

(DRAFT/UNAPPROVED)

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

Wednesday, December 6, 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 9:12AM.

PRESIDING: Dale St Clair, PharmD, Chairman

MEMBERS PRESENT: Cheri Garvin, RPh
Larry Kocot, JD
Ling Yuan, PharmD
Wendy Nash, PharmD
Patricia Richards-Spruill, RPh
Kristopher Ratliff, DPh
Shannon Dowdy, PharmD
Michelle Hoffer, JD

MEMBERS ABSENT: Sarah Melton, PharmD

STAFF PRESENT: Caroline D. Juran, RPh, Executive Director
Ryan Logan, Deputy Executive Director
Ellen B. Shinaberry, PharmD, Deputy Executive Director
Annette Kelley, Deputy Executive Director
Sorayah Haden, Executive Assistant
Arne Owens, DHP Agency Director
James Jenkins, RN, Agency Deputy Director
Erin Barrett, JD, DHP Director of Legislative and Regulatory Affairs
James Rutkowski, Senior Assistant Attorney General
Shannon Harris, Administrative and Office Specialist III

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

David M. Flammia
Wendy Nash
Tim Robertson

QUORUM: With 9 members present, a quorum was established.

APPROVAL OF AGENDA:

The chairman indicated a subsequently amended agenda had been provided as a handout which included one additional topic at the end of the Legislative/Regulatory/Guidance section to Amend Guidance Document 110-9, *Pharmacy Inspection Deficiency Monetary Penalty Guide*. A handout related to this topic was also provided. Hearing no additional items, the Chairman stated the amended agenda was accepted as presented and the Board proceeded.

**APPROVAL OF PREVIOUS
BOARD MEETING MINUTES**

Hearing no corrections or additions, the Chairman indicated the minutes for the meetings held between September 26, 2023 and November 8, 2023 were approved as presented.

PUBLIC COMMENT:

Jamie Fisher, Executive Director, Virginia Pharmacy Association (VPhA), provided a public comment expressing VPhA's support of the pharmacy working conditions regulations and progress. VPhA is working with the Department of Medical Assistance Services regarding reimbursement fees. VPhA believes current reimbursement fees will negatively impact patient care by creating pharmacy deserts in vulnerable areas. She is hearing that some pharmacies may feel financially forced to no longer accept Medicaid. Ms. Fisher also stated increasing the pharmacist to pharmacy technician ratio will not help. Nothing precludes the pharmacy from currently scheduling an additional pharmacist who could then supervise up to an additional 4 pharmacy technicians. She announced that VPhA's annual meeting is scheduled for March 7-10 in Roanoke. A handout summarizing the public comment was provided to the Board.

DHP DIRECTOR'S REPORT:

Mr. Owens provided the Director's Report including a welcome to the new board members, Shannon Dowdy, PharmD and Michelle Hoffer, JD. Mr. Owens reported multiple business processes improvements were taking place throughout the agency with a current focus on licensing. New energy-efficient lighting has been installed throughout the building and parking lot. The proposed budget has been submitted and the official numbers will be presented to the upcoming General Assembly. The agency is still waiting to receive the final decision regarding legislative proposals submitted by DHP to the Governor for consideration. Healthcare workforce remains a top priority. Jim Jenkins is a co-lead on the Right Help, Right Now initiative. DHP is engaging with other agencies regarding reimbursement and will provide updates. Mr. Owens thanked the board and the Pharmaceutical Processor Program staff for their hard work with regulating medical cannabis for the past several years. Staff is preparing for the transition of the program to the Virginia Cannabis Control Authority as of 1/1/24.

**LEGISLATIVE/
REGULATORY/GUIDANCE**

CHART OF REGULATORY ACTIONS

Ms. Barrett briefly reviewed the chart of regulatory actions in the agenda packet and provided updated information that has taken place since the preparation of the chart as indicated on Regulatory Town Hall.

ADOPTION OF PROPOSED REGULATIONS FOR PHARMACY WORKING CONDITIONS

The Board reviewed and discussed the draft proposed regulations, Chapter 628 of the 2022 General Assembly Session, and the public comments captured in Attachment 1 of the agenda packet regarding the proposed regulations for Pharmacy Working Conditions. Ms. Barrett systematically reviewed the public comments with the Board and provided opportunity for the Board to affirm or provide direction for any requested regulatory changes. During its discussion, several members expressed concern for patient access to pharmacies and that low reimbursement rates are a contributing factor to poor working conditions.

MOTION:

The Board voted unanimously to adopt the proposed regulations for pharmacy working conditions (18VAC110-20-110 and 18VAC110-20-113) as presented and amended as follows:

- **18VAC110-20-113(C): Amend “all aspects” to “any aspects”;**
- **18VAC110-20-113(D): At the end of the first sentence, insert “...or a form containing information identical to that in the form developed by the board, which may be electronic.”;**
- **18VAC110-20-113(D)(1): At the end of the sentence, insert “...within 48 hours of request.”;**
- **18VAC110-20-113 (D)(3), prior to “result in workplace discipline”, insert “or board”. (Motion by Garvin, Seconded by Dowdy)**

ACTION ITEM:

The Board directed staff to review *Staffing Requests or Concerns* forms during routine pharmacy inspections to educate and encourage use of the form, receive feedback on the form, demonstrate that the Board takes this issue seriously, and to monitor for compliance with the emergency regulations. Staff should seek additional guidance from the board, if needed, regarding the opening of cases.

CONSIDER RECOMMENDATION OF HB 2147 (PRESCRIPTION TRANSLATION SERVICES) WORKGROUP

The Board reviewed and discussed HB 2147. Meeting minutes in the agenda packet from the previous HB 2147 Workgroup Meeting held on September 28, 2023 were used as a reference.

MOTION:

The Board voted unanimously to approve the HB 2147 Work Group’s recommendation to inform pharmacies and pharmacy personnel of certain federal laws prohibiting discrimination, advising they seek legal advice regarding applicability to their practice, and to share the task force report once approved for publication.

REPEAL OF GUIDANCE
DOCUMENTS RELATED TO
THE MEDICAL CANNABIS
PROGRAM

The Board reviewed and discussed the repeal of guidance documents related to the medical cannabis program in preparation of the transfer to the Virginia Cannabis Control Authority on January 1, 2024.

MOTION:

The Board voted unanimously to repeal Guidance Documents 110-14, 110-20, 110-40, 110-45, 110-48, and 110-51 related to the Medical Cannabis Program, effective January 1, 2024. (Motion by Ratliff, seconded by Garvin)

REPEAL OF CHAPTER 60
DUE TO THE TRANSFER OF
THE MEDICAL CANNABIS
PROGRAM

The Board reviewed and discussed the repeal of Chapter 60, *Regulations Governing Pharmaceutical Processors*, in preparation of the transfer to the Virginia Cannabis Control Authority on January 1, 2024.

MOTION

The Board voted unanimously to repeal Chapter 60, *Regulations Governing Pharmaceutical Processors*, by exempt action effective January 1, 2024 due to the transfer of the Medical Cannabis Program to the Virginia Cannabis Control Authority. (motion by Richards-Spruill, seconded by Kocot)

COMPLETION OF PERIODIC
REVIEW OF PUBLIC
PARTICIPATION
GUIDELINES CONTAINED
IN 18VAC110-11

The Board discussed and reviewed the public comments received during the public comment period regarding the Public Participation Guidelines. It was noted that agencies are required to conduct periodic reviews of regulatory chapters every four years. Although this particular chapter is only changed when the Department of Planning and Budget provides new model language, the Board was still required to conduct a periodic review. It was advised that the Board should not initiate any changes, but retain as is until DPB amends the model regulations. The issue addressed in the public comment does not require a regulatory change and does not require a change to the public participation guidelines.

MOTION

The Board voted unanimously to retain 18VAC110-11 as presented. (motion by Dowdy, seconded by Hoffer)

ADOPTION OF EXEMPT
REGULATIONS – ADDITION
OF DRUG TO SCHEDULE IV
PURSUANT TO FEDERAL
CHANGES

The Board discussed the adoption of the exempt regulations pertaining to the addition of drug to Schedule IV pursuant to federal changes. The Board reviewed excerpts of the DEA scheduling change published October 31, 2023 and draft amendments to 18VAC110-20-323.

MOTION

The Board voted unanimously to adopt the exempt regulatory change to 18VAC110-20-323 to place zuranolone into Schedule IV pursuant to recent federal scheduling action changes and subsection E of Va. Code 54.1-3443. (Motion by Ratliff, Seconded by Yuan)

**ADOPTION OF EXEMPT
REGULATIONS – ADDITION
OF CHEMICALS TO
SCHEDULE I**

The Board discussed the adoption of exempt regulations pertaining to the addition of chemicals to Schedule I. The Board reviewed the recommendation from the Department of Forensic Science to place certain chemicals in Schedule I and draft amendments to 18VAC110-20-322.

MOTION

The Board voted unanimously to adopt the exempt regulatory change to 18VAC110-20-322 to add the following chemicals to Schedule I:

- **1-(3,5-Dimethoxy-4-propoxyphenyl)-2-propanamine (other names: 4-propoxy-3,5-DMA; 3C-P; 1-(3,5-Dimethoxy-4-propoxyphenyl)propan-2-amine), 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.**
- **2-(5-methoxy-1H-indol-3-yl)ethanamine (other names: 5-methoxytryptamine, 5-MeOT), 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. (motion by Garvin, seconded by Dowdy)**

**AMEND GUIDANCE
DOCUMENT 110-9,
PHARMACY INSPECTION
DEFICIENCY MONETARY
PENALTY GUIDE**

The Board reviewed and discussed the relevant USP FAQs in the handout and the draft amendment of Guidance Document 110-9, *Pharmacy Inspection Deficiency Monetary Penalty Guide*.

MOTION

The Board voted unanimously to amend Guidance Document 110-9 as presented and as follows:

- **Amend deficiency # 25d to read “No documentation of results of the evaluation to determine cause of failure for a person who failed a media-fill test or gloved fingertip and thumb sampling”; the monetary penalty is changed to read “5000 if performing Category 3, 500 if performing Category 1 and 2”; and,**
- **Repeal deficiency 26a. (motion by Garvin, seconded by Nash)**

NEW BUSINESS:

**PRESENTATION ON USE OF
AGENCY SUBORDINATE**

Ms. Barrett reviewed the PowerPoint slides in the agenda packet entitled “Overview of the Agency Subordinate Process”. The presentation consisted of defining a subordinate and its role to the board, the current informal conference process, the agency subordinate process, and the benefits of using a subordinate. The overview was provided to familiarize the Board with the process as staff hopes to utilize an agency subordinate in 2024 to assist with the increased caseload.

OLD BUSINESS:

**CITING OF DEFICIENCIES
13-16 WITHIN GUIDANCE
DOCUMENT 110-9**

The Board discussed the citing of deficiencies 13-16 within Guidance Document 110-9. On May 23, 2023, the Regulation Committee requested staff to identify how often these deficiencies were cited during quarters ending June 2023 and September 2023. No action was taken.

**REASSESS NEED FOR
POSSIBLE RETREAT**

The Chairman reviewed suggested topics that were provided to staff by several members as requested during the September board meeting.

ACTION ITEM:

The Chairman will work with the executive director to review the list of suggested topics, identify possible topics for the March 2024 board meeting, and provide an update on any other topics. Staff will research the Notice of Intended Regulatory Action resulting from the 2021 periodic review which is under Administrative Review to ensure the Board can receive public comment and act on any overlapping topics.

**STAFF RESEARCH ON
EXISTING PHARMACY
LOCATIONS MAPS**

In response to the Board's request during the September meeting, Ms. Juran reported that the National Association of Chain Drug Stores does not have current geo-mapping of pharmacy locations that it could provide to the Board and that any information would be limited to chain pharmacies. NABP does not have current geo-mapping to provide either, but it did connect us with the National Community Pharmacists Association (NCPA) based on past research on this subject with the University of Southern California. Ms. Juran reported she was awaiting additional information from NCPA.

REPORTS:

CHAIRMAN'S REPORT

Dale St. Clair, PharmD, provided the Chairman's report including a welcome to the newest board member, Michelle Hoffer, JD. Recognition was given to William Lee, PharmD, former Board Member, for his service on the Board. He indicated that Dr. Lee could not attend the meeting to receive his appreciation plaque, but that it had been mailed to him upon his request. Dr. St. Clair attended the NABP Member Forum in Chicago during the prior week. He served as a panelist and thought the meeting was very informative. Dr. St. Clair extended his thanks and appreciation to Board staff for their consistent hard work throughout the year.

ACTION ITEM:

Dr. St. Clair indicated he would like the board to discuss pharmacy technician educational training requirements at the March 2024 board meeting.

**BOARD OF HEALTH
PROFESSIONS**

No report was provided.

REPORT ON LICENSURE

Ryan Logan, RPh, Deputy Executive Director presented the Licensing Report which included data from May 2022 through November 2023. As of November 1, 2023, the Virginia Board of Pharmacy licensure count for Q1 2024 is 47,526, up from 45,203 in Q1 2023. It was noted that in-state pharmacy permits in Q1 2024 equaled 1,751, down from Q1 2023 which equaled 1,765. Nonresident pharmacy registrations were up at 923, from 910 the previous Q1 2023. Pharmacy technician registrations were at 13,310, down slightly from previous Q1 2023 at 13,522, but that pharmacy technician trainee registrations were at 8,190, up from previous Q1 2023 at 6,977. Pharmacist licenses were at 16,606, up slightly from previous Q1 2023 at 16,414.

REPORT ON INSPECTION PROGRAM

Ms. Juran presented the Inspections Report, in absence of Ms. Morton, which included data from July 2023 through September 30, 2023. The Enforcement Division conducted 464 inspections between 7/1/23 and 9/30/23, 217 of which were of pharmacies. During the two-year period of 7/1/21 through 7/1/23, 3,901 inspections were performed. Sarah Rogers has accepted the position of Director of Enforcement. There are vacancies in one part-time pharmacist inspector position and one full-time senior inspector position.

PHARMACEUTICAL PROCESSORS

Annette Kelley, MS, CSAC, Deputy Executive Director presented the Pharmaceutical Processors Report. As of November 17, 2023, the Pharmaceutical Processors Program consist of 6,253 Registered Patients, 30 Registered Parents/Guardians, 91 Registered Agents, 3,888 Portal-Issued Written Certifications, 820 Portal-Enrolled Practitioners, and 3,695 Registered Cannabis Products. The Board and agency staff continued to meet bi-monthly with the Virginia Cannabis Control Authority to address the transition of the medical cannabis program to the VCCA on January 1, 2024.

DISCIPLINARY PROGRAM

Ellen B. Shinaberry, PharmD, Deputy Executive Director presented the Disciplinary Program Report. As of November 14, 2023, the Board has a total of 378 current cases consisting of 219 Patient Care Cases and 159 Non-Patient Care Cases.

EXECUTIVE DIRECTOR'S REPORT

Ms. Juran provided a verbal report regarding meetings she has attended or presented at since the last board meeting and upcoming meetings.

CONSIDERATION OF CONSENT ORDERS, SUMMARY SUSPENSIONS, OR SUMMARY RESTRICTIONS

LISA ANNE PUCHALSKI, PHARMACY TECHNICIAN

Sean Murphy, Assistant Attorney General and Jess Weber, DHP APD Specialist presented a presentation for a Possible Summary Suspension for Lisa Anne Puchalski.

DECISION

Upon a motion by Garvin, and duly seconded by Richards-Spruill, the Board unanimously voted to summarily suspend the Pharmacy Technician Registration of Lisa Anne Puchalski, notice Ms. Puchalski for a Formal Hearing, and offer a Consent Order in lieu of a Formal Hearing.

**MARY BURNETT,
PHARMACIST**

David Robinson, Assistant Attorney General and Chris Andreolli, DHP APD Specialist presented a presentation for a Possible Summary Suspension for Mary Burnett.

DECISION

Upon a motion by Nash, and duly seconded by Garvin, the Board unanimously voted to summarily suspend the Pharmacist license of Mary Burnett, notice Ms. Burnett for a Formal Hearing, and offer a Consent Order in lieu of a Formal Hearing.

**RENEE TODD,
PHARMACY TECHNICIAN
TRAINEE**

Jess Weber, DHP APD Specialist, presented a consent order for Board consideration regarding Renee M. Todd.

DECISION

Upon a motion by Kocot, and duly seconded by Dowdy, the Board unanimously voted to accept the Consent Order for the Pharmacy Technician Trainee Registration for Renee Todd.

MEETING ADJOURNED:

With all business concluded, the meeting adjourned at approximately 4:00PM

Caroline Juran,
Executive Director

DATE