FINAL/APPROVED

VIRGINIA BOARD OF PHARMACY
MINUTES OF FULL BOARD MEETING

December 9, 2019
Commonwealth Conference Center
Second Floor
Board Room 4

Department of Health Professions
Perimeter Center
9960 Mayland Drive
Henrico, Virginia 23233

CALL TO ORDER: The meeting of the Board of Pharmacy was called to order at 9:14 AM.

PRESIDING: Cynthia Warriner, Chairman

MEMBERS PRESENT:
Kristopher S. Ratliff, Vice Chairman
Glen Bolyard
Melvin L. Boone, Sr.
James L. Jenkins, Jr.
Ryan Logan
Cheryl H. Nelson
Patricia Richards-Spruill
Rebecca Thornbury

MEMBERS ABSENT: William Lee

STAFF PRESENT:
Caroline D. Juran, Executive Director
Ellen B. Shinaberry, Deputy Executive Director
James Johnson, Deputy Executive Director
Annette Kelley, Deputy Executive Director
Beth O' Halloran, Deputy Executive Director
Elaine Yeatts, Senior Policy Analyst, DHP
David E. Brown, D.C., Director, DHP (Departed 9:51 AM)
James Rutkowski, Assistant Attorney General
Kiara Christian, Executive Assistant

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

APPROVAL OF AGENDA: Ms. Warriner informed the board that an amended agenda had been provided as a handout that included the following new agenda items: Approval of 11-21-2019 Regulation Committee minutes. She added that the agenda item "Consideration of Interpretation of the term "New" Prescription as it related to Requiring an offer to Counsel" was stricken from the agenda as the OAG is no longer in need of assistance, and the honoring of Mr. Saenz had been stricken as the plaque was not received in time. She indicated the board will plan to

honor Mr. Saenz at the March board meeting.

MOTION:

The amended agenda was adopted unanimously as presented. (motion by Nelson , seconded by Boone)

APPROVAL OF PREVIOUS BOARD MEETING MINUTES

The following corrections were noted: 9/25/19 formal hearing minutes – change Rafael Saenz to Kris Ratliff; 11/22/19 Regulation Committee minutes – correct spelling of "the".

MOTION:

The Board voted unanimously to adopt the minutes as presented and amended for the following meetings:

- **September 20, 2019, Special Conference Committee**
- **September 24, 2019, Informal Conference Committee**
- **September 25, 2019, Full Board Meeting**
- **September 25, 2019, Public Hearing Scheduling Chemicals**
- **September 25, 2019, Formal Hearing**
- **October 9, 2019, Telephone Conference Call**
- **October 23, 2019, Special Conference Committee**
- **October 31, 2019, Telephone Conference Call**
- **November 21, 2019, Regulation Committee**

(motion by Jenkins , seconded by Richards-Spruill)

PUBLIC COMMENTS:

Katie Hellebush, Executive Director for Virginia Medical Cannabis Coalition, offered comment related to the draft guidance document for pharmaceutical processor sample size testing. She urged the board to confer with stakeholders to determine a sample size requirement that is sufficiently large enough, but not excessive and wasteful.

Cindy Williams, Vice President, Riverside Health Systems and member of VSHP, provided comment on the draft regulatory action to incorporate allowances for RFID and carousel technology. Ms. Williams offered support to the board for the adoption of the draft amendments to 18VAC110-20-425 and new section 18VAC110-20-505 related to medication carousels and use of RFID technology in provision of floor stock. She added that both technologies are currently in use at Riverside Regional Medical Center via innovative pilot programs. Ms. Williams offered support to the board for publication of a NOIRA to solicit feedback on the draft language.

Christina Barrille, Executive Director, Virginia Pharmacists Association, echoed support provided by Katie Hellebush regarding pharmaceutical processor sample size requirements. She also informed the board that VPhA intends to have legislation introduced regarding pharmacy benefit managers. She referenced the Mercer report provided to DMAS that identified $29 million in waste related to the current PBM practices. She also expressed appreciation to the board for compiling information related to pharmacy closings.

Hunter Jamerson, Esq., Regulatory Counsel for pharmaceutical processors Dalitso and Greenleaf, requested that the board not adopt Guidance Document 110-14 *Statically Valid Sample Size for Pharmaceutical Processors* as written and re-refer to the Regulation Committee for further study. He stated USP chapter <561> is not a standard in many states and that it appears unnecessary and unfeasible. He provided a handout of written comments as well.

Aaron Lopez, representing Dalitso LLC, expressed concern for the sample testing guidance as written. He listed concerns regarding the cost of testing, the backlog of product that the testing may create, potential diversion, and waste.

DHP DIRECTOR'S REPORT:

Dr. Brown shared comment on success rating of the board member training conducted by DHP on October 7, 2019. He encouraged board members to attend future trainings, if possible. Dr. Brown also provided updates regarding new security processes being implemented at DHP. Dr. Brown also offered praise to Ms. O' Halloran for her work in identifying a fraudulent application, Ms. Kelley for her participation at the Cannabiz Summit, Ms. Shinaberry for her work with disciplinary cases, and Ms. Juran for her work at the national level through NABP. He indicated it will likely be a busy legislative session

LEGISLATIVE/ REGULATORY/ GUIDANCE UPDATE

Update on Regulatory/Policy Actions

Ms. Yeatts reviewed the Chart of Regulatory Actions found on page 40 in the agenda packet.

Report from Regulation Committee

Mr. Ratliff addressed documents requiring review, reaffirmation or adoption.

Recommendations for Guidance Documents

Reaffirmation of 110-18

The board reviewed the proposed documents provided in the agenda packet on

Interpretation of "administer" to include preparation for administration and 110-23 *Practitioner of Healing Arts Inspection Deficiency Monetary Penalty Guide*

pages 41-52.

MOTION:

The board voted unanimously to accept the recommendation of the Regulation Committee to reaffirm guidance document 110-18 *Interpretation of "administer" to include preparation for administration.* (motion by Nelson, seconded by Thornbury)

The board had some discussion related to the penalty amount for the line 26 Major Penalty found in Guidance Document 110-23 *Practitioner of Healing Arts Inspection Deficiency Monetary Penalty Guide.*

MOTION:

The board voted unanimously to insert a $1000.00 penalty into line 26 of guidance document 110-23 *Practitioner of Healing Arts Inspection Deficiency Monetary Penalty Guide* and to reaffirm guidance document 110-23 as amended. (motion by Boone, Seconded by Richards-Spruill)

Revision of 110-15 *Delegation of Authority for Disciplinary Matters*

Ms. Juran shared with the board that staff identified two actions that could be delegated to staff to expedite the handling of certain matters such as:

- The offering of a pre-hearing consent order for the voluntary surrender of a license or regulation for a reason not related to disciplinary action.
- Authorizing the Executive Director to issue an advisory letter to the person who was the subject of a complaint pursuant to §54.1-2400.2(G), when it is determined that the proceeding will not be instituted.

Ms. Juran further added that staff receives approximately 1-2 calls each year from pharmacist requesting to voluntarily surrender their license.

MOTION:

The board voted unanimously to accept the Regulation Committee's recommendation to adopt revisions of 110-15 *Delegation of Authority for Disciplinary Matters* proposed by staff as presented.

Revision of 110-27 *PIC Responsibilities*

Ms. Juran reviewed the proposed revisions as show on pages 56-58 of the agenda packet.

MOTION:

The board voted unanimously to accept the recommendation of the Regulation Committee to adopt revisions to guidance document 110-27 *PIC Responsibilities* as presented.

Revision of 110-34 *Manufacturer, Wholesale Distributor Licensure Guidance*

Ms. Juran shared suggestions offered by Mr. Johnson and Ms. O' Halloran as shown on page 60 of the agenda packet.

MOTION:

The board voted unanimously to accept the recommendation of the Regulation Committee to adopt guidance 110-34 as presented.

Adoption of 110-13 *Guidance on Collaborative Practice Agreements*

During a Joint Commission on Health Care study, it was reported to the researcher by various stakeholders that confusion exists regarding whether a collaborative practice agreement is required for each patient to participate. The researcher inquired if the board would consider adopting guidance on this subject to clarify the Board's position. Ms. Yeatts added that once a guidance document is adopted, public comment would be open for 30 days.

MOTION:

The board voted unanimously to accept the recommendation from the Regulation Committee to adopt guidance document 110-13 as presented.

Adoption of 110-14 *Statistically Valid Sample Size for Pharmaceutical Processors*

Regulation 18VAC110-60-300 stated the sample size should be a statically valid sample size determined by the board.

MOTION:

The board voted unanimously to accept the recommendation of the Regulation Committee to adopt guidance document 110-14 as presented.

Recommendation of Emergency Action Prohibiting Vitamin E Acetate in CBD and THC-A Oil Vaping Formulations

The Regulation Committee voted 5:1 to recommend to the full board that it promulgate an emergency regulation to prohibit CBD or THC-A formulations intended to be vaped or inhaled from containing Vitamin E acetate and to recommend to the Health Commissioner that he also consider taking a more immediate action to prohibit these products from containing Vitamin E acetate.

MOTION:

The board voted 8:1 to accept the recommendation of the Regulation Committee to adopt an emergency regulation as presented to prohibit CBD or THC-A formulations intended to be vaped or inhaled from containing Vitamin E acetate. (Warriner Abstained)

MOTION:

The board voted unanimously to adopt the Regulation Committee's recommendation to send a recommendation to the Health Commissioner that he also consider taking a more immediate action to prohibit CBD or

THC-A formulations intended to be vaped or inhaled from containing Vitamin E acetate.

Consideration of Amendments to Incorporate Changes Currently in Approved Innovation Pilots

Mr. Johnson provided an overview to the board of the Medication Carousel and Radio Frequency Identification (RFID) technologies currently in use in certain hospital pharmacies via innovative pilot programs. The Regulation Committee voted unanimously to recommend to the board to amend the language in 18VAC110-20-425(C)(2) to allow for these technologies.

MOTION:

The board voted unanimously to accept the recommendation of the Regulation Committee to adopt a NOIRA to allow for the use of medication carousels and RFID technology in hospital pharmacies.

Discussion of Immunization Records

Mr. Ratliff shared some background on his experience using the Virginia Immunization Information System (VIIS) database.

ACTION ITEM:

The board requested staff to reach out to VDH to determine if an immunization coalition is being formed that would possibly be discussing immunization administration recordkeeping, how a hospital pharmacist would report to the database since the pharmacist may not know if the vaccine was truly administered or if a template exists for hospitals to report immunization administrations, and if the database could potentially support increased usage via mandatory reporting from pharmacists or all health care providers. The board also requested that staff educate pharmacists on the VIIS database in an upcoming board e-newsletter.

OLD BUSINESS:

Review Pharmacy Closing Statistics

Ms. Juran provided a review of pages 104-115 of agenda packet regarding the number of pharmacy permits issued and closed during recent years. She also provide the board with a map indicating the location of current pharmacies in Virginia. She reminded the board that there is only one type of pharmacy permit and that staff could not easily distinguish the type of pharmacy services being provided at each pharmacy location.

NEW BUSINESS:

Discuss Request from VPhA to Require CE for Statewide Standing Order for Dispensing Naloxone

Ms. Juran shared that she is not aware of a current CE program specifically developed on the use of the Virginia Health Commissioner's standing order for naloxone. She also stated that the board is not currently in a position to develop such a program. She reminded the board that the board can require pharmacists to complete up to two hours of CE on a specific subject, but that they must notify licensees prior to January 1. There was some discussion regarding whether to require CE on the general subject of naloxone.

ACTION ITEM:

The board decided to table the discussion of whether to require CE in a particular subject to the March board meeting.

Discuss request from VPhA to Review Recommendations from National Consensus Conference on *Enhancing Well-Being and Resilience Among the Pharmacist Workforce*

Ms. Juran provided a summary of actions taken by the board in 2012/2013 regarding workplace conditions, which were included in the agenda packet. She also stated that organizations such as NABP would like to review the recommendations resulting from the Consensus Conference to ensure the boards can support such recommendations prior to the meeting's final report being published. NABP is currently waiting to receive information from APhA. The board received the information and did not take any action at this time.

Prescription Monitoring Program Update

Ashley Carter, Deputy Director, PMP, provided a presentation to the board as an update on the Prescription Monitoring Program.

REPORTS

Chairman's Report

Ms. Warriner began her report by acknowledging the request received from VSHP during the public comment period at the last meeting. She stated the board would not be forming a Compounding Committee at this time since the USP chapters are currently under appeal. She also thanked staff for the quick turnaround of information from the Regulation Committee meeting. Ms. Warinner shared that she will attend the NABP Member Interactive Forum in January and plans to provide an overview of this event at the March board meeting.

Report on Board of Health Professions

Mr. Logan provided updates on topics shared at the December Board of Health Professions meeting that included updates to the DHP website, enhancements to DHP security at the Perimeter Center, budget, and licensee statistics.

Report on Inspection and Licensure Program

Mr. Johnson reviewed the licensure and inspection report provided in the agenda packet.

Report on Pharmaceutical Processors

Ms. Kelley provided overview of the pharmaceutical processor report provided in the agenda packet.

Report on Disciplinary Program

Ms. Shinaberry reviewed the disciplinary report provided in agenda packet and provided a handout that included quarterly statistics regarding the number of cases received and closed.

Executive Director's Report

Ms. Juran shared news that Carmen Catizone, NABP CEO/Secretary announced his retirement that will take place in December 2020. She also offered that the NABP award nomination deadline is December 31, 2019, and encouraged the board to submit nominations to her if interested. Ms. Juran indicated that she is planning to attend the NABP Annual Meeting this year, taking place in Maryland, and encourages board member attendance.

ADJOURN: With all business concluded, the meeting adjourned at 12:38 PM.

Cynthia Warriner, Chairman

5/20/2020
DATE:

Caroline D. Juran, Executive Director

5/18/2020
DATE: