#### **BOARD MEMBERS**

John J. Bernabei, President Dennis Lewis, Vice President Dave Bowyer, Secretary James Rucker \* Jenna Misiti\* Sam Kapourales Vicky Skaff (\*Public Member)



STAFF
Michael L. Goff,
Executive Director &
CSMP Administrator

John P. Smolder, CFO/COO

Matthew D. Morris, General Counsel

<u>Office</u> 1207 Quarrier Street, 4<sup>th</sup> Floor Charleston, WV 25301 <u>Phone</u> (304) 558-0558 (304) 558-0572 (Fax)

# MINUTES OF THE WEST VIRGINIA BOARD OF PHARMACY JUNE 11, 2023, AND JUNE 12, 2023, MEETING

On Sunday, June 11, 2023, and Monday, June 12, 2023, the West Virginia Board of Pharmacy ("Board") convened at the Canaan Valley Resort in Davis, West Virginia, for the Board's regularly scheduled quarterly meeting. The following morning the Board completed its two-day meeting. The meeting was open to the public.

## **Board Members present:**

John J. Bernabei, President Dennis Lewis, Vice President David Bowyer, Secretary Vicky Skaff James Rucker

Jenna Misiti, in attendance on day one, via video conference

## **Board Staff present:**

Michael Goff, Executive Director, and CSMP Administrator
John Smolder, CFO, and COO
Matthew Morris, General Counsel
Krista Capehart, Director of Professional and Regulatory Affairs
Michael LeMasters, Chief Compliance Officer
Lindsay Acree, Director of Overdose Prevention and Patient Safety
Fred Wagoner, Investigator
Dave Lucas, Investigator, in attendance on day one
Thomas Robinette, Inspector
Stephen Boykin, Inspector
Earl Bennett, Inspector
Mark Rubin, Inspector
Donald Klamut, Inspector
Alyssa Starcher, Inspector

### **Public present:**

#### None

President Bernabei called the meeting to order and recognized that a quorum was present. Notice of the meeting was previously posted on the West Virginia Secretary of State's website. The agenda for the meeting was previously posted on the Board's website and made available through the Board's office. The meeting was opened with a prayer.

- 1. Motion was made by Board Secretary Bowyer to re-elect John J. Bernabei, President, and re-elect Dennis Lewis, Vice President of the Board. The motion was seconded by Board Member Rucker. The motion passed unanimously without discussion.
- 2. Motion was made by Board Vice President Lewis to re-elect David Bowyer, Secretary of the Board. The motion was seconded by Board Member Rucker. The motion passed unanimously without discussion.
- 3. Motion was made by Board Vice President Lewis to re-appoint Board President John J. Bernabei and Board Member James Rucker to the Complaint Committee and to appoint Board Secretary Bowyer to replace Board Member Skaff as a backup committee member.
- 4. Motion was made by Board Member Rucker to approve the March 19th, and 20th, 2023, Board Meeting Minutes, the May 3, 2023, Board Meeting Minutes, and the April 21, 2023, Board Meeting Minutes. The motion was seconded by Board Vice President Lewis. The motion passed unanimously without discussion.
- 5. The Executive Director gave his report. Mr. Goff announced that Board member Vicky Skaff's term was expiring at the end of June and recognized her years of service to the Board. Director Goff then provided a brief update about the office and staff. He then gave summary of some the activities he and staff members were involved in, and stated that those details would be mentioned during the individual reports. Motion was made by Board Member Skaff to approve the report. The motion was seconded by Board Member Rucker and passed unanimously without discussion.
- 6. The Chief Financial Officer then gave his report. Mr. Smolder gave FY2018, 2019, 2020, 2021, and 2022, Year End Summaries along with FY 2023 YTD comparison. Mr. Smolder then followed with the cash balance and remaining Fiscal Year Budget along with reports that are provided on a quarterly basis. Mr. Smolder finalized his report with the Safety Committee Update meeting that was held in March for the new office. Motion was made by Board Member Misiti to approve the report. The motion was seconded by Board Secretary Bowyer and passed unanimously without discussion.
- 7. The General Counsel then gave his report. Mr. Morris gave an update on discipline, stating that all complaint cases were up-to-date and statutorily compliant. Mr. Morris then discussed his review of the NABP Blueprint State Agreement and explained the Board's obligations as it relates to inspections. Mr. Morris then discussed database system updates. Finally, Mr. Morris discussed a proposed complaint resolution option that he had been working on with the Attorney General's Office. Motion was made by Board Vice President Lewis to approve the report. The motion was seconded by Board Member Skaff and passed unanimously without discussion.
- 8. The Director of Professional and Regulatory Affairs (DPRA) then gave her report. DPRA Capehart provided an update on the current status of COVID-19 vaccinations. There are

three additional collaborative practice agreement notifications that have been received and processed (Hugh Quinn, Brittany Kocher, Rachel Broscious-Schauble). The contraception protocol has been updated with DHHR and will be working to complete the tobacco cessation protocol. DRPA Capehart then provided an update of the developing pseudoephedrine information coming out from the DEA for situational awareness of the Board. Motion was made by Board Member Skaff to approve the report. The motion was seconded by Board Vice President Lewis and passed unanimously without discussion.

- 9. Motion was made by Board Vice President Lewis to enter Executive Session. The motion was seconded by Board Secretary Bowyer and passed unanimously without discussion.
- 10. The Board exited Executive Session. Motion was made by Board Member Skaff to approve the use of Consent Agreements in lieu of discipline as a complaint resolution option. The motion was seconded by Board Secretary Bowyer and passed unanimously without discussion.
- 11. Motion was made by Board Member Skaff to re-enter Executive Session. The motion was seconded by Board Secretary Bowyer and passed unanimously without discussion.
- 12. Motion was made by Board Vice President Lewis to reduce the fine and assess administrative costs in Complaint Case No. 2022-09-65; to find probable cause to pursue disciplinary action in Complaint Case Nos. 2023-01-02, 2023-01-08, and 2023-04-40, and to accept the recommendations of the complaint committee in the remaining cases. The motion was seconded by Board Secretary Bowyer and passed unanimously without discussion. Board Member Skaff was recused from all cases involving Walgreens.
- 13. Motion was made by Board Member Skaff to deny Earl Claycomb's petition for reconsideration to act as a pharmacist-in-charge. The motion was seconded by Board Member Rucker. The motion passed unanimously without discussion. Mr. Claycomb's petition was related to his Consent Agreement settling Complaint Case Nos. 2018-11-72, 2019-01-02, and 2019-11-62.
- 14. The Chief Compliance Officer (CCO) then gave his report. CCO LeMasters stated that a total of 273 inspections were conducted during the period from March 1, 2023, through May 31, 2023. The Board had received 1,277 suspicious order reports, of which 288 were zero reports, during the period from March 1, 2023, through May 31, 2023, with 38 reports requiring further investigation. After inquiries into each, no further action was required, as all 38 cases were resolved. LeMasters revisited the topic of use of the Accreditation Commission for Health Care (ACHC) inspection as an alternative to the NABP Verified Pharmacy Program (VPP) Inspection for non-resident sterile compounding pharmacies, which are licensees of the West Virginia Board of Pharmacy. This item was tabled from the previous Board meeting. He asked the Board to approve the use of an ACHC inspection, for those licensees who are not eligible for a VPP inspection, to satisfy the requirements for licensure of a non-resident sterile compounding pharmacy. The Board approved the use of this alternative inspection to evaluate nonresident sterile compounding licensees. A motion was made by Board member Skaff to approve the use of ACHC inspections for this purpose. The motion was seconded by Board Vice President Lewis and passed unanimously without discussion. The Chief Compliance Officer discussed collaborative efforts with the Office of Health Facility Licensure and Certification (OHFLAC) to optimize the compliance of facilities which are required to have a Controlled Substance Permit (CS Permit) with the Board. LeMasters went on the say that the CS Permit Only Inspection Form had been finalized and that

those inspections would begin this quarter. He then spoke of the upcoming changes to the Drug Supply Chain Security Act (DSCSA), possible methods to implement the requirements into the inspection process, and potential ways to train the inspectors on the changes to the DSCSA. Then he went on to speak about the inspectors who are currently enrolled in training programs during the past quarter. To close his report, LeMasters discussed the topics covered from a meeting of the inspectors, which was held on June 8, 2023. Motion was made by Board Member Skaff to approve the report. The motion was seconded by Board Vice President Lewis and passed unanimously without discussion.

- 15. The Controlled Substances Monitoring Program Administrator then gave his report. Mr. Goff stated that overall doses of most controlled substances dispensed in West Virginia continues to decline. He also provided an analysis conducted by staff epidemiologists regarding prescriber behavior after receiving overdose notifications. Motion was made by Board Member Skaff to accept the report. The motion was seconded by Board Secretary Bowyer and passed unanimously without discussion.
- 16. DRPA Capehart then gave her update on training programs, permits, and licensing. DRPA Capehart reviewed and recommended the following programs for Board approval: St. Mary's Medical Center Ambulatory Pharmacy, Preston-Taylor Pharmacy, Main Street Pharmacy, and Marshall Pharmacy. Motion was made by Board Member Skaff to approve the pharmacy programs listed above. The motion was seconded by Board Secretary Bowyer.
- 17. Board Secretary Bowyer then gave his CE Committee update.
- 18. Board President Bernabei then gave a brief Medical Cannabis Advisory Board update.
- 19. DPRA Capehart then gave her update on the Legislative Session. DRPA Capehart presented each of the following rules: W. Va. 15 CSR 1, 15 CSR 3, 15 CSR 7, 15 CSR 12, 15 CSR 14, 15 CSR 15, and 15 CSR 17. Motion was made by Board Member Skaff to accept legislative changes as amended. The motion was seconded by Board Secretary Bowyer and passed unanimously without discussion.
- 20. President Bernabei then opened the floor to discuss pharmacy closing issues.
- 21. The Board selected September 17th and 18th as the dates for the next quarterly board meeting. The meeting shall take place at the Board Office in Charleston, West Virginia.
- 22. Motion to adjourn was made by Board Member Skaff. The motion was seconded by Board Vice President Lewis and passed unanimously without discussion.

John J/Bernabei, President

West Virginia Board of Pharmacy

David Bowyer, Secretary

West Virginia Board of Pharmacy