

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

**October 14-15, 2015**  
**Holiday Inn Express & Suites**  
**1402 Cinnamon Hill Lane**  
**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 Christina Lindsay at approximately 8:02 a.m. on October 14, 2015, at Holiday Inn Express & Suites, Columbia, Missouri.

**Board Members Present**

Christina Lindsay, PharmD., President  
Christian Tadrus, R.Ph., Vice-President  
Barbara Bilek, PharmD., Member  
Douglas Lang, R.Ph., Member  
Pamela Marshall, R.Ph., Member  
Anita Parran, Public Member

**Staff Present**

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

**Others Present**

Curtis Thompson, Legal Counsel

**MOTION TO CLOSE 8:03 A.M.**

At 8:03 a.m., Anita Parran made a motion, seconded by Christian Tadrus, 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), (14) and (17), RSMo, and under Section 324.001.8, and .9, RSMo. Motion passed 5:0:0:0 with roll call vote as follows:

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**Barbara Bilek – yes**  
**Anita Parran – yes**

**Douglas Lang – yes**  
**Christian Tadrus- yes**

**Pamela Marshall – yes**

### **RETURN TO OPEN**

By motion duly made, seconded, passed and recorded in closed session minutes, the Board returned to open session at approximately 8:40 a.m.

PRESIDENT LINDSAY CALLED THE OPEN SESSION MEETING TO ORDER AT APPROXIMATELY 9:09 A.M. MEMBERS OF THE PUBLIC ENTERED THE MEETING ROOM.

President Lindsay welcomed Douglas Lang to the Board.

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

DISCUSSION: Christian Tadrus reported he attended the Tri-Regulator Symposium in Arlington, Virginia in September 2015. Mr. Tadrus reported there was a robust discussion regarding the intersection of, and collaboration between, different healthcare providers.

Doug Lang reported he attended the NABP/AACP District 6,7,8 meeting in Nevada. Discussions centered around the 2020 technician education/training/certification initiative. Kimberly Grinston commented the 2020 date may be pushed back.

Pamela Marshall reported she attended the Missouri Joint Regulator Patient Safety Conference in Jefferson City on August 28, 2015, and reported beneficial presentations were made regarding compassion fatigue, professional impairment, sign language and telehealth.

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

DISCUSSION: Kimberly Grinston provided the following updates:

- Financial Update: Kimberly Grinston presented the financial report and indicated drug distributors and pharmacies are in renewal with a current 88% renewal rate.
- 2016 Legislative Proposals: Thirty-five legislative proposals were presented to the Governor by the Division with all of the Board's proposals submitted for approval. The Office of Administration has asked multiple questions regarding the third-party outsourcer proposal. It is likely that a revised, shorter prescription monitoring drug program bill will be filed this year.
- Patient Safety Advisory Group: Meeting scheduling has been difficult because of summer travel, however, an in-person meeting is scheduled for October 23, 2015. The Center for Patient Safety is looking for nominations for a public member for their Advisory Committee; suggested names should be forwarded to Kimberly Grinston.
- Hospital Advisory Committee: Bert McClary was elected chairman of the Committee; the Committee reviewed the Board's current draft sterile compounding rule at the last Committee meeting. Comments from the Advisory Committee are

included in the sterile compounding agenda materials. The next meeting is scheduled for 11/6/15.

- New Licensing System: Contract delays have occurred, however, the anticipated implementation date is 12-2-2015. Staff has been busy testing the system.
- Personnel Updates: Amber Cundiff and Christa Nilges were introduced as new Board employees.
- District 6, 7 and 8 Meeting: Kimberly Grinston attended the meeting in Nevada. Presentations were made regarding the new ACPE standards and pharmacy use of the PCOA administered by NABP. Ms. Grinston reported several schools indicated the examination may not count towards a student's grades and questioned how the examination would be used. Board members asked if ACPE participated in creating the examination and Ms. Grinston indicated they were reportedly involved.
- NABP Executive Officer's Forum: The NABP meeting was held on the same day as the current Board meeting (October 14, 2015) and Missouri could not attend.
- NABP Sterile Compounding Training: NABP will be providing additional training for Board inspectors. Tom Glenski reported NABP is also encouraging states to submit comments on the revised USP Chapter 797 draft.
- UMKC Accreditation Visit: Board members should contact the office if they would like to participate in the upcoming ACPE accreditation visit.
- New Sterile Compounding Inspector: The new sterile compounding inspector will begin employment on 11/12/15.

