

**OPEN MINUTES
Missouri Board of Pharmacy**

**October 24, 2012
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 8:01 a.m. on October 24, 2012, 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 8:01 AM

At 8:01 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 8:01 AM.

RECONVENE OPEN 8:54 AM

By motion duly made, seconded, passed and recorded in closed session minutes, the Board returned to open session at approximately 8:54 a.m.

JASON MENKEN, REGINA BLANCHARD AND MEMBERS OF THE PUBLIC ENTERED THE MEETING ROOM AT 8:54 AM

#A1 Agenda Additions/Corrections

Additional information for items #A2 and #A3 is found in Board member folders.

#A2 Board Member Report

Anita Parran reported regarding her attendance at NABP's Interactive Forum September 19-20, 2012.

Janine Burkett reported regarding her attendance at NABP's Program Review and Training July 24-25, 2012.

#A3 General Administration Report:

- **Office Updates** – Kimberly Grinston reported the Board office is currently processing pharmacist renewals and intern renewals were mailed October 1st.

Ms. Grinston reported she attended the NABP/AACP District 6, 7, and 8 meeting in Little Rock, Arkansas, October 22-23, 2012, and that this was the first time in several years she was able to attend due to travel restrictions.

Ms. Grinston reported she and Tom Glenski will attend the DEA Drug Diversion Conference November 14-15, 2012, in Cincinnati, Ohio.

Kimberly Grinston reported inspectors George McConnell, Barbara Wood and Tom Glenski attended St. Louis College of Pharmacy's MTS training, and that Regina Blanchard is currently processing MTS applications. Tom Glenski and George McConnell also attended an Immunization Administration training in Kansas City. St. Louis College of Pharmacy has another MTS training scheduled for January 19-20, 2013.

Ms. Grinston also reported the Board office is currently preparing an Inspector Q & A webinar for December, and that revisions have been made to the Board's lawbook which will be posted to our website.

Kimberly Grinston reported the proposed revisions to the Board's licensing rules are still being processed; she will meet with Division and Department representatives about them. Connie Clarkson, Division Legislation and Budget Director, has been promoted to the position of Executive Director for the Board of Healing Arts.

- **BeSafeRx Campaign**

- Who Are We Trying To Reach

- Know Your Pharmacy
- Get The Facts

Kimberly Grinston reported.

- **Patient Safety Initiative** – Kimberly Grinston reported the Board office is currently in the process of updating its Pharmacy Practice Guide, and reported about the Board’s Patient Safety Initiative.

- **2013 Meeting Dates** – Tammy Siebert reported the 2013 Board meetings will be held at Courtyard by Marriott, Columbia, Missouri. The 2013 dates are in the Board member folders will be posted to the Board’s website.

- **Well-Being Program** – Kimberly Grinston reported the request for bid proposal has been issued again for the Well-Being Program; it is anticipated the bid proposals will be ready for review at the January meeting.

#A4 Approval of Minutes

- July 11, 2012 Meeting

Motion was made by James Riddle, seconded by Barbara Bilek, to approve the July 11, 2012, open session minutes as printed. Motion passed, all in favor, none opposed.

- August 15, 2012 Conference Call

Motion was made by Janine Burkett, seconded by Anita Parran, to approve the August 15, 2012, open session conference call minutes as printed. Motion passed, all in favor, none opposed, Barbara Bilek abstained.

- September 19, 2012 Conference Call

Motion was made by Barbara Bilek, seconded by Janine Burkett, to approve the September 19, 2012, open session conference call minutes as printed. Motion passed, all in favor, none opposed, Anita Parran abstained.

#C1 Applications for Intern Training Pharmacy Special Site

- Perniciaro and Associates Senior Care Consultants
- Shared Care Free Clinic of Jackson County
- Truman Medical Center – Lakewood Outpatient Pharmacy

Tom Glenski reported Truman Medical Center has the wrong name and instead should say Clinic. **Motion was made by James Riddle, seconded by Janine Burkett, to approve these three 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 – Tom Glenski reported this list includes CVS District Office but it should be a special site, so should not be approved here. **Motion was made by Janine Burkett, seconded by Barbara Bilek, to approve the STLCOP site list as presented, except for CVS District Office, all in favor, none opposed.**

- STLCOP Preceptor Listing - **Motion was made by Barbara Bilek, seconded by Anita Parran, to approve the STLCOP preceptor list as presented, all in favor, none opposed.**

- UMKC Site Listing - **Motion was made by Barbara Bilek, seconded by James Riddle, to approve the UMKC site list as presented, all in favor, none opposed.**
- UMKC Preceptor Listing - **Motion was made by Barbara Bilek, seconded by Janine Burkett, to approve the UMKC preceptor list as presented, all in favor, none opposed.**

#D3 Faxed Prescription Forms

- Letter from Missouri State Medical Association

Kimberly Grinston reported. James Riddle commented regarding the cost involved in pharmacies changing software programs, not sure the Board should pursue this type of change. Discussion was held. It was Board consensus for the Board office to send a response letter advising of the Board's concerns about possible costs and that the Board is not authorized to create a standardized form. Phil Wickizer of Express Scripts commented that FDA has requirements that could be used as part of the Board's response.

#D4 Implementation of HB 1563

- HB 1563
- 20 CSR 2220-5.020 Proposed Amendment
- 21 CFR Section 203.1
- NABP Model Language--DD Intra-company Shipments
- FDA FAQ About Drug Shortages
- Intra-Company Shipments
- Patient Returns

Kimberly Grinston reported regarding HB1563 and proposed revisions to the Board's regulation 20 CSR 2220-5.020 concerning shipment issues. Ms. Grinston reported some language in the proposed revision was taken from the federal rule and that some portions were specifically excluded—intracompany sales, exemptions between certain charitable organizations, samples language, and purchasing within a health buying group purchasing situation. Ms. Grinston further reported that the Board's Drug Distributor Advisory Committee has been sent the proposed rule revision, but only one comment from Christian Tadrus has been received (handout in Board member folders). Kimberly Grinston reported regarding the change involving Strategic National Stockpile drugs (handout). Discussion was held.

Janine Burkett asked for clarification as to why the excluded items were not included in our regulation. Ms. Grinston explained there were a lot of unanswered questions regarding intracompany sales, group purchasing, etc.

Kimberly Grinston asked if on page 113, 7. whether there is a need to include a 5% limit for this area or to insert language about restricted resale pricing? Tom Glenski commented the Board has no way to determine if an out-of-state facility is complying with the 5% limit. James Gray commented regarding federal language for purchasing rather than redistributing.

James Riddle commented whether language is needed for out-of-state licenses, but rather for the facility where drugs are shipped from on page 112, 8.

Sam Leveritt commented if an exception is needed for nuclear pharmacy or if it will be addressed in the new nuclear pharmacy regulations. Kimberly Grinston reported the revisions to 20 CSR 2220-5.020 will be finalized before the nuclear pharmacy rules revisions. It was Board consensus to address it in the nuclear pharmacy regulations.

James Riddle asked if intracompany transfers should be addressed in this regulation. Ms. Grinston reported we now require a license if shipping within Missouri, even if within the same company ownership. Steve Callaway reported he noticed some changes in this version versus what was presented during the Board's Strategic Planning meeting—specifically “or other healthcare entities” and if offsite owned clinics/infusion centers are part of the deletion. Kimberly Grinston reported there are problems with what “other healthcare entities” means, and questioned if it should be defined within the rule. Steve Callaway commented better control of samples in facilities may need to be addressed in the rule. He further asked if “charitable organizations” should be defined.

Tom Glenski commented that “other healthcare entities” may not be regulated by the Department of Health, Board of Nursing, Board of Healing Arts or any other agency, which is a problem. James Gray commented about 340B entities (such as BJC) doing “bill to/ship to” processes within the same hospital ownership. Kimberly Grinston commented this is a good discussion for the Board's Hospital Working Group.

It was Board consensus to proceed with the rule as printed, with changes noted and to remove “other healthcare entities” at this time. Ms. Grinston reported revisions will be made and returned to the Board for approval.

Kimberly Grinston commented regarding patient returns. Discussion was held involving whether patient returns are allowed, disposal requirements, recordkeeping, cost to the pharmacy, etc. It was Board consensus to bring this back to the Board to review with other states' laws/regulations.

#D5 Consolidation of Refills

- Kansas Senate Bill No 211
- Quantity Limits

Kimberly Grinston reported she met with Department of Insurance representatives and was told insurance companies are required to comply with laws/regulations, but it would not be a priority enforcement issue at this time by the Department of Insurance. Discussion was held. James Riddle commented his concerns involve patient choice—specifically in the instance when a 90-day supply is dispensed after the patient requested a 30-day supply. Janine Burkett commented that it may be an insurance company requirement because the 90-day cost is the same as a 30-day supply. Discussion was held. James Gray commented pharmacists should be able to use professional judgment at the request of the patient to make the quantity change without calling the prescriber. Steve Callaway commented he would rather call prescribers for

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clinical questions versus authorization to combine refills. Tony Mangiapanello commented insurance plans differ as to what drugs are automatically consolidated on first dispensing. Brian Newton of RxOutreach (no insurance involved) commented their patients are able to request three or six-month consolidated refills, and refill requests to the prescriber takes time and delays delivery of medications to the patient. President Marshall commented the regulation could be amended to allow patient choice.

Christian Tadrus commented the Board should consider long-term care patients usually have many dosing changes, and that there may be odd quantities (19 and 27), rather than the typical 30- and 90-day supplies.

Anita Parran commented that the public likely doesn't realize they have the choice to consolidate refills.

It was Board consensus to draft language that will allow consolidation of refills, will address patient choice, and patient notification for increase/decrease in quantity dispensed.

#A3 General Administration Report:

- **Employee Recognition**

Pam Marshall recognized George McConnell for five years of service to the Board and presented him with a five-year service pin.

Pam Marshall recognized Regina Blanchard for fifteen years of service to the Board and presented her with a desk clock.

#D1 Pharmacists Preventing Suicide Presentation

- Tricia Leann Tharp Act Proposal
- Fact Sheet For Suicide Prevention & Pharmacists Role
- Suicidality Card – Patient's 3x5
- Suicidality Card – Preventer's 3x5
- Suicidality Card – Sources 3x5

DISCUSSION:

Licensee legislation recommendation

Pharmacists Patrick Tharp and Robert Salter entered the meeting room at 11:05 a.m. and presented to the Board concerning Mr. Tharp's proposed legislation, and responded to questions by the Board. James Riddle suggested Mr. Tharp contact the Board of Healing Arts about his organization. Mr. Tharp and Mr. Salter left the meeting room at 11:46 a.m.

#D2 BNDD Update

Michael Boeger presented to the Board at approximately 11:47 a.m. concerning the following:

- Effective 12/2/11 BNDD implemented their online registration application process; 70% of 11,000 registrants since 12/2/11 applied online with no paper involved.
- 200 advanced practice nurses and 50 physician assistants have registered with BNDD.
- According to DEA, the physician is responsible for prescribing, not the pharmacy's staff and pharmacists are not considered agents of the physician, so therefore, pre-populated prescription authorizations faxed to prescribers are not allowed. The DEA rule applies to all practice settings—long-term care, hospital, retail, etc.
- BNDD is currently working to scan 40 file cabinets of documents.
- BNDD will move to Knipp Drive in Jefferson City on 11/7/12.
- BNDD has employed a new investigator, Andrew Hayden.
- The Prescription Drug Monitoring legislation will be filed again in 2013.

#D6 2013 Legislative Initiatives

- Immunization
- Emergency Refills
- Medication Therapy Services Requirements
- Classes of Pharmacy
- Regulation of Hospital Pharmacy Practice
- Hospital Advisory Committee

Kimberly Grinston reported the Governor's deadline for submitting proposed legislation was in July. The Board's emergency dispensing, MTS, and pharmacy classification general language have all been approved by the Department and forwarded to the Governor's office for approval to file. The Department did not approve the Board's immunization proposal or the technician language. Ms. Grinston also reported concerning a call she received from Patricia Straeder, lobbyist for the Missouri Osteopathic Association, about the Association's concerns about pharmacists having the ability to immunize other than flu vaccines.

Kimberly Grinston reported about meetings with Department of Health and Senior Services and Missouri Hospital Association representatives to create a proposed revision to Chapter 338 to give the Board authority over hospital in-patient pharmacies. Although the Missouri Hospital Association is generally in favor of pursuing such a change, it is concerned about moving too quickly. Ms. Grinston reported that section 6. would establish a hospital advisory committee, and she asked the Board to preliminarily establish such a committee to meet so that the Board is ready to proceed with a legislative proposal in 2014. It was Board consensus to proceed with establishing a hospital advisory committee; Barbara Bilek offered to serve on the committee. Kimberly Grinston suggested that an outside, neutral individual be appointed to lead the committee, and James Gray suggested an individual from a large academic institution also be included on the committee.

MOTION TO CLOSE 12:25 PM

At 12:25 p.m. Janine Burkett 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 12:25 PM. MICHAEL BOEGER REMAINED IN THE ROOM TO DISCUSS CLOSED ITEMS WITH THE BOARD.

RECONVENE OPEN 1:31 PM

By motion duly made, seconded, passed and recorded in closed session minutes, the Board returned to open session at approximately 1:31 p.m.

#D7 Clarification of Medication Therapy Services Rules

- 338.010
- 20 CSR 2220-6.080 Medication Therapy Services By Protocol Proposed Amendment
- Applicability of Administration by Prescription Order to MT Certificate Holders?
- Scope of Immunization Authority Under Medication Therapy Rules (See A2 in Closed Session)

DISCUSSION:

Discussion requested regarding scope of immunization authority for pharmacists with MT authority. Can a pharmacist with an MT certificate administer vaccines other than those identified in 338.010?

- Applicability of MTS certificate to pharmacists practicing in a hospital

Kimberly Grinston reported the Board's Medication Therapy Services rules became effective 8/30/12; she and President Marshall attended the Board of Healing Arts' meeting when they discussed proposed revisions to their MTS regulations. Discussion was held. **Motion was made by Barbara Bilek, seconded by Janine Burkett, to approve revisions to 20 CSR 2220-6.080 as presented, all in favor, none opposed.** Ms. Grinston further reported the Board of Healing Arts specifically voted to not discuss the Board of Nursing's request.

Ms. Grinston reported how physician supervision of nursing staff parallels pharmacist supervision of technicians.

President Marshall reported the Board of Healing Arts also discussed proposed legislation for a prescription drug monitoring program.

Tom Glenski commented about questions raised concerning whether a pharmacist can administer vaccines other than those authorized by Chapter 338 now that the medication therapy services rules are in place. **Motion was made by Barbara Bilek, seconded by Janine Burkett, that a pharmacist, using a MTS protocol, cannot**

administer a vaccine or drug other than those listed in Section 338.010, all in favor, none opposed.

Barbara Bilek commented that MTS certification is required for pharmacists providing immunizations in hospitals. Steve Callaway commented Missouri Society of Health-System Pharmacists (MSHP) understood that the MTS rules were not to prevent hospital pharmacists from doing what they've been doing for years. Tom Glenski commented the discussion before the Board now is only about MTS certification, not protocols. **Motion was made by Barbara Bilek, seconded by Anita Parran, to work with the Missouri Department of Health and Senior Services to establish a joint statement about the need for MTS certification by hospital pharmacists, all in favor, none opposed.** Further discussion was held about including a date in the joint statement for required compliance; Kimberly Grinston commented that the Department of Health and Senior Services would be the one to enforce such a compliance date.

#D8 Automated Filling Machines

- 20 CSR 2220-2.950 Automated Filling Systems Proposed Rule
- Comments
- Comments

Kimberly Grinston reported automated dispensing and automated filling are two different issues, and will be handled as two separate regulations. Barbara Bilek reminded everyone that the proposed rule does not address hospital settings.

Kimberly Grinston commented that “2% quality testing” found in (4)g. should be considered for high volume pharmacies where 2% could be a very large amount. Charlie Hartwig of Omnicare commented other states require between 2% and 10%. Phil Wickizer of Express Scripts commented they test 2% to 5%. Discussion was held about using “random sampling” rather than a specific percentage in the rule. Janine Burkett suggested “or as approved by the Board” be added; Kimberly Grinston commented the Board would have no criteria for approval unless established in regulation. Discussion was held concerning how the 2% would be established. Barbara Bilek suggested adding “on a validated system.” Kimberly Grinston suggested “on a current or previous day’s sampling” be used. Anita Parran commented public comment may be useful from smaller entities. Language such as “sample size of daily 2% or greater filled by the system as designated by the pharmacist-in-charge, and must be the same established standard and not fluctuating” could be used. James Riddle stated a pharmacist must conduct the testing.

James Riddle questioned page 194 of the agenda, (6) “If the verification requirements of (4)c. and (4)d...” Kimberly Grinston reported (4)c. should be deleted. Mr. Riddle also asked about an electronic verification system—who logs in and who verifies what is loaded into the filling system? Mr. Wickizer stated it’s always a pharmacist at Express Scripts; Mr. Hartwig responded a technician, supervised by a pharmacist, usually loads their system. Tom Glenski asked for clarification of what the pharmacist actually sees.

Kimberly Grinston pointed out the definitions of “repackager” and “repacked” in (1). Express Scripts expressed concerns about drugs that are repackaged by an outside source.

Mr. Wickizer questioned (4)b. and Kimberly Grinston questioned manipulation during the filling process. Mr. Hartwig commented the only human contact in their system is when the product is loaded into the machine before the actual filling begins. Ms. Grinston suggested adding “no manual intervention after the medication is loaded into the automated filling system.”

James Riddle asked what is “direct supervision of a pharmacist” as referenced in (2) Medication Stocking? Express Scripts commented line of sight is used; Omnicare requires one pharmacist to two technicians.

It was Board consensus for office staff to revise the proposed rule and return it for further review by the Board.

Christian Tadrus suggested the name of the regulation be changed to “Automated Packaging Systems.”

#D9 Approval of Revised Board Policies and Procedures

- President Duties
- Executive Director Authority
- Delegation of Duties
- Conflicts of Interest
- Personal Interviews
- Outside Employment
- License-Membership Fees
- Honorariums
- Professional Development

Kimberly Grinston reported and discussion was held. **Motion was made by Barbara Bilek, seconded by James Riddle, to approve the policies as printed, all in favor, none opposed.**

#B1 The Medicine Shoppe, #2001019642, 547 N Scott, Belton, MO 64012, #2005-006704

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

A disciplinary hearing was scheduled for October 24, 2012, at 3:30 p.m. A court reporter was present and the hearing began at approximately 3:34 p.m. The Board was represented by Joshua Hill, and neither a representative of The Medicine Shoppe nor its counsel was present. The hearing concluded at approximately 3:41 p.m. A copy of the transcript is on file with the Board of Pharmacy.

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 CPE Releases Quality Criteria for Certification of International Professional Degree Programs in Pharmacy

- Email from Hudson

#E4 Illinois Pharmacists

MOTION TO CLOSE 3:44 PM

At 3:44 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 3:45 PM.

RECONVENE OPEN 6:30 PM

By motion duly made, seconded, passed and recorded in closed session minutes, the Board returned to open session at approximately 6:30 p.m.

MOTION TO ADJOURN 6:31 PM

At approximately 6:31 p.m., motion was made by Barbara Bilek, seconded by James Riddle, to adjourn the October 24, 2012, open session meeting. Motion passed, all in favor, none opposed.

KIMBERLY A. GRINSTON
EXECUTIVE DIRECTOR

DATE APPROVED: 1/16/13