(FINAL/APPROVED)

VIRGINIA BOARD OF PHARMACY
MINUTES OF FULL BOARD MEETING

December 18, 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 9:11 am

PRESIDING: Rafael Saenz, Chairman

MEMBERS PRESENT:
Glenn L. Bolyard, Jr.
Melvin L. Boone, Sr.
James. L. Jenkins, Jr.
Ryan K. Logan
Cheryl H. Nelson
Kristopher S. Ratliff
Patricia Richards-Spruill
Rebecca Thornbury
Cynthia Warriner

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
David Brown, Director, DHP
James Rutkowski, Assistant Attorney General

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

APPROVAL OF AGENDA: An amended agenda was provided as a handout. Amendments included: approval of draft minutes from the December 12, 2018 Special Conference Committee and the re-adoption of regulatory action regarding brown bagging and white bagging. **(motion by Thornbury, second by Boone)**

APPROVAL OF PREVIOUS BOARD MEETING MINUTES

MOTION: **The Board voted unanimously to approve the minutes as presented for the following meetings:**

- **September 24, 2018, Special Conference Committee**
- **September 25, 2018, Full Board Meeting**
- **September 25, 2018, Public Hearing**
- **October 9, 2018, Telephone Conference Call**
- **October 17, 2018, Special Conference Committee**
- **October 25, 2018, Formal Hearings**

- **November 27, 2018, Special Conference Committee**
- **November 28, 2018, Formal Hearings**
- **November 28, 2018, Full Board Meeting**
- **November 28, 2018, Public Hearing**
- **December 7, 2018, Telephone Conference Call**
- **December 12, 2018, Special Conference Committee**

(motion by Bolyard, second by Richards-Spruill)

PUBLIC COMMENTS:

Denise Frank with Gates Healthcare Associates offered comment regarding Gates' request for the Board to accept a cGMP inspection performed by Gates of outsourcing facilities for licensure purposes, in lieu of an FDA inspection. She stated Gates has provided an excerpt of a proposed inspection form checklist, that she has recently completed a cGMP certification program, and that Gates has hired a second former FDA inspector, Frank Minella. Mr. Minella also offered comment and later clarified that he is not a former FDA inspector, but has worked for many years with the pharmaceutical industry such as with submissions of New Drug Applications and is very familiar with the regulatory aspects imposed on the industry.

Farzanah Kennedy commented that the five pharmaceutical processors awarded conditional approval have recently established the Virginia Medical Cannabis Coalition and that she is serving as President. She stated Katie Hellebush and Caley Crawford will manage the Coalition.

Christina Barrille, Executive Director, Virginia Pharmacists Association, commented that VPhA has several 2019 legislative initiatives. The first contemplates authorizing the Boards of Medicine and Pharmacy to regulate a limited prescriptive authority for pharmacists to treat minor conditions that do not require a diagnosis or for which there is a CLIA-waived test to assist in assessing the patient. Other initiatives contemplate addressing PBM audit reform and carving out Medicaid pharmacy benefits from managed care organization control. She also stated the association has recently created an Academy for Medical Cannabis to assist in educating pharmacists on the subject.

Randall Eads, City Manager and Attorney for the City of Bristol, Virginia thanked the Board for its confidence in Dharma Pharmaceuticals. He stated they believe Dharma Pharmaceuticals will play a role in addressing the opioid addiction. He provided an explanation for the change of location application submitted by Dharma. The city realized, due to the nature of the business, that having a pharmaceutical processor located in the vacant mall may limit the other types of businesses that could be co-located in the mall. The city asked Dharma to consider relocating to another location within the city. Mr. Eads stated that while the city would prefer Dharma to not be located in the mall based on other possible economic opportunities, the city would support Dharma's efforts at a location approved by the Board. When questioned, Mr. Eads acknowledged that it is possible a casino could be located at the mall if legislation is passed.

Michael Johnson, owner of Michaels Pharmacy and tentative pharmacist-in-

charge of Dharma Pharmaceuticals, stated that he has concerns for patient comfort if Dharma Pharmaceuticals is located in the mall, along with a casino.

Nathan Payne, pharmacist in Danville, Virginia and representing Wellness Pharmaceuticals, which submitted a pharmaceutical processor application in health service area III, urged the Board to deny the change of location application submitted by Dharma. He stated that location and site layout was part of the initial application evaluation process, that other applicants did not have the same luxury of extra time for finding a better location, and that the Board should deny the request as it denied Dalitso's change of location application at the last board meeting.

