

OPEN MINUTES
Missouri Board of Pharmacy

September 21, 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 7:48 a.m. on September 21, 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
Dale Smith, R.Ph., Member
Anita Parran, Public Member

Board Members Absent

Barbara Bilek, R.Ph., Vice President

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 7:49 AM

At 7:49 a.m. Pam Marshall made a motion, seconded by Anita Parran, that the Board go into closed session and that all votes, to the extent permitted by law,

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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, Barbara Bilek absent.

MEMBERS OF THE PUBLIC LEFT THE MEETING ROOM AT 7:49 AM.

RECONVENE OPEN 8:56 AM

By motion duly made, seconded, passed and recorded in closed session minutes, the Board returned to open session at approximately 8:56 a.m.

MEMBERS OF THE PUBLIC ENTERED THE MEETING ROOM AT 8:57 AM

#A1 Agenda Additions/Corrections

Kim Grinston reported regarding additional information for items #A3, #A4, #B2, #D3, #D8 and #D10, and new items at #E3 and #E4. Item #D4 has been removed from the agenda.

#D4 Proper Signature on Immunization Protocols

#A2 Board Member Report - Nothing reported.

#A3 General Administration Report:

- **Financial Report** – Kim Grinston reported.
- **2012 Meeting Dates** – Tammy Siebert reported.
- **Compliance Is Key** – Kim Grinston reported the Board has conducted three webinars thus far and all experienced good attendance. An immunization webinar is scheduled for September 29th at 7:00 p.m., and on November 10th BNDD and the Board will do a joint controlled substances frequently asked questions webinar.
 - **Rule status** – Kim Grinston reported the Board's digitized records rule is not yet on the report but it has been submitted to the Division for processing.

#D12A Expedited Partner Therapy Rule

Kim Grinston reported.

#A4 Approval of Minutes

- May 10, 2011 Email Ballot

Motion was made by Melissa Graham, seconded by Anita Parran, to approve the minutes of the May 10, 2011, open session email ballot meeting. Motion passed, all in favor, none opposed, Barbara Bilek absent.

- June 23, 2011 Email Ballot

Motion was made by Janine Burkett, seconded by Pam Marshall, to approve the minutes of the June 23, 2011, open session email ballot meeting. Motion passed, all in favor, none opposed, Barbara Bilek absent.

- June 30, 2011 Conference Call

Motion was made by Pam Marshall, seconded by Melissa Graham, to approve the minutes of the June 30, 2011, open session conference call meeting. Motion passed, all in favor, none opposed, Barbara Bilek absent.

- August 17, 2011 Conference Call

Motion was made by Anita Parran, seconded by Janine Burkett, to approve the minutes of the August 17, 2011, open session conference call meeting. Motion passed, all in favor, none opposed, Melissa Graham abstained, and Barbara Bilek absent.

- August 20, 2011 Email Ballot

Motion was made by Janine Burkett, seconded by Pam Marshall, to approve the minutes of the August 20, 2011, open session conference call meeting. Motion passed, all in favor, none opposed, Melissa Graham abstained, and Barbara Bilek absent.

- April 14, 2011 Technician Working Group – Removed from agenda.
- May 12, 2011 Technician Working Group – Removed from agenda.
- July 8, 2011 Technician Working Group – Removed from agenda.

#B1 Interlock Pharmacy Systems, #2009033411, #2010-007146

- Notice of Hearing On Violation of Disciplinary Order
- Complaint

President Riddle reported the Interlock Pharmacy Systems violation of discipline hearing scheduled for 1:30 p.m. has been continued.

#B2 Winowiecki, Jill, #2001007711, #2008-007384

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

President Riddle reported the Jill Winowiecki felony disciplinary hearing scheduled for 1:30 has been cancelled due to settlement.

#C1 Applications for Intern Training Pharmacy Special Site

- CVS/Pharmacy Regional Business Office
- Express Scripts, Inc. – Client Benefit Administration
- Pfizer, Inc. – medial Outcomes Specialists
- Program of All-Inclusive Care for the Elderly (PACE)
- Angela Paniagua, Zablocki VA Medical Center

Tom Glenski reported there were no concerns about any of these intern training special site applications. **Motion was made by Melissa Graham, seconded by Janine Burkett, to approve all the Intern Training Special Site applications for 500 hours each. Motion passed, all in favor, none opposed, Barbara Bilek absent.**

#C2 STLCOP and UMKC College of Pharmacy

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

Tom Glenski reported National Association of Chain Drug Stores had already been approved for STLCOP. **Motion was made by Pam Marshall, seconded by Melissa Graham, to approve the STLCOP and UMKC site and preceptor lists as presented except for NACDS. Motion passed, all in favor, none opposed, Barbara Bilek absent.**

#D5 Continuing Education for Board Meeting Attendance

Tom Glenski reported and discussion was held. It was Board consensus for staff to gather more information on how other states handle this matter.

#D6 HB 552 Implementation

- House Bill No. 552
- MASAC Recommendations

DISCUSSION:

The Board has been asked to consider adopting Recommendation 188 in its entirety. How would the Board like to proceed?

Kim Grinston reported and discussion was held. It was Board consensus for staff to return proposed regulations to a future meeting.

#D7 338.315 Receipt of Drugs from Unlicensed Distributor or Pharmacy, Unlawful—Penalty

- 338.315
- Florida 64F-12.011 (1) (f)
- Kentucky 315.400
- Texas 229.421 (12) and (28)
- Nebraska 172.131
- Illinois Section 1510.10 Definitions
- Wisconsin Wholesale Distributor of Drugs

Kim Grinston reported and requested the Board consider a legislative proposal for 2012 to amend Section 338.315 to allow the Board to waive drug distributor licensing when there is an emergency or a national drug shortage as defined by the Board. It was Board consensus for staff to draft a proposed revision to Section 338.315.

#D8 Pharmacy Technician Qualifications/Revision of 338.013

- Option A
- Option B
- Option C
- Option D
- Email from Bert McClary
- Technician Training Comparison

Kim Grinston verbally reported regarding each of the options; discussion was held. President Riddle reported Barbara Bilek wishes to participate in this discussion, but she was not able to attend today's meeting. Therefore, she will participate via conference call at approximately 1:00 p.m. Further discussion was held.

#D9 Compounding For Office Use

Kim Grinston reported this item has been tabled to the November meeting.

#D10 Drop Site

- 20 CSR 2220-2.013
- Minnesota Rule
- Montana Rule
- Oregon Rule
- Texas Rule
- Virginia Rule

President Riddle and Kim Grinston reported; discussion was held. Leanne Peace of the Missouri Kidney Program presented to the Board. Sam Leveritt of Cardinal Health presented to the Board regarding Class E pharmacies, and asked for specific documentation outlining where medications are authorized to be delivered. Kim Grinston asked the Board for specific direction concerning delivery to physician offices. It was Board consensus to begin drafting regulations and hold enforcement in abeyance concerning delivery to a licensed healthcare practitioner/clinic.

#D1 BNDD Update with Mike Boeger

- DEA – CII Changes

Michael Boeger presented to the Board beginning at 10:34 a.m. He stated concerning the drop site issue, the Drug Enforcement Administration has directed that controlled substances should be mailed by a pharmacy to the patient's home or can be mailed to the doctor's office if the pharmacy is registered as a drug distributor with BNDD and DEA. DEA requires the use of a 222 form or CSOS if a schedule II prescription is being sent to a doctor's office.

Mr. Boeger reported the regulation for mid-level practitioners to write controlled substances will be effective November 30, 2011. BNDD will begin registering advanced practice nurses and physician assistants December 1st. BNDD is federally required to provide the public with survey results indicating low-service areas of the state; information is provided with their BNDD applications.

It was reported that BNDD has gone paperless as much as possible; the agency prefers online application submissions but still does allow paper applications.

Mr. Boeger thanked the Board for the assistance provided by the inspectors with getting Missouri pharmacies enrolled in the pseudoephedrine tracking database, and also expressed appreciation for work done by the Board staff involving the Joplin tornado

emergency. It was also noted the Board's Compliance is Key initiative is to be commended.

#D2 Missouri Association of Osteopathic Physicians and Surgeons' Physician Health System

- MAOPS Flyer

Kim Grinston reported the Board's history of a bid proposal for a well-being program and that the bid received was rejected by the Board. James Wieberg and Colin Duggan of the MAOPS program presented to the Board at 11:10 a.m. Information was provided about the MAOPS program they provide for the Board of Healing Arts, and Mr. Wieberg indicated they may increase staff if the Board of Pharmacy also utilizes their services. Bert McClary commented about his good experience with the MAOPS program.

#D7 338.315 Receipt of Drugs from Unlicensed Distributor or Pharmacy, Unlawful—Penalty

A new handout was distributed to the Board members for a revision to 338.333 with regard to waiver of drug distributor licensure in the event of an emergency or a supply shortage. **Motion was made by Melissa Graham, seconded by Janine Burkett, to approve the new language presented and to include it with the Board's 2012 legislative proposal. Motion passed, all in favor, none opposed, Barbara Bilek absent.**

#D11 Election of Officers

- 338.120

President Riddle reported the Board's new officers will begin serving at the end of this meeting.

- a) President

Janine Burkett nominated Pam Marshall for president, nomination seconded by Melissa Graham. Nomination passed, all in favor, none opposed, Pam Marshall abstained and Barbara Bilek absent.

- b) Vice President

Pam Marshall nominated Janine Burkett for vice-president, nomination seconded by Anita Parran. Nomination passed, all in favor, none opposed, Janine Burkett abstained and Barbara Bilek absent.

MOTION TO CLOSE 11:48 AM

At 11:48 a.m. Anita Parran made a motion, seconded by Pam 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) and (14), RSMo, and under Section 324.001.8, RSMo. Motion passed, all in favor, none opposed, Barbara Bilek absent.

MEMBERS OF THE PUBLIC AND THE COURT REPORTER LEFT THE MEETING ROOM AT 11:48 AM.

RECONVENE OPEN 1:05 PM

By motion duly made, seconded, passed and recorded in closed session minutes, the Board returned to open session at approximately 1:05 p.m.

MEMBERS OF THE PUBLIC, INCLUDING A COURT REPORTER, ENTERED THE MEETING ROOM AT 1:05 PM

BARBARA BILEK JOINED THE MEETING VIA CONFERENCE CALL AT 1:05 PM.

#D8 Pharmacy Technician Qualifications/Revision of 338.013

Kim Grinston reported she had provided Barbara Bilek Option E via email. Discussion was held. Barbara Bilek provided information about her inquiries to Missouri Society of Health-System Pharmacists and gained no support for a certification requirement in the proposed language. Pam Marshall commented that 400 hours should be changed to 500 hours. Ron Fitzwater of Missouri Pharmacy Association voiced a concern about introducing this legislation in an election year, and suggested the Board approach this cautiously and be uniform in its decision. David Overfelt of the Missouri Retailers Association spoke in support of grandfathering currently registered technicians. Tim Koch of Wal-Mart Corporation commented that he prefers an unprinted Option F, which is to not hurry a decision and to do nothing at this point in time. Mr. Koch commented he would like to see the Technician Working Group reconvene and come up with two options for the Board's consideration. Bert McClary of the Department of Health and Senior Services commented he supported a training program based on a standardized, responsible entity, and an examination of competency whether implemented by statute or regulation. Steve Callaway of the University of Missouri commented he would support a competency-based program even though there is no data to support that as a better option. Sam Leveritt of Cardinal Health asked the Board to consider specialty pharmacies when making its decision. Board discussion was held. Pam Marshall and Janine Burkett suggested the Technician Working Group go back to work and the matter be returned to the November meeting for a decision.

BARBARA BILEK DISCONNECTED FROM THE MEETING AT 1:53 PM

#D3 Missouri Health Connection Pharmacy Survey

- Missouri Health Connection Overview
- Survey
- Webpage – About Us
- Webpage – Mission
- Webpage – Board of Directors
- Webpage – Consumer Advisory Council
- Webpage – Legal and Policy Workgroup

DISCUSSION:

Missouri Health Connections would like to conduct the survey with the Board of Pharmacy.

Raul Recarey presented to the Board at approximately 2:03 p.m. Questions by Board members.

MOTION TO CLOSE 2:15 PM

At 2:15 p.m. Janine Burkett made a motion, seconded by Melissa Graham, 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, Barbara Bilek absent.

MEMBERS OF THE PUBLIC LEFT THE MEETING ROOM AT 2:15 PM.

RECONVENE OPEN 2:54 PM

By motion duly made, seconded, passed and recorded in closed session minutes, the Board returned to open session at approximately 2:54 p.m.

MEMBERS OF THE PUBLIC, INCLUDING A COURT REPORTER, ENTERED THE MEETING ROOM AT 2:55 PM

#D12A Expedited Partner Therapy Rule

- 20 CSR 2150-5.021 Expedited Partner Therapy proposed rule
- 20 CSR 2150-5.020 Nonpharmacy Dispensing proposed amendment

Kim Grinston reported information pertaining to this subject is found in Board member folders. President Riddle reported and discussion was held. It was Board consensus for Board staff to relay its concerns to the Board of Healing Arts.

#A3 General Administration Report:

- Renewal of Legal Contracts

Kim Grinston reported and discussion was held. **Motion was made by Pam Marshall, seconded by Janine Burkett, to approve renewal of Loretta Schouten and Newman, Comley & Ruth's legal contracts as presented. Motion passed, all in favor, none opposed, Barbara Bilek absent.**

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

#E1 Licensees Presently Under Discipline

#E2 Board Licensee Statistics

#E3A Letter from ISMP-NABP Response

Note: Material is being posted for informational purposes only

#E4A Dispensing Emergency Contraceptives

- American Society for Pharmacy Law article

MOTION TO CLOSE 3:00 PM

At 3:00 p.m. Pam Marshall 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, Barbara Bilek absent.

MEMBERS OF THE PUBLIC LEFT THE MEETING ROOM AT 3:00 PM.

RECONVENE OPEN 8:27 PM

By motion duly made, seconded, passed and recorded in closed session minutes, the Board returned to open session at approximately 8:27 p.m.

MOTION TO ADJOURN 8:28 PM

At approximately 8:28 p.m., motion was made by Melissa Graham, seconded by Janine Burkett, to adjourn the September 21, 2011, regular open session meeting. Motion passed, all in favor, none opposed, Barbara Bilek absent.

KIMBERLY A. GRINSTON
EXECUTIVE DIRECTOR

DATE APPROVED: 7/11/12