#### **#C1 Special Sites/Non-Pharmacist Preceptors**

- CVS/Caremark
- Independent Pharmaceutical Consultants/ Evergreen Rx
- Kentucky Professionals Recovery Network
- Missouri Healthnet Division Pharmacy Program, DSS
- National Community Pharmacists Association (NCPA)
- Tria Health

DISCUSSION: Tom Glenski reported and recommended approval of all sites/preceptors listed. **A motion was made by Pamela Marshall, seconded by Barbara Bilek, to approve all the special sites/non-pharmacist preceptors for 500 hours each as recommended. Motion passed 5:0:0:0 with roll call vote as follows:**

**Barbara Bilek – yes                      Douglas Lang – yes                      Pamela Marshall – yes**  
**Anita Parran – yes                      Christian Tadrus- yes**

#### **#C2 STLCOP Sites/Preceptors**

- STLCOP Site List
- STLCOP Preceptor List

#### **#C2A STLCOP Sites/Preceptors**

- STLCOP Site List (e-mail addition)

DISCUSSION: Tom Glenski reported and recommended approval of all sites/preceptors listed. **A motion was made by Pamela Marshall, seconded by Christian Tadrus, to approve the site/preceptor lists as recommended. Motion passed 5:0:0:0 with roll call vote as follows:**

**Barbara Bilek – yes  
Anita Parran – yes**

**Douglas Lang – yes  
Christian Tadrus- yes**

**Pamela Marshall – yes**

#### **#D1 Pharmacy Technician Working Group**

DISCUSSION: Kimberly Grinston provided historical information on the previous working group. Multiple Board members supported reconvening the working group. Christian Tadrus suggested the Board should ensure technicians are included in the group. Douglas Lang commented the working group should include a good cross-section of licensees and indicated the working group's objectives should be well defined by the Board. Public attendees spoke in favor of reconvening the working group; Bert McClary reported MSHP has a sub-committee for hospital technicians. Christina Lindsay suggested providing the previous membership roster to the Board for review. Kimberly Grinston suggested asking the working group to review the pharmacist-technician ratio and the technician education issues raised in the patient safety survey. Board consensus to review the previous membership roster during the November conference call.

#### **#D2 Inspection Procedures**

- AR Inspection Procedures
- KS Inspection Procedures
- OK Inspection Procedures
- Inspection Checklist

DISCUSSION: Kimberly Grinston reported she has been working with Tom Glenski on revisions to the inspection process to incorporate a risk-based inspection program. Kimberly Grinston presented a proposed checklist that would be used in conjunction with the current compliance notice and quality assurance forms. Discussion was held. Christian Tadrus and Pamela Marshall commented in favor of the checklist. Christian Tadrus asked if the form would be made public; Ms. Grinston reported the blank form would be public but completed inspection forms would still remain private. Anita Parran asked if an end inspection time should be included. Kimberly Grinston reported the actual inspection ending time may not include time spent consulting with the licensee. Board consensus to add the ending inspection time. Kimberly Grinston reported she anticipated implementing the new process/checklist in January 2016 which would allow inspectors to provide feedback before the July meeting. Public attendee Samuel Leveritt suggested adding information to the checklist for nuclear pharmacies. Bert McClary suggested that the Board work with the Department of Health and Senior Services to inspect hospital pharmacies using the new sterile compounding inspector. **A motion was made by Barbara Bilek, seconded by Doug Lang, to approve the checklist with the addition of the specialty/nuclear pharmacy language. Motion passed 5:0:0:0 with roll call vote as follows:**

**Barbara Bilek – yes**  
**Anita Parran – yes**

**Douglas Lang – yes**  
**Christian Tadrus- yes**

**Pamela Marshall – yes**

Kimberly Grinston further reported that the Board has been asked to reconsider the current process of inspecting pharmacies when the pharmacist-in-charge is not present especially when inspecting larger/complex pharmacies. Barbara Bilek indicated busy pharmacies should not be inspected after a major holiday. Pamela Marshall and Christian Tadrus indicated all pharmacy staff should be aware of where documents can be located during an inspection. Douglas Lang commented the Board should maintain the current process, however, inspectors should have discretion to reschedule or postpone an inspection when appropriate.

#### **#D4 Sterile Compounding Rule**

- Draft Rule
- Revised 797

DISCUSSION: Kimberly Grinston reported the proposed draft included in the agenda includes comments/revision from Eric Kastango, Tom Glenski, the Hospital Advisory Committee and the Board rule review sub-committee consisting of Barbara Bilek, Douglas Lang and Christian Tadrus. Ms. Grinston reported proposed changes to USP Chapter 797 were published shortly after the draft rule was completed and asked if the Board wanted to proceed with finalizing a draft sterile compounding rule or wait for finalization of the revised Chapter 797. Christian Tadrus, Barbara Bilek and Pamela Marshall suggested holding further revisions of the Board's rule until the revisions to Chapter 797 have been finalized. Several public attendees remarked the proposed draft may create compliance difficulties and could result in significant licensee costs. Douglas Lang suggested that the Board proceed with revising the current draft rule with the knowledge that additional changes may be needed after USP Chapter 797 is finalized. Christina Lindsay asked about the proposed timeline for filing a rule; Kimberly Grinston responded the rule would not be finalized until the end of 2016 at the earliest. Douglas Lang asked if an emergency rule was possible; Kimberly Grinston replied it may be harder to justify given the length of time since the New England Compounding Center events. Kimberly Grinston and Tom Glenski reported that it was mentioned at previous NABP meetings that the final Chapter 797 revisions would be completed in late 2016 or early 2017. Discussion was held. Board consensus to ask the Board rule review sub-committee to review the draft along with the proposed USP Chapter 797 changes and to make a recommendation to the full Board on suggested next steps.

#### **#D3 Invitation to Sign Revised FDA Information Sharing Agreement**

- Kehoe E-mail
- Proposed agreement
- Compounding Domestic Inspection Information and Sharing Chart

DISCUSSION: Kimberly Grinston reported Tom Glenski is the Board's only FDA commissioned officer and expressed concerns with the Board's legal authority to comply with the draft Agreement. Douglas Lang suggested the Sharing Agreement might be

discussed at the upcoming FDA 50-State compounding meeting. Board consensus to table the discussion until after the FDA meeting in November.

**#D5A Board Fund**

- Funding Options

DISCUSSION: Kimberly Grinston reported a subcommittee of Board members and staff consisting of Dan Vandersand, Christian Tadrus and Pamela Marshall met to discuss potential options for utilizing the Board’s funds to reduce the current fund balance and to avoid a fund sweep to general revenue. Christian Tadrus commented the subcommittee focused on the Board’s mission of protecting the public. Pamela Marshall presented the three funding options provided in the agenda. Barbara Bilek inquired about working with the Board of Healing Arts. Kimberly Grinston reported the proposal would allow the Board to partner with different state agencies. Kimberly Grinston also indicated that she met with the Missouri Department of Health and Senior Services and suggested including in the proposal formal authorization for the Board to work with the Department of Health and Senior Services given the initiatives currently operated by the Department. Kimberly Grinston shared information from Scott Collier with the DEA regarding the costs and procedures for the DEA’s drug return program. Kimberly Grinston reported the proposal would impact FY17 and provided a fund projections prepared by Sherry Hess, Division Budget Director, indicating the Board could safely allocate up to \$2,000,000 to the proposed funding project without threatening Board solvency. Ron Fitzwater, Executive Director of the Missouri Pharmacy Association, indicated a proactive approach would be better than sweeping into general revenue and would likely be preferable for licensees. Douglas Lang suggested funding should be available for an extended period of time and not just one year. Discussion was held. **A motion was made by Barbara Bilek, seconded by Anita Parran, to submit the proposed funding initiative to the Governor’s office to allow the allocation of a maximum of \$2,000,000 to fund the initiatives listed as approved by the Board and to further allow the Board to partner with the Missouri Department of Health and Senior Services. Motion passed 5:0:0:0 with roll call vote as follows:**

<b>Barbara Bilek – yes</b>	<b>Douglas Lang – yes</b>	<b>Pamela Marshall – yes</b>
<b>Anita Parran – yes</b>	<b>Christian Tadrus- yes</b>	

**MOTION TO CLOSE 12:18 P.M.**

**At 12:18 p.m., Barbara Bilek made a motion, seconded by Pamela Marshall, 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), (14) and (17), RSMo, and under Section 324.001.8, and .9, RSMo. Motion passed 5:0:0:0 with roll call vote as follows:**

<b>Barbara Bilek – yes</b>	<b>Douglas Lang – yes</b>	<b>Pamela Marshall – yes</b>
<b>Anita Parran – yes</b>	<b>Christian Tadrus- yes</b>	

## **RETURN TO OPEN**

By motion duly made, seconded, passed and recorded in closed session minutes, the Board returned to open session at approximately 2:09 p.m.

MEMBERS OF THE PUBLIC ENTERED THE MEETING ROOM. ANITA PARRAN LEFT THE MEETING ROOM FOR THE DAY.

### **#B1 Mary Ellison, #042428, #2012-003949**

- Notice of Disciplinary Hearing
- Complaint
- Administrative Hearing Commission Decision

DISCUSSION: The Board convened a disciplinary hearing at 2:22 p.m. Joshua Hill was present as counsel for the Board. Mary Ellison was present and was not represented by counsel. President Christina Lindsay convened the hearing; Board introductions were made. Mr. Hill and Ms. Ellison provided opening statements. Exhibits and witnesses were presented and questions were presented by the Board. Mr. Hill and Ms. Ellison provided closing statements. The hearing adjourned at 2:45 p.m. A transcript of the hearing is available in the Board's records.

### **#B2 Shannon Krieg, #2005000313, #2014-003733**

- Notice of Hearing on Violation of Disciplinary Order
- Violation Complaint

DISCUSSION: The Board convened a violation of discipline hearing at 2:50 p.m. Joshua Hill was present as counsel for the Board. Shannon Krieg was present and was represented by counsel Johnny Richardson. President Christina Lindsay convened the hearing; Board introductions were made. Mr. Hill and Mr. Richardson provided opening statements. Exhibits and witnesses were presented and questions were presented by the Board. Mr. Hill and Mr. Richardson provided closing statements. The hearing adjourned at 4:12 p.m. A transcript of the hearing is available in the Board's records.

### **#B3 Hillary Jackson, #2012013212, #2012-000525**

- Notice of Disciplinary Hearing
- Complaint
- Stipulation of Cause to Discipline
- Consent Order

DISCUSSION: The Board convened a disciplinary hearing at 4:25 p.m. Joshua Hill was present as counsel for the Board. Hillary Jackson was present and was represented by counsel Terry Allen. President Christina Lindsay convened the hearing; Board introductions were made. Mr. Hill and Mr. Allen provided opening statements. Exhibits and witnesses were presented and questions were presented by the Board. Mr. Hill and Mr. Allen provided closing statements. The hearing adjourned at 5:28 p.m. A transcript of the hearing is available in the Board's records.

### **#B4 Dwight Nyberg, #028845, #2012-003950**

- Notice of Disciplinary Hearing
- Complaint
- Stipulation of Cause to Discipline
- Consent Order

**#B5 Nyberg Pharmacy, #004441, #2012-006767**

- Notice of Disciplinary Hearing
- Complaint
- Stipulation of Cause to Discipline
- Consent Order

DISCUSSION: Pursuant to a joint stipulation, the Board convened a joint disciplinary hearing for Dwight Nyberg and Nyberg Pharmacy. Joshua Hill was present as counsel for the Board. Dwight Nyberg was present and represented by counsel Ryan Harding and Liz Lafoe. Nyberg Pharmacy was also represented by counsel Ryan Harding and Liz Lafoe. President Christina Lindsay convened the hearing; Board introductions were made. Mr. Hill and Mr. Harding provided opening statements. Exhibits and witnesses were presented and questions were presented by the Board. Mr. Hill and Mr. Harding provided closing statements. The hearing adjourned at 6:58 p.m. A transcript of the hearing is available in the Board’s records.

**MOTION TO CLOSE 6:59 P.M.**

At 6:59 p.m., Barbara Bilek made a motion, seconded by Douglas Lang, 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), (14) and (17), RSMo, and under Section 324.001.8, and .9, RSMo. Motion passed 4:0:0:1 with roll call vote as follows:

Barbara Bilek – yes	Douglas Lang – yes	Pamela Marshall – yes
Anita Parran – absent	Christian Tadrus- yes	

**THURSDAY, OCTOBER 15, 2015**

**RETURN TO OPEN**

By motion duly made, seconded, passed and recorded in closed session minutes, the Board returned to open session at approximately 2:23 p.m. on October 15, 2015.

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

**#E1 Licensees Presently Under Discipline**

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

**#E2 Board Licensee Statistics**

**#E3 Internet Drug Outlet Identification Program**

- NABP Progress Report

**#E4 Occupational Licensing: A Framework for Policy Makers**

- Whitehouse Report

**MOTION TO ADJOURN 2:24 P.M.**

At approximately 2:24 p.m., a motion was made by Christian Tadrus, seconded by Barbra Bilek, to adjourn the October 14-15, 2015 meeting. Motion passed 3:0:0:2 with roll call vote as follows:

Barbara Bilek – yes	Douglas Lang – yes	Pamela Marshall – absent
Anita Parran – absent	Christian Tadrus- yes	

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KIMBERLY A. GRINSTON  
EXECUTIVE DIRECTOR

DATE APPROVED: 1/13/2016