OPEN MINUTES
Missouri Board of Pharmacy

June 23, 2017
Missouri Council of School Administrator’s Conference Center
3550 Amazonas Drive
Jefferson City, MO

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 8:30 a.m. on June 23, 2017. Each item in the minutes is listed in the order discussed.

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

**Board Members Absent**
Barbara Bilek, PharmD., Member

**Staff Present**
Kimberly Grinston, Executive Director
Tom Glenski, R.Ph., Chief Inspector
Katie DeBold, Inspector
Jennifer Luebber, Executive Assistant
Shelda Sternberg, Compliance Coordinator

**Others Present**
Curtis Thompson, Legal Counsel

**OPEN SESSION**

#4. General Administration Report

**DISCUSSION:** Kimberly Grinston provided the following updates:

- Several pieces of pharmacy related legislation were enacted during the 2017 legislative session that are pending final Governor signature; Updates will be provided in July.
- The August newsletter will include legislative implementation information and will be mailed to all Missouri pharmacists; a draft will be presented to the Board in July.
- The next Lunch with the Chief Webinar is scheduled for July 16, 2017. Staff proposed hosting a pharmacy technician webinar; Christian Tadrus recommended
alternative scheduling options to prevent pharmacy staffing issues. Kimberly Grinston suggested hosting both a daytime and evening webinar; Additional information will be provided once confirmed.

- The Joint Patient/Opioid Safety program with the Board of Healing Arts will likely be postponed until the spring of 2018 due to limited Healing Arts staff availability.
- The Tri-Regulators Meeting will be held in Chicago in July 2017; Christian Tadrus and Anita Parran will be attending.
- NABP’s District 6, 7 and 8 meetings will be held in Texas; Douglas Lang expressed an interest in attending.
- The Board has received a survey from the Governor’s Boards and Commission Task Force and Mrs. Grinston will be meeting with the Governor’s Office on June 28, 2017. Mrs. Grinston reported she plans to convey the Board’s concerns with a single health regulatory Board; updates will be provided in the future. In addition to the Task Force, the Governor has hired an outside organization to review state government rules. The Governor’s Office has preliminarily asked the Boards to eliminate 30 – 35% of mandatory directive language such as “shall” or “may.” Mrs. Grinston reported the rule review will be a significant undertaking but the Division has offered support/guidance.

Christian Tadrus provided the following additional updates:

- The sterile compounding committee met to preliminarily review public comments and develop a review approach; Additional information will be provided in the future.
- The Long Term Care Working Group met in June to discuss the current state of Missouri long-term care regulation, including, areas of concern and opportunities to streamline/advance long-term care practice. The Working Group generally agreed Missouri’s regulations allow licensees to operate freely but identified several provisions that could be modernized, revised or enhanced.

#5 STLCOP and UMKC College of Pharmacy
- STLCOP Site Listing
- STLCOP Preceptor Listing
- UMKC Site Listing
- UMKC Preceptor Listing

DISCUSSION: Tom Glenski recommended approval of the sites/preceptors presented. A motion was made by Christian Tadrus, seconded by Anita Parran, to approve all sites/preceptors. Motion passed 4:0:0:1 with roll call vote as follows:

Anita Parran – yes         Christian Tadrus – yes

#7 Applications for Intern Training Special Sites/Non-Pharmacist Preceptors
- Astellas Pharma Global Development
- Ayder Referral Hospital
- Clement J. Zablocki VA Medical Center

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• Mercy Hospital  
• Nelson Mandela Metropolitan University  
• Pharmacy & Retail Operations- Walgreens Corporate Office  
• ProPharma Group  
• Rite Aid District Office  
• US Food and Drug Administration  
• Washington County Memorial Hospital  

**DISCUSSION:** Tom Glenski recommended approval of the special sites/non-pharmacist preceptors presented but noted several of the sites will be supervised by non-pharmacists. Douglas Lang asked if the FDA application was complete; Mr. Glenski reported the site was previously approved by the Board until 2019. **A motion was made by Pamela Marshall, seconded by Douglas Lang, to approve all Intern Training Special Sites/Non-Pharmacist Preceptors for 500 hours. Motion passed 4:0:0:1 with roll call vote as follows:**  

