

The 2018 Board Member Retreat was held at the Proximity Hotel located in Greensboro, NC, on October 4 & 5, 2018. President Dr. Andy Bowman called the meeting to order at 12:00am on October 4, 2018 with Board Members Robert Graves, Ashley Duggins, Bill Mixon, Gene Minton, and Keith Vance present. Also present were Executive Director Jay Campbell, Associate Executive Director Ellen Vick, Board Counsel Clint Pinyan, Administrative Assistant Leslie Wilson, and Investigation and Inspections Coordinator Cindy Parham

Ethics Statement & Welcome

President Bowman read the Ethics Statement regarding any conflicts of interest and/or appearances of conflicts of interest of any Board member. No conflicts were noted by any Board member.

Chapter 93B Training

Board members received their required biennial Chapter 93B training, which was conducted by Board counsel Clint Pinyan.

The Board adjourned for a break at 2:37pm and resumed open session at 2:52pm.

Discussion of FDA 20.88 Sharing Agreement

FDA has proposed a 20.88 agreement governing information sharing among the FDA and the North Carolina Board of Pharmacy. Board counsel and staff reviewed the 20.88 agreement with the members, including specifically its confidentiality requirements. Board counsel discussed the intersection of the requirements and the North Carolina Public Records Act, explaining how the Board could comply with both if FDA agrees to a proposed procedure for resolving any potential conflicts between the two, as detailed in a draft letter to FDA. If FDA agrees with that procedure, Board counsel and staff recommend signing the 20.88 agreement

After discussion on a motion from Mr. Minton, seconded by Mr. Mixon with no dissenting votes, the Board approved staff signing the proposed 20.88 agreement on the condition that FDA raises no objection to the accompanying letter.

The Board adjourn at 3:51pm.

The Board members resumed the meeting on Friday, October 5, 2018 at 8:00am at the Proximity Hotel.

Ethics Statement & Welcome

President Bowman read the Ethics Statement regarding any conflicts of interest and/or appearances of conflicts of interest of any Board member. No conflicts were noted by any Board member.

On a motion from Mr. Minton, seconded by Dr. Vance with no dissenting votes, the following consent agenda items were approved.

Consent Agenda

Prehearing Conference

RPh. Christopher Todd Collins, license #13343, was subject of a prehearing conference held on September 24, 2018, heard by Ashley Duggins, regarding reinstatement of his pharmacist license after he let it lapse for non-renewal after he was working at his place of employment impaired; **Recommendation:** License reinstated; then suspended indefinitely with active 6 month suspension deemed served while license was inactive; Remainder of suspension is stayed with conditions including not serving as pharmacist manager for one (1) year (must petition the Board to lift restriction after one year and approved by NCPHP).

RPh. Kresa Cummings, license #19011, was subject of a prehearing conference held on September 24, 2018, heard by Ashley Duggins, regarding modification of her 2017 reinstatement order to lift the condition as not serving as pharmacist manager and taking ownership interest in a pharmacy. **Recommendation:** approve requested modification

A copy of the consent orders can be found elsewhere in the minutes and are incorporated by reference herein.

Should the Board Only Accept Board of Pharmacy Inspections of Out-of-State Sterile Compounding Facilities from Board that Participate in the NABP Blueprint Program

At the September 2017 Retreat, the Board agreed to enter into an “blueprint” agreement with the National Association of Board of Pharmacy (NABP) whereby states shoulder certain responsibilities to ensure that sterile compounding inspections will be deemed to be sufficiently rigorous by other states.

Out-of-State permit applicants who engage in sterile compounding are required to submit a USP 797 compliant home-state Board inspection or provide an NABP VPP inspection for review. Some applicants have had difficulty obtaining USP 797 compliant inspection from non-blueprint state boards. It is often difficult for staff to determine whether these non-blueprint states are inspecting to USP 797 compliance. Staff requested that the Board approve only accepting sterile compounding inspections from blueprint states or a NABP VPP inspection.

After discussion, on a motion from Dr. Bowman, seconded by Mr. Mixon on a five (5) to one (1) split vote, the Board approved staff to only accept a NABP VPP inspection or an inspection from a Blueprint state beginning in April 2019.

Discussion of the Latest of Proposed Memorandum of Understanding Among the Food and Drug Administration and States Concerning Shipments of “Inordinate Amounts” of Compounded Product Instate

The Food and Drug Administration (FDA) has proposed drafts of Memorandum of Understanding (MOU) regarding the interstate distribution of compounded drugs under the Drug Quality and Security Act. At the May 2015 Board meeting, the Board instructed Mr. Campbell to send comments to the FDA, on the first draft raising concerns with, among other things, the FDA calculations regarding interstate shipping of compounded medications and the obligations of field staff if the Board entered into the MOU.

Mr. Campbell stated that the FDA has again revised the proposed MOU which now clarifies the calculations process and increases the allowed interstate shipments by pharmacies in states that adopt the MOU. Mr. Campbell stated, however, that there are additional concerns by staff regarding the proposed MOU.

After discussion, it was the consensus of the Board to direct staff to draft a letter to the FDA in response to the MOU detailing remaining concerns and offering solutions.

Discussion of Standard-of-Care Based Regulation of Pharmacy Practice Act

Board members discussed ways to apply standard -of-care based approaches to regulations when creating or amending rules. The members agreed that, whenever possible, Board rules establishing standards to protect the public safety should maximize the ability of pharmacists to devise practice-need-specific means of meeting them and minimize highly prescriptive instruction on meeting such standards.

The Board adjourned for a break at 10:05am and resumed open session at 10:25am.

Legislative Actions

The members discussed ways to best offer its educational expertise to lawmakers when they are considering legislation that impacts the practice of pharmacy and implicates public health and safety issues.

Use of Technology as a Means of Allowing Pharmacists to Expand Their Practice; and Remote Order Entry in Community Pharmacy Practice Setting

Board members discussed ways to improve technology by pharmacists including Remote Medication Order Entry by pharmacies outside of a health system.

After discussion, it was the consensus of the Board to discuss forming a committee or task force to review Remote Order Medication Entry in the community pharmacy setting at the October 16, 2018 Board meeting.

Discussion on Law Surrounding Sales of CBD-containing products

Mr. Pinyan stated that there have been many updates from the FDA, DEA and Department of Justice (DOJ) regarding products that contain CBD. Most recently, FDA has approved a CBD product for treatment of seizure disorders, and DEA has placed that product into Schedule V under the Federal Controlled Substance Act. Those actions, and the accompanying statements

from the FDA and DEA, bear significantly on sales and marketing of other CBD products. As well, a pending federal farm bill, if passed, will further alter the regulatory picture.

After discussion, it was the consensus of the Board to direct staff to take down the current FAQ regarding CBD and hemp products from the Board website and replace it with current information provided to the Board from the FDA, DEA and DOJ.

Pharmacist-Manager on Permit Application Who is Still Serving as a Pharmacist-Manager at Another Pharmacy

At the September 18, 2018 Board meeting, members discussed concerns that a pharmacist manager on a new permit application who is still working as pharmacist manager at a different permitted location would, by law, have to relinquish the pharmacist manager position of the permitted facility. This could create a hardship on the pharmacist if the newly permitted facility is not providing patient services for a period of time while it secures other needed licenses, registrations, or permits.

Board staff presented a proposed rule change to .2502(g) to allow a pharmacist to simultaneously serve as a pharmacist manager at more than one pharmacy if one pharmacy is newly permitted and has not yet begun providing services to patient. The pharmacist would be required to relinquish the pharmacist manager position of the other permit once the newly permitted facility begins to service patients or six (6) months for the issuance of the permit, whichever occurs earlier.

After discussion, it was the consensus of the Board to add the proposed rule change to the October 16, 2018 agenda for discussion.

The Board members adjourn for lunch at 12:01pm and resumed open session at 1:25pm.

When open session resumed, Board member Robert Graves was absent from the meeting.

Discussion of Prescription Drug Take-Back Events

At the 2018 NABP District III meeting, John Kirtley, Executive Director of the Arkansas Board of Pharmacy, discussed ways that Arkansas is addressing the opioid crisis including drug take back programs. The member discussed possibilities of developing take-back resources in North Carolina.

After discussion, it was the consensus of the Board to direct staff to reach out to the Medical Board, NC Department of Health and Human Services, and other agencies regarding developing and funding a website that could serve as an universal resource on disposal and take-back of medications.

There being no further business, on a motion from Mr. Mixon, seconded by Ms. Duggins with no dissenting votes, the meeting adjourned at 1:34pm.

Dr. Andy Bowman, President

Robert Graves, Vice-President

Gene Minton

Bill Mixon

Ashley Duggins

Keith Vance