The Missouri Board of Pharmacy met in open session during the times and dates stated in the following minutes. The regular meeting was called to order by President Christina Lindsay at approximately 8:07 a.m. on July 12, 2017. Each item in the minutes is listed in the order discussed.

**Board Members Present**
Christina Lindsay, PharmD, President
Christian Tadrus, PharmD, Vice-President
Barbara Bilek, PharmD., Member
Douglas R. 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
Shelda Sternberg, Compliance Coordinator
Bennie Dean, R.Ph., Inspector
Katie DeBold, PharmD., Inspector
Joe Dino, R.Ph., Inspector
Jennifer Luebbert, Administrative Coordinator
Andi Miller, PharmD, Inspector
Lisa Thompson, R.Ph., Inspector
Dan Vandersand, R.Ph., Inspector
Elaina Wolzak, R.Ph., Inspector
Barbara Wood, R.Ph., Inspector

**Others Present**
Curtis Thompson, Legal Counsel

PRESIDENT CHRISTINA LINDSAY CALLED THE MEETING TO ORDER AT 8:07 A.M. AND ROLL CALL WAS TAKEN.

**MOTION TO CLOSE 8:07 A.M.**
At 8:07 a.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), (17) and (20), RSMo, and under Section 324.001.8, and .9, RSMo. Motion passed 5:0:0:0 by roll call vote as follows:

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

PUBLIC ATTENDEES LEFT THE MEETING ROOM AT APPROXIMATELY 8:07 A.M.

RETURN TO OPEN
By motion duly made, seconded, passed and recorded in closed session minutes, the Board returned to open session on July 12, 2017, at approximately 8:49 A.M.

#A4. PUBLIC HEARING ON BOARD RULES PURSUANT TO EXECUTIVE ORDER 17-03

DISCUSSION: President Lindsay opened the hearing pursuant to Executive Order 17-03 and asked for public comments. The following public comments were received:

• Tomson George with Walgreens Co. asked the Board to revise 20 CSR 2220-2.080, 2.083 and 2.085 to accommodate electronic records in order to provide more efficient delivery of patient care.
• Joel Kurzman with the National Association of Chain Drug Stores (NACDS) asked the Board to amend 20 CSR 2220-6.040 to remove the additional continuing education requirements for pharmacists administering medication. Mr. Kurzman indicated pharmacists are already required to complete continuing education as part of their pharmacist license renewal requirements and noted administration techniques are not likely to significantly change over time.

#A5. 2018 Proposed Legislation

• Pharmacy Technician Standards/Registration- The Board asked to amend the draft to define a registered technician as someone who supports or assists with the practice of pharmacy as defined by § 338.010. Bert McClary suggested modifying the advanced technician language to clarify the listed advanced technician duties are discretionary and not mandatory. Board consensus to revise the draft as discussed for approval at the next Board meeting.
• Licensing of Third Party Logistics Providers/Drug Outsourcers- Board consensus to proceed as drafted; Board members noted this proposal has been submitted for approval multiple times.
• Pharmacist Continuing Education- Board consensus to proceed as drafted.
• Charitable Pharmacy- Board members inquired about possible legal implications of the current language and asked if the legislative goal could be accomplished by rule. Board consensus to discuss further after consultation with general counsel.
• Civil Penalties- Board consensus to proceed as drafted.

#A6. 2020 Rule Review

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1 A full transcript of this agenda item is available at the Board office.

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• 20 CSR 2220-2.400 (Compounding Standards of Practice): No public comments received; Douglas Lang and Christian Tadrus questioned if the Board should delay amending the rule in light of potential federal changes. Board consensus to hold for one (1) year and monitor federal changes.

• 20 CSR 2220-2.500 (Nuclear Pharmacy- Minimum Standards for Operation): Public attendee Samuel Leveritt expressed strong support for revising the rule; Christina Lindsay proposed establishing a nuclear sub-committee to review potential changes. Board consensus to establish a nuclear sub-committee as recommended; Public attendees Samuel Leveritt, Richard Vansant and Brent McHugh volunteered to participate. Douglas Lang volunteered to serve as the coordinating Board member. Mr. Lang recommended the sub-committee limit its review given USP’s anticipated nuclear pharmacy chapter.

• 20 CSR 2220-2.600 (Standards of Operation for a Class F: Renal Dialysis Pharmacy): No public comments received; Christian Tadrus asked if inspectors have observed compliance issues in this area. Tom Glenski indicated no significant compliance trends have been observed for in-state pharmacies. Board consensus not to revise at this time but to reconsider if compliance issues arise.

• 20 CSR 2220-2.675 (Standards of Operation/Licensure for Class-L Veterinary Pharmacies): No public comments received; Tom Glenski noted the rule was recently promulgated and reported no significant compliance issues have been reported/discovered. Board consensus not to revise at this time.

• 20 CSR 2220-6.100 (Pharmacy Standards for Dispensing Blood-Clotting Products): Douglas Lang noted the rule is based on national standards that haven’t changed; Tom Glenski indicated no significant compliance issues have been reported/discovered. Christian Tadrus asked if the rule could be narrowed; Kimberly Grinston reported the rule incorporates national standards required by statute. Board consensus not to revise the rule at this time.

#A7. Draft Rules Under Review: The Board reviewed the following rules:

- 20 CSR 2220-2.010 Pharmacy Standards of Operation:
- 20 CSR 2220-2.012 Pharmacy Supervision
- 20 CSR 2220-2.090 Pharmacist-In-Charge

Suggested rule changes have been incorporated into Attachment A. A transcript of the full Board discussion is available at the Board’s offices. Board consensus to review the proposed changes at a future meeting prior to final approval.

#A9. Board Member Reports: The following reports were given:

- Douglas Lang reported he attended the pharmacy practice advancement meeting organized by Bert McClary and other MSHP representatives. Mr. Lang noted the group discussed potential legislation to expand pharmacy practice and legislation that would address pharmacist insurance reimbursement. Mr. Lang noted the meeting was productive and that organizers intended to consult other pharmacy stakeholders to
minimize legislative opposition. Mr. Lang reported he also attended the APhA Substance Abuse Institute in Salt Lake City, Utah, which provided valuable information on addiction and addiction treatment. Mr. Lang recommended other Board members attend, if possible.

- Pamela Marshall reported she attended the NABP meeting in Orlando which included several informative discussions on topics such as expanded technician roles, USP 800 and naloxone dispensing/administration. Ms. Marshall also reported attending the Missouri Health Advocacy Alliance meeting in June in her personal capacity and not as a Board member where she presented on PDMPs and the potential impact on Missouri pharmacists; Rep. Fredrick was in attendance. Presentations were also given on tort reform and healthcare access.

#A10. General Administration Report: Kimberly Grinston reported Joe Dino will be retiring at the end of July and thanked him for his commendable service to the Board; Mrs. Grinston also recognized Laura Henke for five (5) years of employment with the Board. Board members joined Mrs. Grinston in extending their congratulations and gratitude to Mr. Dino and Mr. Henke; President Lindsay presented recognition gifts on behalf of the Board.

#A7. Draft Rules Under Review (Cont’d): Additional Board discussion was held on the following rules:

- 20 CSR 2220-2.025 Non-Resident Pharmacies: A motion was made by Pamela Marshall, seconded by Douglas Lang, to approve the rule for official filing. Motion passed 5:0:0:0 by roll call vote as follows:
  
<table>
<thead>
<tr>
<th>Name</th>
<th>Vote</th>
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<tbody>
<tr>
<td>Barbara Bilek</td>
<td>yes</td>
</tr>
<tr>
<td>Douglas Lang</td>
<td>yes</td>
</tr>
<tr>
<td>Pamela Marshall</td>
<td>yes</td>
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</tbody>
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- 20 CSR 2220-2.950 Automated Filling Systems: No public comments; Board consensus to table pending additional review of an appropriate sample size.

- 20 CSR 2220-6.040 Administration by Medical Prescription Order: Board consensus to remove the continuing education requirement and to return the final draft for approval at a future Board meeting.

- 20 CSR 2220-6.050 Administration of Vaccines Per Protocol: Joel Kurzman (NACDS) indicated NACDS is recommending that pharmacists comply with ACIP guidelines when immunizing with minor modifications based on CDC recommendations; Mr. Kurzman further recommended lowering the minimum vaccination age to seven (7). Tom Glenski and Barbara Bilek indicated ACIP is part of the CDC which is referenced in the current rule draft. Board consensus to retain the continuing education requirement and to return the final rule amendment for approval at a future Board meeting.

#A15. Remote Technician Supervision/Remote Medication Verification: The following public comments were received:
• Adam Chessler with TelePharm spoke in favor of allowing remote technician supervision/verification and offered to assist with gathering language from other states.
• Greg Teale with St. Luke’s Hospital commented remote supervision/verification technology is currently used in hospital settings and noted the allowance would advance patient care if also allowed in care settings under the Board’s jurisdiction. Mr. Teale offered to demonstrate St. Luke’s system for the Board at a later date.
• Greg Guenther commented pharmacy practice is changing resulting in a greater demand for direct pharmacist patient care activities. Mr. Guenther suggested remote supervision/verification would allow an expanded patient care role and potentially decrease pharmacy operational costs. Mr. Guenther noted pharmacy operational costs are particularly significant given the continued decline in pharmacy reimbursement. Mr. Guenther suggested remote supervision/verification would also allow lower volume pharmacies to assist higher volume pharmacies which would increase patient services.
• Bert McClary supported the concept of remote supervision/verification and noted the allowance may help health systems expand services in rural areas. However, Mr. McClary cautioned the definition of remote supervision/verification should be carefully tailored to avoid unintended consequences.

Board discussion held; Christian Tadrus and Tom Glenski suggested the Board address remote supervision separately from remote verification and tech-check-tech. Barbara Bilek suggested the Board address the greatest need and the highest risk areas first. Public member Greg Teale commented there may be limited dispensing oversight in physician clinic areas and asked the Board consider remote supervision/verification as soon as possible to allow pharmacists to assist in non-pharmacy care settings in lieu of allied professionals who may not be as appropriately trained or qualified as a pharmacist. Further Board discussion held; Board consensus to have staff identify all rules that may be impacted or need to be amended if remote verification or remote supervision is allowed.

#A11. Inspection/Investigation Report: Tom Glenski reported on current inspection/investigation activities and provided the following updates:
• A new inspector will be starting August 4th in the territory left vacant after Joe Dino’s retirement.
• Sterile Compounding: Katie DeBold has created a revised sterile compounding guide and a sterile compounding handout for conducting remedial investigations. Inspectors visited a local pharmacy on July 11, 2017, where Mrs. DeBold provided hands-on training on inspecting/using isolators. Inspectors will be doing another sterile compounding training program at St. Louis College of Pharmacy at the end of July that will also be led by Mrs. DeBold. A sterile compounding webinar will be held on October 4th to provide compliance updates since the revised sterile compounding rule became effective a year ago.
• A full electronic inspection program has been initiated. Inspection reports will be e-mailed and will no longer be provided on CD.
#A12. Hospital Advisory Committee Update: Bert McClary reported the Committee met on May 5th and will be meeting again on July 17th. Mr. McClary provided the following updates:

- The Committee reviewed the proposed Class-J rule and Class-B guidance document and made preliminary suggestions for the Class-N Automated Dispensing Rule and an automated distribution rule. Mrs. Grinston noted staff is holding the Class-B guidance document in light of new legislation that is under review by the Missouri Dept. of Health and Senior Services.
- The Committee reviewed the Board’s medication therapy services rule and recommended the Board not revise the rule at this time given other legislative developments that may impact the rule.
- The Committee discussed the Board’s sterile compounding rule and did not have any formal comments at this time.
- Neil Schmidt resigned as the MSHP representative to focus on other family and professional goals; A new representative may be named shortly.
- Mr. McClary reported he has voluntarily resigned as chairman of the Committee and that a new chair will be selected. Mr. McClary will remain an active member of the Committee but noted rotating chairmanship will allow for a diversity of leadership and opinion.

#A13. Sterile Compounding Committee Update: Christian Tadrus reported the Committee met on June 23, 2017. Katie DeBold provided an update on reporting rates for positive environmental tests; The Committee discussed ways to address pharmacies suspending compounding in the event of a positive test. Discussion was also held on the impact of the beyond-use-date/in-use time rule requirements on nuclear pharmacy. Committee members expressed strong concerns about extended BUDs/in-use times particularly for multi-dose units that have stability beyond a 6-hour time frame. The Committee will continue discussions on if or how nuclear pharmacy should be accommodated.

#A14. Fiscal Year 2018-2019 Strategic Plan: Mrs. Grinston reported the Board previously asked staff to provide a template for a strategic plan to implement the recommendations from the Board’s 2016 strategic planning meeting. Board members suggested the following:

- Douglas Lang and Christina Lindsay asked if the Governor’s rule review goals could be used as a benchmark in Goal # 1.
- Christian Tadrus ask if the goal related to updating technician rules/statutes should be removed. Christina Lindsay suggested a performance measure could be to meet with relevant stakeholders regarding technician issues.
- Christian Tadrus and Anita Parran suggested a benchmark for goal # 2 could be producing information that could be published by the Missouri Pharmacy Association and other entities. Christina Lindsay recommended the Board focus on technology.
needs and suggested this may be an opportunity to ask for additional resources from the Governor’s office.

#A16. STLCOP and UMKC College of Pharmacy Site/Preceptor Lists: Tom Glenski recommended approval of both lists. A motion was made by Barbara Bilek, seconded by Douglas Lang, to approve the site/preceptor lists as presented. Motion passed 5:0:0:0 by roll call vote as follows:

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

Kimberly Grinston asked if the office could approve pharmacies and pharmacist preceptors if no discipline is listed. Board consensus to allow staff to approve pharmacies and pharmacist preceptors presented by STLCOP and UMKC if no discipline is identified; Disciplinary cases and special sites/non-pharmacist preceptors should still be approved by the Board.

#A17. Applications for Intern Training Special Site/Non-Pharmacist Preceptor: Tom Glenski noted a curriculum vitae for Pharmacie De La Tour has been included in the Board’s handouts. Mr. Glenski recommended approving all special sites/non-pharmacist preceptors listed but recommended the Board advise the Faith Community Health site that interns cannot be involved in the dispensing process since the site is not a pharmacy. Douglas Lang asked if the FDA site was previously approved; Mr. Glenski reported the site has been approved through 2019 but is adding a new non-pharmacist preceptor. A motion was made by Barbara Bilek, seconded by Christian Tadrus, to approve the special sites/non-pharmacist preceptors listed with a caution to Faith Community Health that interns cannot be involved in the dispensing process. Motion passed 5:0:0:0 by roll call vote as follows:

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

Douglas Lang indicated he would like to talk with the pharmacy schools about the level of use and the quality of experience at both the domestic and foreign special sites.

#A18. Election of Officers: Christina Lindsay nominated Christian Tadrus for President; Mr. Tadrus accepted the nomination. No other presidential nominations were made. A motion was made by Christina Lindsay, seconded by Pamela Marshall, to elect Christian Tadrus as president. Motion passed 4:0:1:0 by roll call vote as follows:

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

A motion was made by Pamela Marshall, seconded by Barbara Bilek, to elect Douglas Lang as Vice-President. Motion passed 4:0:1:0 by roll call vote as follows:

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

#A19. Legal Contract Approval: Board decision to hold pending further discussion in closed.

**MOTION TO CLOSE 4:00 P.M.**
At 4:00 p.m., Pamela 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, pertaining to and/or resulting from this closed meeting be closed under Section 610.021(1), (3), (5), (7), (13), (14), (17) and (20), RSMo, and under Section 324.001.8, and .9, RSMo. Motion passed 5:0:0:0 by roll call vote as follows:

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

PUBLIC ATTENDEES LEFT THE MEETING ROOM AT APPROXIMATELY 4:01 P.M.

JULY 13, 2017

RETURN TO OPEN

By motion duly made, seconded, passed and recorded in closed session minutes, the Board returned to open session on July 13, 2017, at approximately 10:23 A.M. All Board members/staff in attendance on July 12, 2017, were also in attendance on July 13, 2017.

#A19. Legal Contract Approval: A motion was made by Douglas Lang, seconded by Pamela Marshall, to approve the legal contract for Newman, Comley and Ruth. Motion passed 5:0:0:0 by roll call vote as follows:

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

A motion was made by Douglas Lang, seconded by Pamela Marshall, to approve the legal contract for Curtis Thompson. Motion passed 5:0:0:0 by roll call vote as follows:

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

#A20. Gerald Cipponeri Disciplinary Hearing, #042806, #2014-002902

DISCUSSION: The Board convened a disciplinary hearing at 10:30 a.m. Cotton Walker was present as counsel for the Board. Gerald Cipponeri was not present and was not represented by counsel. Mr. Walker provided an opening statement and presented exhibits. No closing statement was provided. The hearing adjourned at 10:37 a.m. A transcript of the hearing is available in the Board’s records.

MOTION TO CLOSE 10:38 A.M.

At 10:38 a.m., Barbara Bilek made a motion, seconded by Douglas 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), (17) and (20), RSMo, and under Section 324.001.8, and .9, RSMo. Motion passed 5:0:0:0 by roll call vote as follows:

- Barbara Bilek – yes
- Douglas Lang – yes
- Pamela Marshall – yes
- Anita Parran – yes
- Christian Tadrus – yes
RECONVENE OPEN
By motion duly made, seconded, passed and recorded in closed session minutes, the Board returned to open session at approximately 12:57 a.m. on July 13, 2017.

THE FOLLOWING ITEMS WERE PROVIDED TO THE BOARD FOR INFORMATIONAL PURPOSES; NO DISCUSSION WAS HELD.

#A21. Board Disciplinary Report

#A22. Board Licensing Statistics

MOTION TO ADJOURN 12:58 PM
At approximately 12:58 p.m., a motion was made by Barbara Bilek, seconded by Douglas Lang, to adjourn the July 2017 meeting. Motion passed 4:0:0:1 with roll call vote as follows:

Anita Parran – yes       Christian Tadrus – yes

____________________________________
Kimberly A. Grinston
Executive Director

Date Approved: 01/10/2018