Delegate O'Quinn, representing the City of Bristol, thanked the Board for the initial awarding of conditional approval to Dharma Pharmaceuticals. He commented that Dharma Pharmaceuticals worked with the City of Bristol to determine the best placement of the pharmaceutical processor that would provide for the best economic impact and serve as a central location for patients to obtain the dispensed oils. Del O'Quinn requested that the Board approve the change of location application submitted by Dharma Pharmaceuticals.

Alexis Long, interim vice-chair of the Academy of Medical Cannabis, introduced herself to the Board and indicated that the Academy will partner with other providers to serve as an educational resource for pharmacists, pharmacy technicians, and patients and will assist with internship opportunities in the medical cannabis area.

Aaron Lopez, speaking on behalf of Dalitso, urged the Board to approve the change of location application submitted by Dharma Pharmaceuticals, stating that the request should be considered separately from the Board's previous consideration, and subsequent denial, of the change of location application submitted by Dalitso.

DHP DIRECTOR'S REPORT:

Dr. Brown stated there have been recent positive indicators surrounding the opioid addiction crisis. The overdose death rate has decreased and the dispensing of opioids have decreased by 50% in the past few years. Dr. Brown also indicated the availability of treatment opportunities have increased, especially for those who could not previously afford such treatment. He also stated that number of prescribers who have obtained a waiver to provide medication assisted treatment has increased as well.

LEGISLATIVE/REGULATORY/ GUIDANCE UPDATE

Regulatory Update

Ms. Yeatts reviewed the Chart of Regulatory Actions found in the agenda packet and provided updates to the following actions:

- Brown bagging and white bagging is on the agenda for consideration of readoption based on an amendment;
- A public hearing for placing Epidiolex in Schedule V has been set for February 6; and,
- A comment period on the delivery of Schedule VI devices will open on

12/24/18.

Adoption of Exempt Regulation to Schedule Certain Chemicals in Schedule I

There was a public hearing conducted at 9:07am this morning pursuant to requirements of §54.1-3443 of the Drug Control Act to receive comment on scheduling certain chemicals in Schedule I.

MOTION:

The Board voted unanimously to place the referenced drugs into Schedule I by amending 18VAC110-20-322 by inserting a new subsection D as listed below:

"D. 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-phenyl-N-[1-(2-phenylethyl)-4-piperidinyl]-benzamide (other names: Phenyl fentanyl, Benzoyl fentanyl), 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. Research chemicals.

a. 4-acetyloxy-N,N-diallyltryptamine (other name: 4-AcO-DALT), its optical, position, and geometric isomers, salts and salts of isomers, whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation.

b. 4-chloro-N,N-dimethylcathinone, its optical, position, and geometric isomers, salts and salts of isomers, whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation.

c. 4-hydroxy-N,N-methylisopropyltryptamine (other name: 4-hydroxy-MiPT), its optical, position, and geometric isomers, salts and salts of isomers, whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation.

d. 3,4-Methylenedioxy-alpha-pyrrolidinohexanophenone (other name: MDPHP), its optical, position, and geometric isomers, salts and salts of isomers, whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation.

3. Cannabimimetic agent.

Methyl 2-[1-(5-fluoropentyl)-1H-indole-3-carboxamido]-3,3-dimethylbutanoate (other name: 5-Fluoro-MDMB-PICA), 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.

The placement of drugs listed in this subsection shall remain in

effect until (18 months from the effective date of the regulation), unless enacted into law in the Drug Control Act." (motion by Warriner, second by Thornbury)

Amend 18VAC110-20-10, Storage Temperature Definition Reference to Freezer

USP has revised the allowable temperature range for drug storage in a freezer, therefore, the Board should consider amending regulation to conform to this standard. Historically, USP's definition for storage temperature in a freezer was between 20 and 10 degrees Celsius. The definition now is a "controlled temperature between 25 and 10 degrees Celsius" and that in "some instances articles may have a recommended storage condition below 20 degrees Celsius. In such cases, the temperature of the storage location should be controlled to +/- 10 degrees."

MOTION:

The Board voted unanimously to adopt a fast-track action to amend the meaning of "cold" within the definition of "storage temperature" in 18VAC110-20-10 by striking "maintained thermostatically between -20° and -10°C (-4° and 14°F)" following the phrase "A freezer is a cold place in which the temperature is" and replacing with "controlled between −25° and −10°C (-13° and 14°F). In those instances in which articles may have a recommended storage condition below -20° C (-4°F), the temperature of the storage location should be controlled to +/-10°". (motion by Warriner, second by Jenkins)

Adoption of Final Regulations for E-Profile Requirement

Ms. Yeatts provided background on the proposed regulations and indicated that no public comment was received. The final regulations for consideration are identical to the proposed regulations. Applicants as well as renewal applicants would be required to provide the board with their e-profile ID number issued by NABP. Ms. Juran confirmed that most applicants already have an e-profile ID and there is no cost for obtaining the ID. Use of the e-profile ID will assist board staff in securely and efficiently communicating with NABP on licensure or disciplinary-related matters.

