DRAFT/UNAPPROVED

VIRGINIA BOARD OF PHARMACY
MINUTES OF BOARD MEETING

September 7, 2016
Second Floor
Board Room 2

Perimeter Center
9960 Mayland Drive
Henrico, Virginia 23233-1463

CALL TO ORDER: The meeting was called to order at 9:07am

PRESIDING: Rebecca Thornbury, Chairman

MEMBERS PRESENT:
Jody H. Allen
Melvin L. Boone, Sr.
Freeda Cathcart (arrived at 9:55am)
Michael I. Elliott
Sheila K. W. Elliott (arrived at 9:35am)
Ryan K. Logan
Rafael Saenz
Ellen B. Shinaberry
Cynthia Warriner (arrived 9:10am)

STAFF PRESENT:
Caroline D. Juran, Executive Director
J. Samuel Johnson, Jr., Deputy Executive Director
David Brown, Director, DHP
James Rutkowski, Assistant Attorney General
Elaine J. Yeatts, Senior Policy Analyst, DHP
Beth O'Halloran, Individual Licensing Manager

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

APPROVAL OF AGENDA: The agenda was amended to include new business, a request for waivers of the 91-day waiting period for retaking the NAPLEX examination after receiving a failing score. The agenda was approved as amended.

APPROVAL OF MINUTES: The following minutes were considered for approval:

- June 8, 2016, Special Conference Committee
- June 14, 2016, Full Board Meeting
- June 14, 2016, Public Hearing for Scheduling Certain Chemicals
- June 15, 2016, Inspection Special Conference Committee
- June 14, 2016, Special Conference Committee, 9am and 1pm
- August 15, 2016, Telephone Conference Call

MOTION: **The Board voted unanimously to adopt the minutes from June 8, 2016 through August 15, 2016 as presented.**
(motion by Warriner, second by Boone)

PUBLIC COMMENTS:

Marla Watson, legislative chair for Community Coalitions of Virginia and concerned parent, provided comment on the recommended language for the regulations regarding THC-A oil and cannabidiol oil. She reminded the Board that Cannabis is not an FDA-approved product and that the allowance for THC-A and cannabidiol oils for epilepsy will open the door to approval of other conditions in the future. Ms. Watson is concerned with comments made during the Regulatory Advisory Panel meeting regarding desires for the ability to dispense a 90-day supply, the ability for manufacturing and dispensing to occur at separate locations, and the ability to deliver the dispensed oils to the patient's residence.

John Lubkowski, Director, Augusta Health, provided comments regarding the new pilot inspection process using the draft NABP uniform inspection report. Mr. Lubkowski was pleased with the process, however, suggested that the flow of the inspection may be smoother if the pharmacy were to have the ability to fill out the interview portion prior to the inspection. Mr. Lubkowski stated that advance notice of 24-48 hours would be helpful as the interview portion may create a safety concern if the pharmacist were taken away from patient care for a period of time to be interviewed by the inspector.

Lennice Wirth, drug policy advocate, stated that the marijuana oils were much less toxic than other drugs for seizures. Ms. Wirth feels the allowance for 90-day supply is appropriate.

DHP DIRECTOR'S REPORT:

Dr. Brown offered his thanks to the Regulatory Advisory Panel for all their work and commended Ryan Logan for chairing the Panel and doing a tremendous job. Dr. Brown also thanked Ms. Juran and Ms. Yeatts for their work on the regulations.

Dr. Brown spoke about the Task Force on Heroin and Prescription Drug Abuse and its outcomes:

- The Board of Medicine convened a workgroup on buprenorphine. Best practices are scheduled to be presented to the Board of Medicine at its October meeting.
- PMP will have an advisory panel to establish criteria for identifying suspicious prescribing and dispensing activities which can be forwarded to the Enforcement Division for investigation.
- PMP also in a regulatory process to allow additional elements to be reported.
- Department of Health Professions (DHP) has taken the lead to establish a website on prescription drug abuse. DHP currently working with the Governor's office regarding implementation.

Dr. Brown also provided information regarding the upcoming board member training on October 24, 2016. He then reported that the two legislative proposals adopted by the board in June regarding collaborative practices and requiring PTCB certification received considerable negative feedback from key stakeholders and therefore, they would not be

advancing to the Secretary's office for consideration for the 2017 General Assembly session.

REGULATORY ACTIONS:

- Regulatory Update: Ms. Yeatts provided a handout with updated information regarding the status of pending regulatory actions.

- Legislative Update: Ms. Yeatts did not have any additional information to provide regarding a legislative update.

- Adoption of Regulation to Schedule Certain Chemicals in Schedule I: There was a public hearing conducted at 9:00am this morning pursuant to requirements of §54.1-3443 of the Drug Control Act. No comment was received during the hearing.

MOTION: **The Board voted unanimously to adopt an exempt action amendment of Regulation 18VAC110-20-322 as presented by adding subsection C which places the following chemicals into Schedule I:**

Classified as research chemicals:
- **1-propionyl lysergic acid diethylamide (other name: 1P-LSD)**
- **(2-methylaminopropyl)benzofuran (other name: MAPB)**

Classified as stimulants:
- **Ethyl phenyl(piperidin-2-ly)acetate (other name: Ethylphenidate)**
- **2-(3-flurophenyl)-3-methylmorpholine (other name: 3-flurophenmetrazine)**

Classified as powerful synthetic opioids:
- **N-(4-fluorophenyl)-N-[1-(2-phenylethyl)-4-piperidinyl] – butanamide (other name: para-fluorobutyrylfentanyl), its optical, positional, and geometric isomers, salts and salts of isomers. (motion by Warriner, second by Boone)**

REPORT FROM REGULATORY ADVISORY PANEL FOR ADOPTION OF EMERGENCY REGULATIONS FOR PHARMACEUTICAL PROCESSORS TO PRODUCE AND DISPENSE CANNABIDIOL OIL AND THC-A OIL: In response to SB701, the Regulatory Advisory Panel met on three occasions during the summer of 2016 to draft emergency regulations for consideration by the full board for pharmaceutical processors to cultivate, produce, and dispense cannabidiol oil and THC-A oil for the treatment of intractable epilepsy. These emergency regulations must be adopted within 280 days from the signing of the bill. However, an enactment clause on the bill requires the issue to be reconsidered by the 2017 General Assembly prior to the law or regulations becoming effective. If the bill changes, this Board will likely need to amend its regulations. The Board reviewed the recommended regulatory language and offered several amendments.

MOTION: **The Board voted 9 to 1 to amend the proposed emergency Regulation**

18VAC110-60-310 H by striking the words "in consultation with the certifying physician". (motion by Shinaberry, second by Warriner; Cathcart opposed)

MOTION:

The Board voted 8 to 0 with two abstentions to adopt the emergency regulations for pharmaceutical processors to cultivate, produce, and dispense cannabidiol oil and THC-A oil for the treatment of intractable epilepsy as amended and with the following additional amendments:

- **18VAC110-60-30, correct numbering sequence;**
- **18VAC110-60-170 (B), after "A pharmacist with a current, unrestricted license issued by the Virginia board shall provide personal supervision on the premises of the pharmaceutical processor at all times during hours of operation" insert "and at any time the facility is accessed";**
- **18VAC110-60-170 F, after "Persons who do not maintain licensure as a pharmacist or registration as a pharmacy technician, but have received a degree in chemistry, pharmacology, or have at least two years of experience extracting chemicals from plants may perform duties associated with the extraction of cannabidiol oil and THC-A oil" insert ", as authorized by the pharmacist-in-charge" to the end.**
- **18VAC110-60-170 H, after "At no time shall a pharmaceutical processor operate" insert "or be accessed". (motion by Allen, second by Saenz; Warriner and Cathcart abstained)**

ACTION ITEM:

There was consensus that an educational presentation should be provided to the board members on cannabidiol oil and THC-A oil and the associated law and regulations prior to issuing licenses for pharmaceutical processors. (recommend by S. Elliott)

ADOPT FAST TRACK REGULATIONS FOR THIRD-PARTY LOGISTIC PROVIDERS, NONRESIDENT MANUFACTURERS, AND TRACK AND TRACE REQUIREMENTS:

Ms. Yeatts explained that HB528 passed during the 2016 General Assembly conformed several sections of state law to Title II of the Drug Quality and Security Act. The bill authorized the Board to license in-state third-party logistics providers and non-resident manufacturers, struck requirements for a pedigree and required compliance with the federal track and trace requirements. The federal law precludes the individual states from licensing third-party logistic providers as wholesale distributors.

MOTION:

The Board voted unanimously to adopt as presented the fast-track regulatory amendments of 18VAC110-50-10 et seq. regarding third-party logistics providers, non-resident manufacturers and track and trace requirements. (motion by Warriner, second by S. Elliott)

ADOPT EXEMPT REGULATIONS FOR NONRESIDENT MEDICAL

Ms. Yeatts reviewed HB527 which created a new licensing category for nonresident medical equipment suppliers. She explained that the existing applicable fees for medical equipment suppliers would apply to the

EQUIPMENT SUPPLIERS:

nonresident medical equipment suppliers and there was no need to specifically delineate this in the fees section. The only suggested amendment is in 18VAC110-20-680 E which states, "A nonresident medical equipment supplier shall register and practice in accordance with 54.1-3435.3:1 of the Code of Virginia." The amendment could be made through an exempt action.

MOTION:

The Board voted unanimously to adopt the exempt regulatory action as presented regarding nonresident medical equipment suppliers by creating a subsection E which states "A nonresident medical equipment supplier shall register and practice in accordance with 54.1-3435.3:1 of the Code of Virginia." (motion by Warriner, second by S. Elliott)

PETITIONS FOR RULEMAKING

- Permit pharmacists to dispense quantity of Schedule VI greater than face amount prescribed, up to total amount authorized

The Board reviewed a request from Derek Phillips to permit a pharmacist to dispense a quantity of a Schedule VI drug greater than the face amount prescribed, up to the total amount authorized in refills. During the comment period which ended June 29, 2016, the board received one comment which supported the request. Currently a pharmacist may not dispense more than the specific quantity prescribed at each dispensing and may not exceed that quantity by taking authorized refills into consideration.

MOTION

The Board voted unanimously to accept the petition for rulemaking authorizing a pharmacist, when deemed appropriate in his professional judgement and upon request by the patient, to dispense a quantity of a Schedule VI drug, excluding psychotherapeutic drugs, in excess of the specific quantity prescribed for a dispensing, not to exceed the total amount authorized in refills and to adopt a notice of intended regulatory action (NOIRA). (motion by Warriner, second by Saenz)

- Permit the use of electronic devices in lieu of manual emergency kits and stat drug boxes

The Board reviewed a request from Roger StClair to amend 18VAC110-20-540, 18VAC110-20-550 and 18VAC110-20-555 to authorize the use of electronic devices in lieu of manual emergency drug kits and stat-drug boxes. The petition states that current regulation does not distinguish between automated dispensing devices being utilized for first dose non-routine administration vs routine drug administration. Ms. Juran explained that DEA does not require a provider pharmacy to a long term care facility to obtain DEA registration for the use of an automated dispensing device in the facility if the device is used solely for obtaining drugs for non-routine "emergency" administration. DEA does require the provider pharmacy to obtain a DEA registration at the address of the long term care facility for the automated dispensing device if the device is for obtaining drugs for routine administration. Currently, 18VAC110-20-555 authorizes the use of an automated dispensing device in a nursing home and requires a nursing home without an in-house pharmacy to obtain

a controlled substances registration prior to using an automated dispensing system, regardless of its intended use for obtaining routine or non-routine drugs. Additionally, while 18VAC110-20-555 3c does allow access to drugs in the device that would be stocked in an emergency drug kit pursuant to 18VAC110-20-540, it does not specifically authorize access to drugs that would be stocked in a stat-drug box in 18VAC110-20-550. However, the board has historically applied the regulation in a manner to permit such. Lastly, Mr. Johnson indicated the quantity limitations of Schedule II-V drugs in 18VAC110-20-550 5b may not be appropriate when using an automated dispensing device.

MOTION:

The Board voted unanimously to accept the petition for rulemaking and adopt a notice of intended regulatory action (NOIRA) for amending Regulation 18VAC110-20-555 to specifically authorize the use of an automated dispensing device in a nursing home for obtaining drugs that would be stocked in a stat-drug box and to clarify the quantity of drugs in Schedules II-V that may be stocked in the device for this purpose, and to consider the appropriateness of requiring a provider pharmacy to the nursing home to obtain a controlled substances registration at the location of the facility for the purpose of placing an automated dispensing device in the facility. (motion by Saenz, second by M. Elliott)

OLD BUSINESS:

- Consideration for accepting inspection from Bestech GMP Contracting, Inc. in lieu of FDA inspection for outsourcing facility

Matthew Bestercy, Owner and Principal Consultant for Bestech GMP Contracting, Inc., provided a handout with additional information for board consideration in follow-up to the discussion during the June 2016 full board meeting. He is requesting the board to accept an inspection report of outsourcing facilities resulting from inspections performed by his company for satisfying the requirement for an outsourcing facility to submit a current inspection report when the FDA has not performed an inspection in the required timeframe as authorized in 54.1-3434.05 and 54.1-3434.5. Bestech would provide the board with the complete inspection report, collect a written corrective action plan from the outsourcing facility within 15 days of the inspection, and provide the board with a written opinion regarding the appropriateness of the written corrective action plan. Mr. Bestercy indicated his inspectors would be able to provide testimony during a disciplinary case, if necessary. It was stated that all inspection reports of outsourcing facilities resulting from an FDA inspection must be considered by the board and that an inspection from Bestech would not preclude this requirement. However, the board could consider accepting an inspection from Bestech for licensure purposes when the FDA had not performed an inspection in the required timeframe.

MOTION:

The board voted 7 to 3 in support of accepting an inspection report

from Bestech GMP Contracting, Inc. for licensure purposes of outsourcing facilities when the FDA has not performed an inspection within the required timeframe for a "current" inspection report pursuant to 54.1-3434.05 and 54.1-3434.5. (motion by Saenz, second by Shinaberry; M. Elliott, Boone, and S. Elliott opposed)

NEW BUSINESS:

- Amend Bylaws

Ms. Juran stated the description of the Examination Administrator Selection Committee and Item Review Committee in the bylaws needed to be amended to reflect the change from no longer administering the Virginia Federal and State Drug Law Exam and the board's participation in the Multistate Pharmacy Jurisprudence Examination.

MOTION:

The Board voted unanimously to amend the bylaws as presented. (motion by S. Elliott, second by Cathcart)

- FDA Guidance Document, Insanitary Conditions at Compounding Facilities

The open comment period for an FDA proposed a Guidance Document regarding Insanitary Conditions at Compounding Facilities closes October 3, 2016. The board considered a draft comment supporting the publishing of the guidance document as written.

MOTION:

The Board voted unanimously to submit the draft comment as presented to support the FDA publishing the proposed guidance document for insanitary conditions at compounding facilities as written. (motion by Allen, second by Logan)

- Requests for Waivers of the 91-day Waiting Period between Retakes of the NAPLEX after Receiving a Failing Score

Ms. Juran stated that the National Association of Boards of Pharmacy (NABP) currently requires a candidate who fails the NAPLEX examination to wait 91 days before being eligible to sit for the exam again. However, NABP will decrease this waiting period to 45 days effective November 1, 2016. In the interim, NABP will allow a candidate to test after waiting 45 days if a board approves such a waiver. Board staff has received approximately 5 waiver requests. Most are residents who failed their first attempt at NAPLEX. They are requesting a shorter waiting period for retaking NAPLEX so as to remain eligible for their residency program or to progress through the residency program in a timeframe that is contemporary with their peers who passed NAPLEX.

MOTION:

The board voted 8 to 2 to reduce the waiting period between retakes of the NAPLEX examination to 45 days and to apply this approval retroactively to any candidates who recently received a failing score on the NAPLEX. (motion by M. Elliott, second by Cathcart; Warriner and S. Elliott opposed)

REPORTS:

- Chairman's Report

Ms. Thornbury provided a report to the Board mentioning that three

members, Allen, Warriner, and Cathcart, had been appointed by the NABP President to serve on NABP committees later this year, along with Ms. Juran who will serve as an NABP Executive Committee liason to one of committees. Ms. Thornbury reminded everyone of the upcoming NABP/AACP Districts 1 and 2 Meeting to be held in West Virginia on September 15, 16 and 17th. Ms. Warriner, Mr. Boone, Ms. Juran, Ms. Shinaberry, and Mr. Logan are planning to attend this meeting. Ms. Thornbury encouraged each member to attend the DHP board member training in October. Ms. Thornbury thanked Ms. Warriner for her service to the Board as the previous chairman.

- Report on the Board of Health Professions

Mr. Logan stated the agency is developing a website on prescription drug and heroin abuse which is an initiative resulting from the Governor's Task Force on Heroin and Prescription Drug Abuse. It will be unveiled in the near future.

- Report on Licensure Program:

Mr. Johnson provided a handout and reported the Board currently licenses 36,814 individuals and facilities. The Board issued 1,452 licenses and registrations for the period of June 1, 2016 through August 31, 2016. Inspectors conducted 492 facility inspections including 204 routine inspections of pharmacies: 46 (23%) resulted in no deficiency, 84 (41%) with deficiencies and 74 (36%) with deficiencies and a consent order. Mr. Johnson also discussed a chart providing a graphic display of inspection deficiencies by quarter since September 2012. Mr. Johnson reviewed the report of Inspection Deficiencies. It was noted that deficiency 142, regarding compliance with CQI requirements, is the most frequently cited deficiency. Other frequently cited deficiencies include deficiency 15 regarding the perpetual inventory, deficiency 109 regarding expired drugs, deficiency 113 regarding drug inventories, and deficiency 130a regarding the labeling of compounded drug products

- Report on Disciplinary Program:

Ms. Juran stated that Ms. Reiniers-Day is on approved leave. No handout of a report is available at this time. However, she reported that the clearance rate for cases is down from previous reporting periods due to staffing shortages. Anne Joseph from the Administrative Proceedings Division is currently assisting board staff on a temporary basis with the processing of cases in an effort to improve the clearance rate.

- Executive Director's Report:

Ms. Juran provided a handout of her report which summarizes outside meetings attended recently or presentations provided and those scheduled in the near future. Additionally, she reported that the transition to the MPJE examination occurred July 1, 2016 and occurred smoothly. There has been no significant change in the passing rate for Virginia applicants and staff has recently completed its annual review of the item pool for the MPJE. She also reported that the Enforcement Division recently piloted the draft NABP uniform inspection form in approximately 10 pharmacies and is providing feedback to NABP on the form. Lastly, she reported that staff is currently recruiting for two vacant P-14 administrative assistant positions and

one full-time administrative assistant to support the disciplinary program. Two temporary workers were also recently hired, one of which is dedicated to a scanning project for scanning the facility licensure files so as to move toward an electronic recordkeeping system.

MEETING DATES FOR 2017:

The Board discussed meeting dates for 2017 and decided upon the dates as follows:

Full Board meetings:

- March 21, 2017
- June 27, 2017
- September 26, 2017
- December 11, 2017

Regulation Committee Meetings:

- May 10th or 31st, 2017
- November 2, 2017

SUMMARY SUSPENSION:

SHERRI A. KNOX
Registration No: 0230-018157

Wayne Halbleib, Senior Assistant Attorney General, presented a summary of the evidence in the case for the Board to consider a summary suspension. Mykl D. Egan, DHP Adjudication Specialist, was also present.

