

(FINAL/APPROVED)

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

Thursday, March 30, 2023

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

CALL TO ORDER: A full board meeting was called to order at 9:10AM.

PRESIDING: Dale St. Clair, PharmD, Chairman

MEMBERS PRESENT: William Lee, DPh
Kristopher Ratliff, DPh
Patricia Richards-Spruill, RPh
Cheri Garvin, RPh
Larry Kocot, JD
Ling Yuan, PharmD
Sarah Melton, PharmD
Wendy Nash, PharmD

STAFF PRESENT: Caroline D. Juran, RPh, Executive Director
James Rutkowski, Senior Assistant Attorney General
Erin Barrett, JD, DHP Director of Legislative and Regulatory Affairs
Arne Owens, DHP Director (arrived approx. 10AM)
James Jenkins, Jr., DHP Chief Deputy Director
Ellen Shinaberry, PharmD, Deputy Executive Director
Ryan Logan, RPh, Deputy Executive Director
Annette Kelley, MS, CSAC, Deputy Executive Director
Beth O'Halloran, RPh, Deputy Executive Director (departed approx. 11AM)
Sorayah Haden, Executive Assistant

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

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

APPROVAL OF AGENDA: **An amended agenda was provided as a handout. The amended agenda was adopted as presented.**

APPROVAL OF PREVIOUS
BOARD MEETING MINUTES

Draft minutes for meetings held between November 21, 2022 and February 16, 2023 were presented.

MOTION:

The Board voted unanimously to adopt the minutes for the meetings held between November 21, 2022 and February 16, 2023 as presented. (motion by Garvin, seconded by Ratliff)

PUBLIC COMMENT:

Christine Barrille, VPhA, provided public comment informing the board of two bills VPhA sponsored regarding Medicaid provider status for pharmacists and test and treat initiation by pharmacists which were recently passed during the 2023 General Assembly. She stated the position of the Department of Labor and Industry on pharmacy technician training programs in high schools is a significant barrier, and she thanked staff for attending the recent VPhA Annual Meeting.

DHP DIRECTOR'S REPORT:

James Jenkins, Jr., RN, DHP Chief Deputy Director presented the Director's Report on behalf of Arne Owens. Jenkins informed the Board that all four of DHP's submitted bills were passed during the 2023 General Assembly. DHP is working with the Healthcare Workforce to continue to provide survey reports for the Commonwealth. He acknowledged several at DHP are currently working on the Governor's Right Help, Right Now initiative.

NEW BUSINESS:

ADOPTION OF 2022
PHARMACISTS AND
PHARMACY TECHNICIAN
WORKFORCE SURVEY
REPORTS:

Dr. Barbara Hodgdon provided a PowerPoint presentation of highlights of the draft 2022 Pharmacists and Pharmacy Technician Healthcare Workforce Survey Reports.

MOTION

The Board voted unanimously to adopt the 2022 Pharmacist and Pharmacy Technicians Workgroup Survey Reports as presented. (motion by Melton, seconded by Kocot)

ACTION ITEM:

The Board requested staff to tabulate the number of current active pharmacy permits and closed permits annually for the last several years to potentially identify any trends or access shortages for patients across the Commonwealth.

LEGISLATIVE/
REGULATORY/GUIDANCE:

REPORT OF THE 2023
GENERAL ASSEMBLY

Erin Barrett referenced the legislative report included in the agenda packet regarding relevant bills considered or passed by the 2023 General Assembly.

CHART OF REGULATORY
ACTIONS

Erin Barrett briefly reviewed the chart in the agenda packet and provided updated information.

ADOPTION OF EXEMPT
FINAL REGULATIONS TO
PLACE CERTAIN
CHEMICALS IN SCHEDULE
I

Pursuant to 54.1-3443(D), the Board considered the adoption of exempt regulations regarding the addition of chemicals into Schedule I.

MOTION:

The Board voted unanimously to adopt the exempt changes to 18VAC10-20-322 to place certain chemicals in Schedule I as presented 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 compounds.

a. N-(4-fluorophenyl)-N-(1-phenethylpiperidin-4-yl)pentanamide (other names: para-fluoro valeryl fentanyl, para-fluoro pentanoyl 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.

b. N-(4-fluorophenyl)-N-[1-(2-phenylethyl)piperidin-4-yl]acetamide (other name: para-fluoroacetyl 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.

2. Compounds expected to have hallucinogenic properties.

a. 1-[1-(3-fluorophenyl)cyclohexyl]piperidine (other names: 3-fluoro Phencyclidine, 3F-PCP), 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.

b. 2-(ethylamino)-2-(2-fluorophenyl)-cyclohexanone (other names: 2-fluoro-2-oxo PCE, 2-fluoro NENDCK), 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.

3. Central nervous system stimulant.

2-(3-chlorophenyl)-3-methylmorpholine (other name: 3-chlorophenmetrazine), its salts, isomers (optical, position, and geometric), and salts of isomers.

The placement of drugs listed in this subsection shall remain in effect until [September 30], 2024, unless enacted into law in the Drug Control Act. (motion by Yuan, seconded by Garvin)

ADOPTION OF EXEMPT
FINAL REGULATIONS TO
CONFORM DRUG
SCHEDULES TO FEDERAL
SCHEDULING ACTION

Pursuant to 54.1-3443 (E), the Board considered the adoption of the exempt final regulations to conform drug schedules to recent federal scheduling actions. It was stated the Board must make a motion to adopt or deny the exempt changes to 18VAC110-20-323 pursuant to federal scheduling changes.

MOTION:

The Board voted unanimously to adopt the exempt changes to 18VAC110-20-323 to conform drug schedules to recent federal scheduling actions as presented below:

- 31. Adds N-methyl-1-(thiophen-2-yl)propan-2-amine (other name: methiopropamine) to Schedule I;**
 - 32. Adds N -phenyl- N'-(3-(1-phenylpropan-2-yl)-1,2,3-oxadiazol-3-ium-5- yl)carbamimidate (other name: mesocarb) to Schedule I;**
 - 33. Adds 1-methoxy-3-[4-(2-methoxy-2-phenylethyl)piperazin-1-yl]-1-phenylpropan-2-ol (other name: zipeprol) to Schedule I;**
 - 34. Adds 7-[(10,11-dihydro-5H-dibenzo[a,d]cyclohepten-5-yl)amino]heptanoic acid (other name: amineptine) to Schedule I; and,**
 - 35. Deletes Fenfluramine from Schedule IV.**
- (motion by Richards-Spruill, seconded by Lee)**

ADOPTION OF FINAL
REGULATIONS FROM 2021
PHARMACISTS INITIATING
TREATMENT LEGISLATION

The Board considered the adoption of final regulations pertaining to the implementation of 2021 legislation for pharmacists initiating treatment. Two comments in support were received during the recently open public comment period.

MOTION

The Board voted unanimously to adopt the final regulatory changes to 18VAC110-21-46 pertaining the implementation of 2021 legislation for pharmacists initiating treatment as presented. (motion by Melton, seconded by Yuan)

ADOPTION OF PROPOSED
REGULATIONS
FOLLOWING PERIODIC
REVIEW OF CHAPTER 30

The Board considered the adoption of proposed regulations to Chapter 30 following periodic view.

MOTION

The Board voted unanimously to adopt the proposed regulatory changes to 18VAC110-30-21, 18VAC110-30-55, and 18VAC110-30-80 as presented. (motion by Garvin, seconded by Richards-Spruill)

ADOPTION OF PROPOSED
REGULATIONS FOR
EXEMPTION OF ADDs
STOCKED SOLELY WITH
STAT-USE OR EMERGENCY

The Board considered the adoption of proposed regulatory changes to exempt ADDs exclusively stocked with emergency or stat-use medications from certain requirements. This action resulted from a petition for rulemaking received in 2022.

DRUGS

MOTION

The Board voted 8-0 to adopt the proposed regulatory action as presented to amend 18VAC110-20-555 to exempt the requirement for pharmacist review of the prescription order and electronic authorization of a drug stored in an automated dispensing device (ADD) when the ADD is stocked exclusively with emergency or stat-use medications. (motion by Garvin, seconded by Kocot; St.Clair abstained,)

ADOPTION OF FAST-TRACK
ACTION TO REPEAL
18VAC110-21-140 AND
18VAC110-21-150

The Board considered the adoption of fast-track regulatory changes to remove provisions no longer effective based on delayed enactment of the educational requirements when the statutory language regarding pharmacy technician trainees was first passed.

MOTION

The Board voted unanimously to adopt the fast-track regulatory change to repeal 18VAC110-21-140 and 18VAC110-21-150 as presented. (motion by Ratliff, seconded by Melton)

AMEND GUIDANCE
DOCUMENT 110-9

The Board considered the amendment of Guidance Document 110-9 to include the relatively new licensing category of pharmacy technician trainees in deficiency #4.

MOTION

The Board voted unanimously to amend Guidance Document 110-9 as presented by inserting “pharmacy technician trainees” into Deficiency #4. (motion by Garvin, seconded by Ratliff)

ACTION ITEM:

The Board requested that staff compare the recommended monetary penalties in Guidance Document 110-9 to other states and that this subject be included on the next Regulatory Committee meeting agenda.

ADOPTION OF GUIDANCE
DOCUMENT 110-37 FOR
ANTICIPATED SHORTENED
HOURS OF PHARMACY
OPERATION

To address recent concerns with patients not being able to obtain dispensed prescriptions from a pharmacy that temporarily closes unexpectedly, the Board considered the adoption of Guidance Document 110-37 regarding access to prescriptions during unanticipated shortened hours.

MOTION

The Board voted unanimously to adopt Guidance Document 110-37 as presented and amended by changing “54.1-3316(2), (3)” to “54.1-3316(2), (13)”. (motion by Ratliff, seconded by Garvin)

ADOPTION OF GUIDANCE
FOR PHARMACY
ADMINISTRATION
RECORDS

To address recent concerns when a drug is administered by someone other than the pharmacist listed on the dispensing record, the Board considered the adoption of Guidance Document 110-50 regarding pharmacy administration records.

MOTION

The Board voted unanimously to adopt Guidance Document 110-50 as

presented. (motion by Garvin, seconded by Lee)

GUIDANCE DOCUMENT
110-44, PROTOCOL FOR THE
PRESCRIBING AND
DISPENSING OF
NALOXONE

At the request of VDH to include reference to a new formulation with a higher concentration of naloxone, the Board considered the revision of Guidance Document 110-44 pertaining to the protocol for the prescribing and dispensing of Naloxone. Staff provided a handout of 110-44 that contained an additional revision for Board consideration.

MOTION

The Board voted unanimously to amend Guidance Document 110-44 as presented by inserting “or 5mg” into both charts under “Auto-Injector” and on page 5, inserting the phrase “* Only those DBHDS-approved trainers who have successfully completed DBHDS-approved training on proper drug administration with, and disposal of hypodermic needles and syringes, and who are otherwise authorized to dispense injectable naloxone through a standing order issued in compliance with this protocol, and whose organizations has first obtained a controlled substances registration from the Board of Pharmacy may dispense injectable naloxone with hypodermic needles and syringes.” which was inadvertently removed during a previous revision. (motion by Kocot, seconded by Garvin)

AMEND STATEWIDE
PROTOCOLS FOR
VACCINES FOR ADULTS
AND MINORS

Ms. Juran informed the Board that staff had received feedback following the December board meeting that the adopted language requiring 20 hours of training for pharmacy technicians and pharmacy interns was inconsistent with requirements in the PREP Act. The Board considered an amendment of the statewide protocols for vaccines for adults and minors three years and older to align the educational requirements with the PREP Act.

MOTION

The Board voted unanimously to adopt the amended statewide protocols for vaccines for adults and minors as presented. (motion by Melton, seconded by Richards-Spruill)

ADOPTION OF EMERGENCY
REGULATIONS AND NOIRA
PURSUANT TO 2023
PHARMACISTS INITIATING
TREATMENT LEGISLATION

Staff provided a handout regarding the adoption of emergency regulations and NOIRA pursuant to 2023 pharmacists initiating treatment legislation.

MOTION

The Board voted unanimously to adopt the emergency regulations and NOIRA pursuant to 2023 legislation regarding pharmacist initiation of treatment as presented. (motion by Ratliff, seconded by Melton)

REPORTS:

CHAIRMAN’S REPORT

Dale St.Clair presented the Chairman’s report. He stated he would attend the

upcoming NABP 119th Annual Meeting in Nashville, TN, along with Ms. Juran, Ms. Garvin, and Dr. Melton. He will also serve as the District 2 representative on the NABP Resolutions Committee. It was noted that Dr. Melton will have two pharmacy students with her in attendance who were chosen for the poster session and will highlight the Board's adoption of Guidance Document 110-32 regarding Possible Drug Interactions with Cannabis.

BOARD OF HEALTH
PROFESSIONS

Dr. Sarah Melton indicated that the Board of Health Professions has not met since the previous Board meeting. The next meeting is scheduled to be held in May 2023.

LICENSURE OF
INDIVIDUALS AND IN-
STATE FACILITIES

Ryan Logan, Deputy Executive Director, presented the Licensing Report of Individuals and In-State Facilities which included data from August 2021 to March 2023. As of March 6, 2023, the Virginia Board of Pharmacy has a total of 41,968 current active in-state and individual licensees.

LICENSURE OF
NONRESIDENT FACILITIES

Ryan Logan, Deputy Executive Director, presented the Licensing Report of Nonresident Facilities on behalf of Beth O'Halloran, Deputy Executive Director which included data from August 2021 through February 2023. As of February 21, 2023, the Virginia Board of Pharmacy has 2,524 current active nonresident facility registrants.

INSPECTION PROGRAM

Timothy Reilly, DHP Pharmacist Inspector presented the Inspections Report on behalf of Melody Morton which included data from October 2022 through December 2022. The report included statistics regarding the number of inspections completed, identified deficiencies, and the rate of deficiency occurrences.

PHARMACEUTICAL
PROCESSORS

Annette Kelley, Deputy Executive Director, presented the Pharmaceutical Processors Report. She noted a recent change to the report included in the agenda packet in that there are now 14 cannabis dispensing facilities in Virginia as four additional facilities have been permitted during the last quarter. The Board has seen a 98% decrease in patient applications due to the change in the registration requirements as of July 1, 2022. There is an anticipated transition date of the medical cannabis program to the Virginia Cannabis Control Authority of January 1, 2024. As of the March 7, 2023, the medical cannabis program consists of the following registrations: 881 registered practitioners, 28,958 registered patients, 130 registered parents/guardians, 154 registered agents, and 2,627 registered cannabis oil products.

DISCIPLINARY PROGRAM

Dr. Ellen B. Shinaberry, Deputy Executive Director presented the Disciplinary Program Report. She highlighted a recent change to the report

included in the agenda packet in that there are now 364 open cases.

EXECUTIVE DIRECTOR'S
REPORT

Ms. Juran presented the Executive Director's report. Mrs. Juran reviewed upcoming meetings and meetings recently attended by her and/or board members. She stated that the reference to an upcoming meeting for VPhA on her report in the agenda packet should have read VSHP. Also, she reported that her role as Chairman of the National Association of Boards of Pharmacy will end in May 2023.

CONSIDERATION OF
CONSENT ORDERS,
SUMMARY SUSPENSIONS, OR
SUMMARY RESTRICTIONS

Dr. Shinaberry presented a request from OptumRX (0214-000508) to amend a recent Order.

CLOSED MEETING

Upon a motion by Garvin and duly seconded by Nash, 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 OptumRX (0214-000508). Additionally, she moved that Caroline D. Juran, James Rutkowski, Dr. Ellen B. Shinaberry, and Sorayah Haden attend the closed meeting because their presence is deemed necessary and will aid the Board in its deliberations.

RECONVENE


Upon a motion by Garvin, and duly seconded by Yuan, 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

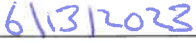
Upon a motion by Ratliff, and duly seconded by Nash, the Board voted 8-0 to deny the request for OptumRX (0214-000508). (Kocot abstained)

MEETING ADJOURNED:

1:25pm



Caroline D. Juran
Executive Director



Date