITEM: The Board voted unanimously to adopt as presented a new Guidance Document regarding emergency medical services (EMS) drug kits and to invite a representative from the Office of Emergency Medical Services to the next Regulation Committee meeting to further discuss any issues of concern regarding EMS drug kits. (motion by Ratliff, seconded by Lee)

The Board voted unanimously to adopt as presented the policy regarding meetings with electronic participation. (motion by St. Clair, seconded by Melton)

OLD BUSINESS:

FDA MOU ON
COMPOUNDING
INORDINATE AMOUNTS

The Board requested that it be noted in the minutes that no action will be taken on the FDA MOU since the MOU has been withdrawn based on a recent federal court ruling.

NEW BUSINESS:

REQUEST FROM VHHA FOR
STAKEHOLDER MEETINGS
ON WHITE BAGGING

ACTION ITEM:

The Board requested that Ms. Juran respond to VHHA that the matter was discussed, no action will be taken at this time, and that they are welcome to share with the Board any specific requests it may have for rulemaking in the future.

REPORT FROM HEALTH
PRACTITIONER'S
PRESCRIPTION
MONITORING PROGRAM

Dr. Allison-Bryan, Amy Ressler, and Chris Buisset presented a PowerPoint presentation to explain the functions and goals of the Health Practitioner's Monitoring Program. The program was created to assist in recovery, not treatment. It is considered an alternative to disciplinary action. The program has a contract with VCU which monitors the compliance of client's recovery plan. The program included a dedicated case manager and ongoing monitoring. Scholarships have been created to assist with the cost of the program. Contracts last 3-5 years, most commonly 5 years. Screening tests can cost approximately \$35-50 per screen. VCU will assist with negotiating treatment options and will help client get on Medicaid, if necessary, to lower costs. Client must call test line daily. Most are diagnosed with substance use disorder (alcohol 40%; opioid 30%); mental health diagnosis about 10%. Cannot look for work without case manager cooperation. Pharmacist typically allowed to work at one location, no more than 40 hours per week, cannot serve as pharmacist-in-charge upon initial return, required to work with another pharmacist initially for most of the shift, worksite monitor and employer reports to HPMP monthly, peer monitor may be engaged.

REPORTS

CHAIRMAN'S REPORT:

The chairman recalled her experience during her recent trip to Annapolis, MD for the NABP/AACP Districts 1 & 2 Meeting.

REPORT ON BOARD OF
HEALTH PROFESSIONS

Ms. Juran commented that there are a number of vacant member positions on the Board of Health Professions and that it has not met recently. This includes a vacancy from the Board of Pharmacy since Ryan Logan accepted the position of Deputy Executive Director with the Virginia Board of Pharmacy.

REPORT ON LICENSURE
PROGRAM

Ms. O'Halloran provided a licensing report including data for various licenses issued by the Board. Page 309 of the agenda packet provides the number of newly issued licenses, registrations and permits for each category as well as a total number of licensees.

REPORT ON INSPECTION
PROGRAM

Tim Reilly, DHP Pharmacist Inspector, presented the inspection report. He introduced to the Board Srini Peddi who is a new pharmacist inspector with the Department of Health Professions' Enforcement Division. Mr. Reilly reported that 431 inspections were conducted last quarter. Due to COVID-19, the inspectors are conducting 14-18 inspections per month per inspector. Page 310 of the agenda displayed a chart reporting the various types of inspections conducted from April 1, 2021 through June 30, 2021.

REPORT ON
PHARMACEUTICAL
PROCESSORS

Ms. Kelley provided a Pharmaceutical Processors Report. All four currently permitted pharmaceutical processors are now submitting medical cannabis product applications for approval. The Board is receiving, on average, 1,000 to 1,200 patient applications per week. The Board is currently recruiting three additional temporary staff members. The agency is working on acquiring a new patient registration platform for future Pharmaceutical Processors applicants.

REPORT ON DISCIPLINARY
PROGRAM

Dr. Shinaberry presented the Disciplinary Report. The Board currently has 351 total cases, with majority regarding patient care. She reported the overall case load increased by 51 cases since last reported.

EXECUTIVE DIRECTOR'S
REPORT

Ms. Juran provided the Executive Director's Report. She informed the Board of the vacant staffing positions available. The staff is continuing to telework with limited hours on-site. She provided an update on current projects of the Board including EMS guidance, E-newsletters, and the new licensing software for the cannabis program.

RATIFICATION OF
CONSENT ORDERS

Dr. Shinaberry presented three signed consent orders for ratification.

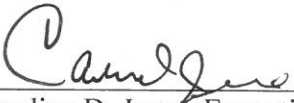
MOTION:

The Board voted unanimously to accept and ratify the three signed consent orders as presented by Dr. Shinaberry. (motion by Melton, seconded by Richards-Spruill)

MEETING ADJOURNED:

3:14 PM


Cheryl H. Nelson, Chairman


Caroline D. Juran, Executive Director

12-7-21
DATE:

12/7/2021
DATE: