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 Christian Tadrus at approximately 8:01 a.m. on October 25, 2017. Each item in the minutes is listed in the order discussed.

**Board Members Present**
- Christian Tadrus, PharmD, President
- Douglas R. Lang, R.Ph., Vice-President
- Christina Lindsay, PharmD, Member
- Pamela Marshall, R.Ph., Member
- Anita Parran, Public Member

**Staff Present**
- Kimberly Grinston, Executive Director
- Tom Glenski, R.Ph., Chief Inspector
- Bennie Dean, R.Ph., Inspector
- Katie DeBold, PharmD, Inspector
- Sarah Decker, Compliance Coordinator
- Jennifer Luebbert, Administrative Coordinator
- Andi Miller, PharmD, Inspector
- Scott Spencer, R.Ph., 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 CHRISTIAN TADRUS CALLED THE MEETING TO ORDER AT 8:01 A.M. AND ROLL CALL WAS TAKEN.

**MOTION TO CLOSE 8:01 A.M.**
At 8:01 a.m., Christina Lindsay made a motion, seconded by Pamela 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),
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(7), (13), (14), (17) and (20), RS Mo, and under Section 324.001.8, and .9, RS Mo. Motion passed 4:0:0:1 by roll call vote as follows:

Anita Parran – yes  Christina Lindsay – yes

PUBLIC ATTENDEES LEFT THE MEETING ROOM AT APPROXIMATELY 8:01 A.M.

RETURN TO OPEN
By motion duly made, seconded, passed and recorded in closed session minutes, the Board returned to open session on October 25, 2017, at approximately 8:43 A.M.

#A3. Agenda Additions/Corrections

No open session additions/corrections identified.

#A4. Executive Order 17-03 Public Rule Hearing

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

- Adam Chessler (Cardinal Health) questioned if the proposed Class-J Shared Services rule would allow pharmacists to remotely verify prescriptions for a pharmacy in another facility. Mr. Glenski indicated the proposed rule revision would not allow the activity described; Kimberly Grinston noted remote verification may be relevant to 20 CSR 2220-2.010 which is in the agenda for discussion later in the meeting.

President Tadrus thanked the public for their participation; A full transcript of the public rule hearing is available in the Board’s office.

#A5. 2020 Rule Review

- 20 CSR 2220-2.013 (Prescription Delivery Requirements)
- 20 CSR 2220-2.110 (PRN Refills)
- 20 CSR 2220-2.120 (Transfer of Prescription Information for the Purpose of Refill)
- 20 CSR 2220-2.130 (Drug Repackaging)
- 20 CSR 2220-2.800 (Vacuum Tube Drug Delivery System)
- 20 CSR 2220-2.950 (Automated Filling Systems)
- 20 CSR 2220-2.190 (Patient Counseling)

DISCUSSION: Except as reflected below for 20 CSR 2220-2.190, no public comments were provided on the included rules. The following action was taken by the Board:

- 20 CSR 2220-2.013 (Prescription Delivery Requirements): Board consensus not to modify at this time.
- 20 CSR 2220-2.110 (PRN Refills): Tom Glenski noted the rule was primarily intended to establish that a prescription is not valid after a year. Christian Tadrus
suggested the rule may need to be revisited given the payor industry is beginning to focus on the quantity remaining instead of the number of fills. Douglas Lang questioned if the rule should address expiration dates for controlled substance prescriptions. Board consensus to open the rule for revision; Kimberly Grinston asked Board members to e-mail suggestions to her attention.

- 20 CSR 2220-2.120 (Transfer of Prescription Information for the Purpose of Refill): Douglas Lang suggested the rule may need to reference DEA guidance on transferring original or electronic prescriptions. Tom Glenski suggested the rule also address mass prescription transfers. Board consensus to open the rule for revision.

- 20 CSR 2220-2.130 (Drug Repackaging): Douglas Lang suggested the Board review recent FDA guidance on this topic. Board consensus to open the rule for revision.

- 20 CSR 2220-2.800 (Vacuum Tube Drug Delivery System): Christian Tadrus asked if the rule accommodates current technology. Tom Glenski inspectors are not currently seeing significant compliance issues under the rule. Board discussion held; Board consensus not to revise at this time.

- 20 CSR 2220-2.950 (Automated Filling Systems): Tom Glenski reported licensees confuse this rule with 20 CSR 2220-2.900. Board discussion held; Board consensus not to revise the rule at this time but to provide further licensee education.

- 20 CSR 2220-2.190 (Patient Counseling): Public attendee Adam Chessler asked the Board to consider allowing remote patient counseling. Board discussion held; Board consensus to open the rule for revision. Staff asked to research patient counseling language from other states.

A full transcript of the 2020 rule review discussion is available in the Board’s offices.

#A6. Draft Rules Under Review

- 20 CSR 2220-2.010 Pharmacy Standards of Operation
- 20 CSR 2220-2.012 Pharmacy Supervision
- 20 CSR 2220-2.085 Electronic Prescriptions and Medication Orders
- 20 CSR 2220-2.090 Pharmacist-In-Charge
- 20 CSR 2220-6.040 Administration by Medical Prescription Order
- 20 CSR 2220-6.050 Administration of Vaccines Per Protocol

DISCUSSION:

- 20 CSR 2220-2.010 (Pharmacy Standards of Operation): Public Attendee Nathan Hanson asked if primary source verification could serve as proof of licensure. Douglas Lang recommended the rule require humidity monitoring and suggested a standard humidity range of 50% - 60%. Barbara Bilek noted federal requirements reference 50% - 60% humidity. Douglas Lang further suggested defining what constitutes “adequate” pharmacy security. Board consensus to research other state humidity requirements.

- 20 CSR 2220-2.012 (Pharmacy Supervision): Public Attendee Tomson George with Walgreens Pharmacy asked the Board to consider allowing remote supervision of
technician activities. Adam Chessler (Cardinal Health) and Nathan Hanson (Truman Medical Center) also spoke in favor of allowing remote supervision/remote technician activities. Mr. Chessler noted 22 states allow some form of remote technician supervision; Mr. Hanson reported the Department of Defense and the Veterans Administration also has strong remote supervision programs. Board discussion held; Board consensus to define supervision in the draft rules. Christian Tadrus proposed establishing a Board sub-committee to assist in formulating language; Board consensus to establish a sub-committee to develop language addressing technician supervision and allowed activities during a pharmacist’s temporary absence. Pamela Marshall and Christina Lindsay volunteered to serve as sub-committee members.

- 20 CSR 2220-2.090 (Pharmacist-In-Charge): Board discussion held; Board consensus to have the rule sub-committee review language for defining the pharmacy permit area. Douglas Lang also suggested the rule clearly provide that policies and procedures must be accessible to pharmacy personnel. Board consensus to revise as suggested and review at a future meeting.

- 20 CSR 2220-2.085 (Electronic Prescriptions and Medication Orders): Douglas Lang suggested the rule state that controlled substance prescriptions must be signed as required by state and federal law. A motion was made by Douglas Lang, seconded by Christina Lindsay, to approve the proposed rule for filing with the Missouri Secretary of State’s Office with the additional requirement that controlled substance prescriptions must be signed as required by state and federal law. Motion passed 4:0:0:1 by roll call vote as follows:

  Anita Parran – yes  Christina Lindsay – yes

- 20 CSR 2220-6.040 (Administration by Medical Prescription Order) and 20 CSR 2220-6.050 (Immunization by Protocol): Board discussion held regarding allowing ShowMeVax reporting; Board members questioned if the Board could legally allow ShowMeVax reporting as a form of notification. Board consensus to hold pending additional discussion with legal counsel.

#A7. Approval of Final Amended Rule 20 CSR 2220-2.650

- Proposed Amendment 20 CSR 2220-2.650

DISCUSSION: No public comments received; A motion was made by Douglas Lang, seconded by Christina Lindsay, to approve the final order of rulemaking for filing with the Missouri Secretary of State’s Office. Motion passed 4:0:0:1 by roll call vote as follows:

  Anita Parran – yes  Christina Lindsay – yes
#A8. **Board Member Reports**

- NABP Task Force on Defining The Pharmacist-Patient Relationship
- Missouri Pharmacy Association Annual Meeting
- FDA Inter-Governmental Working Meeting on Pharmacy Compounding
- NABP District 6, 7 & 8 Meeting
- Bd. of Pharmacy 2017 Patient Safety Conference

**DISCUSSION:** The following Board member reports were provided:

- Christian Tadrus recently attended an NABP task force meeting in Chicago, Illinois, regarding defining the pharmacist-patient relationship. Several state representatives attended; Representatives from Canada and the national medical boards also attended. Task force recommendations should be issued by December 2017.
- Pamela Marshall attended the joint Missouri and Illinois Pharmacist Association meeting in St. Louis. Presentations were informative; Executive Director Grinston provided a Board update.
- Mr. Lang attended the FDA Inter-Governmental Working Meeting with Kimberly Grinston in Maryland. The FDA provided updates on their compounding regulatory goals. Multiple state breakout sessions were held to discuss regulatory issues/suggestions. Mr. Lang reported the meeting was informative overall.
- Mr. Tadrus attended the District 6, 7 and 8 meeting in San Antonio, Texas, along with Douglas Lang and Mrs. Grinston. Informative presentations were given on naloxone, opioid education, prescription drug monitoring programs and FDA compounding issues.
- Pamela Marshall and Anita Parran attended the Board’s 2017 Patient Safety Conference in St. Charles. Presentations were provided on patient literacy, naloxone dispensing and the opioid crisis. Approximately 92 people attended. Mrs. Grinston reported final costs were less than $4,000 which was under budget.
- Mrs. Grinston participated in a “Meeting of the Minds” program hosted by St. Louis College of Pharmacy that focused on prescription drug monitoring programs and related regulatory issues. MPA and other legislative lobbyists also participated.

#A9. **Approval of Minutes**

- May 17, 2017
- June 23, 2017

A motion was made by Douglas Lang, seconded by Pamela Marshall, to approve the open session minutes for May 17, 2017. Motion passed 3:0:1:1 by roll call vote as follows:

Anita Parran – yes        Christina Lindsay – abstain

A motion was made by Pamela Marshall, seconded by Anita Parran, to approve the open session minutes for June 23, 2017. Motion passed 4:0:0:1 by roll call vote as follows:

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Anita Parran – yes  Christina Lindsay – yes

#A10. General Administration Report

- Staff/Office Update
- Financial Report
- 2018 Renewal Fee Decrease
- Governor’s Board and Commissions Task Force
- “Red-Tape” Reduction Initiative
- Bd. of Healing Arts Opioid Safety Conference
- 2018 Proposed Legislation/New Decision Items
- Upcoming Webinars
- Revised Pharmacy Practice Guide
- Pending Rules

DISCUSSION: Kimberly Grinston provided the following updates:

- Scott Spencer will replace Joe Dino as the Mid-Missouri inspector. Board members welcomed Scott to the Board. Mrs. Grinston also introduced Sarah Decker, the newly appointed Compliance Coordinator.
- Pharmacy and drug distributor renewals will end on October 31st; the renewal period has gone well with few complications.
- The Inspector December training meeting will be held on December 19th; board members are welcome to attend.
- The Board’s fund is strong; Revenue continues to increase. Mrs. Grinston asked the Board to consider a technician renewal fee decrease. The Board reviewed budget scenarios provided by the Division’s budget director; Board discussion held. A motion was made by Christina Lindsay, seconded by Pamela Marshall, to decrease the technician renewal fee to twenty dollars ($ 20). Motion passed 4:0:0:1 by roll call vote as follows:

Anita Parran – yes  Christina Lindsay – yes

- The Governor’s office has asked the agencies to submit performance measures for budgeting purposes with both a base and target/stretch goal. Mrs. Grinston has been appointed to a Committee to attempt to identify standard goals that could be used by all PR boards. Mrs. Grinston reported the Board does not have strong data, however, she is attempting to identify performance measures the Board can reasonably accomplish given current resources.

MOTION TO CLOSE 12:12 P.M.

At approximately 12:12 p.m., Pamela Marshall made a motion, seconded by Christina Lindsay, 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) and (14), RSMo, and under Section 324.001.8, and .9, RSMo. Motion passed 4:0:0:1 by roll call vote as follows:
RETURN TO OPEN
By motion duly made, seconded, passed and recorded in closed session minutes, the Board returned to open session on October 25, 2017, at approximately 1:20 P.M.

#A10. General Administration Report (Cont’d)
- Missouri Hospital Association Opioid Conference

DISCUSSION: The following additional information was provided by Mrs. Grinston:
- Kimberly Grinston reported positive feedback was received on the August newsletter mailed to licensees. Board discussion held; Board consensus to also mail the November newsletter.
- Kimberly Grinston reported MHA asked the Board to financially co-sponsor a statewide opioid conference along with the other Division health boards. Mrs. Grinston reported the Board cannot co-sponsor a private entity conference but could assist as a partner. Mrs. Grinston indicated the requested financial assistance is currently unknown given MHA is in the preliminary planning stages. Mrs. Grinston noted MHA proposed an attendance fee of $75 - $100. Board discussion held; Board members expressed concerns with limited pharmacy program content. Board consensus not to sponsor the opioid conference at this time but to allow pharmacist continuing education credits if an application is submitted.
- Ron Fitzwater with the Missouri Pharmacy Association (MPA) asked if the Board would be interested in publishing information in MPA’s newsletter; Board members expressed interest. Board consensus to submit an article for future publication by MPA.
- Mrs. Grinston has communicated with the Missouri Department of Health and Senior Services (DHSS) on ideas for implementing the Rx Cares for Missouri program; DHSS has advised they would be interested in direction from the Board. Board discussion held on implementing the program. Board consensus to review the suggestions submitted to the Governor’s office when the Rx Cares for Missouri language was originally drafted by the Board. Board consensus to discuss at a future meeting.
- Mrs. Grinston reported DHSS has indicated a statutory change would be required to implement the drug take back program approved by SB 501. Additional information will be provided once received.
- Board members were asked if the Board wanted to revise the Pharmacy Practice Guide at this time given several rule amendments have been approved/filed. Board consensus to begin revisions but note in the Practice Guide that rule changes are pending.

#A6. Draft Rules Under Review (Cont’d)
- 20 CSR 2220-6.040 Administration by Medical Prescription Order
- 20 CSR 2220-6.050 Administration of Vaccines Per Protocol

DISCUSSION: After consultation with legal counsel, the following Board discussion was held:
20 CSR 2220-6.040 & 20 CSR 2220-6.050: Board discussion held; A motion was made by Douglas Lang, seconded by Christina Lindsay, to approve the proposed rule for filing with the Missouri Secretary of State’s Office. Motion passed 4:0:0:1 by roll call vote as follows:

Anita Parran – yes  Christina Lindsay – yes

Final approved rule language is included in Attachment A.

#A12. USP Chapter 800 & 797 Updates

- Staff Updates

DISCUSSION: Mrs. Grinston reported USP has delayed implementation of Chapter 800 to coincide with the anticipated USP Chapter 797 revision. Board discussion held; Board consensus to monitor future USP developments.

#A15. St. Louis College of Pharmacy Report- Foreign Intern Training Sites/Special Sites

DISCUSSION: St. Louis College of Pharmacy provided information regarding their selection, evaluation and monitoring of foreign intern training sites. Gloria Grice, STLCOP, indicated all foreign training complies with ACPE guidelines for international sites. Additionally, preceptors are English speaking and students have to provide mandatory reports of internship activities. Board discussion held. A student presentation was provided by Adrian Brown regarding her foreign intern training in South Africa; Mrs. Brown indicated the internship was eye-opening and provided valuable patient care experience.

#A16. STLCOP and UMKC College of Pharmacy

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

DISCUSSION: Tom Glenski recommended approval of both lists. Douglas Lang asked if disciplinary action has been verified for all sites; Tom Glenski reported discipline has been verified by office staff. A motion was made by Christina Lindsay, seconded by Anita Parran, to approve the site/preceptor lists as presented. Motion passed 4:0:0:1 by roll call vote as follows:

Anita Parran – yes  Christian Tadrus – yes

#A17. Special Sites/Non-Pharmacist Preceptors

DISCUSSION: Tom Glenski recommended approval of all sites and preceptors listed. A motion was made by Pamela Marshall, seconded by Christina Lindsay, to approve the
special sites/non-pharmacist preceptors listed for 500 hours. Motion passed 4:0:0:1 by roll call vote as follows:

   Anita Parran – yes  Christian Tadrus – yes

#A19. Kamlesh Trivedi, Disciplinary Hearing, # 040885, #2016-000986

   Wednesday, October 25, 2017
   3:00 P.M. – 2nd case

**DISCUSSION:** The Board convened a disciplinary hearing at 3:04 p.m. Alicia Embley-Turner was present as counsel for the Board. Kamlesh Trivedi was present and represented by counsel David Barrett. Both Mr. Barrett and Mrs. Turner provided opening statements and presented exhibits. Closing statements were provided. The hearing adjourned at approximately 4:20 p.m. A transcript of the hearing is available in the Board’s records.

#A11. Inspection/Investigation Report

**DISCUSSION:** Tom Glenski provided the following updates:

- Inspection/Investigation numbers remained consistent. Board members were provided a report of all continuing education/training programs completed by Board inspectors.
- Katie DeBold and Daniel Vandersand will be attending NABP’s Compliance Officer’s Forum. Andi Miller will be attending the DEA state conference meeting in Dallas.
- Board members inquired about the Board’s participation in NABP’s sterile compounding blueprint program. Kimberly Grinston reported she met with NABP legal counsel Scotti Russell who cross-walked Missouri’s form to the blueprint form. NABP has identified four (4) outstanding Missouri issues: (1) Missouri’s BUD requirements do not comply with USP Chapter 797, (2) Missouri doesn’t require or inspect for the use of sterile gloves, (3) Inspections are not always conducted when compounding is being performed, and (4) Missouri does not require temperature monitoring in all drug storage areas. Mrs. Grinston indicated Missouri’s sterile compounding inspections may not be accepted by other states if Missouri is not part of the blueprint program. Mrs. Grinston reported the temperature issue has been addressed in the revised sterile compounding rule. However, a rule change may be needed to address the other issues identified by NABP. Board discussion held; Board members expressed options may be limited for those issues needing rule changes. Additionally, Board members expressed concerns with noting items on an inspection report that are not required by Missouri law. Board consensus to take no further action at this time but to consider NABP’s identified concerns in future rule discussions.
#A11. Hospital Advisory Committee Update

DISCUSSION: Committee Member Bert McClary provided the following updates:

- The Committee will be working with DHSS to review rules as required by SB 501 which preempted designated DHSS rules that duplicate or conflict with CMS Conditions of Participation.
- The next Committee meeting will take place in November. Kimberly Grinston advised the meeting may need to be rescheduled due to a possible conflict.

#A10. General Administration Report (Cont’d)

DISCUSSION: Additional Board discussion held on future meeting dates. Board members discussed support for exploring options to more efficiently handle Board agendas and decrease the number of Board meetings, including, delegating additional authority to staff. Board consensus to continue to host conference calls on Wednesdays. Further consensus to check location availability for the following 2018 meeting dates:

- January 10-11, 2018 (Columbia)
- February 7, 2018 (Kansas City)
- April 10-12, 2018 (Columbia)
- August 15, 2018 (Springfield)
- October 24 (Columbia)

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

#A21. Board Disciplinary Report

#A23. Board Licensing Statistics

MOTION TO CLOSE 5:35 P.M.
At 5:35 p.m., Christina Lindsay made a motion, seconded by Pamela 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), (6), (7), (13), (14), (17) and (20), RSMo, and under Section 324.001.8, and .9, RSMo. Motion passed 4:0:0:1 by roll call vote as follows:

Anita Parran – yes  Christina Lindsay – yes

PUBLIC ATTENDEES LEFT THE MEETING ROOM AT APPROXIMATELY 5:35 P.M.

OCTOBER 26, 2017

#A22. Board Introductory Meeting/Question & Answer Session With Pharmacy Students: The Q&A session was originally scheduled as an open session item for October 26, 2017. At the Missouri Board of Pharmacy Open Minutes October 25-26, 2017 Page 10 of 11
host school’s request, no formal meeting/session was held. Board members individually greeted students during the Board’s scheduled breakfast.

RETURN TO OPEN
By motion duly made, seconded, passed and recorded in closed session minutes, the Board returned to open session on October 26, 2017, at approximately 11:46 A.M. All Board members/staff in attendance on October 25, 2017, were also in attendance on October 25, 2017.

MOTION TO ADJOURN 11:46 AM
At approximately 11:46 a.m., a motion was made by Douglas Lang, seconded by Anita Parran, to adjourn the October 2017 meeting. Motion passed 3:0:0:2 with roll call vote as follows:

Anita Parran – yes   Christina Lindsay – absent

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KIMBERLY A. GRINSTON
EXECUTIVE DIRECTOR

DATE APPROVED: 2/7/18