

FINAL/APPROVED

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

March 29, 2018
Second Floor
Board Room 4

Perimeter Center
9960 Mayland Drive
Henrico, Virginia 23233-1463

- CALL TO ORDER: The meeting was called to order at 9:17AM
- PRESIDING: Ryan K. Logan, Chairman
- MEMBERS PRESENT: Jody Allen
Melvin L. Boone, Sr.
Freeda Cathcart
Michael I. Elliott (arrived at 9:18)
Sheila K. W. Elliott
Rafael Saenz
Rebecca Thornbury
- MEMBERS ABSENT: Cynthia Warriner
- STAFF PRESENT: Caroline D. Juran, Executive Director
James Samuel Johnson, Jr. Deputy Executive Director
Beth O'Halloran, Deputy Executive Director
Ellen B. Shinaberry, Deputy Executive Director
Barbara Allison-Bryan, Chief Deputy Director, DHP
James Rutkowski, Assistant Attorney General
Elaine J. Yeatts, Senior Policy Analyst, DHP
Sylvia Tamayo-Suijk, Executive Assistant
- QUORUM: With eight members present, a quorum was established.
- APPROVAL OF AGENDA: The agenda was amended to include:
- The minutes list was corrected to reflect that the December minutes were for 2017, not 2018.
 - Amending Guidance Document 110-44 "Protocol for the Prescribing of Naloxone and Dispensing by Pharmacists and Distribution to Authorized Entities", and
 - Requesting guidance from the Board regarding whether certain tasks associated with medication synchronization were tasks restricted to a pharmacy technicians
- The Board voted unanimously to approve the agenda as amended. (motion by Cathcart, second by Saenz)**
- APPROVAL OF MINUTES: The following minutes were considered for approval:
- December 4, 2017, Inspection Special Conference Committee
 - December 7, 2017, Special Conference Committee
 - December 11, 2017, Public Hearing for Scheduling Certain

Chemicals

- December 11, 2017, Full Board Meeting
- January 11, 2018, Telephone Conference Call
- January 17, 2018, Special Conference Committee
- February 14, 2018, Special Conference Committee
- February 27, 2018, Formal Hearings

MOTION: **The Board voted to adopt the minutes from December 4, 2017 through February 27, 2018 as presented. (motion by Allen, second by Boone; Thornbury abstained)**

PUBLIC COMMENTS: There was no public comment.

DIRECTOR'S REPORT: Dr. Allison-Bryan, Chief Deputy Director of the Department of Health Professions, delivered the report on behalf of Dr. Brown. Dr. Allison-Bryan introduced herself, shared that she has been a pediatrician for 20 years, and as a former member of the Board of Medicine, she convened two regulatory advisory panels relating to opioids. She further stated that Dr. Daniel Carey, formerly Chief Medical Officer of Centra, has been appointed as the new Secretary of Health and Human Resources and Marvin Figueroa is the new Assistant Deputy Secretary. Dr. Allison-Bryan confirmed that Dr. Brown was reappointed as Director of DHP and that Lisa Hahn, former Chief Deputy Director, is the new Chief Operations Officer. This position will provide continuity from one administration to another. Dr. Allison-Bryan mentioned that DHP has a new logo, that the agency has migrated from Outlook to Google email, and that the Business and IT Departments have relocated to the new office space on the first floor of the building.

**LEGISLATIVE &
REGULATORY ACTIONS:**

- Legislative Update on 2018 General Assembly: Ms. Yeatts provided an overview of the summary of bills contained in the agenda packet which were recently considered by the General Assembly. She highlighted several bills related to pharmacy:
- Regulatory Update: Ms. Yeatts reviewed the chart of regulatory actions provided in the agenda packet and gave updates on the status.
- Adoption of exempt regulation to add certain chemicals to Schedule I: There was a Public Hearing conducted at 9:13 a.m. this morning pursuant to the requirements of §54.1-3443 of the Drug Control Act.

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

- **2-(ethylamino)-2-phenyl-cyclohexanone (other name: deschloro-N-ethyl-ketamine)**

- 3,4-methylenedioxy-N-tert-butylcathinone
- 4-fluoro-N-ethylamphetamine
- beta-keto-4-bromo-2,5-dimethoxyphenethylamine (other name: bk-2C-B)

Classified as powerful synthetic opioids:

- N-phenyl-N-[1-(2-phenylethyl)-4-piperidinyl]-2-butenamide (other name: Crotonyl fentanyl)
 - 2-(3,4-dichlorophenyl)-N-[2-(dimethylamino)cyclohexyl]-N-methylacetamide (other name: U-51754)
 - N-phenyl-N-[4-phenyl-1-(2-phenylethyl)-4-piperidinyl]-propanamide (other name: 4-phenylfentanyl)
- (motion by Saenz, second by S. Elliott)

**PETITION FOR
RULEMAKING:**

- Amend 18VAC110-20-240, *Manner of maintaining records, prescriptions, inventory records*

The Board reviewed a petition for rulemaking submitted by Judy Dietrick to amend Regulation 18VAC110-20-240 to extend the requirement for retention of records beyond two years, to include records of vaccine administration. The Board reviewed the comments regarding this petition and several questions arose. One was regarding the reporting to the VIIS system for immunizations. Ms. Allyson-Bryant informed the Board that reporting to the VIIS system is only required for EMS, although several physicians voluntarily register with VIIS for reporting even though it is not required. The request to maintain records of immunizations longer than the required 2 years was discussed and it was stated this may be overly burdensome based on volume of records. Ms. Allen noted that since there was already a system in place to report to the VIIS, possibly the Board should discuss requiring pharmacies to register and report to the system for immunizations. Ms. Yeatts stated this would be a legislative change to require such registration.

MOTION:

The Board voted unanimously to deny the petition for rulemaking and to refer the subject to the Regulation Committee for exploration of further options for immunization reporting and improvements to records retention. (motion by Allen, second by M. Elliott)

**ADOPTION OF PROPOSED
REGULATIONS FOR:**

- Requirement for E-profile number on applications

Ms. Yeatts provided a handout of the suggested regulatory language to require pharmacists, pharmacy technicians, and pharmacy interns to provide an e-profile ID number upon application and renewal.

MOTION:

The Board voted unanimously to adopt proposed language to require pharmacists, pharmacy technicians, and pharmacy interns to provide an E-profile ID number upon application and renewal. (motion by Cathcart, second by Boone)

- Fee increase for all

Staff provided several handouts to the Board indicating the Board will

professions and facilities

experience a shortfall in the coming years if it does not increase its licensure fees. Charles Giles, DHP Budget Manager provided background information explaining the need for an increase in fees. The last fee increase was in 2002 and in those 16 years the following expenditure increases have occurred:

- 283% increase in the number of licensees
- 12 Full time employees at the Board vs. 6 in 2002
- 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

Ms. Yeatts and Ms. Juran provided additional comments for why this fee increase is necessary. Ms. Cathcart provided comment in opposition of raising fees for free clinic pharmacies.

MOTION:

The Board voted 7 to 1 to adopt the proposed fee increases for all Board of Pharmacy professions and facilities as presented. (motion by S. Elliott, second by Boone; Cathcart opposed)

- Amend Guidance Document 110-44, *Protocol for the Prescribing of Naloxone and Dispensing by Pharmacists and Distribution to Authorized Entities*

A handout was provided by staff. The Department of Behavioral Health and Developmental Services found the word “kit” and its specific contents to be confusing for licensees. Therefore, they requested that the language be removed from the guidance document.

MOTION:

The Board voted unanimously to amend Guidance Document 110-44, *Protocol for the Prescribing of Naloxone and Dispensing by Pharmacists and Distribution to Authorized Entities*, as presented. (motion by S. Elliott, second by Boone)

- Amend Guidance Document 110-45, *Protocol for the Prescribing of Naloxone and Dispensing by Trainers*

A handout was provided by staff. HB842 was recently passed which allows a Department of Behavioral Health and Developmental Services-approved REVIVE! trainer the ability to provide syringes and needles for the administration of naloxone in accordance with 54.1-3408(Y). Therefore, amendments of Guidance Document 110-45 are required to authorize the dispensing of injectable naloxone with syringes.

MOTION:

The Board voted unanimously to amend Guidance Document 110-45, *Protocol for the Prescribing of Naloxone and Dispensing by Trainers*, as presented in the handout. (motion by Saenz, second by Allen)

- Amend Guidance Document 110-5, *Theft*

Ms. Juran indicated the suggested language regarding theft or loss reporting had been twice reported in board e-newsletters, but that staff

or Loss of Drugs

recommends it be captured in a guidance document to increase access and awareness to the information.

MOTION:

The Board voted unanimously to amend Guidance Document 110-5, *Theft or Loss of Drugs*, to include the additional information as presented. (motion by Thornbury, second by S. Elliott)

- Amend Guidance Document 110-47, *Guidelines for Provision of Counseling and Information by Pharmacists regarding Proper Disposal of Unused Dispensed Drugs*

Ms. Juran stated that she was contacted by a VDH medical director requesting the board encourage pharmacies to provide drug deactivation or disposal pouches when dispensing opioids. It was determined that the Board may wish to include this disposal option in Guidance Document 110-47 in an effort to increase awareness of this option. There was discussion as to why Virginia differs from other states with respect to their drug take-back programs.

MOTION:

The Board voted unanimously to amend Guidance Document 110-47, *Guidelines for Provision of Counseling and Information by Pharmacists regarding Proper Disposal of Unused Dispensed Drugs*, to include the new language as presented. (motion by Cathcart, second by M. Elliott)

ACTION ITEM:

Board staff will research how the state could increase the number of drug collection boxes throughout Virginia and a means of reducing drug destruction-related costs. Staff will also research the possibility of NABP encouraging pharmacies to implement more collection boxes for drug destruction. Staff will report information back at a future meeting.

NEW BUSINESS:

- Request from Gates Healthcare Associates, Inc. regarding cGMP inspections

Ernie Gates, President and CEO of Gates Healthcare Associates and Denise Frank, former MN Board member and former NABP inspector provided a presentation regarding the FDA 503B/cGMP Compliance services provided by Gates Healthcare Associates. Because facilities in Virginia are getting products from other states, and FDA inspections are not always timely, Gates Healthcare Associates can assist to ensure that out of state facilities are compliant. Ms. Juran stated that in the past, outside entities wishing to have their cGMP inspections for initial application of an outsourcing facility, accepted by the Board, were required to provide:

- A sample inspection report and the requirement of a written response to the inspection report within 15 days
- A willingness to testify at a hearing if needed
- Background on each of the inspectors

Mr. Johnson asked if the Gates Healthcare cGMP inspection report was being accepted for licensure of outsourcing facilities in other states. Mr. Gates indicated that it was not, however, Gates Healthcare will be visiting

several other states within the coming weeks to make a similar presentation. Mr. Gates and Ms. Frank indicated they would provide board staff with a copy of their inspection report for review and further consideration.

- Update on
Pharmaceutical
Processor Request for
Application Process

Ms. Juran indicated the Request for Applications for the pharmaceutical processor permits would open in the near future and that registered users of Regulatory Town Hall would receive an electronic notification once it has been posted. She requested the Board delegate authority to the Chairman, in consultation with the Executive Director, to appoint persons to an ad hoc committee for reviewing the applications. The ad hoc committee would tentatively recommend to the full Board in September which applicants should be potentially awarded conditional approval. Once conditional approval is received, the applicant would have one year to operationalize the facility. An application for initial permit with fee would then be submitted, a final inspection would be performed, and if compliant, the pharmaceutical processor permit would be issued. The facility could then possess Cannabis seeds for cultivation and production of the CBD or THC-A oil.

Ms. Juran reminded staff and Board members that this is a competitive application process and to direct all inquiries to her. She informed the members that a procurement officer has advised that the names of the ad hoc committee members must remain confidential during the application review process. Mr. Rutkowski also provided the ethics rule in a procurement process that includes a prohibition of providing non-public information to a bidder and a prohibition on accepting gifts from a bidder.

MOTION:

The Board voted unanimously to delegate authority to the Board of Pharmacy Chairman, in consultation with the Executive Director, to appoint members to an ad hoc committee for reviewing pharmaceutical processor permit applications. (motion by Cathcart, second by Saenz)

- Medication
Synchronization and
Duties of a Pharmacy
Technician

Ms. Juran indicated a pharmacist working for a pharmacy that offers medication synchronization as a service to patients wanted to know if a non-pharmacy technician could perform the following tasks:

- identify which patients would soon be in need of medications based on the last date of fill; and,
- Send a request for additional refills to the prescriber's office, if the patient required additional refills.

The pharmacist informed Ms. Juran that the non-pharmacy technician would not receive the response to the request for additional refills, but that the response would be transmitted directly from the prescriber's office to the pharmacist or pharmacy technician on-duty. Additionally, the non-pharmacy technician would not perform any data entry.