MOTION:

Upon a motion by Ms. Warriner, and duly seconded by Mr. Boone, the Board voted 8-0 in favor of the motion that, according to the evidence presented, the continued practice by Sherri A. Knox, as a pharmacy technician poses a substantial danger to the public; and therefore, the registration of Sherri A. Knox to practice as a pharmacy technician be summarily suspended. Further, in lieu of a formal hearing, a Consent Order shall be offered to Ms. Knox for the revocation of her pharmacy technician registration.

CONSIDERATION OF CONSENT ORDERS

Closed Meeting:

Upon a motion by Ms. Thornbury, and duly seconded by Ms. Warriner, the Board voted 9-0 to convene a closed meeting pursuant to § 2.2-3711(A)(27) of the Code of Virginia for the purpose of deliberation to reach a decision in the matter of a Consent Order. Additionally, she moved that Caroline D. Juran, J. Samuel Johnson, Jr., Beth O'Halloran, and James Rutkowski attend the closed meeting because their presence in the closed meeting was deemed necessary and would aid the Board in its deliberations.

Reconvene: The Board voted unanimously that only public business matters lawfully exempt 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 meeting were heard, discussed or considered during the closed meeting.

MOTION: **Upon a motion by Ms. Warriner and duly seconded by Mr. Saenz, the Board voted 8-0 in favor of accepting the Consent Order as presented by Ms. Juran in the matter of Lindy M. Knight, a pharmacy technician.**

ADJOURN: With all business concluded, the meeting adjourned at approximately 3:25pm.

_____
Rebecca Thornbury, Chairman

_____
Caroline D. Juran, Executive Director

_____
DATE:

_____
DATE:

(DRAFT/UNAPPROVED)

VIRGINIA BOARD OF PHARMACY
PUBLIC HEARING FOR SCHEDULING CERTAIN SUBSTANCES

September 7, 2016
Second Floor
Board Room 2

Perimeter Center
9960 Mayland Drive
Henrico, Virginia 23233-1463

CALL TO ORDER: The public hearing was called to order at 9:05a.m.

PRESIDING: Rebecca Thornbury, Chairman

MEMBERS PRESENT:
Melvin L. Boone, Sr.
Ryan K. Logan
Raphael Saenz
Ellen B. Shinaberry
Jody H. Allen
Michael Elliott

MEMBERS ABSENT:
Sheila K. W. Elliott
Cindy Warriner
Freeda Cathcart

STAFF PRESENT:
Caroline D. Juran, Executive Director
J. Samuel Johnson, Jr., Deputy Executive Director
Beth O'Halloran, Individual Licensing Manager
David E. Brown, D.C., Director, DHP
Elaine J. Yeatts, Senior Policy Analyst, DHP
James Rutkowski, Assistant Attorney General

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

Pursuant to subsection D of 54.1-3443 of the Code, a public hearing to consider placement of chemical substances in Schedule I of the Drug Control Act was held. If approved by the Board of Pharmacy, the placement of these substances in Schedule I in the Virginia Drug Control Act shall go into effect 30 days following publication of the proposed regulation and remain in effect for a period of 18 months. The chemicals will then be de-scheduled unless a general law is passed by the General Assembly placing the chemicals into Schedule I.

CALL FOR COMMENT: Ms. Thornbury called for comment to consider placement of the following chemical substances into Schedule I:

Classified as research chemicals:

- 1-propionyl lysergic acid diethylamide (other name: 1P-LSD)

- (2-methylaminopropyl)benzofuran (other name: MAPB)

Classified as stimulants:

- Ethyl phenyl(piperidin-2-ly)acetate (other name: Ethylphenidate)
- 2-(3-flurophenyl)-3-methylmorpholine (other name: 3-flurophenmetrazine)

Classified as powerful synthetic opioid:

- N-(4-fluorophenyl)-N-[1-(2-phenylethyl)-4-piperidinyl] – butanamide (other name: para-fluorobutyrylfentanyl), its optical, positional, and geometric isomers, salts and salts of isomers

No public comment was provided.

ADJOURN: The public hearing adjourned at 9:07am.

Rebecca Thornbury, Chairman

Caroline D. Juran, Executive Director

Date

Date