(FINAL/APPROVED)

VIRGINIA BOARD OF PHARMACY
MINUTES OF BOARD MEETING

June 27, 2017
Second Floor
Board Room 2

Perimeter Center
9960 Mayland Drive
Henrico, Virginia 23233-1463

CALL TO ORDER: The meeting was called to order at 9:12AM.

PRESIDING: Rebecca Thornbury, Chairman

MEMBERS PRESENT:
Melvin L. Boone, Sr.
Freeda Cathcart
Michael I. Elliott
Sheila K. W. Elliott (arrived at 11:10)
Rafael Saenz
Cynthia Warriner

MEMBERS ABSENT:
Jody H. Allen
Ryan Logan
Ellen B. Shinaberry

STAFF PRESENT:
Caroline D. Juran, Executive Director
Cathy M. Reiniers-Day, Deputy Executive Director
J. Samuel Johnson, Jr., Deputy Executive Director
Beth O'Halloran, Deputy Executive Director
David Brown, Director, DHP
Elaine J. Yeatts, Senior Policy Analyst, DHP
James Rutkowski, Assistant Attorney General
Sylvia Tamayo-Suijk, Executive Assistant

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

APPROVAL OF AGENDA: An amended agenda was provided to the board which included an additional topic - amendment of Guidance Documents 110-44 and 110-45 regarding naloxone protocols.

Motion: **The Board voted unanimously to approve the amended agenda that included amending Guidance Documents 110-44 and 110-45 (naloxone protocols) as presented (motion by Saenz, second by Cathcart)**

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

- March 21, 2017, Public Hearing of Scheduling Certain Chemicals
- March 21, 2017, Full Board Meeting
- March 22, 2017, Special Conference Committee
- April 4, 2017, Possible Summary Suspension
- April 4, 2017, Formal Hearings
- April 25, 2017 Special Conference Committee

- May 10, 2017, Regulation Committee
- May 30, 2017, Special Conference Committee
- June 8, 2017, Special Conference Committee

Motion:

The Board voted unanimously to adopt the minutes from March 21, 2017 through June 8, 2017 as presented. (motion by Warriner, second by Boone)

PUBLIC COMMENTS:

Patrick Wiggins, Health Systems Interventions Coordinator with the Virginia Department of Health, provided comment with regard to pharmacists and their role in collaborative practice agreements. Mr. Wiggins is partnering with the four pharmacy schools in Virginia to ascertain the scope a pharmacist may have within a collaborative practice and hopes the Board would assist in collecting this information. Mr. Wiggins requested the Board consider adding four questions to the annual pharmacist healthcare workforce survey given to all licensees upon renewal. The questions are as follows:

- Does your pharmacy have collaborative practice agreement?
- If yes, what type of collaborative practice agreement?
- How many licensed pharmacists in your pharmacy participate in the collaborative practice agreement?
- Does your pharmacy plan to implement a collaborative practice within the next year?

Michael Thomas and Michelle Sutherland, consultants representing Temp Time, provided support for the ad-hoc committee created by HB1956 to discuss a possible by which a consumer may be able to determine if there were any issues with temperature during the shipping of their temperature-sensitive medications. Mr. Thomas provided a letter from Mike Rush, Executive Director for Temp Time, to the Board also in support of such ad-hoc committee.

Kristen Russo, patient advocate for people living with arthritis, discussed her own personal experiences with temperature-sensitive medications such as biologics arriving via mail order with issues regarding temperature control.

Chloe Shaffer, PGY1 community based resident for Kroger, appeared on behalf of David Flammia with Kroger to discuss their opposition to the pending regulatory change to require a minimum of two years of experience for a pharmacist prior to being deemed eligible to be a pharmacist-in-charge. Ms. Shaffer believes the determination for a pharmacist-in-charge should be based on the individual and not simply on the number of years of practice. Ms. Juran thanked Ms. Shaffer for her comments but also reminded her that her comments may not be considered by the Board at this meeting and encouraged her to comment on this action once the public comment period has begun for this regulatory change.

Jeenu Philip, Senior Manager for Pharmacy Affairs with Walgreens, echoed the comments of Ms. Shaffer. Mr. Philip also commented on the pending regulatory change requiring a manual signature on prescriptions and made a recommendation to forgo this requirement.

Joseph Domino, representing a medical marijuana company located out-of-state provided comment on SB1027 allowing the Board to issue pharmaceutical processor permits. Mr. Domino had several questions regarding the cost, application and process for applying for such permit. Ms. Juran provided information with regard to the emergency regulations that were awaiting signature by the Governor.

DIRECTOR'S REPORT:

Dr. David Brown, Director of the Department of Health Professions, introduced and welcomed Ms. Michele Schmitz, the new Executive Director for Enforcement. Ms. Schmitz also provided a brief introduction and her hopes to provide the boards with more comprehensive detailed investigative reports in a timely manner. Dr. Brown discussed the changes in policy on how informal conferences will be conducted. He reported that as of July 1st, adjudication specialists will not be in attendance at closed hearings. However, special requests to have an adjudication specialist present can be made. Dr. Brown stated the final numbers for 2016 are in and there was a 40% increase in deaths due to opioid overdose in comparison with 2015. Dr. Brown reviewed the new Board of Medicine Regulations regarding opioid prescribing and encouraged pharmacists with any concerns to offer comments during the comment periods for the promulgation of permanent regulations. He stated that the Secretary of Health will convene two workgroups on electronic prescribing of opioids and developing some core competencies for professional schools to educate students regarding the prescribing and dispensing of opioids.

REGULATORY ACTIONS:

- Regulatory update

Ms. Yeatts briefly reviewed the chart of regulatory actions provided in the agenda, offering updates on pending regulatory actions voted on by the Board and providing the status of several pending actions.

- Adoption of regulations to schedule certain chemicals in Schedule I

There was a public hearing conducted at 9:10 a.m. this morning pursuant to requirements of §54.1-3443 of the Drug Control Act where no public comment was offered.

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:

- **4-Bromo-2,5 dimethoxy-N-[(2-hydroxyphenyl)methyl]-benzeneethanamine (250-NBOH)**

Classified as a cannabimimetic agent:

- **Methyl N-[1-(cyclohexylmethyl)-1H-indole-3-carbonyl]valinate (MMB-CHMICA)**

Classified as powerful synthetic opioids:

- **N-(1-phenethylpiperidin-4-yl)-N-phenyltetrahydrofuran-2-carboxamide (Tetrahydrofuran fentanyl)**

(motion by Warriner, second by Boone)

- NABP presentation

In the interest of travel arrangements, the board agreed to take an agenda item out of order to hear a presentation from Neal Watson, Member Relations and Government Affairs Liaison with the National Association of Boards of Pharmacy. Mr. Watson provided a presentation to the Board that gave background on what an e-profile ID number is and how it is used by NABP and may be useful to the Board. Most pharmacists, pharmacy technicians, and pharmacy interns already possess an e-profile ID since it is assigned anytime someone uses an NABP service, e.g., examination, CPE monitoring, licensure endorsement, etc.. Mr. Watson stated the board may wish to consider adopting a regulation to require an applicant to obtain an e-profile ID number prior to applying that may be utilized by the applicant and the board to track discipline, exam scores as well as continuing education. Advantages include decreased administrative burden with daily communications with NABP for licensure or examination information, and elimination of board's need to communicate sensitive identification information to NABP when verifying identify of applicant. Mr. Watson indicated 10 states already require applicants to obtain the number and there is no cost to obtain an e-profile ID number. NABP hopes to expand e-profile IDs to facilities in the near future.

MOTION:

The Board voted unanimously to adopt a Notice of Intended Regulatory Action (NOIRA) to require an e-profile ID number on initial application for pharmacists, pharmacy technicians and pharmacy interns and upon renewal of such licenses and registrations. (motion by Saenz, second by M. Elliott)

- Periodic Regulatory Review, Adoption of amendments Chapter 20, *Regulations Governing Practice of Pharmacy,* Parts VI-VIII, X-XII and Chapter 50, *Regulations Governing Wholesale Distributors, Manufacturers, and Warehouses,* Parts I-II

Ms. Yeatts reminded the board of actions taken thus far during the periodic regulatory review process: a Notice of Periodic Review was published with 2 comments received; a Notice of Intended Regulatory Review Action was published with comment from 7/11/16 to 8/10/16; the Regulation Committee reviewed regulatory sections on 11/26/16, 2/28/17, and 5/10/17 with Board adoption of those amendments on 12/12/16 and 3/21/17. The remaining amendments must be adopted by the Board today. She then reviewed the proposed regulatory amendments in Chapters 20 and 50 as recommended by the Regulation Committee. In addition, she highlighted written comment provided by Ms. Shinaberry who could not attend the full board meeting. The Board then considered the recommended amendments and offered amendments as necessary.

Ms. Yeatts indicated the suggested 18VAC110-20-112 is not new language, but simply moved to the general provisions section.

MOTION: **The Board voted unanimously to amend the recommended regulatory amendments to Regulation 18VAC110-20-240 by inserting in subsection (A)(2) "the count of drugs" in the second sentence after "estimating". (motion by Warriner, second by Boone)**

MOTION: **The Board voted unanimously to insert in 18VAC110-20-425(A)(4) "complied with, and" following "maintained and", and to insert in 18VAC110-20-425(A)(4)(a) "and assigned bar codes" following "chapter" as presented in the agenda packet. (motion by Warriner, second by Saenz)**

MOTION: **The Board voted unanimously to adopt an amendment of Regulation 18VAC110-20-490 (B)(1) using Ms. Shinaberry's recommended language. (motion M. Elliott, second by Warriner)**

MOTION: **The Board voted unanimously to adopt the proposed regulatory amendments to Chapter 20, *Regulations Governing the Practice of Pharmacy,* Parts VII-VIII, X-XII as presented and amended. (motion by Warriner, second by Saenz)**

MOTION: **The Board voted unanimously to adopt the proposed regulatory amendments to Chapter 50 of the *Regulations Governing Wholesale Distributors, Manufacturers, and Warehouses,* Parts I-II as presented. (motion by Cathcart, second by M. Elliott)**

MOTION: **The Board voted unanimously to adopt Chapter 16, *Regulations Governing Delegation of Informal Fact-Finding Proceedings to an Agency Subordinate,* by relocating existing Regulation 18VAC110-20-15 into this new chapter. (motion by Boone, second by Warriner)**

2018 LEGISLATIVE PROPOSALS:

- Require reporting of Schedule V drugs and naloxone to PMP

Ms. Yeatts indicated the Prescription Monitoring Program (PMP) Advisory Panel had recently adopted a legislative proposal to require the dispensing of Schedule V drugs and naloxone to be reported to the PMP.

MOTION: **The Board voted unanimously to support the legislative proposal to require the dispensing of Schedule V drugs and naloxone to be reported to the PMP. (motion by Cathcart, second by Warriner)**

- Proposal to report information relating to persons picking up

Ms. Yeatts reported that the PMP received a request to consider requiring information relating to the person picking up the controlled substance to be reported to the PMP. The PMP Advisory Panel referred the matter to

controlled substance to PMP	the Board of Pharmacy for future consideration as it would directly impact pharmacies and dispensing physicians licensed by the Board and require an amendment to the Drug Control Act which is administered by the Board of Pharmacy.
MOTION:	**The Board voted unanimously to refer to the Regulation Committee the request to require information relating to persons picking up controlled substance to the PMP for further consideration. (motion by S. Elliott, second by Boone)**
• Non-resident third-party logistics provider and non-resident warehouser	Ms. Juran explained there are gaps in the law regarding oversight for non-resident third party logistics providers, a new licensing category created by the passage of the federal Drug Quality and Security Act, and non-resident warehousers. Currently, the law does not authorize these entities to ship drugs or devices into the Commonwealth. Because the Drug Control Act is viewed as a permissive act, these entities cannot legally ship into Virginia without the law expressly authorizing the activity. In the interest of patient access and safety, it is necessary to amend the law to authorize these entities to ship into Virginia after obtaining appropriate registration with the Board. Ms. Juran stated a few corrections were needed to the legislative proposal as presented in the agenda packet. On page 103, the term "non-resident warehouser" in 54.1-3435.1 should be underlined and the term "registration" in 54.1-3435.4:2(B) should be changed to "license".
MOTION:	**The Board voted unanimously to adopt the legislative proposal to authorize registration of non-resident third-party logistics providers and non-resident warehousers as presented and amended by changing the term "registration" in 54.1-3435.4:2(B) to "license". (motion by Warriner, second by M. Elliott)**
• Adoption of amendments to Guidance Document 110-1, Categories of Facility Licensure	Amendments are necessary to reflect recent changes in the issuance of a facility permits for distribution of medical gases and controlled substance registrations following legislation passed in the 2017 General Assembly.
MOTION:	**The Board voted unanimously to adopt the amendments to Guidance Document 110-1, Categories of Facility Licensure, as presented. (motion by S. Elliott, second by Boone)**
• Formation of ad hoc committee to address HB1956, HB 2046, and develop guidance on USP Chapter <800>	Ms. Warriner, Ms. Elliott, Ms. Shinaberry and Mr. Saenz volunteered to be on the Committee. Ms. Juran will send an email to the full board for further solicitation.

- Adoption of amendments to Guidance Documents 110-44 and 110-45 regarding Naloxone

Ms. Juran explained that she had received comment that the current language for the directions in the standing order within the board-adopted protocol might suggest that naloxone may only be administered one additional time, if unresponsive. Because multiple administrations of naloxone may be necessary to counteract a very potent fentanyl overdose, the individual was concerned that the person may not administer a sufficient amount of naloxone if on-hand.

MOTION:

The Board voted unanimously to amend the directions for the standing order within Guidance Documents 110-44 and 110-45 as presented. (motion by M. Elliott, second by Saenz)

NEW BUSINESS:

- Request to amend the pharmacist healthcare workforce survey regarding collaborative practice agreements

While the Board heard comment earlier in the meeting requesting an amendment to the survey regarding collaborative practice agreements, Ms. Juran explained that she had already received a request from a VCU School of Pharmacy professor to include a couple of questions on the survey to more appropriately assess pharmacist involvement with collaborative practice agreements. Ms. Juran worked with Elizabeth Carter, PhD, Executive Director, Healthcare Workforce Data Center to develop the questions which were presented to the Board on the handout.

MOTION:

To better assess pharmacist involvement in collaborative practice agreements, the Board voted unanimously to amend question #22 within the pharmacist healthcare workforce survey to read "Do you provide any of the following services at this location? Check all that apply. Central filling, compounding, comprehensive medication reviews, remote consulting, remote order processing, immunization administration, medication synchronization, point-of-care testing" and to insert a new #23 to read "If you participate in a collaborative practice agreement for disease state management, which disease states are being managed? Check all that apply. Hypertension, hypercholesterolemia, asthma, tobacco cessation, travel medications, anticoagulation, diabetes, pain management". (motion by Cathcart, second by Saenz)

- Select Standard for the Admissibility of Expert Testimony

James Rutkowski, Assistant Attorney General, discussed a Virginia Supreme Court decision regarding the Standard for the Admissibility of Expert Testimony. The Office of the Attorney General recommends using the traditional Virginia Standard to identify expert witnesses.

MOTION:

The Board voted unanimously to adopt the traditional Virginia Standard for the Admissibility of Expert Testimony which states: "To qualify to serve as an expert witness, an individual: must possess sufficient knowledge, skill, or experience regarding the subject matter of the testimony to assist the trier of fact in the search for the truth. Generally, a witness possesses sufficient expertise when, through experience, study or observation the witness acquires

knowledge of a subject beyond that of persons of common intelligence and ordinary experience.". (motion by Warriner, second by Saenz).

- Election of Chairman and Vice-Chairman

MOTION: **The Board voted unanimously to elect Ryan Logan as Board Chairman for the term July 1, 2017 through June 30, 2018. (motion by Warriner, second by Thornbury)**

MOTION: **The Board voted unanimously to elect Michael Elliott for the office of Vice-Chairman for the term July 1, 2017 through June 30, 2018. (motion by Saenz, second by Warriner)**

REPORTS:

Chairman's Report — Ms. Thornbury thanked the Board for the opportunity to serve as Chairman. She thanked Mr. Logan for stepping in during her absence.

Report on Board Of Health Professions — There was no report.

Report on Licensure Program — Mr. Johnson reported that the board issued 998 licenses for the period of March 1 through May 31, 2017 including 166 pharmacist licenses and 513 technician registrations. There were a total of 281 pharmacy inspections of which 184 were routine inspections.

Report on Disciplinary Program — Ms. Reiniers-Day provided the Board with a handout and discussed the Board's Open Disciplinary Case Report as of June 22, 2017. She noted that the report has a new format and that these specific status numbers for both patient care and non-patient care cases can be compared with the previous March 9, 2017, numbers. The report indicates that the Board had 310 open cases as of that date with 124 being patient care cases and 186 being non-patient care cases.

Executive Director's Report: — Ms. Juran provided a handout summarizing recent or ongoing projects, recent or upcoming presentations and meetings, and staffing issues. Projects included: implementation of oversight for pharmaceutical processors and development of Request for Proposal for needed computer software; preparations for E-prescribing workgroup to meet August 2nd and 29th, if necessary, which resulted from HB2165; assisting with response to Congressional inquiry regarding high cost of topical compounded drugs charged to Workers' Compensation; responding to inquiries for Joint Commission on Healthcare studies. Ms. Juran stated Sylvia Tamayo-Suijk began June 25th as the new executive assistant, Maria Damico was recently hired by Enforcement as a part-time pharmacist inspector, and Michelle Schmitz recently began as the new

Enforcement Director.

ADJOURN: With all business concluded, the meeting adjourned at approximately 12:50pm.

Rebecca Thornbury, Chairman

9-26-17
DATE:

Caroline D. Juran, Executive Director

9/26/17
DATE: