

(FINAL/APPROVED)

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

June 5, 2019
Commonwealth Conference
Center
Second Floor
Board Room 2

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

- CALL TO ORDER:** The meeting of the Board of Pharmacy was called to order at 9:07 am.
- PRESIDING:** Rafael Saenz, Chairman
- MEMBERS PRESENT:** Melvin L. Boone, Sr.
Cheryl H. Nelson
Kristopher S. Ratliff
Patricia Richards-Spruill
Cynthia Warriner
- MEMBER ABSENT:** James L. Jenkins, Jr.
Ryan Logan
Glen Bolyard
Rebecca Thornbury
- STAFF PRESENT:** Caroline D. Juran, Executive Director
Beth O'Halloran, Deputy Executive Director
Ellen B. Shinaberry, Deputy Executive Director
Annette Kelley, Deputy Executive Director
Elaine Yeatts, Senior Policy Analyst, DHP
David E. Brown, D.C., Director, DHP
Barbara Allison-Bryan, M.D., Chief Deputy Director, DHP
James Rutkowski, Assistant Attorney General
Kiara Christian, Executive Assistant
- QUORUM:** With six members present, a quorum was established.
- APPROVAL OF AGENDA:** Mr. Saenz advised the board that the panel meeting at 1pm originally outlined in the agenda had been cancelled. He also recommended that a report from board counsel be added under the "Reports" section of the agenda. The agenda was unanimously adopted as amended.
- APPROVAL OF PREVIOUS BOARD MEETING MINUTES**
- MOTION:** **The Board voted unanimously to adopt the minutes as presented for the following meetings:**
- **March 26, 2019, Full Board Meeting**
 - **March 26, 2019, Public Hearing for Chemicals and**

Pharmaceutical Processor Regs

- **March 28, 2019, Special Conference Committee**
- **April 16, 2019, Board Retreat**
- **April 17, 2019, Special Conference Committee**
- **May 3, 2019, Regulation Committee**
- **May 14, 2019, Special Conference Committee
(motion by Ratliff, second by Boone)**

PUBLIC COMMENTS:

Christina Barrille, Executive Director, Virginia Pharmacist Association, began her comment by thanking the chairman for his leadership provided to the board over the past year. Ms. Barrille addressed the public comment offered by VPhA and VSHP to the board in a letter dated May 22, 2019 that was included in the agenda packet and asked for consideration of the suggested language for the legislative proposal addressing pharmacy technician educational standards.

Natalie Nguyen, Legislative Committee Chairman for Virginia Society of Health-System Pharmacists (VSHP) asked that the board consider the written comment provided by VSHP and VPhA regarding the pharmacy technician legislative proposal.

Monet Stanford with Kaiser Permanente offered comment on the recently passed legislation placing gabapentin into Schedule V. She inquired if dispensers would receive a grace period for coming into compliance.

**DHP DIRECTOR'S
REPORT:**

Dr. Brown provided an update introducing the new DHP website. He shared that the new website was designed to be more user-friendly for the public. The new website functionality will also allow for board staff to amend the content directly, in lieu of coordinating with the agency IT department.

**LEGISLATIVE/
REGULATORY/
GUIDANCE UPDATE**

**Update on Regulatory/Policy
Actions**

Ms. Yeatts reviewed the Chart of Regulatory Actions found in the agenda packet.

**Revenue and Expenditure
Analysis**

Ms. Yeatts provided an overview of the Revenue and Expenditure Analysis letter in the agenda packet. She stated the board has already taken action on this matter by proposing an amendment to regulations to increase licensure fees.

**Report on Regulation
Committee Meeting:**

**Recommendation on proposed
regulations for labeling
dispensed prescriptions**

The Regulation Committee recommended adoption of the proposed regulatory language that would insert the following statement into 18VAC110-20-275(B)(2)(d): "A unique identifier on the prescription label is not required to

identify a pharmacy solely involved in the holding of a prescription for pick-up or further delivery when that pharmacy has not shared in other filling or dispensing functions.” However, there was discussion during the board meeting that listing only the dispensing pharmacy’s name on the prescription label and not listing the name of the pharmacy where the patient picked up the prescription may create confusion for patients. It was requested that staff contact consumer groups such as Senior Connections and AARP to obtain consumer feedback on the proposed regulatory action.

ACTION ITEM:

Staff will contact consumer groups such as Senior Connections and AARP to obtain consumer feedback on the proposed regulatory action for labeling dispensed prescriptions.

MOTION:

The board voted unanimously to table the discussion until September when it could take the consumer groups’ feedback into consideration. (motion by Saenz, second by Richards-Spruill)

Recommendation to adopt
final regulations for
Pharmaceutical processors

Staff reviewed with the board a summary of the public comments received found on pages 62-64 of the agenda packet, the Regulation Committee’s recommendation, along with additional suggested amendments offered by staff for the board’s consideration. Ms. Yeatts stated that it is recommended that no additional adjustment to fees be made until the program is fully operational and the board has a better idea of expenditures. She reminded the board that the pharmaceutical processor budget is separate from the Board of Pharmacy’s main budget. There was discussion that a “delivery agent” could possibly be a contracted employee that otherwise complies with the laws and regulations, and that staff could consider adopting guidance or amending the regulations at a later time to provide clarification on this subject, if necessary. It was also stated that the board could potentially adopt guidance in September to recognize a valid sample size.

MOTION:

The board voted unanimously to adopt the final regulations for pharmaceutical processors as recommended by the Regulation Committee and subsequently amended as shown in [brackets] in the agenda packet. The amendments listed in the agenda packet include the following actions:

- **Amend the definition of “90-day supply” in 18VAC110-60-10 by striking “which cannot exceed 60 fluid ounces”. The definition of “Batch” was added to mean “a quantity of cannabidiol oil or THC-A oil from a production lot that is identified by a batch number or other unique identifier”;**
- **Insert in 18VAC110-60-20 fees for “change of ownership not requiring a criminal background \$100.00” and “change of ownership requiring a criminal background check \$250”;**
- **Amend 18VAC110-60-150 by adding a subsection E(3) that reads: “If a new owner’s share constitutes 5% or greater of the total ownership, the new owner shall submit to fingerprinting and the criminal history record search required by subsection E of §54.1-3442.6”;**

- Amend 18VAC110-60-220 (H) by inserting “or an agent of the processor”;
- Amend 18VAC110-60-285 (A)(5) by striking “Any other active ingredient that constitutes at least 1.0% of the batch used in the product”;
- Amend 18VAC110-60-285 (B) by replacing “97% to 103%” with “90 to 110%”;
- Amend 18VAC110-60-290 (B)(2)(e) by inserting “based on stability testing”;
- Amend 18VAC110-60-290 (B)(2)(g)((5)) by striking “Any other active in gradient that constitutes at least 1.0% of the batch used in the product, and;” and inserting “residual solvents” to subsection B(2)(h);
- Strike 18VAC110-60-295 in its entirety;
- Amend 18VAC110-60-300 (B) to read “After processing and before dispensing the cannabidiol oil or THC-A oil product, a pharmaceutical processor shall make a sample available from each batch of product for a laboratory to (i) test for microbiological contaminants, mycotoxins, heavy metals, residual solvents, and pesticide chemical residue and (ii) conduct an active ingredient analysis and terpenes profile. The sample size shall be a statistically valid sample as determined by the board”;
- Amend 18VAC110-60-300 (C) by striking the word “cannabis”, “and eventual packaging”, and “of Cannabis” in the first sentence.
- Amend 18VAC110-60-300 (D) by striking “include Cannabis in a cannabidiol oil or THC-A oil product or sell it” and replace with “sell a cannabidiol oil or THC-A oil product”;
- Amend 18VAC110-60-300 (E) by replacing the term “Cannabis” with “cannabidiol oil or THC-A oil”;
- Amend 18VAC110-60-300 (F) by replacing the term “Cannabis” with “cannabidiol oil or THC-A oil product”;
- Amend 18VAC110-60-300 (F)(2) by striking “Cannabis” and inserting “cannabidiol oil or THC-A oil product” after “sample of”;
- Amend 18VAC110-60-300 (F)(3) by replacing “Natural Health Products Acceptable Limits ug/kg body weight/Day” with “Limits – parts per million (ppm)”;
- Amend 18VAC110-60-300 (F)(4) by striking “Cannabis” and inserting “of cannabidiol oil or THC-A oil product” after “sample”;
- Amend 18VAC110-60-300(F)(5), (F)(6), (G) and (H) and 18VAC110-60-310 as presented in the agenda packet. (Warriner, second by Nelson)

Recommendation on number of patients associated with registered agent

It was reported that the Regulation Committee did not deliberate on this topic since no action could be taken until the law becomes effective on July 1, 2019. The board agreed to table this topic until the September board meeting.

Consideration of possible
2020 legislative proposals

Pharmacy Technician
Education Standards

The Regulation Committee recommended adoption of the legislative proposal included in the agenda packet. The board considered comment received and recognized that the legislative proposal did not include language to grandfather current pharmacy technician trainees.

MOTION:

The Board voted unanimously to not adopt the legislative proposal included in the agenda packet as recommended by the Regulation Committee.

The Board then focused its discussion on amending the draft legislative proposal to include language as jointly recommended by VPhA and VSHP and to address grandfathering pharmacy technician trainees. Ms. Yeatts stated that there is no need to grandfather current pharmacy technician registrants since they have already satisfied compliance with current standards for obtaining a pharmacy technician registration. It was determined that the delayed effective date should be established in regulation, not in the legislative proposal.

MOTION:

The board voted unanimously to direct staff to draft a legislative proposal on pharmacy technician education standards that requires (i) completion of a training program that meets accreditation standards approved by the Board or operated through a federal services, (ii) passing a national examination administered by the Pharmacy Technician Certification Board or National Healthcareer Association, (iii) grandfathers pharmacy technician trainees enrolled in a board-approved training program prior to the effective date of the requirements, and (iv) requires the board to promulgate emergency regulations for implementation. (motion by Ratliff, Second by Richards-Spruill)

Compounding of
Essentially Copies

The Regulation Committee recommended the board to adopt the legislative proposal to amend §54.1-3410.2 as presented on page 152 of the agenda packet.

MOTION:

The Board voted unanimously to adopt the legislative proposal as presented that would amend §54.1-3410.2 by striking from (H)(2), “or (v) the mixing of two or more commercially available products regardless of whether the end product is a commercially available product;”.

Telepharmacy

The Regulation Committee recommended that the board take no action on a legislative proposal to address telepharmacy at this time. No action was taken by the Board.

White/Brown
Bagging

The board has already adopted proposed regulation on this subject. The Regulation Committee recommended that the board take no additional action on this subject at this time. No action was taken by

the Board.

CONSIDERATION OF
COMMENTS RECEIVED
DURING PERIODIC
REGULATORY REVIEW
THAT EXCEED THE
SCOPE OF NOIRA

Ms. Yeatts recommended to the board that it take no action at this time since the board has numerous regulatory actions in place. The board determined that the Regulation Committee should consider these comments at a future meeting.

GUIDANCE DOCUMENT
110-1, CATEGORIES OF
FACILITY LICENSURE

Staff recommended language as found on page 156 of the agenda packet to amend Guidance Document 110-1 to include additional licensure categories that were recently implemented.

MOTION:

The board voted unanimously to adopt Guidance Document 110-1, *Categories of Facility Licensure*, as presented. (motion by Warriner, second by Boone)

GUIDANCE DOCUMENT
110-36, COMPLIANCE
WITH USP STANDARDS
FOR COMPOUNDING

Based on comments offered by USP at the recent NABP annual meeting, staff is recommending the board amend Guidance Document 110-36 to clarify that enforcement of USP Chapter 800 standards will primarily apply to compounding. Enforcement of Chapter 800 may also apply to repackaging if the proposed regulation requiring repackaging to comply with USP standards becomes final. There was discussion that question #63 should be deleted as it may not be written clearly.

MOTION:

The board voted unanimously to adopt Guidance Document 110-36 as presented and amended by striking question #63. (motion by Nelson, second by Ratliff)

NEW BUSINESS

Election of Chairman and
Vice-Chairman

MOTION:

The board voted unanimously to elect Ms. Warriner as Chairman. (motion by Boone, second by Richards-Spruill)

The board voted unanimously to elect Mr. Ratliff as Vice-Chairman. (motion by Nelson, second by Boone)

Schedule dates for 2020
Meetings

Tentative dates were provided on pages 178-181 of the agenda packet for the board to review and confirm eligibility. Because four members were not in attendance, it was decided to email the dates to the full board for determining availability.

REPORTS

- Chairman's Report Mr. Saenz shared his experience attending the NABP Annual meeting, noting Ms. Juran's recent election as Treasurer of NABP. He also shared that the June board meeting was his last board meeting as his term expires June 30, 2019.
- Report on Board of Health Professions Ms. Juran provided an update on behalf of Mr. Logan.
- Report on Inspection and Licensure Program Ms. O' Halloran provided an overview of the update included in the agenda packet.
- Report on Disciplinary Program Ms. Shinaberry provided an overview of the update included in the agenda packet. She noted that the Disciplinary Case Manager position interviews were conducted on June 7, 2019. Ms. Shinaberry also stated that the CE audits were in process which may cause an increase in case load moving forward.
- Executive Director's Report Ms. Juran provided an overview of the update included in the agenda packet. She shared information regarding the upcoming NABP District 1 & 2 Meeting in Vermont and encouraged attendance. Ms. Juran also shared her experiences at the Rx Drug Summit in Atlanta, GA.
- Board Counsel's Report Mr. Rutkowski provided the board with an update on the appeal for pharmaceutical processors, alerting the board of the upcoming court date scheduled for June 7, 2019.
- Motion:** **The board voted unanimously to enter into closed session pursuant to §2.2-3711(A)(11) to consult with counsel regarding actual or probable litigation. Additionally, it was moved that Caroline Juran, Sammy Johnson, Beth O'Halloran, Ellen Shinaberry, Annette Kelley, and Kiara Christian attend the closed meeting because their presence was deemed necessary and would aid the Board. (motion by Nelson, second by Richards-Spruill)**
- Motion:** **The Board voted unanimously that only public business matters lawfully exempted from open meeting requirements and only such public business matters as were identified in the motion for a closed meeting were heard, discussed, or considered during the closed session just concluded. (motion by Nelson, second by Warriner)**
- Jane P. Wright
Registration No.
0202-010363 A Possible Summary Suspension was held in the matter of Jane P. Wright to discuss allegations that she may have violated certain laws and regulations governing the practice of pharmacist in Virginia.

DECISION:

Upon a motion by Ms. Warriner, and duly seconded by Ms. Nelson, the panel voted unanimously that, with the evidence presented, the practice as a pharmacist by Jane Wright, poses a substantial threat to the public; and therefore the license of Ms. Wright shall be summarily suspended. Further, with the Notice of Hearing, a Consent Order shall be offered to Ms. Wright for the revocation of her pharmacist license.

James Misenko

Consideration of consent order

License No.

0202-010856

DECISION:

Upon a motion by Ms. Warriner, and duly seconded by Mr. Ratliff, the panel voted unanimously to accept the consent order for revocation of his pharmacist license.

Taylor's Pharmacy dba Florida
Discount Drug

Consideration of consent order

Permit No. 0214-001420

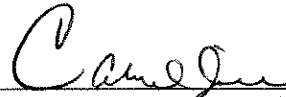
DECISION:

Upon a motion by Mr. Ratliff, and duly second by Ms. Nelson, the panel voted unanimously to accept the consent order to reinstate the non-resident pharmacy registration.

ADJOURN:

With all business concluded, the meeting adjourned at 12:52 pm.

for Rafael Saenz 
Rafael Saenz, Chairman


Caroline D. Juran, Executive Director

9/25/19
DATE: _____

9/25/19
DATE: _____