

BOARD MEMBERS

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Vicky Skaff, Secretary
*Everett Frazier **
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Kim Knuckles
*(*Public Member)*



STAFF

David E. Potters,
Executive Director &
General Counsel

John P. Smolder,
CFO/COO

Michael L. Goff
CSMP Administrator

Office

2310 Kanawha Blvd. East
Charleston, WV 25311

www.wvbop.com

Phone

(304) 558-0558
(304) 558-0572 (fax)

MINUTES OF THE WEST VIRGINIA BOARD OF PHARMACY
CHARLESTON, WEST VIRGINIA, MARCH 19-20, 2017

The Board convened in the Board Office Conference Room, 2310 Kanawha Boulevard, East, Charleston, West Virginia, at 5:00 p.m., on Sunday, March 19, 2017, with President Dennis Lewis presiding. Present with Mr. Lewis were the following Board members: “J.J.” Bernabei, Vicky Skaff, John Everett Frazier, Chuck Jones, Sam Kapourales, and Kimberly Knuckles. Also present were David Potters, Executive Director and General Counsel; CFO/COO John Smolder; CSMP Administrator Mike Goff; the Board Inspectors: Don Klamut, Roger Shallis, Charles “Buck” Selby, Pat Regan, Tom Robinette, and Dave Gerkin; and Board Investigators Fred Wagoner and David Lucas.

Members of the public present included Mark Polen of LGCR-Government Solutions; Sherrie Armstrong of Thomas Combs & Spann; and Devon Stewart of Steptoe & Johnson PLLC.

President Lewis called the meeting to order and stated that a quorum was present. He then stated that proper notice of this meeting had been filed with the Secretary of State. The Agenda was also posted on the Board’s website and made available through the Office. Mr. Lewis then opened the meeting with prayer.

President Lewis called for the review of the minutes from the meeting of February 15, 2017. Chuck Jones made a motion to approve them as written, seconded by Kim Knuckles. All in favor with no votes against, the motion carried.

President Lewis called for the review of the minutes from the meeting of February 23, 2017. Mr. Jones pointed out three spelling corrections in the first continued paragraph of page 2. Mr. Jones made a motion to approve the minutes as corrected, seconded by Vicky Skaff. All in favor with no votes against, the motion carried.

John Smolder gave an update on the Board’s financial status. Motion was made by Kim Knuckles to receive the financial report subject to audit. Seconded by Vicky Skaff. All in favor with no votes against, the motion carried.

Next, Mr. Potters gave a Director’s Report. First, he announced that the two new inspectors, Pat Regan and Thomas Robinette, and the new CFO/COO John Smolder, had all started work on March 6, 2017 as welcome additions to the Board staff. Next, he presented a

plaque on behalf of the Board to Inspector Dave Gerkin to recognize him on his retirement at the end of March, 2017, after 17 years of service to the Board. Inspector Gerkin's years of work on behalf of the Board are very much appreciated.

Next, Mr. Potters indicated that there is some minor building maintenance to be done in the spring/summer which will include paint touch-up and pressure washing that needs done to the outside of the Board office building, and there is a contractor already lined up to do the work. Continuing with the report, Mr. Potters next indicated that the bid process for the new licensing database was moving forward, that it had been advertised and the mandatory pre-bid meeting held. Only one potential bidder, Alberton's Consulting (Big Picture Software) came to the pre-bid and is eligible to submit a bid. They have implemented licensing databases for other West Virginia licensing boards as well as other licensing boards around the country.

Mr. Potters next indicated that formal employee evaluations would be undertaken in June, 2017. Discussion centered on using the Division of Personnel forms, and addressing expectations as well as future goals and objectives. The director's report then shifted to an update on the status of suspicious order report draft rules changes and input. Mr. Potters indicated that he had some feedback from two wholesalers supporting the idea of zero reports and looking at related activity such as when a wholesaler determines not to do business with a pharmacy. The Board will hear more in a presentation from the Healthcare Distributors Alliance (HDA) during the continued meeting on Monday, March 20. Finally, Mr. Potters gave a brief update on the ongoing Legislative Session and highlighted several bills which the Board and Board staff have been following through the process. Of particular importance, Mr. Potters provided copies of SB 333 as amended which, among other things, would require overdoses or suspected overdoses of illicit or prescribed medication to be reported to the Controlled Substance Monitoring Program (CSMP), would allow Deans of West Virginia Medical Schools access to the CSMP to track prescribing practices of their residents, and adds a new section to allow the Board pursuant to emergency rule to add "drugs of concern" which have a "high potential for abuse" to a list of drugs that must be reported to the CSMP even though they are not controlled substances. The bill did have access for employers to monitor prescribing habits of their employees, but that was stripped out by an amendment in the Senate Health Committee, and Senate Judiciary Committee is working on language to provide for it in some fashion. A separate bill is running which gives OHFLAC access to the CSMP, and discussion is to amend this into SB 333 as well. Some of the other legislation discussed included HB 2653 which would extend the sunset date for the NPLEX system used to track pseudoephedrine sales, HB 2540 allowing out-of-state pharmacists and other professionals to volunteer at charitable events up to 21 days in length without having to get licensed, and a bill to move the CSMP to the DHHR which does not appear to be moving.

Dennis Lewis again complimented Mike Goff on working with Maier Institute and Dr. Shirley Neitch for their project on prescribing to the elderly. The data he provided from the CSMP has been used to help them obtain a grant and was very much appreciated.

Mike Goff gave an update on the CSMP, and provided the quarterly update and report. Mr. Goff presented, among other things, that the CSMP Annual Report was submitted by January 1, 2017; that we are now sharing data with 21 states and continue to work with Pennsylvania and its new program to add them as soon as they are capable. He indicated that the bid for the new CSMP is still progressing through the Purchasing Process, and bids should be in by March 28, 2017. A new feature we are looking forward to is that the new database will include the ability to do prescriber report cards to help educate prescribers where their own

practices fall compared to their peers. The specifications also provide for new capabilities for ad hoc reporting and canned queries which the Advisory Committee can review and determine whether to make parameters for use by the Review Committee. Continuing, he indicated that the newly hired epidemiologist Nathan Wood started work on February 4, 2017, paid through grant funds, and has already started mining CSMP data. New computers, tablets and other related accessories were purchased for Mr. Goff and Mr. Wood with grant funds. Unfortunately, the report included that there were 850 overdose deaths reported through the end of November, 2016, which represents approximately a 20% increase over 2016 by the time the full numbers for 2016 are reported. Much of this appears to be due to the street-fentanyl, carfentanyl, and heroin. Because of the sustained overdose problem, discussions with DHHR, CDC, and SAMSHA are that future grant opportunities are likely, and we are continuing to work on workflow integration for both prescribers and pharmacies. Mr. Goff also mentioned SB 333 which will expand access to the CSMP.

Motion was made by Mrs. Skaff and seconded by Mrs. Knuckles to go into Executive Session to receive the Complaint Committee's report. After discussion of the Complaint Committee Report, President Dennis Lewis declared the Board back into public session with no official action taken. Motion was made by Sam Kapourales and seconded by Everett Frazier to approve the Complaint Committee recommendations as presented, except that the recommendation for Case No. 2 in the report (Complaint No. 2016-08-61) have its recommended discipline modified to a Letter of Reprimand with \$42,000 fine plus costs of \$2,500, and place the pharmacist-in-charge/owner on 5 years' probation. All in favor with no votes against, the motion carried.

President Dennis Lewis then declared the meeting to recess, to be continued in the conference room at the Board Office, 8:00 a.m., March 20, 2017.

The Board Meeting continued on Monday, March 20, 2017, at 8:00 a.m., in the Board Office Conference Room, 2310 Kanawha Boulevard, East Charleston, West Virginia, with President Dennis Lewis presiding. Present with Mr. Dennis Lewis were the following Board members: "J.J." Bernabei, Vicky Skaff, John Everett Frazier, Chuck Jones, Sam Kapourales and Kimberly Knuckles. Also present were David Potters, Executive Director and General Counsel; CFO/COO John Smolder; the Board Inspectors, Charles "Buck" Selby; Roger Shallis, Don Klamut, Pat Regan, and Tom Robinette; and Board Investigators Fred Wagoner and David Lucas.

Members of the public present included Hope Stanley from West Virginia Retailers Association; Mike Brown; Jim Bennett on behalf of Mike Brown; Mark Polen of LGCR Government Solutions representing Rite Aid; Linden Barber and Matt Diloreto representing HDA; Devon Stewart, from Steptoe and Johnson; Betsy Wright from Kroger; Kristin Rife from OIC Training Academy, and Sherrie Armstrong of Thomas Combs & Spann.

President Lewis called the meeting back to order and stated that a quorum was present. He then reiterated that proper notice of this meeting had been filed with the Secretary of State and that the Agenda was posted on the Board's website and made available through the Office. Mr. Lewis opened the meeting with prayer.

First, Mr. Lewis announced that Vicky Skaff would work more with staff on issues at the Legislature, and that Kim Knuckles and Chuck Jones would work more on Human Resources issues.

Next, the Board took up the next item on the Agenda, a presentation by the Healthcare Distribution Alliance (HDA), Linden Barber (an expert from private practice and formerly of the DEA), and Matt DiLoretto, concerning suspicious order report monitoring. Mr. DiLoretto presented an introduction and a letter from HDA outlining several topics on suspicious order reporting and reviewing draft rules that the Board has previously worked on. Mr. Barber then gave the Board an overview of how suspicious order reporting came into existence at the DEA, and generally, how each wholesaler, with some historical guidance from DEA, takes its own approach to monitoring its own data for suspicious orders. Importantly, HAD noted that the term “suspicious order” does not imply the presence of any illegal or illegitimate active which has occurred, and even when an order is “flagged” or a customer is terminated from supply by a wholesaler, it does not necessarily mean that a customer has engaged in illegal activity. Therefore, HDA supports the efforts in draft rules to monitor terminations of service by a wholesaler to a customer, or refusals of service, both based upon suspicious orders or “related activity”. Further, with regard to the rules asking for specific reasons for why an order is deemed suspicious, that would get into the entire algorithms used and be extremely voluminous, but HDA supports having the contact information for the department or contact points in the wholesaler responsible for working with regulatory authorities provided to the Board for when an suspicious order is determined and reported, or when service is refused or cut off.

The Board then took up the Application of Gary Mike Brown for Reinstatement of his Pharmacist License. He had a felony conviction for forging a controlled substance prescription due to addiction. Due to the felony conviction, his license was revoked in 2011. He quit using substances in the end 2009, and has been in active recovery since January 16, 2010. He is also the Executive Director of the West Virginia Pharmacy Recovery Network, having devoted himself to helping others overcome addiction as well. Jim Bennett, M.A., L.P.C., spoke on Mr. Brown’s behalf concerning his stable recovery, the daily work Mr. Brown does to stay in recovery, and the fact that, as a clinician, he feels Mr. Brown is safe to return to active practice of pharmacy. The Board also reviewed written recommendations from Jim Bennett, Dr. Michael O’Neil, a pharmacy professor and former Executive Director of the WVPRN, and Joseph Lee a pharmacy and other business owner for whom Mr. Brown has worked. Sam Kapourales made a motion to allow Mr. Brown’s license to practice pharmacy to be reinstated pending satisfaction of all requirements for reinstatement, including testing. Kim Knuckles seconded the motion. All in favor with no votes against, the motion carried.

The Board then reviewed the request of PTT Alison Washburn and Jennifer Dye, RPh, to recognize prior hours worked as a PTT by Ms. Washburn although the Board did not receive the Pharmacy Technician Trainee Notification which Ms. Dye indicates was sent to the Board under the old PTT registration system. Because this involves employees of a Rite Aid pharmacy, Board Member Vicky Skaff recused herself and left the room for this item. Following a review of the documentation, which included in part a copy of the Notification and of Ms. Washburn’s successful passage of the PTCB examination to be a Nationally Certified Pharmacy Technician, Kim Knuckles made a motion to approve the hours worked as a PTT to allow Ms. Washburn to move forward and apply for her PT Registration. Seconded by Everett Frazier. All in favor with no votes against, the motion carried. Ms. Skaff was then brought back into the room to rejoin the meeting.

At that time, the Board took up review of the Naloxone protocol in place for pharmacists to furnish Naloxone products without a prescription from another practitioner. The current protocol requires pharmacists dispensing Naloxone per the protocol to provide the recipient a

copy of two brochures developed by the West Virginia Department of Health and Human Resources, Bureau for Public Health, Office of Emergency Services. One brochure entitled “I Have Narcan” is for information on Naloxone Administration. However, it only provides for the 2 mg intramuscular product with the nasal adapter, and there is also a 4 mg intranasal product on the market. Therefore, the Board considered language to adjust the protocol to assure that it applied to any FDA-approved naloxone hydrochloride product, and that the pharmacist provide the brochures, “or other appropriate patient information for the naloxone hydrochloride FDA-approved product dispensed.” Vicky Skaff made a motion to amend the language of the protocol as described and drafted, and send it to DHHR Bureau for Public Health for their input, seconded by Everett Frazier. All in favor with no votes against, the motion carried.

Inspector Selby gave a status update for Inspectors/Inspections. Following are some highlights from the report: with the exception of the two new inspector territories due to the transitions, inspections are up to date; the two new areas will be caught up through the regular cycle. Inspectors Selby and Shallis completed the annual MPJE new question writing assignment from NABP March 10, 2017, and the questions were submitted to NABP. The Inspectors held a meeting with the investigators on January 10-12, and, among other things, had a presentation on Medication Assisted Therapy for opioid abuse focusing on buprenorphine products (Suboxone and Subutex). They learned that many patients have to go out of state to see a provider as there are not enough in West Virginia, and some areas of the state have none. The inspectors suggest that the Board consider getting with other affected State agencies to encourage more in-state providers and pharmacy access. Vicky Skaff made a motion to accept the Inspectors Report and to pursue drafting letters from the Board to the appropriate Boards and other agency stakeholders for MAT, and to undertake work on best practices. Seconded by Kim Knuckles. All in favor with no votes against, the motion carried.

Next, the Board reviewed a proposed letter drafted by NABP for Boards to consider sending to select members of Congress, in this case, to Senator Manchin, regarding opposition to legislation that would allow Americans to purchase prescription medications directly from Canada. The letter and attached graphic highlight the insecurity of drugs coming into the United States in this fashion and outside the controls and protections of the FDA, and ask members of Congress not to support the legislation. Kim Knuckles made a motion to send the letter under the Board President’s signature, seconded by Vicky Skaff. All in favor with no votes against, the motion carried.

The Board then addressed the request of Baxter International Inc. to consider its direct delivery model of peritoneal dialysis solutions directly from the wholesaler to the patient. After review and discussion, Kim Knuckles moved to approve the request by seeking statutory changes similar to the NABP model language and other state language supplied by Baxter; seconded by Vicky Skaff. All in favor with no votes against, the motion carried.

Thereafter, the Board reviewed the request submitted the National Community Pharmacists Association on behalf of itself and the American Pharmacists Association, American Society of Consultant Pharmacists, College of Psychiatric and Neurologic Pharmacists, International Academy of Compounding Pharmacists, National Alliance of State Pharmacy Associations, and National Association of Chain Drug Stores regarding USP 800. In short, the organizations indicate that they will need time to comply with USP 800 which is set to go into effect in 2018, and ask for a delay in enforcement until July 1, 2021. A motion was made by Vicky Skaff, seconded by Kim Knuckles, to accept the request and delay enforcement until July 1, 2021. All in favor with no votes against, the motion carried.

The next item on the Agenda was the recommendation for Appointment of James Henderson, DDS, MD, to the CSMP Advisory Committee, to replace Lee Allen, DDS, MD, who resigned from the dentist position. After review of Dr. Henderson's credentials and the recommendation, motion was made by JJ Bernabei to accept the recommendation and appoint Dr. Henderson to the Advisory Committee, seconded by Chuck Jones. All in favor with no votes against, the motion carried.

The Board then reviewed the request by Giant Eagle Pharmacy to approve its on-the-job Pharmacy Technician Training Course. After review of the course, motion was made by Kim Knuckles, seconded by JJ Bernabei, to approve the training course for use in the Giant Eagle Pharmacies in West Virginia. All in favor with no votes against, the motion carried.

Similarly, the Board reviewed the request of Ahold USA (Martin's Pharmacy) to approve its on-the-job Pharmacy Technician Training Course. After review of the course, motion was made by Kim Knuckles, seconded by Chuck Jones, to approve the training course for use in the Martin's Pharmacy locations in West Virginia. All in favor with no votes against, the motion carried.

Next, the Board took up the request of North Central WV Opportunities Industrialization Center, Inc., to approve its learning institution based Pharmacy Technician Training Course. After review of the materials provided, motion was made by Chuck Jones, seconded by Kim Knuckles, to approve the course. All in favor with no votes against, the motion carried.

The Board then addressed the request from Pass Assured LLC to approve its PTT Training and Test Preparation materials and program for use in pharmacies as the didactic portion of a pharmacy's on-the-job PTT training program, with the pharmacy using the materials to have to provide the remainder of the West Virginia specific portions of the program and on-the-job experiential hours. Motion was made by JJ Bernabei to approve Pass Assured's request solely for use as the didactic portion, and any pharmacy using the materials would have to present its program to the Board for approval to show compliance with the requirements of Rule § 15-7-4 for its training program; seconded by Chuck Jones. All in favor with no votes against, the motion carried.

The next item on the Agenda considered by the Board was the blanket acceptance of any learning institution based PTT training programs approved by the West Virginia Community and Technical College System. Mr. Potters explained that he had learned that this is the approving body for two-year programs in West Virginia. The Board had granted prior approval to such programs approved by the Higher Education Policy Commission which is the approving body for four-year programs. Motion was made by Vicky Skaff, seconded by Kim Knuckles to approve all PTT training programs in leaning institution sites approved by WVCTCS. All in favor with no votes against, the motion carried.

The Board discussed Central Fill Pharmacy. J.J. Bernabei went over the draft rules which follow NABP Model language, and language from Pennsylvania, Ohio, and Alabama. Language from several other states were considered by Mr. Bernabei and Mr. Potters during the drafting phase. After review of the draft, a motion was made by Dennis Lewis, seconded by Vicky Skaff, to circulate the document to stakeholders for comment and input. All in favor with no votes against, the motion carried.

The Board next looked at attendance at the National Association of Boards of Pharmacy Annual Meeting scheduled for May 23, 2017, and election of official delegates to the meeting. Sam Kapourales nominated Dennis Lewis to be the Official delegate, and Vicky Skaff to be the alternate. No other nominations were made. Sam Kapourales then moved to approve Mr. Lewis and Mrs. Skaff as the delegate and alternate, respectively, and for any board member and the executive director to attend the meeting, seconded by Chuck Jones. All in favor with no votes against, the motion carried. The following indicated their intention to attend: Dennis Lewis, Vicky Skaff, Kim Knuckles, Sam Kapourales, Chuck Jones, JJ Bernabei, and Mr. Potters.

The next regular Board Meeting will be held in Morgantown, West Virginia on June 11-12, 2017.

Mr. Smolder announced that travel reimbursement forms can be scanned and e-mailed, and asked Board Members if they could help him in tracking their days to turn in for per diem by e-mailing him.

Motion was then made by Kim Knuckles and seconded by JJ Bernabei to adjourn. Mr. Lewis declared the meeting adjourned.

President, Dennis Lewis
West Virginia Board of Pharmacy