OPEN MINUTES
Missouri Board of Pharmacy

February 22, 2017 8:00 am
Missouri Association of School Administrators
3550 Amazonas Dr.
Jefferson City, MO 65109

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 8:00 a.m. on February 22, 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
Anita Parran, Public Member

Board Members Absent
Pamela Marshall, R.Ph., Member

Staff Present
Kimberly Grinston, Executive Director
Tom Glenski, R.Ph., Chief Inspector
Katie DeBold, PharmD., Inspector
Amber Cundiff, Compliance Coordinator
Jennifer Luebbert, Administrative Coordinator

Others Present
Curtis Thompson, Legel Counsel

PRESIDENT LINDSAY CALLED THE OPEN SESSION MEETING TO ORDER AT APPROXIMATELY 8:00 AM

MOTION TO CLOSE 8:00 A.M.
At 8:01 a.m., Christian Tadrus made a motion, seconded by Barbara Bilek, that the Board go into closed session and that all votes, to the extent permitted by law, pertaining to and/or resulting from this closed meeting be closed under Section 610.021(1), (3), (5), (7), (13), (14), (17) and (20), RSMo, and under Section 324.001.8, and .9, RSMo. Motion passed 4:0:0:1 with roll call vote as follows:

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

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MEMBERS OF THE PUBLIC LEFT THE MEETING ROOM AT 8:10 AM

RETURN TO OPEN
By motion duly made, seconded, passed and recorded in closed session minutes, the Board returned to open session at approximately 8:37 a.m.

MEMBERS OF THE PUBLIC ENTERED THE MEETING ROOM AT 8:37 A.M. PRESIDENT LINDSAY CALLED THE OPEN SESSION MEETING TO ORDER AT APPROXIMATELY 8:38 a.m.

SECTION D-OPEN

#D1 2020 Rule Review
- Rule Review Calendar
- 20 CSR 2220-2.010 Pharmacy Standards of Operation
  - Current Rule
- 20 CSR 2220-2.025 Non-Resident Pharmacies
  - Current Rule
- 20 CSR 2220-2.090 Pharmacist-In-Charge
  - 2015 Preliminary Draft
- 20 CSR 2220-2.700 Pharmacy Technician Registration
  - 2014 Approved Draft
- 20 CSR 2220-2.950 Automated Filling Systems
  - 2015 Discussion Draft

DISCUSSION: President Lindsay asked for public comments and indicated comments may be limited to three (3) minutes per speaker to accommodate all attendees. The following discussion was held:
- 20 CSR 2220-2.010:
  a. Sam Leveritt suggested line 57 should read "must be completed under clean and aseptic conditions." Mr. Leveritt further suggested including a timeframe for licensee change of addresses and amending section (9) to reference Class-C pharmacies. Board consensus to require notification of name and address changes within thirty (30) days.
  b. Christian Tadrus suggested revising the rule to reference vaccines and devices and not just "drugs" or "medicine". Mr. Tadrus further proposed amending section (1)(A) to address pharmacist breaks and noted current tele-pharmacy laws may impact the requirement that a pharmacist must be on duty and present at all times. Christina Lindsay suggested allowing a thirty (30) minute break during which time pharmacy operations would be allowed to continue. However, Ms. Lindsay recommended the Board prohibit dispensing during an authorized break if a patient requests to consult with a pharmacist. Board consensus to draft language as suggested.
  c. Douglas Lang proposed allowing reference materials and required rules/statutes to be maintained electronically. Christian Tadrus suggested allowing multiple
references and not requiring a single reference source; Board consensus to revise as suggested and to allow peer-reviewed and other scholastic periodicals.

d. Mr. Lang asked if a hot and cold water source should be required if the pharmacy is not dispensing; Ms. Grinston proposed adding language from the drug distributor rule requirement that would allow pharmacies to request an exemption.

e. Douglas Lang asked if the rule’s diversion and security requirements should be strengthened to provide additional direction for licensees; Board members suggested words like “adequate” and “proper” are ambiguous and need further definition. Mr. Lang further suggested rule language regarding food storage should be consistent with the Practice Guide.

f. Tom Glenski proposed deleting the offsite storage language and instead requiring offsite centers to be licensed as drug distributors. Mr. Glenski noted the rule was promulgated prior to the drug distributor license statutes being enacted. Board discussion held; Board members commented drug distributor licensure may be burdensome. Board consensus not to require drug distributor licensure at this time.

g. Christian Tadrus expressed concerns regarding the mandatory disciplinary language for permit holders in section (1)(O); Mr. Tadrus stated the language appears to impose strict liability which may be inappropriate in instances where the permit holder is unaware of, or takes reasonable steps to prevent, violations. Mr. Glenski noted this language has been successfully used in disciplinary prosecutions.

h. Barbara Biele proposed amending section (9) referencing home health agencies to include all authorized prescribers; Board consensus to revise as suggested. Further Board consensus to forward section (9) to the Missouri Department of Health and Senior Services (DHSS) for review.

i. Tom Glenski questioned if the Class-I language was still required given the non-dispensing rule; Staff will research and provide recommendations.

- **20 CSR 2220-2.025**: Sam Leveritt proposed including a timeframe for the required non-resident inspection. Douglas Lang suggested the timeframe should be based on the services provided and proposed requiring that a non-resident inspection must have been completed within 18-24 months before the application date; Board discussion held on what a fair timeframe would be. Kimberley Grinston advised other states may not be meeting the 18-24 month timeframe for all pharmacies. Staff proposed deleting the licensure exemption in section (1) for dispensing to patients in an institutional setting.

- **20 CSR 2220-2.390**: Board members suggested the rule clearly indicate that the permit holder is also responsible for compliance and further suggested removing duplicate requirements that apply to the permit holder. The following additional changes were proposed/discussed:
  a. Curtis Thompson stated the definition of a pharmacy technician would be governed by law and not the pharmacist-in-charge.
  b. Sam Leveritt proposed using assure vs. ensure throughout the rule and further proposed expanding section (2)(F)'s provisions regarding suspicious activity to all licensees.
c. Bert McClary suggested the automated system language in (2)(E)(E) should be inclusive of all practice settings in light of the ongoing automated system discussions.

d. Douglas Lang questioned if section (4) should require immediate replacement of the pharmacist-in-charge or allow replacement within 5 to 7 business days; Staff advised the Practice Guide recommends replacement within a "reasonable time." Christian Tadrus suggested any timeframe under seven (7) days may be problematic for small business owners. Board discussion held; Board consensus to allow Board notification within two (2) weeks provided the pharmacy cannot operate until a new pharmacist-in-charge is named.

e. Board discussion held on allowing electronic or alternative license verifications; Ms. Grinston asked if the license posting requirements are appropriate and noted licenses are commonly posted in areas that are not viewable to the public. Ms. Grinston reported consumer complaints have been received from customers who were unable to identify if they were talking with a pharmacist or a technician. Douglas Lang asked if the rule should require a name tag and title instead of displaying a license. Public attendees commented it is hard to distinguish between a pharmacist and technician even in small towns where individuals may be familiar with the local community; Other public attendees noted a name badge and title are already required at their practice sites. Board consensus to draft language requiring a name tag with title; James Gray suggested this requirement should not apply to pharmacies that are not open to the public.

Board consensus to revise the rule drafts as discussed and review at a future meeting.

#D10 Use of Telepharmacy in Pharmacy Practice/Remote Technician Supervision

Adam Chelser, Cardinal Health, Director of Regulatory Affairs, provided a presentation on tele-pharmacy practice and trends. Mr. Chessler advised tele-pharmacy can be an effective means for providing pharmacy services to needed areas; Mr. Chessler indicated Missouri has 55 pharmacy deserts affecting 44,982 Missouri residents and 162 at-risk communities. Board discussion held; Mr. Chessler encouraged the Board to further address/allow tele-pharmacy and offered his assistance with future rule/statutory language.

MOTION TO CLOSE 10:55 A.M.
At 10:55 a.m., Douglas Lang 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)and (3), RSMo, and under Section 324.001.8, and .9, RSMo. Motion passed 4:0:0:1 with roll call vote as follows:

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

MEMBERS OF THE PUBLIC LEFT THE MEETING ROOM AT 10:55 AM

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RETURN TO OPEN

By motion duly made, seconded, passed and recorded in closed session minutes, the Board returned to open session at approximately 12:31 p.m.

MEMBERS OF THE PUBLIC ENTERED THE MEETING ROOM AT 12:32 P.M.

- **20 CSR 2220-2 700**: Christina Lindsay asked for public comments; Bert McClary supported revising the rule to accommodate current practice. Ms. Lindsay suggested holding discussions pending input from the Pharmacy Technician Working Group. Board consensus to hold as recommended.
- **20 CSR 2220-2.950**: Douglas Lang recommended the Board consider a statistically validated sample size in lieu of the 2% review requirement; Christian Tadrus suggested the same issue may apply to remote verifications if allowed by the Board. Board consensus to research the current sample size requirement and discuss at a future meeting.

#D10 Use of Telepharmacy in Pharmacy Practice/Remote Technician Supervision

The following comments were received:
- Bert McClary indicated DHSS’s technician rules are limited and noted DHSS has traditionally looked to the Board of Pharmacy for technician standards; Mr. McClary recommended the Board consider both traditional in-patient settings and settings within a hospital under the Board’s jurisdiction. Mr. McClary read a comment from Kevin Kinkade asking that the Board consider allowing remote video supervision of technicians filling automated dispensing cabinets; Mr. Kinkade suggested the allowance would assist small and rural hospitals with limited staffing ability.
- Greg Teale commented remote supervision would benefit practice sites such as oncology centers where pharmacists are asked to assist with dispensing; Mr. Teale suggested remote supervision would increase patient safety by allowing pharmacists to be directly involved in patient care. Mr. Teale noted pharmacists can adequately verify products and remote technician activities with proper video capability. Mr. Teale also commented that recent changes to USP Chapter 800 may require remote supervision and asked if the Board had legal authority to authorize a pilot program.

Board discussion held; Board consensus to research the topic for review at a future meeting.

#D2 Draft Rule Discussion

- **20 CSR 2220-6.050**: Board discussion held regarding CDC compliance; Douglas Lang asked if the rule should reference/require compliance with CDC vaccine storage guidelines. Board discussion held; Christina Lindsay asked how many pharmacies would be impacted and noted the guidelines could affect offsite centers for under-served patients. Staff indicated storage guidelines could potentially impact a large number of pharmacies who may not currently have adequate refrigerator/freezer units. Public member Greg Teale estimated pharmacy
compliance costs could range from $250 - $3,000. Board consensus to include CDC’s vaccine storage guidelines in the next rule draft for discussion purposes.

- 20 CSR 2220-2.650: Board discussion held on which pharmacy should be designated as the dispensing pharmacy on the label when a prescription is filled and dispensed under a Class-J arrangement and which pharmacy should be responsible for patient counseling. Christian Tadrus suggested the label should at a minimum include an identifier that tells the patient where the prescription was filled to ensure traceability (e.g., an NDI number). Douglas Lang indicated both Class-J pharmacies would have a license with the Board and be required to keep records of prescription activity in the event of a recall; Mr. Lang further commented patients may be confused if multiple pharmacies are on the same label. Barbara Bilek and Anita Parran commented consumers need to know who to call in the event of a problem and may not want to know all of the pharmacies engaged in dispensing. Board consensus to require the name of the pharmacy responsible for patient counseling on the label. Barbara Bilek and Christian Tadrus asked staff to include suggested language requiring notification to the patient when a prescription is filled at another pharmacy.

#D9 Prescription Status OTC Antimicrobials

**DISCUSSION:** Tom Glenski reported the FDA created a new class of drugs called veterinary food directive drugs (VFDs) that can only be purchased with a VFD from a veterinarian. Mr. Glenski reported VFDs are not considered “prescription” drugs, however, the FDA is requiring food distributors to register with them. Mr. Glenski asked if entities disposing VFD products need to register as drug distributors or pharmacies and noted states have taken variant approaches. Board discussion held regarding the lack of clarity; Board consensus to not require a license at this time pending further guidance from the FDA.

#A5 Approval of Minutes

- Board Meeting (10/26/16 and 10/27/16)
- Conference Call (11/16/2016)

**DISCUSSION:** A motion was made by Douglas Lang, seconded by Barbara Bilek, to approve the October 26 and 27, 2016 minutes. Motion passed 4:0:0:1 by roll call vote as follows:

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

Douglas Lang asked staff to correct the spelling for pharmacist Marty Michel. A motion was made by Douglas Lang, seconded by Anita Parran, to approve the November 16, 2016, minutes with the suggested revision. Motion passed 3:0:1:1 by roll call vote as follows:

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

SECTION C - OPEN

#C1 Applications for Intern Training Special Sites/Non-Pharmacist Preceptors
- Hillside Health Care Clinic International
- Bureau of Pharmacy and Clinical Support Services
- International Pharmaceutical
- Lumeris Healthcare Outcomes (formerly Essence Healthcare)
- UMKC School of Pharmacy, Division of Pharmacy Practice and Administration
- EPI-Q, Inc.
- Lloyd’s Pharmacy
- East Coast Institute for Research
- Komfo Anokye Teaching Hospital
- Sioux San Indian Health Service ( HIS) Hospital Pharmacy

DISCUSSION: Tom Glenski recommended approval of the special sites/non-pharmacist preceptors presented. A motion was made by Christian Tadrus, seconded by Anita Parran, 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:

Anita Parran – yes Christian Tadrus – yes

#C2 STLCOP and UMKC School 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 Barbara Bilek, seconded by Anita Parran, to approve all sites/preceptors for 500 hours. Motion passed 4:0:0:1 with roll call vote as follows:

Anita Parran – yes Christian Tadrus – yes

Christian Tadrus inquired about the status of UMKC’s and STLCOP’s request to have foreign students licensed/registered with the Board before they arrive in the United States. Staff reported the schools have been told that foreign students could be registered as technicians which would allow them to work based on their pending application; Mr. Glenski reported the schools are still reviewing options and other implementation issues.

MOTION TO CLOSE 2:45P.M.

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At 2:45 p.m., Douglas Lang made a motion, seconded by Barbara Bilek, that the Board go into closed session and that all votes, to the extent permitted by law, pertaining to and/or resulting from this closed meeting be closed under Section 610.021(1), (3), (5), (7), (13), (14), (17) and (20), RSMo, and under Section 324.001.8, and .9, RSMo. Motion passed 4:0:0:1 with roll call vote as follows:

Anita Parran – yes  Christian Tadrus – yes

MEMBERS OF THE PUBLIC LEFT THE MEETING ROOM AT 2:45 P.M.

RECONVENE OPEN 3:32 P.M.

By motion duly made, seconded, passed and recorded in closed session minutes, the Board returned to open session at approximately 3:32 p.m.

MOTION TO ADJOURN 3:32 PM
At approximately 3:32 p.m., a motion was made by Douglas Lang, seconded by Barbara Bilek, to adjourn the February 22, 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: 9/3/17