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

#8 **Public Comments on 20 CSR 2220-2.200 (Sterile Compounding)**  

**DISCUSSION:** President Lindsay opened the floor for public comments. The following public comments were received:  

- Pharmacist Dennis Wormington asked the Board to revise the current requirement that sterile compounding must be terminated if a highly pathogenic microorganism (HPM) is detected in any ISO classified area if the cfu count exceeds USP recommended action levels. Mr. Wormington indicated the requirement was unreasonable for ISO-7 areas where generally no sterile compounding is performed. Mr. Wormington further suggested the requirement can detrimentally impact patient care if pharmacies are required to shut down for minor or corrected variations in the ISO-7 area pending test results. Mr. Wormington noted pharmacies may also be discouraged from voluntarily testing more frequently if mandatory termination is required. Mr. Wormington suggested the rule requires no further compounding if action levels are exceeded in an ISO-5 classified area but allow additional activities if the HPM/higher cfu count is detected in an ISO-7 classified area and resampling confirms a proper state of microbial control. Board members asked if allowing low-risk compounding pending test results would be a suitable alternative; Mr. Wormington suggested this may detrimentally impact ICU/TPN patients that may need a higher risk product.  

- Alison Smith (University of Kansas Health System) submitted written comments and agreed with Mr. Wormington. Ms. Smith stressed the hardship sterile compounding pharmacies may have if required to cease all sterile compounding for minor or easily corrected testing variations. Ms. Smith further suggested the required three (3) media fill tests exceeds USP Chapter 797 recommendations and commented the requirement does not enhance compounding safety.
• Nathan Hanson (Truman Medical Centers) - Mr. Hanson agreed with prior commenters and further suggested full garbing should not be required when using a RABS. Mr. Hanson indicated a RABS is designed to protect the product rendering additional garbing unnecessary.

• Jerry Brown (Triad Isotopes) - Mr. Brown indicated enforcement of the current in-use and beyond-use-date (BUD) requirements are inappropriate for nuclear. Mr. Brown reported the nuclear industry frequently extends BUDs past manufacturer recommendations to serve geographically distant patients. In other instances, an extended BUD may be needed in emergencies. Due to the limited number of nuclear pharmacies in Missouri, Mr. Brown suggested allowing extended BUDs or in-use dating if the product is within USP’s limits. Mr. Brown further commented the Board’s rules do not address multi-dose vials without a preservative. Christian Tadrus asked if the Board should table its review of nuclear requirements pending action on USP’s proposed Chapter 825; Mr. Brown recommended the Board address pressing nuclear issues at this time but hold full revision of the nuclear rule until Chapter 825 is finalized.

Douglas Lang suggested the Board’s Sterile Sub-Committee review the comments and provide recommendations to the Board in July; Christian Tadrus recommended a conference call in lieu of an in-person meeting. Board consensus to convene the Sub-Committee as suggested.

#8 Rules Under Review

20 CSR 2220-2.010: The following discussion was held:

• Christian Tadrus indicated 20 CSR 2220-2.010 and 20 CSR 2220-2.090 include repetitive language and cautioned against being unnecessarily restrictive. Mr. Tadrus asked if the rule could refer to the Practice Guide; Curtis Thompson advised this may raise legal concerns. Douglas Lang suggested referencing the appropriate rule number in lieu of duplicating language throughout the Board’s rules.

• Consensus to require a controlled substance inventory in compliance with federal law in the event of a PIC change.

• Douglas Lang asked if the Board needed to address/further define controlled room temperature; Board discussion held. Consensus to consider a general requirement in the future that would be applicable to all rules.

• Consensus to prohibit animals or vermin of any kind in the pharmacy except for service animals allowed by federal/state law.

• Consensus to amend the rule to require identification badges that identify an individual’s name and title in lieu of posted wall licenses.

• Consensus to require Board notification of address changes for all licensees/registrants.

• Consensus to amend the rule to allow discipline for pharmacy violations “reasonably known” to the permit holder.

• Consensus to only require Board notification of final employee actions that would be actionable under § 338.055.2, RSMo. Christian Tadrus suggested amending the rule to include any new classifications of pharmacy technicians in the future.
• Consensus to clearly provide pharmacies must maintain documentation that medication was stored at proper temperatures; further consensus to remove duplicate record retention language throughout the rule.
• Consensus to amend the rule to require a sequential number or other unique identifier as authorized by § 338.059, RSMo.
• Consensus to consider better placement for the Class-I language; Kim Grinston advised the Missouri Department of Health and Senior Services has been asked for comments on the home health/hospice agency provisions.

Minor technical/clerical edits were also made to the rule draft; Board consensus to revise and review at a future meeting.

20 CSR 2220-2.012: The following discussion was held:
• Kimberly Grinston asked if individuals designated as pharmacist-in-charge (PIC) of an automated dispensing system located in Missouri should be required to hold a Missouri pharmacist license; Tom Glenski reported inquiries have been received from non-resident companies seeking to operate machines physically located in Missouri. Board discussion held; Pamela Marshall asked if the PICs in question should be registered instead of licensed. Douglas Lang suggested registration may be easier from a business continuity perspective, however, Mr. Lang noted the Board has required a licensed Missouri pharmacist for other pharmacy services provided in this state. Board discussion held; Consensus to preliminarily draft language requiring a Missouri pharmacist license for designated PICs of an automated dispensing machine located in Missouri.

• Board discussion held regarding defining the pharmacy permit area; Christian Tadrus asked if this is a topic of inquiry from licensees. Tom Glenski reported licensees have asked and noted the current policy is that the permit area includes any area inspected and approved curing the pharmacy’s opening inspection. Mr. Glenski noted no formal record is made of the designated inspection area which causes confusion and uncertainty when an inspector leaves or if significant time has passed since the opening inspection. Board discussion held on alternatively defining the permit area as the area where medication is held or where the practice of pharmacy occurs; Consensus to include a broad definition provided the areas have been inspected and approved by the Board. Staff asked to draft language for future review.

• Board members questioned the feasibility of tracking/monitoring the number of authorized absences per day; Consensus not to include a daily limit for authorized temporary absences.

• Board discussion held regarding allowed technician activities during an authorized temporary pharmacist absence; Christian Tadrus commented the current language could be modified to protect patients while accommodating business activities. Board discussion held. Board consensus to allow receipt of prescriptions during an authorized absence, including electronic prescriptions. Further Board consensus that technicians may receive drug deliveries/shipments during a temporary absence but cannot stock, inventory or handle order contents.
- Consensus to modify language to require compliance “except as otherwise authorized by law” to accommodate future tele-pharmacy or remote technician supervision
- No public comments received.

Minor technical/clerical edits were also made to the rule draft; Board consensus to revise and review at a future meeting.

20 CSR 2220-2.650:

The following discussion was held:

- **Emergency Rule:** Public Attendee Dennis Wormington suggested amending the emergency rule to only require that Class-J pharmacies have common access to the specific patient's profile; Mr. Wormington noted pharmacy services may be limited to a small group of patients and access to a pharmacy’s entire recordkeeping system may not be necessary or appropriate. Mr. Wormington suggested access should only be required to records needed to complete the pharmacy’s Class-J shared service obligations. Board members expressed patient safety concerns if Class-J pharmacies do not have access to recent patient profile changes or to sufficient information to adequately perform a drug utilization review. Board discussion held; Board consensus not to modify the emergency rule but to reconsider the scope of required records access after public comments are submitted. A motion was made by Pamela Marshall, seconded by Anita Parran, to approve the emergency rule for filing. Motion passed 4:0:0:1 by roll call vote as follows:

  Anita Parran – yes  Christian Tadrus – yes

- **Amended Rule:** Christian Tadrus asked if the amended rule complies with DEA’s central fill requirements; Tom Glenski noted this is a legal question but indicated licensees are advised to contact the DEA to ensure compliance with federal law which is more restrictive than the Board’s Class-J rule. Board discussion held regarding proper prescription labeling. Douglas Lang suggested the pharmacy that offers patient counseling should be identified on the label; Christian Tadrus noted patients may be confused if multiple labels are on a vial. Mr. Tadrus further suggested specialty pharmacies that are contracted to provide patient counseling may be unable to comply with the proposed labeling language.