MOTION:

The Board voted unanimously to adopt final regulations to require pharmacists, pharmacy technicians and pharmacy interns to provide an e-profile ID number when applying for a new license or registration or renewing their license or registration. (motion by Nelson, second by Bolyard)

Adoption of Proposed Regulations for Labeling of Dispensed Medications

Ms. Yeatts reminded the Board that a petition for rulemaking was received on this subject and that the Board had adopted a NOIRA. She reported that comments received on the NOIRA generally favored rulemaking. One commenter did not support the petitioner's request for rulemaking. The Board now needed to consider the adoption of proposed regulations on the subject. The draft proposed regulations provided in the agenda packet amended 18VAC110-25-275(B) to clarify requirements for the policies and procedure manual when a pharmacy delivers a dispensed drug to another pharmacy. Additionally, it stated that the identity of the pharmacy solely involved in the holding of a prescription for pick-up or further delivery is not required on the prescription label, or may be included in a unique identifier, when that

pharmacy has not shared in other filling or dispensing functions. Ms. Warriner expressed concern for patients and other caregivers potentially not being able to identify both pharmacies on the prescription label. Ms. Thornbury agreed with Ms. Warriner's comments. It was stated that it may be confusing to the patient to have two phone numbers listed on the label and that it may be more appropriate to list only the number of the pharmacy that was involved in the dispensing of the drug. Ms. Yeatts reminded the Board that the action is still at the proposed stage so there will be an additional 60-day comment period for the public to provide comment on the proposed regulations.

MOTION:

The Board voted unanimously to refer the matter to the Regulation Committee for further consideration of the draft proposed regulatory language. (motion by Logan, second by Richards-Spruill)

Adoption of Fast-Track Regulation for Pharmacy Permit Recession

The Board previously adopted a proposed regulatory action to authorize the Board to rescind a pharmacy permit if the pharmacy did not become operational within a defined period. Counsel subsequently advised that the action was not consistent with statutory authority and needed to be revised. Ms. Juran reminded the Board that this action was intended to address concerns with what appears to be suspicious fraudulent activity. The revised language indicates that once a pharmacy permit is issued, a pharmacy must be operational within 90 days of issuance. The Board may grant an extension for good cause shown. If not operational and no extension is granted, the pharmacy would be subject to possible disciplinary action for violating the regulatory requirement.

MOTION:

The Board voted unanimously to adopt a fast track regulatory action to amend 18VAC110-20-140 by inserting a new subsection F that reads:

- **"Once a permit has been issued, the pharmacy shall be fully operational within 90 days of issuance. For good cause shown, such as circumstances beyond the control of the permit holder, the board may grant an extension." (motion by Warriner, second by Nelson)**

Review of Guidance Documents

The Board completed its review of guidance documents that have not been reviewed or re-adopted in the past 4 years. Ms. Juran indicated that Guidance Document 110-43 should be amended to accurately reflect the current edition of the FDA's Orange Book.

MOTION:

The Board voted unanimously to amend sentences within the first paragraph of Guidance Document 110-43 in accordance with the underlined additions and strikethroughs listed below:

- **"However, according to the preface of the ~~32nd~~ 38th edition of the FDA's Orange Book, ~~page vii,~~ "Any drug product in the ~~List~~ Orange Book repackaged and/or distributed by other than the ~~application holder~~ applicant is considered to be therapeutically equivalent to the**

~~application holder's~~ applicant's drug product even if the ~~application holder's~~ applicant's drug product is single source or coded as non-equivalent (e.g., BN). ~~Also, distributors or repackagers of an application holder's drug product are considered to have the same code as the application holder.~~"

(motion by Logan, second by Warriner)

MOTION:

The Board voted unanimously to re-adopt the following Guidance Documents as presented, along with the amended Guidance Document 110-43:

- **110-3–Guidance on alternate delivery of prescriptions, pharmacy to physician or pharmacy to controlled substance registration type of delivery**
- **110-21 – Sanction Reference Points Manual**
- **110-28 – Guidance for Free Clinic Pharmacy Permit Applicants**
- **110-30 – Drugs within animal shelters and pounds**
- **110-32 – Use of a drop-box for the collection of prescriptions**
- **110-33 – Pharmacy interns as pharmacy technicians, Pharmacy technician ratio**
- **110-37 – Guidance for conducting informal fact-finding by an agency subordinate.**
- **110-40 – Storage of Schedule II drugs in a pharmacy**
- **110-41 – Changes a pharmacist may make to a Schedule II prescription**
- **110-42 – Continuing Education audit and recommended sanctions**
- **110-43 – Dispensing with an authorized generic**

(motion by Logan, second by Richards-Spruill)

Re-Adoption of White Bagging/Brown Bagging Regulations

Following the Board's adoption of proposed regulatory amendments to 18VAC110-20-275 in November 2018, staff received several comments expressing concern that the adopted language would prohibit hemophiliac patients from receiving blood factors delivered to their residence that may be needed for emergent treatment. A handout of the proposed regulatory amendment was provided to the Board for their consideration that included an exception in subsection G that would allow emergent blood factor treatment 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 required special storage, reconstitution or compounding prior to administration, to be delivered to a patient's residence.

MOTION:

The Board voted 9 to 0 to readopt the proposed regulatory amendment to 18VAC110-20-275 as presented that inserted the following sentence at the end of subsection G, "An exception to this requirement may be made for patients with hemophilia who may require emergent blood factor treatment." (motion by Logan, second by Boone; abstention by Warriner)

OLD BUSINESS

MOTION FOR CLOSED MEETING:

Upon a motion by Ms. Warriner, and duly seconded by Mr. Logan, the Board unanimously voted to convene a closed meeting pursuant to § 2.2-2711 (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 will reasonably aid the board.

MOTION TO RECONVENE:

Upon motion by Ms. Warriner, and duly seconded by Ms. Nelson, 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.

Finalize Pharmaceutical Processor Conditional Approvals

Prior to the Board considering the finalizing of the conditional approval for the fifth pharmaceutical processor, Dharma Pharmaceuticals, and their submission of an application for change of location, Mr. Ratliff stated that he would recuse himself from the discussions since he wrote a letter of support for Dharma Pharmaceuticals prior to being appointed to the Board.

Ms. Nelson suggested that the Board consider denying the change of location application, consistent with the handling of Dalitso's change of location application, because the Board has completed an extensive RFA evaluation process and it may not be fair to other applicants to approve the change of location at this time. Ms. Warriner disagreed, because Dharma's request for a change of location involved concerns with patient issues, unlike the request from Dalitso. Ms. Thornbury agreed with Ms. Warriner that this request involved concerns with patient safety and the request from Dalitso was focused more on allowing the processor to open earlier. Ms. Warriner also commented that the alternate site is in the same municipality as the originally proposed site, there is broad support from the municipality and legislators, and valid reasons exist for supporting the change of location. Ms. Thornbury also commented that from the information the applicant provided with the change of location application that the alternate site might be a more secure location. Mr. Logan requested clarity from Board members that were advocating for the approval based on security. Ms. Warriner commented that since the alternate location is a stand-alone facility, there would be better security as opposed to being in a building with other businesses. Also, potentially being located next to a casino does not lend itself to mixing well with medical care from a security standpoint. Mr. Bolyard commented that he does not feel that the Board should consider approving another location other than what was considered initially during the awarding of the conditional approvals. Ms. Warriner commented that she thoroughly reviewed all 51 applications and feels the Board would have awarded the same conditional approvals even if Dharma had listed the alternate site on its initial application.

MOTION:

The board voted 3-4 to approve the change of location application for Dharma Pharmaceuticals in Health Service Area 3, therefore, the motion

failed. (motion by Warriner, seconded by Thornbury; opposed by Nelson, Bolyard, Jenkins, Saenz; abstentions by Logan and Boone; Ratliff recused).

MOTION:

The Board voted 7-3 to finalize the awarding of the conditional approval for Dharma Pharmaceuticals at the location listed on the original application. (motion by Nelson, seconded by Bolyard; abstentions by Warriner, Boone, and Logan; Ratliff recused)

Request from Gates Healthcare Associates, Inc. regarding cGMP Inspections

The board reviewed the information presented by Gates Healthcare Associates. There was some discussion regarding the allowance for accepting cGMP inspections performed by Bestech, in lieu of an FDA inspection for licensure purposes. Mr. Johnson confirmed that there have been no issues of concern thus far. There was some discussion regarding whether a need existed for approving a second entity to perform these inspections.

MOTION:

The Board voted 3-0 to deny the request by Gates Healthcare Associates, Inc. (motion by Nelson, seconded by Richards-Spruill; abstentions by Saenz, Warriner, Thornbury, Logan, Jenkins, Bolyard, and Boone. It was determined that the motion did not pass due to the number of abstentions.)

MOTION:

The Board voted unanimously to obtain and review, in consultation with Mr. Johnson and Ms. O'Halloran, additional information from Gates Healthcare regarding its proposed inspection report and to further consider the expertise of the persons who would be performing the cGMP inspections. (motion by Logan, second by Warriner)

NEW BUSINESS

Presentation on Sanction Reference Points

Mr. Neal Kauder and Ms. Kim Small from Visual Research provided a training presentation on the Sanction Reference Points, explaining its creation and how the Board is currently utilizing it.

MOTION:

The Board voted unanimously to amend letter D on the SRP Worksheet for Pharmacists within Guidance Document 110-21 to read "Violations associated with multiple cases". (motion by Warriner, second by Boone)

Review of Pharmaceutical Processor Inspection Report

Mr. Johnson provided an overview of the current draft of the pharmaceutical processor inspection report. Mr. Johnson, Melody Morton and two pharmacy inspectors will be traveling to Connecticut in January to visit three pharmaceutical processor locations and learn more about CT's inspection process which may lead to additional amendments to the document. Current Good Manufacturing Practices (cGMP) information may be added to the inspection report prior to use of the form.

REPORTS

Chairman's Report

Mr. Saenz provided a report regarding the ASHP mid-year meeting that he attended. At the meeting, the discussions revolved around topics such as drug

shortages, Board of Pharmacy meetings, pharmacy technician training, and the roles of the pharmacy technician.

Report on Board of Health Professions

Mr. Logan did not information to share with the board at this time.

Report on NABP Interactive Member Forum

Ms. Warriner provided a report on the NABP interactive member forum that discussed topics such as opioid lawsuits, competency exams, and suspicious ordering. Ms. Warriner indicated that it was very informative to meet with other state board members to ascertain the work being done in other states.

Report on Licensure Program

Mr. Johnson reported the Board currently licenses 38,773 individuals and facilities. The Board issued 1,100 licenses and registrations for the period of September 1, 2018 through November 30, 2018. Inspectors conducted 562 facility inspections including 222 routine inspections of pharmacies: 109 (49%) resulted in no deficiency, 64 (29%) with deficiencies and 49 (22%) with deficiencies and a consent order. Mr. Johnson commented that two factors may have contributed to the reduction in inspections with a consent order: 1) the implementation of not issuing a consent order for the "First Documented Occurrence" for certain deficiencies that began on July 1, 2018 and 2) improved compliance by pharmacies as a result of the inspection program.

Report on Disciplinary Program

Ms. Shinaberry indicated Ileita Redd and Rose DeMatteo continue to assist with administrative functions in the absence of our Discipline Program Specialist. As of November 15, 2018, the Board had a total of 289 open cases. There were 23 cases pending an Informal Conference or Formal Hearing. There were only 7 patient-care cases at the Board level that exceeded 250 work-days, substantially below the 10% threshold for open cases. The board continues to experience a decrease in the number of inspection-related cases that result in a pre-hearing consent order. It was noted, however, that the complexity of cases is increasing as the board is seeing more cases involving fraud and indiscriminant dispensing, and mandatory suspensions of outsourcing facilities. The Board is currently recruiting for a Disciplinary Case Manager to assist with the caseload.

Executive Director's Report

Ms. Juran listed the meetings attended and presentations recently provided by board staff. She also provided a summary of board-related accomplishments over the past year and thanked board members and staff for their hard work and dedication.

MOTION FOR CLOSED MEETING:

Upon a motion by Ms. Nelson, and duly seconded by Mr. Jenkins, the Board unanimously voted to convene a closed meeting pursuant to Section 2.2-3711(A)(27) of the Code of Virginia for the purpose of deliberation to reach a decision in the matter of Cantrell Drug Company. In addition, Mr. Nelson moved that Caroline Juran, Jim Rutkowski, and Ellen Shinaberry attend the closed session because their presence was necessary and would reasonably aid the board.

MOTION TO RECOVENE OPEN MEETING:

Having certified that the matters discussed in the preceding closed meeting met the requirements of Virginia Code § 2.2-3712, the Board reconvened in open meeting and announced the decision.

DECISION:

The Board voted to accept the Consent Order for Cantrell Drug Company.

ADJOURN:

With all business concluded, the meeting adjourned at approximately 2:15pm.

Rafael Saenz, Chairman

3/24/19
DATE:

Caroline D. Juran, Executive Director

3/26/19
DATE: