

OPEN MINUTES
Missouri Board of Pharmacy

January 13-14, 2016
Hilton Garden Inn
3300 Vandiver 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 8:01 a.m. on January 13, 2016, at Hilton Garden Inn, 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
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
Elaina Wolzak, R.Ph., Inspector
Barbara Wood, R.Ph., Inspector

Staff Absent

Bennie Dean, R.Ph., Inspector
Katie DeBold, PharmD, Inspector

Others Present

Curtis Thompson, Legal Counsel

MOTION TO CLOSE 8:02 A.M.

At 8:02 a.m., Barbara Bilek 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), (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:

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

RETURN TO OPEN

By motion duly made, seconded, passed and recorded in closed session minutes, the Board returned to open session at approximately 8:42 a.m.

PRESIDENT LINDSAY CALLED THE OPEN SESSION MEETING TO ORDER AT APPROXIMATELY 8:42 A.M. MEMBERS OF THE PUBLIC ENTERED THE MEETING ROOM.

President Lindsay welcomed Elaina Wolzak as one of our new inspectors.

#A1 Agenda Additions/Corrections

Kimberly Grinston reported Patient Safety Working Group information is in the Board's addendum, and the Shawn Borman felony hearing has been continued.

#B3 Shawn Borman, #2002027612, #2014-005336

- Notice of Felony Disciplinary Hearing
- Felony Conviction Complaint

#A2 Board Member Report - Nothing reported.

#A3 General Administration Report

- New Licensing System - Kimberly Grinston reported the Division's new licensing system's vendor is still working on changes to suit the boards, the Office of Administration has hired an outside evaluator to determine if the changes are within or outside the original proposal. Ms. Grinston reported technician renewals will be processed as usual, but pharmacists may be able to renew with the new system in the fall. The Board's final payment for the system has not yet been paid.
- Rule Updates - Kimberly Grinston reported the Board's emergency amendment to 20 CSR 2220-2.020 was approved yesterday by the Governor's office for filing; it should be effective in approximately two weeks. The Board of Healing Arts has organized a task force on telemedicine/telehealth; a tentative agenda has not been released. Barbara Bilek, Christian Tadrus and Doug Lang volunteered to participate in the Healing Arts task force.

- Fund Reduction - Kimberly Grinston reported the Board's proposed partnership with the Department of Health and Senior Services regarding patient safety initiatives was approved yesterday. A legislative proposal will need to be written, which will be reviewed on a conference call.
- NABP Annual Meeting - Kimberly Grinston reported NABP's Annual Meeting will be held in San Diego in May. Anita Parran, Christina Lindsay and Barbara Bilek asked to attend on behalf of the Board; Doug Lang and Pam Marshall will attend with their employers.
- Strategic Planning Meeting - Kimberly Grinston reported the Center for Patient Safety meeting is scheduled for April 7th, which conflicts with the Board's original plan to hold its strategic planning meeting in April. Discussion was held about postponing strategic planning to the July meeting; preference was given for July 19th in conjunction with the July 20-21 Board meeting. It was the consensus that a facilitator be engaged to lead the meeting.
- Webinar Update - Kimberly Grinston reported approximately 324 participated in the Lunch With The Chief webinar held yesterday at noon. The Board's new inspection checklist process has been implemented, and a new Inspection Document Request form has been posted to the Board's website to facilitate the inspection process. Ms. Grinston asked for future webinar topics.
- MPJE Program Updates - Kimberly Grinston reported NABP will be shutting down MPJE registration for approximately two weeks in April to implement recent changes.
- New Inspectors - Kimberly Grinston reported Elaina Wolzak has already been introduced as one of our new inspectors. Katie DeBold has been hired as our sterile compounding inspector, and is in Mississippi this week for training.
- FY15 Financial Summary - Kimberly Grinston reported the final FY15 financial summary is in the agenda. The full report is available if anyone wants to review specific expenditures. The Board experienced a drop in revenue in FY15 due to previous fee decreases, which was anticipated.

#A4 Approval of Minutes

July 14-15, 2015 Regular Meeting - **Motion was made by Barbara Bilek, seconded by Pam Marshall, to approve the July 14-15, 2015 open session minutes as printed. Motion passed 3:0:2:0 with roll call vote as follows:**

Barbara Bilek – yes	Pam Marshall – yes	Anita Parran – abstain
Doug Lang - abstain	Christian Tadrus - yes	

July 26, 2015 Conference Call - **Motion was made by Pam Marshall, seconded by Doug Lang, to approve the July 26, 2015 open session conference call minutes as printed. Motion passed 4:0:1:0 with roll call vote as follows:**

Barbara Bilek – yes	Pam Marshall – yes	Anita Parran – abstain
Doug Lang - yes	Christian Tadrus - yes	

October 14-15, 2015 Regular Meeting - **Motion was made by Doug Lang, seconded by Barbara Bilek, to approve the October 14-15, 2015 open session minutes as printed. Motion passed 5:0:0:0 with roll call vote as follows:**

Barbara Bilek – yes Pam Marshall – yes Anita Parran – yes
Doug Lang - yes Christian Tadrus - yes

November 10, 2015 Conference Call - **Motion was made by Doug Lang, seconded by Anita Parran, to approve the November 10, 2015 open session conference call minutes as printed. Motion passed 5:0:0:0 with roll call vote as follows:**

Barbara Bilek – yes Pam Marshall – yes Anita Parran – yes
Doug Lang - yes Christian Tadrus - yes

#D1 Update from NABP Compliance Officers' Meeting

Andi Miller reported she attended this meeting on behalf of the Board. She reported there is still no consensus among the Boards about how to handle 503B/3PL entities, NABP has a strong push for their unified inspection form, diversion is on the rise nationwide, and ways were discussed on how inspectors and pharmacies can remain safe.

JENNIFER LUEBBERT AND AMBER CUNDIFF ENTERED THE MEETING ROOM.

#D2 Annual Report

Kimberly Grinston reported the FY15 Annual Report is ready for approval. Ms. Grinston reported the cost of the new licensure system on page 7 should be \$73,900 instead of \$73,200, which also increased the total expenditures for the fiscal year. Ms. Grinston reported a change to the disciplinary actions section is provided in the Board member handout folders. Barbara Bilek suggested discussions be held regarding why only 28% of inspections had no violations; Tom Glenski reported FY14 was also 28%. Kimberly Grinston reported the new licensing system and the new inspection checklist process will allow us to track data where major violations are occurring. Barbara Bilek expressed an interest in knowing what violations were cited. Kimberly Grinston indicated additional information could be provided. Christian Tadrus inquired why technician registrations leveled out over recent years. Ms. Grinston reported staff changes could be the reason for the drop in newly registered technicians. **A motion was made by Pamela Marshall, seconded by Doug Lang, to approve the FY15 Annual Report with the changes noted. 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

#D3 Invitation to Sign Revised FDA Information Sharing Agreement

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

During the October 2015 meeting, the Board voted to table to January after the FDA meeting in Washington DC

Kimberly Grinston reported this matter was not discussed at the FDA meeting in November, and that legal issues were discussed with legal counsel in closed session. The Board's original concern was that information could not be shared with Board members, but that issue has been addressed. **A motion was made by Barbara Bilek, seconded by Anita Parran, to sign the FDA Information Sharing Agreement. 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

#D5 Pharmacy Activities During a Short Term Absence of a Pharmacist

Kimberly Grinston reported the Board recently received an inquiry about a nursing mother, who is also a pharmacist, asking if they can leave the pharmacy for a short period of time to pump. Other reasons for similar absences were discussed in closed session with legal counsel. Barbara Bilek suggested this be added as a discussion topic for the strategic planning meeting. Members of the public provided additional reasons for absence from the pharmacy are administering immunizations, patient counseling, and Sam Leveritt commented pharmacy policies should be in place to allow for such absences. President Lindsay requested office staff to gather other states' regulations and provide it during the strategic planning meeting for further discussion.

#D6 Pharmacy Technician Working Group

- Technician Working Group Roster

DISCUSSION:

The Board voted to reconvene the Pharmacy Technician Working Group at the October meeting and asked to review the previous membership roster. This item was postponed from the December meeting.

Kimberly Grinston reported Tim Koch of Wal-Mart wants to continue to serve on the Working Group, but the other individuals have not yet been verified. It was Board consensus that continuity in the membership will be beneficial. Discussion was held and the following participants were suggested: Everett McAllister of the Pharmacy Technician Certification Board, three independents should be maintained, Doug Lang commented either he or a different mail order representative should participate, school representatives previously provided valuable input, an ACPE representative, and practicing technicians from each practice type--independent, chain, hospital, mail order nuclear, long term care. Board members should submit names of individuals interested in serving by February 1st. It was Board consensus that all members of the Working Group be voting members. The Group's time commitment was discussed. Bert McClary suggested expanded scope of practice be included in the Group's discussion topics, PTCB's 2020 initiative could be used as a guide for discussions, plus pharmacist/technician ratio, and a definition of "technician" should be discussed. Christian Tadrus suggested a pros/cons list for expanded scope of

practice be created. It was also suggested the scope of the Group's goals and a revised list of participants be provided to the Board at the February conference call.

#D7 Non-Resident Sterile Compounding Survey

- Survey Draft

Kimberly Grinston reported about sending the Non-Resident Sterile Compounding survey again to get the most recent data. It was Board consensus to allow for online survey submissions this time. Changes to the survey questions should be submitted to Kimberly Grinston. Ms. Grinston reported she anticipates releasing the new survey in early 2016, and the revised questions will be provided to the Board during the February conference call.

Wednesday January 13, 2016

10:30 AM Annual Meeting with the Schools

#C2 STLCOP and UMKC College of Pharmacy

- UMKC Site Listing
- UMKC Preceptor Listing
- Email from Grice

#C2A STLCOP and UMKC College of Pharmacy

- STLCOP Site Listing
- STLCOP Preceptor Listing

- UMKC - Dean Russell Melcher, Valerie Reuther and Angela Brownfield were present for UMKC. Dean Melcher presented to the Board regarding UMKC's recent accreditation process, which included the Kansas City, Springfield and Columbia locations. Numerous positive comments were made and the facilities were non-compliant in none of the 30 standards. Dean Melcher reported recruitment for five faculty vacancies will be pursued, and salaries increased. Barbara Bilek asked about the number of unsubstantiated complaints, and also suggested the physical assessment curriculum be improved. President Lindsay asked about the standards for working with the Board of Pharmacy. Barbara Bilek commented UMKC students are better prepared for the APPE programs, and thanked Valerie Reuther for her work. Kimberly Grinston asked if the PCOA has been implemented at UMKC. Dean Melcher replied the Pre-NAPLEX has been required, but will be replaced with the PCOA in April 2016. Doug Lang inquired about the faculty positions and recruitment issues; Dean Melcher reported they received 12 applications for 2 positions on the Springfield campus. Doug Lang asked how cultural competency is being addressed; Valerie Reuther reported concerning development of inter-professional activities for students. Ms. Reuther also reported that a new urinalysis policy has been implemented for P2 and P3 students.

- STLCOP - Gloria Grice, Nicole Gattas, Allison Stevens and Brenda Gleason were present for STLCOP. Nicole Gattas presented to the Board regarding the school's construction project, curriculum and international programs. Two of the three construction projects have been completed as of August 2015; anticipated completion of

phase three is early 2017 and will consist of a recreation/student center, dorms and a cafeteria. STLCOP changed from a 6- to a 7-year program, with the first students entering in 2014; 150 students are expected for the P1 program this fall. Inter-professional education will be addressed and expanded, and dual degrees are now offered to students. Several international initiatives have been implemented--three faculty members from the Nelson Mandela University in South Africa visited STLCOP's campus, an MOU has been signed with the Trinity School in Dublin, Ireland, and a MOU has been signed with Saudi Arabia to allow 7-10 Saudi students to enroll at STLCOP. Kimberly Grinston asked if STLCOP has implemented the PCOA. It was reported that P2 students will take the PCOA in April this year. The exam is not designated as a high stakes exam, but students will receive an individual report of their performance on the PCOA. Barbara Bilek thanked Ms. Gattas for holding the meeting between DEA and students. Christian Tadrus inquired about what standards are being taught regarding sterile compounding, and Tom Glenski asked if the school has an ante room in their sterile compounding location. It was reported USP 797 is used as a training guide, and they do have an ante room, but do not have an isolator in the building. Christian Tadrus asked about a posting on the STLCOP website regarding collaborative agreements. Ms. Gattas reported only a few faculty are doing MTS, but mostly because recordkeeping requirements are cumbersome. Students are exposed to MTS and programs are initiated annually on how to develop protocols/collaborative practice agreements. Upon graduation, students are prepared to perform MTS. Gloria Grice reported the new curriculum has resulted in changes for the APPE/IPPE office. Ms. Grice introduced Allison Stevens who has been hired to oversee hospital/health system rotations, Nicole Gaddis will take over community/ambulatory care, and a third person will handle specialty/electives. Ms. Grice reported STLCOP will no longer sign student affidavits for intern licenses during pre-pharmacy college years, but will only sign for students in the P3 academic year.

#C1 Applications for Intern Training Special Site/Non-Pharmacist Preceptor

- Jordan Valley Community Health
- Lafayette Regional Health Center
- MedSocket
- National Institutes of Health (NIH)
- Novo Nordisk
- St. Louis VA Health Care System – North County Community Based Outpatient Clinic (CBOC)
- St. Louis VA Health Care System – St. Charles Community Based Outpatient Clinic (CBOC)
- Trinity College Dublin, The School of Pharmacy and Pharmaceutical Sciences

Tom Glenski reported. **A motion was made by Pamela Marshall, seconded by Barbara Bilek, to approve all special sites/non-pharmacist preceptors for 500 hours each. 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

Tom Glenski reported STLCOP asked that Christian Tadrus be removed from their preceptor list. **A motion was made by Christian Tadrus, seconded by Doug Lang, to approve the revised UMKC and STLCOP site/preceptor lists. 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

BARBARA WOOD, ELAINA WOLZAK AND AMBER CUNDIFF LEFT THE MEETING AT 11:43AM.

#D8 Outsourcing Information

- Catizone Memo
- Outsourcing Survey Memo (sent via e-mail)

Kimberly Grinston reported this information is here for information purposes only.

#D9 2016 Legislation

- HB 1892 (PDMP)
- HB 1922 (Drug Abuse Registry)
- HB 1366 (Biosimilars)
- HB 1839 (Cultural Competency Training)
- SB 768 (PDMP)
- HB 1679 (RPh Contraceptive Prescribing)
- HB 1568 (Naloxone Dispensing)

Kimberly Grinston reported a few specific legislative proposals are included for Board information, and that additional bills are being reviewed and monitored. Doug Lang asked what the goal of the drug abuse registry is; Ms. Grinston commented it's a smaller/targeted version of the prescription drug monitoring program bill. Ron Fitzwater reported the bill does not have a lot of support at this time.

- HB 1568 (Naloxone Dispensing) - Kimberly Grinston asked for a Board position on this bill, and reported she has requested independent rulemaking authority for this legislation. It was Board consensus to not take a formal position on this legislative proposal.

- HB 1679 (RPh Contraceptive Prescribing) - Kimberly Grinston asked for a Board position on this bill. It was Board consensus to remain neutral with regard to this legislation. Ron Fitzwater reported the osteopaths are supporting this bill. Barbara Bilek inquired about pharmacists providing contraceptives.

- HB 1366 (Biosimilars) - Kimberly Grinston changes have been requested to this proposal, and asked that any other revisions be submitted to her. Doug Lang commented the Orange Book is now the Purple Book and should be changed in the language. Doug Lang also questioned if the 2-line format needs to be eliminated.

#D10 2019 Rule Review

- Memo from Grinston

Kimberly Grinston reported all state agencies are required to review all of their regulations and file a report of their impact on small business. The Board's rules have been categorized in an effort to facilitate the Board's review process. Amendments are not required to each of the rules, but a report must be filed with the Joint Commission on Administrative Rules and is open for public comment. Ms. Grinston asked the Board if they want a sub-committee to participate in the rule review; Pam Marshall suggested the categories are a good start for portions to be reviewed at each Board meeting. Christian Tadrus suggested a survey be used to get public input, which would not require a specific response to each comment. It was suggested the surveys be provided on the Board's website, with e-alert notifications to make individuals aware of the surveys, and the Missouri Pharmacy Association will be asked to publish to their members. Christian Tadrus asked if a license is required to complete the survey; Ms. Grinston replied that it could be optional. It was also suggested that practice settings be surveyed. It was suggested to launch each review at in-person Board meetings with follow up during conference call meetings. It was Board consensus to begin the rule review process at the April meeting.

MOTION TO CLOSE 12:11 P.M.

At 12:11 p.m., Barbara Bilek made a motion, seconded by Doug 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 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**

MEMBERS OF THE PUBLIC LEFT THE MEETING ROOM.

RETURN TO OPEN

By motion duly made, seconded, passed and recorded in closed session minutes, the Board returned to open session at approximately 1:29 p.m.

THE COURT REPORTER AND MEMBERS OF THE PUBLIC ENTERED THE MEETING ROOM. ATTORNEY DONNA WHITE WAS ALSO PRESENT.

VICE-PRESIDENT CHRISTIAN TADRUS ASSUMED CHAIR OF THE MEETING.

#B1 Joseph Floyd, #2001018151, #2012-002486

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

The Board convened a disciplinary hearing at 1:40 p.m. Joshua Hill was present as counsel for the Board. Joseph Floyd was not present and was not represented by counsel. Vice-President Christian Tadrus convened the hearing; Board introductions were made. Mr. Hill provided an opening statement. Exhibits and a witness were presented. Mr. Hill provided a closing statement. The hearing adjourned at 1:51 p.m. A transcript of the hearing is available in the Board's records.

PRESIDENT LINDSAY RESUMED CHAIR OF THE MEETING AT 1:52PM

#B2 Amanda Radtke, #2009011857, #2012-005409

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

The Board convened a disciplinary hearing at 1:54 p.m. Joshua Hill was present as counsel for the Board. Amanda Radtke was not present and was not represented by counsel. President Christina Lindsay convened the hearing; Board introductions were made. Mr. Hill provided an opening statement. Mr. Hill requested sub-sections (2) and (17), RSMo, be withdrawn from consideration as reasons for discipline. Doug Lang asked why (2) was being withdrawn; Mr. Hill responded there is no evidence to support conviction in the Complaint. He requested the Board only consider (5), (13) and (15) as reasons for discipline. Exhibits and a witness were presented. Mr. Hill provided a closing statement. The hearing adjourned at 2:03 p.m. A transcript of the hearing is available in the Board's records.

#D4 REMOVED FROM AGENDA

#D11 Hospital Advisory Committee Update (Bert McClary)

Bert McClary presented to the Board about the work and future plans of the Hospital Advisory Committee that he chairs. The Committee has met three times in Jefferson City and two times by conference call.

#D13 Review of Draft DHSS Hospital Pharmacy Rules (19 CSR 30-20.100)

- Proposed Amendment

Bert McClary reported and welcomed any questions regarding the rule draft. Kimberly Grinston reported the Hospital Advisory Committee reviewed the draft on Monday, January 11th, and the Committee's revised draft is in Board member handout folders. The role of the Committee is to review and report to the Board and then the Board will decide what recommendations to send to the Department of Health and Senior Services for consideration in their rulemaking process. Discussion was held. Doug Lang questioned if page 2, section (3) should indicate that technicians need to be registered with the Board. Bert McClary commented the definitions section defines "technician," so it does not need to be added here. Doug Lang commented section (13) on page 4 should be added "and if required notification to regulatory authorities within the required timeframe". Mr. McClary commented this is addressed in a different section. Doug Lang asked if (16) on page 5 will

address hazardous waste; this subsection does not specifically address Chapter 800. Doug Lang further questioned if (18) on page 5 should include language for medication reconciliation. Discussion was held about reconciliations.

BARBARA WOOD RETURNED TO THE MEETING AT 2:34PM

Doug Lang asked if there's a definition of "non-pharmacist" in (A)1. Barbara Bilek commented the word "record" should be added on page 6, line 238, after the word medication. Doug Lang asked how medication can be delivered to a pharmacy where there is no record for it in (F)1. and 2. on page 7. Bert McClary reported this regulation is for inpatient services not medication from a community pharmacy delivered to the nurses' station. The goal is for the prescription to come to the pharmacy first for validation before it is dispensed to the patient in the hospital. James Gray commented this is a way to prevent the hospital from dispensing another pharmacy's error. The intent of (G) was also discussed. Christian Tadrus inquired if authorization is needed for discharge medications from an outside source; Mr. McClary will research the question but believes the medication is part of the patient's personal property.

Doug Lang suggested for line 313 that drugs with a beyond use date must be quarantined, documented and disposed of; discussion was held, and it is noted again in (D), page 13, line 584. Doug Lang inquired if (25) on page 8, line 328, should list a specific regulation. Bert McClary clarified that the reference is correct and was intended to mean the whole chapter of 20 CSR 2220.

Bert McClary reported a prior Committee member didn't want to give the Board authority to inspect in hospitals, thus the Committee was swayed, but the Department of Health and Senior Services is happy to have the Board's input on its regulation and help in enforcing. Mr. McClary further reported DHSS has not yet been able to find a pharmacist to take a half-time position at a state employee's salary, and also requested Katie DeBold's experience be utilized for DHSS sterile compounding inspections. Kimberly Grinston reported Katie DeBold and Tom Glenski will be involved in training DHSS surveyors/staff.

The Board's discussion and suggested changes will be incorporated into the draft and provided to the Board during the February conference call for final review.

#D12 20CSR 2220-2.100-Collection of Non-Controlled Medication for Destruction

- Draft Rule

Kimberly Grinston reported this rule draft is not ready for finalization, but she is asking for Board direction. Barbara Bilek commented this is a good service if the pharmacy wants to take on the expense. Doug Lang asked how long records should be kept. It was Board consensus to keep records for two (2) years. Andi Miller reported it was discussed at the NABP Compliance Officers' Training about how pharmacy owners are entering pharmacies after hours and diverting from this type of drop box. Sam Leveritt asked if (3)(B), about the program being voluntary, should be moved to (1). Page 3, lines 98-100,

should be changed to 50 United States and territories. Doug Lang commented that if the pharmacy is selling a box for the patient to use, no records need to be kept in the pharmacy--see Page 5(D). Tom Glenski commented this section was written for mail back boxes that go back to the pharmacy rather than back to a waste disposal company. Kimberly Grinston asked if a record should be kept at lines 184-187. It was Board consensus that mail backs to the pharmacy should require records to be kept. The rule will be revised and provided back to the Board during the February conference call.

#D14 Road Runner Pharmacy

- Guidance for Industry Compounding Animal Drugs from Bulk Drug Substances – Draft Guidance
- Interim Policy on Compounding Using Bulk Drug Substances Under Section 503B of the Federal Food, Drug, and Cosmetic Act – Draft Guidance
- Veterinary Adverse Drug Reaction, Lack of Effectiveness, or Product Defect Report
- *Eaton Letter*
- *AVMA Response*
- *Congressman Kurt Schrader and Congressman Matt Salmon Letter*

At the November meeting the Board voted to table until the December meeting, after the FDA meeting. At the December meeting the Board voted to table until the January meeting. How would the Board like to proceed?

Kimberly Grinston reported this agenda item is here because letters were addressed to all Board members, and is for information purposes only. No specific action is required.

#D15 Sterile Compounding Rule Update

At the October 2015 meeting, the Board voted 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.

Christian Tadrus reported the Sterile Compounding Rule Review Committee met yesterday, outside resources were invited to meet with the Committee, a CETA representative talked to the Committee about costs. USP Chapter 800 is expected in February and will be reviewed by the Committee. The Board's current rule proposal is tracking along USP 797.

#D16 FDA 50-State Intergovernmental Meeting

- Meeting Agenda

Kimberly Grinston reported she and Doug Lang attended the FDA 50-State Intergovernmental meeting in November in Washington. Doug Lang reported FDA had one of their scientists do a presentation on sterility, and commented FDA was going to send an electronic copy but has not yet been received. Mr. Lang reported FDA nearly begged for participation and input from the states, which gave the states an opportunity to ask FDA if they had considered particular issues. Kimberly Grinston commented FDA was

listening to the states. It was determined the current Memorandum of Understanding will not work, another draft will be distributed to the states. It was reported the cGMP presentation was probably the strongest at the meeting. There is no consistency among the states concerning how to handle 503B facilities.

#D17A Patient Safety Working Group Recommendations

- Final Summary

Kimberly Grinston and Pam Marshall reported that the Group's focus was on technician training and pharmacist/technician ratios. Ms. Marshall suggested the Group's report be included in strategic planning in order to do a specific review of the sections.

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 Animal Drug Compounding

- Letter from Mathews

#E4 ASHP and ACPE Update Pharmacy Technician Accreditation Standards

- Email from ASHP

#E5 CriticalPoint, LLC's Proposed Development of a Comprehensive Pharmacy Sterile Compounding Certification Program

- Memo from Catizone
- CriticalPoint's Proposed Roadmap for the Development of a Comprehensive Pharmacy Sterile Compounding Certification Program

#E6 Revised Hospital Guidance for Pharmaceutical Services and Expanded Guidance Related to Compounding of Medications

- CMS Memo

#E7 Approval of Sterile Compounding Group Minutes

- August 26, 2015 Sterile Compounding Minutes
- September 23, 2015 Sterile Compounding Minutes

Note: These only need to be approved by Christian Tadrus and Doug Lang.

#E8A Hospital Advisory Group Minutes

- September 25, 2015

MOTION TO CLOSE 4:08 P.M.

At 4:08 p.m., Barbara Bilek 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:

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

MEMBERS OF THE PUBLIC LEFT THE MEETING ROOM AT 4:08PM

THURSDAY, JANUARY 14, 2016

RETURN TO OPEN

By motion duly made, seconded, passed and recorded in closed session minutes, the Board returned to open session at approximately 6:57 p.m. on January 14, 2016.

MOTION TO ADJOURN 6:58 P.M.

At approximately 6:58 p.m., a motion was made by Doug Lang, seconded by Barbara Bilek, to adjourn the January 13-14, 2016 meeting. 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

KIMBERLY A. GRINSTON
EXECUTIVE DIRECTOR

DATE APPROVED: 3/23/16