Mr. Saenz stated there should not be any harm with performing these tasks as described.

MOTION:

The Board voted unanimously that a person working in a pharmacy who is not registered as a pharmacy technician or pharmacist could identify patients for medication synchronization and transmit a refill authorization request to a prescriber's office but may not perform data entry of prescriptions or any subsequently authorized refills. (motion by Cathcart, second by Allen)

ACTION ITEM:

Develop a Guidance Document of pharmacy technician exempt duties in the future and look at the pharmacist to pharmacy technician ratio.

REPORTS:

- Chairman's Report: Mr. Logan stated that he had nothing to report at this time.
- Report on Board of Health Professions: Mr. Logan stated that he had nothing to report at this time.
- Report on Licensure Program: Mr. Johnson reported the Board currently licenses 32,502 individuals and facilities. The Board issued 957 licenses and registrations for the period of December 1, 2017 through February 28, 2018. Inspectors conducted 272 facility inspections including 232 routine inspections of pharmacies: 77 (33%) resulted in no deficiency, 77 (33%) with deficiencies and 78 (34%) with deficiencies and a consent order. Mr. Johnson reviewed the chart providing a graphic display of inspection deficiencies by quarter since September 2016 and reviewed the most frequently cited deficiencies for the reporting period.
- Report on Disciplinary Program: Ms. Shinaberry reported that DHP's goal is to maintain a 100% case clearance rate; in Q2 2018, the Board of Pharmacy's clearance rate was 121%. DHP's goal for pending caseload older than 250 days is no greater than 20%; in Q2 2018, the Board of Pharmacy's clearance rate was 9%. DPHs' goal for percent of cases closed within 250 business days is 90%; in Q2 2018, the Board of Pharmacy was at 84%. Ms. Shinaberry reported that as of March 23, 2018, the Board had 281 open cases with 112 being patient care cases and 169 being non-patient care cases.
- Executive Director's Report: Ms. Juran reviewed her report with the board. She provided an update on three ongoing projects: implementation of oversight for pharmaceutical processors, amending the routine pharmacy inspection report to include USP Chapter<800>, and review of the current routine pharmacy inspection process. She discussed upcoming or recent meetings which she attended and indicated that she presented at the VACDS meeting in January and at VCU School of Pharmacy in February. At the May NABP Annual Meeting, Ms. Juran will moderate a Medical Marijuana presentation. Ms. Juran welcomed former board member, Ellen Shinaberry, who joined the Board in February 2018 as Deputy Executive

Director. Ms. Shinaberry will travel to the May NABP Annual Meeting to give a presentation on how PMP data is used in the regulatory environment. Ms. Juran indicated that there is a vacancy for Deputy Executive Director for Discipline and a vacancy for an Executive Assistant.

OTHER BUSINESS:

Melody Morton introduced herself as the new Inspections Manager of Enforcement. She shared that in an effort to reduce the cost of inspections, the Enforcement division proposes to add a residency requirement for its inspectors to help reduce travel costs.

**CONSIDERATION OF
CONSENT ORDER**

Closed Meeting:

Upon a motion by Mr. Elliott, and duly seconded by Ms. Allen, the Board voted 8-0 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 one Consent Order. Additionally, he moved that Ellen Shinaberry, Caroline D. Juran, Sammy Johnson, Jim Rutkowski and Sylvia Tamayo-Suijk attend the closed meeting because their presence in the closed meeting was deemed necessary and would aid the Board in its deliberations.

Reconvene:

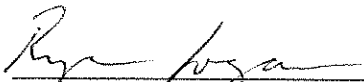
The Board voted unanimously that only public business matters lawfully exempt from open meeting requirements under the Virginia Freedom of Information Act and only such public business matters as were identified in the motion for closed meeting were heard, discussed or considered during the closed meeting.

MOTION:

Upon a motion by Ms. Allen and duly seconded by Mr. Boone, the Board voted 8-0 in favor of accepting the Consent Order as presented by Ms. Juran in the matter of Anthony J. Labashouskly, Pharmacist.

ADJOURN:


With all business concluded, the meeting adjourned at approximately 12:26 pm.



Ryan Logan, Chairman

6/21/18

DATE:



Caroline D. Juran, Executive Director

6/21/18

DATE: