FINAL/APPROVED

VIRGINIA BOARD OF PHARMACY
MINUTES OF BOARD MEETING

September 26, 2017
Second Floor
Board Room 4

Perimeter Center
9960 Mayland Drive
Henrico, Virginia 23233-1463

CALL TO ORDER: The meeting was called to order at 9:15AM

PRESIDING: Ryan K. Logan, Chairman

MEMBERS PRESENT:
Jody Allen
Melvin L. Boone, Sr.
Freeda Cathcart
Michael I. Elliott
Sheila K. W. Elliott (arrived at 10:09AM)
Rafael Saenz
Ellen B. Shinaberry
Rebecca Thornbury
Cynthia Warriner

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

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

APPROVAL OF AGENDA: The agenda was amended to include approval of the draft minutes (handout) for the Ad Hoc Committee meeting held September 18, 2017.

MOTION: **The Board voted unanimously to amend the agenda to include approval of the draft minutes (handout) for the Ad Hoc Committee meeting held September 18, 2017. (motion by Allen, second by Boone)**

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

- June 26, 2017, Pilot Program Informal Conference Committee
- June 27, 2017, Full Board Meeting
- June 27, 2017, Public Hearing of Scheduling Certain Chemicals
- June 27, 2017, Formal Hearing
- June 28, 2017, Special Conference Committee
- July 17, 2017, Special Conference Committee
- July 31, 2017, Formal Hearings
- September 18, 2017, Ad Hoc Committee Meeting on Delivery of

Prescription Drug Order (HB1956), Guidelines for Counseling on Drug Disposal (HB2046), and Guidance for Complying with USP Chapter <800>

MOTION: **The Board voted unanimously to adopt the minutes from June 26, 2017 through July 31, 2017 as presented, along with the handout of the minutes from September 18, 2017. (motion by Shinaberry, second by M. Elliott)**

The following minutes (handouts) were later considered for approval prior to adjournment of the Full Board Meeting:

- August 31, 2017, Formal Hearings
- August 31, 2017, Special Conference Committee

MOTION: **The Board voted unanimously to amend the minutes for the August 31, 2017 Formal Hearings to correct the spelling of Ms. Warriner's name on page 3 and to adopt the minutes as amended, along with the minutes from the August 31, 2017 Special Conference Committee as presented. (motion by Warriner, second by Shinaberry)**

PUBLIC COMMENTS:

Jackie Bright, the new Executive Director for the Virginia Pharmacists Association, introduced herself to the Board.

Jill Abernathy, INOVA Health System, stated that they deliver TPN and chemo to hospitals and physician offices. She requested that they not be required to use temperature monitoring devices for these shipments as these deliveries are short and the drugs are not left in an unattended area for a long period of time. Regarding USP <800>, she requested that if the Board enforces the 3 dates of implementation, that it be clearly communicated to the licensees.

Alexander Pytlarz, Leesburg Compounding Center, shared his concerns with USP <800> and requested a delay in implementation until 2021. He stated that West Virginia will delay implementation until 2021. He recommended one date for implementation of all requirements instead of the phase-in approach considered by the ad hoc committee. Further, he requested guidance on what exactly is needed in order to perform a risk assessment.

Michele Satterlund, McGuire Woods Consulting representing Temptime, commented on patient representative letters provided to the Board regarding their concerns with the safe delivery of temperature sensitive medications and the need for assurance that the medications had not been compromised. Her client supports a guidance document related to importance of proper delivery of temperature sensitive drugs as contemplated by the ad hoc committee. She also requested that the Board take action to require mail-order pharmacies to collect and provide temperature data to the Board since brick and mortar pharmacies must keep temperature data and non-resident pharmacies must provide a toll free number to report temperature issues.

John Beckner, representing the National Community Pharmacists Association (NCPA), provided comments in opposition to USP <800>. He stated that implementation will create a substantial economic impact and will cause some providers to cease compounding and therefore limit access for many consumers in Virginia. Mr. Beckner stated that full compliance by July 1, 2018 will be too difficult and proposed a delay in the enforcement until 2021. He stated that NCPA supports the inclusion of temperature monitoring devices for mail order deliveries.

Lauren Schmitt, VSHP, supports the delay in enforcement of USP <800> and the phase-in approach. She requested that the Board appoint a task force to develop guidance.

Hunter Jamerson, attorney representing EPIC Pharmacies, supports the use of temperature monitoring devices in biologics with mail order delivery products and would like to see the development of a guidance document. He mirrored the comments of John Beckner and Alexander Pytlarz and applauded the ad hoc committee's recommendation to delay enforcement of Chapter <800>. He stated that there is a need for consistency with other states regarding compliance with the effective date. In addition, Mr. Jamerson pointed out that even if non-compliance matters are cited without a monetary penalty, such action may have an adverse effect on accreditation, Pharmacy Benefits Manager contracts and licensing. He suggested that the inspection report contain a statement clarifying that any comments regarding non-compliance with chapter <800> prior to the board's enforcement date do not constitute disciplinary action.

John Sisto, representing Express Scripts, suggested that regulation on the delivery of temperature sensitive drugs should focus on prevention, not detection. He recommended the use of qualified engineered packaging and regulation of the cold chain process in order to reduce waste. He stated that binary devices don't solve the problem and can create false positives/false negatives resulting in a false sense of security or in the drug being wasted unnecessarily. He urged the Board to consider the use of continuous quality improvement in order to identify the problem before it occurs.

DIRECTOR'S REPORT:

Dr. David Brown, Director of the Department of Health Professions, spoke about two workgroups the Secretary of Health convened. The workgroup charged with developing some core competencies for professional schools to educate students regarding the prescribing and dispensing of opioids determined that curricula is not easily adaptable across different types of schools or professions. Therefore, a set of core competencies was developed and will be reviewed. The workgroup on electronic prescribing of opioids met twice and an interim report will be sent to the Secretary of Health and legislators in November. Dr. Brown informed the Board that an online complaint form is now available and that DHP is expanding its office space and will utilize the 1st floor of the

building as well. Dr. Brown also shared that the agency will begin filming an educational video on probable cause review.

REGULATORY UPDATE:

Ms. Yeatts reviewed the chart of regulatory actions provided in the agenda and gave updates on the status.

REPORT FROM AD HOC COMMITTEE MEETING:

- Delivery of Prescription Drug Orders (HB1956)

Ms. Shinaberry discussed the Committee's recommendation that no action be taken to mandate temperature monitoring devices, but that the Board develop guidance for pharmacies that highlights the importance for using appropriate packaging materials when delivering temperature-sensitive drugs, to include temperature monitoring devices, if warranted.

Ms. Warriner expressed concern regarding possible inconsistency in the enforcement of requirements between brick and mortar pharmacies and mail order pharmacies. She stated that there is a need for assurance that the drug is safe and effective. Ms. Elliott and Ms. Thornbury expressed similar concerns.

Ms. Allen expressed concern for the possibility of false positives if the device was not used correctly.

There were general comments regarding the lack of data indicating this was a problem needing a mandated solution.

Ms. Juran shared that she did not believe the board's regulations were inconsistent on this matter. The requirements for a pharmacy to store drugs within the appropriate temperature range applies to all pharmacies permitted with Virginia as an in-state pharmacy or registered as a non-resident pharmacy. Additionally, drug delivered by any pharmacy in a manner that does not maintain appropriate temperature requirements could potentially be deemed adulterated under current State and federal law. Therefore, there is already an expectation under law that pharmacies deliver drugs in a manner that maintains appropriate temperatures or they could be found in violation of dispensing adulterated drugs. Ms. Juran further stated that drug manufacturers generally provide for allowable excursions in temperature during the transport and storage of drugs. While the recommended temperature monitoring devices may indicate if a particular temperature was reached, they do not typically indicate how long the drug was held at that particular temperature. Without knowing how long a drug was maintained at a temperature excursion, it is difficult to know if the drug has been negatively affected.

Ms. Cathcart questioned how this issue was impacted by pharmacy benefit managers.

MOTION:

The Board voted unanimously to close the discussion. (motion by Cathcart, second by Allen)

MOTION: **The Board voted seven to three to approve the Ad Hoc Committee's recommendation that no action be taken to mandate temperature monitoring devices, but that the Board develop guidance for pharmacies that highlights the importance for using appropriate packaging materials when delivering temperature-sensitive drugs, to include temperature monitoring devices, if warranted. (a motion was offered, second by Allen; Warriner, Thornbury and S. Elliott opposed)**

- Guidance For Complying With USP <800>

Ms. Shinaberry discussed the Committee's recommendation for inspectors to begin citing deficiencies as of July 1, 2018, but not to impose monetary sanctions. Beginning January 1, 2019, monetary sanctions should be imposed for non-compliance with the non-physical standards of chapter <800>. Beginning July 1, 2019, monetary sanctions should be imposed for the physical and engineering standards of Chapter <800>.

MOTION: **The Board voted unanimously to amend the ad hoc committee's recommendation to read: ..." inspectors begin *commenting on* deficiencies as of July 1, 2018, *and* impose no monetary sanctions. Beginning January 1, 2019, monetary sanctions (to be established at a later date) should be imposed for non-compliance with the non-physical standards of chapter <800>, e.g., list of hazardous drugs received or stored in the pharmacy, performance of assessment of risk, etc. Beginning July 1, 2019, monetary sanctions (to be established at a later date) should be imposed for the physical and engineering standards of Chapter <800>". (motion by Warriner, second by Allen)**

MOTION: **The Board voted eight to two to adopt the ad hoc committee's recommendation on enforcement of USP Chapter <800> as amended which reads "inspectors begin commenting on deficiencies as of July 1, 2018, and impose no monetary sanctions. Beginning January 1, 2019, monetary sanctions (to be established at a later date) should be imposed for non-compliance with the non-physical standards of chapter <800>, e.g., list of hazardous drugs received or stored in the pharmacy, performance of assessment of risk, etc. Beginning July 1, 2019, monetary sanctions (to be established at a later date) should be imposed for the physical and engineering standards of Chapter <800>". (a motion was offered, second by Allen; Warriner and Saenz opposed)**

MOTION: **The Board voted unanimously to review draft amendments of Guidance Document 110-36, to include frequently asked questions on the enforcement of Chapter <800>, at the November Regulation Committee meeting with recommendations to the full board in December. (motion by Shinaberry, second by Warriner)**

- Guidelines for

Ms. Shinaberry reviewed the Committee's decision for staff to create a

Counseling on Drug Disposal (HB2016)	guidance document regarding the disposal of controlled substances.
MOTION:	**The Board voted unanimously to accept the ad hoc committee's recommendation for staff to create a guidance document regarding the disposal of controlled substances which should include resources of information on the subject.**
REGULATORY ACTIONS: • Adoption of Regulation to Schedule Certain Chemicals in Schedule I	There was a public hearing conducted at 9:10AM this morning pursuant to 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 in Schedule I:** **Research chemicals:** • **5-methoxy-N,N-dimethyltryptamine (other name: 5-MeO-DMT)** • **5-methoxy-N-methyl-N-isopropyltryptamine (other name: 5-MeO-MIPT)** • **5-methoxy-N-ethyl-N-isopropyltryptamine (other name: 5-MeO-EIPT)** • **4-hydroxy-N,N-diisopropyltryptamine (other name: 4-OH-DIPT)** • **(N-methyl aminopropyl)-2,3-dihydrobenzofuran (other name: MAPDB)** • **3,4-tetramethylene-alpha-pyrrolidinovalerophenone (other name: (TH-PVP)** • **4-chloro-alpha-methylamino-valerophenone (other name: 4-chloropentedrone)** **Synthetic opioids:** • **2-methoxy-N-phenyl-N-[1-(2-phenylethyl)-4-piperidinyl]-acetamide (other name: Methoxyacetyl fentanyl)** • **N-(1-phenethylpiperidin-4-yl)-N-phenylcyclopropanecarboxamide (other name: Cyclopropyl fentanyl)** **Cannabimimetic agent:** • **N-(1-amino-3,3-dimethyl-1-oxobutan-2-yl)-1-(5fluoropentyl)indazole-3-carboxamide (other name: 5-fluoro-ADB-PINACA)** **(motion by Warriner, second by Boone)**
• Adoption of Proposed Regulations for Controlled Substances Registration for Entities that Dispense Naloxone	Emergency regulations were required to meet the mandate of the statute; they became effective May 8, 2017. A NOIRA was published simultaneously with the emergency regulations to replace them with permanent regulations. A comment period on the NOIRA ended 6/28/17; there were no comments.

or for Telemedicine

MOTION:

The Board voted unanimously to adopt the proposed replacement regulations for controlled substances registrations issued to certain entities that use DBHDS-approved REVIVE! Trainers to dispense naloxone or that participate in telemedicine resulting in the issuance of a prescription for a drug in Schedules II-V. (motion by Saenz, second by M. Elliott)

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

Amendments are necessary to reflect recent decisions by some hospitals to dispense naloxone upon discharge from a hospital for patients with opioid prescriptions. Those patients would not have completed a REVIVE! training program, so they must receive counseling on the use and purpose of naloxone within the hospital.

MOTION:

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

- Exempt Regulatory Action to Amend 18VAC110-20-10 to Conform Definition of "Electronic Prescription"

The definition for electronic prescription in Regulation 18VAC110-20-10 is inconsistent with the definition in §54.1-3401of the Code, as of July 1, 2017. The amendment conforms the definition in the regulations to the definition of the Code.

MOTION:

The Board voted unanimously to amend the definition of "electronic prescription" in Regulation 18VAC110-20-10 as presented, to conform with the definition in §54.1-3401. (motion by Thornbury, second by Warriner)

- Adoption of Amendments to Guidance Document 110-35, Guidance on Virginia Prescription Requirements

It was determined that clarification was needed regarding which drugs may be electronically transmitted.

MOTION:

The Board voted unanimously to amend Guidance Document 110-35, *Guidance on Virginia Prescription Requirements*, as presented. (motion by Boone, second by Allen)

- Repeal Guidance Document 110-26, Re-dispensing Drugs Previously Dispensed in

It came to the attention of board staff that Guidance Document 110-26, *Re-dispensing Drugs Previously Dispensed in Compliance Packaging,* adopted on September 26, 2015, is in direct conflict with FDA Repackaging Guidance published January 2017. Board staff requested the

Compliance Packaging	Board repeal the guidance document so that licensees are not performing tasks that are in direct conflict with FDA guidelines.
MOTION:	**The Board voted to repeal Guidance Document 110-26, Re-dispensing Drugs Previously Dispensed in Compliance Packaging. (motion by Saenz, second by Boone, Cathcart abstained)**
• Adoption of Amendment to Guidance Document 110-12, Bylaws of the Virginia Board of Pharmacy	On March 21, 2017, the Board elected to discontinue the administration of the Virginia Pharmacy Technician Examination as of September 1, 2017. Beginning September 1, 2017, students who have successfully completed a Board-approved pharmacy technician training program must choose to take either the PTCE or ExCPT examination prior to submitting an application to the Board for pharmacy technician registration. As a result, the Examination Committee is no longer necessary and should be removed from Guidance Document 110-12, *Bylaws of the Virginia Board of Pharmacy.*
MOTION:	**The Board voted unanimously to amend Guidance Document 110-12, *Bylaws of the Virginia Board of Pharmacy*, as presented which deletes reference to a standing Examination Committee. (motion by Warriner, second by Saenz)**
• Revenue and Budget Analysis	Following a review of the Board of Pharmacy's Projected Revenue, Expenditure and Cash Balance for July 1, 2016 through June 30, 2020, the Board is projected to incur a deficit in FY18-20. It is recommended that the Board begin the process of increasing fees for persons and entities regulated by the Board. If a fee increase is enacted in anticipation of expenditures exceeding revenue, the increase can be smaller than if the action is taken at the time the deficit actually occurs.
MOTION:	**The Board voted unanimously to submit a Notice of Intended Regulatory Action (NOIRA) for an increase in fees for persons and entities regulated by the Board of Pharmacy. (motion by Allen, second by Boone)**
NEW BUSINESS:	
• Conflict of Interests	James Rutkowski provided an overview of prohibited conduct, definition of gifts and criminal and civil penalties related to Title 2.2, Chapter 31 - State and Local Government Conflict of Interests Act (2.2-3100 thru 2.2-3131). He encouraged the Board to review the chapter.
• Meeting Dates For 2018	The Board discussed meeting dates for 2018 and decided upon the following dates: FULL BOARD MEETINGS: • March 29, 2018 • June 21, 2018 • September 25, 2018 • December 18, 2018

REGULATION COMMITTEE MEETINGS:

- May 3, 2018
- November 28, 2018

REPORTS:

- Chairman's Report: Mr. Logan thanked the Board for the opportunity to attend the NABP-AACP District I and II Annual Meeting held on September 14, 2017 and encouraged other Board members to attend future meetings. He briefly mentioned the resolutions passed by NABP District I.

- Report on Board of Health Professions: Mr. Logan provided an update on the most recent Board of Health Professions (BHP) meeting. Draft minutes of the BHP meeting were included in the Board's agenda packet.

- Report on Licensure Program: Ms. O'Halloran delivered the licensing report on behalf of Mr. Johnson who was attending an FDA meeting. She provided a handout summarizing that the Board issued 438 Pharmacists licenses and 621 Pharmacy Technician registrations from June 1, 2017 through August 31, 2017. Inspectors conducted 313 facility inspections including 232 routine inspections of pharmacies: 116 (37%) resulted in no deficiency, 117 (37%) with deficiencies, and 80 (26%) with deficiencies resulting in the issuance of a consent order.

ACTION ITEM: **The Board discussed the number of repeat deficiencies listed on the report. There was consensus that the Regulation Committee should consider the need for possible disciplinary action for repeat deficiencies and provide a recommendation to the Board in December.**

- Report on Disciplinary Program: Ms. Reiniers-Day provided the Board with a handout and discussed the Board's Open Disciplinary Case Report as of September 21, 2017. The report indicates that the Board had 294 open cases as of that date with 117 being patient care cases and 177 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 include: implementation of licensing pharmaceutical processors; HB2165 E-prescribing workgroup that met August 2nd and 29th with the preparation of an interim progress report for legislators.

CONSIDERATION OF CONSENT ORDER

Closed Meeting: Upon a motion by Mr. Elliott, and duly seconded by Mr. Boone, the Board voted 10-0 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, He moved that Caroline Juran, Cathy Reiniers-Day, James 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. Warriner, and duly seconded by Mr. Saenz, the Board voted 10-0 in favor of accepting the Consent Order as presented by Ms. Reiniers-Day in the matter of Ryan Hypes, a pharmacy technician.**

ADJOURN: With all business concluded, the meeting adjourned at approximately 2:25pm.

Ryan Logan, Chairman

12/11/17
DATE:

Caroline D. Juran, Executive Director

12/11/17
DATE: