

OPEN MINUTES
Missouri Board of Pharmacy

July 13-14, 2011
Hilton Garden Inn
3300 Vandiver Drive
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 James Riddle at 8:02 a.m. on July 13, 2011, at Hilton Garden Inn, Columbia, Missouri.

Board Members Present

James Riddle, R.Ph., President
Barbara Bilek, R.Ph., Vice President
Janine Burkett, R.Ph., Member
Melissa Graham, R.Ph., Member
Pamela Marshall, 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
Steven Smith, R.Ph., Inspector
Dan Vandersand, R.Ph., Inspector
Frank VanFleet, R.Ph., Inspector
Sid Werges, R.Ph., Inspector
Barbara Wood, Inspector
Tammy Siebert, Executive I

Others Present

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

MOTION TO CLOSE 8:03 AM

At 8:03 a.m. Pam Marshall made a motion, seconded by Barbara Bilek, 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 8:50 AM

By motion duly made, seconded, passed and recorded in closed session minutes, the Board returned to open session at approximately 8:50 a.m.

MEMBERS OF THE PUBLIC ENTERED THE MEETING ROOM AT 8:50 AM

#A1 Agenda Additions/Corrections

Kim Grinston reported regarding additional information for items #A3, #B3, #C1, #D4 and #D7.

#A2 Board Member Report

- NABP Meeting
- DEA Meeting

Pam Marshall reported that she, Kim Grinston and Jim Riddle attended the NABP Annual meeting in San Antonio, Texas, in May.

Kim Grinston reported that she and Tom Glenski attended the DEA conference in Ft. Worth, Texas, June 15-16. Ms. Grinston reported the meeting was very beneficial and provided specific information about pain clinics and indicated Missouri and Vermont are the only states that do not have a prescription monitoring program.

Pam Marshall reported she attended a National Association of Chain Drug Stores-Drug Enforcement Administration conference in St. Louis on June 30th.

Kim Grinston reported the Board office and inspectors are now not automatically issuing a permit upon inspection of a pharmacy located within a physician's office in order to give staff time to do research and contact BNDD/DEA if needed.

#A3 General Administration Report

- **2011 Legislation** – Kim Grinston reported regarding HB412, which will be discussed later in the meeting. HB552, the bleeding disorder bill, passed and will become effective 8/28/11. The Board will be required to write rules for HB552. Kim Grinston reported regarding HB136 which provides for temporary licenses for non-resident spouses of active military personnel; additional discussion will be held at a future meeting. Ms. Grinston also reported the legend drug bill passed.

Jan Burkett inquired if any of the legislation will cause an additional administrative burden on Board staff. Ms. Grinston responded the temporary license is already being done for other licensing situations; other professionals are necessary to advise Board staff concerning HB552 and HB412.

- **Financial Report** – Kim Grinston reported our technician count is down, but the Board's fund is still solvent.

- **Executive Update** – Kim Grinston reported the Division is looking to purchase a new licensing system that will allow for an electronic inspection process. Although it may be a few years before implementation, the Board of Pharmacy will pilot the electronic inspection process. Kim Grinston also reported our inspection staff may receive tablets computers to use during the electronic inspection process. The Board of Nursing will bear the majority of the cost of the new licensing system; however, each Board will be asked to pay a portion. Kim Grinston also reported Tom Glenski and three other inspectors will be provided state-owned cell phones; phone numbers will not be publicly provided.

- **Renewal of Legal Contracts** – Kim Grinston commented this will be discussed later in the meeting.

- **Proposed 2012 Meeting Dates** – Kim Grinston reported and discussion was held. President Riddle asked the Board members to notify Tammy Siebert if they have conflicts with any of the proposed 2012 meeting dates.

#B2 David Park, #044263, #2009-007509

- Notice of Disciplinary Hearing
- Complaint
- Answer
- Waiver Of Hearing, Joint Stipulation And Request For Consent Order
- Settlement Order

President Riddle reported the David Park disciplinary hearing scheduled for 1:30 p.m. today has been continued pending settlement.

#B3 Jill Winowiecki, #2001007711, #2008-007384

- Notice Of Felony Disciplinary Hearing
- Judgment Reversing Board's Order And Remanding For A New Hearing On The Board's Felony Conviction Complaint
- Felony Conviction Complaint
- Motion for Continuance

President Riddle reported the Jill Winowiecki felony disciplinary hearing scheduled for 2:00 p.m. today has been continued.

#C1 Applications for Intern Training Pharmacy Special Sites

- Allergan, Inc.
- Bassett Army Community Hospital Pharmacy
- CVS/Pharmacy Regional Business Office
- Global Service Corps
- NACDS
- Natural Standard Research Collaboration
- Pack Pharmaceutical

- National Association of Drug Stores

Tom Glenski reported the Global Service Corps application does not provide a pharmacist and cannot be approved. Discussion was held. **Motion was made by Barbara Bilek, seconded by Janine Burkett, to approve the Intern Training Pharmacy Special Site applications for 500 hours, except for Global Service Corps. 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 the STLCOP listing has John Pieper as president of STLCOP, but he is not licensed in Missouri. **Motion was made by Barbara Bilek, seconded by Melissa Graham, to approve the STLCOP and UMKC site and preceptor lists as presented. Motion passed, all in favor, none opposed.**

#D1 Electronic Records Rule

- **20 CSR 2220-2.017** – Tom Glenski reported that “or” on line 17 needs to be changed to “and”.
- **20 CSR 2220-2.018** – Kim Grinston reported our original 20 CSR 2220-2.018 has been broken down and separated into 20 CSR 2220-2.017 and 20 CSR 2220-2.018.
- **20 CSR 2220-2.080** – Krystal Chisolm of Walgreens commented that line 17 “that pharmacist” should be changed to “a pharmacist”.
- **20 CSR 2220-2.083** – Kim Grinston reported lines 27-29 require electronic recordkeeping systems be able to store the reverse side of prescriptions. Discussion was held regarding this requirement and Barbara Bilek commented it may have an adverse affect on small businesses. Christian Tadrus commented scanners will be required and will be a huge burden on small business even though they are not capturing much information. Kim Grinston commented that it’s possible to delete “including reverse side of the prescription if applicable” on line 28. Kim Grinston also reported that sequential numbering system language or a unique readily retrievable identifier was changed. Kim Grinston reported the requirement for prescription hard copies was removed and will be taken up at a later date, and further commented a hard copy of the prescription is not necessary if an electronic recordkeeping system is in place.

Motion was made by Barbara Bilek, seconded by Pam Marshall, to begin the rulemaking amendment process for 20 CSR 2220-2.017, 20 CSR 2220-2.018, 20 CSR 2220-2.080, and 20 CSR 2220-2.083. Motion passed, all in favor, none opposed.

#D2 Drug Distributor Advisory Committee

- See amended section 338.140 in HB 412

Kim Grinston reported HB412 will require rules to be drafted, which will require review by the Drug Distributor Advisory Committee. Linda Gartner and Michael Novak have been reappointed to the Drug Distributor Advisory Committee, and, due to expired terms, new members have been appointed for the drug manufacturer, pharmacy and veterinary representatives. The drug manufacturer representative is Drue Duncan of Pfizer, Inc.; the pharmacy representative is Christian Tadrus of Sam's Health Mart Pharmacy #1; and the veterinary representative is Scott Fray, DVM of Cooper County Animal Hospital.

#D3 Compounding Hydroxyprogesterone Caproate

- FDA Statement
- 20 CSR 2220-2.400(9)

Kim Grinston reported and discussion was held. Sam Leveritt of Cardinal Health recommended the Board follow FDA's position; Janine Burkett inquired if the Board could hold and wait for a decision from FDA. Jim Riddle commented that the drug is still available to the public and Barbara Bilek asked if the office is still getting inquiries on this issue and are companies still compounding the product? It was Board consensus to table a decision until further information from FDA is received.

#D4 House Bill 412 and Regulation of Veterinarian Prescription Dispensing

- 20 CSR 2220-2.675

Kim Grinston reported the Missouri Veterinary Medical Board approached her about a statutory change in 2011 to overturn the Supreme Court decision involving UPCO; i.e., HB412 was passed and signed into law by the Governor and will become effective August 28, 2011. Ms. Grinston reported the Board office is creating an educational brochure for distribution to educate the public about who will need to be licensed as a Class L pharmacy, and staff is working with the Department to create an educational video for our website. Proposed regulation 20 CSR 2220-2.675 is in the agenda for review. The rule will allow for dispensing without a pharmacist, except in certain situations, and is being proposed to be filed as an emergency rule on August 29th. Ms. Grinston asked for clarification on how often a pharmacist must be present to review records, etc., and indicated the rule will have a fiscal impact on the Board. Ms. Grinston also advised the Board there is an issue involving the Board's definition of pharmacy technician and how it will pertain to technicians in a Class L pharmacy. Discussion was held. Ms. Grinston reported MFA and Orschlen represent 80% of the entities affected by the statute/regulation. Kim Grinston reported inspections will be our biggest obstacle because all new facilities will be required to be initially inspected, and at this point, we have no way to know how many we are talking about.

Doug Lang commented (8)(B), line 17, should be changed to "clients" rather than "patients" and asked about reporting of errors. Tom Glenski stated the Board wanted an ability to monitor problems at these facilities even though there will not be a pharmacist present when dispensing is occurring. Further discussion tabled till later in the meeting.

#D6 Review of Technician Working Group Status/Proposed Technician Requirements

Kim Grinston reported and information was distributed to the Board for review. Ms. Grinston provided a history of the Technician Working Group. Tim Koch, Becky Rabbitt and Christian Tadrus presented to the Board on the Group's behalf. Questions were presented by the Board and discussion was held. James Riddle asked about continuing education requirements for certification, and Anita Parran asked about whether grandfathering is the same for a technician that's worked one week vs one that's worked 15 years. Tony Mangiapanello asked if grandfathered individuals will be required to complete CE like the certified technicians do; answer is no. Doug Lang responded to Ms. Parran's inquiry about length of experience, suggesting an attestation be utilized for the number of hours a technician works. Steve Callaway commented about the need to think beyond current use of technicians in the pharmacy practice. Ron Fitzwater presented to the Board regarding the Missouri Pharmacy Association's position that if certification is required for technicians, an expanded technician role will be next as well as a fiscal impact to the state and to the public.

Discussion was held regarding time constraints for pursuing in the 2012 legislative session, and need to thoroughly consider before proceeding. Curt Thompson stated the Board could agree to pursue legislation in 2012, but change its decision at a later meeting. Further discussion was held. Anita Parran asked if the proposed revisions to 338.014 was modeled after other states' language. Tim Koch presented to the Board regarding his involvement in other states' laws/regulations and some of the problems he's experienced because of bad language. He doesn't see those types of problems with Missouri's proposed language.

President Riddle asked for a preliminary vote of the Board with regard to pursuing a technician proposal in the 2012 legislative session; Janine Burkett and Pam Marshall in favor; Melissa Graham, Barbara Bilek and Anita Parran opposed. Informal consensus was given to continue development of a proposal to be officially voted on at a later time.

Kim Grinston commented the Board needs to clarify what a technician is allowed to do. Tim Koch commented that on behalf of Wal-Mart, technicians work today with no requirements, and the Technician Working Group is proposing advanced training requirements to protect the public. Curt Thompson commented the Administrative Hearing Commission has found against the Board because there are no special qualifications to be a pharmacy technician. Tom Glenski commented training is not addressed in the proposed language, and asked if a two-prong approach (training and certification) should be considered. Discussion was held regarding a training component in the proposal. It was Board consensus for the Technician Working Group to reconvene and consider a training aspect for the proposed language, which can be reviewed at the September meeting.

MOTION TO CLOSE 12:01 PM

At 12:01 p.m. Barbara Bilek made a motion, seconded by Melissa Graham, that the Board go into closed session and that all votes, to the extent permitted by

Missouri Board of Pharmacy

Open Minutes

July 13-14, 2011

Page 6 of 10

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 12:02 PM.

RECONVENE OPEN 1:37 PM

By motion duly made, seconded, passed and recorded in closed session minutes, the Board returned to open session at approximately 1:37 p.m.

MEMBERS OF THE PUBLIC ENTERED THE MEETING ROOM AT 1:38 PM

#D4 House Bill 412 and Regulation of Veterinarian Prescription Dispensing

Kim Grinston reported regarding drafted language for 20 CSR 2220-2.675. Discussion was held and the following revisions were offered:

- (1) Line 15, change “may” to “must”.
- (4) Pharmacy operations – President Riddle commented that “except” on Line 28 needs to be changed to allow for the exceptions listed in (A)-(J). “with the following modifications:” should be inserted instead.
- (l) Line 1, insert “in the defined area”.
- (6) Discussion of weekly/bi-weekly/monthly.
- (7) (D) delete “prescriber indication of”
- (8) Discussion of weekly/bi-weekly/monthly.
- (8)(B) “patient” should be changed to “client”.

Motion was made by Barbara Bilek, seconded by Anita Parran, to require monthly review of compliance in (6). Motion passed, all in favor, none opposed.

Motion was made by Barbara Bilek, seconded by Anita Parran, to require monthly review of prescription records in (8). Motion passed, all in favor, none opposed.

Motion was made by Barbara Bilek, seconded by Anita Parran, to proceed with filing 20 CSR 2220-2.675 as an emergency regulation. Motion passed, all in favor, none opposed.

#D7 “Compliance Is Key” Initiative

- Flyer for Webinar
- Compliance Top 10
- Self-Assessment Form

Kim Grinston reported and discussion was held.

#B4 Wendy Young-Guffey, #2005007715, 2010-007974

- Notice Of Violation of Disciplinary Order
- Complaint

A violation of discipline hearing was scheduled for July 13, 2011, at 2:00 p.m. A court reporter was present and the hearing began at approximately 2:10 p.m. The Board was represented by Joshua Hill, and Wendy Young-Guffey was present and was not represented by counsel. The hearing recessed at approximately 3:40 p.m. to allow Ms. Young-Guffey to print documents from her computer.

#B1 Rebecca Kraft, #2002027593, #2007-001394

- Notice Of Disciplinary Hearing
- Complaint
- Answer
- Joint Motion For Consent Order, Joint Stipulation Of Facts And Conclusions Of Law, And Waiver of Hearing Before The Administrative Hearing Commission
- Consent Order

A disciplinary hearing was scheduled for July 13, 2011, at 1:30 p.m. The Board's attorney mistakenly thought the hearing was continued, and did not appear until approximately 3:00 p.m.. A court reporter was present and the hearing began at approximately 3:48 p.m. The Board was represented by Daniel Jacob, and Rebecca Kraft was present and was not represented by counsel. The hearing concluded at 4:02 p.m. A copy of the transcript is on file with the Board of Pharmacy.

#B5 John Peer, #028198, #2011002142

- Notice Of Violation of Disciplinary Order
- Complaint

A violation of discipline hearing was scheduled for July 13, 2011, at 3:00 p.m. A court reporter was present and the hearing began at approximately 4:07 p.m. The Board was represented by Joshua Hill, and John Peer was present and was not represented by counsel. The hearing concluded at 4:31 p.m. A copy of the transcript is on file with the Board of Pharmacy.

#B6 Center Pharmacy, #003570, #2011-001349

- Notice Of Violation of Disciplinary Order
- Complaint

A violation of discipline hearing was scheduled for July 13, 2011, at 3:00 p.m. A court reporter was present and the hearing began at approximately 4:36 p.m. The Board was represented by Joshua Hill, and John Peer, owner of Center Pharmacy, was present and was not represented by counsel. The hearing concluded at 4:45 p.m. A copy of the transcript is on file with the Board of Pharmacy.

#B4 Wendy Young-Guffey, #2005007715, 2010-007974

The violation of discipline hearing reconvened at approximately 4:46 p.m. The hearing concluded at 5:03 p.m. A copy of the transcript is on file with the Board of Pharmacy.

#D5 Election of Officers

- 338.120

President Riddle reported Item #D5 will be postponed to the September meeting.

#D8 2012 Legislation

- Creation of Separate Permit Classifications for Automated Systems
 - 338.220
- Section 338.315/Return Medications
 - 338.315
- Section 338.013/Technician Requirements
- Additional Board Suggestions

Kim Grinston reported and discussion was held regarding 338.220 and 338.315.

Motion was made by Pam Marshall, seconded by Melissa Graham, to approve revisions to Section 338.220 as presented. Motion passed, all in favor, none opposed.

Motion was made by Barbara Bilek, seconded by Melissa Graham, to approve revisions to Section 338.315 as presented. Motion passed, all in favor, none opposed.

#A3 General Administration Report

- **Renewal of Legal Contracts** – Kim Grinston reported this item will be reviewed at the next conference call meeting.

Kim Grinston reported the MPJE question review is scheduled for August 8-22, 2011, and asked for a Board member volunteer to participate in the review.

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

#E1 Licensees Presently Under Discipline

#E2 Board Licensee Statistics

MOTION TO CLOSE 5:24 PM

At 5:24 p.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 5:25 PM, EXCEPT JOSHUA HILL REMAINED IN THE MEETING ROOM.

RETURN TO OPEN

THURSDAY, JULY 14, 2011

By motion duly made, seconded, passed and recorded in closed session minutes, the Board returned to open session at approximately 12:00 p.m. on Thursday, July 14, 2011.

MOTION TO ADJOURN 12:01 PM

At approximately 12:01 p.m., motion was made by Barbara Bilek, seconded by Melissa Graham, to adjourn the July 13-14, 2011, regular open session meeting. Motion passed, all in favor, none opposed, Pam Marshall absent.

KIMBERLY A. GRINSTON
EXECUTIVE DIRECTOR

DATE APPROVED: 7/11/12