(FINAL/APPROVED)

VIRGINIA BOARD OF PHARMACY
MINUTES OF BOARD MEETING

November 28, 2018
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 11:09am

PRESIDING: Rafael Saenz, Chairman

MEMBERS PRESENT:
James. L. Jenkins, Jr.
Ryan K. Logan
Cheryl H. Nelson
Kristopher S. Ratliff
Patricia Richards-Spruill

MEMBERS ABSENT:
Rebecca Thornbury
Cynthia Warriner
Glenn L. Bolyard, Jr.
Melvin L. Boone, Sr.

STAFF PRESENT:
Caroline D. Juran, Executive Director
J. Samuel Johnson, Jr., Deputy Executive Director
Beth O'Halloran, Deputy Executive Director
Ellen B. Shinaberry, Deputy Executive Director
Elaine Yeatts, Senior Policy Analyst, DHP
James Rutkowski, Assistant Attorney General

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

APPROVAL OF AGENDA: The agenda was unanimously approved as presented. **(motion by Logan, second by Nelson)**

PUBLIC COMMENTS: Christina Barrille, Executive Director, VPhA, offered comment on behalf of VPhA members thanking the Board for the recent regulations that went into effect regarding the dispensing of Schedule VI drugs.

Aaron Lopez, Principle, Political Capital, spoke on behalf of compounding pharmacies and Medisca on two issues. First, he was requesting the board acknowledge to its licensees that a third party may perform stability testing on behalf of a compounding pharmacy, in compliance with USP standards. Secondly, he commented on the FDA's revised draft memorandum of understanding (MOU), indicating that some states appear reluctant to sign the MOU.

LEGISLATIVE/REGULATORY/

GUIDANCE:

Regulatory Update

Ms. Yeatts reviewed the Chart of Regulatory Actions found in the agenda packet and provided updates to the following actions that had taken place after the agenda packet was printed:

- Periodic review proposed regulations have been approved for publication and a 60-day comment period will commence on 12/24/18. A public hearing on the matter to receive comment is scheduled for 1/9/19.
- The action regarding the increase in fees has moved to the Governor's office for administrative review.
- Regulations for the issuance of a controlled substances registration for naloxone and teleprescribing have been approved and will become effective on 1/23/19.
- Pending regulations for the registration of nonresident third party logistics providers and nonresident warehousers have moved to the Secretary's office for administrative review.

Final Report of the Workgroup on E-Prescribing

Ms. Yeatts briefly reviewed the Secretary's final report of the E-prescribing workgroup and recommendations for legislation contained within the report.

Adoption of Regulations to Conform to DEA Scheduling of Epidiolex

Staff provided a handout containing an excerpt from the Federal Register regarding the placement of approved cannabidiol drugs into Schedule V and an amended version of draft regulatory language for 18VAC110-20-323. There was a public hearing conducted at 11:00am this morning pursuant to §54.1-3443(E) of the Drug Control Act to receive comment on scheduling the drug Epidiolex in Schedule V in the Drug Control Act.

MOTION:

The Board voted unanimously to adopt an exempt action amendment of Regulation 18VAC110-20-323 as presented in the handout which reads:

"Pursuant to subsection E of § 54.1-3443 of the Code of Virginia and in order to conform the Drug Control Act to recent scheduling changes enacted in federal law or rule, the board:
1. Adds MT-45 (1-cyclohexyl-4-(1,2-diphenylethyl)piperazine) to Schedule I;

2. Adds Dronabinol ((-)-delta-9-trans tetrahydrocannabinol) in an oral solution in a drug product approved for marketing by the U.S. Food and Drug Administration to Schedule II; ~~and~~

3. Deletes naldemedine from Schedule II; and

4. Adds a drug product in finished dosage formulation that has been approved by the U.S. Food and Drug Administration that contains cannabidiol (2-[1R-3-methyl-6R-(1-methylethenyl)-2-cyclohexen-1-yl]-5-pentyl-1,3-benzenediol) derived from cannabis and no more than 0.1 percent (w/w) residual tetrahydrocannabinols to Schedule V." (motion by Logan, second by Richards-Spruill)

Consider Draft Proposed Regulation for White Bagging and Brown Bagging

The Board considered the draft proposed language in the agenda packet regarding regulations for white bagging and brown bagging. Staff commented that §54.1-3420.2(B) requires the delivery location to hold a current permit, license, or registration with the Board of Pharmacy that authorizes the possession of controlled substances at that location. As such, the draft regulatory language provided in the agenda packet would need to be amended since the board cannot exempt a hospital, medical clinic, or prescriber's office from this statutory requirement if a Board of Pharmacy license is not already maintained. Any reference to delivering to another pharmacy could remain in the draft regulatory language since that pharmacy would already hold licensure with the board. Additionally, it was commented that an exemption from subsection A is unnecessary.

MOTION:

The Board voted unanimously to adopt the proposed amendments to 18 VAC 110-20-275 as presented and amended by inserting subsections F and G as indicated below:

"F. The pharmacy and alternate delivery site is exempt from compliance with subsections B-E if: (1) the alternate delivery site is a pharmacy, a practitioner of healing arts licensed by the board to practice pharmacy or sell controlled substances, or other entity holding a controlled substances registration for the purpose of delivery of controlled substances; (2) it does not routinely receive deliveries from the pharmacy; and (3) compliance with subsections B-E would create a delay in delivery that may result in potential patient harm.

1.To ensure appropriate coordination of patient care, the pharmacy shall notify the alternate delivery site of the anticipated arrival date of the shipment, the exact address to where the drug was shipped, the name of the patient for whom the drug was dispensed, and any special storage requirements.

2. The pharmacy shall provide counseling or ensure a process is in place for the patient to receive counseling.

3. Prescriptions delivered to the alternate delivery site shall be stored in a lockable room or lockable cabinet, cart, or other device which cannot be easily moved and which shall be locked at all times when not in use. Access shall be restricted to the licensed prescriber, pharmacist, or either person's designee.

4. The pharmacy shall provide a procedure for the return of any prescription drugs not delivered or subsequently administered to the patient.

G. A pharmacy shall not deliver dispensed drugs to a patient's residence that are intended to be subsequently transported by the patient or patient's agent to a hospital, medical clinic, prescriber's office, or pharmacy for administration and that require special storage,

reconstitution or compounding prior to administration." (motion by Nelson, second by Ratliff)

Consider Submission of Public Comment regarding FDA Revised Draft Guidance Document – MOU Addressing Certain Distributions of Compounded Drug Products

The Board reviewed the revised draft memorandum of understanding (MOU) in the agenda packet along with the suggested changes from NABP. Ms. Juran stated that this is an opportunity for the board to offer comment to the FDA regarding the specific language within in the MOU and that the board does not need to determine at this time if it will sign the MOU.

MOTION:

The Board voted unanimously to direct staff to submit written comment to the FDA urging the FDA to strongly consider the suggested edits presented by NABP. (motion by Logan, second by Richards-Spruill)

MOTION FOR CLOSED MEETING:

Upon a motion by Mr. Logan and duly seconded by Mr. Nelson, the Board unanimously voted to convene a closed meeting pursuant to § 2.2-3711 (A) (8) of the Code of Virginia to receive legal advice regarding the Virginia Freedom of Information Act and the consideration of the applications for pharmaceutical processor permits. In addition, Mr. Saenz moved that Caroline Juran, Jim Rutkowski, Elaine Yeatts, and Sammy Johnson attend the closed session because their presence is necessary and would reasonably aid the board.

MOTION TO RECONVENE:

Upon motion by Mr. Logan and duly seconded by Mr. Jenkins, the Board certified to the best of their knowledge, that only public business matters lawfully exempted from open meeting requirements under the Virginia Freedom of Information Act and only such public business matters as were identified in the motion for closed session were heard, discussed, or considered during the closed session that just concluded.

Board Member Statements:

Mr. Saenz announced that as part of his responsibilities serving as the Pharmacy Director of the UVA Hospital Pharmacy, he also serves as an assistant dean of VCU School of Pharmacy at a satellite campus located in Charlottesville. He stated that he believes he can render a fair and impartial decision in the consideration of pharmaceutical processor applications.

Mr. Ratliff announced that he had written a letter of support for the Dharma pharmaceutical processor application prior to being appointed to the Board and that he would recuse himself from the Board's consideration of this particular pharmaceutical processor application.

Consider Criminal Background Check Results for Pharmaceutical Processor Conditional Approvals and Any Related Matters

Ms. Juran indicated that criminal background checks for those pharmaceutical processors awarded conditional approval did not reveal any barrier violations. Mr. Saenz indicated that two pharmaceutical processors awarded conditional approval contingent upon criminal background checks, Dalitso and Dharma, had submitted applications for a change of location and the Board would need to accept or deny the change of locations.

MOTION:

The Board voted unanimously to finalize the conditional approval for Pharmacann in health service area (HSA) I, Green Leaf in HSA IV, and Columbia Care in HSA V. (motion by Jenkins, second by Nelson)

The Board deliberated on whether to accept or deny the change of location application for Dalitso in HSA II. Mr. Jenkins commented that the new location would allow for a larger facility that could be advantageous for business growth and potentially facilitate a greater production of oils. Ms. Nelson commented that allowing the applicant to perform a change of location at this point in the competitive application process might be perceived as being unfair to those applicants that were denied conditional approval.

MOTION: **The Board voted 5-1 to deny the application for a change of location for Dalitso in HSA II. (motion by Nelson, second by Ratliff; Jenkins opposed)**

MOTION: **The Board voted unanimously to finalize the conditional approval for Dalitso in HSA II at the address listed in the originally submitted application. (motion by Logan, second by Nelson)**

Mr. Saenz acknowledged that Mr. Ratliff was recused of considerations for Dharma. He then stated that the Board would not be able to consider the change of location application submitted by Dharma or finalize the conditional approval for Dharma, because the Board no longer had a quorum. The matter was deferred to the December 18, 2018 full board meeting.

ADJOURN: With all business concluded, the meeting adjourned at approximately 1:30pm.

Rafael Saenz, Chairman

DATE: 12/18/18

Caroline D. Juran, Executive Director

DATE: 12/18/18