  President Lindsay opened the floor for public comments. Public attendee Greg Guenther suggested the Board address tele-pharmacy and electronic pharmacist verification in the amended rule. Board discussion held. Board consensus to discuss tele-pharmacy and electronic verification/supervision at the July meeting. Further discussion postponed due to a pre-scheduled closed session meeting.

**MOTION TO CLOSE**

At 12:11 p.m., Pamela Marshall 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), (7), (13)

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and (14), RSMo, and under Section 324.001.8, and .9, RSMo. Motion passed 4:0:0:1 with roll call vote as follows:

Barbara Bilek – absent
Anita Parran – yes

Douglas Lang- yes
Christian Tadrus – yes

Pamela Marshall – yes

MEMBERS OF THE PUBLIC LEFT THE MEETING ROOM AT APPROXIMATELY 12:11 P.M.

RECONVENE OPEN 1:37 P.M.

By motion duly made, seconded, passed and recorded in closed session minutes, the Board returned to open session at approximately 1:37 p.m.

#8  Rules Under Review (Con’t)

20 CSR 2220-2.650- Discussion continued regarding proper labeling for Class-J pharmacies; Kimberly Grinston proposed modifying section (1)(C)5. of the amended rule to require: “A designation of the pharmacy responsible for offering patient counseling as required by 20 CSR 2220-2.190 and federal law. For purposes of § 338.059, RSMo, either the name and address of the pharmacy responsible for offering patient counseling or the pharmacy responsible for dispensing to the patient may be listed on the label as designated by the pharmacies by contract.” Board consensus to amend as suggested.

Further consensus to amend section (3) to provide: “A pharmacy participating in Class-J shared services with a pharmacy that is not under common ownership must notify patients that his/her prescription or medication order may be filled or compounded by another pharmacy.” A motion was made by Douglas Lang, seconded by Christian Tadrus, to approve the proposed amendment of 20 CSR 2220-2.650 with the recommended changes. Motion passed 4:0:0:1 by roll call vote as follows:

Barbara Bilek – absent
Anita Parran – yes

Douglas Lang- yes
Christian Tadrus – yes

Pamela Marshall – yes

20 CSR 2220-6.040 & 20 CSR 2220-6.050: Christina Lindsay opened the floor for public comments; Justin May with Red Cross Pharmacy commented the annual notification of intent requirement in 20 CSR 2220-6.050 is burdensome and unnecessary. Mr. May further requested the Board eliminate the 50-mile requirement. Christina Lindsay noted both suggestions have been incorporated in the Board’s proposed amendments; however, the changes would need to be approved by the Board of Healing Arts. No other public comments received. Due to time constraints, Board consensus to table Board discussion until the July meeting.

#9  2018 Proposed Legislation

Section 338.013 (Pharmacy Technician Training & Education): The following discussion was held:

- Bert McClary, Hospital Advisory Committee Chairman, presented the following timeline of technician regulation:

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1. 1974: The Missouri Society for Health-System Pharmacists (MSHP) developed technician practice guidelines.
2. 1982: MSHP suggested a draft technician rule. The Missouri Attorney General confirmed use of unlicensed personnel to assist pharmacists.
3. 1984: Board technician rule for hospital support staff promulgated.
4. 1989: MSHP proposed a resolution for standardized technician education/training.
5. 1991: MSHP and the Board convened a pharmacy technician working group.
6. 1995: DHSS promulgated a rule that addressed, in part, assisting pharmacy staff.
7. 1997: Pharmacy technician legislation passed
9. 2007: Bd. discussed remote pharmacy technician activities during its annual strategic planning meeting.
10. 2008: Further Board discussion held.
11. 2009: DHSS and MSHP asked the Board to form a hospital practice committee.
12. 2010: MSHP issues position statement on pharmacy technician training/education. Board holds an open discussion forum.
13. 2011: Bd. convened a working group resulting in draft legislative recommendations.
15. 2013- Bd. proposed rule language addressing technician activities.

Mr. McClary indicated MSHP continues to recommend standardized training and certification for advanced technician activities and encouraged the Board to pursue needed legislative changes. The following additional discussion was held:

- Justin May (Red Cross Pharmacy) spoke in favor of advanced technician training but cautioned the Board that allowing pharmacy technicians to perform final dispensing verification could impact patient safety and diminish the role of the pharmacist. Christina Lindsay noted the Board’s goal is to accommodate both current and future practice models in a way that would allow pharmacists to practice at the apex of their training/capability. Pamela Marshall suggested advanced technician activities may also allow pharmacists more direct patient contact.

- David Wolfrath (MSHP) reported MSHP continues to support the enhancement of technician functions to facilitate expanded pharmacist duties and responsibilities. Mr. Wolfrath commented new integrative technology can be utilized to ensure proper pharmacist supervision while increasing efficiency and minimizing costs.

- Daniel Good (Mercy Health) expressed support for expanding technician activities under appropriate pharmacist supervision. Mr. Good noted a distinction has developed between hospital and retail practice models. Specifically, Mr. Good indicated hospitals are traditionally focused on patient safety first and costs second while retail pharmacy

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may be more revenue focused. Mr. Good suggested establishing rules specifically for hospital technicians given the difference in functioning and regulatory oversight. Mr. Good noted the nurse is an important quality check in hospitals that is generally not present with retail pharmacy. Mr. Good urged the Board to be proactive and recommended pursuing any needed legislation during the 2017-2018 legislative year.

- Nathan Hanson (Truman Medical Centers) expressed support for the proposed grandfathering provisions and suggested a distinction be made between authorized technician duties when medication is being dispensed directly to the patient and when medication is being dispensed for administration by a healthcare practitioner. Mr. Hanson further suggested the Board consider allowing tech-check-tech.

- Ron Fitzwater (Missouri Pharmacy Association) reported this topic is an evolving discussion for MPA and noted questions still exist regarding statutory vs. regulatory solutions. Mr. Fitzwater expressed MPA is willing to engage in the process and take a fresh look at options/regulatory approaches.

- James Gray (Barnes-Jewish Hospital) indicated the Working Group’s recommendations were balanced and well thought out. Mr. Gray noted the practice of pharmacy is not uniformed and recommended a legislative approach that would allow practitioners to adjust the workforce to minimize costs and better serve patients, including, patients in under-privileged areas.

Board discussion held on a potential 2017-2018 legislative proposal. Christian Tadrus recommended the Board take a measured approach to avoid unintended consequences and asked if the law should allow Board approved pilot programs. Douglas Lang cautioned other states have faced legal challenges to pilot programs while other Boards have experienced additional workload related to due diligence reviews. Board members agreed to provide suggested legislative comments/changes to the office by July 3rd and to further discuss legislative options at the July meeting.

Due to time constraints, the remainder of the open agenda was tabled until the July meeting.

**MOTION TO CLOSE**

At 2:58 p.m., Douglas Lang 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), (7), (13), (14) and (17), RSMo, and under Section 324.001.8, and .9, RSMo. Motion passed 4:0:0:1 with roll call vote as follows:

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

**MEMBERS OF THE PUBLIC LEFT THE MEETING ROOM AT APPROXIMATELY 2:58 P.M.**

**RECONVENE OPEN 3:16 P.M.**

By motion duly made, seconded, passed and recorded in closed session minutes, the Board returned to open session at approximately 3:16 p.m. on June 23, 2017.

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MOTION TO ADJOURN 3:17 P.M.
At approximately 3:17 p.m., a motion was made by Pamela Marshall, seconded by Christian Tadrus, to adjourn the June 23, 2017 meeting. Motion passed 4:0:0:1 with roll call vote as follows:

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


KIMBERLY A. GRINSTON
EXECUTIVE DIRECTOR

DATE APPROVED: October 25, 2017