### (FINAL/APPROVED)

### VIRGINIA BOARD OF PHARMACY MINUTES OF FULL BOARD MEETING

Tuesday, December 6, 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 9:16am.

PRESIDING:

Dale St. Clair, PharmD, Chairman

MEMBERS PRESENT:

Larry Kocot, J.D.
William Lee, DPh
Wendy Nash, PharmD
Kristopher Ratliff, DPh
Potricio Richards Serville

Patricia Richards-Spruill, RPh

Ling Yuan, PharmD Cheryl Garvin, RPh

MEMBER ABSENT:

Sarah Melton, PharmD

STAFF PRESENT:

Caroline Juran, RPh, Executive Director

James Rutkowski, J.D., Assistant Attorney General

Arne W. Owens, Director, DHP

James Jenkins, Jr., RN, Chief Deputy Director, DHP

Erin Barrett, J.D., DHP Senior Policy Analyst

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

Sorayah Haden, Executive Assistant

Patricia Mason, Individual Licensing Supervisor

PHARMACISTS AWARDED 1-HOUR OF LIVE OR REAL-

Wendy C. Nash, PharmD

TIME INTERACTIVE

Ryan Logan, RPh

CONTINUING EDUCATION

Ellen B. Shinaberry, PharmD

FOR ATTENDING MEETING:

David Flammia, RPh

QUORUM:

With 8 members present, a quorum was established.

#### APPROVAL OF AGENDA:

An amended agenda was provided, along with handouts. A new item was inserted into New Business the section under Legislative/Regulatory/Guidance. The fourth bullet in the section was amended to read "Withdraw changes to Guidance Document 110-33 Pharmacy Interns as Pharmacy Technicians, Pharmacy Technician Ratio, and Pharmacy Technician Trainees and Amend Vaccine Protocol". Two handouts for this new item were provided, a copy of the current Guidance Document 110-33 and a copy of the Pharmacist Vaccine Statewide Protocol for adults with draft amendments.

Hearing no additional items, the chairman stated that the amended agenda was accepted as presented.

APPROVAL OF PREVIOUS BOARD MEETING MINUTES:

The chairman stated that on page 1 of the 9/6/22 full board meeting minutes, Mrs. Patricia Richards-Spruill should be listed as being awarded 1-hour of CE.

MOTION:

The Board voted unanimously to adopt the minutes for the meetings held between September 6, 2022 and November 17, 2022 as presented and amended as follows:

- Page 1 of the 9/6/22 full board meeting minutes, Mrs. Patricia Richards-Spruill should be listed as being awarded 1-hour of CE;
- Page 8 of the 9/6/22 full board meeting minutes should read "motion by Ratliff, seconded by Richards-Spruill". (motion by Ratliff, seconded by Garvin)

PUBLIC COMMENT:

Becky Hobden, Lab Director, Green Analytics Virginia provided comment that propane and butane should be considered for inclusion on the proposed list of approved hydrocarbon solvents (Guidance Document 110-45). While the solvents are not listed on the AHP list, she noted that the AHP states that it is not an exhaustive list. She believes supportive documentation exists. She stated Maryland and Pennsylvania allow use of the solvents, but testing thresholds may vary among the states. She commented that toxicology information needs to be reviewed.

Christina Barrille, Executive Director, VPhA, thanked Dr. David Brown for his service as former DHP Director and welcomed Arne W. Owens and Jim Jenkins on their new roles at DHP. She stated it is difficult to obtain an appointment in a primary care setting and that VPhA will introduce a bill to expand access by authorizing pharmacists to treat certain conditions. She also expressed concern for recent interpretations of the Department of Labor and Industry restricting use of pharmacy technician trainees under the age of 18. She commented that the DOE should be authorized to produce well-trained pharmacy technician trainees and not discourage high school students from seeking a career in healthcare. She invited everyone to participate in an

upcoming CE webinar regarding statewide protocols and the upcoming annual meeting in Roanoke in February.

Natalie Nguyen, PharmD, representing the Virginia Society of Health-Systems Pharmacists provided comment in support of exempting automated dispensing devices stocked solely with emergency or stat-use medications from certain requirements of 18VAC110-20-555. The public comment period for the NOIRA closes on 11/7/2022.

#### DHP DIRECTOR'S REPORT:

Mr. Arne W. Owens introduced himself as the newest appointed Director of the Department of Health Professions. He provided a brief overview of his career, including time spent as the former Chief Deputy Director of DHP. He acknowledged the important role of pharmacists and expressed appreciation for their role in the administration of COVID-19 vaccines. Mr. Owens then welcomed his Chief Deputy Director, James Jenkins, Jr., RN who will also serve as a special advisor for healthcare workforce matters.

# UPDATES FROM THE HEALTH PRACTITIONER MONITORING PROGRAM:

Training updates on HPMP were requested since the Board has several new members. PowerPoint slides regarding the Health Practitioner Monitoring Program were provided by Christina C. Buisset, DHP Health Practitioners' Monitoring Program Manager and Amy Ressler, VCU Health Practitioners' Monitoring Program Administrative Director. Mrs. Buisset provided foundational facts of the program such as the history, purpose, and goal of the program. The goal of the HPMP is to assist and support the recovery process for licensees impaired by substance abuse or mental health and navigate the practitioner to return to safe and productive clinical practice.

The program resulted from legislation passed in 1997. There is no participation fee. DHP has an MOU with VCU Addiction Psychiatry. There are currently 6 case managers that make collective decisions and a medical review officer. HPMP makes referrals for treatment, drug toxicology screens, requires a daily check-in line, determines approval to work, and requires work-site monitoring. The HPMP Advisory Committee reviews noncompliance, dismissals, resignations, and successful completions. medication assisted treatment, participants will be referred to a physician to determines best form of treatment, e.g., naltrexone or buprenorphine. Completion of a participation contract happens quickly, and the licensee agrees to not practice until approved to work. Completion of the recovery monitoring contract can take longer as more information is needed. Dr. Nash requested that we assess prevalence of suicide, but that information is not required to be reported to HPMP or the Board.

As of December 31, 2021, the program consists of 349 participants in which Pharmacy licensees made up 4% of the program participants (7 pharmacists and 1 pharmacy technician). The most common drug of choice currently is

#### **OLD BUSINESS:**

PHARMACY TECHNICIAN TRAINEES WHO ARE MINORS: alcohol, followed by opioids. Mrs. Buisset and Mrs. Ressler explained the intake process of a participant joining the program through various methods. Details of the contract requirements were explained such as routine check-ins and toxicology monitoring.

The chairman reminded members that during the September board meeting, the Board tabled the adoption of a draft guidance document regarding minors working as pharmacy technician trainees that would have recommended trainees under the age of 18 handle only Schedule VI drugs in the course of their training. The document referenced concerns raised by the Department of Labor and Industry (DOLI) related to the application of Virginia Code 40.1-100(A)(4) and 16VAC15-30-200(4). The Board requested that staff invite a representative of DOLI to further discuss the issue.

Jay Withrow, Director of the Division of Legal Support, ORA, OPPPI, and OWP at the Virginia Department of Labor and Industry appeared in-person. He stated certain occupations are considered hazardous as they deal with "dangerous and poisonous chemicals" which may cause the child's life to be endangered. He stated that pharmacists serve in a custodial capacity when working with minors and can be criminally charged or fined civil penalties if the child is harmed. DOLI recently initiated rulemaking and entered into a MOA with DOE and DHP. The agreement requires pharmacy technician trainees under 18 to only handle Schedule VI drugs. There was reference to whether a youth apprenticeship could be used. There was discussion regarding the use of the term "handling" when the law references "preparing". Mr. Withrow stated that it is primarily concerned with the handling of "loose" He indicated DOLI has previously addressed minors working as lifeguards and in kitchens. He stated this is the first healthcare professional training program to be addressed, but that it intends to address others such as licensed practical nurses and emergency medical technicians involving the training of minors.

#### **MOTION**

LEGISLATIVE/ REGULATORY/GUIDANCE

CHART OF CURRENT REGULATORY ACTIONS

ADOPTION OF FINAL REGULATIONS – PLACEMENT OF CHEMICALS IN SCHEDULE The Board voted unanimously to not adopt the draft Guidance Document on page 40 of the agenda packet regarding minors working as Pharmacy Technician Trainees. (motion by Garvin, seconded by Nash)

Erin Barret, J.D. briefly reviewed the regulatory action chart in the agenda packet and provided updated information.

The Board considered the adoption of the final regulations regarding the placement of chemicals in Schedule I.

#### **MOTION**

The Board voted unanimously to adopt the exempt final changes to 18VAC110-20-322 as presented regarding the placement of the following chemicals in schedule I:

The following compound is classified as a synthetic opioid. Compounds of this type have been placed in Schedule I (§ 54.1-3446(1)) in previous legislative sessions.

1. 2-methyl-N-phenyl-N-[1-(2-phenylethyl)piperidin-4-yl]butanamide (other name: 2-methyl butyryl fentanyl), 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.

Based on their chemical structures, the following compounds are expected to have hallucinogenic properties. Compounds of this type have been placed in Schedule I (§ 54.1-3446(3)) in previous legislative sessions.

- 2. 1-(7-methoxy-1,3-benzodioxol-5-yl)propan-2-amine (other names: 5-methoxy-3,4-methylenedioxyamphetamine, 3-methoxy MDA, MMDA), its salts, isomers (optical, position, and geometric), and salts of isomers, whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation.
- 3. 1-[1-(3-chlorophenyl)cyclohexyl]-piperidine (other names: 3-Chloro Phencyclidine, 3Cl-PCP, 3-chloro PCP), 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.

Based on its chemical structure, the following compound is expected to have depressant properties. Compounds of this type have been placed in Schedule I (§ 54.1-3446(4)) in previous legislative sessions.

4. 7-bromo-5-phenyl-1,3-dihydro-1,4-benzodiazepin-2-one (other names: Desalkylgidazepam, Bromonordiazepam), its salts, isomers (optical, position, and geometric), and salts of isomers, whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation.

The following compound is classified as a cannabimimetic agent. Compounds of this type have been placed in Schedule I (§ 54.1-3446(6)) in previous legislative sessions.

5. Methyl N-[(5-bromo-1H-indazol-3-yl)carbonyl]-3-methyl-valinate

(other name: MDMB-5Br-INACA), 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. (motion by Richards-Spruill, seconded by Yuan)

ADOPTION OF GUIDANCE DOCUMENT 110-45: APPROVED CHEMICALS FOR USE AS HYDROCARBON OR OTHER FLAMMABLE SOLVENTS BY PHARMACEUTICAL PROCESSORS The Board considered the adoption of Guidance Document 110-45 as approved chemicals for use as hydrocarbon or other flammable solvents in the cultivation, extraction, production, or manufacturing of cannabis products. There was discussion regarding the public comment received to consider adding butane and propane to the approved list.

#### **ACTION ITEM:**

It was determined that staff will further research which states authorize the use of these chemicals and the established testing thresholds for safety.

#### **MOTION:**

The Board voted unanimously to adopt Guidance Document 110-45 as presented in the agenda packet. (motion by Ratliff, seconded by Garvin)

WITHDRAW CHANGES TO GUIDANCE DOCUMENT 110-33: PHARMACY INTERNS AS PHARMACY TECHNICIANS, PHARMACY TECHNICIAN RATIO, AND PHARMACY TECHNICIAN TRAINEES AND AMEND VACCINE PROTOCOL

Ms. Juran reminded the Board that at the September board meeting, the Board adopted amendments to Guidance Document 110-33 that would have prohibited a pharmacy technician trainee from administering vaccines. During the public comment period following adoption, the Board received comment that the proposed amendment appeared contrary to statutory changes effective July 1, 2022. Board counsel advised that the Board should withdraw the proposed amendments but could amend the Vaccine Protocol to include additional training requirements for personnel prior to administering vaccines.

#### MOTION:

The Board voted unanimously to withdraw the proposed amendments to Guidance Document 110-33 and revert back to the current language. (motion by Ratliff, seconded by Lee)

MOTION:

The Board voted unanimously to amend the vaccine protocol for adults as presented and listed below:

- Under "Pharmacist Education and Training", insert "The pharmacist shall also have a current certificate in basic cardiopulmonary resuscitation." at the end of the paragraph;
- Insert new section "Pharmacy Technician and Pharmacy Intern Training" with the following verbiage "Prior to administering a vaccine, a pharmacy technician, pharmacy technician trainee, or pharmacy intern shall have completed a practical training program of at least 20 hours that is approved by the

Accreditation Council for Pharmacy Education ("ACPE"). This training program must include hands-on injection technique, clinical evaluation of indications and contraindications of vaccines, and the recognition and treatment of emergency reactions to vaccines. The pharmacy technician, pharmacy technician trainee, or pharmacy intern shall also have a current certificate in basic cardiopulmonary resuscitation." (motion by Ratliff, seconded by Richards-Spruill)

It was acknowledged by the chairman that pharmacy technician trainees may administer adult vaccines pursuant to this statewide protocol but may not administer vaccines to patients under the age of 18 until the emergency regulations and the vaccine statewide protocol for minors becomes effective. Counsel has previously advised that the PREP Act does not authorize pharmacy technician trainees to administer vaccines.

# PERIODIC REVIEW OF GUIDANCE DOCUMENTS

ADOPT REVISIONS TO GUIDANCE DOCUMENT 110-10: MOBILE UNITS FOR DISPENSING FOR THE INDIGENT OR UNDERSERVED POPULATION: The Board considered the adoption of Guidance Document 110-10 as presented.

#### **MOTION:**

**MOTION** 

The Board voted unanimously to amend Guidance Document 110-10 as presented. (motion by Garvin, seconded by Ratliff)

The Board considered the adoption of Guidance Document 110-11 as

ADOPT REVISIONS TO GUIDANCE DOCUMENT 110-11: PROOF OF IDENTITY WHEN DISPENSING SCHEDULE II DRUGS

The Board voted unanimously to amend Guidance Document 110-11 as presented (motion by Richards-Spruill, seconded by Yuan)

# ADOPT REVISIONS TO GUIDANCE DOCUMENT

The Board considered the adoption of Guidance Document 110-24.

presented.

110-24: COMPETENCY EXAMINATION REQUIRED FOR LICENSURE AS A PHARMACIST NAPLEX PASSING SCORE

#### **MOTION**

The Board voted unanimously to amend Guidance Document 110-24 as presented. (motion by Lee, seconded by Garvin)

ADOPT REVISIONS TO GUIDANCE DOCUMENT 110-28: GUIDANCE FOR FREE CLINIC PHARMACY APPLICANTS The Board considered the adoption of Guidance Document 110-28.

## **MOTION**

The Board voted unanimously to amend Guidance Document 110-28 as presented. (motion by Ratliff, seconded by Garvin)

REPEAL GUIDANCE DOCUMENT 110-37: CONDUCT OF AN INFORMAL CONFERENCE BY AN AGENCY SUBORDINATE

The Board considered the repeal of Guidance Document 110-37, because the agency now has Guidance Document 76-10.01 that applies to all health regulatory boards and is consistent with current legal advice to the agency.

#### **MOTION**

The Board voted unanimously to repeal Guidance Document 110-37 as presented (motion by Yuan, seconded by Garvin)

ADOPT REVISIONS TO GUIDANCE DOCUMENT 110-43: DISPENSING WITH AN AUTHORIZED GENERIC The Board considered the adoption of Guidance Document 110-43 as presented.

#### **MOTION**

The Board voted unanimously to amend Guidance Document 110-43 as presented. (motion by Ratliff, seconded by Kocot)

ADOPT REVISIONS TO GUIDANCE DOCUMENT 110-47: GUIDELINES FOR PROVISION COUNSELING AND INFORMATION BY PHARMACISTS REGARDING PROPER DISPOSAL OF UNUSED DISPENSED DRUGS

#### MOTION:

The Board voted unanimously to amend Guidance Document 110-47 as presented. (motion by Lee, seconded by Garvin)

#### REPORTS:

CHAIRMAN'S REPORT

Dr. St. Clair acknowledged former board members that recently left the board due to the end of their appointments: Jim Jenkins, Glenn Bolyard, Bernie Henderson, and Cheryl Nelson. Dr. St. Clair also congratulated James Jenkins, Jr., RN on his new appointment as the Chief Deputy Director of the Department of Health Professions.

BOARD OF HEALTH PROFESSIONS

Dr. St. Clair provided the Board of Health Professions report on behalf of Dr. Sarah Melton in her absence. The Board of Health Professions did not have any updates to provide as the Board has not met since the most recent full board meeting.

LICENSURE OF INDIVIDUALS AND IN-STATE FACILITIES Ryan Logan provided a verbal summary of the Licensure of Individuals and In-State Facilities report included in the agenda packet. As of November 17, 2022, the Virginia Board of Pharmacy has a total of 44,775 individual and instate facilities licensed.

LICENSURE OF NON-RESIDENT FACILITIES Beth O'Halloran provided a verbal summary of the Licensure of Non-Resident Facilities report included in the agenda packet. As of November 15, 2022, the Virginia Board of Pharmacy has a total of 2,484 non-resident facilities licensed.

INSPECTION PROGRAM

Melody Morton, Inspections Manager with the Enforcement Division presented the Inspections Report including data from July 1, 2022 through September 30, 2022. The report detailed the various types of inspections conducted as well as the deficiencies noted.

PHARMACEUTICAL PROCESSORS

Annette Kelley presented a handout containing the Pharmaceutical Processors Report. Three additional cannabis dispensing facilities have been permitted during the last quarter totaling 10 cannabis dispensing facilities. Due to the change in the requirements for patients/parents/legal guardians to register with the Board, the amount of applications received has decreased significantly. The Department of Health Professions and the Virginia Board of Pharmacy has completed contract negotiations for a new patient portal with BioTrack. The portal is anticipated to be operational in the first quarter of 2023.

#### DISCIPLINARY PROGRAM

Ellen B. Shinaberry presented a handout of the Disciplinary Program Report. The Virginia Board of Pharmacy currently has 414 disciplinary cases consisting of 186 patient care cases and 228 non-patient care cases.

# EXECUTIVE DIRECTOR'S REPORT

Ms. Juran provided a verbal summary of the Executive Director's Report included in the agenda packet. The agency has implemented various IT upgrades such as the migration to Microsoft 365, Cardinal payroll system, Windows 11, and transitioned to digital case files via Box. Various meetings recently attended by Ms. Juran were mentioned. Ms. Garvin provided additional comments on the Tri-Regulator Symposium that she and Ms. Juran recently attended.

# CONSIDERATION OF CONSENT ORDERS, SUMARY SUSPENSIONS, OR SUMMARY RESTRICTIONS

### COAST QUALITY PHARMACY LLC PERMIT #0214000324

Sean Murphy, AAG presented a consent order for Board consideration regarding Coast Quality Pharmacy LLC (Permit #0214000324/ Case #194504).

#### DECISION:

Upon a motion by Ratliff and duly seconded by Yuan, the Board unanimously voted to accept the consent order for Coast Quality Pharmacy LLC as presented (Permit #0214000324/ Case #194504).

# WARREN PAGE MCCANN LICENSE #0202204817

Ann Joseph, APD Specialist, presented a consent order for Board consideration regarding Warren Page McCann (License #0202204817/Case #218439).

#### DECISION:

Upon a motion by Garvin, and duly seconded Richards-Spruill, the Board unanimously voted to accept the consent order for Warren Page McCann as presented (License #0202204817/Case #218439).

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The meeting adjourned at 1:22PM.

Caroline D. Juran Executive Director

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DATE: