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

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MINUTES OF THE WEST VIRGINIA BOARD OF PHARMACY MARCH 19, 2023, AND MARCH 20, 2023, MEETING

On Sunday, March 19, 2023, and Monday, March 20, 2023, the West Virginia Board of Pharmacy ("Board") convened at the West Virginia Board of Pharmacy office in Charleston, 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, in attendance on day two
Sam Kapourales
James Rucker
Jenna Misiti

Board Staff present:

Michael Goff, Executive Director, and CSMP Administrator
John Smolder, CFO, COO
Matthew Morris, General Counsel
Krista Capehart, Director of Professional and Regulatory Affairs
Michael LeMasters, Chief Compliance Officer
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

Public present:

Robert Duncan, in attendance on day two

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 had previously been 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 Member Misiti to approve the December 11, and 12, 2022, Board Meeting Minutes, and the January 17, 2023, Board Meeting Minutes. The motion was seconded by Board Vice President Lewis. The motion passed unanimously without discussion.
- 2. The Executive Director gave his report. Mr. Goff gave a brief update on the new office and the recently concluded Legislative session. Director Goff also discussed the status of the grant-funded pharmacist positions and also plans regarding another full-time inspector and an investigator. Mr. Goff also mentioned the upcoming NABP National Meeting, which will be held in Nashville this May. Director Goff also pointed out some interesting pharmaceutical information that was available on sMotion was made by Board Secretary Bowyer to approve the report. The motion was seconded by Board Member Kapourales and passed unanimously without discussion.
- 3. 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. Motion was made by Board Vice President Lewis to approve the report. The motion was seconded by Board Secretary Bowyer and passed unanimously without discussion.
- 4. The Director of Professional and Regulatory Affairs (DPRA) then gave her report. DPRA Capehart provided an update on COVID-19 vaccinations. The new Collaborative Pharmacy Practice process was summarized along with 2 new CPA applicants verified. The web-based system is functioning, and applicants can both apply for verification and submit their notifications online. One application for a naloxone vending machine is pending further clarification. WVU School of Pharmacy requests that Master of Science exchange students from Oman completing a 5-week rotation through the WVU School of Pharmacy be granted a WV Pharmacy Intern permit. Motion was made by Board Member Misiti to approve the Oman students to apply for the permits. The motion was seconded by Board Member Kapourales and passed unanimously without discussion. Motion was made by Board Secretary Bowyer to allow waivers for all Board fees associated with licensing for the students that are part of this program. The motion was seconded by Board Vice President Lewis. Motion was made by Board member Skaff to approve the report. The motion was seconded by Board Member Rucker and passed unanimously without discussion.
- 5. 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 explained that in the coming weeks, he would begin working with DPRA Capehart on legislative matters. Motion was made by Board Vice President Lewis to approve the report. The motion was seconded by Board Member Rucker and passed unanimously without discussion.
- 6. Motion was made by Board Vice President Lewis to enter Executive Session. The motion was seconded by Board Member Misiti and passed unanimously without discussion.
- 7. Motion was made by Board Member Kapourales to find probable cause to pursue Board action in Complaint Case Nos. 2022-09-68, 2022-10-76, 2022-11-80B, 2022-11-84, and

- 2022-12-90B, and to accept the recommendations of the complaint committee in the remaining cases. The motion was seconded by Board Member Misiti and passed unanimously without discussion.
- 8. The Chief Compliance Officer (CCO) then gave his report. CCO LeMasters stated that a total of 124 inspections were conducted during the period from December 1, 2022, through February 28, 2023. The Board had received 870 suspicious order reports, of which 280 were zero reports, during the period from December 1, 2022, through February 28, 2023, with 33 reports requiring further investigation. After inquiries into each, no further action was required, as all 33 issues were resolved. CCO LeMasters further reported that he and Tom Robinette, Assistant Chief Compliance Officer, had been discussing the 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. He stated that they would like the Board to advise if the use of an ACHC inspection would be acceptable to satisfy the requirements for licensure of a non-resident sterile compounding pharmacy. The Board opted to table this discussion pending further investigation into the NABP VPP requirements for blueprint states. Then, CCO LeMasters stated that he and Michelle Pauley, Program Coordinator, created a method to record and track those licensees performing compounding of non-sterile pharmaceutical products. He went on to discuss the development of the Controlled Substance Permit Only Inspection Form and the continued work with the West Virginia Department of Environmental Protection (DEP) regarding pharmacy compliance with DEP regulations. LeMasters then introduced the Board to the newest member of the team of inspectors, Alyssa Starcher. To close his report, LeMasters discussed the topics covered in a meeting of the inspectors, which was held on March 6, 2023. 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.
- 9. The Controlled Substances Monitoring Program Administrator then gave his report. Mr. Goff discussed the current trends, including the continuing increase in integrated CSMP integrations usage and the sustained rise in the number of drug overdose-related deaths. Director Goff also mentioned that it appears that grant funding would continue to fund CSMP activities for the next five years. Motion was made by Board Vice President Lewis to accept the report. The motion was seconded by Board Member Skaff and passed unanimously without discussion.
- 10. The CE Committee Report was then given by Board Secretary Bowyer.
- 11. Board President Bernabei then gave a brief Medical Cannabis Advisory Board update.
- 12. DPRA Capehart then gave her update on the Legislative Session. DRPA Capehart reported passage of all Board Rules including, §15-1, §15-2, §15-7, §15-15, §15-19, §15-20, and joint rule §11-8 with the Boards of Medicine and Osteopathic Medicine. We await the Governor to sign the rules. The following bills impacting pharmacy also passed this legislative session: SB 546 (updating controlled substances), SB 577 (cap on insulin prices), HB 2754 (adds technicians to those who may immunize under supervision of an immunizing pharmacist and lowers the age to 3 years and up without a prescription), HB 3077 (makes the multi-state tracking system for pseudoephedrine permanent). We will begin drafting the required rules.
- 13. President Bernabei then opened the floor to discuss issues affecting patient access and workload. Motion was made by Board Member Skaff to establish a limited-purpose workgroup tasked with proposing draft rules to the Board that fairly address permanent, temporary, and emergency pharmacy closures. The workgroup members will include

DPRA Capehart, CCO LeMasters, General Counsel Morris, Board President Bernabei, Board Member Skaff, and Board Member Misiti. The motion was seconded by Board Member Misiti and passed unanimously without discussion.

John J. Bernabei, President

West Virginia Board of Pharmacy

David Bowyer, Secretary

West Virginia Board of Pharmacy