BOARD MEMBERS

Dennis Lewis, President
David Bowyer, Vice President
Jenna Misiti*, Secretary
James Rucker *
John J. Bernabei
Sam Kapourales
Robert Duncan
(*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, 4th Floor Charleston, WV 25301 <u>Phone</u> (304) 558-0558 (304) 558-0572 (Fax)

MINUTES OF THE WEST VIRGINIA BOARD OF PHARMACY SEPTEMBER 29, AND SEPTEMBER 30, 2024, MEETING

On Sunday, September 29, and Monday, September 30, 2024, the West Virginia Board of Pharmacy ("Board") convened for its regularly scheduled quarterly meeting at Canaan Valley Resort State Park in Davis, West Virginia. The meeting was open to the public.

Board Members present:

Dennis Lewis, President
David Bowyer, Vice President
Jenna Misiti, Secretary
John J. Bernabei
James Rucker
Robert Duncan

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 – In attendance on Sunday
Dave Lucas, Investigator
Michael Smith, Investigator
Thomas Robinette, Inspector
Earl Bennett, Inspector
Brandon Dolly, Inspector
Donald Klamut, Inspector
Stephen Boykin, Inspector

Public present:

Danny Schwaber

President Lewis 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 at the Board's office. The meeting was opened with a prayer.

- Board Member Bernabei made a motion to approve the June 2 and 3, 2024, July 23, 2024, and August 30, 2024, Board Meeting Minutes and the September 19, 2024, Complaint Committee Meeting Minutes. Board President Lewis seconded the motion. The motion passed unanimously without discussion.
- 2. The Executive Director gave his report. Mr. Goff introduced the newest Board Inspector, Brandon Dolly, and gave a general office update. Director Goff also provided a brief report on the NABP forum he attended the week before, an update on the Joint Board meeting and summary of other projects. Board President Lewis made a motion to approve the report. Board Member Rucker seconded the motion. The motion passed unanimously without discussion.
- 3. The Chief Financial Officer then gave his report. Mr. Smolder gave FY2018, 2019, 2020, 2021, 2022, 2023 and 20243, Year End Summaries along with FY 2025 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 with no update. Board President Lewis made a motion to approve the report. Board Secretary Misiti seconded the motion. The motion passed unanimously without discussion.
- 4. 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 he had been working with DPRA Capehart and the Legislative Committee to prepare for the upcoming legislative session. Finally, Mr. Morris explained that he would discuss confidential complaint case information and litigation information during the executive session. Board Member Bernabei made a motion to approve the report. Board President Lewis seconded the motion. The motion passed unanimously without discussion.
- 5. The Director of Professional and Regulatory Affairs (DPRA) then gave her report. DPRA Capehart presented an update on vaccination status, the most recent Newsletter, naloxone boxes (unlocked) being placed throughout the state now that the medication is OTC and the update of recently opened and closed pharmacies. There have been two newly permitted pharmacies (Mingo/Wayne Co) and seven recently closed pharmacies (3 Kanawha, 3 Cabell and 1 Raleigh) since the last Board meeting. DPRA Capehart presented the package of information regarding Board requirements to determine Epclusa (sofosbuvir /velpatasvir) being considered a "specialty drug" in WV as per W.Va. Code §33-51-11(a)(7) and WV CSR §114-99-9.2.1. After consideration, the Board voted to determine that Epclusa (sofosbuvir /velpatasvir) does not meet the definition of a prescription drug as

defined in Code and Rule. Specialty Drug vote motion was made by Board Secretary Misiti, seconded Board Member Duncan and passed unanimously). Board Member Bernabei made a motion to approve the report. The motion was seconded by Board Member Duncan. The motion passed unanimously without discussion.

- 6. The Board then entered Executive Session to discuss confidential complaint case information and litigation information with the General Counsel. There was no opposition to entering Executive Session.
- 7. The Board exited Executive Session. Board Member Bernabei made a motion to find probable cause to pursue disciplinary action in Complaint Case Nos. 2023-12-105, 2023-12-106, 2024-03-26, 2024-05-37, 2024-05-44B, 2024-06-47, 2024-07-50, 2024-07-54, 2024-07-55, and 2024-08-63B, but to hold enforcement in cases 2024-07-50, 2024-07-54, and 2024-07-55, until the next Board Meeting on December 8, and 9, 2024, to allow Southern District of West Virginia Federal Court sufficient time to decide a preliminary injunction motion related to enforcement of these cases. Board Secretary Misiti seconded the motion. The motion passed unanimously without discussion. Board Secretary Misiti made a motion to table Complaint Case No. 2024-07-53 for additional investigation. Board Member Bernabei seconded the motion. The motion passed unanimously without discussion. Board Member Bernabei made a motion to accept the recommendations of the Complaint Committee in the remaining cases and to allow Mr. Morris to negotiate and offer consent agreements to settle cases where possible. The motion was seconded by Board Member Duncan and passed unanimously without discussion.
- 8. The Chief Compliance Officer (CCO) then gave his report. CCO LeMasters stated that a total of 330 inspections were conducted during the period from May 25, 2024, through September 15, 2024. The Board received 1,187 suspicious order reports, of which 385 were zero reports, during the period from May 25, 2024, through September 15, 2024, with 56 reports requiring further investigation. After inquiries into each, no further action was required, as all 56 reports were resolved. The CCO stated that eight (8) reports were received which identified individuals licensed by other agencies in the State of West Virginia and that those reports were forwarded to the corresponding licensing agency. LeMasters discussed a meeting with representatives from Cardinal Health regarding suspicious orders and possible methods to assist pharmacies that need more access to medications for opioid use disorder, specifically buprenorphine. The CCO then spoke about a group of licensees, which primarily manufacture and/or distribute medical gases within the state, that has been added to the facilities to be inspected in the state. LeMasters went on to speak about the inspection closeout form that will be used by inspectors to formally document and finalize any necessary follow-up after an inspection. The CCO continued his report with discussion about his recent attendance and speaking opportunity at the 2024 USP 4th Annual Compounding Implementation Workshop. To close his report, LeMasters discussed the topics that were covered during a meeting of the inspectors, which was held on September 18, 2024. Board Member Bernabei made a motion to approve the report. Board Member Duncan seconded the motion. The motion passed unanimously without discussion.

- 9. The Controlled Substances Monitoring Program Administrator then gave his report. Mr. Goff provided an update on current vendor contracts and mentioned some of the projects being undertaken my staff epidemiologists. Board Member Bernabei made a motion to approve the report. Board Secretary Misiti seconded the motion. The motion passed unanimously without discussion.
- 10. The Directory of Overdose Prevention and Patient Safety then gave her report. DOPPS Acree provided an update regarding opioid antagonist training, distribution, and tracking through ODMAPs. Comparing the first quarter of 2024 to the first quarter of 2023, OD deaths have decreased by 28% in WV and 11% nationally. Discussed SOR's for buprenorphine mono-product and combination product (buprenorphine/ naloxone). Multiple SOR's which are mostly attributable to a small number of pharmacies (repeat orders). Acree also provided an update on the PSA videos discussed at a previous meeting and the HALO Initiative. Board Member Duncan made a motion to approve the report. Board Member Bernabei seconded the motion. The motion passed unanimously without discussion.
- 11. DPRA Capehart then presented training programs, permits, and licensing information. DRPA Capehart reviewed programs and recommend for approval for Giant Eagle, Davis Brothers, Cabell Huntington Hospital, Martinsburg Pharmacy (uses same program for Reed's Pharmacy, #5, Spring Mills Pharmacy, Shepherdtown Pharmacy, Lambert Drug), Harless Center Pharmacy (already approved-will change name to Southern WV Health System and this will include Harless Center Pharmacy, Lincoln Primary R-eXcellence Program, Dennis' Pharmacy, Madison Medical Pharmacy, Man R-eXcellence Program, Guyan Valley Pharmacy, Oceana Medical Pharmacy, Whitesville Medical Pharmacy). Additionally, five programs have been approved by the WV Board of Education including Fred W. Eberle Technical Center, Preston High School, Greenbrier East High School, Ben Franklin Career Center, and Webster County High School. Motion to approve the technician training programs by Board Member Bernabei, Seconded by Board Member Rucker and passed unanimously. Two pharmacists applied for Collaborative Practice Agreements for pharmacists Taylor Thompson, PharmD and Martha Abraham, PharmD. Motion to approve the Collaborative Practice applications by Vice President Bowyer and seconded by Board Member Bernabei and passed unanimously.
- 12. Board Member Duncan then gave his CE Committee update.
- 13. Board President Bernabei then gave a brief Medical Cannabis Advisory Board update.
- 14. The Legislative update was then presented by DPRA Capehart updating status of legislative rules and upcoming special session.
- 15. Board President Lewis then opened the floor to discuss any new information not previously discussed. Mr. Smolder discussed the upcoming November 7, 2024, Chapter 30 Board Meeting and offered to sign up any Board Member who wished to attend.

- 16. The Board selected December 8 and 9, 2024, as the next quarterly board meeting dates. The meeting will be held at the Board's office in Charleston.
- 17. Board Secretary Misiti moved to adjourn. Board Member Rucker seconded the motion, which passed unanimously without discussion.

Dennis Lewis, President

West Virginia Board of Pharmacy

Jenna Misiti, Secretary

West Virginia Board of Pharmacy