

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

**January 16-17, 2013**  
**Courtyard By Marriott**  
**3301 LeMone Industrial Blvd.**  
**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 8:02 a.m. on January 16, 2013, at Courtyard By Marriott, Columbia, Missouri.

**Board Members Present**

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

**Staff Present**

Kimberly Grinston, Executive Director  
Tom Glenski, R.Ph., Chief Inspector  
George McConnell, R.Ph., Inspector  
Andi Miller, R.Ph., Inspector  
Steve Smith, R.Ph., Inspector  
Dan Vandersand, R.Ph., Inspector  
Sid Werges, R.Ph., Inspector  
Barbara Wood, Inspector  
Tammy Siebert, Executive I

**Staff Absent**

Frank VanFleet, R.Ph., Inspector

**Others Present**

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

**MOTION TO CLOSE 8:03 AM**

**At 8:03 a.m. Barbara Bilek made a motion, seconded by James Riddle, 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 8:03 AM.

### **RECONVENE OPEN 8:19 AM**

By motion duly made, seconded, passed and recorded in closed session minutes, the Board returned to open session at approximately 8:19 a.m.

MEMBERS OF THE PUBLIC ENTERED THE MEETING ROOM AT 8:19 AM

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

Kimberly Grinston reported regarding additional information for Items #A3, #A4, #C1, #C2, #D7, and a new Item #D8A.

**#A2 Board Member Report** – No one reported.

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

- **FDA Compounding Meeting** – Kimberly Grinston reported regarding an all-state meeting hosted by the Food and Drug Administration in Maryland on December 19<sup>th</sup>. The Utah Board of Pharmacy was represented by Carmen Catizone of NABP at this meeting. Ms. Grinston reported about discussions concerning traditional pharmacy compounding vs. manufacturing. Discussion was held. Bert McClary commented regarding federal regulation of long-term care facilities.

- **Non-Missouri State Inspections** – Kimberly Grinston reported the Iowa Board of Pharmacy will be inspecting Missouri sterile compounding pharmacies that are also licensed in Iowa. It appears other states will be doing the same. Ms. Grinston reported our inspection staff will not participate in these inspections. Discussion was held. Ms. Grinston reported notice was sent via an e-alert to our licensees about the Iowa Board inspections.

- **Sterile Compounders** – Kimberly Grinston reported a proposed Advisory is in the agenda for review and if approved, it will be sent to all Missouri sterile and non-sterile compounding pharmacies. It was suggested the Advisory be sent to all Missouri-licensed pharmacies. Ms. Grinston further reported the Board will conduct a survey of randomly selected non-resident pharmacies concerning shipments that are not by patient specific prescription. Discussion was held. It was Board consensus to survey a small sample initially. **Motion was made by Barbara Bilek, seconded by James Riddle, to initially survey 25. Motion passed, all in favor, none opposed.**

Kimberly Grinston reported the Board's inspectors will complete sterile compounding 797 training before the end of January. Inspectors will prioritize Missouri sterile compounding pharmacies for inspection within the first six months of this year. Ms. Grinston referred to #D5 of the agenda which is a proposed revision to Section 338.150 to make our drug testing program mandatory rather than voluntary. Kimberly Grinston asked the Board if they are interested in adopting USP 797 or to revise its compounding regulations. Barbara Bilek suggested Tom Glenski lead a review during

the April Strategic Planning meeting. Doug Lang requested the Board also review USP 795.

- **Pharmacy Practice Guide** – Kimberly Grinston reported a revised Pharmacy Practice Guide will be ready for review in February.

- **Financial Report** – Kimberly Grinston reported positive comments have been received about lowering our pharmacist renewal fees, and she will be working with the Division Accounting office to determine if it's necessary to lower pharmacy and/or drug distributor renewal fees. James Riddle inquired if the Board's current drug testing appropriation will be enough to cover future drug testing changes.

- **NABP 2013 Meeting - St. Louis** – Kimberly Grinston reported the NABP Annual Meeting will be held in St. Louis May 18-21, 2013. The Board will be hosting a display table, and Board members are invited to a brunch and dinner on Sunday with NABP. Board members wishing to attend should send her an email.

- **Hospital Working Group Update** – Kimberly Grinston reported regarding formation of the Board's Hospital Working Group. Former Board Executive Director Kevin Kinkade will facilitate the group's meetings.

- **CE Audit** – Kimberly Grinston reported.

JASON MENKEN ENTERED THE MEETING ROOM AT 9:36 A.M.

- **Vet Pharmacies** – Kimberly Grinston reported a new veterinary brochure has been mailed from the Board explaining licensure requirements.

- **Pending Rule Update** – Kimberly Grinston reported the Governor's office has approved our licensing rules to be filed with the Secretary of State. The Board's Electronic Prescription Rule (20 CSR 2220-2.080) has been filed with the Secretary of State, the Prescription Delivery Rule (20 CSR 2220-2.013) has been finalized, and Medication Therapy Services revisions are in the review process by the Division.

- **Inspector Territories** – Kimberly Grinston reported some of the inspector territories have been changed in order to shrink the chief inspector's territory.

- **Electronic Inspections** – Kimberly Grinston reported progress is being made on a new electronic inspection program. A new Division licensing system has been placed on hold, so the decision was made to pursue our own electronic inspection process. Jason Menken reported about the new program he's been working on and stated pharmacies and drug distributors will be given a CD with the inspection burned to it. Kimberly Grinston showed a sample of the CD to be used. James Riddle asked about posting inspections in the pharmacy; Kim Grinston reported some agencies require it, but the Board does not. Ms. Grinston reported the process will be implemented slowly. Tom Glenski reported inspector laptops have to be updated first, and we are currently working with Office of Administration for hardware options. Curt Thompson suggested voice recognition software might be an option.

- **Patient Safety Initiative**

- **MoSafeRx** - Kimberly Grinston reported the Board's website will be updated to include a new Patient Safety icon. Mr. Grinston reported our prior webinars are now on YouTube, and plans are in place for President Marshall record a patient safety introductory video for the Board's website. The Board's Patient Safety Working Group

is being formed and will hold its first meeting January 29<sup>th</sup>. St. Louis College of Pharmacy's Terry Seaton has agreed to provide a CE program on patient safety. Barbara Bilek suggested an area of the Group's work be focused on the patient's responsibility for his/her own medications.

- **Patient Safety Month** - Ms. Grinston reported March 2013 is National Patient Safety month and the Board will participate by hosting a pharmacist CE program. Kimberly Grinston requested the Board approve the programs listed in the National Patient Safety month flyer for one hour of pharmacist continuing education each. **Motion was made by James Riddle, seconded by Anita Parran, to approve the programs listed in the flyer for one hour of CE each. Motion passed, all in favor, none opposed.** Barbara Bilek commented hospitals have been doing this for years.

- **Patient Safety Survey** – Kimberly Grinston reported the Pharmacy Survey on Patient Safety will be posted on our website and is voluntary. President Marshall commented about the Survey's questions and how they could be perceived. Bert McClary commented the Department of Health's hospital licensing rule proposals will likely require a hospital medication safety program.

- **Annual Report FY12** – Kimberly Grinston reported. **Motion was made by Barbara Bilek, seconded by Janine Burkett, to approve the FY12 Annual Report as printed. Motion passed, all in favor, none opposed.**

- **General Office Update** – Nothing reported.

### **#C3 Annual Meeting with STLCOP and UMKC Colleges of Pharmacy**

Tricia Berry and Interim Dean of Pharmacy Sheldon Holstad presented to the Board. STLCOP's new curriculum will be rolled out the fall of 2014--changing from a 6-year to a 7-year program. They commented on the school's strategic planning and building projects underway. Barbara Bilek asked if many schools are moving to a 7-year program. Mr. Holstad responded many students enter pharmacy school after they have completed a bachelor's degree. Discussion was held. Barbara Bilek asked if STLCOP has problems identifying initial pharmacy practice experience settings. Ms. Berry responded that it is challenging, some are done during the summer near the student's home, and they are always looking for other options.

Valerie Reuhter presented for UMKC. She provided information about the school upgrading to live video conferencing the fall of 2013 at its Springfield campus, and actual attendance in Springfield will begin in the fall of 2014. Faculty recruitment for the Springfield location will begin this year. It is anticipated 30 students per class will be accepted in Springfield and Columbia, in addition to their enrollment in Kansas City.

Kimberly Grinston inquired about how student impairment issues are handled at each school. Tricia Berry reported STLCOP has a handbook for faculty and students; it's a matter of policy. Ms. Reuhter reported UMKC has a policy/procedure book that was updated 1 ½ years ago. Ms. Grinston asked if students are initially notified that a drug violation may cause problems with Board licensure. Ms. Berry said yes, and Ms. Reuhter stated an associate dean usually asks her if particular situations will be a problem for rotation placements. Ms. Grinston suggested it be added to the admission

process at each school. Tom Glenski reported that former Board member Gary Sobocinski does a one-day program at STLCOP regarding impairment, legal issues, etc; and he suggested UMKC pursue such a program.

Tom Glenski stated the Board office periodically receives calls from students indicating they've been told by their admissions office to contact the Board about licensure problems following a criminal conviction. Mr. Glenski reminded everyone about the possible need for BNDD and DEA waivers when a drug offense is involved.

Tom Glenski reported the Board will begin pursuing compounding rule revisions and asked if the schools offer compounding training within their curriculums. Tricia Berry reported STLCOP does within the curriculum and in rotations. Valerie Reuhter reported UMKC provides lectures, videos and testing plus a 6-hour lab.

Tom Glenski asked the school representatives if they have any issues to bring to the Board. Valerie Reuhter asked if students can be supervised by someone other than a licensed pharmacist (specifically a nurse practitioner)? Kimberly Grinston responded that pharmacy students must be supervised by a pharmacist, and also commented that the Board's licensing rules have been filed with the Secretary of State.

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

- Hope Family Care Center
- Kentucky Professionals Recovery Network - KYPRN
- Lafayette Regional Health Center
- Ranken Jordan, A Pediatric Specialty Hospital
- Rural Pharmacy Practice Elective - APPE
- MO HealthNet Division Pharmacy Program, Department of Social Services

Tom Glenski reported and recommended all the special site applications be approved for 500 hours each. **Motion was made by Barbara Bilek, seconded by James Riddle, to approve the listed Intern Training Pharmacy Special Site Applications 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

President Marshall commented the Walgreens Pharmacy #9771 on STLCOP's site list has address problems, and that Lance Lomax on STLCOP's preceptor list is licensed in Missouri and Illinois. **Motion was made by Barbara Bilek, seconded by Janine Burkett, to approve the STLCOP site and preceptor lists as presented, with the change to Walgreens #9771 as noted, all in favor, none opposed.**

**Motion was made by Anita Parran, seconded by James Riddle, to approve the UMKC site and preceptor lists as presented, all in favor, none opposed.**

**MOTION TO CLOSE 11:27 AM**

At 11:27 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 11:27 PM.

**RECONVENE OPEN 1:40 PM**

By motion duly made, seconded, passed and recorded in closed session minutes, the Board returned to open session at approximately 1:40 p.m.

MEMBERS OF THE PUBLIC ENTERED THE MEETING ROOM AT 1:40 PM

**#B2 Brad M. Conley, #2008029245, 7161 Longview Dr, Fulton, MO 65251, #2011-002327-V1 (Sid Werges)**

- Notice of Violation of Disciplinary Hearing
- Amended Probation Violation Complaint

Kimberly Grinston reported the violation of discipline hearing scheduled for 2:30 p.m. today has been cancelled due to settlement.

**#A4 Approval of Minutes**

- November 28, 2012 Conference Call

**Motion was made by Anita Parran, seconded by Barbara Bilek, to approve the November 28, 2012, open session conference call minutes as printed. Motion passed, all in favor, none opposed.**

- October 24, 2012 Meeting

**Motion was made by Barbara Bilek, seconded by Janine Burkett, to approve the October 24, 2012, open session minutes as printed. Motion passed, all in favor, none opposed.**

- December 27, 2012 Conference Call

**Motion was made by Barbara Bilek, seconded by Anita Parran, to approve the December 27, 2012, open session conference call minutes as printed. Motion passed, all in favor, none opposed, James Riddle abstained.**

**#D1 American Academy of Ophthalmology Letter on Compounding Pharmacies**

Kimberly Grinston reported and discussion was held. Barbara Bilek commented this process has been occurring since the 1970's. James Gray commented the letter is requesting approval for the product to be provided as office stock. Doug Lang reported there have been 29 cases of blindness in the United States in the past two years. It was Board consensus to table this matter till the April meeting.

**#D3 Well-Being Program**

- 338.380

Kimberly Grinston reported the Board received no bids on its recent Request For Proposal (RFP) for its Well-Being Program. Ms. Grinston provided information about three options for the Board. 1) no longer pursue a Board well-being program; 2) a Board well-being committee could be established to review and suggest to the Board, which would require re-bid, and 3) hire a consultant to advise the Board regarding addicted licensees. Discussion was held. It was general consensus that establishing a committee would not be beneficial. It was Board consensus to seek an expert to serve as a consultant for the Board for a six-month trial basis. Ms. Grinston suggested the Board's website be updated to include resources for licensees.

**#B1 Mary R. Richardson, #029924, PIC/Sun Fresh Pharmacy #156, #2002025827, 10225 North Oak Trafficway, Kansas City, Missouri 64155, #2010-004980 (Andi Miller)**

- Notice of Disciplinary Hearing
- Complaint
- Answer
- Waiver of Hearing, Settlement Agreement, and Request For Consent Order

**Consent Order**

A disciplinary hearing was scheduled for January 16, 2013, at 2:30 p.m. A court reporter was present and the hearing began at approximately 2:30 p.m. Mary Richardson was present and was represented by Emily Little; the Board was represented by Loretta Schouten. The hearing concluded at approximately 3:00 p.m. A copy of the transcript is on file with the Board of Pharmacy.

**#D4 2013 Legislative Proposals** – Kimberly Grinston reported.

**#D5 Proposed 2013 Statutory Language**

- 338.150.1

Kimberly Grinston reported and discussion was held. **Motion was made by Barbara Bilek, seconded by Janine Burkett, to move forward with language that does not include paragraph 2. Motion passed, all in favor, none opposed.**

**#D6 DEA Proposed Drug Destruction Rule**

- Email from BNDD
- 21 CFR PARTS 1300, 1301, 1304, 1305, 1307, 1317, and 1321

Kimberly Grinston reported this DEA proposed regulation is in the comment period and is here for discussion/comments from the Board. Discussion was held. Bert McClary commented the ultimate consumer or decedent (no other person) would be able to handle the product, location of the container immediately adjacent to where drugs are stored, some pharmacies may have no single full-time employee, and only option for long-term care drug would be through a pharmacy that has such a disposal container or the patient would have to personally destroy. Steve Calloway inquired to whom and how comments should be submitted.

#### **#D7 Implementation of House Bill 1563**

- HB 1563
- 20 CSR 2220-5.020 Proposed Amendment
- 21 CFR Section 203.1
- 20 CSR 2220-5.020 Proposed Amendment

Kimberly Grinston reported; discussion was held. Barbara Bilek commented about how 5% is determined if the hospital does not actually sell the product.

Janine Burkett commented about 4. concerning “hospitals under common control”. Should this be changed to “hospitals and pharmacies under common control”? Bert McClary asked the Board to consider the use of “hospitals or other healthcare entities under common control” as is in federal language. Infusion centers, imaging centers, emergency locations, outpatient clinics are all hospital-owned entities and considered healthcare entities that are allowed to purchase drugs. Is it possible to use the CMS provider number as the qualifier for being an “other healthcare entity.” Sam Leveritt suggested “pharmacies” be added, but not specify it to retail pharmacies. Lengthy discussion as held. **Motion was made by Janine Burkett, seconded by Barbara Bilek, to clarify it now with “pharmacy” language and then amend the regulation after the Hospital Working Group makes their proposals. Motion passed, all in favor, none opposed.**

Kimberly Grinston suggested “The name and address of the non-Missouri pharmacy and” be deleted from 8a. and instead moved to b.

It was Board consensus to table this matter for further discussion with legal counsel in closed session.

#### **#D2 20 CSR 2220-2.950 Automated Filling Systems**

- 20 CSR 2220-2.950 Draft

Kimberly Grinston reported and discussion was held. Barbara Bilek commented this rule does not apply to hospitals not licensed by the Board. James Riddle commented about (3) and exemption provided in (4). He asked how long proof of compliance must be maintained; Ms. Grinston commented it is addressed in (6). Mr. Riddle commented “If the verification requirements of (4)(d)” in (6) is ambiguous. Ms. Grinston clarified, and Curt Thompson suggested “when” be inserted instead of “if”. It was Board consensus to change “if” to “when”.

Bert McClary commented 4(c) “automated” should be “automatic” and “fill” should be changed to “filling” in 5(m).

**Motion was made by Barbara Bilek, seconded by Janine Burkett, to approve 20 CSR 2220-2.950 as printed, with revisions as previously noted. Motion passed, all in favor, none opposed.**

#### **#D8A Election of Officers**

President - **Barbara Bilek** nominated **Pam Marshall** for President, seconded by **Anita Parran**. Motion passed, all in favor, none opposed.

Vice-President - **Barbara Bilek** nominated **Janine Burkett** for Vice-President, seconded by **Anita Parran**. Motion passed, all in favor, none opposed.

**MOTION TO CLOSE 4:03 PM**

At 4:03 p.m. **Barbara Bilek** made a motion, seconded by **James Riddle**, 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.

INSPECTOR SID WERGES AND MEMBERS OF THE PUBLIC LEFT THE MEETING ROOM AT 4:03 PM.

**RECONVENE OPEN 4:50 PM**

By motion duly made, seconded, passed and recorded in closed session minutes, the Board returned to open session at approximately 4:50 p.m.

MEMBERS OF THE PUBLIC ENTERED THE MEETING ROOM AT 4:50 PM

**#D7 Implementation of House Bill 1563**

Janine Burkett commented 4. should not be changed because statute describes pharmacies. Paragraph 8. should be changed to include resident and non-resident, and suggested to use the word “transfer” in addition to “sale, purchase or trade” throughout the rule. Pam Marshall suggested “or drug product” be deleted wherever “drug or drug product” is used, as well as previously mentioned change to 8(a) and (b). It was Board consensus for office staff to make changes and return the proposed rule to the Board for further discussion.

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 Staff Report to US Senate Commerce and HELP Committees - Shining Light**

**on the Gray Market**

- Staff Report
- Appendix
- Transmittal Letter

**MOTION TO CLOSE 5:01 PM**

At 5:01 p.m. Barbara Bilek made a motion, seconded by James Riddle, 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 5:01 PM.

**RECONVENE OPEN 10:03 AM**

By motion duly made, seconded, passed and recorded in closed session minutes, the Board returned to open session at approximately 10:03 a.m.

**MOTION TO ADJOURN 10:04 AM**

At approximately 10:04 a.m., motion was made by Barbara Bilek, seconded by Anita Parran, to adjourn the January 16-17, 2013, meeting. Motion passed, all in favor, none opposed, Pamela Marshall absent.

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KIMBERLY A. GRINSTON  
EXECUTIVE DIRECTOR

DATE APPROVED: 7/17/13