(FINAL/APPROVED)

VIRGINIA BOARD OF PHARMACY
MINUTES OF FULL BOARD MEETING

Tuesday, September 26, 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 9:15AM.
PRESIDING:	Dale St. Clair, PharmD, Chairman
MEMBERS PRESENT:	Cheri Garvin, RPh Larry Kocot, JD Ling Yuan, PharmD Wendy Nash, PharmD Kristopher Ratliff, DPh Sarah Melton, PharmD Shannon Dowdy, PharmD
STAFF PRESENT:	Caroline D. Juran, RPh, Executive Director Ryan Logan, Deputy Executive Director Beth O'Halloran, Deputy Executive Director Ellen B. Shinaberry, PharmD, Deputy Executive Director Arne W. Owens, DHP Agency Director Erin Barrett, JD, DHP Director of Legislative and Regulatory Affairs James Rutkowski, Senior Assistant Attorney General Sorayah Haden, Executive Assistant Yvonne Miller, Records Administrative Assistant Cecelia Robinson, Licensing Administrative Assistant
PHARMACISTS AWARDED 1-HOUR OF LIVE OR REAL-TIME INTERACTIVE CONTINUING EDUCATION FOR ATTENDING MEETING:	David Flammia - #0202011380 Yeh Ling Yuan Lee - #0202218262
QUORUM:	With 8 members present, a quorum was established.
APPROVAL OF AGENDA:	An amended agenda was provided listing a new item at the beginning of the "Legislative/Regulatory/Guidance" section entitled "Consideration of Fee Increase". The amended agenda was accepted as presented.

APPROVAL OF PREVIOUS BOARD MEETING MINUTES

The Chairman reviewed with the Board DHP Policy 76.80-26 included in the agenda packet. Minutes for meetings held on June 13, 2023, June 27, 2023, August 11, 2023, and August 23, 2023 were approved as presented.

PUBLIC COMMENT:

Karen Winslow, PharmD, Interim Executive Director, Virginia Pharmacy Association (VPhA), provided public comment expressing how pleased VPhA is for the collaboration of the Board of Pharmacy, Board of Medicine, and Virginia Department of Health regarding recent development of statewide protocols. She stated VPhA has been working with DMAS on payment reimbursement issues. She encouraged the Board to have the Governor sign previously submitted working condition regulations, and appreciates the disciplinary action taken on unsafe conditions. She questioned the striking of language presented in Guidance Document 110-46 on page 113 of the agenda. She informed the Board that Jamie Fisher will be starting as the new Executive Director of VPhA. A handout summarizing her verbal comments was provided to the Board.

Natalie Nguyen, PharmD, provided public comment on behalf of the Virginia Society of Health-System Pharmacists. The public comment included: request that Board allow a 6-month transition period for enforcement of USP chapters <795> and <797> revisions similar to The Joint Commission; clarification regarding documentation for flavoring; recommendation that Board allow media-fill, gloved fingertip and garbing test requirements for multiple sites operating under same health system with same configuration of hoods; and request that the Board allow pharmacies to document shortage of testing supply, e.g., media-fill and agar plates, within the personnel file, allow 30 days for procurement of testing item in shortage, and allow compounding personnel to continue compounding in the interim. She additionally recommended the Board create a work group to monitor for necessary revisions of Guidance Document 110-36.

Cindy Warriner, RPh, provided public comment on behalf of the Community Pharmacy Enhanced Services Network. Ms. Warriner stated they are pleased that the Board provided preliminary maps of current pharmacy locations within the agenda packet. She expressed concern for patient access to needed medications and care, and encouraged the Board to address the issue and collaborate with other State agencies and professional associations to ensure awareness and developing strategy.

Chad Baker provided verbal comment on behalf of FLAVORx that mirrored written comment provided by Ursula Chizhik, PharmD with FLAVORx. Board staff provided copies of the written comment to the members and public. The comments included language in states addressing flavoring; he recommended reviewing Arizona and Iowa's language that provide basic

guard rales. Newly proposed or approved rules on flavoring, a state of flavoring regulatory map, and an overview of how FLAVORx program works were also provided.

