FINAL/APPROVED

VIRGINIA BOARD OF PHARMACY MINUTES OF FULL BOARD MEETING

March 15, 2022 Department of Health Professions

Perimeter Center 9960 Mayland Drive

Henrico, Virginia 23233

CALL TO ORDER: A full board meeting was called to order at 9:07am.

PRESIDING: Cheryl H. Nelson, PharmD, Chairman

MEMBERS PRESENT: R. Dale St. Clair Jr, PharmD, Vice Chairman

William Lee, DPh Sarah Melton, PharmD Glenn Bolyard, RPh Cheryl Garvin, RPh Kristopher Ratliff, DPh James L. Jenkins, Jr., RN

MEMBERS ABSENT: Bernard Henderson, Jr.

Patricia Richards-Spruill, RPh

STAFF PRESENT: Caroline D. Juran, RPh, Executive Director

Annette Kelley, MS, CSAC, Deputy Executive Director

Ryan Logan, RPh, Deputy Executive Director Beth O'Halloran, RPh, Deputy Executive Director

Ellen B. Shinaberry, PharmD, Deputy Executive Director

Elaine Yeatts, Senior Policy Analyst, DHP Erin Barrett, JD, Senior Policy Analyst, DHP

David Brown, DC, DHP Agency Director (left at 9:58am)

James Rutkowski, JD, Assistant Attorney General

Sorayah Haden, Executive Assistant

PHARMACISTS AWARDED 1-HOUR OF LIVE OR REAL-

TIME INTERACTIVE

CONTINUING EDUCATION

FOR ATTENDING MEETING: John Lubkowski Derek Parvizi

QUORUM: With 8 members present, a quorum was established.

APPROVAL OF AGENDA:

The following amendments to the agenda were presented as follows:

- The presentation of the 2021 Pharmacist and Pharmacy Technician Workforce Survey Reports by Dr. Yetty Shobo was moved up on the agenda to be presented after the Director's Report
- A discussion of pharmacy technician training programs was added to the New Business section.

MOTION

The agenda was adopted as presented and amended. (motion by Ratliff, seconded by Garvin)

APPROVAL OF PREVIOUS BOARD MEETING MINUTES

One amendment was offered to the draft minutes included in the agenda packet.

MOTION:

The Board voted unanimously to adopt the minutes for the meetings held between December 7, 2021 and March 2, 2022 as presented and amended as follows:

On page 4 of January 18, 2022 Workgroup Regarding Unprofessional Working Conditions – Pharmacy Work Conditions minutes, amend "St. Clair recommended limiting staffing collaboration to the Pharmacist-in-Charge (PIC)." to read "St. Clair discussed limiting staffing collaboration to the Pharmacist-in-Charge (PIC)." (motion by Jenkins, seconded by Melton)

PUBLIC COMMENT:

Lauren Paul, Executive Director of Pharmacy Regulatory Affairs Team at CVS expressed support of the workgroup's efforts to improve the working conditions. She raised concerns regarding the draft guidance document stating pharmacists can assess staffing needs very differently, practice settings can vary, and the measures appear subjective. CVS supports objective measures and recommends further discussion with stakeholders, including citizen members, prior to adopting the guidance document.

Christina Barrille, Executive Director of VPhA, provided a handout of written comment in addition to her verbal comment. She stated the workgroup's discussions regarding pharmacy working conditions were very productive and VPhA supports the recommendations. She stated that she has heard that pharmacy technician hours are being cut again. She expressed appreciation to Del. Hodges for introducing HB 1324 and recognized Elaine Yeatts for her retirement.

Laura Churns, Senior Manager, Pharmacy Regulatory Affairs at Publix

Pharmacy, encouraged additional dialogue regarding the draft guidance document on pharmacy working conditions to ensure it is applied correctly by everyone. She stated the guidance as written could be applied inconsistently.

Jodi Roth, Director of Government Affairs at Virginia Retail Merchants Association representing the Virginia Association of Chain Drug Stores (VACDS) stated they associate their comments with CVS and Publix.

DHP DIRECTOR'S REPORT:

David Brown, D.C., Director, DHP presented the Director's Report. He informed the Board of the departure of Barbara Allison-Bryan, MD and expressed that she will be missed by the agency. He explained the "new normal" of the agency which will go into effect in April consisting of a hybrid work schedule with staff being on-site at least two days a week. He referenced a new CDC COVID-19 tool which indicates Henrico and Chesterfield Counties have a low-level of community spread. The new security team received praises as they continue to improve the security of the building including scanners and metal detectors which will be installed in the future. Upgrades to the conference center audio-visual equipment is taking slightly longer than expected due to supply chain challenges.

ADOPTION OF 2021 PHARMACISTS AND PHARMACY TECHNICIAN WORKFORCE SURVEY REPORTS:

Yetty Shobo, PhD, Deputy Director, DHP Healthcare Workforce Data Center and Data Analytics Division presented an overview via PowerPoint of the 2021 Pharmacists and Pharmacy Technician Workforce Survey Reports. She explained the statistics of the 2021 Pharmacist and Pharmacy Technicians report to reports of the previous years. Highlights included: pharmacist diversity slightly less than national healthcare average; increase in female pharmacists; age of pharmacists less than 30 has declined by 1%; 70% of pharmacists hold a PharmD degree; overall increase of pharmacist educational debt with median debt almost the same as median income; previously income was higher than debt; higher retirement intention of pharmacists with more planning to retire by age 65. She commented that educational debt and retirement intentions are a bit concerning. Regarding use of the pharmacist statewide protocols to initiate treatment effective in January 2021, 27% of survey respondents indicated they utilize the protocols. Breakdown: naloxone (17%); hormonal contraception and prenatal vitamins (1% each); emergency contraception (2%); epinephrine and lowering out-ofpocket expenses (3% each). Highlights of pharmacy technician survey report included: decline in number of pharmacy technicians over last 4 years; 85% female has stayed about the same; diversity index increased slightly and is about the same as state diversity index; shrinkage in nearly every age group; educational debt has not changed much and income remains higher than debt; retirement intention is about 50%.

ACTION ITEM:

Dr. Shobo will work with Mike Gallini in IT to amend the statewide protocol question in the Pharmacist Survey to include the additional medical conditions which became effective in December 2021 and the Board can consider the amended question at the June board meeting.

MOTION The Board voted unanimously to adopt the Pharmacist and Pharmacy Technicians Workgroup Survey Reports as presented and amended by inserting data regarding the use of statewide protocols into the Pharmacist report. (motion by Jenkins, seconded by Bolyard)

CHART OF REGULATORY ACTIONS

REGULATORY/GUIDANCE

Ms. Yeatts briefly reviewed the chart in the agenda packet and provided updated information.

REPORT OF THE 2022 GENERAL ASSEMBLY

Ms. Yeatts referenced the legislative report included in the agenda packet regarding relevant bills considered or passed by the 2022 General Assembly.

ACTION ITEM: Staff will research SB591 and if appropriate, send an communication in June to pharmacies to cease selling products containing delta-8 THC as of July 1, 2022.

ADOPTION OF NOIRA The Board considered the adoption of a Notice of Intended Regulatory Review (NOIRA) regarding Chapters 20, 21, and 30 and the one comment received during the comment period that ended 2/25/22. It was stated that the Board must adopt emergency regulations on pharmacy working conditions in September as mandated by HB 1324. The Board decided to leave reference to pharmacy working conditions in the NOIRA for now and remove later, if necessary, based on development of emergency regulations.

> The Board voted unanimously to adopt the Notice of Intended Regulatory Action as presented for chapters 20, 21, and 30 and amended by striking "retail" from Chapter 20 regarding a change in the definition of "personal supervision" allowing audio-visual technology by pharmacists on premises for supervision of compounding in pharmacies. (motion by St. Clair, seconded by Bolyard)

No public comments were received during the comment period ending 2/16/22. Staff reminded the Board that this action results from a petition for rulemaking related to an ongoing innovative pilot program.

> The Board voted unanimously to refer to the Regulation Committee the development of proposed regulations to allow a pharmacist at a central distribution company to verify Schedule VI drugs to be placed in an automated dispensing device (ADD) prior to delivery to the receiving hospital and pharmacy technicians to load the drugs directly into the ADD without further verification by a pharmacist at the hospital.

LEGISLATIVE/

FROM PERIODIC REVIEW

MOTION:

PROPOSED REGULATIONS FOR REMOTE PROCESSING OF DRUGS IN AUTOMATED DISPENSING DEVICES FOR **HOSPITALS**

MOTION:

(motion by Jenkins, seconded by Bolyard)

ADOPTION OF FINAL REGULATIONS FOR USE OF MEDICATION CAROUSELS AND RFID TECHNOLOGY: The Board fully considered the public comments received during the comment period that ended on 3/4/22. Ms. Yeatts indicated that the typo in 18VAC110-20-425 (C)(2)(c) had been corrected to read "A nurse "or" other person...".

MOTION

The Board voted unanimously to adopt the final regulations for the use of medication carousels and RFID technology as presented. (motion by St. Clair, seconded by Ratliff)

ADOPTION OF PROPOSED REGULATIONS FOR PHARMACISTS INITIATING TREATMENT: The Board considered proposed regulations for pharmacists initiating treatment to replace the emergency regulations currently in effect.

MOTION

The Board voted unanimously to adopt the proposed regulations for pharmacists initiating treatment as presented. (motion by Ratliff, seconded by Melton)

ADOPTION OF EXEMPT REGULATIONS FOR PHARMACEUTICAL PROCESSORS: No comments were received during the public comment period that ended on 3/4/22. The Board considered adoption of exempt regulations for pharmaceutical processors.

MOTION

The Board voted unanimously to adopt the exempt regulations for pharmaceutical processors as presented. (motion by Jenkins, seconded by Garvin)

ADOPTION OF GUIDANCE DOCUMENT REGARDING PHARMACY WORKING CONDITIONS:

The Board considered a draft guidance document as recommended by the workgroup regarding unprofessional conduct - pharmacy working conditions.

MOTION

The Board voted unanimously to adopt the guidance document regarding pharmacy working conditions as presented and amended by inserting "; and all other duties required by Virginia Code §§ 54.1-3300 et seq., 54.1-3400 et seq., and 18VAC110-20-10 et seq." after "patient testing" on page 2 of the document. (motion by Bolyard, seconded by Ratliff)

CONSIDERATION OF REQUIRNG CONTINUING EDUCATION ON BUPRENORPHINE IN 2023

Juran provided background regarding a recent SAMHSA Region 3
Buprenorphine Summit held to address the significant increase in overdose deaths and patient inability to access buprenorphine from pharmacies.

Challenges discussed during the summit included stigma and reluctance to

dispense drugs for opioid use disorder (OUD) for various reasons. She stated it was recommended during the summit that the Board consider mandating up to 2 hours of CE for pharmacists on buprenorphine to further educate pharmacists on the use of buprenorphine for OUD which may potentially increase access. Past required CE topics include: 1 hour in opioid use or abuse (2015); and, 1 hour in proper opioid use, opioid overdose prevention, or naloxone administration (2017).

MOTION

Pursuant to 54.1-3314.1 of the Code of Virginia and of the 15 hours of CE that pharmacists must obtain in 2023, the Board voted unanimously that 2 of the hours must address the following subject: medication for OUD, including methadone, buprenorphine, naltrexone, naloxone, or any other drug indicated for OUD. (motion by Ratliff, seconded by Melton)

NEW BUSINESS:

DISCUSSION OF PHARMACY TECHNICIAN TRAINING PROGRAMS:

Ratliff expressed concern that the new statutory requirement, effective July 1, 2022, for pharmacy technician training programs to be accredited may negatively impact the work pool of pharmacy technicians, particularly for independent pharmacies. He stated many chain pharmacies have accredited training programs, but worried there may be insufficient programs for independent pharmacies to use. Juran commented that staff has had ongoing conversations with ASHP regarding questions received. She stated there appears to be a lot of confusion on the subject and that staff will send a subsequent communication to licensees to clarify the issue. ASHP has been clarifying to independent pharmacies that they can take advantage of distance learning programs and do not necessarily need to implement an accredited training program. They can also serve as a practical experience site for any existing school-based programs. Garvin and Ratliff expressed concern for the cost of a student completing an accredited program. Juran reminded the Board that this was a subject the Board previously supported due to ongoing discussions to expand pharmacy technician scope of practice and address hospitals' inability to hire sufficiently trained pharmacy technicians. She referenced Louisiana having mandated accredited training programs and was not aware of a decrease in its work pool. She also reminded the Board that there is an allowance for obtaining a pharmacy technician registration during this transitional time. Specifically, 18VAC110-21-141, effective July 1, 2022 states "D. A person who successfully completed or was enrolled in a Boardapproved pharmacy technician training program but did not successfully pass a national examination prior to July 1, 2022 may be eligible to obtain registration as a pharmacy technician after successfully passing a national certification examination administered by PTCB or NHA and submitting to the board documentation of such completion or enrollment in a Boardapproved pharmacy technician training program and passing examination E. A person who passed a national certification examination administered by PTCB or NHA but did not complete a Board-approved

pharmacy technician training program prior to July 1, 2022 may be eligible to obtain registration as a pharmacy technician upon documentation of having passed such examination." The Board will further discuss the subject in June when adopting regulations on the subject to replace the emergency regulations currently in effect.

RECOGNITION OF FORMER BOARD MEMBER RYAN LOGAN AND RETIRING SENIOR POLICY ANALYST ELAINE YEATTS The Board presented a plaque and expressed appreciation to former board member, Ryan Logan, for his almost 8 years of service on the Virginia Board of Pharmacy. The Board also recognized the upcoming retirement of Senior Policy Analyst, Elaine Yeatts, who has worked for the Department of Health Professions for 33 years.

REPORTS:

CHAIRMAN'S REPORT

Chairman Nelson offered brief comments and expressed her appreciation for everyone's participation. She thanked the pharmacists and pharmacy technicians for stepping up to provide extraordinary health care and ensure public safety to the world during the pandemic. She thanked the workgroup members for continuing to work hard to improve pharmacy working conditions. She informed the Board of her participation in a NABP virtual interactive member forum held in January 2022, along with Ms. Juran. Chairman Nelson, St. Clair, and Juran will be attending the NABP Annual Meeting in Phoenix, AZ in May 2022.

BOARD OF HEALTH PROFESSIONS

Melton informed the Board that the Board of Health Professions has not met since the last Board of Pharmacy meeting and therefore, there is no update to provide. The next meeting will be held on March 29, 2022. Additional information will be provided to the Board at the June meeting.

LICENSURE OF INDIVIDUALS AND IN-STATE FACILITIES Logan presented the Licensing Report of Individuals and In-State Facilities which included data from August 2020 through February 2022. He stated there is a typo in the report and that the last column regarding license count should read "2/17/22", not "2/17/21". As of February 17, 2022, the Virginia Board of Pharmacy holds a current licensure count of 39,764 licenses representing individuals and various in-state permit categories.

LICENSURE OF NONRESIDENT FACILITIES

O'Halloran presented the Licensing Report of Nonresident Facilities which included data from August 2020 through February 2022. She stated there is a typo in the report and that the last column regarding license count should read "2/17/22", not "2/17/21". As of February 17, 2022, the Virginia Board of Pharmacy holds a current licensure count of 2,460 Nonresident facilities licensees. The 2,460 licensees consists of 7 license types.

INSPECTION PROGRAM

Melody Morton, Inspections Manager with the Enforcement Division

presented the Inspections Report including data from October 1, 2021 through December 21, 2021. The report included the number of inspections completed per licensing type, deficiencies noted during routine inspections per licensing type, and the categories for deficiencies for reoccurrences recorded more than 20 times with examples. She stated they have resumed more "normal practice" and are performing fewer virtual inspections.

PHARMACEUTICAL PROCESSORS

Kelley presented the Pharmaceutical Processors Report informing the Board of the continuation of adding licensed facilities. The Board currently has 6 licensed cannabis dispensing facilities. Assistant Attorney General, Jim Rutkowski, informed the Board that the Henrico County Circuit Court Judge ruled in favor of Board regarding PharmaCann's appeal. Kelley expressed her appreciation of the staff's hard work as the Pharmaceutical Processor Program will soon have registered 50,000 patients. The program continues to receive approximately 1,000 applications weekly.

DISCIPLINARY PROGRAM

Shinaberry presented the Disciplinary Program Report reporting as of February 22, 2022 the Board currently has 381 open cases consisting of 207 patient care cases and 174 non-patient care cases. Thirty-five of the non-patient care cases are compliance cases. There are currently two cases being appealed to Circuit Court. Shinaberry provided the dates for upcoming disciplinary proceedings.

EXECUTIVE DIRECTOR'S REPORT

Juran stated the agency will be transitioning to a hybrid schedule in April consisting of a schedule allowing up to 3 days of teleworking. The license count for the board has more than doubled consisting of approximately 41,000 traditional Board of Pharmacy licenses and approximately 46,000 cannabis licensees.

The Board recently filled one full-time licensing administrative position and one records management position. Licensing Administrative Assistant Sheila Sheranek will be retiring April 1, 2022. There is ongoing recruitment to fill her position. Recruitment for an additional full-time licensing administrative assistant and licensing supervisor for the pharmaceutical processor program continues. The Pharmaceutical Processor Program has recently filled 3 temporary positions and 2 P-14 positions.

The agency is preparing for the transition to utilizing digital disciplinary evidence packets. Also, Juran has attended multiple NABP meetings. She stated that Shinaberry and Logan recently offered a board presentation at the VCU School of Pharmacy.

CONSIDERATION OF CONSENT ORDERS, SUMARY SUSPENSIONS, OR SUMMARY RESTRICTIONS Shinaberry presented a consent order for Board consideration regarding Denise A. Foley (License #0202215458).

CLOSED MEETING

Upon a motion by St. Clair, and duly seconded by Jenkins, the Board voted unanimously to convene a closed meeting pursuant to §2.2-3711(A)(27) of the Code of Virginia ("Code") to reach a decision regarding the matter of Denise A. Foley (License #0202215458). Additionally, he moved that Caroline Juran, James Rutkowski, Ellen Shinaberry, and Sorayah Haden attend the closed meeting because their presence is deemed necessary and will aid the Board in its deliberations.

RECONVENE

Upon the motion by St. Clair, and duly seconded by Garvin, having certified that the matters discussed in the closed meeting met the requirements of §2.2-3712 of the Code, the Board reconvened an open meeting and announced the decision.

DECISION

Upon a motion by St. Clair, and duly seconded by Lee, the Board unanimously voted to accept the consent order for Denise A. Foley (License #0202215458).

Shinaberry presented a consent order for Board consideration regarding Williamsburg Drug #1963 (License #0201000676). Ratliff and St. Clair recused themselves from the presentation and attending the closed meeting.

CLOSED MEETING

Upon a motion by Bolyard, and duly seconded by Garvin, the Board voted unanimously to convene a closed meeting pursuant to §2.2-3711(A)(27) of the Code of Virginia ("Code") to reach a decision regarding the matter of Williamsburg Drug #1963 (License #0201000676). Additionally, he moved that Caroline Juran, James Rutkowski, Ellen Shinaberry, and Sorayah Haden attend the closed meeting because their presence is deemed necessary and will aid the Board in its deliberations.

RECONVENE

Upon the motion by Bolyard, and duly seconded by Lee, having certified that the matters discussed in the closed meeting met the requirements of §2.2-3712 of the Code, the Board reconvened an open meeting and announced the decision.

DECISION

Upon a motion by Jenkins, and duly seconded by Melton, the Board unanimously voted to accept the consent order for Williamsburg Drug #1963 (License #0201000676); Ratliff and St. Clair recused.

Shinaberry presented a possible settlement for Board's consideration regarding Green Health Integrative and Wellness Pharmacy (License #0201004861). Bolyard recused himself from the presentation and closed session.

CLOSED MEETING

Upon a motion by St. Clair, and duly seconded by Ratliff, the Board voted

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> unanimously to convene a closed meeting pursuant to §2.2-3711(A)(27) of the Code of Virginia ("Code") to reach a decision regarding the matters of Green Health Integrative and Wellness Pharmacy (License #0201004861). Additionally, he moved that Caroline Juran, James Rutkowski, Ellen Shinaberry, and Sorayah Haden attend the closed meeting because their presence is deemed necessary and will aid the Board in its deliberations. Upon a motion by St. Clair, and duly seconded by Ratliff, having certified that the matters discussed in the closed meeting met the requirements of §2.2-3712 of the Code, the Board reconvened an open meeting and announced the decision. Upon a motion by Melton, and duly seconded by Garvin, the Board

DECISION

RECONVENE

unanimously voted to not accept the settlement for Green Health Integrative and Wellness Pharmacy (License #0201004861); Bolyard recused.

| MEETING ADJOURNED: | 1:40 PM |
|----------------------------|---------------------------------------|
| Cheryl H. Nelson, Chairman | Caroline D. Juran, Executive Director |
| DATE: | DATE: |

| RECONVENE | | | |
|----------------------------|---------|---------------------------------------|---|
| DECISION | | | |
| MEETING ADJOURNED: | 1:40 PM | | |
| Cheryl H. Nelson, Chairman | , | Caroline D. Juran, Executive Director | - |
| 6-3-22 DATE: | | 616 Zozz DATE: | |