

**OPEN MINUTES**  
**Missouri Board of Pharmacy**

**April 9-10, 2014**  
**Courtyard by Marriott**  
**3301 Lemone Industrial Boulevard**  
**Columbia, MO**

The Missouri Board of Pharmacy met in open session during the times and dates stated in the following minutes. Each item in the minutes is listed in the order it was discussed at the meeting. The regular meeting was called to order by President Pamela Marshall at 3:00 p.m. on April 9, 2014, at Courtyard by Marriott, Columbia, Missouri.

**Board Members Present**

Pamela Marshall, R.Ph., President  
Janine Burkett, R.Ph., Vice President  
Barbara Bilek, PharmD., Member  
Anita Parran, Public Member

**Staff Present**

Kimberly Grinston, Executive Director  
Tom Glenski, R.Ph., Chief Inspector  
Joe Dino, R.Ph., Inspector  
Bennie Dean, R.Ph., Inspector  
Andi Miller, PharmD, Inspector  
Lisa Thompson, R.Ph., Inspector  
Dan Vandersand, R.Ph., Inspector  
Frank VanFleet, R.Ph., Inspector  
Barbara Wood, R.Ph., Inspector  
Tammy Siebert, Administrative Coordinator  
Nikkie Spratt, Compliance Coordinator

**Others Present**

Curtis Thompson, Legal Counsel  
Visitors as recorded in the visitor register

**MOTION TO CLOSE 3:00 PM**

**At 3:00 p.m. Barbara Bilek made a motion, seconded by Anita Parran, that the Board go into closed session and that all votes, to the extent permitted by law, pertaining to and/or resulting from this closed meeting be closed under Section 610.021(1), (3), (5), (7), (13) and (14), RSMo, and under Section 324.001.8, RSMo. Motion passed, all in favor, none opposed.**

## **THURSDAY, APRIL 10, 2014**

### **RETURN TO OPEN**

By motion duly made, seconded, passed and recorded in closed session minutes, the Board returned to open session at approximately 8:18 a.m. on Thursday, April 10, 2014.

MEMBERS OF THE PUBLIC ENTERED THE MEETING ROOM AT 8:18 AM

PRESIDENT MARSHALL CALLED THE OPEN SESSION MEETING TO ORDER AT 8:35 AM

### **#A1 Agenda Additions/Corrections**

Kimberly Grinston reported regarding additional information for Items #A3, #C1, and #D2, plus new Items #D3A-D5A.

### **#A2 Board Member Report**

- DEA Conference,
- Center for Patient Safety Annual Meeting

President Marshall reported Barbara Bilek, she and several inspectors attended the DEA conference in St. Louis last week.

President Marshall also reported she, Barbara Wood, Joe Dino, Bennie Dean, and Lisa Thompson attended the Missouri Center for Patient Safety Conference in St. Louis.

### **#A3 General Administration Report**

- **St. Louis Patient Safety Conference** - Kimberly Grinston reported this conference was co-sponsored by the Board with the Board of Nursing.

- **January 2014 Financial Report** - Kimberly Grinston reported the Board's fund is excessive and is growing. A request for filing of an emergency rule is at the Governor's Office that will reduce pharmacist, intern and technician renewal fees. It is expected the emergency rule will be effective prior to the pharmacist renewal period that begins in August.

- **Rule Update** - Kimberly Grinston reported the Board of Healing Arts has requested the 50-mile requirement be removed from the medication therapy services regulation. The Board's Compounding for Office Use rule is still under consideration. Ms. Grinston reported the Governor's Office is not comfortable with the regulation and has asked for more information.

- **FDA Meeting Update -**

- Agenda
- Pharmacy Compounding Legislation and Implementation
- Memorandum of Understanding With the States Under Section 503A

Kimberly Grinston reported regarding her attendance at the FDA meeting in Maryland about the Drug Quality & Security Act (DQSA); FDA was attentive to the states' input/comments. Ms. Grinston reported Tom Glenski is FDA commissioned and is able to investigate complaints for these types of facilities. However, the FDA commission does restrict him from sharing information with non-commissioned individuals, including

the Board. Doug Lang inquired if NABP will be proposing model rule revisions; Kimberly Grinston reported NABP will be looking at this at their annual meeting and may be appointing a special task force.

- **Webinar Updates**

- BNDD Regulatory Update (August 14<sup>th</sup>) [1.0 CE required]
- Board Regulatory Update (Include in July “Lunch With The Chief”)

Kimberly Grinston reported 220 people participated in Tuesday’s Lunch With The Chief webinar. The BNDD Regulatory Update webinar date will be changed, and Ms. Grinston requested the Board approve the BNDD Regulatory Update for one (1) hour of pharmacist CE credit. **Motion was made by Barbara Bilek, seconded by Janine Burkett, to approve the BNDD Regulatory Update for one (1) hour of pharmacist CE. Motion passed, all in favor, none opposed.**

Ms. Grinston further reported the Board Regulatory Update will be conducted in July as a Lunch With The Chief webinar.

- **August Missouri Regulator Patient Safety Meeting** - Kimberly Grinston reported a regulator-focused patient safety conference is being planned for August in Columbia, Missouri. The conference is being hosted by the Board of Pharmacy, Board of Nursing, Board of Healing Arts and Missouri Dental Board. The conference will be offered at no cost to licensees. The program will be recorded by Department of Elementary and Secondary Education staff and will be provided on our website following the conference. It is anticipated that healthcare legislators will be invited to participate in the conference; Steve Calloway suggested Department of Health and Senior Services employees/inspectors be invited to participate.

- **Sterile Compounding Training, North Carolina** - Kimberly Grinston reported Tom Glenski attended Critical Pointe’s Sterile Compounding Boot Camp, Dan Vandersand will attend it in June, and all inspectors will be attending a sterile compounding training in North Carolina sponsored by Campbell University tailored specifically to Missouri.

- **Status of Board Rules** - Previously reported.
- **Joint Regulator Patient Safety Conference** - Previously reported.
- **HCCA- Certificate in Healthcare Compliance** - Kimberly Grinston reported and requested Board approval for her to be tested and certified. It was Board consensus to approve Ms. Grinston’s request.

- **FY13 Annual Report** - Kimberly Grinston reported the FY13 Annual Report is here for Board approval. Janine Burkett asked if it should be noted about the vacant Board member positions. **Motion was made by Janine Burkett, seconded by Anita Parran, to approve the FY13 Annual Report as printed. Motion passed, all in favor, none opposed.**

- **State Audit** - Kimberly Grinston reported the Board of Pharmacy, the Board of Accountancy and the Missouri Real Estate Commission are being audited by the State Auditor’s Office.

- **New Division Licensing System** - Kimberly Grinston reported the Division’s new licensing system will be operational by June 2015. It will include a fully electronic inspection process.

- **Drug Distributor Licensing: Will the Board like to issue a pharmacy (drug) distributor license?**

- 338.330
- 338.333

Kimberly Grinston reported and asked if the Board is interested in tracking the “pharmacy distributor” designation--the new licensing system will have this capability. Discussion was held regarding whether outsourcing facilities will fall into that category. Tom Glenski reported it has never been used by our Board. It was Board consensus to eliminate the pharmacy distributor designation. Ms. Grinston reported about the new system’s ability to keep/reinstate prior license numbers; and that unlicensed individuals/entities will be better tracked. President Marshall asked if the new system offers level of access; i.e., pharmacies able to search status of their technicians’ renewals; or corporate, district and individual store levels? Barbara Bilek inquired about reporting capabilities, Christian Tadrus requested flexibility for floater pharmacists, Kristol Chism asked about online search capabilities, availability of public information; and Steve Calloway asked about hospital/community pharmacist designations, as well as pending complaint status available to the public.

- **Annual Renewals:** Would the Board be interested in an annual renewal or renewal based on birthdate for Missouri pharmacists/interns?

Kimberly Grinston reported the Board of Nursing is asking for annual renewals based on the licensee’s date of birth. It was Board consensus to not change our Board’s renewal dates. It was also general consensus of the public to make no change.

- **Drug, Quality and Security Act:**

- Discussion regarding regulation of an “outsourcing facility”? Should these be licensed/regulated by the Board? If yes, how (i.e.- should we establish a different license/compliance standards)?

Tom Glenski reported Missouri currently has one of these facilities, and Doug Lang commented large hospital systems may create outsourcing facilities. Discussion was held. It was Board consensus to treat them as drug distributors at this time, with an exemption for hospital facilities. This type of facility will need to be identified as an “outsourcing drug distributor” and kept separate from a regular drug distributor license. Kimberly Grinston reported the outsourcing facilities will need to comply with GMP and Board staff will need training to inspect these facilities. The DQSA only applies to sterile compounding facilities.

- Should we require separation of pharmacy & outsourcing activities?

Kimberly Grinston reported FDA’s perspective is that once an outsourcer, always an outsourcer. There will be a problem with inspections, especially if only inspected once every three years. It was Board consensus to comingle the licensees--would be too cost prohibitive to keep them separate; however, records should be kept separate. Kimberly Grinston reported the Hospital Working Group will need to review this topic.

- Update on MOU requirements

Kimberly Grinston reported. John Hamilton of Bellevue Pharmacy commented 20% would be difficult to comply with. Doug Lang inquired if the MOU is between the Board of Pharmacy and FDA, or with all states where the pharmacy is located and FDA. Ms. Grinston clarified the main one is between the resident state and FDA, and this is where

the question of release of information came up during the FDA meeting. Doug Lang suggested an automatic blanket apply after the facility has reached the 5% limit.

- Does the Board want to modify drug distributor rules to accommodate facilities distributing sterile compounding preparations intrastate?

Ms. Grinston withdrew this question.

- According to the FDA, the DQSA applies to human drugs only and does not apply to vet drugs. Does the Board want to modify Missouri law to address drug distributors compounding veterinary drugs?

Kimberly Grinston suggested the Board deal with human drugs only at this time and pursue veterinary drugs at a later date.

- Does the Board want to disclose administrative letters of warning? [See Sec. 105]

Curt Thompson reported the Board currently has authority to share closed information with other state and law enforcement agencies. It was Board consensus to disclose those Letters of Warning.

- **Sterile Compounding:**

- Does the Board want to proceed with preliminary rule drafting?

It was Board consensus to proceed with preliminary rule drafting. Ms. Grinston reported the fiscal note for this regulation will be huge.

#### **#C1 Applications for Intern Training Pharmacy Special Site**

- Allergen, Inc.
- American Pharmacists Association
- Alzheimer's Disease Research Center at Washington University
- East Coast Institute for Research
- EPI-Q, Inc.
- Express Scripts – Research Lab
- Jewel Osco / Shop 'n Save District Office
- National Association of Chain Drug Stores (NACDS)
- Sioux San Indian Health Service (HIS) Hospital Pharmacy
- University of Florida College of Pharmacy, Pharmacotherapy and Translational Research
- VA Nebraska-Western Iowa
- Walmart Corporate Office – Health and Wellness Preceptor
- Genelex Corporation
- Hope Family Care Center
- Lloyd's Pharmacy
- Walgreens Regional Office

#### **International Special Site**

- Memo from Ferguson
- Komfo Anokye Teaching Hospital
- St. Phillip's Mission

Tom Glenski reported. **Motion was made by Janine Burkett, seconded by Barbara Bilek, to approve the special sites/non-pharmacist preceptors listed for 500 hours each. Motion passed, all in favor, none opposed.**

**#C2 STLCOP and UMKC College of Pharmacy**

- STLCOP Site Listing
- STLCOP Preceptor Listing
- UMKC Site Listing
- UMKC Preceptor Listing

Tom Glenski reported. **Motion was made by Barbara Bilek, seconded by Anita Parran, to approve the STLCOP and UMKC Site and Preceptor Lists as presented. Motion passed, all in favor, none opposed.**

**#D1 DEA Hydrocodone Rescheduling Rule**

- 21 CFR Part 1308

Kimberly Grinston reported public comments are due April 28, 2014, and asked if the Board wants to provide an official comment. Discussion was held. Barbara Bilek commented hydrocodone abuse is a big problem. Doug Lang inquired if BNDD has indicated a rescheduling action for Missouri.

**#D2 2014 Legislative Update**

- Missouri Lawmakers Propose Reforms to Distorted Pharmacy Reimbursement System That Endangers Patient Care
- Executive Director Summary
- HB 1683

Kimberly Grinston reported the Board's hospital proposal was heard in the Senate a few weeks ago, there was much support in favor of the bill, and Missouri State Medical Association (MSMA) objected nicely to the bill.

Kimberly Grinston reported that HB1683 will prevent government regulation of professions, and that most bills with this language tacked on them will likely not get out of the Senate.

Ron Fitzwater reported the immunization bill is moving, but may require some changes. The Board has requested permission from the Governor's Office to testify in favor of this legislation.

Bert McClary reported James Gray of BJC submitted changes to the legislature for the hospital bill.

Sam Leveritt asked about HB2145 for medication synchronization. Ron Fitzwater reported the bill was proposed by Pfizer, MPA supports the language, but it likely won't get traction this year in the legislature. Joel Kurzman reported NACDS is tracking similar legislation in 23 other states.

Kimberly Grinston reported regarding the medical marijuana/hemp oil bill that is supported by the Missouri Society of Hospital Pharmacists and other organizations.

#### **#D3A Patient Safety Working Group Report**

Kimberly Grinston and President Marshall reported.

#### **#D4A Mandatory Report of Pharmacist Discipline**

In 2013, the Board voted to amend 20 CSR 2220-2.150 to incorporate Section 383.133 that require mandatory pharmacist reporting. Rule draft is attached.

Would the Board like to begin enforcement prior to the rule revision?

- Draft 20 CSR 2220-2.150
- 383.133

Kimberly Grinston reported; discussion was held. It was consensus to discuss with legal counsel in closed session prior to reviewing this rule proposal.

#### **#D5A July Strategic Goal Setting Proposals**

- AHC Consulting
- Collaborative Strategies, Inc.
- People Centric Consulting Group

#### **DISCUSSION**

Does the Board want to conduct an official strategic goal setting meeting?

If so, would the Board like to meet in July?

Kimberly Grinston reported; discussion was held. President Marshall suggested the Board wait for new Board member appointments to pursue a goal setting meeting. A regular strategic planning meeting is planned for July 17<sup>th</sup>.

#### **#D6A NABP Proposed Resolutions**

Information was provided to the Board in the handout folders.

#### **MOTION TO CLOSE 11:12AM**

**At 11:12 a.m. Barbara Bilek made a motion, seconded by Janine Burkett, that the Board go into closed session and that all votes, to the extent permitted by law, pertaining to and/or resulting from this closed meeting be closed under Section 610.021(1), (3), (5), (7), (13) and (14), RSMo, and under Section 324.001.8, RSMo. Motion passed, all in favor, none opposed.**

MEMBERS OF THE PUBLIC LEFT THE MEETING ROOM AT 11:12PM.

#### **RECONVENE OPEN 11:51AM**

By motion duly made, seconded, passed and recorded in closed session minutes, the Board returned to open session at approximately 11:51 a.m.

MEMBERS OF THE PUBLIC ENTERED THE MEETING ROOM AT 11:51AM

**#D4A Mandatory Report of Pharmacist Discipline**

Kimberly Grinston reported. Barbara Bilek suggested to begin education about Section 383.133. It was Board consensus to begin implementation, draft education materials for Board review at the July meeting, and prepare for electronic reporting of the actions to the Board. Ms. Grinston reported the drafted regulation will be revised based on the definition of “disciplinary action.” Tom Glenski commented this should apply to all professions, not just pharmacists. Christian Tadrus requested a guidance statement on what is to be reported, and Tim Koch asked for clarification if this pertains only to terminations or all disciplinary actions. It was also suggested that the Board’s regulation define healthcare services.

**#A3 General Administration Report**

• **Staff Recognitions**

President Marshall recognized Kimberly Grinston for her five years of service to the Board.

THE FOLLOWING ITEMS WERE REVIEWED IN SECTION E, WHICH REQUIRED NO ACTION OR DISCUSSION.

**#E1 Licensees Presently Under Discipline**

- Pharmacists
- Pharmacy Interns
- Pharmacies
- Drug Distributors
- Pharmacy Technicians – Conditional Registration
- Pharmacy Technicians – Employment Disqualification List

**#E2 Board Licensee Statistics**

**#E3 Pharmacist Provider Status Legislation**

- California Pharmacists Association – SB 493 (Hernandez Summary)

LUNCH BREAK 12:01-1:00PM

**#B1 Kimberly Turner, #042688, 765 Southridge, Baxter Springs, KS 66713, #2011-001712**

- Notice of Disciplinary Hearing
- Consent Order
- Joint Stipulation For Cause To Discipline

The disciplinary hearing scheduled to begin at 1:00p.m. was convened at 1:01pm. President Marshall read the opening statement. Kimberly Turner and her counsel David Barrett were present; Daryl Hylton represented the Board. The hearing was adjourned at 1:41pm. A transcript of the proceedings is on file with the Board.

**MOTION TO CLOSE 1:42PM**

At 1:42 p.m. Barbara Bilek made a motion, seconded by Anita Parran, that the Board go into closed session and that all votes, to the extent permitted by law, pertaining to and/or resulting from this closed meeting be closed under Section 610.021(1), (3), (5), (7), (13) and (14), RSMo, and under Section 324.001.8, RSMo. Motion passed, all in favor, none opposed.

MEMBERS OF THE PUBLIC LEFT THE MEETING ROOM AT 1:42PM.

**RECONVENE OPEN 2:06PM**

By motion duly made, seconded, passed and recorded in closed session minutes, the Board returned to open session at approximately 2:06 p.m.

**MOTION TO ADJOURN 2:07 PM**

At approximately 2:07 p.m., motion was made by Anita Parran, seconded by Barbara Bilek, to adjourn the April 9-10, 2014, meeting. Motion passed, all in favor, none opposed.

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KIMBERLY A. GRINSTON  
EXECUTIVE DIRECTOR

DATE APPROVED: 10/16/14