DHP DIRECTOR'S REPORT:

Arne Owens, DHP Agency Director, stated they are communicating with the Secretary regarding legislative proposals and will hear soon which ones may be introduced in the upcoming session. DHP's budget request has been submitted and the Board of Pharmacy will need an increase in fees. He commented that the Prescription Monitoring Program has applied to the Opioid Abatement Authority for funding to help sustain the program. Regarding workforce, he is aware of current pharmacy issues. He was informed by the Healthcare Workforce Development Authority that while pharmacists were not included in the current study, they will be included in future workforce studies. He stated that Ms. Juran has inserted pharmacy into workforce discussions of the Claude Moore Foundation and Deloitte.

LEGISLATIVE/ REGULATORY/GUIDANCE

CONSIDERATION OF FEE INCREASE

The Board reviewed and discussed a handout that included a memorandum from Arne Owens, DHP Director, to the Board regarding a revenue and expenditure analysis and the need for a fee increase. The handout included the following staff notes:

- The Board last raised fees in 2017. Prior to that time, the last fee increase was in 2002. In between 2002 and 2017, the Board instituted one-time fee reductions three times.
- At the time the Board increased fees in 2017, staff for the Board and agency communicated that another fee increase would be required. At the time of the previous increase, the following differences between 2002 and 2017 in Board operations were cited:
    - 283% increase in the number of licensees
    - 100% increase in employees of the Board (6 in 2002 to 12 in 2016)
    - 7 cost of living increases for staff
    - 5% increase in salary due to mandatory retirement system contribution
    - 84% increase in inspections and investigations
    - 40% increase in Administrative Proceedings Division hours and number of cases
    - 613% increase in mandated information technology costs

• As noted, the 30% increase in fees which took effect in 2020 could not cover these changes for more than a few years.

• In 2023, five compounded state salary increases have accelerated the need for a fee increase. When the General Assembly enacts salary increases, other state agencies receive increased allocations from the general fund through the budget process to cover the increase. As a special fund agency, DHP and its boards only receive funds from fees provided by licensees, which by statute

must be sufficient to cover the operating expenses of the board.
Additional operational increases affecting available funds:

- License counts have increased significantly over the years:
  - 2002: 12,861
  - 2018: 37,608
  - Q4 2023: 45,486
- Additional regulated categories:
  - In 2019 began registering nonresident third-party logistics providers; nonresident warehousers; limited-use physician selling;
  - In 2021 began registering pharmacy technician trainees
- Cases received regarding Board regulated individuals or entities has increased:
  - 2002: 269
  - 2018: 651
  - Q4 2023: 878
- Number of full-time employees has increased:
  - 2002: 6
  - 2018: 12
  - Q4 2023: 14
  - *Note: if FTE count had increased at a rate consistent with increase in licensees and cases, the Board should have 20-21 FTEs instead of 14.*
- Cash balance projections without a fee increase:
  - FY2023 (Actual): $2,270,363
  - FY2024 (Estimate): $1,446,128
  - FY2025 (Estimate): $434,063
  - FY2026 (Estimate): -$688,083
  - FY2027 (Estimate): -$1,926,100

MOTION:

The Board voted unanimously to adopt the Notice of Intended Regulatory Action to initiate a fee increase as presented. (motion by Ratliff seconded by Garvin)

CHART OF REGULATORY ACTIONS

Ms. Barrett reviewed the Chart of Regulatory Actions as of September 12, 2023 within the agenda packet.

ADOPTION OF EXEMPT FINAL REGULATION TO PLACE CERTAIN CHEMICALS INTO SCHEDULE I

The Board reviewed and discussed the recommendations and consultation from the Department of Forensic Science to place certain chemicals into Schedule I. Ms. Barrett stated that DFS provided her with recommended language for listing tianeptine in regulation and that she would revise the proposed amendment of 18 VAC110-20-322 by inserting the chemical nomenclature, if approved by the Board.

MOTION:

The Board voted unanimously to adopt exempt changes to 18VAC110-20-322 to add chemicals to Schedule I as follows:

E. 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 opioid. N-ethyl-2-[5-nitro-2-[(4-propan-2-yloxyphenyl)methyl]benzimidazol-1- yl]ethanamine (other name: N-desethyl Isotonitazene), 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. **Cannabimimetic agent. Ethyl-3,3-dimethyl-2-[(1-(pent-4-enylindazole-3-carbonyl)amino]butanoate (other name: EDMB-4en-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.**
3. **7-[(3-chloro-6-methyl-5,5-dioxo-11H-benzo[c][2,1]benzothiazepin-11-yl)amino]heptanoic acid (other name: Tianeptine), 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.**

The placement of drugs listed in this subsection shall remain in effect until [May 1], 2025, unless enacted into law in the Drug Control Act. (motion by Kocot, seconded by Garvin)

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

The Board reviewed and discussed the Public Participation Guidelines contained in 18VAC110-11.

MOTION:

The Board voted unanimously to initiate periodic review of 18VAC110-11. (motion by Garvin, seconded by Yuan)

ADOPTION OF FAST-TRACK REGULATORY ACTION TO CHANGE "NURSE PRACTITIONER" TO "ADVANCED PRACTICE REGISTERED NURSE

The Board reviewed and discussed the changes to regulations in Chapter 30 to amend references to Nurse Practitioners to Advanced Practice Registered Nurse based on recent statutory changes.

The Board voted unanimously to adopt fast-track regulatory changes to

MOTION

Chapter 30 to amend references to "Nurse Practitioners" to "Advanced Practice Registered Nurses". (motion by Ratliff, seconded by Melton)

AMENDMENT OF GUIDANCE DOCUMENTS TO REFLECT TITLE CHANGE OF "NURSE PRACTITIONER" TO "ADVANCED PRACTICE REGISTERED NURSES"

The Board reviewed and discussed Guidance Documents 110-1, 110-7, 110-8, 110-13, and 110-29, all amended to change "Nurse Practitioner" to "Advanced Practice Registered Nurse" based on recent statutory changes.

MOTION

The Board voted unanimously to amend Guidance Documents 110-1, 110-7, 110-8, 110-13, and 110-29 to amend references to "Nurse Practitioners" to "Advances Practice Registered Nurses". (motion by Yuan, seconded by Garvin)

AMENDMENT TO GUIDANCE DOCUMENT 110-35 TO REFLECT TITLE CHANGE OF "NURSE PRACTITIONERS" TO "ADVANCED PRACTICE REGISTERED NURSES" AND ADDRESS DEA FINAL RULE FOR TRANSFERRING ELECTRONIC PRESCRIPTIONS

The Board reviewed and discussed Guidance Document 110-35 with suggested amendments to change "Nurse Practitioner" to "Advanced Practice Registered Nurse" and address the DEA's final rule regarding transferring electronic prescriptions between pharmacies for initial filling. Ms. Barrett stated that she will insert references into the document as a hyperlink.

MOTION

The Board voted unanimously to amend Guidance Document 110-35 as presented and amended by inserting DEA-related references as a hyperlink. (motion by Garvin, seconded by Dowdy)

AMENDMENT TO GUIDANCE DOCUMENT 110-36 TO INCLUDE ADDITIONAL FAQs RELATED TO REVISIONS OF USP CHAPTERS <795> AND <797>

The Board reviewed and discussed the excerpt from June 2008 board meeting minutes regarding flavoring that resulted in enforcement discretion of USP compounding standards when flavoring products, the excerpt from USP FAQs indicating that flavoring is considered compounding, and Guidance Document 110-36 with draft amendments. There was a robust discussion regarding draft FAQ #8 regarding flavoring found on page 99 of the agenda packet. It was noted that if flavoring is considered compounding, then a prescription is required. There was some discussion regarding risk of changing pH. Dr. Ratliff was supportive of flavoring not being considered compounding. Ms. Garvin suggested pharmacies use a resource to guide flavoring and have guardrails. There was some discussion regarding the phrasing of the draft FAQ.

MOTION

A motion to change the response of draft FAQ #8 "Is flavoring considered compounding?" to "No" failed by a vote of 3:5. (motion by Nash, seconded by Ratliff; opposed by Kocot, Garvin, Melton, St. Clair, and Yuan)

MOTION

The Board voted 7:1 to amend draft FAQ #8 to read "Does USP consider flavoring to be compounding?" and amend the response to read "Yes, but the Board will exercise enforcement discretion of USP compounding standards for flavoring." (motion by Garvin, seconded by Melton; opposed by Nash)

The Board discussed the draft language for FAQ #11 found on page 100 of the agenda packet regarding when the Board will begin enforcing USP revisions to chapters <795> and <797>. Ms. Garvin and Dr. Yuan recommended a delay in enforcement due to supply chain issues.

MOTION

The Board voted unanimously to:

- **amend the draft response to FAQ #11 in Guidance Document 110-36 to reflect that inspectors will begin citing deficiencies for noncompliance of USP revised standards as of November 1, 2023, but will exercise enforcement discretion for the first 6 months, e.g., through April 30, 2024, and not take disciplinary action unless egregious in nature, staff will consult with a committee of the Board for direction regarding possible disciplinary action for deficiencies that appear egregious**
- **adopt the remaining FAQs as presented and amended (recognizing that #8 was amended in the previous motion). (motion by Garvin, seconded by Kocot)**

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

FDA recently approved two formulations of nalmefene, an opioid antagonist. Therefore, the Board reviewed and discussed amendments made to *Guidance Document 110-44 Naloxone Protocol* and the *Pharmacist Naloxone Statewide Protocol* to insert nalmefene. Ms. Juran stated that the nasal spray appears to be more appropriate for lay-person administration while the injectable formulation appears more appropriate for administration in a healthcare setting.

MOTION

The Board voted unanimously to amend *Guidance Document 110-44 Naloxone Protocol* and the *Pharmacist Naloxone Statewide Protocol* as presented to insert allowances for nalmefene. (motion by Melton, seconded by Yuan)

AMENDMENT OF GUIDANCE DOCUMENT

Based on discussions at the June board meeting, the Board reviewed amendments to Guidance Document 110-46 to include allowances for drone

110-46 REGARDING USE OF DRONES

delivery of drugs.

MOTION:

The Board voted unanimously to amend Guidance Document 110-46 as presented to include allowances for drone delivery of drugs. (motion by Garvin, seconded by Kocot)

NEW BUSINESS:

ADOPT STATEWIDE PROTOCOLS FOR COVID-19, STREP, UTI, AND INFLUENZA

The Board reviewed recommended protocols for pharmacist initiation of test and treat for COVID-19, Group A Streptococcal Bacteria, Influenza, and Urinary Tract Infections as developed by a workgroup composed of representatives from the Board of Pharmacy, Board of Medicine, and Department of Health.

MOTION

The Board voted unanimously to approve the statewide protocols for pharmacists to initiate test and treat for COVID-19, Group A Streptococcal Bacteria, Influenza, and Urinary Tract Infections as presented and amended as follows:

- **Page 120 of agenda packet on the Paxlovid Patient Assessment Form for Pharmacist, change "advanced nurse practitioner" to "advance practice registered nurse";**
- **Pages 141 and 146, change "Cefdanir" to "Cefdinir". (motion by Yuan, seconded by Melton)**

AMENDMENTS TO VACCINE PROTOCOLS FOR AGES 3-17 AND ADULTS TO INCLUDE EPINEPHRINE TO TREAT ANAPHYLAXIS

Ms. Juran indicated she had received multiple requests to insert an allowance for initiating epinephrine within the statewide vaccine protocols for treatment of anaphylaxis resulting from vaccine administration. She indicated that such an allowance would be consistent with standard of care and the PREP Act, that a statewide protocol to initiate epinephrine in adults already exists, and that 54.1-3408 D allows numerous individuals to possess and administer epinephrine such as pharmacists, and employees of public places and restaurants. She stated that she had consulted with staff from the Board of Medicine and Department of Health and that they were comfortable with the draft language in the interest of patient safety.

MOTION

The Board voted unanimously to amend the *Vaccine Statewide Protocol for Persons Ages 3-17* and the *Pharmacist Vaccine Statewide Protocol for Persons Eighteen Years of Age or Older* as presented to insert an allowance to initiate epinephrine for treatment of anaphylaxis. (Motion by Ratliff, seconded by Garvin)

RESCISSION OF PHARMACEUTICAL PROCESSOR PERMIT RFA

Ms. Juran provided an overview of the Request for Application (RFA) process for awarding a pharmaceutical processor permit in Health Service Area I. The RFA was issued on September 25, 2020, but review of the

FOR HSA I

applications was halted by the court in 2021 pending PharmaCann's appeal. Although the Board of Pharmacy was successful in the Virginia Court of Appeals, staff indicated there is insufficient time to receive revised applications and award conditional approval of a permit prior to January 1, 2024, when the Cannabis Control Authority (CCA) will assume oversight of the Commonwealth's medical cannabis program. Board staff has been working closely with CCA staff over the last year. The CCA intends to open a new RFA after the January 1st transition. Ms. Garvin recused herself from discussions based on her involvement with an applicant prior to being appointed to the Board.

MOTION

The Board voted unanimously to rescind RFA No. PHR-2020-01 for awarding a pharmaceutical processor permit in Health Service Area I and direct staff to refund the application fee to the 26 applicants who submitted application prior to the RFA deadline of December 4, 2020. (motion by Ratliff, seconded by Nash; Garvin recused)

PRELIMINARY MAPS OF CURRENT PHARMACY LOCATIONS BASED ON PRACTICE TYPE

To facilitate the Board's recent discussion at the June board meeting regarding pharmacy locations, staff reviewed the list of current active pharmacy permits located in Virginia and assigned a practice type to each permit. The assigned practice type was not verified directly with permit holders. There was some discussion regarding how frequently these maps could be updated, whether staff has sufficient resources to address this issue or if public data could simply be provided to a researcher or school to further analyze, and if national data regarding pharmacy locations already exists.

ACTION ITEM

Staff to research ability to include a field on the pharmacy permit application for the applicant to designate a practice type/environment.

ACTION ITEM

Mr. Owens recommended gathering information from associations and stakeholders regarding concerns for patient access to pharmacies, taking this information forward, and letting the Board be part of the discussion.

ACTION ITEM

Staff to research access to national data regarding pharmacy locations such as through NABP, NCPA, or NACDS. Based on this information, the Board will decide in December the frequency of requesting staff to provide pharmacy location maps for its review.

REQUEST FROM MEMBER FOR RETREAT

Dr. Nash requested consideration for a half-day or full day board member retreat to brainstorm and prioritize meeting the needs of the "current situation in pharmacy". She requested the Board design a dashboard of metrics to monitor trends, determine which metrics need to be amended, and determine what things the Board should do. agenda topics pertaining to the current needs of the pharmacy industry. The Chairman indicated there is only one available date prior to the end of January 2024. Several board members expressed reservation for convening a retreat without specific agenda items.

MOTION	**A motion to convene a retreat on January 11, 2024 and for members to bring agenda topics to the December board meeting failed for a lack of a second. (motion by Nash)**
ACTION ITEM	**There was consensus that Board members will send agenda ideas to staff by November 15, 2023 (3 weeks prior to December full board meeting) and reassess at the December meeting if a retreat, possibly in the spring, should be convened.**

REPORTS:

APhA Substance Use Disorder Institute 2023	Dr. Nash presented a PowerPoint presentation (slides in agenda packet) documenting her experience at the APhA Institute on Substance Use Disorders Workshop in Salt Lake City, Utah. She explained the history and mission of the program, the wonderful people she met, her experience staying in the college dorms, and more. Dr. Nash encourages the board members to attend the next one. She informed the Board of that the American Society of Health-System Pharmacists (ASHP) and the American Pharmacists Association (APhA) have partnered together to establish Pharmacy Workforce Suicide Awareness Day, which will be observed annually on September 20, as part of Suicide Prevention Month.
CHAIRMAN'S REPORT	Dr. St. Clair provided the Chairman's Report. He welcomed Dr. Shannon Dowdy to the Board. The Board is still waiting on the fulfillment of the citizen board member position. Cheri Garvin provided an update from the NABP District 1&2 Meeting which she attended with Caroline Juran. Garvin detailed the Past, Present, and Future of Pharmacy presentation given. She commented hearing suggestions of offering virtual meeting attendance and holding full board meetings at Schools of Pharmacy throughout the state.
BOARD OF HEALTH PROFESSIONS	Dr. Melton provided an update regarding the Virginia Board of Health Professions. The Board has not met since the last full board meeting. The next meeting has been scheduled for October 27th.
LICENSURE OF INDIVIDUALS AND IN-STATE FACILITIES	Ryan Logan presented the Licensing Report of Individuals and In-State Facilities which included data from February 2022 – August 2023. Mr. Logan provided a resident and nonresident license count for pharmacists, pharmacy interns, pharmacy technicians, and pharmacy technician trainees.
LICENSURE OF NONRESIDENT FACILITIES	Beth O'Halloran presented the Licensing Report of Nonresident Facilities which included data from August 2022 – August 2023. As of August 2023, there are a total of 2,499 nonresident licenses consisting of manufacturers, medical equipment suppliers, outsourcing facilities, pharmacies, third-party logistics providers, warehousers, and wholesale distributors.

ACTION ITEM	**There was consensus that the Board only needs to review the report on page 201A annually, not quarterly, and that staff can delete the report found on page 202 and use the report on page 204 instead, going forward.**
INSPECTION PROGRAM	Beth O'Halloran presented the Inspections report on behalf of Melody Morton, Inspections Manager with the Enforcement Division. The report included statistics regarding the number of inspections completed, identified deficiencies, and the rate of deficiency occurrences.
PHARMACEUTICAL PROCESSORS	Caroline Juran presented the Pharmaceutical Processors Report on behalf of Annette Kelley. Three additional cannabis dispensing facilities have been permitted during the last quarter totaling 18 cannabis dispensing facilities. Board and agency staff continue to meet bimonthly with the Virginia Cannabis Control Commission to address the anticipated transition of the medical cannabis program to the VCCA on January 1, 2024. As of September 11, 2023 there are 7,425 registered patients, 37 registered parents/guardians, 108 registered agents, and 3,392 registered cannabis products.
DISCIPLINARY PROGRAM	Dr. Ellen Shinaberry presented the Disciplinary Program Report. As of September 6, 2023, the Discipline Program consists of 208 patient care cases and 210 non-patient care cases. The Board currently has two cases being appealed in the Circuit Court.
ACTION ITEM	**The Board enjoyed receiving the additional disciplinary reports included in the agenda packet and would like this information going forward.**
EXECUTIVE DIRECTOR'S REPORT	Caroline Juran provided the Executive Director's report. The report detailed previous meetings attended and reviewed upcoming meetings.
CONSIDERATION OF CONSENT ORDERS, SUMARY SUSPENSIONS, OR SUMMARY RESTRICTIONS	David Robinson, AAG offered a presentation for a possible summary suspension order for pharmacy technician registration issued to Whitney Gatewood.
DECISION	Upon a motion by Garvin, and duly seconded by Ratliff, the Board voted unanimously to summarily suspend the pharmacy technician registration issued to Whitney Gatewood.
MEETING ADJOURNED:	With all business concluded, the Board adjourned the meeting at 3:04PM.

12\6\2023
Date

Caroline D. Juran, RPh
Executive Director