

(FINAL/APPROVED)

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

December 7, 2021

CALL TO ORDER: A full board meeting was called to order at 9:19 AM.

PRESIDING: Cheryl H. Nelson, Chairman

MEMBERS PRESENT: R. Dale St. Clair Jr, Vice Chairman
Bernard Henderson, Jr.
William Lee
Sarah Melton
Patricia Richards-Spruill (arrived at 9:21 AM)
Glenn Bolyard
Cheryl Garvin
Kristopher Ratliff

MEMBER ABSENT: Jim Jenkins

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
David Brown, D.C., DHP Agency Director
Barbara Allison-Bryan, M.D., Chief Deputy, DHP
James Rutkowski, Assistant Attorney General
Sorayah Haden, Executive Assistant

PHARMACISTS AWARDED
1-HOUR OF LIVE OR REAL-
TIME INTERACTIVE
CONTINUING EDUCATION
FOR ATTENDING MEETING: None

QUORUM With nine members participating, a quorum was established.

APPROVAL OF AGENDA:

The following handouts were provided to the board and the public: written comments regarding amendments to 18VAC110-20-25 Unprofessional Conduct from NCPA, Cindy Warriner, Jim Jenkins, Jr, and multiple VPhA members, along with the original red-lined suggested language for 18VAC110-20-25 from the November Regulation Committee meeting. Elaine Yeatts also provided a handout regarding the Exempt Regulations for Schedule I drugs. No additional items were added to the agenda and it 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 the meetings held between September 17, 2021 and November 15, 2021 as presented and amended as follows:

- **On page 1 and 2 of October 12, 2021 Formal Hearing minutes, amend the name of the permit holder correctly to read “Pharmacy Services America, LLC” instead of “Pharmacy Services of America, LLC.”**
- **On page 1 of the November 11, 2021 Regulation Committee Meeting, insert a link to view the agenda (motion by Ratliff, seconded by Bolyard)**

PUBLIC COMMENTS:

Pharmacist Dave McClellan commented that “something needs to be done”. He has been told by corporate supervisors that he wasn’t fast enough despite his many years of experience and that he doesn’t have the right to schedule staff. He expressed concern that the staffing model is based on past activity and not anticipated activity. He stated many pharmacy staff fear retaliation. He requested the Board to revisit the unprofessional conduct language and allow all pharmacists to express concern so the Board can get a full breadth of the issue.

Pharmacist Michelle Harmen commented that there is no time for a bathroom break or meal break. Staff often work over 12 hours and dispense more than 500 prescriptions which equates to one prescription every 1 to 1.5 minutes. She stated this does not leave adequate time to check for drug interactions, counseling patients, administering vaccines. Clinical decisions must be performed in approximately 30 seconds. She commented that she suffered a hemorrhage from working conditions and spent 9 days in an intensive care unit. Two days later, another pharmacist was admitted to the hospital with a massive heart attack. She implored the Board to hear pharmacists’ concerns and speak on behalf of those who cannot speak.

Pharmacist Terri Powers expressed concern regarding the unrealistic metrics and quotas in community pharmacy at the expense of patient safety. She

stated the pharmacist-in-charge is provided no authority to staff the pharmacy. She commented that inadequate staffing is the root cause of dispensing errors. She expressed concern that quotas are based on historical data and not anticipated workload. She encouraged the Board to pass the originally proposed language for unprofessional conduct and that it has already been passed in another state. She commented that a prohibition of quotas is not vague.

Pharmacist Karen Winslow representing the VPhA Academy for Workplace Well-being commented that there is a mass exodus from many working the frontlines. She stated allowing public comment regarding unprofessional practice is critical and that burnout has affected patient safety. Many pharmacies are 150-200 prescriptions behind at closing time and critical drugs are not ready at pick up. Critical to have appropriate staffing. She encouraged the Board to hear from those individuals that served on NABP's Task Force regarding workplace conditions.

Pharmacist Cindy Warriner provided a handout in addition to offering verbal comment. She commented that the Regulation Committee not recommending inclusion of all suggested language regarding unprofessional conduct was disappointing. She emphasized the need for patient safety, timely access to prescriptions, and professional pharmacy services. She referenced the law regarding specific powers authorizing the Board. She commented that the suggested language was not vague and that perception of the profession by the public is important. She stated 54.1-3316 of the Code of Virginia can be seen as vague.

Cristina Barrille, Executive Director of VPhA, commented that pharmacy staff have reached a breaking point and that this issue is not limited to certain regions of the state. She urged the Board to include the unprofessional conduct language in the periodic regulatory review process which would demonstrate to pharmacy staff that "we got your back". She commented that she believed an official vote on the unprofessional conduct language was taken at the Regulation Committee meeting.

The Chairman then provided board members time to review all handouts containing public comment.

DHP DIRECTOR'S REPORT:

David Brown, D.C., Director, DHP presented the Director's Report. He acknowledged Board member Bernie Henderson and his wife for sponsoring the VaNews publication that day. The agency has a new security staffing company, RMC Events. In Spring 2022, the conference center will receive various audio/visual upgrades including ceiling microphones. Dr. Brown reassured the Board that the agency's core duties will not change, despite the upcoming change in the Administration's political party.

Dr. Allison-Bryan commented that Virginia ranks 10th in the country for citizens receiving the COVID-19 vaccine. 45% of Virginia children are fully vaccinated. She applauded pharmacists and pharmacy technicians who have administered the bulk of the vaccinations. She commented that transmission is fluid and that Henrico County is back in the “red zone”. Two oral medications are on the horizon that interrupt replication of the virus.

Chairman Nelson thanked them both for their service to DHP and that she hopes to continue working with Dr. Brown in the future as he seeks reappointment.

CHART OF REGULATORY ACTIONS

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

REGULATORY/POLICY ACTIONS RESULTING FROM 2021 GENERAL ASSEMBLY SESSION

Ms. Yeatts referenced the legislative reports included in the agenda packets regarding expanded duties for pharmacy technicians and statewide protocols for pharmacists initiating treatment.

PETITION FOR RULEMAKING- PHARMACY TECHNICIAN ADMINISTRATION OF VACCINES

Ms. Yeatts provided an overview of the petition for rulemaking and commented that allowing pharmacy technicians to administer vaccines would require legislative action. She additionally referenced the legislative report regarding expanded duties for pharmacy technicians wherein the work group expressed support for such an authority.

MOTION:

The Board voted unanimously that it was in favor of authorizing pharmacy technicians to administer vaccines, but to take no action on the petition for rulemaking since legislative action was necessary. (motion by St. Clair, seconded by Henderson)

ADOPTION OF EXEMPT REGULATIONS FOR SCHEDULE I

Ms. Yeatts provided an overview of the item, referencing the handout regarding the suggested regulatory action as the pages in the agenda packet for this item were out of order. She recommended the Board strike the chemicals in regulation that have permanently been placed into Schedule I by the General Assembly during the recent session and add the five proposed chemicals into Schedule I temporarily as recommended by the Department of Forensic Science.

MOTION:

The Board voted unanimously to amend 18VAC110-20-322 by striking the chemicals already in Schedule I and inserting the five proposed chemicals as presented in the handout and listed below:

The following compounds are classified as synthetic opioids. Compounds of this type have been placed in Schedule I (§ 54.1-3446(1)) in previous legislative sessions.

1. **1-(4-cinnamyl-2,6-dimethylpiperazin-1-yl)propan-1-one (other name: AP-238)**, 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 its chemical structure, the following compound is expected to have hallucinogenic properties. Compounds of this type have been placed in Schedule I (§ 54.1-3446(3)) in previous legislative sessions.

2. **4-methallyloxy-3,5-dimethoxyphenethylamine (other name: Methallylescaline)**, 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. **alpha-pyrrolidino-2-phenylacetophenone (other name: alpha-D2PV)**, 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 compounds are classified as cannabimimetic agents. Compounds of this type have been placed in Schedule I (§ 54.1-3446(6)) in previous legislative sessions.

4. **ethyl 2-[1-pentyl-1H-indazole-3-carboxamido]-3,3-dimethylbutanoate (other name: EDMB-PINACA)**, 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.
5. **N-(1-amino-3,3-dimethyl-1-oxobutan-2-yl)-1-phenethyl-1H-indazole-3-carboxamide (other name: ADB-PHETINACA)**, 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 Bolyard, seconded by Richards-Spruill)

ADOPTION OF RECOMMENDATIONS ON PERIODIC REVIEW

Ms. Yeatts reminded the Board that a notice of periodic review was published in December 2020/January 2021 and that no public comments were received. She commented that the Regulation Committee has recommended certain topics to be included in the periodic regulatory review. After Board consideration of these topics today, a notice will be published soliciting public comment regarding the identified topics and any other topics for inclusion in the periodic review. The Board will consider these comments at the March 2022 meeting prior to adopting a Notice of Intent. She stated the Board is not obligated to amending regulations on these topics at this time, but is simply identifying topics for which it may consider amending or drafting regulations to address. She recommended the Board address 18VAC110-20-25 regarding unprofessional conduct separately given the public comment received. Ms. Juran suggested the Board consider including recommendations from the legislative work groups to 1) make it clear that pharmacists and pharmacy technicians may administer CLIA-waived tests which is consistent with the Board's longstanding position and confirmed with board counsel, 2) that pharmacy technicians may independently take medication histories including drug name, dose, and frequency, and 3) to allow a nationally certified pharmacy technician to electronically transfer a Schedule VI refill prescription that is not an on-hold prescription when

authorized by the pharmacist-in-charge.

MOTION:

The Board voted unanimously to continue Chapters 20, 21, and 30 with amendments and to include the topics recommended by the Regulation Committee as found on pages 80-82 of the agenda packet, along with the following topics to 1) make it clear that pharmacists and pharmacy technicians may administer CLIA-waived tests, 2) that pharmacy technicians may independently take medication histories including drug name, dose, and frequency, and 3) allow a nationally certified pharmacy technician to electronically transfer a Schedule VI refill prescription that is not an on-hold prescription when authorized by the pharmacist-in-charge. (motion by St. Clair, seconded by Henderson)

MOTION:

The Board voted unanimously to continue Chapters 40 and 50 without amendment. (motion by Ratliff, seconded by Richards-Spruill)

The Board had extensive discussion regarding 18VAC110-20-25, unprofessional conduct. Ms. Yeatts commented that 1) the Board could accept the Regulation Committee's recommendation to not include the suggested language for 18VAC110-20-25 in the periodic review because authority for disciplinary action already exists in 54.1-3316 (13) of the Code of Virginia, 2) include the suggested language to the Regulation Committee in the periodic review which will take approximately two years to complete the regulatory action, 3) take the subject up separately and create a work group to specify regulatory language, or 4) an association could have a bill introduced in the General Assembly with specific language. There was discussion regarding whether an emergency regulation could be passed. It was stated that the Office of Attorney General would need to confirm that the board acted properly and that evidence of an emergency exists. Evidence would likely need to go beyond anecdotal comment. Dr. Melton commented that it wouldn't hurt to form a work group and include it in the periodic regulatory review. Mr. Henderson recommended a work group to improve the vague language. Mr. Bolyard commented that the suggested language as written gives corporations loopholes, but that this language could be used as a checklist to evaluate activities. He recommended improving the language if the board elects for regulatory action. Dr. St.Clair provided background regarding the Regulation Committee's recommendation and indicated the following regarding the red-lined suggested language in the handout for 18VAC110-20-25: "engaging in a manner that discourages individuals from providing information regarding public safety concerns.." has already been included in the periodic review; "assuming duties and responsibilities within the practice of pharmacy without adequate training..." Appears to be addressed in 18VAC110-21-40; and, "incenting or inducing the transfer of a prescription absent professional rationale" is already at the Governor's office in a stalled regulatory action.

MOTION:

The Board voted unanimously to include the following suggested topics in the periodic regulatory review and convene a work group to further address the subject:

failure to provide a working environment for all pharmacy personnel that protects the health, safety and welfare of a patient including:

- sufficient personnel to prevent fatigue, distraction or other conditions that interfere with a pharmacist's ability to practice with competency and safety or creates an environment that jeopardizes patient care;
- appropriate opportunities for uninterrupted rest periods and meal breaks;
- adequate time for a pharmacist to complete professional duties and responsibilities including:
 - drug utilization review;
 - immunization;
 - counseling;
 - verification of the accuracy of a prescription
- introducing external factors such as productivity or production quotas or other programs to the extent that they interfere with the ability to provide appropriate professional services to the public;

(motion by Ratliff, seconded by Richards-Spruill)

**ADOPTION OF FINAL
REGULATIONS FOR
MEDICATION CAROUSELS**

Ms. Yeatts stated that the Regulation Committee is recommending significant changes to the proposed regulations for use of medication carousels and RFID technology based on significant public comment received from VSHP. She recommended that the Board publish its adopted language for an additional public comment period with final adoption at the March 2022 full board meeting. Dr. Nelson asked several questions regarding the recommended changes and expressed concern for allowing visual verification by pharmacy technicians. A typographical error was noted on page 100.

MOTION:

The Board voted 8:1 to approve a 60-day public comment period on the recommended changes to the proposed regulations for medication carousels and RFID technology as presented in the agenda packet and recommended by the Regulation Committee. (motion by Bolyard, seconded by Melton; opposed by Nelson)

**ADOPTION OF LIMITED
LICENSES FOR NON-PROFIT
CLINICS**

There were no public comments submitted during the public comment period that ended on 10/15/21 regarding the adoption of limited-use licenses for practitioners of the healing arts to sell controlled substances in non-profit clinics.

MOTION:

The Board voted unanimously to adopt final regulations for limited-use licenses for practitioners of the healing arts to sell controlled substances in non-profit clinics as presented without changes from the proposed and emergency regulations. (motion by St. Clair, seconded by Bolyard)

AMENDMENTS TO
GUIDANCE DOCUMENTS
110-42 CE AUDITS

Ms. Juran provided an overview of the subject and reviewed the amendments to Guidance Document 110-42 as recommended by the Regulation Committee.

MOTION

The Board voted unanimously to amend Guidance Document 110-42 as presented in the agenda packet. (motion by Ratliff, seconded by Richards-Spruill)

AMENDMENTS TO
GUIDANCE DOCUMENT
110-19 USE OF AUTOMATED
DISPENSING DEVICES IN
CERTAIN FACILITIES

Ms. Yeatts reviewed the amendments notated in red in the agenda packet. She indicated that these result from comment received from DBHDS during the recent public comment period.

MOTION

The Board voted unanimously to re-adopt Guidance Document 110-19 as presented in the agenda packet. (motion by St. Clair, seconded by Ratliff)

ADOPTION OF EXEMPT
REGULATIONS FOR
PHARMACEUTICALS
PROCESSORS

Ms. Yeatts reviewed the statutory authority in 54.1-3442.6(N) of the Code of Virginia for adoption of exempt regulations regarding pharmaceutical processors, the notice of public comment, and proposed regulations as adopted by the Board at its September meeting.

MOTION

The Board voted unanimously to adopt the exempt regulatory action for 18VAC110-60-10, 18VAC110-60-160, 18VAC110-60-190, 18VAC110-60-230, and 18VAC110-60-300 as presented in the agenda packet. (motion by Bolyard, seconded by Ratliff)

ADOPTION OF PROPOSED
REGULATIONS FOR
PHARMACEUTICALS
PROCESSOR

Ms. Yeatts reviewed the proposed regulatory action to be published for a 60-day comment period and then adopted by the Board as an exempt action in March 2022. The actions address access to the patient registration database to determine eligibility for accessing the facility and streamlining labeling requirements.

MOTION

The Board voted unanimously to publish for a 60-day public comment period the proposed amendments to 18VAC110-60-210 and 18VAC110-60-310 as presented in the agenda packet and then adopt as an exempt action at the March 2022 full board meeting. (motion by Bolyard, seconded by Richards-Spruill)

WITHDRAWAL OF NOIRA
FOR CHAPTER 60:
REGULATIONS
GOVERNING
PHARMACEUTICALS
PROCESSORS

Ms. Yeatts commented that the issues set out in the NOIRA published on 3/1/21 in response to a petition for rulemaking have been addressed in other regulatory proposals adopted by exempt action and she recommends withdrawing the response to petition for rulemaking action.

MOTION

The Board voted unanimously to withdraw the NOIRA for Chapter 60 published on 3/1/21. (motion by Henderson, seconded by St. Clair)

REPORTS

**PRESCRIPTION
MONITORING PROGRAM**

Ralph Orr presented a PowerPoint presentation regarding the dynamics of the Prescription Monitoring Program. Current statistics for the year were included in the presentation.

CHAIRMAN'S REPORT

Chairman Nelson offered brief comments and expressed her appreciation for everyone's participation.

**BOARD OF HEALTH
PROFESSIONS**

Ms. Juran reported that Dr. Melton was recently appointed by the Governor to serve as the Board of Pharmacy representative to the Board of Health Professions and attended her first meeting on 12/2/2021. It was noted that this was the first meeting of the Board in several months and that 14 new board members had recently been appointed. Leslie Knachel is now serving as the Board's Executive Director.

LICENSURE PROGRAM

Ryan Logan presented the Licensing Report which included data from May 1, 2020 through November 10, 2021. As of November 10, 2021 The Virginia Board of Pharmacy holds a current licensure count of 43,767 licensees. 43,767 licensees consists of 32 license types.

INSPECTION PROGRAM

Melody Morton presented the Inspections Report including data from July 1, 2021 through September 30, 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.

**PHARMACEUTICAL
PROCESSORS**

Annette Kelley presented the Pharmaceutical Processors Report informing the Board of two additional cannabis dispensing facilities, one in Health Service Area II (Sterling) and one in Health Services Area IV (Glen Allen). 26 applications have been received as a result of the RFA for a pharmaceutical processor permit in Health Service Area I that was posted from September 25, 2020 through December 4, 2020. The application review process has been placed on hold due to a court order. The Board is receiving an average of 1,000 – 1,200 patient applications per week. The program intends to hire a full time administrative specialist, licensing supervisor, and additional temporary and part-time staff to process the high volume of applications.

DISCIPLINARY PROGRAM

Dr. Ellen Shinaberry presented the Disciplinary Program Report reporting as of November 12, 2021 the Board currently has 335 open cases consisting of 186 patient care cases and 149 non-patient care cases. The number of cases

remains fairly consistent in an upward trend overall. There are currently two cases being appealed to Circuit Court.

EXECUTIVE DIRECTOR'S
REPORT

Ms. Juran stated the recruitment for two licensing administrative assistants for processing facility applications and pharmacy technician registration applications is near completion. One of the three temporary licensing positions for cannabis program have been filled. The recruitment of three P-14 employees is still ongoing. Ms. Juran provided statistics for each discipline within the Board. There is ongoing efforts to acquire new licensing software for the cannabis program. Ms. Juran has attended multiple monthly staff meetings with deputies, BOP staff, DHP executive directors and DHP executive leadership staff and several NABP meetings since the last full board meeting.

RATIFICATION OF
CONSENT ORDER

Dr. Shinaberry presented a consent order for Board consideration regarding BETPharm.

MOTION:

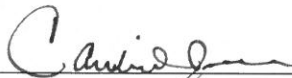
The Board unanimously voted to accept and ratify the consent order for BETPharm as presented. (motion by St. Clair, seconded by Bolyard)

MEETING ADJOURNED:

2:11 PM



Cheryl H. Nelson, Chairman



Caroline D. Juran, Executive Director

3/15/2022

DATE:

3/15/2022

DATE: