FINAL/APPROVED

VIRGINIA BOARD OF PHARMACY
MINUTES OF BOARD MEETING

September 29, 2015
Second Floor
Board Room 2

Perimeter Center
9960 Mayland Drive
Henrico, Virginia 23233-1463

CALL TO ORDER: The meeting was called to order at 9:15 a.m.

PRESIDING: Cynthia Warriner, Chairman

MEMBERS PRESENT:
Melvin L. Boone, Sr.
Michael Elliott
Freeda Cathcart
Ryan Logan
Rafael Saenz
Rebecca Thornbury
Ellen Shinaberry
Jody Allen
Sheila Elliott

STAFF PRESENT:
Caroline D. Juran, Executive Director
Cathy M. Reiniers-Day, Deputy Executive Director
J. Samuel Johnson, Jr., Deputy Executive Director
David Brown, Director, Department of Health Professionals
James Rutkowski, Assistant Attorney General
Elaine J. Yeatts, Senior Policy Analyst, DHP
Beth O'Halloran, Individual Licensing Manager
Sharon Davenport, Administrative Assistant

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

APPROVAL OF AGENDA: The agenda was approved as presented.

APPROVAL OF MINUTES: Staff provided as a handout an amended version of the draft minutes for the June 16, 2015 Special Conference Committee which replaced the version in the agenda packet. The board reviewed draft minutes in the agenda packet for June 15, 2015 (Public Hearing for Scheduling Certain Chemicals); June 15, 2015 (Full Board Meeting); July 9, 2015 (Telephone Conference Call); July 23, 2015 (Special Conference Committee); August 4, 2015 (Panel Formal Hearings); August 11, 2015 (Special Conference Committee); and the handout for the June 16, 2015 (Special Conference Committee).

MOTION: **The Board voted unanimously to approve the minutes as presented for the meetings held between June 15, 2015 and August 11, 2015. (motion by Ryan, second by Boone)**

PUBLIC COMMENTS:

The following individuals addressed the Board during public comment:

Cynthia Williams from Riverside PACE provided comment in support of HB1733 and the emergency regulations that provide PACE facilities with similar allowances as CSB and BHA for repackaging dispensed prescriptions for their clients. She requested the board allow a reasonable amount of time for the PACE facilities to meet requirements for obtaining the associated controlled substances registrations.

Gill Abernathy, pharmacist with INOVA Fairfax Hospital, provided comment in support of the board's consideration of issuing a single controlled substance registration to a sole ownership of a building with multiple practices within as may be allowed by the DEA.

Matthew Jenkins, pharmacist with University of Virginia Health System, provided comment also in support of the board's consideration for issuing a single controlled substance registration to a building with multiple outpatient clinics located within the building.

DHP DIRECTOR'S REPORT:

Dr. Brown welcomed the two new board members, Freeda Cathcart and Rafael Saenz to the Board of Pharmacy. Dr. Brown provided comment that the board member development day went very well. Dr. Brown provided an update on the pharmacy benefit manager workgroup (PBM) that DHP will host. Invitations to 18 stakeholders have been sent. The workgroup will tentatively discuss the role of a PBM, how PBMs work with insurance companies, the credentialing process, drug coverage, and if additional oversight of PBMs is warranted. Cynthia Warriner and Jody Allen both thanked Dr. Brown for the board member development session.

REPORT ON SHENANDOAH UNIVERSITY, BERNARD J. DUNN SCHOOL OF PHARMACY

Dr. Penny S. Shelton, Associate Dean for Academic Affairs from Shenandoah University School of Pharmacy, provided a report to the board. Dean McKay is presently on sabbatical and will retire at the end of the academic year; there is an active search for a new dean. Due to changes in the ACPE standards for 2016, the university has made some changes to the pharmacy program. Some of these changes include adding labs in physical assessment so that the students may better understand the importance of direct patient care, moving basic science to a prerequisite for entry into the program, changes to the health information technology, an additional APPE in May 2017, a focus on problem solving, a three component capstone including outcomes assessment, top 200 exam and multi-station clinical exam, and additional training for preceptors. Dr. Shelton also commented that Shenandoah was awarded a SAMHSA grant to address interprofessional development and the provision of training for screening for substance abuse.

REGULATORY ACTIONS:

Ms. Yeatts reviewed the chart of regulatory actions in the agenda packet as of September 11, 2015. Ms. Yeatts stated the NOIRAs for prohibition against incentives to transfer prescriptions and continuous hours worked by pharmacists have been moved to the Governor's office.

- CONSIDERATION OF ANY SCHEDULING FROM PUBLIC HEARING:

Ms. Yeatts requested that the Board consider whether the chemicals discussed during the public hearing should be placed into Schedule I.

MOTION:

Pursuant to subsection D of 54.1-3443, the Board voted unanimously to adopt amendments to 18VAC110-20-322 to place the following six chemicals identified by the Department of Forensic Science into Schedule I:

- **Acetyl fentanyl (other name: desmethylfentanyl);**
- **Etizolam;**
- **4-Iodo-2,5-dimethoxy-N-[(2-hydroxyphenyl) methyl]-benzeneethanamine (other name: 251-NBOH);**
- **Alpha-Pyrrolidinohexiophenone (other name: alpha-PHP), a substituted cathinone;**
- **Alpha-Pyrrolidinoheptiophenone (other name: PV8), a substituted cathinone; and,**
- **1-(5-fluoropentyl)-3-(4-methyl-1-naphthoyl) indole (MAM-2201), a cannabimimetic agent. (motion by Allen, second by Saenz)**

- ADOPTION OF PROPOSED REGULATIONS FOR AUTHORIZED COLLECTORS OF DRUGS

Ms.Yeatts reviewed the NOIRA for collection sites for disposal of unused drugs, a fact sheet from Drug Enforcement Administration on the Secure and Responsible Drug Disposal Act of 2010 that allows ultimate users to deliver unused controlled substances to authorized entities for disposal, and draft proposed regulations to be considered by the Board. A definition for "collector" will be added to Chapter 50 as requested. Ms. Warriner suggested a guidance document be created to provide information to a licensee who wishes to become a collector. Ms. Thornberry suggested adding a definition of "ultimate user" to both regulations, Chapter 20 and Chapter 50.

MOTION:

The Board voted unanimously to amend the proposed regulations authorizing the collection of drugs as permitted in the Secure and Responsible Drug Disposal Act of 2010 by adding the definition for "collector" in Chapter 50 and adding the definition of "ultimate user" as "a person who has lawfully obtained, and who possesses, a controlled substance for his own use or for the use of a member of his household or for an animal owned by him or a member of his household" to Chapters 20 and 50, and adopt the proposed regulations as amended. (motion by Thornberry, second by Allen).

REPORT FROM THE REGULATION COMMITTEE

- Adoption of Emergency Regulations for Outsourcing Facilities and Compounding

Ms. Yeatts reviewed the 2015 legislation mandating issuance of permits to resident and non-resident outsourcing facilities and the emergency regulations as recommended by the regulation committee. It was recognized that no mention of expiration date was included in the records for compounding and therefore verbiage was added to that effect.

MOTION: **The board voted unanimously to amend proposed subsection C, 2, b of Regulation 18VAC110-20-215 as recommended by the Regulation Committee to read, "Compounding records shall include identification and strength of the drugs and shall provide the ingredient with expiration dates; and the source of such ingredients, including the national drug code number of the source drug or bulk active ingredient, if available; the strength of the active ingredient per unit; the dosage form and route of administration; the package description; the number of individual units produced; the national drug code number of the final product, if assigned, or lot number and appropriately assigned expiration date or beyond use date." (motion by S. Elliott, second by Boone)**

MOTION: **The board voted unanimously to adopt the proposed emergency regulations for outsourcing facilities as previously amended. (motion by S. Elliott, second by M. Elliott)**

- Adoption of Emergency Regulations for Permitting Facilities in which Practitioners of the Healing Arts Sell Controlled Substances

Ms. Yeatts reviewed the 2015 legislation mandating the issuance of permits to facilities in which practitioners of the healing arts dispense drugs. She also reviewed the emergency regulations as recommended by the Regulation Committee.

MOTION: **The board voted unanimously to adopt the proposed emergency regulations for permitting facilities in which practitioners of the healing arts sell controlled substances as recommended by the Regulation Committee.**

- Adoption of Fast-Track Regulations for Repackaging Drugs at PACE Facilities

Ms. Yeatts reviewed 2015 legislation mandating promulgation of regulations relating to training, packaging, labeling, and recordkeeping for drug repackaging for individual patients receiving services at programs for all-inclusive care for the elderly (PACE). Ms. Yeatts also reviewed proposed regulations as recommended by the Regulation Committee.

MOTION: **The board voted unanimously to adopt the proposed fast-track regulations for repackaging drugs at PACE programs as recommended by the Regulation Committee.**

OLD BUSINESS:

- Request to Amend Guidance Document 110-36

Ms. Juran reviewed with the board a letter from VPhA requesting an amendment to Guidance Document 110-36 to allow for alternative sterility testing methods. Mr. Logan requested staff to research if other states allow for alternative methods of testing. There was discussion of whether USP allows for alternative testing under USP Chapter <71>. There was also discussion of how the inspector would determine its validity. Several members of the board stated more information is needed

before amending the guidance document albeit they were supportive of utilizing new technology.

ACTION ITEM:

The board requested that staff survey other states to determine if they are allowing alternative methods of sterility testing, contact USP experts for their opinions on the subject, and consult with board counsel to determine if USP chapters <71> and <797> presently allow alternative methods of sterility testing. The matter will be discussed further at the December full board meeting.

NEW BUSINESS:

- Request to Amend Guidance Document 110-18

Ms. Juran reviewed a request by the Department of Education (DOE) to re-insert into Guidance Document 110-18 a paragraph relating to advance preparation of drugs for school field trips. The paragraph had been removed in 2013 when the board believed guidance was no longer needed based on changes in law. The DOE recently indicated to board staff that continued guidance on the subject would benefit schools.

MOTION:

The Board voted unanimously to amend Guidance Document 110-18 as presented by adding guidance related to the advance preparation of drugs for school field trips. (motion by M. Elliott, second by Allen)

- Consider Amending Guidance Document 110-34

Ms. Juran explained that Title II of the Drug Quality and Security Act prohibits boards from licensing manufacturers as wholesale distributors. Therefore reference in Guidance Document 110-34, *Wholesale Distributor Licensure Guidance*, advising certain manufacturers to obtain licensure as a wholesale distributor should be amended to conform with federal law.

MOTION

The Board voted unanimously to amend Guidance Document 110-34 as presented (motion by S. Allen, second by Boone)

- Consider Adopting Guidance for Re-dispensing Drugs Previously Dispensed in Compliance Packaging

Ms. Juran reviewed the allowance in subsection A (2) of 54.1-3411.1 for certain drugs to be accepted for return for the purpose of re-dispensing by the pharmacist. She stated that after speaking with the FDA it appears that "sealed individual dose" as used in the statute could be interpreted to mean compliance packaging, e.g., bingo cards, and that drugs in these compliance packages that "meet official compendium class A or B container requirements, or better" could potentially be accepted and re-dispensed under specific conditions. She then reviewed with the board the draft guidance document prepared by staff to address the re-dispensing of drugs previously dispensed in compliance packaging. Mr. Logan questioned who would be liable if patient harm were to occur from re-dispensing drug from this type of returned product. Mr. Rutkowski mentioned there is an exemption in law to release the manufacturer from this liability. The board discussed different types of compliance packaging and concerns over possible adulteration. It was stated that the pharmacist must exercise professional judgement to determine if official compendium storage requirements are assured prior to re-dispensing any

qualifying drug. Ms. Juran noted that there should be verbiage added with respect to recalled product.

MOTION:

The board voted unanimously to amend the draft guidance document by adding at the end "If the lot number for the drugs removed from the sealed individual doses is not known, then the drug shall be removed from stock upon any recall of that drug product and returned to the manufacturer or otherwise disposed of in accordance with Regulation 18VAC110-20-210." and adopt the guidance document as amended. (motion by S. Elliott, second by M. Elliott).

- Request for Guidance on Issuance of Controlled Substance Registrations to Multiple Medical Clinics Located within a Medical Office Building with Same Ownership

Mr. Saenz recused himself from the discussion on this subject as the issue directly relates to his employer.

Ms. Juran explained that historically the board has issued a controlled substances registration (CSR) to each office practice or department since the drugs stored within that practice or department are typically used exclusively by that office or department. Additionally, while not directly prohibited in law or regulation, the board has informally advised against a supervising practitioner and responsible party serving on multiple CSRs or providing oversight for a stock of drugs that they are not directly accessing or overseeing.

DEA recently indicated it will consider issuing a single DEA registration to a medical office building when the medical practices have the same owner. Therefore, staff requested guidance for how CSRs should be issued.

ACTION ITEM:

The board requested that staff survey other states to determine if they are issuing a single controlled substances registration to a medical office building with multiple practices located within the building operating under the same ownership and referred the issue to the Regulation Committee for further consideration. (motion by Shinaberry, second by Allen)

ELECTION OF VICE-CHAIRMAN:

Because Ms. Munden was not reappointed for a second term to the board, Ms. Warriner, who was elected vice-chairman at the June full board meeting, recently assumed the role as chairman and therefore, the board was required to elect a new vice-chairman.

MOTION:

The board voted unanimously to elect Ms. Thornberry as vice-chairman for the term of September 29, 2015 through June 30, 2016. (motion by Shinaberry, second by Logan)

- Dates for 2016 Full Board Meetings and Tentative Regulation Committee Meetings

The following dates were chosen for full board meetings in 2016: March 29, June 14, September 7, and December 12. The following dates were chosen for tentative Regulation Committee Meetings in 2016: May 26 and November 29.

REPORTS:

- Chairman's Report

Ms. Warriner announced her appointments to the standing committees on the board. Ms. Warriner commended the new board member training held by DHP and provided an update from the NABP/AACP District 1 and 2 meeting recently held in New Hampshire. She, Mr. Boone, Ms. Juran and former board member, Leo Ross, attended the meeting. Ms. Warriner reported that Ms. Juran was elected the nominee for District 2 to serve on the NABP executive committee. She also reported on the resolutions passed at the meeting and encouraged all to consider attending the NABP 112th Annual Meeting in San Diego, California, May 14-17, 2016.

- Report on Board of Health Professions

Ms. Shinaberry provided an update on the Board of Health Professions recent discussion for the need of a multi-level funeral director license. Ms. Shinaberry also stated that they are planning a spring retreat.

- Report on Wildlife Rehabilitator Workgroup

Ms. Shinaberry provided the board with an overview of the two-meeting wildlife rehabilitator workgroup and the information in the report to be sent to the Senate Committee on Education and Health and the Senate Committee on Agriculture, Conservation and Natural Resources as requested.

- Report on PMP

Ralph Orr, Director, Prescription Monitoring Program, provided an update on statistics regarding number of records maintained in the database, number of requests processed annually, and the impact of interoperability with other states and pilots involving the integration of PMP data into prescriber/pharmacist workflow. He also stated pharmacists who have provided the board with a current email address will receive an email on October 5th regarding automatic registration as a user of the PMP.

- Report on Licensure Program

Mr. Johnson reported the Board currently licenses 35,106 individuals and facilities. The Board issued 1,338 licenses and registrations for the period of June 1, 2015 through August 31, 2015. Inspectors conducted 437 facility inspections including 171 routine inspections of pharmacies: 45 (26%) resulted in no deficiency, 63 (37%) with deficiencies and 63 (37%) with deficiencies and a consent order. Mr. Johnson reviewed the report of Major & Minor Inspection Deficiencies. Mr. Johnson also discussed a chart providing a graphic display of inspection deficiencies by quarter since September 2012.

- Report on Disciplinary Program

Ms. Reiniers-Day was pleased to introduce Loni Dickerson to the Board. Ms. Dickerson has been with the Board since August 25, 2015, and is employed as the Disciplinary Program Specialist.

Ms. Reiniers-Day then provided the Board with the Open Disciplinary Case Report comparing the case stages between the four report dates of December 8, 2014; March 24, 2015; June 12, 2015; and September 28, 2015. For the final date, the number of

open cases were none at the entry stage; 62 at the investigation stage; 182 at the probable cause stage; two at the administrative proceedings division stage; four at the informal stage; three at the formal stage; and 108 at the pending closure stage.

- Executive Director's Report

Ms. Juran reported that two reports for legislative committees, as requested by the legislators, were about to be sent to the Secretary for his review – one involved consideration for expanded use of epinephrine and the other possession and administration of drugs by wildlife rehabilitators. Ms. Juran will provide a copy of the final reports to the board. She also provided an update on the Governor's Task Force on Heroin and Prescription Drug Abuse. Ms. Juran will provide a copy of the implementation plan when finalized. She indicated she served as a panelist at the Appalachian Opioid Summit recently held in Wise, VA. Ms. Juran acknowledged Ms. Warriner for her good work running the business sessions as district 2 chairman at the NABP District 2 meeting. She stated she will attend the upcoming Tri-Regulator meeting and ACPE Stakeholder Invitational Conference. Ms. Juran reported that Ms. Thornbury will represent the board during the ACPE accreditation meetings of Appalachian College of Pharmacy in mid-November. She indicated that she also recently participated in the cut score development process of the MPJE. Ms. Juran also indicated that USP has published a notice of intent to revise Chapter <797>. The comment period opens November 2, 2015 and closes January 31, 2016.

CONSIDERATION OF CONSENT ORDERS OR POSSIBLE SUMMARY SUSPENSIONS:

None were presented or considered.

ADJOURN:

With all business concluded, the meeting concluded at approximately 12:36 pm.

Cynthia Warriner, Chairman

12/01/15
Date

Caroline D. Juran, Executive Director

12/1/15
Date